MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ABALOPARATIDE

Generic	Brand	HICL	GCN	Exception/Other
ABALOPARATIDE	TYMLOS	44231		

GUIDELINES FOR USE

The guideline named **ABALOPARATIDE (Tymlos)** requires that the patient has a diagnosis of postmenopausal osteoporosis and has not received a total of 24 months or more of parathyroid hormone therapy with Tymlos or Forteo. In addition, one of the following criteria must be met:

- High risk for fractures defined as ONE of the following:
  - History of osteoporotic (e.g., fragility, low trauma) fracture(s)
  - 2 or more risk factors for fracture (e.g., history of multiple recent low trauma fractures, BMD T-score less than or equal to -2.5, corticosteroid use, or use of GnRH analogs such as nafarelin, etc.)
  - No prior treatment for osteoporosis AND FRAX score ≥ 20% for any major fracture OR ≥ 3% for hip fracture
- Unable to use oral therapy (e.g., upper gastrointestinal [GI] problems - unable to tolerate oral medication, lower GI problems - unable to absorb oral medications, trouble remembering to take oral medications or coordinating an oral bisphosphonate with other oral medications or their daily routine)
- The patient has an adequate trial of, intolerance to, or a contraindication to bisphosphonates (e.g., Fosamax, Actonel, Boniva)

RATIONALE

To ensure safe and appropriate use of abaloparatide per approved indication and dosing and national treatment guidelines.

FDA APPROVED INDICATIONS

Indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Tymlos reduces the risk of vertebral fractures and nonvertebral fractures.

DOSAGE AND ADMINISTRATION

The recommended dosage of Tymlos is 80 mcg subcutaneously once daily. Cumulative use of Tymlos and parathyroid hormone analogs (e.g., teriparatide) for more than 2 years during a lifetime is not recommended. Patients should receive supplemental calcium and vitamin D if dietary intake is inadequate.

REFERENCES

- Tymlos [Prescribing Information]. Waltham, MA: Radius Health, Inc.; October 2018.
- Miller PD, Hattersley G, Riis BJ, et al. Effect of abaloparatide vs placebo on new vertebral fractures in postmenopausal women with osteoporosis: a randomized clinical trial. *JAMA*. 2016;316:722-33.
- American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE) medical guidelines for clinical practice for the diagnosis and treatment of postmenopausal osteoporosis. Accessed online April 13, 2017.

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ABATACEPT - IV

Generic	Brand	HICL	GCN	Exception/Other
ABATACEPT/MALTOSE	ORENCIA - IV		26306	

NOTE: For requests for the SQ dosage form of Orencia, please see the ABATACEPT SQ Guideline.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ABATACEPT - IV (Orencia - IV)** requires the following rule(s) be met for approval:

A. You have ONE of the following indications for treatment:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Moderate to severe Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   3. Psoriatic arthritis (PsA: a type of skin and joint condition)
   4. Prevention of acute graft-versus-host disease (aGVHD)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. You have previously tried at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs): methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   3. You have previously tried **ONE** of the following: Enbrel or Humira

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis (PJIA), approval also requires:**
   1. You are 2 years of age or older
   2. You have previously tried at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs): methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   3. You have previously tried **ONE** of the following: Enbrel or Humira

D. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. You have previously tried at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs): methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   3. You have previously tried **TWO** of the following: Cosentyx, Enbrel, or Humira

E. **For the prevention of acute graft-versus-host disease (aGVHD), approval also requires:**
   1. You are 2 years of age or older
   2. The requested medication will be used concurrently with a calcineurin inhibitor AND methotrexate
   3. You will be concurrently undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated-donor

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ABATACEPT - IV

GUIDELINES FOR USE (CONTINUED)

NOTE: For the diagnosis of acute graft versus host disease (aGVHD), please refer to the Initial Criteria section.

RENEWAL CRITERIA

The guideline named **ABATACEPT - IV (ORENCIA - IV)** renewal requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, or moderate to severe juvenile idiopathic arthritis for renewal. In addition, the following criteria must be met:

Renewal for the diagnosis of moderate to severe rheumatoid arthritis, approval requires:

- Documentation (i.e., chart notes) that the patient has experienced or maintained symptomatic improvement while on therapy

Renewal for the diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis, approval requires:

- Documentation (i.e., chart notes) that the patient has experienced or maintained symptomatic improvement while on therapy

Renewal for the diagnosis of psoriatic arthritis, approval requires:

- Documentation (i.e., chart notes) that the patient has experienced or maintained symptomatic improvement while on therapy

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ABATACEPT - IV

RATIONALE
Ensure appropriate diagnostic, utilization and safety criteria are met for the management of requests for abatacept.

FDA APPROVED INDICATIONS
Orencia is a selective T cell costimulation modulator indicated for:

Adult Rheumatoid Arthritis (RA)
Moderately to severely active RA in adults. Orencia may be used as monotherapy or concomitantly with DMARDs other than TNF antagonists.

Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older. Orencia may be used as monotherapy or concomitantly with methotrexate.

Adult Psoriatic Arthritis (PsA)
Orencia is indicated for the treatment of adult patients with active psoriatic arthritis (PsA).

Prophylaxis for acute graft-versus-host disease (aGVHD)
Orencia is indicated for the prophylaxis of acute graft versus host disease (aGVHD), in combination with a calcineurin inhibitor and methotrexate, in adults and pediatric patients 2 years of age and older undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated-donor.

DOSING

Adult Rheumatoid Arthritis (RA) and Adult Psoriatic Arthritis (PsA)
Dose according to body weight as specified in the table below. Following the initial administration, abatacept should be given at 2 and 4 weeks after the first infusion, then every 4 weeks thereafter.

Dose of Orencia for intravenous administration for Adult RA and PsA

BODY WEIGHT OF PATIENT	DOSE	NUMBER OF VIALS
<60 kg	500 mg	2
60 to 100kg	750 mg	3
>100 kg	1,000 mg	4

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ABATACEPT - IV

FDA APPROVED INDICATIONS (CONTINUED)

DOSING

Polyarticular Juvenile Idiopathic Arthritis (PJIA)

Dose according to body weight as specified in the table below. Following the initial administration, abatacept should be given at 2 and 4 weeks after the first infusion, then every 4 weeks thereafter.

Dose of Orencia for intravenous administration for PJIA

BODY WEIGHT OF PATIENT	DOSE (ONCE WEEKLY)
<75 kg	10mg/kg
75 to 100kg	750 mg
>100 kg	1,000 mg

Prophylaxis for acute graft-versus-host disease (aGVHD)

For patients 6 years and older, administer Orencia 10 mg/kg (maximum dose of 1,000 mg) as an intravenous infusion over 60 minutes on the day before transplantation (Day 1), followed by administration on Days 5, 14, and 28 after transplantation.

For patients 2 to less than 6 years old, administer ORENCIA 15 mg/kg as an intravenous infusion over 60 minutes on the day before transplantation (Day 1), followed by 12 mg/kg as an intravenous infusion over 60 minutes on Days 5, 14, and 28 after transplantation.

REFERENCES

- Orencia [Prescribing Information]. Princeton, NJ: E.R. Squibb & Sons, L.L.C. February 2022.
- Beukelman T, Patkar NM, et al. 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: Initiation and safety monitoring of therapeutic agents for the treatment of arthritis and systemic features. Arthritis Care Res, 63: 465–482. doi: 10.1002/acr.20460.
- Singh JA, Guyatt G, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Care & Research. Vol. 71, No. 1, January 2019, pp 2–29. DOI 10.1002/acr.2378.
- Singh JA, Saag KG, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. 2016;68(1):1-25. DOI 10.1002/acr.22783.
- National Comprehensive Cancer Network (NCCN). Hematopoietic Cell Transplantation (HCT) (Version 5.2021). https://www.nccn.org/professionals/physician_gls/pdf/hct.pdf Accessed February 2, 2022.

Created: 02/18
Effective: 03/28/22 Client Approval: 02/22/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ABATACEPT - SQ

Generic	Brand	HICL	GCN	Exception/Other
ABATACEPT - SQ	ORENCIA - SQ, ORENCIA CLICKJECT		30289 41656 43389 43397	

NOTE: For the IV dosage form of Orencia, please see the ABATACEPT IV Guideline.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ABATACEPT SQ (Orencia SQ)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in many joints in children)
   3. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. You have previously tried at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs): methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   3. You have previously tried **ONE** of the following: Enbrel or Humira

C. **If you have polyarticular juvenile idiopathic arthritis (PJIA), approval also requires:**
   1. You are 2 years of age or older
   2. You have previously tried at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs): methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   3. You have previously tried **ONE** of the following: Enbrel or Humira

D. **If you have psoriatic arthritis (PsA), our guideline also requires:**
   1. You are 18 years of age or older
   2. You have previously tried at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs): methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   3. You have previously tried **TWO** of the following: Cosentyx, Enbrel, or Humira

RENEWAL CRITERIA

Our guideline named **ABATACEPT SQ (Orencia SQ)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in joints in children)
   3. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)

B. You have experienced or maintained symptomatic improvement while on therapy.

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ABATACEPT - SQ

RATIONALE
Ensure appropriate diagnostic, utilization and safety criteria are met for the management of requests for abatacept.

FDA APPROVED INDICATIONS
Orencia is a selective T cell costimulation modulator indicated for:

Adult Rheumatoid Arthritis (RA)
Moderately to severely active RA in adults. Orencia may be used as monotherapy or concomitantly with DMARDs other than TNF antagonists.

Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older. Orencia may be used as monotherapy or concomitantly with methotrexate. The safety and efficacy of Orencia ClickJect auto-injector for subcutaneous injection has not been studied in patients under 18 years of age.

Adult Psoriatic Arthritis (PsA)
Orencia is indicated for the treatment of adult patients with active psoriatic arthritis (PsA).

Important Limitations of Use
Orencia should not be given concomitantly with TNF antagonists. Orencia is not recommended for use concomitantly with other biologic rheumatoid arthritis therapy such as anakinra.

DOSING
Adult Rheumatoid Arthritis (RA)
Orencia 125 mg in prefilled syringes or in Orencia ClickJect™ autoinjector should be administered by subcutaneous injection once weekly and may be initiated with or without an intravenous loading dose. For patients initiating therapy with an intravenous loading dose, Orencia should be initiated with a single intravenous infusion, followed by the first 125 mg subcutaneous injection administered within a day of the intravenous infusion.

Adult Psoriatic Arthritis (PsA)
Orencia SC 125 mg should be administered by subcutaneous injection once weekly without the need for an intravenous loading dose.

Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Orencia for subcutaneous injection should be initiated without an intravenous loading dose and be administered utilizing the weight range-based dosing as specified in the Table below.

Dose of Orencia for subcutaneous administration for PJIA

BODY WEIGHT OF PATIENT	DOSE (ONCE WEEKLY)
10 to less than 25 kg	50 mg
25 to less than 50 kg	87.5 mg
50 kg or more	125 mg

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ABATACEPT - SQ

REFERENCES

- Orencia package insert. Princeton, NJ: Bristol-Myers Squibb Company; June 2020.
- Beukelman T, Patkar NM, et al. 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: Initiation and safety monitoring of therapeutic agents for the treatment of arthritis and systemic features. Arthritis Care Res, 63: 465–482. doi: 10.1002/acr.20460.
- Singh JA, Guyatt G, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Care & Research. Vol. 71, No. 1, January 2019, pp 2–29DOI 10.1002/acr.2378.
- Singh JA, Saag KG, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. 2016;68(1):1-25. DOI 10.1002/acr.22783.

Created: 03/15
Effective: 04/11/22 Client Approval: 03/10/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ABEMACICLIB

Generic	Brand	HICL	GCN	Exception/Other
ABEMACICLIB	VERZENIO	44537		

GUIDELINES FOR USE

Our guideline named **ABEMACICLIB (Verzenio)** requires the following rules be met for approval:

A. You have ONE of the following diagnoses:
   1. Early breast cancer (initial stage of breast cancer)
   2. Advanced or metastatic breast cancer (cancer that has progressed or has spread to other parts of the body)

B. **If you have early breast cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive (a type of protein)
   3. Verzenio will be used in combination with endocrine therapy (tamoxifen or an aromatase inhibitor such as letrozole, anastrozole, exemestane) for adjuvant (add-on) treatment
   4. You are at high risk of recurrence (disease returning) and has a Ki-67 score of greater than or equal to 20 percent, as determined by a Food and Drug Administration (FDA)-approved test

C. **If you have advanced or metastatic breast cancer, approval also requires:**
   1. Your cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (a type of protein)
   2. You meet **ONE** of the following:
      a. You are a postmenopausal female or male AND Verzenio will be used in combination with an aromatase inhibitor (such as letrozole, anastrozole, or exemestane) as initial endocrine-based therapy
      b. You are 18 years of age or older AND Verzenio will be used in combination with fulvestrant, and you have had disease progression following endocrine therapy
      c. You are 18 years of age or older AND Verzenio will be used as monotherapy (one drug) and you have had disease progression following endocrine therapy and prior chemotherapy (drugs used to treat cancer)

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ABEMACICLIB

RATIONALE
Promote appropriate utilization of **ABEMACICLIB** (Verzenio) based on FDA approved indications and dosing.

FDA APPROVED INDICATIONS
Verzenio is a kinase inhibitor indicated:

- In combination with endocrine therapy (tamoxifen or an aromatase inhibitor) for the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive, early breast cancer at high risk of recurrence and a Ki-67 score ⩾20% as determined by an FDA approved test
- In combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer
- In combination with fulvestrant for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy
- As monotherapy for the treatment of adult patients with HR positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting

DOSAGE AND ADMINISTRATION
The recommended starting dose in combination with fulvestrant, tamoxifen, or an aromatase inhibitor is 150 mg twice daily. The recommended starting dose as monotherapy is 200 mg twice daily.

The recommended VERZENIO dose modifications for adverse reactions are provided in the table below.

Dose Level	VERZENIO Dose in Combination with Fulvestrant or an aromatase inhibitor	VERZENIO Dose for Monotherapy
Recommended starting dose	150 mg twice daily	200 mg twice daily
First dose reduction	100 mg twice daily	150 mg twice daily
Second dose reduction	50 mg twice daily	100 mg twice daily
Third dose reduction	Not applicable	50 mg twice daily*

*If further dose reduction below 50 mg twice daily is required, discontinue the treatment.

AVAILABLE STRENGTHS
Tablets: 50 mg, 100 mg, 150 mg, and 200 mg

REFERENCES
Verzenio [Prescribing Information]. Indianapolis, IN. Eli Lilly and Company; October 2021.

Created: 10/17
Effective: 01/30/23 Client Approval: 01/04/23 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ABIRATERONE

Generic	Brand	HICL	GCN	Exception/Other
ABIRATERONE ACETATE	ZYTIGA	37571		

GUIDELINES FOR USE

Approval requires a diagnosis of metastatic castration-resistant prostate cancer (CRPC) or metastatic high-risk castration-sensitive prostate cancer (CSPC). In addition, the requested medication must be used in combination with prednisone.

RATIONALE

To ensure appropriate use of Zytiga consistent with FDA approved indication.

FDA APPROVED INDICATIONS

Zytiga is indicated for use in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer CRPC) and metastatic high-risk castration-sensitive prostate cancer (CSPC).

DOSAGE AND ADMINISTRATION

Metastatic castration-resistant prostate cancer: The recommended dose of Zytiga is 1,000 mg (two 500 mg tablets or four 250 mg tablets) administered orally once daily in combination with prednisone 5 mg administered orally twice daily.

Metastatic high-risk castration-sensitive prostate cancer: The recommended dose of Zytiga is 1,000 mg (two 500 mg tablets or four 250 mg tablets) administered orally once daily in combination with prednisone 5 mg administered orally once daily.

Patients receiving ZYTIGA should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy. ZYTIGA must be taken on an empty stomach, either one hour before or two hours after a meal *[see Clinical Pharmacology (12.3)]*. The tablets should be swallowed whole with water. Do not crush or chew tab.

If a strong CYP3A4 inducer must be co-administered, increase the Zytiga dosing frequency to twice a day only during the co-administration period (e.g., from 1,000 mg once daily to 1,000 mg twice a day).

REFERENCES

- Zytiga package insert. Horsham, PA: Centocor Ortho Biotech Inc. February 2018.

Created: 06/15
Effective: 04/15/19 Client Approval: 03/29/18 P&T Approval: 11/13

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ABIRATERONE SUBMICRONIZED

Generic	Brand	HICL	GCN	Exception/Other
ABIRATERONE SUBMICRONIZED	YONSA	44946		ROUTE = ORAL

GUIDELINES FOR USE

The guideline named **YONSA (abiraterone, submicronized)** requires that the patient have a diagnosis of metastatic castration-resistant prostate cancer (CRPC). In addition, the requested medication must be used combination with methylprenisolone.

RATIONALE

Promote appropriate utilization of Yonsa based on FDA approved indication and dosing.

DOSAGE

The recommended dose of Yonsa is 500 mg (four 125 mg tablets) administered orally once daily in combination with methylprednisolone 4 mg administered orally twice daily.

Patients receiving Yonsa should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy.

FDA APPROVED INDICATIONS

Yonsa is indicated for the treatment of patients with metastatic castration-resistant prostate cancer (CRPC).

REFERENCES

- Yonsa [Prescribing Information]. Sun Pharma. Cranbury, NJ. May 2018.

Created: 06/18
Effective: 08/20/18 Client Approval: 07/06/18 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ABROCITINIB

Generic	Brand	HICL	GCN	Exception/Other
ABROCITINIB	CIBINQO	47767		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ABROCITINIB (Cibinqo)** requires the following rule(s) be met for approval:

A. You have moderate to severe atopic dermatitis (a type of skin condition)
B. You are 18 years of age or older
C. You had a trial of a high or super-high potency topical corticosteroid (such as triamcinolone acetonide, fluocinonide, clobetasol propionate, halobetasol propionate) AND one non-steroidal topical immunomodulating agent (such as Eucrisa, Opzelura, pimecrolimus, tacrolimus)
D. You had a trial of or contraindication to Rinvoq (upadacitinib)

RENEWAL CRITERIA

Our guideline named **ABROCITINIB (Cibinqo)** requires the following rule(s) be met for renewal:

A. You have moderate to severe atopic dermatitis (a type of skin condition)
B. You have experienced or maintained improvement in at least TWO of the following:
   1. Intractable pruritus (a type of skin condition)
   2. Cracking and oozing/bleeding of affected skin
   3. Impaired activities of daily living

RATIONALE
Ensure appropriate diagnostic, utilization and safety criteria are used for the management of requests for Cibinqo.

INDICATIONS
Cibinqo is a janus kinase (JAK) inhibitor indicated for the treatment of adults with refractory, moderate-to-severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable.

DOSING
The recommended dosage of Cibinqo is 100 mg orally once daily. If an adequate response is not achieved with Cibinqo 100mg orally daily after 12 weeks, consider increasing dosage to 200 mg orally once daily. Discontinue therapy if inadequate response is seen after dosage increase to 200 mg once daily.

REFERENCES
Cibinqo [Prescribing Information]. New York, NY: Pfizer Labs; January 2022.

Created: 03/22
Effective: 04/18/22 Client Approval: 03/22/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ACALABRUTINIB

Generic	Brand	HICL	GCN	Exception/Other
ACALABRUTINIB	CALQUENCE	44607		
ACALABRUTINIB MALEATE	CALQUENCE	48182		

GUIDELINES FOR USE

Our guideline named **ACALABRUTINIB (Calquence)** requires the following rules be met for approval:

A. You have ONE of the following diagnoses:
   1. Mantle cell lymphoma (MCL: a type of blood cancer)
   2. Chronic lymphocytic leukemia (CLL: a type of blood cancer)
   3. Small lymphocytic lymphoma (SLL: a type of blood cancer)

B. **If you have mantle cell lymphoma (MCL), approval also requires:**
   1. You are 18 years of age or older
   2. You have received at least one prior therapy for mantle cell lymphoma

C. **If you have chronic lymphocytic leukemia or small lymphocytic lymphoma, approval also requires:**
   1. You are 18 years of age or older

RATIONALE

To promote appropriate utilization of Calquence based on FDA approved indication.

FDA APPROVED INDICATIONS

Calquence is a kinase inhibitor indicated for the treatment of adult patients with:

- Mantle cell lymphoma (MCL) who have received at least one prior therapy
- Chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)

DOSING

The recommended dose of Calquence is 100 mg taken orally approximately every twelve hours until disease progression or unacceptable toxicity.

REFERENCES

Calquence [Prescribing Information]. AstraZeneca Pharmaceuticals: Wilmington, DE; August 2022.

Created: 11/17
Effective: 10/17/22 Client Approval: 09/16/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ADALIMUMAB

Generic	Brand	HICL	GCN	Exception/Other
ADALIMUMAB	HUMIRA	24800		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ADALIMUMAB (Humira)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in joints in children)
   4. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   5. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   6. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   7. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)
   8. Moderate to severe hidradenitis suppurativa (skin condition with lumps)
   9. Non-infectious intermediate posterior and panuveitis (serious inflammation of eye)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You have previously tried at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs): methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

C. **If you have moderate to severe polyarticular juvenile idiopathic arthritis (PJIA), approval also requires:**
   1. There is documentation of your current weight if you are less than or equal to 17 years of age

D. **If you have moderate to severe plaque psoriasis (PsO), approval also requires:**
   1. You have previously tried **ONE** of the following conventional therapies: PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

E. **If you have moderate to severe Crohn's disease (CD), approval also requires:**
   1. You have previously tried **ONE** or more of the following conventional agents, corticosteroids (e.g., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

F. If you have moderate to severe hidradenitis suppurativa (HS), approval also requires:
   1. You have previously tried oral or topical antibiotic therapy
   2. You have previously tried oral or injectable corticosteroid therapy

G. **If you have non-infectious intermediate, posterior and panuveitis, approval also requires:**
   1. You have previously tried at least ONE of the following: oral or injectable corticosteroid therapy, methotrexate, mycophenolate, azathioprine, cyclosporine, tacrolimus, or cyclophosphamide
   2. There is documentation of your current weight if you are less than or equal to 17 years of age

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ADALIMUMAB

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **ADALIMUMAB (Humira)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in joints in children)
   3. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   4. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   5. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   6. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   7. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)
   8. Moderate to severe hidradenitis suppurativa (skin condition with lumps)
   9. Non-infectious intermediate posterior and panuveitis (serious inflammation of eye)
B. You have history of paid claim(s) for the requested medication in the past 90 days
C. You have previous authorization on file for the requested medication
D. **If you are requesting Humira 40mg weekly dosing OR Humira 80mg every other week dosing for the treatment of moderate to severe rheumatoid arthritis (RA) or plaque psoriasis (PsO),** renewal also requires ONE of the following:
   1. You have had a previous trial of at least a 3-month regimen of Humira 40mg dosed every other week
   2. **BOTH** of the following:
      a. You have history of paid claim(s) for Humira 40mg dosed every week or 80mg dosed every other week in the past 90 days
      b. You have a previous authorization on file for Humira 40mg dosed every week or 80mg dosed every other week
E. **If you are requesting Humira 40mg weekly dosing for the treatment of moderate to severe Crohn's disease (CD) or ulcerative colitis (UC),** renewal requires ONE of the following:
   1. You have had a previous trial of at least a 3-month regimen of Humira 40mg dosed every other week
   2. **BOTH** of the following:
      a. You have history of paid claim(s) for Humira 40mg dosed every week in the past 90 days
      b. You have a previous authorization on file for Humira 40mg dosed every week

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ADALIMUMAB

RATIONALE

Ensure appropriate diagnostic, utilization and safety criteria are used for the management of requests for adalimumab.

FDA APPROVED INDICATIONS

HUMIRA is indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis. HUMIRA can be used alone or in combination with methotrexate or other non-biologic disease-modifying anti-rheumatic drugs (DMARDs).

HUMIRA is indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older. HUMIRA can be used alone or in combination with methotrexate.

HUMIRA is indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis. Humira can be used alone or in combination with non-biologic DMARDs.

HUMIRA is indicated for reducing signs and symptoms in adult patients with active ankylosing spondylitis.

HUMIRA is indicated for the treatment of moderately to severely active Crohn's disease in adults and pediatric patients 6 years of age and older.

HUMIRA is indicated for the treatment of moderately to severely active ulcerative colitis in adults and pediatric patients 5 years of age and older. The effectiveness of HUMIRA has not been established in patients who have lost response to or were intolerant to TNF blockers.

HUMIRA is indicated for the treatment of moderate to severe hidradenitis suppurativa in patients 12 years of age and older.

HUMIRA is indicated for the treatment of non-infectious intermediate, posterior and panuveitis in adults and pediatric patients 2 years of age and older.

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ADALIMUMAB

FDA APPROVED INDICATIONS (CONTINUED)

DOSING

Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis
40mg every other week. Some patients with RA not receiving methotrexate may benefit from increasing the frequency to 40mg every week or 80mg every other week.

Juvenile Idiopathic Arthritis or Pediatric Uveitis
The recommended dose of HUMIRA for patients 2 years of age and older with polyarticular juvenile idiopathic arthritis (JIA) or pediatric uveitis is based on weight as shown below:
10kg (22 lbs.) to <15kg (33 lbs.): 10mg every other week
15 kg (33 lbs.) to <30 kg (66 lbs.): 20mg every other week
⩾30 kg (66 lbs.): 40mg every other week

Adult Crohn's Disease and Ulcerative Colitis
Initial dose (Day 1) is 160mg (four 40mg injections in one day or two 40mg injections per day for two consecutive days), followed by 80mg two weeks later (Day 15). Two weeks later (Day 29) begin a maintenance dose of 40mg every other week.

Adult Hidradenitis Suppurativa
Initial dose (Day 1) is 160mg (four 40mg injections in one day or two 40mg injections per day for two consecutive days), followed by 80mg two weeks later (Day 15). Two weeks later (Day 29) begin a maintenance dose of 40mg every week.

Plaque Psoriasis or Uveitis
80mg initial dose followed by 40mg every other week starting one week after initial dose.

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ADALIMUMAB

FDA APPROVED INDICATIONS (CONTINUED)

Pediatric Crohn's Disease

	17 kg to <40kg OR 37 lbs. to <88 lbs.	⩾40kg OR ⩾ 88 lbs.
Day 1	**80mg x1** (Two 40mg injections in one day)	**160mg x1** (Four 40mg injections in one day or two 40mg injections for 2 days)
Day 15	**40mg x1**	**80mg x1**
Day 29	**20mg every other week**	**40mg every other week**

Pediatric Ulcerative Colitis

	20 kg to <40kg OR 44 lbs. to <88 lbs.	⩾40kg OR ⩾ 88 lbs.
Day 1	**80mg x1** (Two 40mg injections in one day)	**160mg x1** (Four 40mg injections in one day or two 40mg injections for 2 days)
Day 8	**40mg x1**	**80mg x1**
Day 15	**40mg x1**	**80mg x1**
Day 29	**40mg every other week or 20mg every week**	**80mg every other week or 40mg every week**

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ADALIMUMAB

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE FORMS AND STRENGTHS

- **HUMIRA Pen Carton - 40 mg/0.8 mL**
- **HUMIRA Pen Carton - 40 mg/0.4 mL**
- **HUMIRA Pen Carton - 80 mg/0.4 mL**
- **HUMIRA Pen 40 mg/0.8 mL - Starter Package for Crohn's Disease, Ulcerative Colitis or Hidradenitis Suppurativa**
- **HUMIRA Pen 40 mg/0.4 mL - Starter Package for Crohn's Disease, Ulcerative Colitis or Hidradenitis Suppurativa**
- **HUMIRA Pen 80 mg/0.8 mL - Starter Package for Crohn's Disease, Ulcerative Colitis or Hidradenitis Suppurativa**
- **HUMIRA Pen 40 mg/0.8 mL - Psoriasis, Uveitis or Adolescent Hidradenitis Suppurativa Starter Package**
- **HUMIRA Pen 40 mg/0.4 mL - Psoriasis, Uveitis or Adolescent Hidradenitis Suppurativa Starter Package**
- **HUMIRA Pen 80 mg/0.8 mL and 40 mg/0.4 mL - Psoriasis, Uveitis or Adolescent Hidradenitis Suppurativa Starter Package**
- **HUMIRA Pen 80 mg/0.8 mL - Starter Package for Pediatric Ulcerative Colitis (4 count)**
- **Prefilled Syringe Carton - 40 mg/0.8 mL**
- **Prefilled Syringe Carton - 40 mg/0.4 mL**
- **Prefilled Syringe Carton - 20 mg/0.4 mL**
- **Prefilled Syringe Carton - 20 mg/0.2 mL**
- **Prefilled Syringe Carton - 10 mg/0.2 mL**
- **Prefilled Syringe Carton - 10 mg/0.1 mL**
- **HUMIRA Prefilled Syringe 40 mg/0.8 mL - Pediatric Crohn’s Disease Starter Package (6 count)**
- **HUMIRA Prefilled Syringe 80 mg/0.8 mL - Pediatric Crohn’s Disease Starter Package (3 count)**
- **HUMIRA Prefilled Syringe 40 mg/0.8 mL - Pediatric Crohn’s Disease Starter Package (3 count)**
- **HUMIRA Prefilled Syringe 80 mg/0.8 mL and 40 mg/0.4 mL - Pediatric Crohn’s Disease Starter Package (2 count)**
- **Single-Use Institutional Use Vial Carton - 40 mg/0.8 mL**

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REFERENCES

- Humira [Prescribing Information]. North Chicago, IL: AbbVie Inc. February 2021
- Beukelman T, Patkar NM, Saag KG et al. 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: Initiation and safety monitoring of therapeutic agents for the treatment of arthritis and systemic features. Arthritis Care Res, 63: 465–482. doi: 10.1002/acr.20460
- Braun J, Davis J, et al. First update of the international ASAS consensus statement for the use of anti-TNF agents in patients with Ankylosing Spondylitis. Ann Rheum Dis. 2006; 65(3):316-20
- Kornbluth A, Sachar DB. Ulcerative colitis practice guidelines in adults: American College of Gastroenterology, Practice Parameters Committee. Am J Gastroenterol 2010;105:501-523
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- Singh JA, Guyatt G, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Care & Research. Vol. 71, No. 1, January 2019, pp 2–29. DOI 10.1002/acr.2378
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Created: 03/15
Effective: 08/20/2021 Client Approval: 08/13/2021 P&T Approval: N/A

AFATINIB

Generic	Brand	HICL	GCN	Exception/Other
AFATINIB DIMALEATE	GILOTRIF	40478		

GUIDELINES FOR USE

Approval requires a diagnosis of non-small cell lung cancer (NSCLC) and one of the following:

- The patient has metastatic NSCLC that has progressed after platinum-based chemotherapy.
- The medication is being requested as first line treatment for tumors with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test.

RATIONALE

Promote appropriate utilization of **AFATINIB (Gilotrif)** based on its FDA approved indications.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

AFATINIB

FDA APPROVED INDICATIONS

- Gilotrif is a kinase inhibitor indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test.

Limitation of Use: Safety and efficacy of Gilotrif have not been established in patients whose tumors have other EGFR mutations.

- Gilotrif is indicated for the treatment of patients with metastatic squamous NSCLC progressing after platinum-based chemotherapy.

The recommended dose of Gilotrif is 40 mg orally once daily until disease progression or no longer tolerated by the patient. Take Gilotrif at least 1 hour before or 2 hours after a meal. Do not take a missed dose within 12 hours of the next dose.

Withhold Gilotrif for any drug-related adverse reactions of:

- National Cancer Institute Common Terminology Criteria for Adverse Events Grade 3 or higher
- Diarrhea of Grade 2 or higher persisting for 2 or more consecutive days while taking anti-diarrheal medication
- Cutaneous reactions of Grade 2 that are prolonged (lasting more than 7 days) or intolerable
- Renal dysfunction of Grade 2 or higher

Resume treatment when the adverse reaction fully resolves, returns to baseline, or improves to Grade 1. Reinstitute Gilotrif at a reduced dose, i.e., 10 mg per day less than the dose at which the adverse reaction occurred.

Permanently discontinue Gilotrif for:

- Life-threatening bullous, blistering, or exfoliative skin lesions
- Confirmed interstitial lung disease (ILD)
- Severe drug-induced hepatic impairment
- Persistent ulcerative keratitis
- Symptomatic left ventricular dysfunction
- Severe or intolerable adverse reaction occurring at a dose of 20 mg per day

REFERENCES

- Gilotrif [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc. January 2018.

Created: 06/15
Effective: 02/02/18 Client Approval: 01/17/18 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ALECTINIB

Generic	Brand	HICL	GCN	Exception/Other
ALECTINIB	ALECENSA	42895		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

Our guideline for **ALECTINIB** (Alecensa) requires a diagnosis of metastatic non-small cell lung cancer (NSCLC) AND the patient is positive for anaplastic lymphoma kinase (ALK) oncogene as detected by an FDA approved test.

RATIONALE

Promote appropriate utilization of **ALECTINIB (Alecensa)** based on its FDA approved indication.

FDA APPROVED INDICATIONS

Alecensa is indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer (NSCLC) as detected by an FDA approved test.

DOSAGE

The recommended dose of Alecensa is 600 mg orally twice daily with food. Alecensa therapy is continued until disease progression or unacceptable toxicity.

The dose of Alecensa can be modified if certain adverse reactions or laboratory abnormalities occur (e.g., elevated hepatic transaminases, bradycardia, elevated CPK). The dose should be reduced first to 450 mg twice daily, then to 300 mg twice daily, and discontinued if intolerability persists thereafter. If treatment-related ILD/pneumonitis, elevated ALT or AST greater than 3 times ULN with total bilirubin greater than 2 times ULN in the absence of cholestasis or hemolysis, grade 4 renal impairment, or life-threatening bradycardia occurs, Alecensa should be permanently discontinued.

The contents of the capsule should not be opened or dissolved. If a dose is missed or vomiting occurs after taking a dose, the next dose should be taken at the scheduled time.

REFERENCES

- Alecensa [Prescribing Information]. South San Francisco, CA: Genentech, Inc. November 2017.

Created: 01/16
Effective: 11/01/18 Client Approval: 09/24/18 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ALEMTUZUMAB

Generic	Brand	HICL	GCN	Exception/Other
ALEMTUZUMAB	LEMTRADA		36182	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named **ALEMTUZUMAB (Lemtrada)** requires that the patient has a relapsing form of multiple sclerosis and that the patient has tried at least **TWO** of the following preferred MS agents: Aubagio, Avonex, Copaxone, Gilenya, Rebif, or Tecfidera. Please note that other MS agents may also require prior authorization.

RENEWAL CRITERIA

The guideline named **ALEMTUZUMAB (Lemtrada)** renewal requires that the patient have a relapsing form of multiple sclerosis. Approval also requires that at least 12 months has elapsed since receiving the first course of Lemtrada. Patients are limited to two Lemtrada courses of therapy in a lifetime.

RATIONALE
To ensure appropriate utilization of LEMTRADA.

FDA APPROVED INDICATIONS
LEMTRADA is indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS). Because of its safety profile, the use of Lemtrada should be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.

The efficacy of Lemtrada was evaluated in two studies, known in the literature as CARE- MS I and CARE-MS II studies, and referred to in the prescribing information as Study 2 and 1, respectively. Both studies were 2-year randomized, open-label, rater-blinded, active comparator (interferon 576 beta-1a 44 micrograms administered subcutaneously three times a week) controlled study in patients with RRMS. Patients had to have at least 2 relapses during the 2 years prior to trial entry and at least 1 relapse during the year prior to trial entry. Subjects randomized to Lemtrada received 12mg, once daily, as an infusion for 5 days for the first treatment course and then 1 year later received a 12 mg, once daily, as an infusion for 3 days for the 2nd course of treatment. In Study 1, both co-primary endpoints were statistically significantly lower for Lemtrada than for Rebif. In Study 2, the annualized relapse rate was statistically significantly lower for Lemtrada than for Rebif. There was no significant difference between Lemtrada and Rebif for the time to confirmed disability progression. Neither study showed a difference for the MRI outcome measure of change in T2 lesion volume.

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ALEMTUZUMAB

FDA APPROVED INDICATIONS (CONTINUED)

DOSING

Lemtrada is administered by intravenous infusion over 4 hours and for 2 annual treatment courses. The first course is 12mg/day for 5 consecutive days. The second course, which follows 12 months after the 1st course, is 12mg/day for 3 consecutive days. Patients should be pre-medicated with high dose corticosteroids (1000mg methylprednisolone or equivalent) immediately prior to receiving the Lemtrada infusion for the first 3 days of each treatment course. It is also recommended that patients be treated with anti-viral prophylaxis for herpetic viral infections on the first day of each treatment course and continue for a minimum of two months following treatment or until CD4+ lymphocyte count is ≥ 200 cells per microliter. Lemtrada should be administered in a setting with personnel and equipment to manage any serious infusion reaction or anaphylaxis.

REFERENCES

- Lemtrada [Prescribing Information]. Genzyme Corporation. Cambridge, MA. November 2014. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/103948s5139lbl.pdf [Accessed 12/3/14].
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Created: 02/18
Effective: 06/01/18 Client Approval: 04/10/18 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ALIROCUMAB

Generic	Brand	HICL	GCN	Exception/Other
ALIROCUMAB	PRALUENT	42347		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

Our guideline named **ALIROCUMAB (Praluent)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Established cardiovascular disease (health problems related to narrow or blocked blood vessels of the heart) such as history of myocardial infarction (heart attack) or other acute coronary syndrome, coronary or other revascularization procedure (restoring blood flow to heart and other areas), transient ischemic attack (short, stroke-like attack), ischemic stroke (arteries to your brain become narrowed or blocked), atherosclerotic peripheral arterial disease (arteries get blocked with fats and plaques), coronary atherosclerosis (heart arteries get blocked with fats and plaques), renal atherosclerosis (kidney arteries get blocked with fats and plaques), aortic aneurysm secondary to atherosclerosis (fat and plaque buildup causes enlargement of a heart artery), carotid plaque with 50% or more stenosis (narrowing of blood vessel)
   2. Primary hyperlipidemia (high cholesterol such as heterozygous familial hypercholesterolemia [HeFH: type of inherited high cholesterol])
   3. Homozygous familial hypercholesterolemia (HoFH: type of inherited high cholesterol)
B. You are 18 years of age or older
C. You have a baseline LDL (low density lipoprotein)-cholesterol level greater than or equal to 70 mg/dL
D. You meet ONE of the following:
   1. You are currently taking a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) AND have been taking it for a duration of at least 8 weeks
   2. You have a documented intolerance to BOTH rosuvastatin and atorvastatin
   3. Your prescriber has provided medical rationale against use of statin therapy
E. You will continue to take statin therapy in combination with Praluent, unless contraindicated or not tolerated

RENEWAL CRITERIA

Our guideline named **ALIROCUMAB (Praluent)** requires the following rule(s) be met for approval:

A. You have a history of paid claim(s) for the requested medication in the past 90 days
B. You have a previous authorization on file for the requested medication
C. You meet **ONE** of the following:
   1. You have continued concurrent therapy with a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
   2. You have a documented intolerance to statin therapy
   3. The prescriber has provided medical rationale against use of statin therapy
D. Documentation of reduction in LDL-cholesterol from baseline

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ALIROCUMAB

RATIONALE
Promote appropriate utilization of Praluent based on FDA approved indication.

FDA APPROVED INDICATIONS
Praluent is a PCSK9 (Proprotein Convertase Subtilisin Kexin Type 9) inhibitor antibody indicated:
- To reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease.
- As adjunct to diet, alone or in combination with other low-density lipoprotein cholesterol (LDL-C)-lowering therapies, in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce LDL-C.
- As an adjunct to other LDL-C-lowering therapies in adult patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C.

DOSAGE
In adults with established cardiovascular disease or with primary hyperlipidemia, including HeFH:
- The recommended starting dose of Praluent is either 75 mg once every 2 weeks or 300 mg once every 4 weeks administered subcutaneously.
- For patients receiving Praluent 300 mg every 4 weeks, measure LDL-C just prior to the next scheduled dose, because LDL-C can vary between doses in some patients.
- If the LDL-C response is inadequate, the dosage may be adjusted 150 mg subcutaneously every 2 weeks.

In adults with HeFH undergoing LDL apheresis or in adults with HoFH:
- The recommended dose of Praluent is 150 mg once every 2 weeks administered subcutaneously.
- Praluent can be administered without regard to the timing of LDL apheresis.

Measure LDL-C levels within 4 to 8 weeks of initiating or titrating Praluent, to assess response and adjust the dose, if needed.

REFERENCES
Praluent package insert. Bridgewater, NJ: Sanofi-Aventis US LLC; April 2021.

Created: 02/18
Effective: 05/16/22 Client Approval: 05/02/22 P&T Approval: N/A

ALLERGEN EXTRACT-HOUSE DUST MITE

Generic	Brand	HICL	GCN	Exception/Other
HOUSE DUST MITE	ODACTRA		42527	ROUTE = SUBLINGUAL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ALLERGEN EXTRACT-HOUSE DUST MITE (Odactra)** requires the following rule(s) be met for approval:

A. You have allergic rhinitis (itchy, watery eyes, sneezing) caused by house dust mites, with or without conjunctivitis (type of inflammation of eye and eyelid)
B. Your diagnosis is confirmed by in vitro testing (testing outside of your body in a tube) for IgE (Immunoglobulin E) antibodies *to Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites, or skin testing to licensed house dust mite allergen extracts
C. You are between 18 and 65 years old
D. You have tried or have a contraindication or intolerance to TWO of the following:
    1. Oral antihistamine
    2. Intranasal antihistamine
    3. Intranasal corticosteroid
    4. Leukotriene inhibitor
E. You have tried and failed subcutaneous allergen immunotherapy (SCIT) containing house dust mite allergen

RENEWAL CRITERIA

Our guideline named **ALLERGEN EXTRACT-HOUSE DUST MITE (Odactra)** requires the following rule is met for renewal:

A. You have history of paid claim(s) for the requested medication in the past 90 days
B. You have a previous authorization on file for the requested medication

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ALLERGEN EXTRACT-HOUSE DUST MITE

RATIONALE
Promote appropriate utilization of Odactra based on FDA approved indication, dosage, and guidelines adopted from ARIA (Allergic Rhinitis and its Impact on Asthma) as well as the AAAAI (American Academy of Allergy, Asthma & Immunology) Practice Parameter on Allergen Immunotherapy.

INDICATIONS
Odactra is an allergen extract indicated as immunotherapy for house dust mite (HDM)-induced allergic rhinitis, with or without conjunctivitis, confirmed by in vitro testing for IgE antibodies to Dermatophagoides farinae or Dermatophagoides pteronyssinus house dust mites, or skin testing to licensed house dust mite allergen extracts. ODACTRA is approved for use in adults 18 through 65 years of age.

DOSING
The recommended dose is one tablet daily.

REFERENCES

- Odactra [Prescribing Information]. Merck, Sharp & Dohme Corp. Whitehouse Station, NJ. August 2019.

Created: 10/21
Effective: 03/04/22 Client Aproval: 02/03/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ALLERGEN EXTRACT-MIXED GRASS POLLEN

Generic	Brand	HICL	GCN	Exception/Other
GR POL-ORC/SW VER/RYE/KENT/TIM	ORALAIR	39918		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ALLERGEN EXTRACT-MIXED GRASS POLLEN (Oralair)** requires the following rule(s) be met for approval:

A. You have a diagnosis of allergic rhinitis (itchy, watery eyes, sneezing) caused by grass pollen
B. Your diagnosis is confirmed by a positive skin prick test and/or a positive titer (the amount of antibodies in the blood) to specific IgE (Immunoglobulin E) antibodies for any of the five grass types included in Oralair (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens)
C. You have tried or have a contraindication or intolerance to TWO of the following:
    1. Oral antihistamine
    2. Intranasal antihistamine
    3. Intranasal corticosteroid
    4. Leukotriene inhibitor
D. You have tried and failed subcutaneous allergen immunotherapy (SCIT) containing any of the five grass species included in Oralair (i.e., Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue grass mixed pollens)
E. You are between 5 and 65 years of age

RENEWAL CRITERIA

Our guideline named **ALLERGEN EXTRACT-MIXED GRASS POLLEN (Oralair)** requires the following rules be met for renewal:

A. You have history of paid claim(s) for the requested medication in the past 90 day
B. You have a previous authorization on file for the requested medication

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ALLERGEN EXTRACT-MIXED GRASS POLLEN

RATIONALE
Promote appropriate utilization of Oralair based on FDA approved indication, dosage, and guidelines adopted from ARIA (Allergic Rhinitis and its Impact on Asthma) as well as the AAAAI (American Academy of Allergy, Asthma & Immunology) Practice Parameter on Allergen Immunotherapy.

FDA APPROVED INDICATIONS
Oralair (5-Grass Pollen Allergy Extract Sublingual tablet containing Sweet Vernal, Orchard, Perennial Rye, Timothy and Kentucky Blue Grass) is indicated for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for any of the five grass species contained in Oralair, in people ages 10 through 65 years.

DOSAGE
For adults 18 through 65 years of age, the dose is 300 IR daily.
For children and adolescents 10 through 17 years of age, the dose is increased over the first three days (day 1 = 1 x 100 IR, day 2 = 2 x 100 IR, day 3 = 1 x 300 IR).

REFERENCES

- GREER Laboratories, Inc. Oralair Package Insert. Lenoir, NC. December 2018.

Created: 06/15
Effective: 03/04/22 Client Approval: 02/03/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ALLERGEN EXTRACT-SHORT RAGWEED POLLEN

Generic	Brand	HICL	GCN	Exception/Other
WEED POLLEN-SHORT RAGWEED	RAGWITEK	41079	36402	

GUIDELINES FOR USE
INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ALLERGEN EXTRACT-SHORT RAGWEED POLLEN (Ragwitek)** requires the following rule(s) be met for approval:

A. You have allergic rhinitis (itchy, watery eyes, sneezing) caused by short ragweed pollen
B. Your diagnosis is confirmed by a positive skin test or in vitro testing (testing outside of your body in a tube) for pollen-specific IgE (Immunoglobulin E) antibodies for short ragweed pollen
C. You have tried or have a contraindication or intolerance to TWO of the following:
    1. Oral antihistamine
    2. Intranasal antihistamine
    3. Intranasal corticosteroid
    4. Leukotriene inhibitor
D. You have tried and failed subcutaneous allergen immunotherapy (SCIT) containing short ragweed pollen
E. You are between 5 and 65 years of age

RENEWAL CRITERIA

Our guideline named **ALLERGEN EXTRACT-SHORT RAGWEED POLLEN (Ragwitek)** requires the following rule(s) be met for renewal:

A. You have history of paid claim(s) for the requested medication in the past 90 day
B. You have a previous authorization on file for the requested medication

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RATIONALE
Promote appropriate utilization of Ragwitek based on FDA approved indication, dosage, and guidelines adopted from ARIA (Allergic Rhinitis and its Impact on Asthma) as well as the AAAAI (American Academy of Allergy, Asthma & Immunology) Practice Parameter on Allergen Immunotherapy.

FDA APPROVED INDICATIONS
Ragwitek (short ragweed pollen extract) approved and indicated for the treatment of short ragweed pollen-induced allergic rhinitis, with or without conjunctivitis, confirmed by a positive skin prick test or in vitro testing for pollen-specific IgE antibodies for short ragweed pollen in adults 18 years through 65 years of age.

DOSAGE
For children and adults 5 through 65 years of age, the dose is 1 tablet (12 Amb a 1-U) daily.

REFERENCES

- Merck, Sharp & Dohme Corp. Ragwitek Package Insert. Whitehouse Station, NJ. April 2021.

Created: 06/15
Effective: 03/04/22 Client Approval: 02/03/22 P&T Approval: N/A

ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN

Generic	Brand	HICL	GCN	Exception/Other
GRASS POLLEN-TIMOTHY, STD	GRASTEK	22138		ROUTE = SUBLINGUAL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN (Grastek)** requires the following rule(s) be met for approval:

A. You have a diagnosis of allergic rhinitis (itchy, watery eyes, sneezing) caused by grass pollen
B. You have a positive skin prick test and/or a positive titre (the amount of antibodies in the blood) to specific IgE (Immunoglobulin E) antibodies for Timothy grass or cross-reactive grass pollens
C. You have tried or have a contraindication or intolerance to TWO of the following:
    1. Oral antihistamine
    2. Intranasal antihistamine
    3. Intranasal corticosteroid
    4. Leukotriene inhibitor
D. You have tried and failed subcutaneous allergen immunotherapy (SCIT) containing Timothy grass or cross-reactive grass pollens (e.g., Sweet Vernal, Orchard/Cocksfoot, Perennial Rye, Kentucky Blue/June Grass, Meadow Fescue, or Redtop)
E. You are between 5 and 65 years old

RENEWAL CRITERIA

Our guideline named **ALLERGEN EXTRACT-MIXED GRASS POLLEN (Grastek)** requires the following rules be met for renewal:

A. You have history of paid claim(s) for the requested medication in the past 90 days
B. You have a previous authorization on file for the requested medication

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN

RATIONALE
Promote appropriate utilization of Grastek based on FDA approved indication, dosage, and guidelines adopted from ARIA (Allergic Rhinitis and its Impact on Asthma) as well as the AAAAI (American Academy of Allergy, Asthma & Immunology) Practice Parameter on Allergen Immunotherapy.

FDA APPROVED INDICATIONS
Grastek (Timothy grass pollen extract) approved and indicated for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens, in people ages 5 through 65 years.

DOSAGE
For children and adults 5 to 65 years of age, the dose is 1 tablet (2800 BAU) daily.

REFERENCES

- Merck Sharp & Dohme Corp. Grastek Package Insert. Whitehouse Station, NJ. December 2019.

Created: 06/15
Effective: 03/04/22 Client Approval: 02/03/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ALPELISIB

Generic	Brand	HICL	GCN	Exception/Other
ALPELISIB	PIQRAY		46358 46359 46362	

GUIDELINES FOR USE

Our guideline named **ALPELISIB (Piqray)** requires the following rule(s) be met for approval:

A. You have a diagnosis of advanced or metastatic breast cancer (breast cancer that has spread to other parts of the body)
B. Your breast cancer is hormone receptor (HR: type of gene)-positive, human epidermal growth factor receptor 2 (HER2: type of gene)-negative
C. You are a postmenopausal female or a male
D. Piqray will be used in combination with Faslodex (fulvestrant)
E. You have presence of PIK3CA (type of gene)-mutation as detected by a Food and Drug Administration approved test
F. You have experienced disease progression on or after an endocrine-based regimen (your disease has worsened after using a type of hormone therapy)

RATIONALE

To ensure the appropriate use of ALPELISIB according to diagnosis.

INDICATION

Piqray is a kinase inhibitor indicated in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen.

DOSING

The recommended dose is 300 mg ALPELISIB (Piqray) (two 150 mg film-coated tablets) taken orally, once daily, with food.
When given with ALPELISIB, the recommended dose of fulvestrant is 500 mg administered on Days 1, 15, and 29, and once monthly thereafter.

REFERENCES

Piqray [Prescribing Information]. East Hanover, NJ. Novartis Pharmaceuticals Corp., July 2021.

Created: 07/19
Effective: 07/01/22 Client Approval: 05/20/22 P&T Approval: N/A

ALPHA$_1$-PROTEINASE INHIBITOR, HUMAN

Generic	Brand	HICL	GCN	Exception/Other
ALPHA-1-PROTEINASE INHIBITOR, HUMAN	ARALAST NP	04529		
ALPHA-1-PROTEINASE INHIBITOR, HUMAN	GLASSIA	04529		
ALPHA-1-PROTEINASE INHIBITOR, HUMAN	PROLASTIN C	04529		
ALPHA-1-PROTEINASE INHIBITOR, HUMAN	ZEMAIRA	04529		

GUIDELINES FOR USE

Our guideline for Alpha1-proteinase inhibitor requires a diagnosis of emphysema, serum Alpha1-antitrypsin level less than 11mmols/L or less than 80mg/dL by radial immunodiffusion or less than 50mg/dL by nephelometry, and that the patient does not have an IgA deficiency with antibodies against IgA.

ALPHA1-PROTEINASE INHIBITOR, HUMAN

RATIONALE

Ensure appropriate use of Alpha$_1$-proteinase inhibitor.

FDA APPROVED INDICATIONS

Alpha$_1$-Proteinase Inhibitors are indicated for chronic augmentation and maintenance therapy in individuals with emphysema due to congenital deficiency of Alpha$_1$-proteinase inhibitor (Alpha$_1$-PI), also known as alpha$_1$-antitrypsin (AAT) deficiency.

The effect of augmentation therapy with any Alpha$_1$-PI product on pulmonary exacerbations and on the progression of emphysema in Alpha$_1$-PI deficiency has not been demonstrated in randomized, controlled clinical trials.

Clinical data demonstrating the long-term effects of chronic augmentation and maintenance therapy of individuals with Alpha$_1$-PI are not available.

Alpha$_1$-PI are not indicated as therapy for lung disease in patients in whom severe Alpha$_1$-PI deficiency has not been established.

REFERENCES

1. Glassia® [package insert]. Lexington, MA. Baxalta US Inc. September 2017.
2. Prolastin-C® [package insert]. Research Triangle Park, NC. Grifols Therapeutics, Inc. August 2016.
3. Zemaira® [package insert]. Kankakee, IL. CSL Behring LLC. September 2015.
4. Aralast NP™ [package insert]. Westlake Village, CA. Baxalta US Inc. March 2017.

Created: 10/15
Effective: 02/02/18 Client Approval: 01/17/18 P&T Approval: N/A

AMANTADINE EXTENDED RELEASE

Generic	Brand	HICL	GCN	Exception/Other
AMANTADINE ER	OSMOLEX ER		44471, 44472, 44473, 48017	ROUTE = ORAL

GUIDELINES FOR USE

Our guideline named **AMANTADINE EXTENDED RELEASE (Osmolex ER)** requires the following rule(s) be met for approval:

A. You have Parkinson's disease (nervous system disorder that affects movement) OR you are being treated for drug-induced extrapyramidal symptoms (group of movement disorders)
B. You have previously tried generic amantadine immediate-release capsules, tablets or solution
C. **If you are being treated for drug-induced extrapyramidal symptoms, approval also requires:**
   1. You are 18 years of age or older

RATIONALE
Promote appropriate utilization of Osmolex ER based on FDA approved indication and dosing.

DOSAGE
The recommended dose of Osmolex ER is 1 extended-release tablet by mouth daily (do not chew, crush, or divide) in the morning, beginning at a dose of 129 mg per day. Dosing may be increased in weekly intervals to a maximum of 322 mg daily.

FDA APPROVED INDICATIONS
Osmolex ER is indicated for the treatment of:

- Parkinson's disease
- Drug-induced extrapyramidal reactions in adult patients

REFERENCES
Osmolex ER [Prescribing Information]. Vertical Pharmaceuticals. Bridgewater, NJ. March 2021.

Created: 06/18
Effective: 03/14/22 Client Approval: 02/14/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

AMIFAMPRIDINE

Generic	Brand	HICL	GCN	Exception/Other
AMIFAMPRIDINE	FIRDAPSE	36930		
AMIFAMPRIDINE	RUZURGI	34158	46265	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **AMIFAMPRIDINE (Firdapse)** requires the following rule(s) be met for approval:

A. You have Lambert-Eaton myasthenic syndrome (LEMS - a type of muscle disorder)
B. You are 18 years of age or older
C. Diagnosis is confirmed by electrodiagnostic studies and/or voltage-gated calcium channel (types of lab tests) antibody testing **AND** clinical triad (3 symptoms) of muscle weakness, autonomic dysfunction, and decreased tendon reflexes
D. **If you are requesting Firdapse, approval also requires:**
   1. You are 18 years of age or older
E. **If you are requesting Ruzurgi, approval also requires:**
   1. Documentation of your weight

RENEWAL CRITERIA

Our guideline named **AMIFAMPRIDINE (Firdapse, Ruzurgi)** requires the following rules be met for renewal:

A. You have Lambert-Eaton myasthenic syndrome (LEMS - a type of muscle disorder)
B. You have experienced improvement or stabilization in muscle weakness compared to baseline

RATIONALE

To ensure safe and appropriate use of amifampridine per approved indication and dosing.

FDA APPROVED INDICATIONS

Amifampridine is a potassium channel blocker indicated for the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults.

DOSAGE AND ADMINISTRATION

The recommended starting dosage of amifampridine is 15 mg to 30 mg daily, taken orally in divided doses (3 to 4 times daily). The dosage can be increased by 5 mg daily every 3 or 4 days. The maximum recommended total daily dosage is 80 mg.

REFERENCES

- Firdapse [Prescribing Information]. Coral Gables, FL: Catalyst Pharmaceuticals, Inc: February 2021.
- Ruzurgi [Prescribing Information]. Princeton, NJ: Jacobus Pharmaceutical Company, Inc., May 2019.

Created: 03/19
Effective: 04/11/22 Client Approval: 03/09/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ANABOLIC STEROIDS

Generic	Brand	HICL	GCN	Exception/Other
OXYMETHOLONE	ANADROL-50	01409		ROUTE ≠ MISCELL.
OXANDROLONE	OXANDRIN	01412		ROUTE ≠ MISCELL.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

ANADROL-50:
Our guideline named **ANABOLIC STEROIDS (Anadrol-50)** requires the following rule(s) be met for approval:

A. You have anemia (lack of healthy red blood cells) or cachexia (condition with extreme weight loss and muscle loss) associated with AIDS (acquired immune deficiency syndrome)
B. You will be monitored for peliosis hepatis (blood-filled spaces in the liver), liver cell tumors and blood lipid (fats) changes
C. You do not have ANY of the following reasons why you cannot use anabolic steroid therapy:
    1. Known or suspected prostate or breast cancer in male patients
    2. Known or suspected breast cancer in females with hypercalcemia (high calcium levels)
    3. Known or suspected nephrosis (the nephrotic phase of nephritis-kidney inflammation)
    4. Known or suspected hypercalcemia (high calcium levels)
    5. Severe hepatic (liver) dysfunction
D. **If you have anemia, approval also requires:**
    1. The anemia is caused by one of the following conditions: acquired aplastic anemia, congenital aplastic anemia, myelofibrosis and the hypoplastic anemias, or Fanconi's
E. **If you have cachexia associated with AIDS, approval also requires:**
    1. You are on anti-retroviral therapy (therapy that treats a type of immune system virus)
    2. You have a documented viral load (amount of virus in your blood) of less than 200 copies per mL dated within the past 3 months
    3. You meet ONE of the following:
        a. You have 10% unintentional weight loss over 12 months
        b. You have 7.5% unintentional weight loss over 6 months
        c. You have 5% body cell mass (BCM) loss within 6 months
        d. You have a BCM of less than 35% (men) and a body mass index (BMI) of less than 27 kg per meter squared
        e. You have a BCM of less than 23% (women) of total body weight and a body mass index (BMI) of less than 27 kg per meter squared
        f. You have a BMI of less than 18.5 kg per meter squared

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ANABOLIC STEROIDS

INITIAL CRITERIA (CONTINUED)

OXANDRIN

Our guideline named **ANABOLIC STEROIDS (Oxandrin)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Weight loss
   2. Protein catabolism (breakdown) caused by long-term use of corticosteroids
   3. Bone pain accompanying osteoporosis (weak and brittle bones)
   4. Cachexia (condition with extreme weight loss and muscle loss) associated with AIDS (acquired immune deficiency syndrome)
   5. Turner's Syndrome (disorder where female has one X chromosome

B. You will be monitored for peliosis hepatis (blood-filled spaces in the liver), liver cell tumors and blood lipid (fats) changes

C. You do not have ANY of the following reasons why you cannot use anabolic steroid therapy:
   1. Known or suspected prostate or breast cancer in male patients
   2. Known or suspected breast cancer in females with hypercalcemia (high calcium levels)
   3. Known or suspected nephrosis (the nephrotic phase of nephritis-kidney inflammation)
   4. Known or suspected hypercalcemia (high calcium levels)
   5. Severe hepatic (liver) dysfunction

D. **If you have weight loss, approval also requires:**
   1. Your weight loss is caused by extensive surgery, chronic infections, or severe trauma
   2. Medication is being used as add-on therapy to help weight gain

E. **If you have cachexia associated with AIDS, approval also requires:**
   1. You are on anti-retroviral therapy (therapy that treats a type of immune system virus)
   2. You have a documented viral load (amount of virus in your blood) of less than 200 copies per mL dated within the past 3 months
   3. You meet ONE of the following:
      a. You have 10% unintentional weight loss over 12 months
      b. You have 7.5% unintentional weight loss over 6 months
      c. You have 5% body cell mass (BCM) loss within 6 months
      d. You have a BCM of less than 35% (men) and a body mass index (BMI) of less than 27 kg per meter squared
      e. You have a BCM of less than 23% (women) of total body weight and a body mass index (BMI) of less than 27 kg per meter squared
      f. You have a BMI of less than 18.5 kg per meter squared

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ANABOLIC STEROIDS

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

(**NOTE:** For the diagnosis of anemia, weight loss, protein catabolism associated with prolonged administration of corticosteroids, bone pain accompanying osteoporosis, or Turner's Syndrome, please refer to the Initial Criteria section)

OXANDRIN and ANADROL

Our guideline named **ANABOLIC STEROIDS (Oxandrin and Anadrol-50)** requires the following rule(s) be met for renewal:

A. You have cachexia (condition with extreme weight loss and muscle loss) associated with AIDS (acquired immune deficiency syndrome)
B. You are on anti-retroviral therapy (therapy that treats a type of immune system virus)
C. Your viral load (amount of virus in your blood) is less than 200 copies per mL within the past 3 months
D. You have a 10% increase in weight from baseline (current weight must have been measured within the last 4 weeks, document date of measurement)
E. You have not received more than 24 weeks of therapy in a calendar year

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ANABOLIC STEROIDS

RATIONALE
To cover oxandrolone or oxymetholone for FDA approved indications and the following compendia indication: HIV wasting syndrome or HIV related cachexia.

FDA APPROVED INDICATIONS
Anadrol®-50 Tablets is indicated in the treatment of anemias caused by deficient red cell production. Acquired aplastic anemia, congenital aplastic anemia, myelofibrosis and the hypoplastic anemias due to the administration of myelotoxic drugs often respond. Anadrol®-50 Tablets should not replace other supportive measures such as transfusion, correction of iron, folic acid, vitamin B12 or pyridoxine deficiency, antibacterial therapy and the appropriate use of corticosteroids.

Oxandrin is indicated as adjunctive therapy to promote weight gain after weight loss following extensive surgery, chronic infections, or severe trauma, and in some patients who without definite pathophysiologic reasons fail to gain or to maintain normal weight, to offset the protein catabolism associated with prolonged administration of corticosteroids, and for the relief of the bone pain frequently accompanying osteoporosis

Compendia uses include (but not limited to):
- Anadrol-50 (oxymetholone): Cachexia associated with AIDS & Fanconi's Anemia
- Oxandrin (oxandrolone): Cachexia associated with AIDS & Turner's Syndrome

DOSAGE
Anadrol-50
The recommended daily dose in children and adults is 1-5 mg/kg of body weight per day. The usual effective dose is 1-2 mg/kg/day but higher doses may be required, and the dose should be individualized. Response is not often immediate, and a minimum trial of three to six months should be given. Following remission, some patients may be maintained without the drug; others may be maintained on an established lower daily dosage. A continued maintenance dose is usually necessary in patients with congenital aplastic anemia.

Oxandrin
Therapy with anabolic steroids is adjunctive to and not a replacement for conventional therapy. The duration of therapy with Oxandrin (oxandrolone) will depend on the response of the patient and the possible appearance of adverse reactions. Therapy should be intermittent.

Adults: The response of individuals to anabolic steroids varies. The daily adult dosage is 2.5 mg to 20 mg given in 2 to 4 divided doses. The desired response may be achieved with as little as 2.5 mg or as much as 20 mg daily. A course of therapy of 2 to 4 weeks is usually adequate. This may be repeated intermittently as indicated.

Children: For children the total daily dosage of Oxandrin is $\leqslant$0.1 mg per kilogram body weight or $\leqslant$ 0.045 mg per pound of body weight. This may be repeated intermittently as indicated.
Geriatric Use: Recommended dose for geriatric patients is 5 mg bid.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ANABOLIC STEROIDS

REFERENCES

- Anadrol-50 [package insert]. Marietta, GA: Alfven Pharmaceutical LLC; December 2006.
- Oxandrin [package insert]. East Brunswick, NJ: Savient Pharmaceuticals; January 2006.
- General Nutrition, Weight Loss, And Wasting. HIV Clinical Resource. Syndrome. http://www.hivguidelines.org/clinical-guidelines/adults/general-nutrition-weight-loss-and-wasting-syndrome/
- Ockenga et al. Espen Guidelines on Enteral Nutrition: Wasting in HIV and other Chronic Infectious Diseases. Clinical Nutrition (2006);26: 319-329.
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- Bondy C. Care of Girls and Women with Turner Syndrome: A Guideline of the Turner Syndrome Study Group. J Clin Endocrinol Metab 2007;92(1):10-25.
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- Dufour C, Svahn J. Fanconi anemia: new strategies. Bone Marrow Transplantation 2008;41:S90-S95.
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Created: 05/15
Effective: 04/11/22 Client Approval: 03/09/22 P&T Approval: N/A

ANAKINRA

Generic	Brand	HICL	GCN	Exception/Other
ANAKINRA	KINERET	22953		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ANAKINRA (Kineret)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Cryopyrin-Associated Periodic Syndromes (CAPS) (genetic disorder causing uncontrolled inflammation in multiple parts of the body of newborn)
   3. Deficiency of Interleukin-1 Receptor Antagonist (DIRA: a rare life-threatening autoinflammatory disease caused by genetic mutations)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. You have previously tried at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs): methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   3. You have previously tried **ONE** of the following: Enbrel or Humira

RENEWAL CRITERIA

Our guideline named **ANAKINRA (Kineret)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Cryopyrin-Associated Periodic Syndromes (CAPS)
   3. Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

B. You have experienced or maintained symptomatic improvement while on therapy

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ANAKINRA

RATIONALE

Ensure appropriate diagnostic, utilization, and safety criteria are used for the management of requests for anakinra.

FDA APPROVED INDICATIONS

- Kineret is an interleukin-1 receptor antagonist indicated for:
- Reduction in signs and symptoms and slowing the progression of structural damage in moderately to severely active rheumatoid arthritis, in patients 18 years of age or older who have failed one or more disease modifying antirheumatic drugs (DMARDs)
- Cryopyrin-Associated Periodic Syndromes (CAPS): Treatment of Neonatal-Onset Multisystem Inflammatory Disease (NOMID)
- Treatment of Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

DOSING

- Rheumatoid Arthritis (RA)
- The recommended dose of Kineret for the treatment of patients with rheumatoid arthritis is 100 mg/day administered daily by subcutaneous injection.
- Physicians should consider a dose of 100 mg of Kineret administered every other day for RA patients who have severe renal insufficiency or end stage renal disease (defined as creatinine clearance < 30 mL/min, as estimated from serum creatinine levels).

- Cryopyrin-Associated Periodic Syndromes (CAPS)
- The recommended starting dose of Kineret is 1-2 mg/kg daily for NOMID patients. The dose can be individually adjusted to a maximum of 8 mg/kg daily to control active inflammation.
- Physicians should consider administration of the prescribed KINERET dose every other day for NOMID patients who have severe renal insufficiency or end stage renal disease (defined as creatinine clearance < 30 mL/min, as estimated from serum creatinine levels).

- Deficiency of Interleukin-1 Receptor Antagonist (DIRA)
- The recommended starting dose of Kineret is 1-2 mg/kg daily for patients with DIRA. The dose can be individually adjusted to a maximum of 8 mg/kg daily to control active inflammation.
- Physicians should consider administration of the prescribed Kineret dose every other day for patients with DIRA who have severe renal insufficiency or end stage renal disease (defined as creatinine clearance < 30 mL/min, as estimated from serum creatinine levels).

REFERENCES

- Kineret [Prescribing Information]. SE-112 76 Stockholm, Sweden: Swedish Orphan Biovitrum AB (publ). December 2020.
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Created: 03/15
Effective: 04/11/22 Client Approval: 03/10/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ANTIPSYCHOTICS

Generic	Brand	HICL	GCN	Exception/Other
ARIPIPRAZOLE	ABILIFY, ABILIFY MAINTENA, ABILIFY MYCITE	24551		
ARIPIPRAZOLE LAUROXIL	ARISTADA	42595		
ARIPIPRAZOLE LAUROXIL, SUBMICRONIZED	ARISTADA INITIO	45050		
ASENAPINE	SECUADO	46175		
ASENAPINE MALEATE	SAPHRIS	36576		
BREXPIPRAZOLE	REXULTI	42283		
CARIPRAZINE HCL	VRAYLAR	42552		
CHLORPROMAZINE HCL	CHLORPROMAZINE HCL	01621		
CLOZAPINE	CLOZARIL, FAZACLO, VERSACLOZ	04834		
FLUPHENZINE DECANOATE	FLUPHENZINE DECANOATE	01624		
FLUPHENAZINE HCL	FLUPHENAZINE HCL	01626		
HALOPERIDOL	HALOPERIDOL	01662		
HALOPERIDOL DECANOATE	HALDOL DECANOATE	01660		
HALOPERIDOL LACTATE	HALDOL	01661		
ILOPERIDONE	FANAPT	36778		
LOXAPINE SUCCINATE	LOXAPINE	01664		
LUMATEPERONE	CAPLYTA	46280		
LURASIDONE HCL	LATUDA	37321		
MOLINDONE HCL	MOLINDONE	01666		
OLANZAPINE	ZYPREXA, ZYPREXA ZYDIS	11814		
OLANZAPINE PAMOATE	ZYPREXA RELPREVV	36716		
OLANZAPINE/ SAMIDORPHAN	LYBALVI	47406		
PALIPERIDONE	INVEGA	34343		
PALIPERIDONE PALMITATE	INVEGA HAFYERA, INVEGA SUSTENNA, INVEGA TRINZA	36479		
PERPHENAZINE	PERPHENAZINE	01627		
PIMOZIDE	ORAP	01637		
QUETIAPINE FUMARATE	SEROQUEL, SEROQUEL XR	14015		
RISPERIDONE	RISPERDAL, RISPERDAL CONSTA, PERSERIS	08721 25509		
THIORIDAZINE HCL	THIORIDAZINE HCL	01631		
TRIFLUOPERAZINE HCL	TRIFLUOPERAZINE HCL	01630		

THIOTHIXENE	THIOTHIXENE	01668		
ZIPRASIDONE HCL	GEODON	21974		

GUIDELINES FOR USE

See Appendix 3 for age edits and standard monthly quantity limits. Examples of atypical antipsychotics include aripiprazole, asenapine, brexpiprazole, cariprazine, clozapine, iloperidone, lurasidone, olanzapine, paliperidone, quetiapine, risperidone, and ziprasidone.

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ANTIPSYCHOTICS** does not allow the use of the requested medication under the age of 18 (exception: age 10 for Geodon and Latuda, age 13 for Rexulti). Please consider another antipsychotic without an age restriction.

Our guideline named **ANTIPSYCHOTICS** does not allow the use of the requested medication at the requested dose/regimen. Please consider an alternate dose or dosing schedule.

Our guideline named **ANTIPSYCHOTICS** allows for low dose atypical antipsychotics use for patients with a mental health diagnosis such as bipolar disorder, schizophrenia, psychosis, or major depressive disorder. Please consider an alternate dose or medication.

Our guideline named **ANTIPSYCHOTICS (reviewed for LYBALVI)** for patients with claims in history for opioids requires that EITHER of the following criteria are met:

A. You have not taken a short-acting opioid less than or equal to 7 days prior to initiating Lybalvi therapy
B. You have not taken a long-acting opioid less than or equal to 14 days prior to initiating Lybalvi therapy

Please note that your first fill of Lybalvi must not be greater than a 15-day supply of medication unless you received Lybalvi samples.

Our guideline for **ANTIPSYCHOTICS** for patients with claims suggesting therapeutic duplication requires that the medications are being cross-tapered or that the historical medication is being discontinued. Therapeutic duplication will be allowed for patients who meet the following criteria.

- Patients with a diagnosis of psychosis within the past two years; history of at least 4 weeks of single-agent therapy at an adequate dose for 2 different antipsychotics in the past 2 years; and history of at least 4 weeks of therapy with clozapine in the past 2 years (unless patient has contraindication, allergy, or intolerance to clozapine)
- Patients with a diagnosis of bipolar affective disorder, unspecified episodic mood disorder, or depressed mood disorder within the past two years; and history of at least 4 weeks of single-agent therapy at an adequate dose for 2 different antipsychotics in the past 2 years

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ANTIPSYCHOTICS

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline for **ANTIPSYCHOTICS** renewal requires that **ONE** of the following criteria are met:

A. For patients with claims suggesting therapeutic duplication, **BOTH** of the following:
   1. There is history of paid claims for **BOTH** medications identified in the therapeutic duplication for 90 of the past 120 days
   2. The patient has previous authorizations on file for **BOTH** medications identified in the therapeutic duplication.
B. For renewal of low dose atypical antipsychotics, a mental health diagnosis (such as bipolar disorder, schizophrenia, psychosis, or major depressive disorder) is required.

Our guideline for **ANTIPSYCHOTICS** renewal for patients with claims denying due to age limit and/or standard monthly quantity limit requires that **BOTH** of the following criteria are met:

A. There is history of paid claims for the requested antipsychotic for 90 of the past 120 days
B. The patient has a previous authorization on file for the requested antipsychotic

RATIONALE

To promote prudent prescribing of atypical antipsychotics and antipsychotic duplicate therapies.

A look back period of 120 days will be utilized to identify patients new to therapy with an antipsychotic. First fill of oral antipsychotics cannot exceed 15 days unless patient has previous use in the past four months as seen in claims history or via samples from prescriber.

A look back period of 60 days will be utilized to identify potential therapeutic duplication.

All patients utilizing antipsychotic therapy should have metabolic monitoring completed at least annually.

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RATIONALE (CONTINUED)

APPENDIX 1: Antipsychotic Minimum Effective Doses for Mental Health Diagnoses

Chemical Name	Minimum Effective Dose
aripiprazole	5 mg/ day; 2 mg/ day for depression
asenapine	10 mg/ day
brexpiprazole	2 mg/ day; 1 mg/ day for depression
cariprazine	1.5 mg/ day
iloperidone	6 mg/ day
lurasidone	20 mg/ day
olanzapine + fluoxetine	3/25 mg/ day
olanzapine + samidorphan	5/10 mg/ day
olanzapine	5 mg/ day
paliperidone	3 mg/ day
quetiapine	300 mg/ day; 150 mg/ day for depression
risperidone	1 mg/ day
ziprasidone	40 mg/ day
ziprasidone mesylate	40 mg/ day

APPENDIX 2: Antipsychotic Adequate Doses

Chemical Name	Adequate Dose
aripiprazole	⩾ 5 mg/ day
asenapine	⩾ 10 mg/ day
brexpiprazole	⩾ 2 mg/ day
cariprazine	⩾ 1.5 mg/ day
chlorpromazine HCl	⩾ 30 mg/ day
clozapine	⩾ 300 mg/ day
haloperidol	⩾ 1 mg/ day
haloperidol lactate	⩾ 1 mg/ day
Iloperidone	⩾ 12 mg/ day
loxapine succinate	⩾ 20 mg/ day
lurasidone HCl	⩾ 20 mg/ day
molindone	⩾ 15 mg/ day
olanzapine	⩾ 10 mg/ day
olanzapine + fluoxetine	⩾ 6/25 mg/ day
olanzapine + samidorphan	⩾ 10/10 mg/ day
olanzapine	⩾ 10 mg/ day
paliperidone	⩾ 3 mg/ day
perphenazine	⩾ 12 mg/ day
pimozide	⩾ 1 mg/ day
quetiapine	⩾ 300 mg/ day
risperidone	⩾ 2 mg/ day

thioridazine HCl	⩾ 150 mg/ day
thiothixine	⩾ 6 mg/ day
trifluoperazine HCl	⩾ 2 mg/ day
ziprasidone	⩾ 80 mg/ day
ziprasidone mesylate	⩾ 80 mg/ day

APPENDIX 3: Antipsychotic Age Limits and Quantity Limits

GPID	Generic Name	Product Name	Dosage Form	Route	Strength	Utilization Edit
26305	ARIPIPRAZOLE	ABILIFY	TABS	OR	2 MG	1/DAY
20173	ARIPIPRAZOLE	ABILIFY	TABS	OR	5 MG	1.5/DAY
18537	ARIPIPRAZOLE	ABILIFY	TABS	OR	10 MG	1/DAY
18538	ARIPIPRAZOLE	ABILIFY	TABS	OR	15 MG	1/DAY
18539	ARIPIPRAZOLE	ABILIFY	TABS	OR	20 MG	2/DAY
18541	ARIPIPRAZOLE	ABILIFY	TABS	OR	30 MG	1/DAY
34284	ARIPIPRAZOLE	ABILIFY MAINTENA	SUSR	IM	300 MG	1/28 DAYS; Age 18 years and older
34285	ARIPIPRAZOLE	ABILIFY MAINTENA	SUSR	IM	400 MG	1/28 DAYS; Age 18 years and older
44437	ARIPIPRAZOLE	ABILIFY MYCITE	TABS	OR/PT	2 MG	1/DAY; Age 18 years and older
44438	ARIPIPRAZOLE	ABILIFY MYCITE	TABS	OR/PT	5 MG	1/DAY; Age 18 years and older
44439	ARIPIPRAZOLE	ABILIFY MYCITE	TABS	OR/PT	10 MG	1/DAY; Age 18 years and older
44441	ARIPIPRAZOLE	ABILIFY MYCITE	TABS	OR/PT	15 MG	1/DAY; Age 18 years and older
44442	ARIPIPRAZOLE	ABILIFY MYCITE	TABS	OR/PT	20 MG	1/DAY; Age 18 years and older
44443	ARIPIPRAZOLE	ABILIFY MYCITE	TABS	OR/PT	30 MG	1/DAY; Age 18 years and older
49374	ARIPIPRAZOLE	ABILIFY MYCITE STARTER PAK - SENSOR, STRIPS & POD	TABS	OR/PT	2 MG	1 PAK/90 Days; Age 18 years and older
49371	ARIPIPRAZOLE	ABILIFY MYCITE MAINTENANCE PAK - SENSOR, STRIPS	TABS	OR/PT	2 MG	1 PAK/30 Days; Age 18 years and older
49366	ARIPIPRAZOLE	ABILIFY MYCITE STARTER PAK - SENSOR, STRIPS & POD	TABS	OR/PT	5 MG	1 PAK/90 Days; Age 18 years and older
49365	ARIPIPRAZOLE	ABILIFY MYCITE MAINTENANCE PAK - SENSOR, STRIPS	TABS	OR/PT	5 MG	1 PAK/30 Days; Age 18 years and older
49369	ARIPIPRAZOLE	ABILIFY MYCITE STARTER PAK -	TABS	OR/PT	10 MG	1 PAK/90 Days; Age 18 years

		SENSOR, STRIPS & POD				and older
49376	ARIPIPRAZOLE	ABILIFY MYCITE MAINTENANCE PAK - SENSOR, STRIPS	TABS	OR/PT	10 MG	1 PAK/30 Days; Age 18 years and older
49363	ARIPIPRAZOLE	ABILIFY MYCITE STARTER PAK - SENSOR, STRIPS & POD	TABS	OR/PT	15 MG	1 PAK/90 Days; Age 18 years and older
49364	ARIPIPRAZOLE	ABILIFY MYCITE MAINTENANCE PAK - SENSOR, STRIPS	TABS	OR/PT	15 MG	1 PAK/30 Days; Age 18 years and older
49372	ARIPIPRAZOLE	ABILIFY MYCITE STARTER PAK - SENSOR, STRIPS & POD	TABS	OR/PT	20 MG	1 PAK/90 Days; Age 18 years and older
49375	ARIPIPRAZOLE	ABILIFY MYCITE MAINTENANCE PAK - SENSOR, STRIPS	TABS	OR/PT	20 MG	1 PAK/30 Days; Age 18 years and older
49377	ARIPIPRAZOLE	ABILIFY MYCITE STARTER PAK - SENSOR, STRIPS & POD	TABS	OR/PT	30 MG	1 PAK/90 Days; Age 18 years and older
49373	ARIPIPRAZOLE	ABILIFY MYCITE MAINTENANCE PAK - SENSOR, STRIPS	TABS	OR/PT	30 MG	1 PAK/30 Days; Age 18 years and older
24062	ARIPIPRAZOLE	ARIPIPRAZOLE	SOLN	OR	1 MG/ ML	30 ML/DAY
26445	ARIPIPRAZOLE	ARIPIPRAZOLE ODT	TBDP	OR	10 MG	2/DAY
26448	ARIPIPRAZOLE	ARIPIPRAZOLE ODT	TBDP	OR	15 MG	2/DAY
39726	ARIPIPRAZOLE LAUROXIL	ARISTADA	SUSR	IM	441 MG	1/28 DAYS; Age 18 years and older
39727	ARIPIPRAZOLE LAUROXIL	ARISTADA	SUSR	IM	662 MG	1/28 DAYS; Age 18 years and older
39728	ARIPIPRAZOLE LAUROXIL	ARISTADA	SUSR	IM	882 MG	1/28 DAYS; Age 18 years and older
43488	ARIPIPRAZOLE LAUROXIL	ARISTADA	SUSR	IM	1064 MG	1/56 DAYS; Age 18 years and older
44941	ARIPIPRAZOLE LAUROXIL, SUBMICRONIZED	ARISTADA INITIO	SUSR	IM	675 MG	2.4 ML/180 DAYS; Age 18 years and older
47229	ASENAPINE	SECUADO	PATCH	TD	3.8 MG/ 24 HR	1/DAY; Age 18 years and older
47232	ASENAPINE	SECUADO	PATCH	TD	5.7 MG/ 24 HR	1/DAY; Age 18 years and older
47233	ASENAPINE	SECUADO	PATCH	TD	7.5 MG/ 24 HR	1/DAY; Age 18 years and older
38479	ASENAPINE MALEATE	SAPHRIS	SUBL	SL	2.5 MG	2/DAY

21636	ASENAPINE MALEATE	SAPHRIS	SUBL	SL	5 MG	2/DAY
27528	ASENAPINE MALEATE	SAPHRIS	SUBL	SL	10 MG	2/DAY
38278	BREXPIPRAZOLE	REXULTI	TABS	OR	0.25 MG	1/DAY; Age 13 years and older
38476	BREXPIPRAZOLE	REXULTI	TABS	OR	0.5 MG	1/DAY; Age 13 years and older
38589	BREXPIPRAZOLE	REXULTI	TABS	OR	1 MG	1/DAY; Age 13 years and older
38609	BREXPIPRAZOLE	REXULTI	TABS	OR	2 MG	1/DAY; Age 13 years and older
38618	BREXPIPRAZOLE	REXULTI	TABS	OR	3 MG	1/DAY; Age 13 years and older
38619	BREXPIPRAZOLE	REXULTI	TABS	OR	4 MG	1/DAY; Age 13 years and older
40683	CARIPRAZINE	VRAYLAR THERAPY PACK	KIT	OR	N/A	1 PAK/28 DAYS
39579	CARIPRAZINE	VRAYLAR	CAPS	OR	1.5 MG	2/DAY; Age 18 years and older
39582	CARIPRAZINE	VRAYLAR	CAPS	OR	3 MG	1/DAY; Age 18 years and older
39583	CARIPRAZINE	VRAYLAR	CAPS	OR	4.5 MG	1/DAY; Age 18 years and older
39584	CARIPRAZINE	VRAYLAR	CAPS	OR	6 MG	1/DAY; Age 18 years and older
14391	CHLORPROMAZINE HCL	CHLORPROMAZINE CONCENTRATE	SOLN	OR	30 MG/ML	26.7 ML/DAY
14390	CHLORPROMAZINE HCL	CHLORPROMAZINE CONCENTRATE	SOLN	OR	100 MG/ML	8 ML/DAY
14431	CHLORPROMAZINE HCL	CHLORPROMAZINE HCL	TABS	OR	10 MG	4/DAY
14432	CHLORPROMAZINE HCL	CHLORPROMAZINE HCL	TABS	OR	25 MG	4/DAY
14433	CHLORPROMAZINE HCL	CHLORPROMAZINE HCL	TABS	OR	50 MG	4/DAY
14434	CHLORPROMAZINE HCL	CHLORPROMAZINE HCL	TABS	OR	100 MG	4/DAY
14435	CHLORPROMAZINE HCL	CHLORPROMAZINE HCL	TABS	OR	200 MG	4/DAY
18141	CLOZAPINE	CLOZARIL	TABS	OR	25 MG	3/DAY; Age 18 years and older
18143	CLOZAPINE	CLOZAPINE	TABS	OR	50 MG	3/DAY; Age 18 years and older
18142	CLOZAPINE	CLOZARIL	TABS	OR	100 MG	6/DAY; Age 18 years and older
31672	CLOZAPINE	CLOZAPINE	TABS	OR	200 MG	3/DAY; Age 18 years and older
14336	CLOZAPINE	VERSACLOZ	SUSP	OR	50 MG/ ML	12 ML/DAY; Age 18 years and older
98791	CLOZAPINE	FAZACLO	TBDP	OR	12.5 MG	3/DAY; Age 18

						years and older
21784	CLOZAPINE	FAZACLO	TBDP	OR	25 MG	3/DAY; Age 18 years and older
21785	CLOZAPINE	FAZACLO	TBDP	OR	100 MG	6/DAY; Age 18 years and older
28873	CLOZAPINE	FAZACLO	TBDP	OR	150 MG	3/DAY; Age 18 years and older
28874	CLOZAPINE	FAZACLO	TBDP	OR	200 MG	3/DAY; Age 18 years and older
14602	FLUPHENAZINE HCL	FLUPHENAZINE HCL	TABS	OR	1 MG	4/DAY; Age 18 years and older
14604	FLUPHENAZINE HCL	FLUPHENAZINE HCL	TABS	OR	2.5 MG	4/DAY; Age 18 years and older
14605	FLUPHENAZINE HCL	FLUPHENAZINE HCL	TABS	OR	5 MG	4/DAY; Age 18 years and older
14603	FLUPHENAZINE HCL	FLUPHENAZINE HCL	TABS	OR	10 MG	4/DAY; Age 18 years and older
14580	FLUPHENAZINE HCL	FLUPHENAZINE HCL	ELIX	OR	2.5 MG/ 5 ML	Age 18 years and older
14590	FLUPHENAZINE HCL	FLUPHENAZINE HCL	CONC	OR	5 MG/ ML	Age 18 years and older
14571	FLUPHENAZINE HCL	FLUPHENAZINE HCL	SOLN	IJ	2.5 MG/ ML	Age 18 years and older
14540	FLUPHENAZINE DECANOATE	FLUPHENAZINE DECANOATE	SOLN	IJ	25 MG/ ML	Age 18 years and older
15530	HALOPERIDOL	HALOPERIDOL	TABS	OR	0.5 MG	3/DAY
15531	HALOPERIDOL	HALOPERIDOL	TABS	OR	1 MG	3/DAY
15533	HALOPERIDOL	HALOPERIDOL	TABS	OR	2 MG	3/DAY
15535	HALOPERIDOL	HALOPERIDOL	TABS	OR	5 MG	3/DAY
15532	HALOPERIDOL	HALOPERIDOL	TABS	OR	10 MG	3/DAY
15534	HALOPERIDOL	HALOPERIDOL	TABS	OR	20 MG	3/DAY
14800	HALOPERIDOL DECANOATE	HALDOL DECANOATE	SOLN	IM	50 MG/ ML	Age 18 years and older
14781	HALOPERIDOL DECANOATE	HALDOL DECANOATE	SOLN	IM	100 MG/ ML	Age 18 years and older
28025	ILOPERIDONE	FANAPT	TABS	OR	1 MG	2/DAY; Age 18 years and older
28026	ILOPERIDONE	FANAPT	TABS	OR	2 MG	2/DAY; Age 18 years and older
28027	ILOPERIDONE	FANAPT	TABS	OR	4 MG	2/DAY; Age 18 years and older
28028	ILOPERIDONE	FANAPT	TABS	OR	6 MG	2/DAY; Age 18 years and older
28029	ILOPERIDONE	FANAPT	TABS	OR	8 MG	2/DAY; Age 18 years and older
28030	ILOPERIDONE	FANAPT	TABS	OR	10 MG	2/DAY; Age 18 years and older
28033	ILOPERIDONE	FANAPT	TABS	OR	12 MG	2/DAY; Age 18 years and older
28034	ILOPERIDONE	FANAPT TITRATION	TABS	OR	N/A	2/DAY; Age 18

		PACK				years and older
15562	LOXAPINE SUCCINATE	LOXAPINE	CAPS	OR	5 MG	4/DAY; Age 18 years and older
15560	LOXAPINE SUCCINATE	LOXAPINE	CAPS	OR	10 MG	4/DAY; Age 18 years and older
15561	LOXAPINE SUCCINATE	LOXAPINE	CAPS	OR	25 MG	4/DAY; Age 18 years and older
15563	LOXAPINE SUCCINATE	LOXAPINE	CAPS	OR	50 MG	4/DAY; Age 18 years and older
52616	LUMATEPERONE	CAPLYTA	CAPS	OR	10.5 MG	1/DAY; Age 18 years and older
52617	LUMATEPERONE	CAPLYTA	CAPS	OR	21 MG	1/DAY; Age 18 years and older
47492	LUMATEPERONE	CAPLYTA	CAPS	OR	42 MG	1/DAY; Age 18 years and older
31226	LURASIDONE HCL	LATUDA	TABS	OR	20 MG	1/DAY; Age 10 years and older
29366	LURASIDONE HCL	LATUDA	TABS	OR	40 MG	1/DAY; Age 10 years and older
35192	LURASIDONE HCL	LATUDA	TABS	OR	60 MG	1/DAY; Age 10 years and older
29367	LURASIDONE HCL	LATUDA	TABS	OR	80 MG	2/DAY; Age 10 years and older
33147	LURASIDONE HCL	LATUDA	TABS	OR	120 MG	1/DAY; Age 10 years and older
15653	MOLINDONE HCL	MOLINDONE HCL	TABS	OR	5 MG	4/DAY
15650	MOLINDONE HCL	MOLINDONE HCL	TABS	OR	10 MG	4/DAY
15652	MOLINDONE HCL	MOLINDONE HCL	TABS	OR	25 MG	9/DAY
15084	OLANZAPINE	ZYPREXA	TABS	OR	2.5 MG	1/DAY
15083	OLANZAPINE	ZYPREXA	TABS	OR	5 MG	1/DAY
15081	OLANZAPINE	ZYPREXA	TABS	OR	7.5 MG	1/DAY
15082	OLANZAPINE	ZYPREXA	TABS	OR	10 MG	2/DAY
15085	OLANZAPINE	ZYPREXA	TABS	OR	15 MG	2/DAY
15086	OLANZAPINE	ZYPREXA	TABS	OR	20 MG	3/DAY
92007	OLANZAPINE	ZYPREXA ZYDIS	TBDP	OR	5 MG	1/DAY
92008	OLANZAPINE	ZYPREXA ZYDIS	TBDP	OR	10 MG	2/DAY
34022	OLANZAPINE	ZYPREXA ZYDIS	TBDP	OR	15 MG	2/DAY
34023	OLANZAPINE	ZYPREXA ZYDIS	TBDP	OR	20 MG	3/DAY
27855	OLANZAPINE PAMOATE	ZYPREXA RELPREVV	SUSR	IM	210 MG	2/28 DAYS; Age 18 years and older
27849	OLANZAPINE PAMOATE	ZYPREXA RELPREVV	SUSR	IM	300 MG	2/28 DAYS; Age 18 years and older
27848	OLANZAPINE PAMOATE	ZYPREXA RELPREVV	SUSR	IM	405 MG	1/28 DAYS; Age 18 years and older

49724	OLANZAPINE/ SAMIDORPHAN	LYBALVI	TABS	OR	5-10 MG	1/DAY; Age 18 years and older
49726	OLANZAPINE/ SAMIDORPHAN	LYBALVI	TABS	OR	10-10 MG	1/DAY; Age 18 years and older
49727	OLANZAPINE/ SAMIDORPHAN	LYBALVI	TABS	OR	15-10 MG	1/DAY; Age 18 years and older
49739	OLANZAPINE/ SAMIDORPHAN	LYBALVI	TABS	OR	20-10 MG	1/DAY; Age 18 years and older
27685	PALIPERIDONE	INVEGA	TB24	OR	1.5 MG	1/DAY
97769	PALIPERIDONE	INVEGA	TB24	OR	3 MG	1/DAY
97770	PALIPERIDONE	INVEGA	TB24	OR	6 MG	2/DAY
97771	PALIPERIDONE	INVEGA	TB24	OR	9 MG	1/DAY
50889	PALIPERIDONE PALMITATE	INVEGA HAFYERA	SUSP	IM	1,092 MG/ 3.5 ML	1/168 DAYS; Age 18 years and older
50891	PALIPERIDONE PALMITATE	INVEGA HAFYERA	SUSP	IM	1,560 MG/ 5 ML	1/168 DAYS; Age 18 years and older
27414	PALIPERIDONE PALMITATE	INVEGA SUSTENNA	SUSP	IM	39 MG/ 0.25 ML	1/28 DAYS; Age 18 years and older
27415	PALIPERIDONE PALMITATE	INVEGA SUSTENNA	SUSP	IM	78 MG/ 0.5 ML	1/28 DAYS; Age 18 years and older
27416	PALIPERIDONE PALMITATE	INVEGA SUSTENNA	SUSP	IM	117 MG/ 0.75 ML	1/28 DAYS; Age 18 years and older
27417	PALIPERIDONE PALMITATE	INVEGA SUSTENNA	SUSP	IM	156 MG/ ML	1/28 DAYS; Age 18 years and older
27418	PALIPERIDONE PALMITATE	INVEGA SUSTENNA	SUSP	IM	234 MG / 1.5 ML	1/28 DAYS; Age 18 years and older
38697	PALIPERIDONE PALMITATE	INVEGA TRINZA	SUSP	IM	273 MG / 0.88 ML	1/84 DAYS; Age 18 years and older
38698	PALIPERIDONE PALMITATE	INVEGA TRINZA	SUSP	IM	410 MG / 1.32 ML	1/84 DAYS; Age 18 years and older
38699	PALIPERIDONE PALMITATE	INVEGA TRINZA	SUSP	IM	546 MG / 1.75 ML	1/84 DAYS; Age 18 years and older
38702	PALIPERIDONE PALMITATE	INVEGA TRINZA	SUSP	IM	819 MG / 2.625 ML	1/84 DAYS; Age 18 years and older
14651	PERPHENAZINE	PERPHENAZINE	TABS	OR	2 MG	4/DAY; Age 18 years and older
14652	PERPHENAZINE	PERPHENAZINE	TABS	OR	4 MG	4/DAY; Age 18 years and older
14653	PERPHENAZINE	PERPHENAZINE	TABS	OR	8 MG	4/DAY; Age 18 years and older

14650	PERPHENAZINE	PERPHENAZINE	TABS	OR	16 MG	4/DAY; Age 18 years and older
11153	PIMOZIDE	ORAP	TABS	OR	1 MG	10/DAY
11150	PIMOZIDE	ORAP	TABS	OR	2 MG	5/DAY
67661	QUETIAPINE FUMARATE	SEROQUEL	TABS	OR	25 MG	3/DAY
26409	QUETIAPINE FUMARATE	SEROQUEL	TABS	OR	50 MG	3/DAY
67662	QUETIAPINE FUMARATE	SEROQUEL	TABS	OR	100 MG	3/DAY
93088	QUETIAPINE FUMARATE	SEROQUEL	TABS	OR	150 MG	2/DAY
67663	QUETIAPINE FUMARATE	SEROQUEL	TABS	OR	200 MG	3/DAY
67665	QUETIAPINE FUMARATE	SEROQUEL	TABS	OR	300 MG	4/DAY
26411	QUETIAPINE FUMARATE	SEROQUEL	TABS	OR	400 MG	4/DAY
98994	QUETIAPINE FUMARATE	SEROQUEL XR	TB24	OR	50 MG	2/DAY
16193	QUETIAPINE FUMARATE	SEROQUEL XR	TB24	OR	150 MG	1/DAY
98522	QUETIAPINE FUMARATE	SEROQUEL XR	TB24	OR	200 MG	1/DAY
98523	QUETIAPINE FUMARATE	SEROQUEL XR	TB24	OR	300 MG	3/DAY
98524	QUETIAPINE FUMARATE	SEROQUEL XR	TB24	OR	400 MG	4/DAY
92872	RISPERIDONE	RISPERDAL	TABS	OR	0.25 MG	2/DAY
92892	RISPERIDONE	RISPERDAL	TABS	OR	0.5 MG	2/DAY
16136	RISPERIDONE	RISPERDAL	TABS	OR	1 MG	2/DAY
16137	RISPERIDONE	RISPERDAL	TABS	OR	2 MG	2/DAY
16138	RISPERIDONE	RISPERDAL	TABS	OR	3 MG	2/DAY
16139	RISPERIDONE	RISPERDAL	TABS	OR	4 MG	2/DAY
16135	RISPERIDONE	RISPERDAL	SOLN	OR	1 MG/ ML	8 ML/DAY
24448	RISPERIDONE	RISPERIDONE ODT	TBDP	OR	0.25 MG	2/DAY
19541	RISPERIDONE	RISPERIDONE ODT	TBDP	OR	0.5 MG	2/DAY
19178	RISPERIDONE	RISPERIDONE ODT	TBDP	OR	1 MG	2/DAY
19179	RISPERIDONE	RISPERIDONE ODT	TBDP	OR	2 MG	2/DAY
25024	RISPERIDONE	RISPERIDONE ODT	TBDP	OR	3 MG	2/DAY
25025	RISPERIDONE	RISPERIDONE ODT	TBDP	OR	4 MG	2/DAY
45127	RISPERIDONE	PERSERIS	SUSP	IM	90 MG	1/28 DAYS; Age 18 years and older
45128	RISPERIDONE	PERSERIS	SUSP	IM	120 MG	1/28 DAYS; Age 18 years and older

98414	RISPERIDONE MICROSPHERES	RISPERDAL CONSTA	SUSR	IM	12.5 MG	2/28 DAYS; Age 18 years and older
20217	RISPERIDONE MICROSPHERES	RISPERDAL CONSTA	SUSR	IM	25 MG	2/28 DAYS; Age 18 years and older
20218	RISPERIDONE MICROSPHERES	RISPERDAL CONSTA	SUSR	IM	37.5 MG	2/28 DAYS; Age 18 years and older
20219	RISPERIDONE MICROSPHERES	RISPERDAL CONSTA	SUSR	IM	50 MG	2/28 DAYS; Age 18 years and older
14882	THIORIDAZINE HCL	THIORIDAZINE HCL	TABS	OR	10 MG	4/DAY
14880	THIORIDAZINE HCL	THIORIDAZINE HCL	TABS	OR	25 MG	4/DAY
14881	THIORIDAZINE HCL	THIORIDAZINE HCL	TABS	OR	50 MG	4/DAY
14883	THIORIDAZINE HCL	THIORIDAZINE HCL	TABS	OR	100 MG	4/DAY
15690	THIOTHIXENE	THIOTHIXENE	CAPS	OR	1 MG	3/DAY
15692	THIOTHIXENE	THIOTHIXENE	CAPS	OR	2 MG	3/DAY
15694	THIOTHIXENE	THIOTHIXENE	CAPS	OR	5 MG	3/DAY
15691	THIOTHIXENE	THIOTHIXENE	CAPS	OR	10 MG	3/DAY
14830	TRIFLUOPERAZINE HCL	TRIFLUOPERAZINE HCL	TABS	OR	1 MG	2/DAY
14832	TRIFLUOPERAZINE HCL	TRIFLUOPERAZINE HCL	TABS	OR	2 MG	2/DAY
14833	TRIFLUOPERAZINE HCL	TRIFLUOPERAZINE HCL	TABS	OR	5 MG	2/DAY
14831	TRIFLUOPERAZINE HCL	TRIFLUOPERAZINE HCL	TABS	OR	10 MG	4/DAY
13331	ZIPRASIDONE HCL	GEODON	CAPS	OR	20 MG	2/DAY; Age 10 years and older
13332	ZIPRASIDONE HCL	GEODON	CAPS	OR	40 MG	2/DAY; Age 10 years and older
13333	ZIPRASIDONE HCL	GEODON	CAPS	OR	60 MG	3/DAY; Age 10 years and older
13334	ZIPRASIDONE HCL	GEODON	CAPS	OR	80 MG	3/DAY; Age 10 years and older
17037	ZIPRASIDONE MESYLATE	GEODON	SOLR	IM	20 MG	Age 10 years and older

Created: 07/16
Effective: 01/23/23 Client Approval: 08/31/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

APALUTAMIDE

Generic	Brand	HICL	GCN	Exception/Other
APALUTAMIDE	ERLEADA	44773		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named **APALUTAMIDE (Erleada)** requires a diagnosis of metastatic castration-sensitive prostate cancer (mCSPC) or non-metastatic castration-resistant prostate cancer (nmCRPC). In addition, the requested medication must be used concurrently with a gonadotropin releasing hormone (GnRH) agonist or antagonist (i.e., leuprolide, goserelin, histrelin, degarelix), unless the patient has previously received a bilateral orchiectomy. In addition, the following criteria must be met:

For a diagnosis of non-metastatic castration-resistant prostate cancer (nmCRPC), approval requires:

- The patient has high risk prostate cancer (i.e., rapidly increasing prostate specific antigen [PSA] levels)

RENEWAL CRITERIA

The guideline named **APALUTAMIDE (Erleada)** requires a diagnosis of metastatic castration-sensitive prostate cancer (mCSPC) or non-metastatic castration resistant prostate cancer (nmCRPC).

RATIONALE
To promote appropriate utilization of ERLEADA based on FDA approved indication and dosing.

FDA APPROVED INDICATION
Erleada is an androgen receptor inhibitor indicated for the treatment of patients with:

- Metastatic castration-sensitive prostate cancer
- Non-metastatic castration-resistant prostate cancer

DOSAGE & ADMINISTRATION
Erleada 240 mg (four 60 mg tablets) administered orally once daily. Swallow tablets whole. Erleada can be taken with or without food.

Patients should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy.

REFERENCES

- Erleada [Prescribing Information]. Horsham, PA: Janssen. September 2019.

Created: 04/18
Effective: 07/01/20 Client Approval: 05/12/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

APOMORPHINE

Generic	Brand	HICL	GCN	Exception/Other
APOMORPHINE	APOKYN		42078	
APOMORPHINE SUBL	KYNMOBI	01934	48122 48126 48127 48128 48129 48136	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **APOMORPHINE** requires the following rule(s) be met for approval:

A. You have Parkinson's disease (central nervous system disorder that affects movement, often including tremors)
B. The requested medication is being used for acute, intermittent treatment (sudden and periodic treatment) of "OFF" episodes (when symptoms return due to your medication for Parkinson's disease wearing off)
C. Your doctor has optimized drug therapy as evidenced by BOTH of the following:
   1. Change in levodopa/carbidopa dosing strategy or formulation
   2. Trial of or contraindication to at least TWO Parkinson disease agents from two different classes: dopamine agonist (i.e., ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitors (MAO-I) (i.e., selegiline, rasagiline), or catechol-O-methyl transferase (COMT) inhibitors (i.e., entacapone, tolcapone)

RENEWAL CRITERIA

The guideline named **APOMORPHINE** requires a diagnosis of Parkinson's disease. In addition, the following criterion must be met:

- Physician attestation of patient improvement with motor fluctuations during OFF episodes with the use of apomorphine (e.g., improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair)

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APOMORPHINE

RATIONALE
Ensure appropriate use of apomorphine.

FDA APPROVED INDICATION
Apokyn is indicated for the acute, intermittent treatment of "off" episodes associated with advanced Parkinson's disease.

Kynmobi is indicated for the acute, intermittent treatment of "off" episodes associated with Parkinson's disease.

DOSING
The recommended starting dose of Apokyn is 0.2 mL (2 mg). Titrate on the basis of effectiveness and tolerance, up to a maximum recommended dose of 0.6 mL (6 mg).

The initial dose of Kynmobi is 10 mg. Dose initiation should occur when the patient is in an “off” state. If the patient tolerates the 10 mg dose, and responds adequately, the starting dose should be 10 mg, used on an as needed basis, up to 5 times per day, to treat “off” episodes.

REFERENCES

- Apokyn [Prescribing Information]. Brisbane, CA: Tercica Inc. April 2020.
- Kynmobi [Prescribing Information]. Marlborough, MA: Sunovion Pharmaceuticals Inc., May 2020.

Created: 06/15
Effective: 12/28/20 Client Approval: 12/03/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

APREMILAST

Generic	Brand	HICL	GCN	Exception/Other
APREMILAST	OTEZLA	40967		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **APREMILAST (Otezla)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   2. Plaque psoriasis (PsO: dry, itchy skin patches with scales)
   3. Oral ulcers associated with Behçet's Disease (disorder causing blood vessel inflammation throughout your body)

B. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. You have previously tried ONE of the following DMARDs (disease-modifying antirheumatic drugs): methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   3. You have previously tried TWO of the following: Cosentyx, Enbrel, or Humira

C. **If you have plaque psoriasis (PsO), approval also requires:**
   1. You are 18 years of age or older
   2. You have psoriatic lesions (rashes) involving at least 10% body surface area (BSA) or psoriatic lesions (rashes) affecting the face, hands, feet, or genital area
   3. You have previously tried ONE of the following conventional therapies: PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
   4. You have previously tried TWO of the following: Cosentyx, Enbrel, or Humira

D. **If you have oral ulcers with Behçet's Disease, approval requires:**
   1. You are 18 years of age or older
   2. You have previously tried ONE conservative treatment (such as colchicine, topical corticosteroid, oral corticosteroid)

RENEWAL CRITERIA

Our guideline named **APREMILAST (Otezla)** requires the following rule(s) be met for renewal approval:

A. You have ONE of the following diagnoses:
   1. Psoriatic arthritis (a type of skin and joint condition)
   2. Plaque psoriasis (a type of skin condition)
   3. Behçet's disease (a type of inflammation disorder) with oral ulcers

B. You have experienced or maintained symptomatic improvement while on therapy

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

APREMILAST

RATIONALE
To ensure appropriate diagnostic, utilization and safety criteria are used for the management of requests for apremilast.

FDA APPROVED INDICATIONS
Otezla is an inhibitor of phosphodiesterase 4 (PDE4) indicated for the treatment of:
- Adult patients with active psoriatic arthritis
- Adult patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
- Adult patients with oral ulcers associated with Behçet's Disease

DOSAGE
The recommended initial dosage titration of Otezla from Day 1 to Day 5 is shown in Table 1. Following the 5-day titration, the recommended maintenance dosage is 30 mg twice daily taken orally starting on Day 6. This titration is intended to reduce the gastrointestinal symptoms associated with initial therapy. Otezla can be administered without regard to meals. Do not crush, split, or chew the tablets.

In patients with severe renal impairment (creatinine clearance less than 30 mL per minute estimated by the Cockcroft–Gault equation), Otezla dosage should be reduced to 30 mg once daily. For initial dosage titration in this group, it is recommended that Otezla be titrated using only the AM schedule listed in Table 1 (skip PM doses).

DOSAGE
Table 1: Dosage Titration Schedule

Day 1	Day 2		Day 3		Day 4		Day 5		Day 6 & thereafter	
AM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
10 mg	10 mg	10 mg	10 mg	20 mg	20 mg	20 mg	20 mg	30 mg	30 mg	30 mg

REFERENCES

- Otezla [Prescribing Information]. Summit, NJ: Celgene Corporation; June 2020.
- Braun J, Davis J, et al. First update of the international ASAS consensus statement for the use of anti-TNF agents in patients with Ankylosing Spondylitis. Ann Rheum Dis. 2006; 65(3):316-20.
- Singh JA, Guyatt G, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Care & Research. Vol. 71, No. 1, January 2019, pp 2–29DOI 10.1002/acr.2378.

Created: 03/15
Effective: 04/11/22 Client Approval: 03/10/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ARMODAFANIL

Generic	Brand	HICL	GCN	Exception/Other
ARMODAFANIL	NUVIGIL	34868		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named **ARMODAFANIL (Nuvigil)** requires that the patient is greater than or equal to 18 years of age and has a diagnosis of narcolepsy, excessive daytime sleepiness, obstructive sleep apnea/hypopnea syndrome, shift work sleep disorder, or bipolar depression.

- **For patients with bipolar depression,** our guideline also requires that the patient is currently taking another agent indicated for bipolar depression, such as lithium, lamotrigine, a selective serotonin reuptake inhibitor (e.g., citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline) or an atypical antipsychotic (e.g., quetiapine, lurasidone, cariprazine).

RENEWAL CRITERIA

Our guideline for **ARMODAFINIL (Nuvigil)** renewal requires that the patient has a previous authorization on file for the requested medication **AND** there is history of paid claims for 90 of the past 120 days.

RATIONALE
Promote prudent prescribing of agents for the treatment of narcolepsy.

INDICATIONS
Nuvigil is indicated to improve wakefulness in adult patients with excessive sleepiness associated with obstructive sleep apnea (OSA), narcolepsy, or shift work disorder (SWD).

DOSING
The recommended dosage of Nuvigil for each indication is as follows:
OSA or Narcolepsy: 150 mg to 250 mg once a day in the morning.
SWD: 150 mg once a day, taken approximately one hour prior to start of the work shift.

REFERENCES
Nuvigil [Prescribing Information]. North Wales, PA: Teva Pharmaceuticals, USA, Inc.; February 2017.

Created: 03/20
Effective: 05/01/20 Client Approval: 03/13/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ASCIMINIB

Generic	Brand	HICL	GCN	Exception/Other
ASCIMINIB HYDROCHLORIDE	SCEMBLIX	47647		

GUIDELINES FOR USE

Our guideline named **ASCIMINIB (Scemblix)** requires the following rule(s) be met for approval:

A. You have Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML: type of blood cancer) in chronic phase (CP)
B. You are 18 years of age or older
C. You meet ONE of the following:
   1. Your cancer has a T315I mutation (a type of gene mutation)
   2. You have been previously treated with at least TWO tyrosine kinase inhibitors (TKIs), such as bosutinib, dasatinib, imatinib, nilotinib

RATIONALE

To promote appropriate utilization of Scemblix based on FDA approved indication and dosage.

FDA APPROVED INDICATIONS

Scemblix is a kinase inhibitor indicated for the treatment of adult patients with:

- Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with two or more tyrosine kinase inhibitors (TKIs)
- Ph+ CML in CP with the T315I mutation

DOSAGE AND ADMINISTRATION

- Recommended Dosage in Ph+ CML in CP: 80 mg orally once daily or 40 mg twice daily.
- Recommended Dosage in Ph+ CML in CP with the T315I Mutation: 200 mg orally twice daily.

REFERENCES

- Scemblix [Prescribing Information]. East Hanover, New Jersey: Novartis Pharmaceuticals Co.; October 2021.

Created: 11/21
Effective: 01/17/22 Client Approval: 12/20/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ASFOTASE ALFA

Generic	Brand	HICL	GCN	Exception/Other
ASFOTASE ALFA	STRENSIQ	42649		

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ASFOTASE ALFA (Strensiq)** requires the following rules be met for approval:

A. You have a documented diagnosis of perinatal/infantile-onset hypophosphatasia (HPP: genetic disorder causing abnormal development of bones and teeth) or juvenile-onset hypophosphatasia (HPP)

B. **If you have perinatal/infantile-onset hypophosphatasia (HPP), all of the following criteria must be met:**
   1. You were 6 months of age or younger at hypophosphatasia onset
   2. You are positive for a tissue non-specific alkaline phosphatase (a type of enzyme) (TNSALP) (ALPL) gene mutation as confirmed by genetic testing **OR** you meet at least **TWO** of the following criteria:
      a. Serum alkaline phosphatase (type of enzyme) level below that of normal range for your age
      b. Serum pyridoxal-5'-phosphate (PLP) levels elevated AND you have not received vitamin B6 supplementation in the previous week
      c. Urine phosphoethanolamine (PEA) level above that of normal range for your age
      d. Radiographic evidence of hypophosphatasia [e.g., flared and frayed metaphyses (narrow part of long bone), osteopenia (bone loss), widened growth plates, areas of radiolucency (ability to see through with x-rays/ radiation) or sclerosis (hardening of an area)]
      e. Presence of **two or more** of the following:
         i. Rachitic chest deformity (chest bones are not normal)
         ii. Craniosynostosis (premature closure of skull bones)
         iii. Delay in skeletal growth resulting in delay of motor development
         iv. History of vitamin B6 dependent seizures
         v. Nephrocalcinosis (high calcium levels in kidney) or history of elevated serum calcium
         vi. History or presence of fracture after birth not due to injury or delayed fracture healing

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INITIAL CRITERIA (CONTINUED)

C. **If you have juvenile-onset hypophosphatasia (HPP), approval also requires:**
   1. You were 18 years of age or younger at hypophosphatasia onset
   2. You are positive for a tissue non-specific alkaline phosphatase (a type of enzyme) (TNSALP) (ALPL) gene mutation as confirmed by genetic testing **OR** meet at least **TWO** of the following criteria:
      a. Serum alkaline phosphatase (type of enzyme) level below that of normal range for your age
      b. Serum pyridoxal-5'-phosphate (PLP) levels elevated **AND** you have not received vitamin B6 supplementation in the previous week
      c. Urine phosphoethanolamine (PEA) level above that of normal range for your age
      d. Radiographic evidence of hypophosphatasia (e.g., flared and frayed metaphyses (narrow part of long bone), osteopenia (bone loss), osteomalacia (bone softening), widened growth plates, areas of radiolucency or sclerosis (hardening of an area)
      e. Presence of **two or more** of the following:
         i. Rachitic deformities (rachitic chest, bowed legs, knock-knees)
         ii. Premature loss of primary teeth prior to 5 years of age
         iii. Delay in skeletal growth leading to motor development delay
         iv. History or presence of fracture after birth not due to injury or delayed fracture healing

Strensiq will not be approved for the following patients:

1. Patients currently receiving treatment with a bisphosphonate [e.g., Boniva (ibandronate), Fosamax (alendronate), Actonel (risedronate)]
2. Patients with serum calcium or phosphate levels below the normal range
3. Patients with a treatable form of rickets (A softening and weakening of bones in children, usually due to low Vitamin D)

RENEWAL CRITERIA

Our guideline named **ASFOTASE ALFA (Strensiq)** requires that the following rule is met for renewal:

A. You have experienced improvement in the skeletal characteristics of hypophosphatasia (HPP: genetic disorder causing abnormal development of bones and teeth). Characteristics may include irregularity of the provisional zone of calcification (area on long bone for calcium build-up), physeal widening (area of bone that helps length growth), metaphyseal flaring (a narrow part of long bone grows), radiolucencies (ability to see with x-rays/ radiation), patchy osteosclerosis (parts of abnormal hardening of bone), ratio of mid-diaphyseal cortex to bone thickness, gracile (slender) bones, bone formation and fractures.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ASFOTASE ALFA

RATIONALE
To ensure appropriate use of Strensiq consistent with FDA approved indication.

FDA APPROVED INDICATION
Strensiq is approved for the treatment of patients with perinatal/infantile- and juvenile-onset hypophosphatasia (HPP).

DOSAGE
Perinatal/Infantile-Onset hypophosphatasia (HPP)
Recommended dosage regimen is 2mg/kg administered subcutaneously three times per week, or 1mg/kg six times per week. Injection site reactions may limit the tolerability of the six times per week regimen. The dosage may be increased to 3mg/kg three times per week for insufficient efficacy.

Juvenile-Onset hypophosphatasia (HPP)
Recommended dosage regimen is 2mg/kg administered subcutaneously three times per week, or 1mg/kg six times per week. Injection site reactions may limit the tolerability of the six times per week regimen.

Please refer to prescribing information for tables of weight-based dosing by treatment regimen.

AVAILABLE STRENGTHS:
- 18mg/0.45ml single-use vial
- 28mg/0.7ml single-use vial
- 40mg/ml single-use vial
- 80mg/0.8ml single-use vial

REFERENCES
Strensiq [Prescribing Information]. Cheshire, CT: Alexion Pharmaceuticals, Inc. February 2018.

Created: 03/18
Effective: 03/21/22 Client Approval: 02/17/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ASPARAGINASE ERWINIA-RYWN

Generic	Brand	HICL	GCN	Exception/Other
ASPARAGINASE ERWINIA-RYWN	RYLAZE	47474		

GUIDELINES FOR USE

Our guideline named **ASPARAGINASE ERWINIA-RYWN (RYLAZE)** requires the following rule(s) be met for approval:

A. You have acute lymphoblastic leukemia (ALL: type of blood cancer) or lymphoblastic lymphoma (LBL: type of cancer affecting the immune system)
B. You are 1 month of age or older
C. You have developed hypersensitivity to E. coli-derived asparaginase (you are allergic to an enzyme/protein that is from a type of bacteria)
D. Rylaze will be used as a component of a multi-agent chemotherapeutic regimen

RATIONALE

To ensure appropriate use of Rylaze consistent with FDA approved indication.

FDA APPROVED INDICATIONS

Rylaze is an asparagine specific enzyme indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma (LBL) in adult and pediatric patients 1 month or older who have developed hypersensitivity to E. coli-derived asparaginase.

DOSAGE AND ADMINISTRATION

When replacing a long-acting asparaginase product, the recommended dosage of RYLAZE is 25 mg/m^2 administered intramuscularly every 48 hours.

REFERENCES

- Rylaze [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc., June 2021.

Created: 07/21
Effective: 09/20/21 Client Approval: 08/20/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ASPIRIN ER

Generic	Brand	HICL	GCN	Exception/Other
ASPIRIN ER	DURLAZA		17988	

GUIDELINES FOR USE

Our guideline for **ASPIRIN ER** requires a diagnosis of chronic coronary artery disease, (e.g. a history of MI or unstable angina), or a history of an ischemic stroke or transient ischemic attack (TIA). In addition, the following criteria must also be met:

- Patient has previously tried aspirin over-the-counter (OTC)
- Durlaza is not being used for acute treatment of myocardial infarction or before percutaneous coronary intervention

RATIONALE

Promote appropriate utilization of **Durlaza** based on FDA approved indication and cost-effectiveness.

DURLAZA is a nonsteroidal anti-inflammatory drug indicated to reduce the risk of death and myocardial infarction (MI) in patients with chronic coronary artery disease, such as patients with a history of MI or unstable angina pectoris or with chronic stable angina and to reduce the risk of death and recurrent stroke in patients who have had an ischemic stroke or transient ischemic attack.

Limitation of Use: Use immediate-release aspirin, not DURLAZA in situations where a rapid onset of action is required (such as acute treatment of myocardial infarction or before percutaneous coronary intervention).

Durlaza is a 162.5mg extended release formulation of aspirin. Aspirin is available in multiple strengths as an over the counter (OTC) product. There were no new studies on the safety and efficacy of Durlaza performed. The platelet inhibitory effects of aspirin last for the life of the circulating platelets, which is ~10 days, thus an extended release formulation of aspirin has not been demonstrated to be superior to previously available OTC aspirin.

DOSAGE

The recommended dose is 162.5 mg per day with a full glass of water at the same time each day.

FDA APPROVED INDICATION

DURLAZA is a nonsteroidal anti-inflammatory drug indicated to reduce the risk of death and myocardial infarction (MI) in patients with chronic coronary artery disease, such as patients with a history of MI or unstable angina pectoris or with chronic stable angina and to reduce the risk of death and recurrent stroke in patients who have had an ischemic stroke or transient ischemic attack.

Limitation of Use: Use immediate-release aspirin, not DURLAZA in situations where a rapid onset of action is required (such as acute treatment of myocardial infarction or before percutaneous coronary intervention).

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ASPIRIN ER

REFERENCES

- New haven Pharmaceuticals, Inc. Durlaza Package Insert. North Haven, CT. September 2015.
- Awtry, Eric H., Loscalzo, Joseph. Cardiology Drugs: Aspirin. Journal Circulation: 2000; 101: 1206-1218. Accessed online Ocotber 12, 2015 at: http://circ.ahajournals.org/content/101/10/1206.full

Created: 01/16
Effective: 06/01/16 Client Approval: 04/18/16 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ASPIRIN-OMEPRAZOLE

Generic	Brand	HICL	GCN	Exception/Other
ASPIRIN-OMEPRAZOLE	YOSPRALA	43771		

GUIDELINES FOR USE

The guideline named **ASPIRIN-OMEPRAZOLE (Yosprala)** requires an indication of secondary prevention of cardiovascular or cerebrovascular events and has **ONE** of the following diagnoses: ischemic stroke, transient ischemia of the brain due to fibrin platelet emboli, previous myocardial infarction, unstable angina pectoris, chronic stable angina pectoris, or previous revascularization procedures (i.e., coronary artery bypass graft, percutaneous transluminal coronary angioplasty). In addition, the following criteria must also be met:

- The patient has a risk of developing aspirin associated gastric ulcers due to age (55 years or older) **AND** documented history of gastric ulcers
- The patient has tried both aspirin over-the-counter (OTC) **AND** generic proton pump inhibitors (e.g., omeprazole, lansoprazole, pantoprazole, rabeprazole)

RATIONALE

Promote appropriate utilization of Yosprala based on FDA approved indication and dosing.

FDA APPROVED INDICATIONS

Indicated for patients who require aspirin for secondary prevention of cardiovascular and cerebrovascular events and who are at risk of developing aspirin associated gastric ulcers.

The aspirin component is indicated for:

- Reducing the combined risk of death and nonfatal stroke in patients who have had ischemic stroke or transient ischemia of the brain due to fibrin platelet emboli,
- Reducing the combined risk of death and nonfatal MI in patients with a previous MI or unstable angina pectoris,
- Reducing the combined risk of MI and sudden death in patients with chronic stable angina pectoris,
- Use in patients who have undergone revascularization procedures (Coronary Artery Bypass Graft [CABG] or Percutaneous Transluminal Coronary Angioplasty [PTCA]) when there is a pre-existing condition for which aspirin is already indicated.

The omeprazole component of Yosprala is indicated for decreasing the risk of developing aspirin associated gastric ulcers in patients at risk for developing aspirin-associated gastric ulcers due to age (≥ 55) or documented history of gastric ulcers.

Limitations of Use:

- Not for use as the initial dose of aspirin therapy during onset of acute coronary syndrome, acute myocardial infarction or before percutaneous coronary intervention.
- Has not been shown to reduce the risk of gastrointestinal bleeding due to aspirin.
- Yosprala is not interchangeable with the individual components of aspirin and omeprazole.

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ASPIRIN-OMEPRAZOLE

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE
The recommended dosage is one tablet daily.

Yosprala is available in combinations that contain 81 mg or 325 mg of aspirin. Generally, 81 mg of aspirin has been accepted as an effective dose for secondary cardiovascular prevention. Providers should consider the need for 325 mg and refer to current clinical practice guidelines.

REFERENCES

- Yosprala [Prescribing Information]. Princeton, NJ: Aralez Pharmaceuticals US Inc. September 2016.

Created: 05/17
Effective: 07/01/17 Client Approval: 05/02/17 P&T Approval: N/A

ATOGEPANT

Generic	Brand	HICL	GCN	Exception/Other
ATOGEPANT	QULIPTA	47599		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ATOGEPANT (Qulipta)** requires the following rule(s) be met for approval:
A. The request is for the preventative treatment of episodic migraine
B. You are 18 years of age or older
C. You have tried any THREE of the following preventative migraine treatments (chart notes required in the absence of electronic prescription claims history):
   1. beta-blocker (such as propranolol, timolol, or nadolol)
   2. candesartan
   3. cyproheptadine
   4. lisinopril
   5. tricyclic antidepressant (such as amitriptyline, nortriptyline, or doxepin)
   6. topiramate
   7. valproic acid/ divalproex sodium
   8. venlafaxine/ desvenlafaxine
   9. verapamil
D. ONE of the following:
   1. You have tried TWO injectable calcitonin gene-related peptide (CGRP) antagonists (e.g., Ajovy, Aimovig, Emgality)
   2. You have needle phobia, dexterity issue, or other medical reason you cannot use an injectable CGRP inhibitor

RENEWAL CRITERIA

Our guideline named **ATOGEPANT (Qulipta)** requires the following rule(s) be met for renewal:
A. The request is for the preventative treatment of episodic migraine
B. You have history of paid claim(s) for the requested medication in the past 90 days
C. You have a previous authorization on file for the requested medication

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ATOGEPANT

RATIONALE
To ensure appropriate diagnostic, utilization and safety criteria are used for the management of requests for Qulipta.

FDA APPROVED INDICATIONS
Qulipta is a calcitonin gene-related peptide receptor antagonist indicated for the preventive treatment of episodic migraine in adults.

DOSING
The recommended dosage is 10 mg, 30 mg, or 60 mg taken orally once daily with or without food.

REFERENCES

- Qulipta [Prescribing Information]. North Chicago, IL: AbbVie, Inc., October 2021.

Created: 10/21
Effective: 12/20/21 Client Approval: 11/19/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

AVAPRITINIB

Generic	Brand	HICL	GCN	Exception/Other
AVAPRITINIB	AYVAKIT	46291		

GUIDELINES FOR USE

Our guideline named **AVAPRITINIB (Ayvakit)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Unresectable (cannot be removed completely through surgery) or metastatic (cancer that has spread to other parts of the body) gastrointestinal stromal tumor (GIST: type of growth in the digestive system tract, most commonly in the stomach or small intestine)
   2. Advanced systemic mastocytosis (AdvSM: group of rare diseases in which uncontrolled growth and accumulation of mast cells [type of white blood cell] occurs in one or more organs)

B. You are 18 years of age or older

C. **If you have unresectable or metastatic gastrointestinal stromal tumor (GIST), approval also requires:**
   1. You have a platelet-derived growth factor receptor alpha (PDGFRA: a type of gene/protein) exon 18 mutation, including PDGFRA D842V mutations (a change in your DNA that make up your gene)

D. **If you have advanced systemic mastocytosis (AdvSM), approval also requires:**
   1. Your AdvSM includes aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (abnormal mass of blood and blood-forming tissue that forms when cells grow and divide) (SM-AHN), and mast cell leukemia (MCL: an aggressive subtype of acute myeloid leukemia)

RATIONALE
To ensure appropriate diagnostic, utilization and safety criteria are used for the management of requests for avapritinib.

FDA APPROVED INDICATIONS
Ayvakit is a kinase inhibitor indicated for:

- the treatment of adults with unresectable or metastatic gastrointestinal stromal tumor (GIST) harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations
- the treatment of adult patients with Advanced Systemic Mastocytosis (AdvSM), which includes patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SM-AHN), and mast cell leukemia (MCL)

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

AVAPRITINIB

DOSING

- GIST: The recommended dosage is 300mg orally once daily.
- AdvSM: The recommended dosage is 200mg orally once daily.

REFERENCES

- Ayvakit [Prescribing Information]. Cambridge, MA: Blueprint Medicines Corporation, June 2021.

Created: 03/20
Effective: 11/01/21 Client Approval: 10/15/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

AVATROMBOPAG

Generic	Brand	HICL	GCN	Exception/Other
AVATROMBOPAG	DOPTELET	44942		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **AVATROMBOPAG (Doptelet)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Thrombocytopenia (low amount of a type of blood cell that prevents bleeding)
   2. Chronic immune thrombocytopenia (condition where your body fights against a type of blood cell that prevents bleeding)

B. **If you have thrombocytopenia, approval also requires:**
   1. You are 18 years of age or older
   2. You have chronic liver disease
   3. You are scheduled to undergo a procedure 10 to 13 days after starting Doptelet therapy
   4. You have a platelet (type of blood cell that prevents bleeding) count of less than 50 x 10^9/L measured within the last 30 days
   5. You are not receiving other thrombopoietin receptor agonist therapy such as Promacta

C. **If you have chronic immune thrombocytopenia (cITP), approval also requires:**
   1. You are 18 years of age or older
   2. You have previously tried corticosteroids or immunoglobulins, unless there is a medical reason why you cannot (contraindication) **OR** you had an insufficient response to splenectomy (surgical removal of spleen)

RENEWAL CRITERIA

NOTE: For the diagnosis of thrombocytopenia, please refer to the Initial Criteria section.

Our guideline named **AVATROMBOPAG (Doptelet)** requires the following rule(s) be met for renewal:

A. You have a diagnosis of chronic immune thrombocytopenia (condition where your body fights against a type of blood cell that prevents bleeding)
B. You had a clinical response to therapy as defined by an increase in platelet count to at least 50 x 10^9/L (at least 50,000 per microliter), compared to baseline.

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AVATROMBOPAG

RATIONALE
To ensure appropriate use of avatrombopag consistent with FDA approved indications.

FDA APPROVED INDICATION
Doptelet is a thrombopoietin receptor agonist indicated for the treatment of:
- Thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.
- Thrombocytopenia in adult patients with chronic immune thrombocytopenia who have had an insufficient response to a previous treatment.

DOSAGE AND ADMINISTRATION
Chronic Liver Disease:
Dose Doptelet based upon platelet count prior to procedure, orally for 5 days beginning 10 to 13 days before procedure. For platelet count less than 40×10^9 /L, the dose is 60 mg (3 tablets) once daily; for platelet count 40 to less than 50×10^9 /L the dose is 40 mg (2 tablets) once daily.

Chronic Immune Thrombocytopenia: Initiate Doptelet at 20 mg (1 tablet) once daily. Adjust the dose or frequency of dosing to maintain platelet count greater than or equal to 50×10^9 /L. Do not exceed 40 mg per day.

REFERENCES
Doptelet [prescribing information]. Durham, NC. Dova Pharmaceuticals, Inc. July 2021.

Created: 01/20
Effective: 03/14/22 Client Approval: 02/14/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

AXITINIB

Generic	Brand	HICL	GCN	Exception/Other
AXITINIB	INLYTA	38446		

GUIDELINES FOR USE

Our guideline named **AXITINIB (Inlyta)** requires the following rule(s) be met for approval:
A. You have advanced renal cell carcinoma (RCC: type of kidney cancer)
B. You also meet ONE of the following:
   1. You have tried at least ONE systemic therapy (treatment that spreads throughout the body) for the treatment of renal cell carcinoma such as Nexavar (sorafenib), Torisel (temsirolimus), Sutent (sunitinib), Votrient (pazopanib), or Avastin (bevacizumab) in combination with interferon
   2. Inlyta will be used in combination with avelumab (Bavencio) as a first-line treatment
   3. Inlyta will be used in combination with pembrolizumab (Keytruda) as a first-line treatment

RATIONALE
Ensure appropriate utilization of Inlyta based on FDA approved indication.

FDA APPROVED INDICATION
Inlyta is a kinase inhibitor indicated:
- in combination with avelumab, for the first-line treatment of patients with advanced renal cell carcinoma (RCC).
- in combination with pembrolizumab, for the first-line treatment of patients with advanced RCC.
- as a single agent, for the treatment of advanced renal cell carcinoma (RCC) after failure of one prior systemic therapy.

DOSING
First-Line Advanced RCC
The recommended dose of Inlyta is 5 mg orally taken twice daily (12 hours apart) with or without food in combination with avelumab 800 mg administered as an intravenous infusion over 60 minutes every 2 weeks until disease progression or unacceptable toxicity. When Inlyta is used in combination with avelumab, dose escalation of Inlyta above the initial 5 mg dose may be considered at intervals of two weeks or longer.

The recommended dose of Inlyta is 5 mg orally twice daily (12 hours apart) with or without food in combination with pembrolizumab 200 mg every 3 weeks or 400 mg every 6 weeks administered as an intravenous infusion over 30 minutes until disease progression or unacceptable toxicity. When Inlyta is used in combination with pembrolizumab, dose escalation of Inlyta above the initial 5 mg dose may be considered at intervals of six weeks or longer.

Second-Line Advanced RCC
When Inlyta is used as a single agent, the recommended starting oral dose is 5 mg twice daily. Administer Inyta doses approximately 12 hours apart with or without food.

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AXITINIB (CONTINUED)

REFERENCES

- Inlyta [Prescribing Information]. New York, NY. Pfizer; June 2020.

Created: 06/15
Effective: 01/18/21 Client Approval: 12/04/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

AZACITIDINE

Generic	Brand	HICL	GCN	Exception/Other
AZACITIDINE	ONUREG		48545 48540	

GUIDELINES FOR USE

Our guideline named **AZACITIDINE (Onureg)** requires the following rule(s) be met for approval:

A. You have acute myeloid leukemia (AML: type of blood and bone marrow cancer with too many white blood cells)
B. You are 18 years of age or older
C. You have achieved first complete remission (CR: signs or symptoms of cancer have disappeared) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy (medications for cancer)
D. You are not able to complete intensive curative therapy (treatment to cure the disease)

RATIONALE

Promote appropriate utilization of Onureg based on FDA approved indication and dosing.

FDA APPROVED INDICATIONS

Onureg is a nucleoside metabolic inhibitor indicated for continued treatment of adult patients with acute myeloid leukemia who achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy and are not able to complete intensive curative therapy.

DOSING & ADMINISTRATION

Administer Onureg 300 mg orally once daily on Days 1 through 14 of each 28-day cycle.

REFERENCES

Onureg [Prescribing Information]. Summit, NJ: Celgene Corporation; September 2020.

Created: 10/20
Effective: 11/16/20 Client Approval: 10/16/20 P&T Approval: N/A

AZTREONAM INHALED

Generic	Brand	HICL	GCN	Exception/Other
AZTREONAM LYSINE	CAYSTON		28039	

GUIDELINES FOR USE

Our guideline for approval requires a diagnosis of cystic fibrosis, patient age of at least 7 years, and lung infection with a Gram negative species.

AZTREONAM INHALED

RATIONALE

Promote appropriate utilization of Cayston based on FDA approved indication.

Dosage: One ampule three times daily in repeated cycles of 28 days on drug followed by 28 days off drug.

FDA APPROVED INDICATION

Cayston is indicated to improve respiratory symptoms in cystic fibrosis patients with *Pseudomonas aeruginosa*. Safety and effectiveness have not been established in pediatric patients below the age of 7 years, patients with FEV_1 <25% or >75% predicted, or patients colonized with *Burkholderia cepacia*.

REFERENCES

- Gilead Sciences, Inc. Cayston package insert. Foster City, CA. February 2010.

Created: 06/15
Effective: 07/22/15 Client Approval: 06/15 P&T Approval: 05/12

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

BARICITINIB

Generic	Brand	HICL	GCN	Exception/Other
BARICITINIB	OLUMIANT	44296		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **BARICITINIB (Olumiant)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness of joints)
   2. Severe alopecia areata (a type of hair loss)
B. You are 18 years of age or older
C. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You have previously tried at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs): methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   2. You have previously tried ONE of the following: Enbrel or Humira

NOTE: Olumiant will not be approved for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults.

RENEWAL CRITERIA

Our guideline named **BARICITINIB (Olumiant)** requires the following rule(s) be met for renewal:

A. You have moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in the joints)
B. You have experienced or maintained symptomatic improvement while on therapy

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RATIONALE

Ensure appropriate diagnostic, utilization, and safety criteria are used for the management of requests for Olumiant.

FDA APPROVED INDICATION

Olumiant is a Janus kinase (JAK) inhibitor indicated for:

- the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies.
- the treatment of COVID-19 in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or ECMO.
- the treatment of adult patients with severe alopecia areata.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

BARICITINIB

DOSAGE AND ADMINISTRATION

Rheumatoid Arthritis:

- 2 mg once daily.
- Olumiant may be used as monotherapy or in combination with methotrexate or other non-biologic DMARDs.

COVID-19:

- 4 mg once daily for up to 14 days.

Alopecia Areata:

- 2 mg once daily. Increase to 4 mg once daily, if the response to treatment is not adequate.
- For patients with nearly complete or complete scalp hair loss, with or without substantial eyelash or eyebrow hair loss, consider treating with 4 mg once daily.
- Reduce the dose to 2 mg once daily when an adequate response has been achieved.

REFERENCES

- Olumiant [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company. July 2022.
- Singh JA, Saag KG, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. 2016;68(1):1-25. DOI 10.1002/acr.22783.

Created: 06/18
Effective: 07/18/22 Client Approval: 07/07/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

BEDAQUILINE FUMARATE

Generic	Brand	HICL	GCN	Exception/Other
BEDAQUILINE FUMARATE	SIRTURO		33934	

GUIDELINES FOR USE

The guideline named **BEDAQUILINE FUMARATE (Sirturo)** requires a diagnosis of pulmonary multi-drug resistant tuberculosis (MDR-TB) (i.e., an isolate of M. tuberculosis that is resistant to at least isoniazid and rifampin). In addition, the following must be met:

- Sirturo will be used in combination with at least THREE other antibiotics
- The patient meets **ONE** of the following criteria:
  - The patient is 12 to less than 18 years old **AND** weighs at least 30kg
  - The patient is 18 years of age or older

RATIONALE

To ensure appropriate use aligned with FDA approved indication.

FDA APPROVED INDICATIONS

Sirturo is a diarylquinoline antimycobacterial drug indicated as part of combination therapy in adults (≥ 18 years) with pulmonary multi-drug resistant tuberculosis (MDR-TB). Sirturo is reserved for use when an effective treatment regimen cannot otherwise be provided. Sirturo is not indicated for the treatment of latent, extra-pulmonary, or drug-sensitive tuberculosis.

DOSING

The recommended dosage of Sirturo is 400 mg once daily for 2 weeks followed by 200 mg 3 times per week for 22 weeks. Sirturo should be administered by directly observed therapy (DOT). Sirturo should be swallowed whole and administered with food and water. No dosage adjustment is necessary in patients with mild to moderate renal or hepatic impairment.

Sirturo should only be used in combination with at least 3 other antibiotics to which the patient's MDR-TB isolate has been shown to be susceptible in vitro. If in vitro testing results are not available, treatment may be initiated with Sirturo in combination with at least 4 other drugs to which the patient's MDR-TB isolate is likely to be susceptible.

REFERENCES

- Sirturo [Prescribing Information]. Titusville, NJ: Janssen Therapeutics; August 2019.

Created: 06/15
Effective: 03/09/20 Client Approval: 02/19/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

BELIMUMAB – IV

Generic	Brand	HICL	GCN	Exception/Other
BELIMUMAB	BENLYSTA		29633 29634	

NOTE: For requests for the SQ dosage form of Benlysta, please see the BELIMUMAB SQ Guideline.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

Our guideline named **BELIMUMAB (Benlysta IV)** requires the following rule(s) be met for approval:
A. You have ONE of the following diagnoses:
   1. Autoantibody positive systemic lupus erythematosus (SLE: inflammatory disease caused when the immune system attacks its own tissues)
   2. Active lupus nephritis
B. **If you have autoantibody positive systemic lupus erythematosus (SLE), approval also requires:**
   1. You are 5 years of age or older
   2. You are currently using corticosteroids, antimalarials (drug that treat parasites), non-steroidal anti-inflammatory drugs (NSAIDS), or immunosuppressants (drugs that weaken your immune system)
C. **If you have active lupus nephritis, approval also requires:**
   1. You are 5 years of age or older
   2. You are currently using corticosteroids, antimalarials (drug that treat parasites), non-steroidal anti-inflammatory drugs (NSAIDS), or immunosuppressants (drugs that weaken your immune system)

RENEWAL CRITERIA

Our guideline named **BELIMUMAB (Benlysta IV)** requires the following rule(s) be met for renewal:
A. You have ONE of the following diagnoses:
   1. Autoantibody positive systemic lupus erythematosus (SLE: inflammatory disease caused when the immune system attacks its own tissues)
   2. Active lupus nephritis
B. You have experienced or maintained clinical improvement while on Benlysta

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

BELIMUMAB – IV

RATIONALE
Ensure appropriate utilization of Benlysta consistent with its FDA approved indication and dosing.

FDA APPROVED INDICATION
Benlysta is a B-lymphocyte stimulator (BLyS)-specific inhibitor indicated for the treatment of:
- Patients aged 5 years and older with active, autoantibody-positive systemic lupus erythematosus (SLE) who are receiving standard therapy.
- Patients aged 5 years and older with active lupus nephritis who are receiving standard therapy.

Limitations of Use: The efficacy of Benlysta has not been evaluated in patients with severe active central nervous system lupus. Benlysta has not been studied in combination with other biologics. Therefore, the use of Benlysta is not recommended in these situations.

DOSAGE AND ADMINISTRATION
The recommended intravenous dosage regimen is 10 mg/kg at 2-week intervals for the first 3 doses and at 4-week intervals thereafter.

REFERENCES

- Benlysta [Prescribing Information]. Rockville, Maryland: Human Genome Sciences, Inc. July 2022.
- Bertsias G, Ioannidis JPA, Boletis J et al. EULAR recommendations for the management of systemic lupus erythematosus. Report of a Task Force of the EULAR Standing Committee for International Clinical Studies Including Therapeutics. *Ann Rheum Dis* 2008; 67:195-205.
- Mosca M, Bombardieri S. Assessing remission in systemic lupus erythematosus. *Clin Exp Rheumatol* 2006; 24 (Suppl. 43): S100-S104.

Created: 02/18
Effective: 09/12/22 Client Approval: 08/29/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

BELIMUMAB - SQ

Generic	Brand	HICL	GCN	Exception/Other
BELIMUMAB	BENLYSTA		43658 43661	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

Our guideline named **BELIMUMAB (Benlysta SQ)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
    1. Autoantibody positive systemic lupus erythematosus (SLE: inflammatory disease caused when the immune system attacks its own tissues)
    2. Active lupus nephritis
B. You are 18 years of age or older
C. You are currently using corticosteroids, antimalarials (drugs that treat parasites), non-steroidal anti-inflammatory drugs (NSAIDS), or immunosuppressants (drugs that weaken your immune system)

RENEWAL CRITERIA

Our guideline named **BELIMUMAB (Benlysta SQ)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
    1. Autoantibody positive systemic lupus erythematosus (SLE: inflammatory disease caused when the immune system attacks its own tissues)
    2. Active lupus nephritis
B. You have experienced or maintained clinical improvement while on Benlysta

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RATIONALE
Ensure appropriate utilization of Benlysta consistent with its FDA approved indication and dosing.

INDICATIONS
Benlysta is a B-lymphocyte stimulator (BLyS)-specific inhibitor indicated for the treatment of:

- Patients aged 5 years and older with active, autoantibody-positive systemic lupus erythematosus (SLE) who are receiving standard therapy
- Adult patients with active lupus nephritis who are receiving standard therapy

Limitations of Use: The efficacy of Benlysta has not been evaluated in patients with severe active central nervous system lupus. Benlysta has not been studied in combination with other biologics. Therefore, the use of Benlysta is not recommended in these situations.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

BELIMUMAB - SQ

DOSAGE AND ADMINISTRATION

Subcutaneous dosing of Benlysta has not been evaluated and is not approved for patients younger than 18 years of age.

Recommended Subcutaneous Dosage Regimen - Adult Patients with SLE
The recommended dosage is 200 mg once weekly given as a subcutaneous injection in the abdomen or thigh. Subcutaneous dosing is not based on weight. If transitioning from intravenous therapy with Benlysta to subcutaneous administration, administer the first subcutaneous dose 1 to 4 weeks after the last intravenous dose.

Recommended Subcutaneous Dosage Regimen - Adult Patients with Lupus Nephritis
In patients initiating therapy with Benlysta for active lupus nephritis, the recommended dosage regimen is a 400-mg dose (two 200-mg injections) once weekly for 4 doses, then 200 mg once weekly thereafter. The dose is given via subcutaneous injection in the abdomen or thigh. The 400-mg dose for active lupus nephritis requires administration of 2 autoinjectors or 2 prefilled syringes.

A patient with lupus nephritis may transition from intravenous therapy with Benlysta to subcutaneous therapy any time after the patient completes the first 2 intravenous doses. If transitioning, administer the first subcutaneous dose of 200 mg 1 to 2 weeks after the last intravenous dose.

REFERENCES

- Benlysta [Prescribing Information]. Rockville, Maryland: Human Genome Sciences, Inc. December 2020.
- Bertsias G, Ioannidis JPA, Boletis J et al. EULAR recommendations for the management of systemic lupus erythematosus. Report of a Task Force of the EULAR Standing Committee for International Clinical Studies Including Therapeutics. *Ann Rheum Dis* 2008; 67:195-205.
- Mosca M, Bombardieri S. Assessing remission in systemic lupus erythematosus. *Clin Exp Rheumatol* 2006; 24 (Suppl. 43): S100-S104.

Created: 08/17
Effective: 04/01/21 Client Approval: 03/22/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

BELUMOSUDIL MESYLATE

Generic	Brand	HICL	GCN	Exception/Other
BELUMOSUDIL MESYLATE	REZUROCK	47503		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **BELUMOSUDIL MESYLATE (Rezurock)** requires the following rule(s) be met for approval:

A. You have chronic graft-versus-host-disease (chronic GVHD: a condition in which the donor bone marrow or stem cells attack the receiving person)
B. You are 12 years of age or older
C. You had failure of at least TWO prior lines of systemic therapies (treatment that spreads throughout the body) (e.g., corticosteroids, immunosuppressants)

RENEWAL CRITERIA

Our guideline named **BELUMOSUDIL MESYLATE (REZUROCK)** requires the following rule(s) be met for renewal:

A. You have a diagnosis of chronic graft-versus-host disease (GVHD: a condition in which the donor bone marrow or stem cells attack the receiving person)
B. You have history of paid claim(s) for the requested medication in the past 90 days
C. You have previous authorization on file for the requested medication

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RATIONALE

Promote appropriate utilization and dosing of Rezurock for its FDA approved indication.

FDA APPROVED INDICATIONS

Rezurock is a kinase inhibitor indicated for the treatment of adult and pediatric patients 12 years and older with chronic graft-versus-host disease (chronic GVHD) after failure of at least two prior lines of systemic therapy.

DOSAGE

The recommended dose of Rezurock is 200 mg given orally once daily until progression of chronic GVHD that requires new systemic therapy.

REFERENCES

- Rezurock [Prescribing Information]. Warrendale, PA: Kadmon Pharmaceuticals, LLC, July 2021.

Created: 09/21
Effective: 11/22/21 Client Approval: 10/15/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

BEMPEDOIC ACID

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BEMPEDOIC ACID	NEXLETOL	46382		GPI-10 (3938002000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named **BEMPEDOIC ACID (Nexletol)** requires the following rule(s) be met for approval:

- **A.** You have ONE of the following diagnoses:
  1. Established cardiovascular disease (health problems related to narrow or blocked blood vessels of the heart) such as history of myocardial infarction (heart attack) or other acute coronary syndrome, coronary or other revascularization procedure (restoring blood flow to heart and other areas), transient ischemic attack (short, stroke-like attack), ischemic stroke (arteries to your brain become narrowed or blocked), atherosclerotic peripheral arterial disease (arteries get blocked with fats and plaques), coronary atherosclerosis (heart arteries get blocked with fats and plaques), renal atherosclerosis (kidney arteries get blocked with fats and plaques), aortic aneurysm secondary to atherosclerosis (fat and plaque build up causes enlargement of a heart artery), carotid plaque with 50% or more stenosis (narrowing of blood vessel)
  2. Heterozygous familial hypercholesterolemia [HeFH: type of inherited high cholesterol])
- **B.** You are 18 years of age or older
- **C.** You previously had a trial of or contraindication (a medical reason why you cannot use) to ezetimibe
- **D.** You have an LDL (low density lipoprotein)-cholesterol level greater than or equal to 70 mg/dL
- **E.** **If you are statin tolerant, approval also requires:**
  1. You will continue statin treatment in combination with Nexletol
  2. You meet ONE of the following:
     a. You have been taking a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
     b. You have been taking a maximally tolerated dose of any statin given that you cannot tolerate a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
- **F.** **If you are statin intolerant, approval also requires ONE of the following:**
  1. You have an absolute contraindication (a medical reason why you cannot use) to statin therapy (such as active decompensated liver disease: you have symptoms related to liver damage, nursing female, pregnancy or plans to become pregnant, or hypersensitivity [allergic] reaction)
  2. You have complete statin intolerance as defined by severe and intolerable adverse effects that has occurred with trials of at least two separate statins, and the side effects have improved when you stopped each statin. Some adverse effects include: creatine kinase (type of protein) elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis (severe muscle break down), severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group

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BEMPEDOIC ACID

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **BEMPEDOIC ACID (Nexletol)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
1. Established cardiovascular disease (health problems related to narrow or blocked blood vessels of the heart)
2. Heterozygous familial hypercholesterolemia ([HeFH]: type of inherited high cholesterol)

B. You meet ONE of the following:
1. You have experienced low density lipoprotein-cholesterol (LDL-C) lowering AND will continue therapy with a maximally tolerated dose of any statin
2. You have an absolute contraindication (a medical reason why you cannot use) to statin therapy
3. You have complete statin intolerance

RATIONALE
To ensure appropriate diagnostic, utilization and safety criteria are used for the management of requests for bempedoic acid.

FDA APPROVED INDICATIONS
Nexletol is an adenosine triphosphate-citrate lyase (ACL) inhibitor indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C.

DOSING
The recommended dose of Nexletol, in combination with maximally tolerated statin therapy, is 180 mg administered orally once daily.

REFERENCES
Nexletol [Prescribing Information]. Ann Arbor, MI: Esperion Therapeutics, Inc.; February 2020.

Created: 04/30
Effective: 03/04/22 Client Approval: 02/03/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

BEMPEDOIC ACID AND EZETIMIBE

Generic	Brand	HICL	GCN	Exception/Other
BEMPEDOIC ACID AND EZETIMIBE	NEXLIZET	46386		

GUIDELINES FOR USE
INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **BEMPEDOIC ACID AND EZETIMIBE (Nexlizet)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
1. Established cardiovascular disease (health problems related to narrow or blocked blood vessels of the heart) such as history of myocardial infarction (heart attack) or other acute coronary syndrome, coronary or other revascularization procedure (restoring blood flow to heart and other areas), transient ischemic attack (short, stroke-like attack), ischemic stroke (arteries to your brain become narrowed or blocked), atherosclerotic peripheral arterial disease (arteries get blocked with fats and plaques), coronary atherosclerosis (heart arteries get blocked with fats and plaques), renal atherosclerosis (kidney arteries get blocked with fats and plaques), aortic aneurysm secondary to atherosclerosis (fat and plaque buildup causes enlargement of a heart artery), carotid plaque with 50% or more stenosis (narrowing of blood vessel)
2. Heterozygous familial hypercholesterolemia [HeFH: type of inherited high cholesterol]

B. You are 18 years of age or older
C. You previously had a trial of ezetimibe
D. You have an LDL (low density lipoprotein)-cholesterol level greater than or equal to 70 mg/dL
E. **If you are statin tolerant, approval also requires:**
1. You will continue statin treatment in combination with Nexlizet
2. You meet ONE of the following:
   a. You have been taking a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
   b. You have been taking a maximally tolerated dose of any statin given that you cannot tolerate a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)

F. **If you are statin intolerant, approval also requires ONE of the following:**
1. You have an absolute contraindication (a medical reason why you cannot use) to statin therapy (such as active decompensated liver disease: you have symptoms related to liver damage, nursing female, pregnancy or plans to become pregnant, or hypersensitivity [allergic] reaction)
2. You have complete statin intolerance as defined by severe and intolerable adverse effects that has occurred with trials of at least two separate statins, and the side effects have improved when you stopped each statin. Some adverse effects include: creatinine kinase (type of protein) elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis (severe muscle break down), severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

BEMPEDOIC ACID AND EZETIMIBE

RENEWAL CRITERIA

Our guideline named **BEMPEDOIC ACID AND EZETIMIBE (Nexlizet)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Established cardiovascular disease (health problems related to narrow or blocked blood vessels of the heart)
   2. Heterozygous familial hypercholesterolemia ([HeFH]: type of inherited high cholesterol)

B. You have experienced low density lipoprotein-cholesterol (LDL-C) lowering

C. You meet ONE of the following:
   1. You have continued therapy with a maximally tolerated dose of any statin
   2. You have an absolute contraindication (a medical reason why you cannot use) to statin therapy
   3. You have complete statin intolerance

RATIONALE

Ensure appropriate diagnostic, utilization and safety criteria are used for the management of requests for bempedoic acid/ezetimibe.

FDA APPROVED INDICATIONS

Nexlizet is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C.

DOSING

The recommended dosage of Nexlizet, in combination with maximally tolerated statin therapy, is one tablet orally once daily.

REFERENCES

Nexlizet [Prescribing Information]. Ann Arbor, MI: Esperion Therapeutics Inc., February 2020.

Created: 07/20
Effective: 03/04/22 Client Approval: 02/03/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

BENRALIZUMAB

Generic	Brand	HICL	GCN	Exception/Other
BENRALIZUMAB	FASENRA	44635		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **BENRALIZUMAB (Fasenra)** requires the following rule(s) be met for approval:

A. You have severe asthma with an eosinophilic phenotype (type of inflammatory asthma)
B. You are 12 years of age or older
C. You are currently receiving therapy with **ONE** of the following:
    1. High-dose inhaled corticosteroid (ICS) AND a long-acting beta2 agonist (LABA)
    2. High-dose ICS/LABA combination product
D. Fasenra will be used as add-on maintenance treatment to one of the above inhaled asthma regimens
E. You have experienced at least ONE asthma exacerbation within the past 12 months (exacerbation is defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 or more days)

RENEWAL CRITERIA

Our guideline named **BENRALIZUMAB (Fasenra)** requires the following rule(s) be met for renewal:

a. You have severe asthma with an eosinophilic phenotype (type of inflammatory asthma).
b. You will continue to use inhaled corticosteroid (ICS) or ICS-containing combination inhalers
c. You have shown a clinical response as evidenced by ONE of the following:
    1. Reduction in asthma exacerbations (worsening of symptoms) from baseline
    2. Decreased use of rescue medications
    3. Increase in percent predicted FEV1 (amount of air you can forcefully exhale) from pretreatment baseline
    4. Reduction in severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing, etc.)

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BENRALIZUMAB

RATIONALE
Promote appropriate utilization of benralizumab based on FDA approved indication and dosing.

DOSAGE AND ADMINISTRATION
The recommended dose of Fasenra is 30 mg administered once every 4 weeks for the first 3 doses, and then once every 8 weeks thereafter by subcutaneous injection into the upper arm, thigh, or abdomen.

Fasenra should be administered by a healthcare professional.

FDA APPROVED INDICATION
Fasenra (benralizumab) is an interleukin-5 receptor alpha-directed cytolytic monoclonal antibody (IgG1, kappa) indicated for the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.

Limitations of Use:
- Not for treatment of other eosinophilic conditions.
- Not for relief of acute bronchospasm or status asthmaticus.

REFERENCES
Fasenra [Prescribing Information]. Wilmington, DE. AstraZeneca Pharmaceutical LP. October 2019.

Created: 12/17
Effective: 04/18/22 Client Approval: 03/15/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

BEROTRALSTAT HYDROCHLORIDE

Generic	Brand	HICL	GCN	Exception/Other
BEROTRALSTAT HYDROCHLORIDE	ORLADEYO	47016		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **BEROTRALSTAT (Orladeyo)** requires the following rule(s) be met for approval:
A. You have hereditary angioedema (HAE: life-threatening genetic condition that causes severe swelling)
B. Your diagnosis is confirmed by documented complement testing (blood test that measures the activity of a group of proteins in the bloodstream)
C. You are 12 years of age or older
D. Therapy is prescribed by or given in consultation with an allergist, immunologist (allergy or immune system doctor) or hematologist (blood doctor)
E. The requested medication is being used for prevention of hereditary angioedema attacks

RENEWAL CRITERIA

Our guideline named **BEROTRALSTAT (Orladeyo)** requires the following rule(s) be met for renewal:
A. You have hereditary angioedema (HAE: life-threatening genetic condition that causes severe swelling)
B. You have experienced improvement (reductions in attack frequency or attack severity) compared to baseline in HAE attacks

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RATIONALE
Ensure appropriate utilization of Orladeyo based on FDA-approved indication.

FDA APPROVED INDICATION
Orladeyo is a plasma kallikrein inhibitor indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years of age and older.

DOSING & ADMINISTRATION
The recommended dosage of Orladeyo is one 150 mg capsule taken orally once daily with food.

REFERENCES
Orladeyo [Prescribing Information]. Durham, NC: BioCryst Pharmaceuticals, Inc.; December 2020.

Created: 01/21
Effective: 02/15/21 Client Approval: 01/15/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

BEXAROTENE

Generic	Brand	HICL	GCN	Exception/Other
BEXAROTENE SOFTGEL	TARGRETIN		92373	
BEXAROTENE 1% TOPICAL GEL	TARGRETIN		89921	

GUIDELINES FOR USE

Our guideline for approval requires a diagnosis of cutaneous T-cell lymphoma that is refractory to prior systemic therapy.

BEXAROTENE

RATIONALE
Promote appropriate utilization of Targretin based on FDA approved indication.

FDA APPROVED INDICATIONS
Targretin (bexarotene) capsules are indicated for the treatment of cutaneous manifestations of cutaneous T-cell lymphoma in patients who are refractory to at least one prior systemic therapy.

(Systemic therapy to treat CTCL may include gemcitabine, methotrexate, liposomal doxorubicin, Velcade, and other agents.)

OTHER INFORMATION
Capsules (weight-based dosing of 4 to 14 capsules per day).

Gel (applications may be titrated from every other day up to four times daily; typical application varies from twice daily up to four times daily).

Targretin capsules should be administered once daily with a meal. The initial dose is 300mg/m^2/day. The dose may be increased up to 400mg/m^2/day when there is no tumor response after 8 weeks.

In clinical trials oral Targretin was administered for up to 97 weeks and topical Targretin gel was administered for up to 172 weeks.

Dosing information from http://us.eisai.com/pdf_files/prescribing_caps_information.pdf

Initial Dose Level (300 mg/m^2/day)		
Body Surface Area (m^2)	**Total Daily Dose (mg/day)**	**Number of 75 mg Targretin Capsules**
0.88 - 1.12	300	4
1.13 - 1.37	375	5
1.38 - 1.62	450	6
1.63 - 1.87	525	7
1.88 - 2.12	600	8
2.13 - 2.37	675	9
2.38 - 2.62	750	10

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BEXAROTENE

OTHER INFORMATION (CONTINUED)

Targretin contains a **black box warning** that this product is a member of the retinoid class of drugs and should not be administered to pregnant women (Pregnancy Category X).

REFERENCES

- Eisai Inc. Targretin prescribing information. Woodcliff Lake, NJ. April 2011. Accessed online February 2012 at: http://us.eisai.com/pdf_files/prescribing_caps_information.pdf

Created: 06/15
Effective: 07/22/15 Client Approval: 06/15 P&T Approval: 11/13

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

BINIMETINIB

Generic	Brand	HICL	GCN	Exception/Other
BINIMETINIB	MEKTOVI	45040		

GUIDELINES FOR USE

The guideline named **BINIMETINIB (Mektovi)** requires a diagnosis of unresectable or metastatic melanoma. In addition, the following criteria must be met:

- The patient has BRAF V600E or V600K mutation as detected by an FDA-approved test
- The medication will be used in combination with Braftovi (encorafenib)

RATIONALE

To promote appropriate utilization of MEKTOVI based on FDA approved indication and dosing.

FDA APPROVED INDICATION

Mektovi is a kinase inhibitor indicated, in combination with Braftovi (encorafenib), for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test.

DOSAGE & ADMINISTRATION

The recommended dosage of Mektovi is 45 mg orally taken twice daily, approximately 12 hours apart, in combination with Braftovi (encorafenib) until disease progression or unacceptable toxicity. Refer to the Braftovi (encorafenib) prescribing information for recommended Braftovi (encorafenib) dosing information.

Mektovi may be taken with or without food. Do not take a missed dose of Mektovi within 6 hours of the next dose of Mektovi. Do not take an additional dose if vomiting occurs after Mektovi administration but continue with the next scheduled dose.

REFERENCES

- Mektovi [Prescribing Information]. Boulder, CO: Array BioPharma Inc. June 2018.

Created: 08/18
Effective: 10/22/18 Client Approval: 09/11/18 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

BOSUTINIB

Generic	Brand	HICL	GCN	Exception/Other
BOSUTINIB	BOSULIF	39590		

GUIDELINES FOR USE

The guideline named **BOSUTINIB (Bosulif)** requires that the requested medication is used for newly diagnosed, chronic phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) or for chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML). In addition, the patient must be 18 years of age or older. The following must also be met:

For the diagnosis of chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML), approval requires:

- The patient previously tried or has a contraindication to other tyrosine kinase inhibitors [e.g. Gleevec (imatinib), Sprycel (dasatinib), or Tasigna (nilotinib)]
- The patient had a Breakpoint Cluster Region Abelson Murine Leukemia (BCR-ABL) mutational analysis confirming that the following mutations are NOT present: T315I, V299L, G250E, or F317L

RATIONALE

Ensure appropriate utilization of bosutinib based on FDA approved indication and dosage.

FDA APPROVED INDICATIONS

Bosulif is a kinase inhibitor indicated for the treatment of adult patients with:

- Newly diagnosed chronic phase Ph+ chronic myelogenous leukemia (CML). This indication is approved under accelerated approval based on molecular and cytogenetic response rates. Continued approval for this indication may be contingent upon verification and confirmation of clinical benefit in an ongoing long-term follow up trial
- Chronic, accelerated, or blast phase Ph+ chronic myelogenous leukemia (CML) with resistance or intolerance to prior therapy

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

BOSUTINIB

DOSAGE AND ADMINISTRATION

Newly Diagnosed chronic phase Ph+ CML: The recommended dose of Bosulif is 400 mg orally once daily with food and continues until disease progression or patient intolerance.

Chronic Phase, Accelerated Phase, or Blast Phase Ph+ CML with resistance or intolerance to prior therapy: The recommended dose of Bosulif is 500 mg once daily with food and continues until disease progression or patient intolerance.

The tablet is to be swallowed whole and should not be broken or cut. Dose escalation to 600 mg once daily, by increments of 100 mg once daily, can be considered for patients who do not reach complete hematological response (CHR) by week 8 or have a complete cytogenetic response by week 12, and do not have grade 3 or higher adverse reactions while taking the recommended starting dosage.

If liver transaminases exceed 5x the institutional upper limit of normal (ULN), withhold treatment until recovery of liver transaminases reach a level of no more than 2.5x ULN, and resume at 400mg once daily. If recovery takes longer than 4 weeks or transaminase elevations of at least 3x ULN occur with bilirubin elevations of least 2x ULN, or alkaline phosphates less than 3x ULN, discontinue treatment.

In the presence of grade 3 - 4 diarrhea, withhold Bosulif until recovery to Grade less than or equal to 1, and may resume Bosulif at 400 mg once daily.

For other clinically significant, moderate, or severe non-hematological toxicity, withhold treatment until the toxicity has resolved, then may resume at a dose reduced by 100 mg once daily. If clinically appropriate, consider re-escalating the dose to the starting dose taken once daily. Doses less than 300 mg/day have been used in patients; however, efficacy has not been established. Consider dose reduction by 100 mg in the presence of neutropenia or thrombocytopenia.

For creatinine clearance 30 to 50 ml/min, consider dose reduction to 300 mg daily for newly diagnosed Ph+ CML and 400 mg daily for chronic, accelerated, or blast phase Ph+ CML. For creatinine clearance less than 30 ml/min, consider dose reduction to 200 mg daily for 300mg daily for newly diagnosed Ph+ CML and 300 mg daily for chronic, accelerated, or blast phase Ph+ CML. For mild, moderate, or severe hepatic impairment, consider dose reduction to 200 mg daily.

DOSAGE STRENGTHS

- 100 mg tablets
- 400 mg tablets
- 500 mg tablets

REFERENCES

- Bosulif [Prescribing Information]. New York, NY: Pfizer; October 2019.

Created: 06/15
Effective: 07/01/20 Client Approval: 05/12/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

BOTULINUM NEUROTOXIN

Generic	Brand	HICL	GCN	Exception/Other
ONABOTULINUM TOXIN A	BOTOX	04867		BRAND ≠ BOTOX COSMETIC
ABOBOTULINUM TOXIN A	DYSPORT	36477		
RIMABOTULINUM TOXIN B	MYOBLOC	21869		
INCOBOTULINUM TOXIN A	XEOMIN	36687		

GUIDELINES FOR USE

**** Please use the criteria for the specific drug requested ****

BOTOX INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **BOTULINUM NEUROTOXIN (Botox)** requires the following rule(s) be met for approval:
You are using the requested medication for ONE of the following non-cosmetic (not for appearance) conditions:

1. Overactive bladder (OAB: problem with the bladder function that causes the sudden need to urinate)
2. Urinary incontinence (uncontrolled leakage of urine)
3. Neurogenic detrusor overactivity (NDO: nerve related bladder dysfunction)
4. Prevention of chronic migraine headaches (at least 15 days per month with headache lasting 4 hours a day or longer)
5. Spasticity (stiffness or tightness of your muscles)
6. Cervical dystonia (spasmodic torticollis or involuntary contracting of the neck muscles)
7. Severe axillary hyperhidrosis (excessive underarm sweating)
8. Blepharospasm (involuntary forcible closure of the eyelid); or treatment of strabismus (cross-eyed)

A. **If you have overactive bladder (OAB), approval also requires:**
   1. You are 18 years of age or older
   2. You previously tried **THREE** of the following anticholinergic medications unless there is a medical reason why you cannot (contraindication): Ditropan/Ditropan XL, Detrol/Detrol LA, Enablex, Gelnique, Myrbetriq, Oxytrol, Toviaz, VESIcare, or Sanctura

B. **If you have urinary incontinence, approval also requires:**
   1. You are 18 years of age or older
   2. You have detrusor (bladder muscle) overactivity associated with a neurologic (nervous system) condition such as: spinal cord injury (SCI) or multiple sclerosis (MS)
   3. You previously tried **THREE** of the following anticholinergic medications unless there is a medical reason why you cannot (contraindication): Ditropan/Ditropan XL, Detrol/Detrol LA, Enablex, Gelnique, Myrbetriq, Oxytrol, Toviaz, VESIcare, or Sanctura

C. **If you have neurogenic detrusor overactivity (NDO), approval also requires:**
   1. You are 5 years of age or older
   2. You previously tried **THREE** of the following anticholinergic medications unless there is a medical reason why you cannot (contraindication): Ditropan/Ditropan XL, Detrol/Detrol LA, Enablex, Gelnique, Myrbetriq, Oxytrol, Toviaz, VESIcare, or Sanctura

(Initial criteria for Botox continued on next page)

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BOTOX INITIAL CRITERIA (CONTINUED)

D. **If you have chronic migraine headaches, approval also requires:**
   1. You are 18 years of age or older
   2. You previously tried **THREE** of the following preventive migraine treatments:
      a. beta-blocker (e.g., propranolol, nadolol)
      b. candesartan
      c. cyproheptadine
      d. lisinopril
      e. tricyclic antidepressant (e.g., amitriptyline, nortriptyline, doxepin)
      f. topiramate
      g. valproic acid/divalproex sodium
      h. verapamil

E. **If you have cervical dystonia and severe axillary hyperhidrosis, approval also requires:**
   1. You are 18 years of age or older

F. **If you have spasticity, approval also requires:**
   1. You are 2 years of age or older

G. **If you have blepharospasm and strabismus, approval also requires:**
   1. You are 12 years of age or older

NOTE: This medication will not be approved for the improvement of appearance of glabellar lines in the face (for example, wrinkles).

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BOTULINUM NEUROTOXIN

BOTOX GUIDELINES FOR USE (CONTINUED)

BOTOX RENEWAL CRITERIA

Our guideline for the renewal of **BOTULINUM NEUROTOXIN (Botox)** requires you have one of the following non-cosmetic conditions:

A. You have overactive bladder (OAB: problem with the bladder function that causes the sudden need to urinate)
B. You have urinary incontinence (uncontrolled leakage of urine)
C. You have neurogenic detrusor overactivity (NDO: nerve related bladder dysfunction)
D. You have chronic migraine headaches
E. You have spasticity (stiffness or tightness of your muscles)
F. You have cervical dystonia (spasmodic torticollis or involuntary contracting of the neck muscles)
G. You have severe axillary hyperhidrosis (excessive underarm sweating)
H. You have blepharospasm (involuntary forcible closure of the eyelid)
I. You have strabismus (crossed-eye)

If you have overactive bladder (OAB), urinary incontinence, and neurogenic detrusor overactivity (NDO), approval also requires:

Documentation that you have experienced or maintained at least a 50% reduction in the number of daily urinary incontinent episodes

If you have chronic migraine headaches, approval also requires:

Documentation (i.e., chart notes) that **ONE** of the following criteria has been met:

- You have experienced a reduction in migraine or headache frequency of at least 2 days per month with Botox therapy
- You have experienced a reduction in migraine severity with Botox therapy
- You have experienced a reduction in migraine duration with Botox therapy

NOTE: This medication will not be approved for the improvement of appearance of glabellar lines in the face (for example, wrinkles).

DYSPORT INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **BOTULINUM NEUROTOXIN (Dysport)** requires you have ONE of the following non-cosmetic (not for appearance) diagnoses and meet the associated rule(s) for approval:

A. You have cervical dystonia also called spasmodic torticollis (involuntary contracting of the neck muscles) AND you are 18 years of age or older
B. You have spasticity (stiffness or tightness of your muscles) AND you are 2 years of age or older

NOTE: This medication will not be approved for the improvement of appearance of glabellar lines in the face (for example, wrinkles).

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BOTULINUM NEUROTOXIN

GUIDELINES FOR USE (CONTINUED)

DYSPORT RENEWAL CRITERIA

Our guideline for renewal of **BOTULINUM NEUROTOXIN (Dysport)** requires you have ONE of the following non-cosmetic (not for appearance) diagnoses and meet the associated rule(s) for approval:

A. You have cervical dystonia also called spasmodic torticollis (involuntary contracting of the neck muscles)
B. You have spasticity (stiffness or tightness of your muscles)

NOTE: This medication will not be approved for the improvement of appearance of glabellar lines in the face (for example, wrinkles).

MYOBLOC INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **BOTULINUM NEUROTOXIN (Myobloc)** requires the following rule(s) be met for approval:

A. You have ONE of the following non-cosmetic (not for appearance) conditions:
    1. Cervical dystonia (spasmodic torticollis or involuntary contracting of the neck muscles)
    2. Chronic sialorrhea (drooling or excessive salivation)
B. You are 18 years of age or older

NOTE: This medication will not be approved for the improvement of appearance of glabellar lines in the face (for example, wrinkles).

MYOBLOC RENEWAL CRITERIA

Our guideline for renewal of **BOTULINUM NEUROTOXIN (Myobloc)** requires the following rule(s) be met for approval:

A. You have ONE of the following non-cosmetic (not for appearance) conditions:
    1. Cervical dystonia (spasmodic torticollis or involuntary contracting of the neck muscles)
    2. Chronic sialorrhea (drooling or excessive salivation)

NOTE: This medication will not be approved for the improvement of appearance of glabellar lines in the face (for example, wrinkles).

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

BOTULINUM NEUROTOXIN

GUIDELINES FOR USE (CONTINUED)

XEOMIN INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **BOTULINUM NEUROTOXIN (Xeomin)** requires the following rules be met for approval:

A. You have ONE of the following non-cosmetic (not for appearance) conditions:
   1. Chronic sialorrhea (drooling or excessive salivation)
   2. Cervical dystonia (spasmodic torticollis or involuntary contracting of the neck muscles)
   3. Blepharospasm (involuntary forcible closure of the eyelid)
   4. Upper limb spasticity (stiffness or tightness of your muscles)

B. **If you have cervical dystonia or blepharospasm, approval also requires:**
   1. You are 18 years of age or older

C. **If you have chronic sialorrhea, approval also requires:**
   1. You are 2 years of age or older

D. **If you have upper limb spasticity, approval also requires ONE of the following:**
   1. You are 18 years of age or older
   2. You are 2 to 17 years of age and do not have spasticity caused by cerebral palsy (an illness that affects movement, muscle tone or posture)

NOTE: This medication will not be approved for the improvement of appearance of glabellar lines in the face (for example, wrinkles).

XEOMIN RENEWAL CRITERIA

Our guideline for renewal of **BOTULINUM NEUROTOXIN (Xeomin)** requires the following rules be met for approval:

A. You have ONE of the following non-cosmetic (not for appearance) conditions:
   1. Chronic sialorrhea (drooling or excessive salivation)
   2. Cervical dystonia (spasmodic torticollis or involuntary contracting of the neck muscles)
   3. Blepharospasm (involuntary forcible closure of the eyelid)
   4. Upper limb spasticity (stiffness or tightness of your muscles)

B. **If you have upper limb spasticity and you are 2 to 17 years of age, approval also requires:**
   1. You do not have spasticity caused by cerebral palsy

NOTE: This medication will not be approved for the improvement of appearance of glabellar lines in the face (for example, wrinkles).

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BOTULINUM NEUROTOXIN

RATIONALE
Ensure botulinum neurotoxin is used for non-cosmetic indications.

FDA APPROVED INDICATIONS
BOTOX is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for:
- Treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication
- Treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition [e.g., spinal cord injury (SCI), multiple sclerosis (MS)] in adults who have an inadequate response to or are intolerant of an anticholinergic medication
- Treatment of neurogenic detrusor overactivity (NDO) in pediatric patients 5 years of age and older who have an inadequate response to or are intolerant of anticholinergic medication
- Prophylaxis of headaches in adult patients with chronic migraine (⩾15 days per month with headache lasting 4 hours a day or longer)
- Treatment of spasticity in patients 2 years of age and older
- Treatment of cervical dystonia in adult patients, to reduce the severity of abnormal head position and neck pain
- Treatment of severe axillary hyperhidrosis that is inadequately managed by topical agents in adult patients
- Treatment of blepharospasm associated with dystonia in patients ⩾12 years of age
- Treatment of strabismus in patients ⩾12 years of age

Important limitations:
Safety and effectiveness of Botox have not been established for:
- Prophylaxis of episodic migraine (14 headache days or fewer per month)
- Treatment of hyperhidrosis in body areas other than axillary

DYSPORT is indicated for:
- Treatment of cervical dystonia in adults
- The temporary improvement in the appearance of moderate to severe glabellar lines associated with procerus and corrugator muscle activity in adult patients < 65 years of age
- Treatment of spasticity in patients 2 years of age and older

MYOBLOC is indicated for:
- Treatment of cervical dystonia to reduce the severity of abnormal head position and neck pain associated with cervical dystonia in adults
- Treatment of chronic sialorrhea in adults

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FDA APPROVED INDICATIONS (CONTINUED)

XEOMIN is indicated for the treatment of or improvement of:

- Chronic sialorrhea in adults
- Cervical dystonia in adults
- Blepharospasm in adults
- Upper limb spasticity in adults
- Upper limb spasticity in pediatric patients 2 to 17 years of age, excluding spasticity caused by cerebral palsy
- Temporary improvement in the appearance of moderate to severe glabellar lines with corrugator and/or procerus muscle activity in adults

REFERENCES

- Solstice Neurosciences, Inc. Myobloc package insert. South San Francisco, CA. March 2021.
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Created: 10/15
Effective: 08/11/21 Client Approval: 07/16/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

BRAND MEDICALLY NECESSARY

Generic	Brand	HICL	GCN	Exception/Other
VARIOUS	VARIOUS			

GUIDELINES FOR USE

Our guideline for **BRAND MEDICALLY NECESSARY MEDICATIONS** requires ALL of the following:

- The patient has tried the generic equivalent for the requested medication within the previous 6 months (as verified in prescription claims history or chart notes)
- One of the following:
  - The patient is unable to use the generic equivalent due to hypersensitivity reaction that is documented in the patient's medical record
  - All of the following:
    - The patient is unable to use the generic equivalent due to an adverse outcome (other than hypersensitivity) or due to therapeutic failure
    - The prescriber has submitted a MedWatch form (FDA Form 3500) to the FDA documenting the therapeutic failure or adverse outcome experienced by the patient
    - The prescriber has submitted a photocopy of the aforementioned MedWatch form (FDA Form 3500) with the prior authorization request for the brand medication under review
    - Medical necessity for the brand medication been demonstrated in the documentation received from the prescriber.

RATIONALE

The intent of this prior authorization is to require the use of cost-effective generically equivalent medications before coverage of brand medications.

Health professionals, consumers and patients can voluntarily report observed or suspected adverse events for human medical products to FDA. Such reporting can help FDA identify unknown risk for approved medical products. Reporting can be done through an online reporting portal or by downloading, completing and then submitting FDA Form 3500 (Health Professional) or 3500B (Consumer/Patient) to MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

Information to Report to MedWatch

- Unexpected side effects or adverse events
- Product quality problems
- Product use or medication errors
- Therapeutic failures

REFERENCES

- MedWatch: The FDA Safety Information and Adverse Event Reporting Program. Available at http://www.fda.gov/safety/medwatch/default.htm. Accessed March 1, 2021.

Created: 12/15
Effective: 03/08/21 Client Approval: 03/01/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

BRIGATINIB

Generic	Brand	HICL	GCN	Exception/Other
BRIGATINIB	ALUNBRIG	44226		

GUIDELINES FOR USE

Our guideline named **BRIGATINIB (Alunbrig)** requires the following rule(s) be met for approval:

A. You have metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
B. You are positive for anaplastic lymphoma kinase (ALK) fusion oncogene (a type of gene mutation that causes a change in your DNA)

RATIONALE

Promote appropriate utilization of **BRIGATINIB** based on FDA approved indication and dosage.

FDA APPROVED INDICATIONS

Alunbrig is indicated for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test.

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BRIGATINIB

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

The recommended dose of Alunbrig as treatment is 90 mg orally once daily for the first 7 days; if tolerated, increase to 180 mg orally once daily.

Administer Alunbrig until disease progression or unacceptable toxicity.

If Alunbrig is interrupted for 14 days or longer for reasons other than adverse reactions, resume treatment at 90 mg once daily for 7 days before increasing to the previously tolerated dose.

If a dose of Alunbrig is missed or vomiting occurs after taking a dose, do not administer an additional dose and take the next dose of Alunbrig at the scheduled time.

To manage adverse reactions, consider interruption of treatment or dose reduction. Recommended dose reductions are summarized in Table 1.

Table 1. Recommended Dose Adjustments

Dose	**Dose Reduction Levels**		
	First	Second	Third
90 mg once daily	60 mg once daily	Permanently discontinue	N/A
180 mg once daily	120 mg once daily	90 mg once daily	60 mg once daily

Once reduced for adverse reactions, do not subsequently increase the dose of Alunbrig. Permanently discontinue Alunbrig if patients are unable to tolerate the 60 mg once daily dose.

DOSAGE FORMS AND STRENGTHS

Tablets: 180 mg, 90 mg, and 30 mg

REFERENCES

- Alunbrig [Prescribing Information]. Cambridge, MA: Ariad Pharmaceuticals; May 2020.

Created: 05/17
Effective: 09/27/21 Client Approval: 09/03/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

BRODALUMAB

Generic	Brand	HICL	GCN	Exception/Other
BRODALUMAB	SILIQ	44102		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **BRODALUMAB (Siliq)** requires the following rule(s) be met for approval:

A. You have moderate to severe plaque psoriasis (PsO: scaly, itchy dry skin patches)
B. You are 18 years of age or older
C. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) **OR** psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
D. You have previously tried ONE of the following conventional therapies: PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
E. You have previously tried TWO of the following: Cosentyx, Enbrel, or Humira

RENEWAL CRITERIA

Our guideline named **BRODALUMAB (Siliq)** requires the following rule(s) be met for renewal:

A. You have moderate to severe plaque psoriasis (PsO: scaly, itchy dry skin patches)
B. You have experienced or maintained symptomatic improvement while on therapy

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RATIONALE

Ensure appropriate diagnostic, utilization and safety criteria are used for the management of requests for brodalumab.

FDA APPROVED INDICATIONS

Siliq is indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy and have failed to respond or have lost response to other systemic therapies.

DOSING

The recommended Siliq dose is 210 mg administered by subcutaneous injection at Weeks 0, 1, and 2, followed by 210 mg every 2 weeks.

If an adequate response has not been achieved after 12 to 16 weeks of treatment with Siliq, consider discontinuing therapy. Continued treatment beyond 16 weeks in patients who have not achieved an adequate response is not likely to result in greater success.

REFERENCES

- Siliq [Prescribing Information]. Bridgewater, NJ: Valeant Pharmaceuticals: April 2020.
- Menter A, Strober BE, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.

Created: 04/17
Effective: 04/11/22 Client Approval: 03/10/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

BUDESONIDE - TARPEYO

Generic	Brand	HICL	GCN	Exception/Other
BUDESONIDE	TARPEYO		51745	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **BUDESONIDE - TARPEYO** requires the following rule(s) be met for approval:

A. You have primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
B. You are 18 years of age or older
C. Your diagnosis is confirmed by a renal biopsy (removal of cells or tissue from the kidney for examination)
D. You are currently on an angiotensin converting enzyme inhibitor (ACE-I: a type of drug used to protect kidneys such as benazepril, lisinopril, etc.) or an angiotensin receptor blocker (ARB: a type of drug used to protect kidneys such as losartan, valsartan, etc.) at maximum tolerated dose for at least three months OR have a contraindication (harmful for) to both
E. You have a progressively declining glomerular filtration rate (GFR: a tool for evaluating kidney function) and/or worsening proteinuria (such as greater than 1 gram protein in a 24-hour urine collection or greater than or equal to 1g/g urine protein to creatinine ratio [UPCR: test that measures the amount of protein in urine])
F. You had a trial of one generic oral corticosteroid therapy (such as prednisone or prednisolone)

RENEWAL CRITERIA

Our guideline named **BUDESONIDE - TARPEYO** requires the following rule(s) be met for renewal:

A. You have primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
B. You have improved or stable kidney function compared to baseline OR a reduction in proteinuria

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RATIONALE
Ensure appropriate diagnostic, utilization and safety criteria are met for the management of requests for Tarpeyo.

FDA APPROVED INDICATIONS
Tarpeyo is a corticosteroid indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g.

DOSAGE AND ADMINISTRATION
The recommended dosage of Tarpeyo is 16 mg administered orally once daily, in the morning at least 1 hour before a meal.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

BUDESONIDE – TARPEYO

REFERENCES

Tarpeyo [Prescribing Information]. Stockholm, Sweden: Calliditas Therapeutics, Inc.; December 2021.

Created: 02/22
Effective: 03/21/22 Client Approval: 02/18/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

BUPRENORPHINE ANALGESICS

Generic	Brand	HICL	GCN	Exception/Other
BUPRENORPHINE	BELBUCA	01762	39959 39965 39966 39967 39968 39969 39975	ROUTE = BUCCAL
BUPRENORPHINE	BUTRANS	23438	25308 25309 25312 35214 36946	ROUTE = TRANSDERM

GUIDELINES FOR USE

Please use the RENEWAL GUIDELINE in the following scenarios only:

- For patients active with MDwise for 90 days or longer AND previous prior authorization approval for the same medication with the same strength AND recent paid pharmacy claims for the requested medication. Chart notes and/or cash pay for opioid use is not accepted.
- For patients new to MDwise within the past 90 days AND chart notes are provided that document the patient is stable on the requested medication.

All other requests must be reviewed with the INITIAL CRITERIA.

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

Our guideline for **BUPRENORPHINE ANALGESICS (BUTRANS AND BELBUCA)** for patients with past use of opioid dependency agents (i.e., buprenorphine/naloxone SL tablets/films or buprenorphine SL tablets) requires the buprenorphine/naloxone or buprenorphine prescribing physician be notified about prescribed opiate therapy and must approve the use before the opioid analgesic will be authorized.

Our guideline for **BUPRENORPHINE ANALGESICS (BUTRANS AND BELBUCA)** does not permit concurrent use with carisoprodol-containing products.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

BUPRENORPHINE ANALGESICS

Our guideline for **BUPRENORPHINE ANALGESICS (BUTRANS)** requires that you meet **BOTH** of the following criteria:

- **BUTRANS** is prescribed for one of the following indications:
  - Cancer
  - Sickle cell disease
  - Palliative care
  - Another terminal diagnosis associated with significant pain
- You have had a trial of at least 7 days generic MS Contin in the past 120 days (**NOTE:** This requirement does not apply for **BUTRANS** requests in patients who have difficulty swallowing.)

Please note that additional criteria apply for concurrent use of opioid analgesics and benzodiazepines, including submission of signed prescriber attestation on a state-mandated fax form.

Our guideline for **BUPRENORPHINE ANALGESICS (BELBUCA)** requires that you meet **ALL** of the following criteria:

- **BELBUCA** is prescribed for one of the following indications:
  - Cancer
  - Sickle cell disease
  - Palliative care
  - Another terminal diagnosis associated with significant pain
- You have had a trial of generic MS Contin (**NOTE:** This requirement does not apply for **BELBUCA** requests in patients who have difficulty swallowing.)
- **ONE** of the following:
  - You have had a trial of **BUTRANS** (buprenorphine transdermal system) for at least 7 days with inadequate pain relief
  - Documentation of a current daily MME dose greater than 80mg, and the prescriber's belief that the maximum dose of **BUTRANS** (20mcg/hr) will not provide adequate analgesia

Please note that additional criteria apply for concurrent use of opioid analgesics and benzodiazepines, including submission of signed prescriber attestation on a state-mandated fax form.

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BUPRENORPHINE ANALGESICS

INITIAL CRITERIA (CONTINUED)

Our guideline named **BUPRENORPHINE ANALGESICS**, reviewed for,BUTRANS 5MCG/HR, requires that the opioid is requested for the treatment of moderate to severe pain and that **ALL** of the following criteria are met:

- Your provider submitted documentation of trial and failure of one non-drug treatment for pain (for example, thermotherapy, cryotherapy, massage therapy, transcutaneous electrical nerve stimulation (TENS), spinal cord stimulation (SCS), physical therapy) for 6-weeks duration within the past 2 years unless contraindicated. Documentation must include dates of therapy
- You have tried and failed **TWO** non-opioid drug treatments prescribed for pain from different drug classes (for example, NSAIDs, acetaminophen, anticonvulsants, antidepressants) for at least 4 weeks (7 days for muscle relaxants) at maximum therapeutic doses within the past 365 days. Chart notes documenting doses and dates of therapy are required in the absence of electronic prescription claim history
- You have a documented Opioid Risk Tool score of 8 or higher

Please note that additional criteria apply for concurrent use of opioid analgesics and benzodiazepines, including submission of signed prescriber attestation on a state-mandated fax form.

Our guideline for **BUPRENORPHINE ANALGESICS (BUTRANS 7.5MCG/HR, 10MCG/HR, 15MCG/HR, OR 20MCG/HR)** requires that all patients meet **ALL** of the following criteria:

- You have a diagnosis of severe pain
- You meet the definition of opioid tolerance [defined as those who are taking, for one week or longer, at least 60 morphine milligram equivalents (MME)/day such as 60mg oral morphine/day, 40mg oral oxycodone/day, 15mg oral hydromorphone/day, 60mg oral hydrocodone/day, 400mg oral codeine/day, or an equianalgesic dose of another opioid].
    - Your plan requires that for patients active with MDwise for 90 days or longer, only previously paid claims for opioids may be considered for this criterion. If your prescriber indicates that you have been on opioid therapy, it must be verified in claims history. Chart notes and/or cash pay for opioid use is not accepted. For patients active with MDwise less than 90 days, chart notes are required to verify previous opioid use for this criterion
- You have had a trial of at least 30 days generic MS Contin in the past 120 days (**NOTE:** This requirement does not apply for **BUTRANS** requests in patients who have difficulty swallowing.)
- Your prescriber has consulted with you regarding the risks of opioid therapy and developed a pain management plan with clear treatment goals

Please note that additional criteria apply for concurrent use of opioid analgesics and benzodiazepines, including submission of signed prescriber attestation on a state-mandated fax form.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

BUPRENORPHINE ANALGESICS

INITIAL CRITERIA (CONTINUED)

Our guideline for **BUPRENORPHINE ANALGESICS (BELBUCA)** requires that all patients meet **ALL** of the following criteria:

- You have a diagnosis of severe pain
- Your prescriber has consulted with you regarding the risks of opioid therapy and developed a pain management plan with clear treatment goals
- You meet the definition of opioid tolerance [defined as those who are taking, for one week or longer, at least 60 morphine milligram equivalents (MME)/day such as 60mg oral morphine/day, 40mg oral oxycodone/day, 15mg oral hydromorphone/day, 60mg oral hydrocodone/day, 400mg oral codeine/day, or an equianalgesic dose of another opioid].
    - Your plan requires that for patients active with MDwise for 90 days or longer, only previously paid claims for opioids may be considered for this criterion. If your prescriber indicates that you have been on opioid therapy, it must be verified in claims history. Chart notes and/or cash pay for opioid use is not accepted. For patients active with MDwise less than 90 days, chart notes are required to verify previous opioid use for this criterion
- You have had a trial of at least 30 days of generic MS Contin in the past 120 days (NOTE: This requirement does not apply for BELBUCA requests in patients who have difficulty swallowing.)
- **ONE** of the following:
    - You have had a trial and failure of Butrans (buprenorphine transdermal system) for at least 14 days with inadequate pain relief
    - Documentation of a current daily MME dose greater than 80mg, and the prescriber's belief that the maximum dose of Butrans (20mcg/hr) will not provide adequate analgesia

Please note that additional criteria apply for concurrent use of opioid analgesics and benzodiazepines, including submission of signed prescriber attestation on a state-mandated fax form.

Our guideline named **BUPRENORPHINE ANALGESICS** for concurrent use of more than one long-acting opioid requires patients to meet **ALL** of the following criteria:

- You have a diagnosis of moderate to severe pain
- You experience refractory pain (pain that continues or returns) despite concurrent therapy with one short-acting opioid and one long-acting opioid
- Your prescriber has consulted with you regarding the risks of opioid therapy and developed a pain management plan with clear treatment goals

Exceptions to these criteria may be authorized in patients with cancer, sickle cell disease, another terminal diagnosis associated with significant pain, or those receiving opioids as part of a palliative care (medical care for symptoms related to illness) plan. Please note that additional criteria apply for concurrent use of opioid analgesics and benzodiazepines, including submission of signed prescriber attestation on a state-mandated fax form.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

BUPRENORPHINE ANALGESICS

INITIAL CRITERIA (CONTINUED)

Our guideline for **BUPRENORPHINE ANALGESICS (BUTRANS AND BELBUCA)** for patients with claims in history for benzodiazepines requires that the prescriber submit the required fax form documenting **ALL** of the following:

- The diagnosis contributing to the need for benzodiazepine therapy and previous therapy attempted, including dates and doses of prior therapies
  - For generalized anxiety disorder, one of the following is required: Selective serotonin reuptake inhibitor (SSRI, such as sertraline or citalopram), serotonin-noradrenaline reuptake inhibitor (SNRI, such as duloxetine or venlafaxine), or pregabalin (generic for Lyrica)
  - For panic disorder, one of the following is required: SSRI or tricyclic antidepressant (TCA, such as amitriptyline or nortriptyline)
  - For social anxiety disorder (SAD), a trial of an SSRI is required
  - For obsessive compulsive disorder (OCD), a trial of an SSRI is required
  - For post-traumatic stress disorder (PTSD), one of the following is required: mirtazapine, paroxetine, amitriptyline, or phenelzine
  - For insomnia, one of the following is required: ramelteon or a sedating antidepressant (for example, trazodone, amitriptyline, doxepin, mirtazapine)
- The diagnosis contributing to the need for opioid analgesic therapy and previous therapy attempted, including dates and doses of prior therapies (if applicable).
  - For long-acting opioid therapy requested for chronic moderate to severe pain, **ALL** of the following are required:
    - You meet the definition of opioid tolerance (defined as those who are taking, for one week or longer, at least 60 morphine milligram equivalents (MME)/day such as 60mg oral morphine/day, 40mg oral oxycodone/day, 15mg oral hydromorphone/day, 60mg oral hydrocodone/day, 400mg oral codeine/day, or an equianalgesic dose (a dose of one pain medication that is the same in pain-relieving effects to that of another pain medication) of another opioid). Your plan requires that for patients active with MDwise for 90 days or longer, only previously paid claims for opioids may be considered for this criterion. If your prescriber indicates that you have been on opioid therapy, it must be verified in claims history. Chart notes and/or cash pay for opioid use is not accepted. (**NOTE**: For a diagnosis of moderate to severe cancer-related pain, pain related to sickle cell disease, or pain in patients receiving palliative care, his criterion does not apply.)
    - Your prescriber has consulted with you regarding the risks of opioid therapy and developed a pain management plan with clear treatment goals
    - For any long-acting opioid other than MS Contin, you have had a trial of at least 30 days of generic MS Contin in the past 120 days
- Your prescriber has signed an attestation as to **ALL** of the following:
  - Your provider will regularly review your controlled substance utilization contained within INSPECT (Indiana controlled substance monitoring program)
  - You have been educated about the risks of using benzodiazepines and opioid analgesics together at the same time
  - Both you and your provider accept the risk of using benzodiazepines and opioid analgesics together at the same time

BUPRENORPHINE ANALGESICS

GUIDELINES FOR USE (CONTINUED)

INITIAL CRITERIA

Our guideline named **BUPRENORPHINE ANALGESICS** for patients with claims in history for Lybalvi (olanzapine/samidorphan) requires that you have not taken Lybalvi (olanzapine/samidorphan) less than or equal to 5 days prior to initiating opioid therapy.

RENEWAL CRITERIA

Our guideline for **BUPRENORPHINE ANALGESICS (BUTRANS AND BELBUCA)** does not permit concurrent use with carisoprodol-containing products.

Our guideline for renewal of **BUPRENORPHINE ANALGESICS (BUTRANS AND BELBUCA)** for patients with claims in history for benzodiazepines requires that the prescriber submit the required fax form documenting **ALL** of the following:

- The diagnosis contributing to the need for benzodiazepine therapy and previous therapy attempted, including dates and doses of prior therapies
  - For generalized anxiety disorder, one of the following is required: Selective serotonin reuptake inhibitor (SSRI, such as sertraline or citalopram), serotonin-noradrenaline reuptake inhibitor (SNRI, such as duloxetine or venlafaxine), or pregabalin (generic for Lyrica)
  - For panic disorder, one of the following is required: SSRI or tricyclic antidepressant (TCA, such as amitriptyline or nortriptyline)
  - For social anxiety disorder (SAD), a trial of an SSRI is required
  - For obsessive compulsive disorder (OCD), a trial of an SSRI is required
  - For post-traumatic stress disorder (PTSD), one of the following is required: mirtazapine, paroxetine, amitriptyline, or phenelzine
  - For insomnia, one of the following is required: ramelteon or a sedating antidepressant (for example, trazodone, amitriptyline, doxepin, mirtazapine)
- The diagnosis contributing to the need for renewal of the requested opioid analgesic therapy
- Your prescriber has signed an attestation as to ALL of the following:
  - Your provider will regularly review your controlled substance utilization contained within INSPECT (Indiana controlled substance monitoring program)
  - You have been educated about the risks of using benzodiazepines and opioid analgesics together at the same time
  - Both you and your provider accept the risk of using benzodiazepines and opioid analgesics together at the same time

Please note that additional criteria apply for the benzodiazepine day supply limits. Your benzodiazepine prescription claim must not be greater than a 15-day supply of medication. You cannot receive more than 30 days' supply of benzodiazepine medication in the past 90 days. The current request for medication is also counted as a part of the 30 days' supply in the past 90 days.

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BUPRENORPHINE ANALGESICS

RENEWAL CRITERIA (CONTINUED)

Our guideline for renewal of **BUPRENORPHINE ANALGESICS (BUTRANS AND BELBUCA)** for patients with claims in history for benzodiazepines requires that the prescriber submit the required fax form documenting **ALL** of the following:

- The diagnosis contributing to the need for benzodiazepine therapy and previous therapy attempted, including dates and doses of prior therapies
  - For generalized anxiety disorder, one of the following is required: Selective serotonin reuptake inhibitor (SSRI, such as sertraline or citalopram), serotonin-noradrenaline reuptake inhibitor (SNRI, such as duloxetine or venlafaxine), or pregabalin (generic for Lyrica)
  - For panic disorder, one of the following is required: SSRI or tricyclic antidepressant (TCA, such as amitriptyline or nortriptyline)
  - For social anxiety disorder (SAD), a trial of an SSRI is required
  - For obsessive compulsive disorder (OCD), a trial of an SSRI is required
  - For post-traumatic stress disorder (PTSD), one of the following is required: mirtazapine, paroxetine, amitriptyline, or phenelzine
  - For insomnia, one of the following is required: ramelteon or a sedating antidepressant (for example, trazodone, amitriptyline, doxepin, mirtazapine)
- The diagnosis contributing to the need for renewal of the requested opioid analgesic therapy
- Your prescriber has signed an attestation as to ALL of the following:
  - Your provider will regularly review your controlled substance utilization contained within INSPECT (Indiana controlled substance monitoring program)
  - You have been educated about the risks of using benzodiazepines and opioid analgesics together at the same time
  - Both you and your provider accept the risk of using benzodiazepines and opioid analgesics together at the same time

Our guideline named **BUPRENORPHINE ANALGESICS** for patients with claims in history for Lybalvi (olanzapine/samidorphan) requires that you have not taken Lybalvi (olanzapine/samidorphan) less than or equal to 5 days prior to initiating opioid therapy.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

BUPRENORPHINE ANALGESICS

RATIONALE

To ensure opioid analgesics are used according to FDA approved indications with patient safety in mind, and to encourage the use of more cost-effective analgesics.

From 2000-2014, almost half a million people died due to drug overdose, with 2014 being the highest year for deaths on record. In that time, the number of opioids prescribed, as well as the number of opioid overdoses, has risen exponentially. At least half of all opioid overdose deaths involve a prescription opioid. Indiana was among the states that had a statistically significant increase of overdose deaths from 2013-2014.

According to recent research, the opioid epidemic has a disproportionate impact on Medicaid beneficiaries. Medicaid patients are prescribed opioids at double the rate of non-Medicaid patients, and are subsequently at much higher risk of prescription opioid overdose.
Improving the way that opioids are prescribed can ensure safer and more effective pain treatment, and reduce the addiction, misuse, abuse, and overdose of these drugs. These guidelines are to ensure that the use of opioids is consistent with their FDA approved indications, and to initiate action combating the current opioid epidemic.

When buprenorphine is used for analgesia, individualized dosing should be used for each patient. The patient's opioid tolerance, physical and mental status, and degree of analgesia desired should be considered when initiating patients on buprenorphine treatment. Higher than usual doses may be required when buprenorphine is used in a patient tolerant to opioids. Careful titration of buprenorphine in opioid-naïve patients is required until tolerance develops to some of the side effects. Monitor patients frequently for respiratory depression, particularly during the first 24 to 72 hours after initiation and dose escalation. Patients who experience breakthrough pain may require a dosage increase or a rescue medication.

Transdermal buprenorphine should be reserved for patients in whom alternative treatment options (non-opioids or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide enough management of pain. Butrans potencies of 7.5 mcg/hr and higher should only be used for opioid experienced patients. There is a potential for buprenorphine to precipitate withdrawal in patients who are already on opioids.

Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 morphine milligram equivalents (MME)/day such as 60mg oral morphine/day, 25mcg transdermal fentanyl/hour, 40mg oral oxycodone/day, 15mg oral hydromorphone/day, 60mg oral hydrocodone/day, 400mg oral codeine/day, or an equianalgesic dose of another opioid for a week or longer.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

BUPRENORPHINE ANALGESICS

RATIONALE (CONTINUED)

Buprenorphine Conversion Table

Buprenorphine Product	Oral MME Conversion Factor
Belbuca buccal film (mcg/hr)	0.03
buprenorphine, tablet or film for opioid use disorder	30
Butrans transdermal patch (mcg/hr)	12.6

Example: 900 mcg buprenorphine buccal film x (60 films/30 days) x 0.03=54 MME/day
Example: 5 mcg buprenorphine patch x (4 patches/28 days) x 12.6= 9 MME/day

Fentanyl Conversion Table

Fentanyl Product	Oral MME Conversion Factor
fentanyl buccal or SL tablets, or lozenge/troche (mcg)	0.13
fentanyl film or oral spray (mcg)	0.18
fentanyl nasal spray (mcg)	0.16
fentanyl patch (mcg)	7.2

Opioid Conversion Table

Drug	Oral MME Conversion Factor (1mg of drug to mg morphine)	60mg Morphine Equivalent Dose
benzhydrocodone	1.22	50mg
butorphanol	7	8.5mg
codeine	0.15	400mg
dihydrocodeine	0.25	240mg
hydrocodone	1	60mg
hydromorphone HCl	4	15mg
levorphanol tartrate	11	5.5mg
meperidine HCl	0.1	600mg
morphine	1	60mg
oxycodone HCl	1.5	40mg
oxymorphone HCl	3	20mg
pentazocine HCl	0.37	162mg
tapentadol HCl	0.4	150mg
tramadol HCl	0.1	600mg

Methadone Conversion Table

Methadone daily dose (mg/day)	MME Conversion Factor (1mg of drug to mg morphine)	60mg Morphine Equivalent Dose
>0, <= 20	4	20mg
>20, <=40	8	7.5mg
>40, <=60	10	6mg
>60	12	5mg

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RATIONALE (CONTINUED)

Opioid Usage in Chronic Pain Management

Per systematic review in the CDC Guideline for Prescribing Opioids for Chronic Pain, long-term (≥ 1 year) efficacy of opioids in management of chronic pain, function, or quality of life is not established. Most randomized controlled trials present effectiveness within 6 weeks or less. Conversely, significant risks of adverse events are present with chronic opioid therapy, including opioid abuse and dependence, social role withdrawal, and increased risk of CNS depression, and withdrawal emergencies.

The CDC also recommends re-evaluating and re-establishing treatment goals, including realistic expectation for pain and function, as well as discontinuation strategies when benefits do not outweigh risks. The guideline provides the following recommendations for opioid selection, dosage, duration, follow-up and discontinuation:

- Immediate-release (IR) opioids are preferred over extended-release (ER) forms.
- The lowest effective dosage is preferred with initial opioid use. Caution is warranted at any dose and reassessing benefits and risks is recommended for 50 morphine milligram equivalents (MME) daily or more. 90 MME daily or more should be avoided if possible.
- Within 1 to 4 weeks of therapy, clinicians should evaluate benefits and harms of using opioids to treat chronic pain. Therapy continuation should be evaluated every 3 months or sooner. If benefits do not outweigh harms to continue opioid therapy, other therapies should be optimized and opioid tapering/discontinuation should be considered and encouraged.

Assessing Risk and Addressing Harms of Opioid Use

- Prior to and throughout opioid therapy, adverse events should be evaluated periodically. Factors that increase risk for opioid overdose include history of overdose or substance use disorder, 50 MME daily or more, and concurrent benzodiazepine use.
- Prescription drug monitoring program (PDMP) data (e.g., RXINSPECT) are useful to monitor total opioid dosage. PDMP data is helpful for initial and periodic opioid usage evaluations.
- Prescribing opioids and benzodiazepines concurrently should be avoided.
- For patients with substance use disorder, evidence-based treatment (medication-assisted and behavioral therapy) is recommended.

Analysis performed by the US Department of Health and Human Services Center for Disease Control and Prevention (CDC) determined the risk of harm to individuals increases as their opioid dose increases and as their length of opioid therapy increases. For example:

- Individuals taking opioid doses > 50 morphine milligram equivalents (MMEs) per day had twice the risk of death from an overdose than those taking < 20 MMEs per day.
- Individuals taking opioid doses > 90 (MMEs) per day had 10 times the risk of death from an overdose than those taking < 20 MMEs per day.
- Individuals taking an opioid for > 3 months (even at low doses) had 15 times the risk of addiction to those taking opioids for < 3 months.

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RATIONALE (CONTINUED)
The Opioid Risk Tool (ORT) is a brief, self-report screening tool designed for use with adult patients in primary care settings to assess risk for opioid abuse among individuals prescribed opioids for treatment of chronic pain. Patients categorized as high-risk are at increased likelihood of future abusive drug-related behavior.

Opioid Risk Tool

This tool should be administered to patients upon an initial visit prior to beginning opioid therapy for pain management. A score of 3 or lower indicates low risk for future opioid abuse, a score of 4 to 7 indicates moderate risk for opioid abuse, and a score of 8 or higher indicates a high risk for opioid abuse.

Mark each box that applies:

	Female	Male
Family history of substance abuse		
Alcohol	1	3
Illegal drugs	2	3
Rx drugs	4	4
Personal history of substance abuse		
Alcohol	3	3
Illegal drugs	4	4
Rx drugs	5	5
Age between 16—45 years	1	1
History of preadolescent sexual abuse	3	0
Psychological disease		
ADD, OCD, bipolar, schizophrenia	2	2
Depression	1	1
Scoring totals		

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BUPRENORPHINE ANALGESICS

APPENDIX 1: BENZODIAZEPINE/OPIOID CONCURRENT USE FAX FORM
INDIANA HEALTH COVERAGE PROGRAMS (IHCP) PHARMACY BENEFIT
BENZODIAZEPINE AND OPIOID CONCURRENT THERAPY
PRIOR AUTHORIZATION REQUEST FORM

MDwise
Fax to: (858) 790-7100
c/o MedImpact Healthcare Systems, Inc.
Attn: Prior Authorization Department
10181 Scripps Gateway Court, San Diego, CA 92131
Phone: 1-800-788-2949

Today's Date
☐☐ / ☐☐ / ☐☐☐☐

Note: This form must be completed by the prescribing provider.
****All sections must be completed or the request will be denied.****

Patient's Medicaid # ☐☐☐☐☐☐☐☐☐☐☐☐	**Date of Birth** ☐☐ / ☐☐ / ☐☐☐☐
Patient's Name	**Prescriber's Name**
Prescriber's IN License # ☐☐☐☐☐☐☐☐	**Specialty**
Prescriber's NPI # ☐☐☐☐☐☐☐☐☐☐	**Prescriber's Signature: **Required below within attestation section.****
Return Fax # ☐☐☐ - ☐☐☐ - ☐☐☐☐	**Return Phone #** ☐☐☐ - ☐☐☐ - ☐☐☐☐

PA is required for the following:

- **Claim(s) for new opioid(s) to be used concurrently with benzodiazepines and exceeding 7 days within a 180-day period.**
- **Claim(s) for new benzodiazepine(s) to be used concurrently with opioids and exceeding 7 days of therapy within a 180-day period and/or exceeding established benzodiazepine/opioid concurrent therapy quantity limits (see Sedative Hypnotics/Benzodiazepine PA criteria).**

Benzodiazepine Agent(s)	Prescriber Name*	Quantity	Dosage Regimen/Duration

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PRIOR AUTHORIZATION GUIDELINES

Opioid Agent(s)	Prescriber Name*	Quantity	Dosage Regimen/Duration

***NOTE: If prescribers of the opioid(s) and benzodiazepine(s) are not the same, please answer the following questions:**

- **Are you requesting PA for: Benzodiazepine Agent(s) ☐ Opioid Agent(s) ☐ Both ☐**
- **Is/are the other prescriber(s) aware of the request for concurrent therapy? □ Yes □ No**
- **Has/have the other prescriber(s) been consulted about the risks associated with concurrent therapy, and do all prescribers involved believe continuing with concurrent therapy is warranted, given the risks associated with concurrent use? □ Yes □ No**

PA Requirements:

Patient diagnosis/diagnoses for use of benzodiazepine therapy:

Prior therapies attempted for the above diagnosis/diagnoses (submission of chart notes required in absence of claims history):

Drug Therapy	Dosage Regimen	Dates of Utilization

Do you plan to continue benzodiazepine therapy for this patient? □ Yes □ No
If no, please provide withdrawal plan:

Patient diagnosis/diagnoses for use of opioid therapy:

Prior therapies (both drug and non-drug) attempted for the above diagnosis/diagnoses (submission of chart notes required in absence of claims history):

Drug/Non-Drug Therapy	Dosage Regimen	Dates of Utilization	Reason for Discontinuation or Failure

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Do you plan to continue opioid therapy for this patient? □ Yes □ No
If no, please provide withdrawal plan:

Attestation:

I, _____, hereby attest to the following:
(Prescriber Name)

The patient's INSPECT report has been evaluated and continues to be evaluated on a regular basis (Per IC 35-48-7-11.1, DO NOT attach a copy of the INSPECT report to this PA request).

I have educated the patient in regards to the risks of concurrent utilization of benzodiazepine and opioid therapy, and the patient accepts these risks.

If applicable, I have consulted other prescriber(s) involved in concurrent therapy and all prescribers involved agree to pursue concurrent opioid and benzodiazepine therapy for this patient.

I acknowledge, as the prescriber initiating or maintaining concurrent benzodiazepine and opioid therapy, the risk of adverse event(s), including respiratory depression, coma, and death, associated with concurrent utilization.

Prescriber Signature:_____

****Prescriber signature is required for consideration. Electronic or stamped signature will not be accepted.****

CONFIDENTIAL INFORMATION

This facsimile transmission (and attachments) may contain protected health information from the Indiana Health Coverage Programs (IHCP), which is intended only for the use of the individual or entity named in this transmission sheet. Any unintended recipient is hereby notified that the information is privileged and confidential, and any use, disclosure, or reproduction of this information is prohibited.

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

BUPRENORPHINE ANALGESICS

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Created: 09/19
Effective: 06/13/22 Client Approval: 05/26/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

BUPRENORPHINE IMPLANT/INJECTION

Generic	Brand	HICL	GCN	Exception/Other
BUPRENORPHINE IMPLANT	PROBUPHINE		41432	
BUPRENORPHINE INJECTION	SUBLOCADE		44186 44187	

GUIDELINES FOR USE

PROBUPHINE:

Our guideline for **BUPRENORPHINE IMPLANT (PROBUPHINE)** requires patients to be 16 years of age or older; the physician meets all qualifications (Federal, State, Local) to prescribe buprenorphine or buprenorphine/naloxone; a diagnosis of opioid dependence; the patient has not been previously treated with Probuphine; the patient has achieved and sustained prolonged clinical stability on transmucosal buprenorphine; the patient is currently on a maintenance dose of 8 mg per day or less of a buprenorphine-containing sublingual tablet or its transmucosal buprenorphine product equivalent; the patient has been on the maintenance dose (8 mg per day or less of a buprenorphine-containing sublingual tablet or its transmucosal buprenorphine product equivalent) for three months or longer without any need for supplemental dosing or adjustments; and medical justification (e.g., diversion, non-compliance, misuse) supports inability to continue to use oral (e.g., sublingual, buccal) formulations of buprenorphine.

SUBLOCADE:

Our guideline for **BUPRENORPHINE INJECTION (SUBLOCADE)** requires patients to be 18 years of age or older; the physician meets all qualifications (Federal, State, Local) to prescribe buprenorphine or buprenorphine/naloxone; a diagnosis of opioid dependence; the patient is currently on a maintenance dose of 8 to 24 mg per day of a buprenorphine-containing sublingual tablet or its transmucosal buprenorphine product equivalent for 7 days or longer; medical justification (e.g., diversion, non-compliance, misuse) supports inability to continue to use oral (e.g., sublingual, buccal) formulations of buprenorphine; and dose does not exceed 300 mg buprenorphine per month.

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BUPRENORPHINE IMPLANT/INJECTION

RATIONALE

FDA APPROVED INDICATIONS

- Probuphine is a partial opioid agonist indicated for the maintenance treatment of opioid dependence in patients who have achieved and sustained prolonged clinical stability on low-to-moderate doses of a transmucosal buprenorphine-containing product (i.e., doses of no more than 8 mg per day of buprenorphine-containing sublingual tablet or generic equivalent).
- Sublocade is a partial opioid agonist indicated for the treatment of moderate to severe opioid use disorder in patients who have prescribed treatment with a transmucosal buprenorphine-containing product, followed by dose adjustment for a minimum of 7 days.

Probuphine and Sublocade should be used as part of a complete treatment program to include counseling and psychosocial support.

Probuphine and Sublocade are not appropriate for new entrants to treatment and patients who have not achieved and sustained prolonged clinical stability, while being maintained on buprenorphine 8 mg per day or less of a Subutex or Suboxone sublingual tablet or generic equivalent.

Use of these products is limited under the Drug Addiction Treatment Act.

DOSAGE AND ADMINISTRATION

- Probuphine implant
  - Four Probuphine implants are inserted subdermally in the upper arm for 6 months of treatment and are removed by the end of the sixth month.
  - Probuphine implants should not be used for additional treatment cycles after one insertion in each upper arm.
  - Probuphine implants must be inserted and removed by trained Healthcare Providers only.
  - Probuphine implants should be administered in patients who have achieved and sustained prolonged clinical stability on transmucosal buprenorphine.
- Sublocade injection
  - The recommended dose of Sublocade following induction and dose adjustment with transmucosal buprenorphine is 300 mg monthly for the first two months followed by a maintenance dose of 100 mg monthly.
  - The maintenance dose may be increased to 300 mg monthly for patients who tolerate the 100 mg dose, but do not demonstrate a satisfactory clinical response, as evidenced by self‐reported illicit opioid use or urine drug screens positive for illicit opioid use.
  - Only health care providers should prepare and administer Sublocade.
  - Sublocade is for abdominal subcutaneous injection only.
  - Administer Sublocade monthly with a minimum of 26 days between doses.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

BUPRENORPHINE IMPLANT/INJECTION

FDA APPROVED INDICATIONS (CONTINUED)

Table 1: Brand/Generic Transmucosal Formulations Equivalent to Subutex or Suboxone SL Tablets Containing less than or equal to 8 mg of Buprenorphine

Drug	Transmucosal Formulation	Brand/ Generic	Brand/ Generic Strength	Subutex/Suboxone SLTablet Strength
			Buprenorphine/Naloxone Equivalency	
buprenorphine HCl	Tablet, SL	generic	2 mg 8 mg	2 mg (Subutex) 8 mg (Subutex)
buprenorphine HCl/ naloxone HCl	Tablet, SL	generic	2 mg/0.5 mg 8 mg/2 mg	2 mg/0.5 mg (Suboxone) 8 mg/2 mg (Suboxone)
		Zubsolv	1.4 mg/0.36 mg 2.9 mg/0.71 mg 5.7 mg/1.4 mg	2 mg/0.5mg (Suboxone) 4 mg/1 mg (Suboxone) 8 mg/2 mg (Suboxone)
	Film, buccal	Bunavail	2.1 mg/0.3 mg 4.2 mg/0.7 mg	4 mg/1 mg (Suboxone) 8 mg/2 mg (Suboxone)
	Film, SL or buccal	Suboxone	2 mg/0.5 mg 4 mg/1 mg 8 mg/2 mg	2 mg/0.5 mg (Suboxone) 4 mg/1 mg (Suboxone) 8 mg/2 mg (Suboxone)

Table 2: Therapeutic Alternatives
This table provides a listing of alternative therapies for opioid dependence. Generic sublingual tablets are preferred.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
buprenorphine/naloxone (Suboxone) sublingual (SL) or buccal dissolving film, SL tablet	Maintenance: Target dose buprenorphine 16 mg/naloxone 4 mg once daily; dosage should be adjusted in increments or decrements of 2 mg/ 0.5 mg or 4 mg/1 mg to a level that maintains treatment and suppresses opioid withdrawal symptoms; usual range: 4 mg/1 mg to 24 mg/6 mg per day	24 mg/6 mg per day
Bunavail® (buprenorphine/naloxone) buccal film	Maintenance: Target dose buprenorphine 8.4 mg/naloxone 1.4 mg once daily; dosage should be adjusted in increments or decrements of 2.1 mg/ 0.3 mg to a level that maintains treatment and suppresses opioid withdrawal symptoms; usual range: 2.1 mg/0.3 mg to 12.6 mg/2.1 mg per day	12.6 mg/2.1 mg per day
Zubsolv® (buprenorphine/naloxone) SL tablet	Maintenance: Target dose buprenorphine 11.4 mg/naloxone 2.9 mg once daily; dosage should be adjusted in increments or decrements of 2.9 mg/ 0.71 mg to a level that maintains treatment and suppresses opioid withdrawal symptoms; usual range: 2.9 mg/0.71 mg to 17.2 mg/4.2 mg per day	17.1 mg/4.2 mg per day

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BUPRENORPHINE IMPLANT/INJECTION

REFERENCES

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- Sublocade [prescribing information]. Chesterfield, VA: Indivior, Inc. June 2021.

Created: 05/18
Effective: 03/28/22 Client Approval: 03/07/22 P&T Approval: N/A

Generic	Brand	HICL	GCN	Exception/Other
BUPRENORPHINE-NALOXONE	SUBOXONE FILM	24846	28958 28959 33741 33744	
	ZUBSOLV SUBL TAB	24846	34904 34905 37823 37824 39394 42843	
	BUNAVAIL FILM	24846	36677 36678 36679	

GUIDELINES FOR USE

Our guideline for **BUPRENORPHINE-NALOXONE** requires that ONE of the following are met for approval:

A. The patient has had a hypersensitivity reaction to an inactive ingredient in generic buprenorphine/naloxone tablets AND the hypersensitivity reaction is clearly documented in the patient's medical record.

B. **ALL** of the following:
- i. The patient has failed an adequate trial of generic buprenorphine/naloxone tablets (an adequate trial is defined as at least 28 days of treatment) in the previous 120 days (verified in prescription claims history or in submitted chart notes)
- ii. The patient is unable to use generic buprenorphine/naloxone tablets due to therapeutic failure or adverse outcome. (NOTE: Suboxone film, Zubsolv sublingual tablets, or Bunavail film will not be approved for patients who report lesser efficacy with the generic buprenorphine/naloxone tablets unless it would be clinically inappropriate to address efficacy with dose adjustment.)
- iii. The provider has submitted a copy of the MedWatch form submitted to the FDA which documents the therapeutic failure or adverse outcome associated with the use of the generic buprenorphine/naloxone tablets.

C. **ALL** of the following:
- i. The patient is new to MDwise within the previous 90 days
- ii. The patient has been taking buprenorphine/naloxone films prior to obtaining MDwise coverage (NOTE: Chart notes documenting history of use are required for new patients in lieu of claims history.)
- iii. The patient is currently pregnant

Please note that generic buprenorphine/naloxone SL tablets do not require prior authorization.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

BUPRENORPHINE-NALOXONE

RATIONALE

The intent of this prior authorization criteria is to encourage the use of cost-effective preferred generic medications before considering coverage of brand medications.

NOTES

- GI upset or irritation is not generally considered an allergy or failed treatment. Patients should be referred to their physician or pharmacist for advice on dose adjustment, and/or other options to reduce GI upset/irritation.
- Common documented side effects attributed to buprenorphine/naloxone (e.g., headache, nausea, blurred vision, fatigue, muscle aches) are not considered an allergy and would be expected to occur at the same level in both generic and brand agents.
- Drug hypersensitivity symptoms may include skin rash, hives, itching, fever, swelling, shortness of breath, wheezing, runny nose, itchy and/or watery eyes, and in severe cases, anaphylaxis.

REFERENCE

- MedWatch: The FDA Safety Information and Adverse Event Reporting Program. Available at http://www.fda.gov/safety/medwatch/default.htm. Accessed November 13, 2017.

Created: 11/17
Effective: 08/03/20 Client Approval: 07/22/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

BUTALBITAL/CODEINE-CONTAINING AGENTS FOR HEADACHE

Generic	Brand	HICL	GCN	Exception/Other
CODEINE/BUTALBIT/ ACETAMIN/CAFF	FIORICET WITH CODEINE, BUTALB-CAFF-ACETAMINOPH-CODEINE	01713	34988 70140	
CODEINE/BUTALBITAL /ASA/CAFFEIN	FIORINAL WITH CODEINE	01699	69500	

GUIDELINES FOR USE

Please use the RENEWAL CRITERIA in the following scenarios only:

- For patients active with MDwise for 90 days or longer AND previous prior authorization approval for the same medication with the same strength AND recent paid pharmacy claims for the requested medication. Chart notes and/or cash pay for opioid use is not accepted.
- For patients new to MDwise within the past 90 days AND chart notes are provided that document the patient is stable on the requested medication.

All other requests must be reviewed with the INITIAL CRITERIA.

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

Our guideline for **BUTALBITAL/CODEINE-CONTAINING AGENTS FOR HEADACHE** for patients with past use of opioid dependency agents (such as, buprenorphine/naloxone SL tablets/films or buprenorphine SL tablets) requires the buprenorphine/naloxone or buprenorphine prescribing physician be notified about prescribed opiate therapy and must approve the use before the opioid analgesic will be authorized.

Our guideline for **BUTALBITAL/CODEINE-CONTAINING AGENTS FOR HEADACHE** does not permit concurrent use with carisoprodol-containing products.

Our guideline for **BUTALBITAL/CODEINE-CONTAINING AGENTS FOR HEADACHE** requires a diagnosis of tension-type headaches (TTH). In addition, documentation of trial and failure of **ALL** of the following for TTH is required unless contraindicated:

- Acetaminophen
- Aspirin
- Non-steroidal anti-inflammatory agent (NSAID) (for example, ibuprofen, naproxen)
- Combination therapy of caffeine plus any one of the three aforementioned agents (for example, caffeine/acetaminophen, caffeine/aspirin, caffeine/NSAID)

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

BUTALBITAL/CODEINE-CONTAINING AGENTS FOR HEADACHE

GUIDELINES FOR USE

INITIAL CRITERIA (CONTINUED)

Our guideline for **BUTALBITAL/CODEINE-CONTAINING AGENTS FOR HEADACHE** for patients with claims in history for benzodiazepines requires that the prescriber submit the required fax form documenting **ALL** of the following:

- The diagnosis contributing to the need for benzodiazepine therapy and previous therapy attempted, including dates and doses of prior therapies
  - For generalized anxiety disorder, one of the following is required: Selective serotonin reuptake inhibitor (SSRI, such as sertraline or citalopram), serotonin-noradrenaline reuptake inhibitor (SNRI, such as duloxetine or venlafaxine), or pregabalin (generic for Lyrica)
  - For panic disorder, one of the following is required: SSRI or tricyclic antidepressant (TCA, such as amitriptyline or nortriptyline)
  - For social anxiety disorder (SAD), a trial of an SSRI is required
  - For obsessive compulsive disorder (OCD), a trial of an SSRI is required
  - For post-traumatic stress disorder (PTSD), one of the following is required: mirtazapine, paroxetine, amitriptyline, or phenelzine
  - For insomnia, one of the following is required: ramelteon or a sedating antidepressant (for example, trazodone, amitriptyline, doxepin, mirtazapine)
- A diagnosis of tension-type headache (TTH) and documentation of trial and failure of **ALL** of the following for TTH is required unless contraindicated:
  - Acetaminophen
  - Aspirin
  - Non-steroidal anti-inflammatory agent (NSAID) (for example, ibuprofen, naproxen)
  - Combination therapy of caffeine plus any one of the three aforementioned agents (for example, caffeine/acetaminophen, caffeine/aspirin, caffeine/NSAID)
- Your prescriber has signed an attestation as to **ALL** of the following:
  - Your provider will regularly review your controlled substance utilization contained within INSPECT (Indiana controlled substance monitoring program)
  - You have been educated about the risks of using benzodiazepines and opioid analgesics together at the same time
  - Both you and your provider accept the risk of using benzodiazepines and opioid analgesics together at the same time

Please note that additional criteria apply for the benzodiazepine day supply limits. Your benzodiazepine prescription claim must not be greater than a 15-day supply of medication. You cannot receive more than 30 days' supply of benzodiazepine medication in the past 90 days. The current request for medication is also counted as a part of the 30 days' supply in the past 90 days.

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BUTALBITAL/CODEINE-CONTAINING AGENTS FOR HEADACHE

GUIDELINES FOR USE

INITIAL CRITERIA (CONTINUED)

Our guideline named **BUTALBITAL/CODEINE-CONTAINING AGENTS FOR HEADACHE** for concurrent use of more than one short-acting opioid requires that you meet **ALL** of the following criteria:

- You have a diagnosis of moderate to severe pain
- You have a pain that is not responding to treatment despite concurrent (used at the same time) therapy with one short-acting opioid and one long-acting opioid
- Your prescriber has consulted with you regarding the risks of opioid therapy and developed a pain management plan with clear treatment goals

Exceptions to these criteria may be authorized in patients with cancer, sickle cell disease, another terminal diagnosis associated with significant pain, or those receiving opioids as part of a palliative care (medical care for symptoms related to illness) plan.

Please note that additional criteria apply for concurrent use of opioid analgesics and benzodiazepines, including submission of signed prescriber attestation on a state-mandated fax

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

BUTALBITAL/CODEINE-CONTAINING AGENTS FOR HEADACHE

GUIDELINES FOR USE

INITIAL CRITERIA (CONTINUED)

Our guideline for **BUTALBITAL/CODEINE-CONTAINING AGENTS FOR HEADACHE** for patients with claims in history for benzodiazepines requires that your doctor submit the required fax form documenting **ALL** of the following:

- The diagnosis contributing to the need for benzodiazepine therapy and previous therapy attempted, including dates and doses of prior therapies, documented in chart notes
  - For generalized anxiety disorder, one of the following is required: Selective serotonin reuptake inhibitor (SSRI, such as sertraline or citalopram), serotonin-noradrenaline reuptake inhibitor (SNRI, such as duloxetine or venlafaxine), or pregabalin (generic for Lyrica)
  - For panic disorder, one of the following is required: SSRI or tricyclic antidepressant (TCA, such as amitriptyline or nortriptyline)
  - For social anxiety disorder (SAD), a trial of an SSRI is required
  - For obsessive compulsive disorder (OCD), a trial of an SSRI is required
  - For post-traumatic stress disorder (PTSD), one of the following is required: mirtazapine, paroxetine, amitriptyline, or phenelzine
  - For insomnia, one of the following is required: ramelteon or a sedating antidepressant (for example, trazodone, amitriptyline, doxepin, mirtazapine)
- A diagnosis of tension-type headache (TTH) and documentation of trial and failure of **ALL** of the following for TTH is required unless contraindicated:
  - Acetaminophen
  - Aspirin
  - Non-steroidal anti-inflammatory agent (NSAID) (for example, ibuprofen, naproxen)
  - Combination therapy of caffeine plus any one of the three aforementioned agents (for example, caffeine/acetaminophen, caffeine/aspirin, caffeine/NSAID)
- Your prescriber has signed an attestation as to **ALL** of the following:
  - Your provider will regularly review your controlled substance utilization contained within INSPECT
  - You have been educated about the risks of using benzodiazepines and opioid analgesics together at the same time
  - Both you and your provider accept the of using benzodiazepines and opioid analgesics together at the same time

  Please note that additional criteria apply for the benzodiazepine day supply limits. Your benzodiazepine prescription claim must not be greater than a 15-day supply of medication. You cannot receive more than a 30 days supply of benzodiazepine medication in the past 90 days. The current request for medication is also counted as a part of the 30 days supply in the past 90 days.

Our guideline named **BUTALBITAL/CODEINE-CONTAINING AGENTS FOR HEADACHE** for patients with claims in history for Lybalvi (olanzapine/samidorphan) requires that you have not taken Lybalvi (olanzapine/samidorphan) less than or equal to 5 days prior to initiating opioid therapy.

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BUTALBITAL/CODEINE-CONTAINING AGENTS FOR HEADACHE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline for **BUTALBITAL/CODEINE-CONTAINING AGENTS FOR HEADACHE** does not permit concurrent use with carisoprodol-containing products.

Our renewal guideline for **BUTALBITAL/CODEINE-CONTAINING AGENTS FOR HEADACHE** requires your prescriber to verify that you meet **ALL** of the following criteria:

- Opioid therapy has resulted in a meaningful improvement in your pain and/or function
- Your prescriber has developed an updated pain management plan with clear treatment goals
- Risk assessment has been performed including review of the state prescription drug monitoring program (PDMP) data (for example, INSPECT)
- Adherence to prescribed opioid regimen has been periodically assessed (for example, urine drug screen, pill counts)

Our guideline named **BUTALBITAL/CODEINE-CONTAINING AGENTS FOR HEADACHE** for renewal of opioid analgesic therapy requires that you meet **ALL** of the following rules:

- Opioid therapy has resulted in a meaningful improvement in your pain and/or function
- Your doctor has developed an updated pain management plan with clear treatment goals
- A risk assessment has been performed including review of the state prescription drug monitoring program (PDMP) data (for example, INSPECT)
- Adherence to the prescribed opioid regimen has been periodically assessed (for example, urine drug screen, pill counts)

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BUTALBITAL/CODEINE-CONTAINING AGENTS FOR HEADACHE

RENEWAL CRITERIA (CONTINUED)

Our renewal guideline for **BUTALBITAL/CODEINE-CONTAINING AGENTS FOR HEADACHE** for patients with claims in history for benzodiazepines requires that the prescriber submit the required fax form documenting **ALL** of the following:

- The diagnosis contributing to the need for benzodiazepine therapy and previous therapy attempted, including dates and doses of prior therapies
  - For generalized anxiety disorder, one of the following is required: Selective serotonin reuptake inhibitor (SSRI, such as sertraline or citalopram), serotonin-noradrenaline reuptake inhibitor (SNRI, such as duloxetine or venlafaxine), or pregabalin (generic for Lyrica)
  - For panic disorder, one of the following is required: SSRI or tricyclic antidepressant (TCA, such as amitriptyline or nortriptyline)
  - For social anxiety disorder (SAD), a trial of an SSRI is required
  - For obsessive compulsive disorder (OCD), a trial of an SSRI is required
  - For post-traumatic stress disorder (PTSD), one of the following is required: mirtazapine, paroxetine, amitriptyline, or phenelzine
  - For insomnia, one of the following is required: ramelteon or a sedating antidepressant (for example, trazodone, amitriptyline, doxepin, mirtazapine)
- A diagnosis of tension-type headache (TTH) and previous therapy attempted
- Your prescriber has signed an attestation as to **ALL** of the following:
  - Your provider will regularly review your controlled substance utilization contained within INSPECT
  - You have been educated about the risks of using benzodiazepines and opioid analgesics together at the same time
  - Both you and your provider accept the of using benzodiazepines and opioid analgesics together at the same time

Please note that additional criteria apply for the benzodiazepine day supply limits. Your benzodiazepine prescription claim must not be greater than a 15-day supply of medication. You cannot receive more than 30 days' supply of benzodiazepine medication in the past 90 days. The current request for medication is also counted as a part of the 30 days' supply in the past 90 days.

Our guideline named **BUTALBITAL/CODEINE-CONTAINING AGENTS FOR HEADACHE** for patients with claims in history for Lybalvi (olanzapine/samidorphan) requires that you have not taken Lybalvi (olanzapine/samidorphan) less than or equal to 5 days prior to initiating opioid therapy.

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BUTALBITAL/CODEINE-CONTAINING AGENTS FOR HEADACHE

RATIONALE

To ensure opioid analgesics are used according to FDA approved indications with patient safety in mind, and to encourage the use of more cost-effective analgesics.
From 2000-2014, almost half a million people died due to drug overdose, with 2014 being the highest year for deaths on record. In that time, the number of opioids prescribed, as well as the number of opioid overdoses, has risen exponentially. At least half of all opioid overdose deaths involve a prescription opioid. Indiana was among the states that had a statistically significant increase of overdose deaths from 2013-2014.

According to recent research, the opioid epidemic has a disproportionate impact on Medicaid beneficiaries. Medicaid patients are prescribed opioids at double the rate of non-Medicaid patients, and are subsequently at much higher risk of prescription opioid overdose.
Improving the way that opioids are prescribed can ensure safer and more effective pain treatment, and reduce the addiction, misuse, abuse, and overdose of these drugs. These guidelines are to ensure that the use of opioids is consistent with their FDA approved indications, and to initiate action combating the current opioid epidemic.

Assessing Risk and Addressing Harms of Opioid Use

- Prior to and throughout opioid therapy, adverse events should be evaluated periodically. Factors that increase risk for opioid overdose include history of overdose or substance use disorder, 50 MME daily or more, and concurrent benzodiazepine use.
- Prescription drug monitoring program (PDMP) data (e.g., RXINSPECT) are useful to monitor total opioid dosage. PDMP data is helpful for initial and periodic opioid usage evaluations.
- Prescribing opioids and benzodiazepines concurrently should be avoided.
- For patients with substance use disorder, evidence-based treatment (medication-assisted and behavioral therapy) is recommended.

Analysis performed by the US Department of Health and Human Services Center for Disease Control and Prevention (CDC) determined the risk of harm to individuals increases as their opioid dose increases and as their length of opioid therapy increases. For example:

- Individuals taking opioid doses > 50 morphine milligram equivalents (MMEs) per day had twice the risk of death from an overdose than those taking < 20 MMEs per day.
- Individuals taking opioid doses > 90 (MMEs) per day had 10 times the risk of death from an overdose than those taking < 20 MMEs per day.
- Individuals taking an opioid for > 3 months (even at low doses) had 15 times the risk of addiction to those taking opioids for < 3 months.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

BUTALBITAL/CODEINE-CONTAINING AGENTS FOR HEADACHE

APPENDIX 1: BENZODIAZEPINE/OPIOID CONCURRENT USE FAX FORM
INDIANA HEALTH COVERAGE PROGRAMS (IHCP) PHARMACY BENEFIT
BENZODIAZEPINE AND OPIOID CONCURRENT THERAPY
PRIOR AUTHORIZATION REQUEST FORM

MDwise
Fax to: (858) 790-7100
c/o MedImpact Healthcare Systems, Inc.
Attn: Prior Authorization Department
10181 Scripps Gateway Court, San Diego, CA 92131
Phone: 1-800-788-2949

Today's Date
☐☐ / ☐☐ / ☐☐☐☐

Note: This form must be completed by the prescribing provider.
****All sections must be completed or the request will be denied.****

Patient's Medicaid # ☐☐☐☐☐☐☐☐☐☐☐☐	**Date of Birth** ☐☐ / ☐☐ / ☐☐☐☐
Patient's Name	**Prescriber's Name**
Prescriber's IN License # ☐☐☐☐☐☐☐☐	**Specialty**
Prescriber's NPI # ☐☐☐☐☐☐☐☐☐☐	**Prescriber's Signature: **Required below within attestation section.****
Return Fax # ☐☐☐ - ☐☐☐ - ☐☐☐☐	**Return Phone #** ☐☐☐ - ☐☐☐ - ☐☐☐☐

PA is required for the following:

- **Claim(s) for new opioid(s) to be used concurrently with benzodiazepines and exceeding 7 days within a 180-day period.**
- **Claim(s) for new benzodiazepine(s) to be used concurrently with opioids and exceeding 7 days of therapy within a 180-day period and/or exceeding established benzodiazepine/opioid concurrent therapy quantity limits (see Sedative Hypnotics/Benzodiazepine PA criteria).**

Benzodiazepine Agent(s)	Prescriber Name*	Quantity	Dosage Regimen/Duration

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PRIOR AUTHORIZATION GUIDELINES

Opioid Agent(s)	Prescriber Name*	Quantity	Dosage Regimen/Duration

***NOTE: If prescribers of the opioid(s) and benzodiazepine(s) are not the same, please answer the following questions:**

- **Are you requesting PA for: Benzodiazepine Agent(s) ☐ Opioid Agent(s) ☐ Both ☐**
- **Is/are the other prescriber(s) aware of the request for concurrent therapy? □ Yes □ No**
- **Has/have the other prescriber(s) been consulted about the risks associated with concurrent therapy, and do all prescribers involved believe continuing with concurrent therapy is warranted, given the risks associated with concurrent use? □ Yes □ No**

PA Requirements:

Patient diagnosis/diagnoses for use of benzodiazepine therapy:

Prior therapies attempted for the above diagnosis/diagnoses (submission of chart notes required in absence of claims history):

Drug Therapy	Dosage Regimen	Dates of Utilization

Do you plan to continue benzodiazepine therapy for this patient? □ Yes □ No
If no, please provide withdrawal plan:

Patient diagnosis/diagnoses for use of opioid therapy:

Prior therapies (both drug and non-drug) attempted for the above diagnosis/diagnoses (submission of chart notes required in absence of claims history):

Drug/Non-Drug Therapy	Dosage Regimen	Dates of Utilization	Reason for Discontinuation or Failure

Do you plan to continue opioid therapy for this patient? □ Yes □ No
If no, please provide withdrawal plan:

Attestation:

I, _____, hereby attest to the following:
(Prescriber Name)

The patient's INSPECT report has been evaluated and continues to be evaluated on a regular basis (Per IC 35-48-7-11.1, DO NOT attach a copy of the INSPECT report to this PA request).
I have educated the patient in regards to the risks of concurrent utilization of benzodiazepine and opioid therapy, and the patient accepts these risks.
If applicable, I have consulted other prescriber(s) involved in concurrent therapy and all prescribers involved agree to pursue concurrent opioid and benzodiazepine therapy for this patient.
I acknowledge, as the prescriber initiating or maintaining concurrent benzodiazepine and opioid therapy, the risk of adverse event(s), including respiratory depression, coma, and death, associated with concurrent utilization.

Prescriber Signature:_____

****Prescriber signature is required for consideration. Electronic or stamped signature will not be accepted.****

CONFIDENTIAL INFORMATION
This facsimile transmission (and attachments) may contain protected health information from the Indiana Health Coverage Programs (IHCP), which is intended only for the use of the individual or entity named in this transmission sheet. Any unintended recipient is hereby notified that the information is privileged and confidential, and any use, disclosure, or reproduction of this information is prohibited.

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

BUTALBITAL/CODEINE-CONTAINING AGENTS FOR HEADACHE

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Created: 09/19
Effective: 06/13/22 Client Approval: 05/26/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

C1 ESTERASE INHIBITOR

Generic	Brand	HICL	GCN	Exception/Other
C1 ESTERASE INHIBITOR	BERINERT, CINRYZE, HAEGARDA	18568		
C1 ESTERASE INHIBITOR, RECOMBINANT	RUCONEST	37766		

GUIDELINES FOR USE.

Our guideline named C1 ESTERASE INHIBITOR (Berinert, Cinryze, Haegarda, Ruconest) requires the following rule(s) be met for approval:
A. You have hereditary angioedema (HAE)
B. The medication is prescribed by or in consultation with a hematologist or allergist/immunologist.

RATIONALE
To ensure the appropriate use of C1 esterase inhibitor in patients with hereditary angioedema (HAE).

FDA APPROVED INDICATIONS
Berinert:
- Is a plasma-derived C1 esterase inhibitor (human) indicated for the treatment of acute abdominal, facial, or laryngeal attacks of hereditary angioedema in adult and adolescent patients.
- The safety and efficacy of Berinert for prophylactic therapy have not been established.

Cinryze:
- Is a C1 inhibitor indicated for routine prophylaxis against angioedema in adolescent and adult patients with hereditary angioedema.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

C1 ESTERASE INHIBITOR

FDA APPROVED INDICATIONS (CONTINUED)

Haegarda:

- Is a plasma-derived concentrate of C1 Esterase Inhibitor (Human) (C1-INH) indicated for routine prophylaxis to prevent Hereditary Angioedema (HAE) attacks in adolescent and adult patients.

Ruconest:

- Is indicated for the treatment of acute attacks in adult and adolescent patients with hereditary angioedema (HAE).

Limitation of use: Effectiveness was not established in HAE patients with laryngeal attacks.

DOSAGE

Berinert

The dose is 20 International Units (IU) per kg body weight by intravenous injection. Doses lower than 20 IU/kg body weight should not be administered. Each Berinert vial containing 500 IU of C1 esterase inhibitor as a lyophilized concentrate for reconstitution with 10 mL of Sterile Water for Injection.

Cinryze

A dose up to 2,500 Units can be administered every 3 or 4 days for routine prophylaxis against angioedema attacks in HAE patients. Cinryze is administered at an injection rate of 1 mL per minute. To obtain the required dose, reconstitute two Cinryze vials with two vials Sterile Water for Injection, USP (5 mL each) using aseptic sterile technique.

Haegarda

Haegarda is intended for self-administration after reconstitution at a dose of 60 International Units (IU) per kg body weight by subcutaneous (S.C.) injection twice weekly (every 3 or 4 days). The patient or caregiver should be trained on how to administer Haegarda. Administer at room temperature within 8 hours after reconstitution. For subcutaneous use after reconstitution only.

Ruconest

The dose is 50 IU/kg for patients less than 84 kg, or 4200 IU for patients that weigh 84 kg or more. Each vial (2100 IU) should be reconstituted by adding 14mL of sterile water for injection to obtain a solution of 150 IU/mL. After reconstitution the dose can be administered as a slow intravenous injection over 5 minutes. If appropriately trained, patients may self-administer the dose as needed upon recognition of an HAE attack. No more than two doses should be administered within a 24- hour period, and no more than 4200 IU per dose should be administered.

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- Ruconest [Prescribing Information]. Raleigh, NC: Salix Pharmaceuticals; December 2019.
- Berinert [Prescribing Information]. Kankakee, IL: CSL Behring LLC. May 2019.
- Cinryze [Prescribing Information]. Exton, PA: ViroPharma, Inc. December 2019.

Created: 06/15
Effective: 08/08/22 Client Approval: 07/13/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

CABOZANTINIB S-MALATE

Generic	Brand	HICL	GCN	Exception/Other
CABOZANTINIB S-MALATE	COMETRIQ, CABOMETYX	39815		

****Please use the criteria for the specific drug requested****

GUIDELINES FOR USE

COMETRIQ

Our guideline named **CABOZANTINIB S-MALATE (Cometriq)** requires you have progressive, metastatic medullary thyroid cancer (type of thyroid cancer that has spread).

CABOMETYX

Our guideline named **CABOZANTINIB S-MALATE (Cabometyx)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Advanced renal cell carcinoma (RCC: type of kidney cancer)
   2. Hepatocellular carcinoma (HCC: type of liver cancer)
   3. Locally advanced or metastatic differentiated thyroid cancer (DTC: type of thyroid cancer)

B. **If you have hepatocellular carcinoma, approval also requires:**
   1. You have previously been treated with Nexavar (sorafenib)

C. **If you have locally advanced or metastatic differentiated thyroid cancer, approval also requires:**
   1. You are 12 years of age or older
   2. You have disease progression (disease has gotten worse) following prior vascular endothelial growth factor receptor (VEGFR)-targeted therapy (a type of cancer therapy)
   3. You are radioactive iodine-refractory (resistant to) or ineligible

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RATIONALE
To ensure appropriate diagnostic, utilization and safety criteria are used for the management of requests for Cometriq or Cabometyx.

FDA APPROVED INDICATIONS
Cometriq is a kinase inhibitor indicated for the treatment of patients with progressive, metastatic medullary thyroid cancer (MTC).

Cabometyx is a kinase inhibitor indicated for the treatment of:
- Patients with advanced renal cell carcinoma (RCC)
- Patients with advanced renal cell carcinoma (RCC), as a first-line treatment in combination with nivolumab
- Patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib
- Adult and pediatric patients 12 years of age and older with locally advanced or metastatic differentiated thyroid cancer (DTC) that has progressed following prior VEGFR-targeted therapy and who are radioactive iodine-refractory or ineligible

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CABOZANTINIB S-MALATE

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

Cometriq

The recommended daily dose of Cometriq is 140mg (one 80mg and three 20mg capsules). Patients should not eat for at least 2 hours before and at least 1 hour after taking Cometriq. The daily dose of Cometriq should not exceed 180mg.

Cabometyx

Renal cell carcinoma (RCC)

- The recommended dosage of Cabometyx as a single agent is 60 mg once daily until disease progression or unacceptable toxicity.
- The recommended dosage of Cabometyx in combination with nivolumab is 40 mg once daily until disease progression or unacceptable toxicity.

Hepatocellular carcinoma (HCC)

- The recommended dosage of Cabometyx as a single agent is 60 mg once daily until disease progression or unacceptable toxicity.

Differentiated thyroid cancer (DTC)

- The recommended dosage of Cabometyx as a single agent for adult and pediatric patients 12 years of age and older with BSA greater than or equal to 1.2 m^2 is 60 mg once daily until disease progression or unacceptable toxicity.
- The recommended dosage of Cabometyx as a single agent in pediatric patients 12 years of age and older with BSA less than 1.2 m^2 is 40 mg once daily until disease progression or unacceptable toxicity.

REFERENCES

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Created: 06/15
Effective: 01/01/22 Client Approval: 11/30/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

CANAKINUMAB

Generic	Brand	HICL	GCN	Exception/Other
CANAKINUMAB/PF	ILARIS	36497		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **CANAKINUMAB (Ilaris)** requires the following rule(s) bet met for approval:

A. **You have ONE of the following diagnoses:**
   1. Systemic Juvenile Idiopathic Arthritis (SJIA: inflammation and stiffness in joints of children)
   2. Cryopyrin-Associated Periodic Syndromes such as Familial Cold Autoinflammatory Syndrome (FCAS: inherited inflammatory disorder that is triggered with cold) or Muckle-Wells Syndrome (MWS: disorder characterized by periodic episodes of skin rash, fever, and joint pain)
   3. Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS: genetic disease that causes recurrent episodes of fever)
   4. Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) (genetic disorders that have recurrent fever episodes and inflammation)
   5. Familial Mediterranean Fever (FMF: genetic disorder that causes recurrent episodes of fever and pain in the abdomen, chest, or joints)
   6. Adult-Onset Still's Disease (AOSD: rare autoinflammatory disease caused by abnormalities of the immune system)

B. **If you have systemic juvenile idiopathic arthritis (SJIA), approval also requires:**
   1. You are 2 years of age or older
   2. You have previously tried **ONE** of the following DMARDs (disease-modifying antirheumatic drugs): methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   3. You have previously tried Actemra

C. **If you have Cryopyrin-Associated Periodic Syndromes (CAPS) such as Familial Cold Autoinflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS), approval also requires:**
   1. You are 4 years of age or older

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RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: The guideline named **CANAKINUMAB (Ilaris)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Systemic Juvenile Idiopathic Arthritis (SJIA: inflammation and stiffness in joints of children)
   2. Cryopyrin-Associated Periodic Syndromes such as Familial Cold Autoinflammatory Syndrome (FCAS: inherited inflammatory disorder that is triggered with cold) or Muckle-Wells Syndrome (MWS: disorder characterized by periodic episodes of skin rash, fever, and joint pain)
   3. Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS: genetic disease that causes recurrent episodes of fever)
   4. Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) (genetic *disorders* that have recurrent fever episodes and inflammation)
   5. Familial Mediterranean Fever (FMF: genetic disorder that causes recurrent episodes of fever and pain in the abdomen, chest, or joints)
   6. Adult-Onset Still's Disease (AOSD: rare autoinflammatory disease caused by abnormalities of the immune system)

B. **If you have systemic juvenile idiopathic arthritis (SJIA), approval requires:**
   1. Documentation that you have experienced or maintained symptomatic improvement while on therapy.

RATIONALE

Ensure appropriate diagnostic, utilization and safety criteria are used for the management of requests for canakinumab.

FDA APPROVED INDICATIONS

Ilaris is an interleukin-1β blocker indicated for the treatment of:

- Cryopyrin-Associated Periodic Syndromes (CAPS), in adults and children 4 years of age and older including:
  - Familial Cold Autoinflammatory Syndrome (FCAS)
  - Muckle-Wells Syndrome (MWS)
- Active Still's Disease, including Adult Onset Still's Disease (AOSD) and Systemic Juvenile Idiopathic Arthritis (SJIA) in patients aged 2 years and older
- Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) in adult and pediatric patients
- Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) in adult and pediatric patients
- Familial Mediterranean Fever (FMF) in adult and pediatric patients

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

CANAKINUMAB

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE

Cryopyrin-Associated Periodic Syndromes
150 mg for CAPS patients with body weight greater than 40 kg and 2 mg/kg for CAPS patients with body weight ≥ 15 kg and ≤ 40 kg. For children 15 to 40 kg with an inadequate response, the dose can be increased to 3 mg/kg. Administer subcutaneously every 8 weeks.

Still's Disease (AOSD and SJIA)
4 mg/kg (with a maximum of 300 mg) for patients with a body weight ≥ 7.5 kg. Administer subcutaneously every 4 weeks.

Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS), Hyperimmunoglobulin D Syndrome/Mevalonate Kinase Deficiency (HIDS/MKD), and Familial Mediterranean Fever (FMF)

- 2 mg/kg for patients with a body weight ≤ 40 kg. If clinical response is not adequate, the dose can be increased to 4 mg/kg. Administer subcutaneously every 4 weeks.
- 150 mg for patients with a body weight > 40 kg. If clinical response is not adequate, the dose can be increased to 300 mg. Administer subcutaneously every 4 weeks.

REFERENCES

- Novartis Pharmaceuticals Corporation. Ilaris [prescribing information]. East Hanover, NJ. September 2020.
- Beukelman T, Patkar NM, et al. 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: Initiation and safety monitoring of therapeutic agents for the treatment of arthritis and systemic features. Arthritis Care Res, 63: 465–482. doi: 10.1002/acr.20460.

Created: 10/15
Effective: 04/11/22 Client Approval: 03/10/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

CANNABIDIOL

Generic	Brand	HICL	GCN	Exception/Other
CANNABIDIOL	EPIDIOLEX	45006		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **CANNABIDIOL (Epidiolex)** requires the following rule(s) be met for approval:
A. You have ONE of the following diagnoses:
   1. Seizures associated with Dravet syndrome (a rare type of seizure)
   2. Seizures associated Lennox-Gastaut syndrome (a type of seizure disorder in young children)
   3. Seizures associated tuberous sclerosis complex (TSC: a rare type of tumor disorder)
B. **If you have seizures associated with Dravet syndrome, approval also requires:**
   1. You are 1 year of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
   3. You had a trial of or contraindication (harmful for) to clobazam AND valproic acid derivative
C. **If you have seizures associated with Lennox-Gastaut syndrome, approval also requires:**
   1. You are 1 year of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
   3. You had a trial of or contraindication (harmful for) to TWO of the following: clobazam, valproic acid derivative, topiramate, or lamotrigine
D. **If you have seizures associated with tuberous sclerosis complex, approval also requires:**
   1. You are 1 year of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
   3. You had a trial of or contraindication (harmful for) to TWO anti-epileptic medications (drugs to treat seizures) such as clobazam, valproic acid derivative, topiramate, lamotrigine

RENEWAL CRITERIA

Our guideline named **CANNABIDIOL (Epidiolex)** requires the following rule to be met for renewal:
A. You have ONE of the following diagnoses:
   1. Seizures associated with Dravet syndrome (a rare type of seizure)
   2. Seizures associated Lennox-Gastaut syndrome (a type of seizure disorder in young children)
   3. Seizures associated tuberous sclerosis complex (TSC: a rare type of tumor disorder)

RATIONALE
To promote appropriate utilization of Epidiolex based on FDA approved indication.

FDA APPROVED INDICATIONS
Epidiolex is indicated for the treatment of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex in patients one year of age and older.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

CANNABIDIOL

DOSAGE AND ADMINISTRATION

Epidiolex is to be administered orally.

Dosing for patients with seizures associated with Lennox-Gastaut Syndrome or Dravet Syndrome:

- The starting dosage is 2.5 mg/kg twice daily (5 mg/kg/day).
- After one week, the dosage can be increased to a maintenance dosage of 5 mg/kg twice daily (10 mg/kg/day).
- Patients who are tolerating Epidiolex at 5 mg/kg twice daily and require further reduction of seizures may benefit from a dosage increase up to a maximum recommended maintenance dosage of 10 mg/kg twice daily (20 mg/kg/day), in weekly increments of 2.5 mg/kg twice daily (5 mg/kg/day), as tolerated.

Dosing for seizures associated with Tuberous Sclerosis Complex:

- The starting dosage is 2.5 mg/kg by mouth twice daily (5 mg/kg/day).
- Increase the dose in weekly increments of 2.5 mg/kg twice daily (5 mg/kg/day), as tolerated, to a recommended maintenance dosage of 12.5 mg/kg twice daily (25 mg/kg/day). For patients in whom a more rapid titration to 25 mg/kg/day is warranted, the dosage may be increased no more frequently than every other day.
- The effectiveness of doses lower than 12.5 mg/kg twice daily has not been studied in patients with TSC.

REFERENCES

Epidiolex [Prescribing Information]. Carlsbad, CA: Greenwich Biosciences, Inc.; May 2022.

Created: 12/18
Effective: 06/13/22 Client Approval: 06/01/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

CAPECITABINE

Generic	Brand	HICL	GCN	Exception/Other
CAPECITABINE	XELODA	18385		

GUIDELINES FOR USE

Our guideline for approval of **CAPECITABINE** requires a diagnosis of Stage III (Duke's C) colon cancer; or a diagnosis of metastatic colorectal cancer (mCRC) and that is Xeloda being used in combination with oxaliplatin (CapeOX or XELOX regimen) or as a monotherapy; or a diagnosis of metastatic breast cancer and that Xeloda is being used as monotherapy in patients resistant to both paclitaxel and an anthracycline-containing regimen or is being used in combination with docetaxel after failure of prior anthracycline-containing therapy. The required therapies may require a prior authorization and may be covered under the medical benefit.

CAPECITABINE

RATIONALE

To ensure appropriate use of Xeloda consistent with FDA approved indication and NCCN guidelines.

Xeloda (capecitabine) which is the pro-drug of 5-fluorouracil (5-FU), is administered orally with food. The daily dose is 2500mg/m^2 given in two divided doses approximately 12 hours apart at the end of a meal. Individual doses will vary by patient based on the body surface area. Xeloda is approved as first-line monotherapy for mCRC when treatment with fluoropyrimidine therapy alone is preferred and as adjuvant therapy for patients with Stage III (Duke's C) colon cancer. It is also FDA approved for the treatment of breast cancer and has demonstrated efficacy in several other cancers.

Table 1 XELODA Dose Calculation According to Body Surface Area

Dose Level 1250 mg/m2 Twice a Day		Number of Tablets to be Taken at Each Dose (Morning and Evening)	
Surface Area (m2)	**Total Daily Dose* (mg)**	**150 mg**	**500 mg**
≤ 1.25	3000	0	3
1.26-1.37	3300	1	3
1.38-1.51	3600	2	3
1.52-1.65	4000	0	4
1.66-1.77	4300	1	4
1.78-1.91	4600	2	4
1.92-2.05	5000	0	5
2.06-2.17	5300	1	5
≥ 2.18	5600	2	5

*Total Daily Dose divided by 2 to allow equal morning and evening doses

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RATIONALE (CONTINUED)

NCCN Guidelines Version 2.2013: Colon Cancer / NCCN Guidelines Version 3.2013 Rectal Cancer
Surgical removal is the preferred treatment for early stage disease. Surgery is accompanied by adjuvant chemotherapy for patients with high-risk features or more extensive cancer involvement.

Primary treatment options for resectable synchronous metastases are:

- Chemotherapy (FOLFIRI, FOLFOX, or CapeOX) with or without Avastin
- Chemotherapy (FOLFIRI or FOLFOX) with or without Vectibix (KRAS wild-type patients only)
- Chemotherapy (FOLFIRI) with or without Erbitux (KRAS wild-type patients only)
- Staged resection
- Infusional IV 5-FU with radiation

Primary treatment options for unresectable metachronous metastases previously treated with adjuvant FOLFOX are:

- FOLFIRI with or without Avastin
- FOLFIRI with or without Zaltrap
- Irinotecan with or without Avastin
- Irinotecan with or without Zaltrap
- FOLFIRI or irinotecan with Erbitux or Vectibix (KRAS wild-type patients only)

Initial therapy options for treatment of mCRC in patients appropriate for intensive therapy are:

- FOLFOX, with or without Avastin
- FOLFOX, with or without Vectibix (KRAS wild-type patients only)
- CapeOX with or without Avastin
- FOLFIRI with or without Avastin
- FOLFIRI with our without Erbitux or Vectibix (KRAS wild-type patients only)
- 5-FU/leucovorin or Xeloda with or without Avastin
- FOLFOXIRI

Initial therapy options for treatment of mCRC in patients not appropriate for intensive therapy are:

- Infusional 5-FU with leucovorin or Xeloda with or without Avastin
- Erbitux (KRAS wild-type patients only)
- Vectibix (KRAS wild-type patients only)

Zaltrap in combination with FOLFIRI is a recommended therapeutic regimen following progression of mCRC after an oxaliplatin containing chemotherapy regimen. Stivarga is considered a treatment option in therapy after first, second, or third progression, depending on previous lines of therapy.

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RATIONALE (CONTINUED)

Other treatment options after first or second progression include:

- Erbitux or Vectibix with irinotecan (KRAS wild-type patients only)
- FOLFOX, FOLFIRI, CapeOX, or irinotecan with or without Avastin
- Irinotecan and oxaliplatin with or without Avastin

The Xeloda prescribing information contains one study (X-ACT) supporting its use in the adjuvant setting for patients with Stage III (Duke's C) colon cancer. A total of 1987 patients were randomized to Xeloda or 5-FU/LV. With a median follow-up of 6.9 years, Xeloda was at least equivalent to 5-FU/LV in terms of disease free survival and OS.

There were two pivotal trials of identical design that evaluated Xeloda as a first line treatment for mCRC. The first trial by Hoff randomized a total of 605 patients to treatment with either Xeloda or 5-FU/LV. The Xeloda treated patients experienced a higher overall objective tumor response rate than the 5-FU/LV patients (24.8% vs. 15.5%). The median time to disease progression (4.3 vs. 4.7 months) and median OS (12.5 vs. 13.3) were similar between treatment arms. Quality of life data was not reported. (32) The second trial led by Van Cutsem included 602 patients. The Xeloda treated patients experienced similar overall response rates (18.9% vs. 15.0%), median time to disease progression (5.2 vs. 4.7 months) and OS (13.2 vs. 12.1 months) as the 5-FU/LV group.

Later the XELOX-1 (Study NO16966) trial investigated Xeloda as a first line treatment in combination with oxaliplatin (XELOX) compared to FOLFOX-4. The trial was later amended to include Avastin resulting in four treatment arms: XELOX vs. FOLFOX-4, with either Avastin or placebo. OS was 19.8 months in the pooled XELOX/XELOX placebo/ XELOX Avastin arms vs. 19.5 months in the pooled FOLFOX4/FOLFOX4-placebo/FOLFOX4-Avastin. In the pooled XELOX/XELOX-placebo arms, median OS was 19.0 vs. 18.9 months in the pooled FOLFOX4/FOLFOX4-placebo arms.

A trial led by Ducreux evaluated XELOX vs. FOLFOX-6 for the first line treatment of mCRC. Efficacy of the two regimens was similar with median PFS of 8.8 months with XELOX and 9.3 months with FOLFOX-6, and median OS of 19.9 and 20.5 months, respectively. A quality of life analysis was performed using two scales: the Cancer Quality of Life Questionnaire-C30 (QLQ-C30) and the module 'Chemotherapy Convenience and Satisfaction Questionnaire' (CCSQ) of the Functional Assessment of Chronic Illness Therapy (FACIT) Measurement System; which is a collection of HRQoL questionnaires related to the management of chronic illnesses, measures the health-care satisfaction of patients. Both regimens had a similar quality of life profile but XELOX was perceived as more convenient and satisfactory to patients.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

CAPECITABINE

FDA APPROVED INDICATIONS

Xeloda is approved for:

- Adjuvant Colon Cancer
  - Patients with Stage III (Duke's C) colon cancer
- Metastatic Colorectal Cancer
  - First-line as monotherapy when treatment with fluoropyrimidine therapy alone is preferred
- Metastatic Breast Cancer
  - In combination with docetaxel after failure of prior anthracycline containing therapy
  - As monotherapy in patients resistant to both paclitaxel and an anthracycline-containing regimen

REFERENCES

- Xeloda [Prescribing Information]. South San Francisco, CA: Genentech Inc., March 2015
- National Comprehensive Cancer Network. Colon Cancer Guideline Version 3.2012. Available at: http://www.nccn.org/professionals/physician_gls/pdf/colon.pdf [Accessed October 1, 2012].
- National Comprehensive Cancer Network. Rectal Cancer Guideline Version 3.2012. Available at: http://www.nccn.org/professionals/physician_gls/pdf/rectal.pdf [Accessed October 1, 2012].

Created: 06/15
Effective: 07/22/17 Client Approval: 06/29/17 P&T Approval: 08/13

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

CAPLACIZUMAB-YHDP

Generic	Brand	HICL	GCN	Exception/Other
CAPLACIZUMAB-YHDP	CABLIVI	45591		

GUIDELINES FOR USE

The guideline named **CAPLACIZUMAB-YHDP (Cablivi)** requires a diagnosis of acquired thrombotic thrombocytopenia purpura (aTTP). In addition, the following criteria must be met.

- The patient is 18 years of age or older
- The patient is continuing a regimen of Cablivi that was previously initiated as part of the FDA approved treatment regimen in combination with plasma exchange and immunosuppressive therapy

RATIONALE

For further information, please refer to the Prescribing Information for Cablivi.

INDICATION

CABLIVI is a von Willebrand factor (vWF)-directed antibody fragment indicated for the treatment of adult patients with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange and immunosuppressive therapy.

DOSAGE AND ADMINISTRATION

CABLIVI should be administered upon the initiation of plasma exchange therapy. The recommended dose of CABLIVI is as follows:

- First day of treatment: 11 mg bolus intravenous injection at least 15 minutes prior to plasma exchange followed by an 11 mg subcutaneous injection after completion of plasma exchange on day 1.
- Subsequent treatment during daily plasma exchange: 11 mg subcutaneous injection once daily following plasma exchange.
- Treatment after the plasma exchange period: 11 mg subcutaneous injection once daily for 30 days beyond the last plasma exchange.
- If after initial treatment course, sign(s) of persistent underlying disease such as suppressed ADAMTS13 activity levels remain present, treatment may be extended for a maximum of 28 days.
- Discontinue CABLIVI if the patient experiences more than 2 recurrences of aTTP, while on CABLIVI.

The first dose should be administered by a healthcare provider as a bolus intravenous injection. Administer subsequent doses subcutaneously in the abdomen.

REFERENCE

Cablivi [Prescribing Information]. Cambridge, MA: Genzyme Corporation; February 2019.

Created: 04/19
Effective: 05/20/19 Client Approval: 04/04/19 P&T Approval: N/A

CAPMATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CAPMATINIB	TABRECTA	46519			

GUIDELINES FOR USE

Our guideline named **CAPMATINIB (Tabrecta)** requires the following rule(s) be met for approval:

E. You have metastatic non-small cell lung cancer (NSCLC; type of lung cancer that has spread to other parts of the body)
F. You are 18 years of age or older
G. Your tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping (an abnormal change in a gene that makes MET protein) as detected by an FDA-approved test

RATIONALE

To ensure appropriate diagnostic, utilization, and safety criteria are used for the management of requests for capmatinib.

INDICATIONS

Tabrecta is a kinase inhibitor indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test.

DOSING

The recommended dosage of Tabrecta is 400 mg orally twice daily with or without food.

REFERENCES

Tabrecta [Prescribing Information]. East Hanover, NJ: Novartis; May 2020.

Created: 06/20
Effective: 07/01/20 Client Aproval: 06/05/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

CAPSAICIN

Generic	Brand	HICL	GCN	Exception/Other
CAPSAICIN 8% PATCH	QUTENZA	36916		

GUIDELINES FOR USE

Our guideline for approval of **CAPSAICIN** requires a diagnosis of neuropathic pain associated with postherpetic neuralgia (PHN).

CAPSAICIN

RATIONALE

To ensure appropriate utilization of Qutenza based on FDA indication.

FDA APPROVED INDICATION

Qutenza is a TRPV1 channel agonist indicated for the treatment of neuropathic pain associated with postherpetic neuralgia (PHN) and neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet.

DOSING

Only physicians or healthcare professionals under the close supervision of a physician are to administer and handle Qutenza.

- The recommended dose of Qutenza for neuropathic pain associated with postherpetic neuralgia is a single, 60-minute application of up to four topical systems.
- The recommended dose of Qutenza for neuropathic pain associated with diabetic peripheral neuropathy is a single, 30-minute application on the feet of up to four topical systems.
- Treatment with Qutenza may be repeated every three months or as warranted by the return of pain (not more frequently than every three months).

REFERENCES

NeurogesX, Inc. Qutenza package insert. San Mateo, CA. August 2021.

Created: 06/15
Effective: 08/08/22 Client Approval: 07/13/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

CARBIDOPA-LEVODOPA

Generic	Brand	HICL	GCN	Exception/Other
CARBIDOPA/LEVODOPA	DUOPA		37829	ROUTE = Percutaneous endoscopic gastrostomy with jejunal tube (PEG-J)

GUIDELINES FOR USE

Our guideline for **CARBIDOPA-LEVODOPA** requires a diagnosis of advanced Parkinson's disease.

CARBIDOPA-LEVODOPA

RATIONALE
Promote appropriate utilization of Duopa based on FDA approved indication.

Duopa is the first agent to provide continuous treatment via the enteral route for motor fluctuations in patients with Parkinson's disease. It provides patients with the same active ingredients as orally-administered carbidopa and levodopa immediate release, but is delivered in a suspension that bypasses the stomach and goes directly into the small intestine via a tube placed by a percutaneous endoscopic gastrostomy with jejunal extension (PEG-J).

FDA APPROVED INDICATIONS
Duopa is indicated for the treatment of motor fluctuations in patients with advanced Parkinson's disease.

DOSAGE
Duopa is administered over a 16-hour infusion period. The daily dose is determined by individualized patient titration and composed of a morning dose, a continuous dose, and extra doses. The maximum recommended daily dose of Duopa is 2000mg of the levodopa component. At the end of the daily 16-hour infusion, patients will disconnect with pump from the PEG-J and take their nighttime dose of oral immediate release carbidopa/levodopa tablets.

Duopa is administered into the jejunum through a percutaneous endoscopic gastrostomy with jejunal tube (PEG-J) with the CADD®-Legacy 1400 portable infusion pump. A Duopa cassette should be taken out of the refrigerator and out of the carton 20 minutes prior to use so that it can be administered at room temperature. The cassettes are for single-use only.

REFERENCES

- Duopa [Prescribing Information]. North Chicago, IL: Abbvie, Inc. January 2015.

Created: 05/15
Effective: 07/01/17 Client Approval: 05/01/17 P&T Approval: 05/15

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

CARISOPRODOL PRODUCTS

Generic	Brand	HICL	GCN	Exception/Other
CARISOPRODOL	SOMA	01944	17912 98857	
CARISOPRODOL/ ASPIRIN	SOMA COMPOUND	01942	94380	

GUIDELINES FOR USE

Our guideline for **CARISOPRODOL PRODUCTS (SOMA, SOMA COMPOUND)** requires that the patient has an acute musculoskeletal condition that was diagnosed in the last 6 months. In addition, the following criteria must also be met:

- No history of meprobamate use in the past 90 days
- Trial and failure of at least one of the following preferred muscle relaxants in the past 30 days: baclofen, chlorzoxazone, cyclobenzaprine IR, methocarbamol, orphenadrine citrate or tizanidine
- Patient will not use the requested carisoprodol product concurrently with opioid analgesics or benzodiazepines

RATIONALE

Promote appropriate utilization of carisoprodol products based on FDA approved indications and patient safety.

FDA APPROVED INDICATION

Soma (carisoprodol) is a centrally acting skeletal muscle relaxant indicated for the relief of discomfort associated with acute, painful musculoskeletal conditions in adults.

Soma Compound is a fixed-dose combination product containing a centrally-acting muscle relaxant (carisoprodol) and an analgesic with antipyretic and anti-inflammatory properties (aspirin). Soma Compound is indicated for the relief of discomfort associated with acute, painful musculoskeletal conditions in adults.Soma and Soma Compound should only be used for short periods (up to two or three weeks) because adequate evidence of effectiveness for more prolonged use has not been established and because acute, painful musculoskeletal conditions are generally of short duration.

DOSAGE

The recommended dose of Soma is 250 mg to 350 mg three times a day and at bedtime. The recommended maximum duration of Soma use is up to two or three weeks.

The recommended dose of Soma Compound is 1 or 2 tablets, four times daily in adults. One Soma Compound tablet contains 200 mg of carisoprodol and 325 mg of aspirin. The maximum daily dose (i.e., two tablets taken four times daily) will provide 1600 mg of carisoprodol and 2600 mg of aspirin per day. The recommended maximum duration of Soma Compound use is up to two or three weeks.

REFERENCES

- Meda Pharmaceuticals, Inc. Soma Package Insert. Somerset, NJ. October 2009.
- Meda Pharmaceuticals, Inc. Soma Compound Package Insert. Somerset, NJ. March 2009.

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

CELECOXIB SOLUTION

Generic	Brand	HICL	GCN	Exception/Other
CELECOXIB	ELYXYB		48006	

GUIDELINES FOR USE

Our guideline named **CELECOXIB (Elyxyb)** requires the following rule(s) be met for approval:
A. The request is for the acute (quick onset) treatment of migraines
B. You are 18 years of age or older

RATIONALE

To ensure appropriate diagnostic, utilization and safety criteria are used for the management of requests for Elyxyb.

FDA APPROVED INDICATIONS

Elyxyb is a nonsteroidal anti-inflammatory drug indicated for the acute treatment of migraine with or without aura in adults.

DOSING

The recommended dose of Elyxyb is 120 mg taken orally, with or without food. The maximum dosage in a 24-hour period is 120 mg.

REFERENCES

- Elyxyb [Prescribing Information]. Banjara Hills, India: Dr. Reddy's Laboratories Limited, April 2021.

Created: 11/21
Effective: 01/17/22 Client Approval: 12/20/21 P&T Approval: N/A

CENEGERMIN-BKBJ

Generic	Brand	HICL	GCN	Exception/Other
CENEGERMIN-BKBJ	OXERVATE	45258		

GUIDELINES FOR USE

Our guideline named **CENEGERMIN-BKBJ (Oxervate)** requires the following rule(s) be met for approval:

A. You have a diagnosis of neurotrophic keratitis (an eye disease due to a damaged eye nerve)
B. You are 2 years of age or older
C. You have not received 8 weeks or more of prior cenegermin treatment for the affected eye

RATIONALE

Ensure appropriate diagnostic, utilization and safety criteria are met for the management of requests for Oxervate.

INDICATIONS

Oxervate is a recombinant human nerve growth factor indicated for the treatment of neurotrophic keratitis.

DOSAGE AND ADMINISTRATION

Administer one drop of oxervate in the affected eye(s), 6 times per day at 2-hour intervals, for eight weeks.

REFERENCES

Oxervate [Prescribing Information]. Boston, MA: Dompe U.S., Inc., October 2019.

Created: 09/19
Effective: 03/14/22 Client Approval: 02/14/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

CERITINIB

Generic	Brand	HICL	GCN	Exception/Other
CERITINIB	ZYKADIA	41111		

GUIDELINES FOR USE

Our guideline for **CERITINIB (Zykadia)** requires a diagnosis of metastatic non-small cell lung cancer (NSCLC) with anaplastic lymphoma kinase (ALK)-positive tumors (as detected by an FDA approved test).

RATIONALE

Promote clinically appropriate utilization of Zykadia based on its FDA approved indication and dosage.

The recommended dose of Zykadia is 450 mg orally once daily with food until disease progression or unacceptable toxicity.

If a dose of Zykadia is missed, make up that dose unless the next dose is due within 12 hours.

If vomiting occurs during the course of treatment, do not administer an additional dose and continue with the next scheduled dose of Zykadia.

Table 1: Zykadia Dose Reduction Increments.

Dose Reduction Schedule	Dose Level
Starting dose	450 mg taken orally once daily
First dose reduction	300 mg taken orally once daily
Second dose reduction	150 mg taken orally once daily

Discontinue Zykadia for patients unable to tolerate 150 mg daily.

FDA APPROVED INDICATIONS

Zykadia is a kinase inhibitor indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test.

REFERENCES

- Zykadia [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2019.

Created: 06/15
Effective: 06/24/19 Client Approval: 06/07/19 P&T Approval: 08/14

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

CERTOLIZUMAB PEGOL

Generic	Brand	HICL	GCN	Exception/Other
CERTOLIZUMAB PEGOL	CIMZIA	35554		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline for **CERTOLIZUMAB PEGOL** requires the following rule(s) be met for approval:

A. **You have ONE of the following diagnoses:**
   1. Moderate to severe rheumatoid arthritis (inflammation and stiffness in joints)
   2. Psoriatic arthritis (joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (inflammation and stiffness affecting spine and large joints)
   4. Moderate to severe plaque psoriasis (dry, itchy skin patches with scales)
   5. Moderate to severe Crohn's disease (type of inflammatory disease that affects lining of digestive tract)
   6. Non-radiographic axial spondyloarthritis (type of inflammation in the spine)

B. **If you have moderate to severe rheumatoid arthritis (RA), our guideline also requires:**
   1. You are 18 years of age or older
   2. You have previously tried ONE of the following DMARDs (disease-modifying antirheumatic drugs): methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   3. You have previously tried ONE of the following: Enbrel or Humira

C. **If you have psoriatic arthritis (PsA), our guideline also requires:**
   1. You are 18 years of age or older
   2. You have previously tried at least ONE of the following DMARDs (disease-modifying antirheumatic drugs): methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   3. You have previously tried TWO of the following: Cosentyx, Enbrel, or Humira

D. **If you have ankylosing spondylitis (AS), our guideline also requires:**
   1. You are 18 years of age or older
   2. You have previously tried a non-steroidal anti-inflammatory agent (NSAID), unless there is a medical reason why you cannot
   3. You have previously tried TWO of the following: Cosentyx, Enbrel, or Humira

E. **If you have moderate to severe plaque psoriasis (PsO), our guideline also requires:**
   1. You are 18 years of age or older
   2. Plaque psoriasis (rashes) involves greater than or equal to 10% of body surface area (BSA) OR psoriatic lesions affecting the face, hands, feet, or genital area
   3 You have previously tried ONE of the following preferred therapies: PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
   4. You have previously tried TWO of the following: Cosentyx, Enbrel, or Humira
   5. Documentation of your current weight

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

F. **If you have moderate to severe Crohn's disease (CD), our guideline also requires:**
   1. You are 18 years of age or older
   2. You have previously tried ONE of the following conventional agents: corticosteroids (e.g., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   3. You have previously tried Humira

G. **If you have non-radiographic axial spondyloarthritis (nr-axSpA), our guideline also requires:**
   1. You are 18 years of age or older
   2. You have ONE of the following objective signs (shown by lab data) of inflammation:
      a. C-reactive protein (CRP: measures how much inflammation you have) levels above the upper limit of normal
      b. Sacroiliitis (inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI)

RENEWAL CRITERIA

Our guideline for **CERTOLIZUMAB PEGOL** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (inflammation and stiffness in joints)
   2. Psoriatic arthritis (joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (inflammation and stiffness affecting spine and large joints)
   4. Moderate to severe plaque psoriasis (dry, itchy skin patches with scales)
   5. Moderate to severe Crohn's disease (type of inflammatory disease that affects lining of digestive tract)
   6. Non-radiographic axial spondyloarthritis (type of inflammation in the spine).

B. You have experienced or maintained symptomatic improvement while on therapy.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

CERTOLIZUMAB PEGOL

RATIONALE
Ensure appropriate diagnostic, utilization and safety criteria are used for the management of requests for Cimzia.

FDA APPROVED INDICATIONS
Cimzia is a tumor necrosis factor (TNF) blocker indicated for:

- Reducing signs and symptoms of Crohn's disease and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy.
- Treatment of adults with moderately to severely active rheumatoid arthritis.
- Treatment of adult patients with active psoriatic arthritis.
- Treatment of adults with active ankylosing spondylitis.
- Treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation.
- Treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

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CERTOLIZUMAB PEGOL

FDA APPROVED INDICATIONS (CONTINUED)

DOSING

Crohn's Disease: 400 mg initially and at weeks 2 and 4. If response occurs, follow with 400 mg every four weeks.
Rheumatoid Arthritis: 400 mg initially and at weeks 2 and 4, followed by 200 mg every other week; for maintenance dosing, 400 mg every 4 weeks can be considered.
Psoriatic Arthritis: 400 mg initially and at week 2 and 4, followed by 200 mg every other week; for maintenance dosing, 400 mg every 4 weeks can be considered.
Ankylosing Spondylitis: 400 mg initially and at weeks 2 and 4, followed by 200 mg every other week or 400 mg every 4 weeks.
Non-radiographic Axial Spondyloarthritis: 400 mg initially and at weeks 2 and 4, followed by 200 mg every other week or 400 mg every 4 weeks.
Plaque Psoriasis: 400 mg every other week. For some patients (with body weight ≤ 90 kg), a dose of 400 mg initially and at Weeks 2 and 4, followed by 200 mg every other week may be considered.

REFERENCES

- UCB, Inc. Cimzia product information, Smyrna, GA. September 2019.
- Braun J, Davis J, et al. First update of the international ASAS consensus statement for the use of anti-TNF agents in patients with Ankylosing Spondylitis. Ann Rheum Dis. 2006; 65(3):316-20.
- Lichtenstein G, Loftus EV, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. American Journal of Gastroenterology: April 2018, Volume 113, Issue 4, pp 481-517. doi: 10.1038/ajg.2018.27
- Menter A, Strober BE, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.
- Singh JA, Guyatt G, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Care & Research. Vol. 71, No. 1, January 2019, pp 2–29DOI 10.1002/acr.2378.
- Singh JA, Saag KG, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. 2016;68(1):1-25. DOI 10.1002/acr.22783.

Created: 03/15
Effective: 04/11/22 Client Approval: 03/10/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

CHENODIOL

Generic	Brand	HICL	GCN	Exception/Other
CHENODIOL	CHENODAL	01364		

This drug requires a written request for prior authorization

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline for **CHENODIOL** requires a diagnosis of radiolucent gallstones or cerebrotendinous xanthomatosis. The following criteria must also be met:

For the diagnosis of radiolucent gallstones:
- Previous trial of or contraindication to ursodiol
- The patient has not received previous chenodiol therapy with a total duration exceeding 24 months

RENEWAL CRITERIA

The guideline for **CHENODIOL** requires a diagnosis of radiolucent gallstones or cerebrotendinous xanthomatosis. The following criteria must also be met:

For the diagnosis of radiolucent gallstones:
- The patient has **NOT** exceeded a total of 24 months of previous chenodiol therapy
- The patient does **NOT** have complete or no gallstone dissolution seen on imaging (e.g., oral cholecystograms or ultrasonograms) after 12 months of therapy
- The patient has partial gallstone dissolution seen on imaging (e.g., oral cholecystograms or ultrasonograms) after 12 months of therapy

For the diagnosis of cerebrotendinous xanthomatosis:
- Physician attestation of improvement in **ONE** of the following:
  - Normalization of elevated serum or urine bile alcohols
  - Normalization of elevated serum cholestanol levels
  - Improvement in neurologic and psychiatric symptoms (dementia, pyramidal tract and cerebellar signs)

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CHENODIOL

RATIONALE
Ensure appropriate utilization for chenodiol.

FDA APPROVED INDICATIONS

Chenodiol is indicated for patients with radiolucent stones in well-opacifying gallbladders, in whom selective surgery would be undertaken except for the presence of increased surgical risk due to systemic disease or age. The likelihood of successful dissolution is far greater if the stones are floatable or small. For patients with nonfloatable stones, dissolution is less likely and added weight should be given to the risk that more emergent surgery might result from a delay due to unsuccessful treatment. Safety of use beyond 24 months is not established. Chenodiol will not dissolve calcified (radiopaque) or radiolucent bile pigment stones.

Because of the potential hepatoxicity of chenodiol, poor response rate in some subgroups of chenodiol-treated patients, and an increased rate of a need for cholecystectomy in other chenodiol-treated subgroups, chenodiol is not an appropriate treatment for many patients with gallstones. Chenodiol should be reserved for carefully selected patients and treatment must be accompanied by systematic monitoring for liver function alterations. Aspects of patient selection, response rates and risks versus benefits are given in the package insert.

Chenodiol is used off-label for the treatment of cerebrotendinous xanthomatosis.

DOSAGE AND ADMINISTRATION

Radiolucent gallstones:
The recommended dose range for chenodiol is 13 to 16mg/kg/day in two divided doses, morning and night. Starting with 250 mg two times a day for the first two weeks and increasing by 250 mg/day each week thereafter until the recommended or maximum tolerated dose is reached. If diarrhea occurs during dosage buildup or later in treatment, it usually can be controlled by temporary dosage adjustment until symptoms abate, after which the previous dosage usually is tolerated. Dosage less than 10 mg/kg usually is ineffective and may be associated with increased risk of cholecystectomy, so is not recommended.

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CHENODIOL

DOSAGE AND ADMINISTRATION (CONTINUED)

Cerebrotendinous xanthomatosis:
The recommended dose for chenodiol for adults is 250 mg three times a day and 15 mg/kg per day in three divided doses for children.

REFERENCES

- Chenodal [Prescribing Information]. Manchester Pharmaceuticals, Inc. Fort Collins, CO. Sept 2009.
- Ransohoff DF, Gracie WA. Guidelines for the Treatment of Gallstones. *Ann Intern Med*. 1993; 119:620-622.
- UpToDate, Inc. Cerebrotendinous xanthomatosis. UpToDate [database online]. Last updated Dec 20, 2016.
- UpToDate, Inc. Nonsurgical treatment of gallstones. UpToDate [database online]. Last updated Mar 6, 2018.

Created: 03/19
Effective: 07/01/19 Client Approval: 05/13/19 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

CHOLIC ACID

Generic	Brand	HICL	GCN	Exception/Other
CHOLIC ACID	CHOLBAM	39124		ROUTE = ORAL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline for **CHOLIC ACID** requires that the patient exhibit manifestations of liver disease, steatorrhea, or complications from decreased fat-soluble vitamin absorption secondary to one of the following conditions:

- Bile acid synthesis disorders **or**
- Peroxisomal disorders (i.e., Zellweger spectrum disorders).

RENEWAL CRITERIA

Our guideline for **CHOLIC ACID** renewal requires improvement in liver function (as defined by at least one of the following criteria):

- ALT or AST values reduced to <50 U/L or baseline levels reduced by 80% or
- Total bilirubin values reduced to <1 mg/dL or
- No evidence of cholestasis on liver biopsy.

CHOLIC ACID

RATIONALE

Promote appropriate utilization of Cholbam (cholic acid) based on FDA approved indication.

Cholbam (cholic acid) is the first FDA approved treatment for pediatric and adult patients with bile acid synthesis disorders due to single enzyme defects (SEDs), and for patients with peroxisomal disorders (PDs), including Zellweger spectrum disorders. Ursodeoxycholic acid treatment has been found to have limited benefits for the treatment of bile acid defects, however, oral primary bile acid replacement by chenodeoxycholic acid or cholic acid is required for these defects to down-regulate endogenous bile acid synthesis. Cholic acid is now recognized as the bile acid of choice because it is not hepatotoxic, and it is effective therapy for errors in bile acid synthesis due to SEDs. Cholic acid has previously been available as an Investigation New Drug (IND), and study trials for cholic acid have exceeded eighteen years in duration.

The combined incidence of peroxisomal disorders is in excess of 1 in 20,000 individuals. Zellweger syndrome (ZWS) is the most common peroxisomal disorder to manifest itself in early infancy. Its incidence has been estimated to be 1 in 50,000-100,000. Patients with these rare disorders lack the enzymes needed to synthesize cholic acid, a primary bile acid normally produced in the liver from cholesterol. The absence of cholic acid in these patients leads to reduced bile flow, and malabsorption of fats and fat-soluble vitamins in the diet. If untreated, patients fail to grow and can develop life-threatening liver injury.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

CHOLIC ACID

FDA APPROVED INDICATIONS

- Treatment of bile acid synthesis disorders due to single enzyme defects (SEDs).
- Adjunctive treatment of peroxisomal disorders (PDs) including Zellweger spectrum disorders in patients who exhibit manifestations of liver disease, steatorrhea or complications from decreased fat-soluble vitamin absorption.

Limitations of use: The effectiveness of Cholbam for the management of extrahepatic manifestations of bile acid synthesis disorders due to SEDs or PDs has not been established.

DOSAGE

The dosage regimen for bile acid synthesis disorders due to SEDs and for PDs, including Zellweger Spectrum Disorders, is 10 to 15mg/kg given orally once daily or in two divided doses. Patients with newly diagnosed or a family history of familial hypertriglyceridemia may have poor absorption of Cholbam and require a 10% increase in the recommended dosage (11 to 17mg/kg orally once or twice daily).

Cholbam is available in 50mg and 250mg capsules and should be given in the lowest dose that effectively maintains liver function. Cholbam should be taken with food, and at least one hour before or 4-6 hours after a bile acid binding resin or an aluminum-based antacid. For patients unable to swallow the capsules, the capsules can be opened and the contents mixed with either infant formula or expressed breast milk (for younger children), or soft food such as mashed potatoes or apple puree (for older children and adults) in order to mask any unpleasant taste.

REFERENCES

- Cholbam [Prescribing Information]. Baltimore, MD: Asklepion Pharmaceuticals, LLC; March 2015.

Created: 05/15
Effective: 11/01/15 Client Approval: 09/15 P&T Approval: 05/15

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

CLADRIBINE

Generic	Brand	HICL	GCN	Exception/Other
CLADRIBINE	MAVENCLAD		44338	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named **CLADRIBINE (Mavenclad)** requires a diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., relapsing- remitting MS [RRMS], active secondary progressive MS [SPMS], etc.). In addition, the following criteria must be met:

- The patient is 18 years of age or older
- The patient meets **ONE** of the following:
  - The patient had a previous trial of **ONE** agent indicated for the treatment of multiple sclerosis (MS) (**Please note:** The following agents are preferred and may also require prior authorization: Avonex, Aubagio, Copaxone 40, Gilenya, Glatopa, Rebif, Tecfidera)
  - Physician attestation that the patient shows signs of severe disease requiring high-efficacy disease modifying therapy (DMT) (e.g., high lesion volume and/or count, walking disability, or rapid decline)

RENEWAL CRITERIA

The guideline named **CLADRIBINE (Mavenclad)** requires a diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., relapsing- remitting MS [RRMS], active secondary progressive MS [SPMS], etc.) AND the patient has not received a total of two years of Mavenclad treatment. In addition, the following criteria must be met:

- Physician attestation that the patient has demonstrated a clinical benefit compared to pre-treatment baseline
- The patient does not have lymphopenia

RATIONALE

To ensure safe and appropriate use of Mavenclad per approved indication and dosing.

FDA APPROVED INDICATIONS

Mavenclad is a purine antimetabolite indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, use of Mavenclad is generally recommended for patients who have had an inadequate response to, or are unable to tolerate, an alternate drug indicated for the treatment of MS. Mavenclad is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile.

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CLADRIBINE

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

The recommended cumulative dosage of Mavenclad is 3.5 mg per kg body weight administered orally and divided into 2 yearly treatment courses (1.75 mg per kg per treatment course) (see Table 1).

Each treatment course is divided into 2 treatment cycles:

- Administration of First Treatment Course
  - First Course/First Cycle: start any time.
  - First Course/Second Cycle: administer 23 to 27 days after the last dose of First Course/First Cycle.
- Administration of Second Treatment Course
  - Second Course/First Cycle: administer at least 43 weeks after the last dose of First Course/Second Cycle.
  - Second Course/Second Cycle: administer 23 to 27 days after the last dose of Second Course/First Cycle.

Table 1: Dose of Mavenclad by Patient Weight in Each Treatment Course

Weight Range (kg)	Dose in mg (Number of 10mg Tablets) per Cycle	
	First Cycle	Second Cycle
40* to less than 50	40 mg (4 tablets)	40 mg (4 tablets)
50 to less than 60	50 mg (5 tablets)	50 mg (5 tablets)
60 to less than 70	60 mg (6 tablets)	60 mg (6 tablets)
70 to less than 80	70 mg (7 tablets)	70 mg (7 tablets)
80 to less than 90	80 mg (8 tablets)	70 mg (7 tablets)
90 to less than 100	90 mg (9 tablets)	80 mg (8 tablets)
100 to less than 110	100 mg (10 tablets)	90 mg (9 tablets)
110 and above	100 mg (10 tablets)	100 mg (10 tablets)

*The use of Mavenclad in patients weighing less than 40 kg has not been investigated.

Administer the cycle dosage as 1 or 2 tablets once daily over 4 or 5 consecutive days. Do not administer more than 2 tablets daily.

REFERENCES

- Mavenclad [Prescribing Information]. Rockland, MA: EMD Serono, Inc., March 2019.

Created: 12/19
Effective: 12/16/19 Client Approval: 12/03/19 P&T Approval: N/A

CLONIDINE/GUANFACINE

Generic	Brand	HICL	GCN	Exception/Other
CLONIDINE HCL	CATAPRES	00113		
CLONIDINE	CATAPRES-TTS	00113, 36550		
CLONIDINE HCL	KAPVAY	00113		
GUANFACINE HCL	INTUNIV	00120		
GUANFACINE HCL	GUANFACINE HCL	00120		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

See appendix for standard monthly quantity limits.

Our guideline named **CLONIDINE/GUANFACINE** does not allow the use of the requested medication at the requested dose/regimen. Please consider an alternate dose or dosing schedule.

Our guideline for **CLONIDINE/GUANFACINE** for patients with claims suggesting therapeutic duplication requires that the medications are being cross-tapered. Duplication of therapy will be allowed for patients who meet **ALL** of the following criteria:

- Diagnosis of ADD/ADHD or hypertension
- Systolic blood pressure > 100
- The prescriber has provided rationale as to why the same chemical entity (i.e., clonidine ER with clonidine IR, guanfacine IR with guanfacine ER) cannot be used throughout the day rather than duplicating therapy with two alpha2-adrenergic agonists

**Please note that the following concurrent uses will be allowed:*

- *Clonidine ER product with a clonidine IR product*
- *Guanfacine ER product with a guanfacine IR product*

RENEWAL CRITERIA

The guideline for **CLONIDINE/GUANFACINE** renewal requires that there is history of paid claims for the requested alpha$_2$-adrenergic agonist (i.e., clonidine or guanfacine) for 90 of the past 120 days and that the patient has been previously approved for the requested therapy.

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CLONIDINE/GUANFACINE

RATIONALE
To promote prudent prescribing of alpha$_2$-adrenergic agonists.

Duplicate alpha$_2$-adrenergic agonist therapy is characterized as claims for two different chemical entities.

The following concurrent uses will be allowed:
- Clonidine ER product with a clonidine IR product
- Guanfacine ER product with a guanfacine IR product

APPENDIX: Alpha$_2$-Adrenergic Agonist Quantity Limits

GPID	Generic Name	Product Name	Dosage Form	Route	Strength	Utilization Edit
23870	CLONIDINE HCL	CATAPRES-TTS-1	PTWK	TD	0.1MG/ 24 HR	1 PATCH/ WEEK
23871	CLONIDINE HCL	CATAPRES-TTS-2	PTWK	TD	0.2MG/ 24 HR	1 PATCH/ WEEK
23872	CLONIDINE HCL	CATAPRES-TTS-3	PTWK	TD	0.3MG/ 24 HR	2 PATCHES/ WEEK
29319	CLONIDINE HCL	KAPVAY	TB12	OR	0.1MG	4/DAY
27576	GUANFACINE HCL	INTUNIV	TB24	OR	1MG	1/DAY
27578	GUANFACINE HCL	INTUNIV	TB24	OR	2MG	1/DAY
27579	GUANFACINE HCL	INTUNIV	TB24	OR	3MG	1/DAY
27582	GUANFACINE HCL	INTUNIV	TB24	OR	4MG	1/DAY

Created: 10/19
Effective: 03/02/20 Client Approval: 02/14/20 P&T Approval: N/A

CNS STIMULANTS

Generic	Brand	HICL	GCN	Exception/Other
AMPHETAMINE	ADZENYS XR-ODT, ADZENYS ER, DYANAVEL XR	42716 43652		
AMPHETAMINE SULFATE	EVEKEO, EVEKEO ODT	02064		
AMPHETAMINE/D-AMPHETAMINE	ADDERALL, ADDERALL XR, MYDAYIS	13449		
DEXMETHYPHENIDATE HCL	FOCALIN, FOCALIN XR	22987		
DEXTROAMPHETAMINE	XELSTRYM	47926		
DEXTROAMPHETAMINE SULFATE	DEXEDRINE, PROCENTRA, ZENZEDI	02065		
LISDEXAMFETAMINE DIMESYLATE	VYVANSE	34486		
METHAMPHETAMINE HCL	DESOXYN	02067		
METHYLPHENIDATE	DAYTRANA, COTEMPLA XR-ODT	33556		
METHYLPHENIDATE HCL (ORAL)	ADHANSIA XR, APTENSIO XR, CONCERTA, JORNAY PM, METADATE CD, METADATE ER, METHYLIN, QUILLIVANT XR, RITALIN, RITALIN LA, RITALIN SR, QUILLICHEW ER, RELEXXII	01682		
SERDEXMETHYLPHEDNIDATE / DEXMETHYLPHENIDATE	AZSTARYS	47187		

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

CNS STIMULANTS

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline for **CNS STIMULANTS** for patients with claims suggesting therapeutic duplication requires that the medications are being cross-tapered, or that historical medication is being discontinued. Concurrent use of Vyvanse with either dextroamphetamine IR or amphetamine salts IR will be allowed. Please note that the following concurrent uses will be allowed:

- Methylphenidate ER product with a methylphenidate IR product
- Amphetamine salts (Adderall) ER product with an amphetamine salts IR product
- Amphetamine ER (i.e., Dyanavel) product with an amphetamine IR (i.e., Evekeo) product
- Dexmethylphenidate ER product with a dexmethylphenidate IR product
- Dextroamphetamine ER product with a dextroamphetamine IR product
- Vyvanse with IR dextroamphetamine or IR amphetamine salts

RENEWAL CRITERIA

Our guideline for **CNS STIMULANTS** renewal requires that there is history of paid claims for **BOTH** medications identified in the therapeutic duplication for 90 of the past 120 days and that the patient has previous authorizations on file for **BOTH** medications identified in the therapeutic duplication.

Our guideline for **CNS STIMULANTS** renewal requires BOTH of the following:
A. There is history of paid claims for the requested stimulant(s) for 90 of the past 120 days
B. The patient has been previously approved for the requested therapy

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CNS STIMULANTS

RATIONALE

To promote prudent prescribing of CNS stimulants.

A look back period of 60 days will be utilized to identify potential therapeutic duplication.

Duplicate stimulant therapy is characterized as claims for two different chemical entities.

The following concurrent uses will be allowed:

- Methylphenidate ER product with a methylphenidate IR product
- Amphetamine salts (Adderall) ER product with an amphetamine salts IR product
- Amphetamine ER (i.e., Dyanavel) product with an amphetamine IR (i.e., Evekeo) product
- Dexmethylphenidate ER product with a dexmethylphenidate IR product
- Dextroamphetamine ER product with a dextroamphetamine IR product
- Vyvanse with IR dextroamphetamine or IR amphetamine salts

Concomitant claims for immediate-release dextroamphetamine tablets or amphetamine salts (generic Adderall IR) and Vyvanse do not require prior authorization.

APPENDIX: Stimulant Age Edits and Quantity Limits

GPID	Generic Name	Product Name	Dosage Form	Route	Strength	Utilization Edit
39686	AMPHETAMINE	DYANAVEL XR	SUSP	OR	2.5 MG/ ML	8 ML/DAY; Age 6 years and older
51439	AMPHETAMINE	DYANAVEL XR	TABS	OR	5 MG	1/DAY; Age 6 years and older
51452	AMPHETAMINE	DYANAVEL XR	TABS	OR	10 MG	1/DAY; Age 6 years and older
51453	AMPHETAMINE	DYANAVEL XR	TABS	OR	15 MG	1/DAY; Age 6 years and older
51454	AMPHETAMINE	DYANAVEL XR	TABS	OR	20 MG	1/DAY; Age 6 years and older
40647	AMPHETAMINE	ADZENYS XR-ODT	TBDP	OR	3.1 MG	1/DAY; Age 6 years and older
40648	AMPHETAMINE	ADZENYS XR-ODT	TBDP	OR	6.3 MG	1/DAY; Age 6 years and older
40649	AMPHETAMINE	ADZENYS XR-ODT	TBDP	OR	9.4 MG	1/DAY; Age 6 years and older
40650	AMPHETAMINE	ADZENYS XR-ODT	TBDP	OR	12.5 MG	1/DAY; Age 6 years and older
40653	AMPHETAMINE	ADZENYS XR-ODT	TBDP	OR	15.7 MG	1/DAY; Age

						6 years and older
40654	AMPHETAMINE	ADZENYS XR-ODT	TBDP	OR	18.8 MG	1/DAY; Age 6 years and older
43864	AMPHETAMINE	ADZENYS ER	SUSP	OR	1.25 MG/ML	15 ML/DAY; Age 6 years and older
19822	AMPHETAMINE SULFATE	EVEKEO	TABS	OR	5 MG	2/DAY; Age 3 years and older
19821	AMPHETAMINE SULFATE	EVEKEO	TABS	OR	10 MG	6/DAY; Age 3 years and older
45976	AMPHETAMINE SULFATE	EVEKEO-ODT	TBDP	OR	5 MG	2/DAY; Age 3 years and older
45977	AMPHETAMINE SULFATE	EVEKEO-ODT	TBDP	OR	10 MG	2/DAY; Age 3 years and older
45978	AMPHETAMINE SULFATE	EVEKEO-ODT	TBDP	OR	15 MG	2/DAY; Age 3 years and older
45979	AMPHETAMINE SULFATE	EVEKEO-ODT	TBDP	OR	20 MG	2/DAY; Age 3 years and older
56970	AMPHETAMINE-DEXTROAMPHETAMINE	ADDERALL	TABS	OR	5 MG	3/DAY; Age 3 years and older
29007	AMPHETAMINE-DEXTROAMPHETAMINE	ADDERALL	TABS	OR	7.5 MG	3/DAY; Age 3 years and older
56971	AMPHETAMINE-DEXTROAMPHETAMINE	ADDERALL	TABS	OR	10 MG	3/DAY; Age 3 years and older
29008	AMPHETAMINE-DEXTROAMPHETAMINE	ADDERALL	TABS	OR	12.5 MG	3/DAY; Age 3 years and older
29009	AMPHETAMINE-DEXTROAMPHETAMINE	ADDERALL	TABS	OR	15 MG	3/DAY; Age 3 years and older
56973	AMPHETAMINE-DEXTROAMPHETAMINE	ADDERALL	TABS	OR	20 MG	3/DAY; Age 3 years and older
56972	AMPHETAMINE-DEXTROAMPHETAMINE	ADDERALL	TABS	OR	30 MG	3/DAY; Age 3 years and older
17459	AMPHETAMINE-DEXTROAMPHETAMINE	ADDERALL XR	CP24	OR	5 MG	1/DAY; Age 6 years and older
14635	AMPHETAMINE-DEXTROAMPHETAMINE	ADDERALL XR	CP24	OR	10 MG	1/DAY; Age 6 years and older

17468	AMPHETAMINE-DEXTROAMPHETAMINE	ADDERALL XR	CP24	OR	15 MG	1/DAY; Age 6 years and older
14636	AMPHETAMINE-DEXTROAMPHETAMINE	ADDERALL XR	CP24	OR	20 MG	2/DAY; Age 6 years and older
17469	AMPHETAMINE-DEXTROAMPHETAMINE	ADDERALL XR	CP24	OR	25 MG	2/DAY; Age 6 years and older
14637	AMPHETAMINE-DEXTROAMPHETAMINE	ADDERALL XR	CP24	OR	30 MG	2/DAY; Age 6 years and older
43538	AMPHETAMINE-DEXTROAMPHETAMINE 3-BEAD	MYDAYIS	CP24	OR	12.5 MG	1/DAY; Age 13 years and older
43539	AMPHETAMINE-DEXTROAMPHETAMINE 3-BEAD	MYDAYIS	CP24	OR	25 MG	1/DAY; Age 13 years and older
43542	AMPHETAMINE-DEXTROAMPHETAMINE 3-BEAD	MYDAYIS	CP24	OR	37.5 MG	1/DAY; Age 18 years and older
43543	AMPHETAMINE-DEXTROAMPHETAMINE 3-BEAD	MYDAYIS	CP24	OR	50 MG	1/DAY; Age 18 years and older
14973	DEXMETHYLPHENIDATE HCL	FOCALIN	TABS	OR	2.5 MG	2/DAY; Age 3 years and older
14974	DEXMETHYLPHENIDATE HCL	FOCALIN	TABS	OR	5 MG	2/DAY; Age 3 years and older
14975	DEXMETHYLPHENIDATE HCL	FOCALIN	TABS	OR	10 MG	4/DAY; Age 3 years and older
24733	DEXMETHYLPHENIDATE HCL	FOCALIN XR	CP24	OR	5 MG	1/DAY; Age 6 years and older
24734	DEXMETHYLPHENIDATE HCL	FOCALIN XR	CP24	OR	10 MG	1/DAY; Age 6 years and older
97111	DEXMETHYLPHENIDATE HCL	FOCALIN XR	CP24	OR	15 MG	1/DAY; Age 6 years and older
24735	DEXMETHYLPHENIDATE HCL	FOCALIN XR	CP24	OR	20 MG	1/DAY; Age 6 years and older
30305	DEXMETHYLPHENIDATE HCL	FOCALIN XR	CP24	OR	25 MG	1/DAY; Age 6 years and older
28035	DEXMETHYLPHENIDATE HCL	FOCALIN XR	CP24	OR	30 MG	1/DAY; Age 6 years and older
30306	DEXMETHYLPHENIDATE HCL	FOCALIN XR	CP24	OR	35 MG	1/DAY; Age 6 years and

						older
28933	DEXMETHYLPHENIDATE HCL	FOCALIN XR	CP24	OR	40 MG	1/DAY; Age 6 years and older
52134	DEXTROAMPHETAMINE	XELSTRYM	PTCH	TD	4.5 MG/ 9 HR	1/DAY; Age 6 years and older
52135	DEXTROAMPHETAMINE	XELSTRYM	PTCH	TD	9 MG/ 9 HR	1/DAY; Age 6 years and older
52127	DEXTROAMPHETAMINE	XELSTRYM	PTCH	TD	13.5 MG/ 9 HR	1/DAY; Age 6 years and older
52133	DEXTROAMPHETAMINE	XELSTRYM	PTCH	TD	18 MG/ 9 HR	1/DAY; Age 6 years and older
34734	DEXTROAMPHETAMINE SULFATE	ZENZEDI	TABS	OR	2.5 MG	2/DAY; Age 3 years and older
19881	DEXTROAMPHETAMINE SULFATE	ZENZEDI	TABS	OR	5 MG	2/DAY; Age 3 years and older
34735	DEXTROAMPHETAMINE SULFATE	ZENZEDI	TABS	OR	7.5 MG	2/DAY; Age 3 years and older
19880	DEXTROAMPHETAMINE SULFATE	ZENZEDI	TABS	OR	10 MG	4/DAY; Age 3 years and older
19885	DEXTROAMPHETAMINE SULFATE	ZENZEDI	TABS	OR	15 MG	2/DAY; Age 3 years and older
36463	DEXTROAMPHETAMINE SULFATE	ZENZEDI	TABS	OR	20 MG	2/DAY; Age 3 years and older
36464	DEXTROAMPHETAMINE SULFATE	ZENZEDI	TABS	OR	30 MG	2/DAY; Age 3 years and older
99801	DEXTROAMPHETAMINE SULFATE	PROCENTRA	SOLN	OR	5 MG/ 5 ML	40 ML/DAY; Age 3 years and older
19852	DEXTROAMPHETAMINE SULFATE	DEXEDRINE	CP24	OR	5 MG	2/DAY; Age 6 years and older
19850	DEXTROAMPHETAMINE SULFATE	DEXEDRINE	CP24	OR	10 MG	2/DAY; Age 6 years and older
19851	DEXTROAMPHETAMINE SULFATE	DEXEDRINE	CP24	OR	15 MG	2/DAY; Age 6 years and older
37674	LISDEXAMFETAMINE DIMESYLATE	VYVANSE	CAPS	OR	10 MG	1/DAY; Age 6 years and older

99366	LISDEXAMFETAMINE DIMESYLATE	VYVANSE	CAPS	OR	20 MG	1/DAY; Age 6 years and older
98071	LISDEXAMFETAMINE DIMESYLATE	VYVANSE	CAPS	OR	30 MG	1/DAY; Age 6 years and older
99367	LISDEXAMFETAMINE DIMESYLATE	VYVANSE	CAPS	OR	40 MG	1/DAY; Age 6 years and older
98072	LISDEXAMFETAMINE DIMESYLATE	VYVANSE	CAPS	OR	50 MG	1/DAY; Age 6 years and older
99368	LISDEXAMFETAMINE DIMESYLATE	VYVANSE	CAPS	OR	60 MG	1/DAY; Age 6 years and older
98073	LISDEXAMFETAMINE DIMESYLATE	VYVANSE	CAPS	OR	70 MG	1/DAY; Age 6 years and older
42969	LISDEXAMFETAMINE DIMESYLATE	VYVANSE	CHEW	OR	10 MG	1/DAY; Age 6 years and older
43058	LISDEXAMFETAMINE DIMESYLATE	VYVANSE	CHEW	OR	20 MG	1/DAY; Age 6 years and older
43059	LISDEXAMFETAMINE DIMESYLATE	VYVANSE	CHEW	OR	30 MG	1/DAY; Age 6 years and older
43063	LISDEXAMFETAMINE DIMESYLATE	VYVANSE	CHEW	OR	40 MG	1/DAY; Age 6 years and older
43064	LISDEXAMFETAMINE DIMESYLATE	VYVANSE	CHEW	OR	50 MG	1/DAY; Age 6 years and older
43065	LISDEXAMFETAMINE DIMESYLATE	VYVANSE	CHEW	OR	60 MG	1/DAY; Age 6 years and older
19932	METHAMPHETAMINE HCL	DESOXYN	TABS	OR	5 MG	Age 6 years and older
26801	METHYLPHENIDATE	DAYTRANA	PTCH	TD	10 MG/ 9 HR	1/DAY; Age 6 years and older
26802	METHYLPHENIDATE	DAYTRANA	PTCH	TD	15 MG/ 9 HR	1/DAY; Age 6 years and older
26803	METHYLPHENIDATE	DAYTRANA	PTCH	TD	20 MG/ 9 HR	1/DAY; Age 6 years and older
26804	METHYLPHENIDATE	DAYTRANA	PTCH	TD	30 MG/ 9 HR	1/DAY; Age 6 years and older
43534	METHYLPHENIDATE	COTEMPLA XR-ODT	TB24	OR	8.6 MG	1/DAY; Age 6 years and older

43535	METHYLPHENIDATE	COTEMPLA XR-ODT	TB24	OR	17.3 MG	2/DAY; Age 6 years and older
43536	METHYLPHENIDATE	COTEMPLA XR-ODT	TB24	OR	25.9 MG	2/DAY; Age 6 years and older
40289	METHYLPHENIDATE HCL	QUILLICHEW ER	CHEW	OR	20 MG	1/DAY; Age 6 years and older
40292	METHYLPHENIDATE HCL	QUILLICHEW ER	CHEW	OR	30 MG	2/DAY; Age 6 years and older
40293	METHYLPHENIDATE HCL	QUILLICHEW ER	CHEW	OR	40 MG	1/DAY; Age 6 years and older
44356	METHYLPHENIDATE HCL	ADHANSIA XR	CPCR	OR	25 MG	1/DAY; Age 6 years or older
44358	METHYLPHENIDATE HCL	ADHANSIA XR	CPCR	OR	35 MG	1/DAY; Age 6 years or older
44362	METHYLPHENIDATE HCL	ADHANSIA XR	CPCR	OR	45 MG	1/DAY; Age 6 years or older
44363	METHYLPHENIDATE HCL	ADHANSIA XR	CPCR	OR	55 MG	1/DAY; Age 6 years or older
44364	METHYLPHENIDATE HCL	ADHANSIA XR	CPCR	OR	70 MG	1/DAY; Age 6 years or older
44365	METHYLPHENIDATE HCL	ADHANSIA XR	CPCR	OR	85 MG	1/DAY; Age 6 years or older
20384	METHYLPHENIDATE HCL	METADATE CD	CPCR	OR	10 MG	1/DAY; Age 6 years and older
13176	METHYLPHENIDATE HCL	METADATE CD	CPCR	OR	20 MG	1/DAY; Age 6 years and older
20386	METHYLPHENIDATE HCL	METADATE CD	CPCR	OR	30 MG	1/DAY; Age 6 years and older
26734	METHYLPHENIDATE HCL	METADATE CD	CPCR	OR	40 MG	1/DAY; Age 6 years and older
26735	METHYLPHENIDATE HCL	METADATE CD	CPCR	OR	50 MG	1/DAY; Age 6 years and older
26736	METHYLPHENIDATE HCL	METADATE CD	CPCR	OR	60 MG	1/DAY; Age 6 years and older
15913	METHYLPHENIDATE HCL	RITALIN	TABS	OR	5 MG	3/DAY; Age 3 years and

						older
15911	METHYLPHENIDATE HCL	RITALIN	TABS	OR	10 MG	3/DAY; Age 3 years and older
15920	METHYLPHENIDATE HCL	RITALIN	TABS	OR	20 MG	3/DAY; Age 3 years and older
93075	METHYLPHENIDATE HCL	METHYLPHENIDATE HCL ER	TBCR	OR	10 MG	3/DAY; Age 6 years and older
16180	METHYLPHENIDATE HCL	METADATE ER	TBCR	OR	20 MG	3/DAY; Age 6 years and older
12567	METHYLPHENIDATE HCL	CONCERTA	TBCR	OR	18 MG	1/DAY; Age 6 years and older
17123	METHYLPHENIDATE HCL	CONCERTA	TBCR	OR	27 MG	1/DAY; Age 6 years and older
12568	METHYLPHENIDATE HCL	CONCERTA	TBCR	OR	36 MG	2/DAY; Age 6 years and older
12248	METHYLPHENIDATE HCL	CONCERTA	TBCR	OR	54 MG	2/DAY; Age 6 years and older
52485	METHYLPHENIDATE HCL	RELEXXII	TBCR	OR	45 MG	2/DAY; Age 6 years and older
52486	METHYLPHENIDATE HCL	RELEXXII	TBCR	OR	63 MG	1/DAY; Age 6 years and older
44239	METHYLPHENIDATE HCL	RELEXXII	TBCR	OR	72 MG	1/DAY; Age 6 years and older
22682	METHYLPHENIDATE HCL	METHYLPHENIDATE HCL	CHEW	OR	2.5 MG	3/DAY; Age 3 years and older
22683	METHYLPHENIDATE HCL	METHYLPHENIDATE HCL	CHEW	OR	5 MG	3/DAY; Age 3 years and older
22684	METHYLPHENIDATE HCL	METHYLPHENIDATE HCL	CHEW	OR	10 MG	3/DAY; Age 3 years and older
33887	METHYLPHENIDATE HCL	QUILLIVANT XR	SUSR	OR	25 MG/ 5ML	12ML/DAY; Age 6 years and older
22685	METHYLPHENIDATE HCL	METHYLIN	SOLN	OR	5 MG/ 5 ML	60ML/DAY; Age 3 years and older
22686	METHYLPHENIDATE HCL	METHYLIN	SOLN	OR	10 MG/ 5 ML	30ML/DAY; Age 3 years and older

21763	METHYLPHENIDATE HCL	RITALIN LA	CP24	OR	10 MG	1/DAY; Age 6 years and older
20387	METHYLPHENIDATE HCL	RITALIN LA	CP24	OR	20 MG	1/DAY; Age 6 years and older
20388	METHYLPHENIDATE HCL	RITALIN LA	CP24	OR	30 MG	2/DAY; Age 6 years and older
20391	METHYLPHENIDATE HCL	RITALIN LA	CP24	OR	40 MG	1/DAY; Age 6 years and older
36195	METHYLPHENIDATE HCL	METHYLPHENIDATE HCL ER	CP24	OR	60 MG	1/DAY; Age 6 years and older
97234	METHYLPHENIDATE HCL	APTENSIO XR	CP24	OR	10 MG	1/DAY; Age 6 years and older
97235	METHYLPHENIDATE HCL	APTENSIO XR	CP24	OR	15 MG	1/DAY; Age 6 years and older
97236	METHYLPHENIDATE HCL	APTENSIO XR	CP24	OR	20 MG	1/DAY; Age 6 years and older
97237	METHYLPHENIDATE HCL	APTENSIO XR	CP24	OR	30 MG	1/DAY; Age 6 years and older
97238	METHYLPHENIDATE HCL	APTENSIO XR	CP24	OR	40 MG	1/DAY; Age 6 years and older
97239	METHYLPHENIDATE HCL	APTENSIO XR	CP24	OR	50 MG	1/DAY; Age 6 years and older
97240	METHYLPHENIDATE HCL	APTENSIO XR	CP24	OR	60 MG	1/DAY; Age 6 years and older
12567	METHYLPHENIDATE HCL	METHYLPHENIDATE HCL ER	TBCR	OR	18 MG	1/DAY; Age 6 years and older
45106	METHYLPHENIDATE HCL	JORNAY PM	CP24	OR	20 MG	1/DAY; Age 6 years and older
45107	METHYLPHENIDATE HCL	JORNAY PM	CP24	OR	40 MG	1/DAY; Age 6 years and older
45108	METHYLPHENIDATE HCL	JORNAY PM	CP24	OR	60 MG	1/DAY; Age 6 years and older
45109	METHYLPHENIDATE HCL	JORNAY PM	CP24	OR	80 MG	1/DAY; Age 6 years and older
45110	METHYLPHENIDATE HCL	JORNAY PM	CP24	OR	100 MG	1/DAY; Age 6 years and

						older
49319	SERDEXMETHYLPHENIDATE/ DEXMETHYLPHENIDATE	AZSTARYS	CAPS	OR	26.1 MG/ 5.2 MG	1/DAY; Age 6 years and older
49322	SERDEXMETHYLPHENIDATE/ DEXMETHYLPHENIDATE	AZSTARYS	CAPS	OR	39.2 MG/ 7.8 MG	1/DAY; Age 6 years and older
49323	SERDEXMETHYLPHENIDATE/ DEXMETHYLPHENIDATE	AZSTARYS	CAPS	OR	52.3 MG/ 10.4 MG	1/DAY; Age 6 years and older

Created: 09/16
Effective: 07/01/22 Client Approval: 07/20/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

COBICISTAT

Generic	Brand	HICL	GCN	Exception/Other
COBICISTAT	TYBOST	41076		

GUIDELINES FOR USE

Our guideline for **COBICISTAT** requires that Tybost (cobicistat) be used in combination with once daily Prezista (darunavir) or Reyataz (atazanavir) for the treatment of HIV-1. A trial of Norvir (ritonavir) is also required.

RATIONALE

Ensure cost-effective use of Tybost as per FDA approved indication and dosing and to prefer the formulary alternative, Norvir (ritonavir).

FDA APPROVED INDICATIONS

Tybost is a CYP3A inhibitor indicated to increase systemic exposure of atazanavir or darunavir (once daily dosing regimen) in combination with other antiretroviral agents in the treatment of HIV-1 infection.

Limitations of Use:

- Tybost is not interchangeable with ritonavir to increase systemic exposure of darunavir 600 mg twice daily, fosamprenavir, saquinavir, or tipranavir due to lack of exposure data. The use of Tybost is not recommended with darunavir 600 mg twice daily, fosamprenavir, saquinavir or tipranavir.
- Complex or unknown mechanisms of drug interactions preclude extrapolation of ritonavir drug interactions to certain Tybost interactions. Tybost and ritonavir when administered with either atazanavir or darunavir may result in different drug interactions when used with concomitant medications.

DOSING

One 150mg Tybost tablet must be coadministered with Reyataz or Prezista at the same time, with food, and in combination with other HIV-1 antiretroviral agents.

Recommended dosage

TYBOST Dosage	Coadministered Agent Dosage	Patient Populations
150 mg orally once daily	atazanavir 300 mg orally once daily	Treatment-naïve or experienced
	darunavir 800 mg orally once daily	Treatment-naïve Treatment-experienced with no darunavir resistance associated substitutions

REFERENCES

- Tybost [Prescribing Information]. Foster City, CA: Gilead Sciences Inc., September 2014

Created: 06/15
Effective: 07/22/15 Client Approval: 06/15 P&T Approval: 11/14

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

COBIMETINIB

Generic	Brand	HICL	GCN	Exception/Other
COBIMETINIB FUMARATE	COTELLIC	42796		

GUIDELINES FOR USE

Our guideline for **COBIMETINIB (Cotellic)** requires a diagnosis of unresectable or metastatic melanoma. In addition, both of the following criteria must be met:

- Positive for BRAF V600E **OR** V600K mutation, and
- Cobimetinib will be used in combination with vemurafenib (Zelboraf).

RATIONALE
To ensure appropriate use of Cotellic consistent with FDA approved indication.

FDA APPROVED INDICATION
Cotellic (cobimetinib) is a kinase inhibitor indicated for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with vemurafenib. Cotellic is not indicated for treatment of patients with wild-type BRAF melanoma.

DOSAGE
The recommended dose is 60 mg orally once daily for the first 21 days of each 28-day cycle until disease progression or unacceptable toxicity.

AVAILABLE STRENGTHS:

- 20 mg tablet

REFERENCES

- Cotellic [Prescribing Information]; San Francisco, CA: Genentech USA, Inc.; November 2015.

Created: 02/18
Effective: 07/01/18 Client Approval: 05/21/18 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

COLCHICINE

Generic	Brand	HICL	GCN	Exception/Other
COLCHICINE	GLOPERBA		45974	

GUIDELINES FOR USE

The guideline named **COLCHICINE (Gloperba)** requires that the requested medication is being used for the prophylaxis of gout flares. In addition, the patient must meet the following:

- The patient is 18 years of age or older
- The patient is unable to swallow colchicine tablets or the patient has difficulty swallowing that requires the use of a liquid formulation

RATIONALE

To ensure safe and appropriate use of colchicine per approved indication.

FDA APPROVED INDICATIONS

Gloperba is indicated for prophylaxis of gout flares in adults.

DOSAGE AND ADMINISTRATION

For prophylaxis of gout flares, the recommended dosage of Gloperba is 0.6 mg (5 mL) once or twice daily. The maximum dose is 1.2 mg/day.

REFERENCES

Gloperba. [Prescribing Information]. Alpharetta, GA: Avion Pharmaceuticals, LLC; August 2019.

Created: 12/19
Effective: 04/13/20 Client Approval: 12/09/19 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

CONTINUOUS GLUCOSE MONITORS

Generic	Brand	HICL	GCN	Exception/Other
CONTINUOUS BLOOD-GLUCOSE METER	DEXCOM G4, DEXCOM G5, DEXCOM G6, DEXCOM G7	36756		BRAND ≠ DEXCOM
FLASH GLUCOSE SCANNING READER	FREESTYLE LIBRE 14/10, FREESTYLE LIBRE 2	44578		
BLOOD-GLUCOSE TRANSMITTER	DEXCOM G4, DEXCOM G5, DEXCOM G6, EVERSENSE SMART TRANSMITTER, GUARDIAN CONNECT TRANSMITTER	36760		BRAND = DEXCOM G4, DEXCOM G5, DEXCOM G6, EVERSENSE SMART TRANSMITTER, GUARDIAN CONNECT TRANSMITTER
BLOOD-GLUCOSE SENSOR	DEXCOM G6 SENSOR, DEXCOM G5-G4 SENSOR, DEXCOM G7 SENSOR GUARDIAN SENSOR 3	36696		BRAND = DEXCOM G5-G4 SENSOR, DEXCOM G6 SENSOR, DEXCOM G7 SENSOR, GUARDIAN SENSOR 3
FLASH GLUCOSE SENSOR	FREESTYLE LIBRE 14/10 SENSOR, FREESTYLE LIBRE 2 SENSOR, FREESTYLE LIBRE 3 SENSOR	44576		

Below are the preferred Dexcom G6 NDCs and their associated quantity limits as determined by the state of Indiana:

- Dexcom G6 Receiver (NDC 08627-0091-11): #1 per 365 days.
- Dexcom G6 Sensors (NDC 08627-0053-03): #1 box (three 10-day sensors) per 30 days.
- Dexcom G6 Transmitter (NDC 08627-0016-01): #1 per 90 days.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

CONTINUOUS GLUCOSE MONITORS

GUIDELINES FOR USE

Our guideline for **CONTINUOUS GLUCOSE MONITORS (CGM)** requires **ONE** of the following:
A. You have tried the preferred Dexcom G6 continuous glucose monitor.
B. You are using an insulin pump that requires a non-formulary companion continuous glucose monitor.

RATIONALE

The intent of this guideline is to encourage the use of the preferred continuous glucose monitor before considering coverage of non-preferred alternatives and to encourage testing frequency in accordance with treatment guidelines.

ADDITIONAL INFORMATION

Below are the preferred product NDCs as determined by the state of Indiana:

- Dexcom G6 Receiver: NDC 08627-0091-11
- Dexcom G6 Sensors: NDC 08627-0053-03
- Dexcom G6 Transmitter: NDC 08627-0016-01

REFERENCES

- American Diabetes Association. Standards of Medical Care in Diabetes- 2011. Diabetes Care 2011; 34(suppl 1): S11-S61.
- FreeStyle Libre Flash Glucose Monitoring System and Freestyle Libre 2 System. Abbott Laboratories. Indications and Safety Information. Available at: https://www.freestylelibre.us/safety-information
- Dexcom Continuous Glucose Monitoring Products. Dexcom, Inc. Available at: https://www.dexcom.com/
- Medtronic Guardian Connect. Medtronic MiniMed, Inc. Available at: https://www.medtronicdiabetes.com/products/guardian-connect-continuous-glucose-monitoring-system
- Eversense Continuous Glucose Monitoring System. Senseonics, Inc. Available at: https://www.eversensediabetes.com/

Created: 02/22
Effective: 02/01/23 Client Approval: 12/29/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

CORTICOTROPIN

Generic	Brand	HICL	GCN	Exception/Other
CORTICOTROPIN	H.P. ACTHAR GEL	02830		

GUIDELINES FOR USE

Our guideline for **CORTICOTROPIN** requires a diagnosis of acute exacerbation of multiple sclerosis and an attempt to treat the current exacerbation with corticosteroids, or a diagnosis of infantile spasms in patients less than 2 years of age. For all other FDA indications, consider the use of IV corticosteroids or alternate therapies, as appropriate.

FDA approved indications include: infantile spasm, acute multiple sclerosis, psoriatic arthritis, rheumatoid arthritis including juvenile rheumatoid arthritis, ankylosing spondylitis, systemic lupus erythematosus or systemic dermatomyositis (polymyositis), severe erythema multiforme, Stevens-Johnson syndrome, serum sickness, severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa (such as keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, and anterior segment inflammation), symptomatic sarcoidosis, or to induce a diuresis or a remission of proteinuria (in the nephrotic syndrome without uremia of the idiopathic type, or that due to lupus erythematosus.

CORTICOTROPIN

RATIONALE
Ensure appropriate therapeutic use of this long acting corticotropin formulation.

The recommended regimen for use in infantile spasms is a daily dose of 150 units/m^2 (divided into twice daily intramuscular injections of 75 units/ m^2) then a gradual taper over a 2-week period. A suggested taper schedule is 30 units/ m^2 every morning for 3 days, 15 units/ m^2 every morning for 3 days, 10 units/ m^2 every morning for 3 days, and then 10 units/ m^2 every other morning for 6 days.

8 vials per 28 days supply based on dosage of 150 units/m^2/day with an estimate of 0.7m^2 body surface area, estimated maximum for a child less than 40 pounds (two years old).

The American Academy of Neurology guidelines for treatment of infantile spasms state that response is usually within 2 weeks and current clinical data is insufficient to determine optimum dosage and duration.

The recommended regimen for use of Acthar in treatment of acute exacerbations of multiple sclerosis (MS) is daily intramuscular or subcutaneous doses of 80-120 units for 2-3 weeks.

In a comparable efficacy study to asses IV methylprednisolone (IVMP) versus Acthar, there was no demonstrated difference between efficacy of IVMP and Acthar for the treatment of acute exacerbations of multiple sclerosis.

The manufacturer states that the H.P. Acthar Gel vial expires 28 days after initial puncture, when stored under ideal conditions (per USP standard guidelines).

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CORTICOTROPIN

FDA APPROVED INDICATIONS

Acthar Gel is indicated for the treatment of infantile spasms, for acute exacerbations of multiple sclerosis, and for numerous other diseases and disorders. (See below).

INFANTILE SPASMS: Monotherapy for the treatment of infantile spasms in infants and children under 2 years of age.

MULTIPLE SCLEROSIS: Treatment of acute exacerbations of multiple sclerosis in adults. Controlled clinical trials have shown H.P. Acthar Gel to be effective in speeding the resolution of acute exacerbations of multiple sclerosis. However, there is no evidence that it affects the ultimate outcome or natural history of the disease.

RHEUMATIC DISORDERS: As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: psoriatic arthritis, rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), and ankylosing spondylitis.

COLLAGEN DISEASES: During an exacerbation or as maintenance therapy in selected cases of systemic lupus erythematosus or systemic dermatomyositis (polymyositis).

DERMATOLOGIC DISEASES: Severe erythema multiforme (Stevens-Johnson syndrome).

ALLERGIC STATES: Serum sickness.

OPHTHALMIC DISEASES: Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, and anterior segment inflammation.

RESPIRATORY DISEASES: Symptomatic sarcoidosis.

EDEMATOUS STATE: To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

CORTICOTROPIN

REFERENCES

- H.P. Acthar® Gel (repository corticotropin injection) [prescribing information]. Mallinckrodt ARD, Inc. January 2015. Baram TZ, Mitchell WG et al. High-dose corticotropin (ACTH) versus prednisone for infantile spasms; a prospective, randomized, blinded study. Pediatrics 1996; 97:375–379.
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- Questcor Pharmaceuticals, Inc. HP Acthar Gel package insert. Hayward, CA. June 2011.
- Riikonen R. A long-term follow-up study of 214 children with the syndrome of infantile spasms. Neuropediatrics. 1982; 13:14–23.
- Thompson AJ, Kennard C, Swash M, et al. Relative efficacy of intravenous methylprednisolone and ACTH in the treatment of acute relapse in MS. *Neurology*. 1989; 39:969-971.

Created: 06/15
Effective: 09/01/17 Client Approval: 08/14/17 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

CRISABOROLE

Generic	Brand	HICL	GCN	Exception/Other
CRISABOROLE	EUCRISA	43999		

GUIDELINES FOR USE

Note: Claim history and/or chart notes are required as documentation of tried and failed medications.
- Written notes on the request form regarding tried/failed medications will not be accepted.
- Samples will **not** count toward tried/failed medications.
- If the member has active coverage, then claims history is required (i.e., cash payment for non-covered services during a time in which the member has active coverage will not count toward tried/failed medications).

Our guideline named **CRISABOROLE (EUCRISA)** requires that you are at least 2 years of age and that you have tried preferred options before receiving coverage for this drug.

Approval requires you to try a topical corticosteroid and topical tacrolimus. Exceptions may be granted for patients less than two years of age who have a trial of a topical corticosteroid.

In order for your request to be approved, your provider needs to tell us that you have tried the step therapies listed below. Your provider may give a reason why you cannot take our suggested step therapies, including a statement that these therapies would not work as well or could cause side effects.

RATIONALE
To ensure safe and appropriate use of crisaborole for atopic dermatitis per approved indication.

FDA APPROVED INDICATION
Crisaborole (Eucrisa) is indicated for the topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients ≥3 months of age.

REFERENCES

- Pfizer, Inc. Eucrisa package insert. New York, NY. April 2020.

Created: 06/21
Effective: 07/01/21 Client Approval: 06/04/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

CRIZOTINIB

Generic	Brand	HICL	GCN	Exception/Other
CRIZOTINIB	XALKORI	37916		

GUIDELINES FOR USE

Our guideline named **CRIZOTINIB (Xalkori)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread) with anaplastic lymphoma kinase (ALK: a type of enzyme)-positive tumors
   2. Metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread) with ROS1 (a type of enzyme)-positive tumors
   3. Relapsed (disease returns after a period of remission) or refractory (disease does not respond to treatment), systemic anaplastic large cell lymphoma (ALCL: type of blood cell cancer) with anaplastic lymphoma kinase (ALK: a type of enzyme)-positive tumors. You must also be 1 year of age or older.

RATIONALE

Promote appropriate utilization and dosing of Xalkori for its FDA approved indication and NCCN recommendations.

FDA APPROVED INDICATIONS

Xalkori is a kinase inhibitor indicated for the treatment of:

- patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK) or ROS1-positive as detected by an FDA-approved test.
- pediatric patients 1 year of age and older and young adults with relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL) that is ALK-positive.
  - Limitations of Use: The safety and efficacy of Xalkori have not been established in older adults with relapsed or refractory, systemic ALK-positive ALCL.

DOSAGE

- Metastatic NSCLC: The recommended dosage is 250 mg orally twice daily.
- Systemic ALCL: The recommended dosage is 280 mg/m2 orally twice daily based on body surface area.

REFERENCES

- Xalkori [Prescribing Information]. New York, New York: Pfizer; January 2021.

Created: 06/15
Effective: 08/23/21 Client Approval: 08/11/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

CYSTEAMINE BITARTRATE

Generic	Brand	HICL	GCN	Exception/Other
CYSTEAMINE BITARTRATE	PROCYSBI		34656, 34657, 47723, 47724	

GUIDELINES FOR USE

Our guideline named **CYSTEAMINE BITARTRATE (Procysbi)** requires the following rule(s) be met for approval:

A. You have nephropathic cystinosis (rare genetic, metabolic disease which results in an abnormal accumulation of a protein known as cysteine)
B. You are 1 year of age or older
C. You have previously tried an immediate-release formulation of cysteamine bitartrate such as Cystagon

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RATIONALE
To ensure appropriate use of Procysbi consistent with FDA approved indication and to promote cost-effective treatment alternatives.

FDA APPROVED INDICATIONS
For the management of nephropathic cystinosis in patients one year of age and older.

DOSING
Recommended Dosage in Cysteamine-Naïve Patients:

- See full prescribing information for weight-based dosing tables for the starting and maintenance dosage.
- For initial intolerance, temporarily discontinue and then re-start Procysbi at a lower dosage and gradually increase to the maintenance dosage.

Switching from Immediate-release cysteamine to Procysbi

- Start with a total daily dose of PROCYSBI equal to the previous total daily dose of immediate-release cysteamine bitartrate.

Dose Titration

- Adjust dose to achieve a therapeutic target white blood cell (WBC) cystine concentration.
- If a dose adjustment is required, increase the dosage by 10%. The maximum dosage is 1.95 grams/m2 per day.
- If adverse reactions occur, decrease the dosage. Some patients may be unable to achieve their therapeutic target.

REFERENCES

- Procysbi [Prescribing Information]. Novato, CA: Raptor Pharmaceuticals Inc.; February 2020.

Created: 06/15
Effective: 07/01/21 Client Approval: 05/24/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

CYSTEAMINE HYDROCHLORIDE

Generic	Brand	HICL	GCN	Exception/Other
CYSTEAMINE HCL	CYSTARAN, CYSTADROPS		33485, 40466	

GUIDELINES FOR USE

Our guideline named **CYSTEAMINE HYDROCHLORIDE (Cystaran/Cystadrops)** requires the following rule(s) be met for approval:

A. You have cystinosis (a type of genetic disorder where a substance called cysteine builds up in body organs)
B. You require treatment for corneal cystine crystal accumulation or deposits (build-up of cysteine in the eye)

RATIONALE

To ensure appropriate use aligned with FDA approved indication.

FDA APPROVED INDICATIONS

Cystaran is a cystine-depleting agent indicated for the treatment of corneal cystine crystal accumulation in patients with cystinosis.

Cystadrops is a cystine-depleting agent indicated for the treatment of corneal cystine crystal deposits in adults and children with cystinosis.

DOSING

Cystaran: Instill one drop in each eye, every waking hour. Discard bottle 7 days after first opening.

Cystadrops: Instill one drop in each eye, 4 times a day during waking hours. Discard bottle 7 days after first opening.

REFERENCES

- Cystaran [Prescribing Information]. Gaithersburg, MD: Sigma Tau Pharmaceuticals; April 2020.
- Cystadrops [Prescribing Information]. Lebanon, NJ: Recordati Rare Diseases Inc.; August 2020.

Created: 06/15
Effective: 11/16/20 Client Approval: 10/16/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

DABRAFENIB

Generic	Brand	HICL	GCN	Exception/Other
DABRAFENIB MESYLATE	TAFINLAR	40360		

GUIDELINES FOR USE

Our guideline named **DABRAFENIB (Tafinlar)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Unresectable or metastatic melanoma (skin cancer that cannot be completely removed by surgery or has spread to other parts of the body)
   2. Metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
   3. Melanoma (a type of skin cancer)
   4. Locally advanced or metastatic anaplastic thyroid cancer (ATC: a type of thyroid cancer that has spread from where it started to nearby tissue or lymph nodes, or it has spread to other parts of the body)
   5. Unresectable or metastatic solid tumors (tumors that cannot be completely removed by surgery or has spread to other parts of the body)

B. **If you have unresectable or metastatic melanoma, approval also requires ONE of the following:**
   1. You have BRAF V600E mutation (type of gene mutation) as detected by an FDA (Food and Drug Administration)-approved test AND the requested medication will be used as a single agent (by itself)
   2. You have BRAF V600E or V600K mutations (types of gene mutation) as detected by an FDA (Food and Drug Administration)-approved test AND the requested medication will be used in combination with Mekinist (trametinib)

C. **If you have melanoma, approval also requires:**
   1. You have BRAF V600E or V600K mutations (types of gene mutation) as detected by an FDA (Food and Drug Administration)-approved test
   2. The requested medication has not previously been used for more than one year
   3. The requested medication will be used in combination with Mekinist (trametinib) for adjuvant (add-on) treatment
   4. There is involvement of lymph node(s) following complete resection (removal by surgery)

D. **If you have metastatic non-small cell lung cancer, approval also requires:**
   1. You have BRAF V600E mutation (types of gene mutation) as detected by an FDA (Food and Drug Administration)-approved test
   2. The requested medication will be used in combination with Mekinist (trametinib)

E. **If you have locally advanced or metastatic anaplastic thyroid cancer, approval also requires:**
   1. You have BRAF V600E mutation (types of gene mutation) as detected by an FDA (Food and Drug Administration)-approved test
   2. The requested medication will be used in combination with Mekinist (trametinib)
   3. You have no satisfactory locoregional (restricted to a localized region of the body) treatment options available

(Denial text continued on next page)

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DABRAFENIB

GUIDELINES FOR USE (CONTINUED)

F. **If you have unresectable or metastatic solid tumors, approval also requires:**
   1. You are 6 years of age or older
   2. You have a BRAF V600E mutation (type of gene mutation) as detected by an FDA (Food and Drug Administration)-approved test
   3. The requested medication will be used in combination with Mekinist (trametinib)
   4. You have progressed following prior treatment and have no satisfactory alternative treatment options

DABRAFENIB

RATIONALE
Ensure appropriate use of Tafinlar based on FDA approved indications and dosing.

FDA APPROVED INDICATIONS
Tafinlar is a kinase inhibitor indicated as a single agent for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test.

Tafinlar is indicated, in combination with trametinib, for:
- The treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test
- The adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations, as detected by an FDA-approved test, and involvement of lymph node(s) following complete resection
- The treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA-approved test
- The treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options
- The treatment of adult and pediatric patients 6 years of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options

Limitation of Use: Tafinlar is not indicated for treatment of patients with colorectal cancer because of known intrinsic resistance to BRAF inhibition. Tafinlar is not indicated for treatment of patients with wildtype BRAF solid tumors.

DOSAGE AND ADMINISTRATION
The recommended dose for Tafinlar in adult patients is 150 mg orally twice daily.

The recommended dosage for Tafinlar in pediatric patients who weigh at least 26 kg is based on body weight (Table 1). A recommended dose has not been established in patients who weigh less than 26 kg.

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DABRAFENIB

Table 1: Dosing in Pediatric Patients from 6 to 17 Years Old (Weight-Adjusted Dose)

Body Weight	Recommended Dose
26 to 37 kg	75 mg orally twice daily
38 to 50 kg	100 mg orally twice daily
51 kg or greater	150 mg orally twice daily

REFERENCES

Tafinlar [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2022.

Created: 06/15
Effective: 01/30/23 Client Approval: 01/05/23 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

DACLIZUMAB

Generic	Brand	HICL	GCN	Exception/Other
DACLIZUMAB	ZINBRYTA	16921		ROUTE = SUBCUTANEOUS

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline for **DACLIZUMAB** requires a diagnosis of a relapsing form of multiple sclerosis (MS) and that the patient meets the following criteria:

- Patient 18 years of age or older
- Trial of 2 preferred agents that have been FDA approved for the treatment of relapsing forms of multiple sclerosis (MS) (**Please note:** Other MS agents also require prior authorization [Tecfidera, Copaxone, Glatopa, Rebif, Aubagio, Gilenya, Avonex, Plegridy] and may require a prior trial of other medications first.)
- No pre-existing hepatic disease or impairment, including:
  - Active hepatitis B and C
  - Autoimmune hepatitis or other autoimmune conditions involving the liver
  - Baseline ALT and AST at least 2 times upper limit of normal (ULN)

RENEWAL CRITERIA

Our guideline for renewal of **DACLIZUMAB** requires that the patient meet the following criteria:

- No suspected autoimmune hepatitis
- No hepatic injury
  - Defined as elevated transaminases (>5x ULN), total bilirubin (>2x ULN), or both (ALT/AST ≥3x ULN + total bilirubin >1.5 ULN) with no other etiologies identified as a cause for the increases besides therapy with Zinbryta.

DACLIZUMAB

RATIONALE
Promote appropriate utilization of **DACLIZUMAB** based on FDA approved indication, labeled contraindications and dosing.

DOSAGE
The recommended dosage of Zinbryta is 150 milligrams injected subcutaneously once monthly.

A missed dose should be injected as soon as possible but no more than two weeks late. After two weeks, skip the missed dose and take the next dose on schedule. Administer only one dose at a time.

FDA APPROVED INDICATIONS
Zinbryta is an interleukin-2 receptor blocking antibody indicated for the treatment of adult patients with relapsing forms of multiple sclerosis (MS). Because of its safety profile, the use of Zinbryta should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.

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DACLIZUMAB

HOW SUPPLIED

A carton containing a single-dose prefilled syringe providing 1 mL of 150 mg/mL of daclizumab.

REFERENCES

- Zinbryta [Prescribing Information]. Biogen Inc.: Cambridge, MA; May 2016.

Created: 08/16
Effective: 08/25/16 Client Approval: 08/17/16 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

DACOMITINIB

Generic	Brand	HICL	GCN	Exception/Other
DACOMITINIB	VIZIMPRO	45283		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

The guideline named **DACOMITINIB (Vizimpro)** requires a diagnosis of metastatic non-small cell lung cancer (NSCLC). In addition, the following criteria must be met:

- The patient has epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test
- The requested medication will be used as first-line treatment

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RATIONALE
Promote appropriate utilization of **DACOMITINIB (Vizimpro)** based on its FDA approved indications.

FDA APPROVED INDICATION
VIZIMPRO is a kinase inhibitor indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test.

RECOMMENDED DOSAGE
45mg orally once daily with or without food

HOW SUPPLIED
Tablets: 15mg, 30mg, and 45 mg

REFERENCES

- Vizimpro [Prescribing Information]. New York, NY: Pfizer Labs; September 2018.

Created: 11/18
Effective: 11/23/18 Client Approval: 11/06/18 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

DALFAMPRIDINE

Generic	Brand	HICL	GCN	Exception/Other
DALFAMPRIDINE	AMPYRA	13907		EXCLUDE ≠ MISCELL.; POWDER NON-DRUGS

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **DALFAMPRIDINE (Ampyra)** requires the following rule(s) be met for approval:

A. You have multiple sclerosis (MS, disease in which the immune system eats away at the protective covering of nerves)
B. The medication is prescribed by or recommended by a neurologist (doctor who specializes in disorders of the nervous system)

RENEWAL CRITERIA

Our guideline named **DALFAMPRIDINE (Ampyra)** requires the following rule(s) be met for renewal:

A. You have multiple sclerosis (MS, disease in which the immune system eats away at the protective covering of nerves)
B. You have shown improvement (including stabilization) in gait

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RATIONALE
Ensure appropriate utilization for dalfampridine.

FDA APPROVED INDICATIONS
Dalfampridine is approved in adult patients with multiple sclerosis to improve walking.

REFERENCES

- Acorda Therapeutics. Ampyra package insert. Ardsley, NY. February 2021.

Created: 06/15
Effective: 08/16/21 Client Approval: 07/07/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

DAROLUTAMIDE

Generic	Brand	HICL	GCN	Exception/Other
DAROLUTAMIDE	NUBEQA	45909		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **DAROLUTAMIDE (Nubeqa)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Non-metastatic castration resistant prostate cancer (mmCRPC: prostate cancer that has not spread to other parts of the body and does not respond to hormone therapy)
   2. Metastatic hormone-sensitive prostate cancer (mHSPC: prostate cancer that has spread to other parts of the body and responds to hormone therapy)

B. **If you have non-metastatic castration resistant prostate cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You have high risk prostate cancer (rapidly increasing prostate specific antigen [PSA: lab result that may indicate prostate cancer] levels)
   3. You meet ONE of the following:
      a. You previously received a bilateral orchiectomy (both testicles have been surgically removed)
      b. The requested medication will be used together with a gonadotropin releasing hormone analog (such as leuprolide, goserelin, histrelin, degarelix)

C. **If you have metastatic hormone-sensitive prostate cancer, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication will be used in combination with docetaxel

RENEWAL CRITERIA

Our guideline named **DAROLUTAMIDE (Nubeqa)** requires the following rule(s) be met for renewal:

A. You have non-metastatic castration resistant prostate cancer (mmCRPC: prostate cancer that has not spread to other parts of the body and does not respond to hormone therapy)

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

DAROLUTAMIDE

RATIONALE
Promote appropriate utilization and dosing of Nubeqa for its FDA approved indications.

FDA APPROVED INDICATIONS
Nubeqa is an androgen receptor inhibitor indicated for treatment of adult patients with:
- Non-metastatic castration-resistant prostate cancer (nmCRPC).
- Metastatic hormone-sensitive prostate cancer (mHSPC) in combination with docetaxel.

DOSAGE AND ADMINISTRATION
The recommended dosage of Nubeqa is 600 mg administered orally twice daily.

AVAILABLE STRENGTHS
300 mg tablets

REFERENCES
Nubeqa [Prescribing Information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; August 2022.

Created: 10/19
Effective: 11/28/22 Client Approval: 11/15/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

DASATINIB

Generic	Brand	HICL	GCN	Exception/Other
DASATINIB	SPRYCEL	33855		

This drug requires a written request for prior authorization.
GUIDELINES FOR USE

The guideline named **DASATINIB (Sprycel)** requires a diagnosis of Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic, accelerated, or myeloid or lymphoid blast phase, OR Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL). In addition, the following criteria must be met:

For the diagnosis of Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase, approval requires ONE of the following:

- The patient is 18 years of age or older AND is newly diagnosed
- The patient is between 1 and 17 years of age

For the diagnosis of Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase, accelerated phase, or myeloid or lymphoid blast phase, approval requires:

- The patient is 18 years of age or older
- The patient has a resistance or intolerance to prior therapy including imatinib (Gleevec)
- The patient has had Breakpoint Cluster Region Abelson Murine Leukemia (BCR-ABL) mutational analysis confirming that the patient is negative for the following mutations: T315I, V299L, T315A, or F317L/V/I/C

For the diagnosis of Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL), approval requires ONE of the following:

- The patient is 18 years of age or older AND has a resistance or intolerance to prior therapy [e.g., imatinib (Gleevec) or nilotinib (Tasigna)]
- The patient is newly diagnosed, is between 1 and 17 years of age, AND is using Sprycel in combination with chemotherapy

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RATIONALE
Ensure appropriate utilization of dasatinib based on FDA approved indication and NCCN guidelines.

FDA APPROVED INDICATIONS
Sprycel is a kinase inhibitor indicated for the treatment of:

- Newly diagnosed adults with Philadelphia chromosome-positive (PH+) chronic myeloid leukemia (CML) in chronic phase.
- Adults with chronic, accelerated, or myeloid or lymphoid blast phase Philadelphia chromosome-positive chronic myeloid leukemia with resistance or intolerance to prior therapy including imatinib.
- Adults with Philadelphia chromosome-positive acute lymphoblastic leukemia with resistance or intolerance to prior therapy.
- Pediatric patients with Ph+ CML in chronic phase.

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DASATINIB

FDA APPROVED INDICATIONS (CONTINUED)

DOSING

Chronic phase CML in adults:

- 100 mg once daily.

Accelerated phase CML, myeloid or lymphoid blast phase CML, or Ph+ ALL in adults:

- 140 mg once daily.

Chronic phase CML in pediatrics:

- Starting dose based on body weight.
- Tablet dosing is not recommended for patients weighing less than 10 kg.

Body Weight (kg)	Daily Dose (mg)
10 to less than 20	40 mg
20 to less than 30	60 mg
30 to less than 45	70 mg
At least 45	100 mg

Dose reduction to as low as 20mg daily can be considered for patients taking a strong CYP3A4 inhibitor.

REFERENCES

- Bristol-Myers Squibb. Sprycel package insert. Princeton, NJ. December 2018.

Created: 06/15
Effective: 11/01/19 Client Approval: 10/16/19 P&T Approval: 11/13

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

DECITABINE/CEDAZURIDINE

Generic	Brand	HICL	GCN	Exception/Other
DECITABINE/CEDAZURIDINE	INQOVI	46686		

GUIDELINES FOR USE

Our guideline named **DECITABINE/CEDAZURIDINE (Inqovi)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Myelodysplastic syndromes (MDS: type of blood cancer)
   2. Chronic myelomonocytic leukemia (CMML: rare form of blood cancer)

B. You are 18 years of age or older

C. If you have myelodysplastic syndromes (MDS), approval also requires:
   1. You are in ONE of the following International Prognostic Scoring System groups (scoring system used to predict the course of a patient's disease):
      a. Intermediate-1
      b. Intermediate-2
      c. High-risk

RATIONALE
Ensure appropriate diagnostic, utilization and safety criteria are met for the management of requests for Inqovi.

FDA APPROVED INDICATIONS
Inqovi is a combination of decitabine, a nucleoside metabolic inhibitor, and cedazuridine, a cytidine deaminase inhibitor, indicated for treatment of adult patients with myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups.

DOSING
The recommended dosage of Inqovi is 1 tablet (35 mg decitabine and 100 mg cedazuridine) taken orally once daily on Days 1 through 5 of each 28-day cycle.

REFERENCES

- Inqovi [Prescribing Information]. Pleasanton, CA: Astex Pharmaceuticals, Inc.; July 2020.

Created: 09/20
Effective: 11/16/20 Client Approval: 10/16/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

DEFERASIROX

Generic	Brand	HICL	GCN	Exception/Other
DEFERASIROX	EXJADE, JADENU	33337		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named **DEFERASIROX (Exjade, Jadenu)** requires a diagnosis of chronic iron overload due to blood transfusions or non-transfusion dependent thalassemia (NTDT). Treatment must be by or in consultation with a hematologist or hematologist-oncologist. The following criteria must also be met.
Iron overload due to blood transfusions

- At least 2 years of age and older
- Serum ferritin level consistently greater than 1000 mcg/L (at least 2 lab values in previous 3 months)

Non-transfusion dependent thalassemia (NTDT)

- At least 10 years of age and older
- Serum ferritin level consistently greater than 300 mcg/L (at least 2 lab values in previous 3 months)
- Liver iron concentration (LIC) at least 5 mg Fe/g dry weight or greater

RENEWAL CRITERIA

The guideline named **DEFERASIROX (Exjade, Jadenu)** renewal requires a diagnosis of chronic iron overload due to blood transfusions or non-transfusion dependent thalassemia (NTDT). The following criteria must also be met:
Iron overload due to blood transfusions

- Serum ferritin level consistently greater than 500 mcg/L (at least 2 lab values in previous 3 months)

Non-transfusion dependent thalassemia (NTDT)

- Serum ferritin level consistently greater than 300 mcg/L (at least 2 lab values in previous 3 months)
- Liver iron concentration (LIC) at least 3 mg Fe/g dry weight or greater. (*Liver iron concentration supersedes serum ferritin level when both measurements are available*)

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

DEFERASIROX

RATIONALE
Promote appropriate utilization of **DEFERASIROX** based on FDA approved indication and treatment guidelines.

FDA APPROVED INDICATION
Jadenu (deferasirox, tablets or sprinkles) and Exjade (deferasirox, tablets for oral suspension) are indicated for the treatment chronic iron overload due to blood transfusions in patients 2 years of age and older. In addition, Jadenu and Exjade are indicated for the treatment of chronic iron overload in patients 10 years of age and older with non-transfusion-dependent thalassemia (NTDT) syndromes and with a liver iron (Fe) concentration (LIC) of at least 5 mg Fe per gram of dry weight and a serum ferritin greater than 300 mcg/L.

DOSAGE AND ADMINISTRATION
Exjade (deferasirox, tablets for oral suspension):
- Chronic transfusional iron overload: initial 20mg/kg orally once daily on an empty stomach, as an oral suspension. Calculate dose to the nearest whole tablet. Doses above 40mg/kg/day are not recommended.
- Non-transfusion-dependent thalassemia (NTDT): initial 10mg/kg orally once daily on an empty stomach, as an oral suspension. Calculate dose to the nearest whole tablet. Do not exceed a maximum of 20mg/kg/day.

Jadenu (deferasirox, tablets or sprinkles)
- Chronic transfusional iron overload: initial 14mg/kg orally once daily on an empty stomach or with a low-fat meal. Calculate to nearest whole tablet. Doses above 28mg/kg/day are not recommended.
- Non-transfusion-dependent thalassemia (NTDT): initial 7mg/kg orally once daily on an empty stomach or with a low-fat meal. Calculate to nearest whole tablet. Do not exceed a maximum of 14mg/kg/day.

REFERENCES

- Jadenu [Package Insert]. Novartis Pharmaceuticals Corporation, East Hanover, NJ. July 2017.
- Exjade [Package Insert]. Novartis Pharmaceuticals Corporation, East Hanover, NJ. August 2016.
- Standards of Care Guidelines for Thalassemia. 2012. Children's Hospital & Research Center, Oakland CA. Available from: http://thalassemia.com/documents/SOCGuidelines2012.pdf
- Cappellini MD, et al. Guidelines for the Management of Transfusion Dependent Thalassaemia (TDT): Iron Overload and Chelation. 3rd edition. Nicosia (CY): Thalassaemia International Federation; 2014. Accessed 4/10/2017. Access here: http://www.resonancehealth.com/images/files/clinician-information/patient-management-guidelines/TIF%20Guidelines%20for%20the%20Management%20of%20Transfusion%20Dependent%20Thalassaemia.pdf
- Taher A, et al. Guidelines for the Management of Non Transfusion Dependent Thalassaemia (NTDT): Iron Overload and Chelation. Nicosia (CY): Thalassaemia International Federation; 2013. Accessed 4/10/2017. Access here: http://thalassemia.com/documents/NTDT-TIF-guidelines.pdf

Created: 08/17
Effective: 01/01/18 Client Approval: 12/21/17 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

DEFERIPRONE

Generic	Brand	HICL	GCN	Exception/Other
DEFERIPRONE	FERRIPROX	18544		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **DEFERIPRONE (Ferriprox)** requires the following rule(s) be met for approval:

A. You have **ONE** of the following diagnoses:
   1. Transfusional iron overload due to a thalassemia syndrome (you have too much iron in your body due to a blood disorder)
   2. Transfusional iron overload due to a sickle cell disease or other anemias (you have too much iron in your body due to a group of disorders that affect the red blood cells that deliver oxygen throughout your body)

B. You have tried at least ONE of the following: Exjade (deferasirox), Jadenu (deferasirox), or Desferal (deferoxamine)

C. You meet ONE of the following:
   1. You are experiencing intolerable toxicities or clinically significant adverse effects, or have a contraindication to (medical reason why you cannot use) current chelators (drugs that bind to iron): Exjade (deferasirox), Jadenu (deferasirox), or Desferal (deferoxamine)
   2. Chelation therapy (therapy that lowers iron levels) with Exjade [deferasirox], Jadenu [deferasirox], or Desferal [deferoxamine]) is not working well enough as shown by ONE of the following:
      a. Serum ferritin levels (amount of iron-containing blood cell proteins) stay above 2,500mcg/L (at least 2 lab values in the previous 3 months)
      b. You have evidence of cardiac iron accumulation (iron build up in your heart) as shown by cardiac T2* MRI less than 10 milliseconds, iron induced cardiomyopathy (heart disease), fall in left ventricular ejection fraction (LVEF: amount of blood your heart pumps out), or arrhythmia indicating inadequate chelation (irregular heartbeat because iron was not lowered enough in body)

D. Requests for Ferriprox (deferiprone) tablets require that you are 8 years of age or older

E. Requests for Ferriprox oral solution require that you are 3 years of age or older

RENEWAL CRITERIA

Our guideline named **DEFERIPRONE (Ferriprox)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Transfusional iron overload due to a thalassemia syndrome (you have too much iron in your body due to a blood disorder)
   2. Transfusional iron overload due to a sickle cell disease or other anemias (you have too much iron in your body due to a group of disorders that affect the red blood cells that deliver oxygen throughout your body)

B. Your serum ferritin levels (amount of iron-containing blood cell proteins) stay above 500mcg/L (at least 2 lab values in the previous 3 months)

C. Requests for Ferriprox (deferiprone) tablets require that you are 8 years of age or older

D. Requests for Ferriprox oral solution require that you are 3 years of age or older

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

DEFERIPRONE

RATIONALE
Promote appropriate utilization of **DEFERIPRONE** based on FDA approved indication and treatment guidelines.

FDA APPROVED INDICATIONS
Ferriprox (deferiprone) is indicated for the treatment of transfusional iron overload in adult and pediatric patients 3 years of age and older with thalassemia syndromes.

Ferriprox (deferiprone) is indicated for the treatment of transfusional iron overload in adult and pediatric patients 3 years of age and older with sickle cell disease or other anemias.

DOSAGE AND ADMINISTRATION
The recommended starting oral dosage of Ferriprox tablets (three times a day) is 75 mg/kg/day (actual body weight), in three divided doses per day. Tailor dosage adjustments for Ferriprox tablets (three times a day) to the individual patient's response and therapeutic goals (maintenance or reduction of body iron burden). The maximum oral dosage is 99 mg/kg/day (actual body weight), in three divided doses per day.

The recommended starting oral dosage of Ferriprox tablets (twice a day) is 75 mg/kg/day (actual body weight) in two divided doses per day (taken approximately 12 hours apart), with food. Tailor dosage adjustments of Ferriprox tablets (twice a day) to the individual patient’s response and therapeutic goals (maintenance or reduction of body iron burden). The maximum total daily oral dosage is 99 mg/kg (actual body weight) divided into two doses taken approximately 12 hours apart with food.

The recommended starting oral dosage of Ferriprox oral solution is 25 mg/kg (actual body weight), three times per day for a total of 75 mg/kg/day. Round dose to the nearest 2.5 mL. Tailor dosage adjustments to the individual patient’s response and therapeutic goals (maintenance or reduction of body iron burden). The maximum oral dosage is 33 mg/kg (actual body weight), three times per day for a total of 99 mg/kg/day.

Consider interrupting therapy if serum ferritin level consistently falls below 500mcg/L.

REFERENCES
Ferriprox [Package Insert]. ApoPharma, Inc. Rockville, MD. November 2021.

Created: 09/17
Effective: 03/14/22 Client Approval: 02/14/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

DEFEROXAMINE

Generic	Brand	HICL	GCN	Exception/Other
DEFEROXAMINE	DESFERAL	01104		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **DEFEROXAMINE (Desferal)** requires the following rule(s) be met for approval:

A. You have chronic iron overload due to transfusion-dependent anemias (blood doesn't have enough healthy red blood cells)
B. You are 3 years of age or older
C. Your serum ferritin levels (amount of iron-containing blood cell proteins) stay greater than 1000 mcg/L (shown by at least 2 lab values in the previous 3 months)

RENEWAL CRITERIA

Our guideline named **DEFEROXAMINE (Desferal)** requires the following rules be met for renewal:

A. You have chronic iron overload due to transfusion-dependent anemias (blood doesn't have enough healthy red blood cells)
B. Your serum ferritin levels (amount of iron-containing blood cell proteins) stay greater than 500 mcg/L (at least 2 lab values in the previous 3 months)

RATIONALE
Promote appropriate utilization of **DEFEROXAMINE** based on FDA approved indication and treatment guidelines.

FDA APPROVED INDICATION
Desferal (deferoxamine) is indicated for the treatment of acute iron intoxication and chronic iron overload due to transfusion-dependent anemias.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

DEFEROXAMINE

DOSAGE AND ADMINISTRATION

Desferal (deferoxamine)

- Acute iron intoxication:
  - IM (this route for patient not in shock): 1000mg following by 500mg every 4 hours for two doses. Depending on the clinical response, subsequent 500mg may be administered every 4 to 12 hours. Total amount should not exceed 6000mg in 24 hours.
  - IV (this route for patients in shock): 1000mg at a rate of 15mg/kg/hr. This may be followed by 500mg over 4 hours for two doses. Depending on the clinical response, subsequent 500mg may be administered every 4 to 12 hours. Total amount should not exceed 6000mg in 24 hours.
- Chronic iron overload due to transfusion-dependent anemias:
  - SQ: 1000 to 2000mg per day (20-40mg/kg/day) should be administered over 8 to 24 hours via a continuous infusion pump.
  - IV: in patients with intravenous access, the daily dose is 20-40mg/kg/day for children and 50-40mg/kg/day over 8 to 12 hours in adults for 5-7 days per week. Max dose in children is 40mg/kg/day and adults is 60mg/kg/day. In patients who are poorly compliant, Desferal may be administered prior to or following same day blood transfusion; however, the contribution of this mode of administration to iron balance is limited.
  - IM: 500 to 1000mg daily.

REFERENCES

Desferal [Prescribing Information]. Novartis Pharmaceuticals Corporation: East Hanover, NJ. December 2011.

Created: 08/17
Effective: 03/14/22 Client Approval: 02/14/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

DEFLAZACORT

Generic	Brand	HICL	GCN	Exception/Other
DEFLAZACORT	EMFLAZA	11668		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **DEFLAZACORT (Emflaza)** requires the following rules be met for approval:

A. You have Duchenne muscular dystrophy (inherited muscular weakness that gets worse)
B. You are 2 years of age or older
C. You doctor confirms your diagnosis with genetic testing

RENEWAL CRITERIA

Our guideline named **DEFLAZACORT (Emflaza)** requires the following rules be met for renewal:

A. You have Duchenne muscular dystrophy (inherited muscular weakness that worsens)
B. You have history of paid claim(s) for the requested medication in the past 90 day
C. You have a previous authorization on file for the requested medication
D. Your prescriber provided documentation indicating improvement (including stabilization) in your current clinical status (e.g., Brooke Score, 6-minute walk test)

RATIONALE

Promote appropriate utilization of **DEFLAZACORT** based on FDA approved indication.

FDA APPROVED INDICATION

Indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 2 years of age and older.

DOSING

The recommended once-daily dosage is approximately 0.9 mg/kg/day administered orally. If tablets are used, round up to the nearest possible dose. Any combination of the four Emflaza tablet strengths can be used to achieve this dose. If the oral suspension is used, round up to the nearest tenth of a milliliter (mL). Discontinue gradually when administered for more than a few days.

AVAILABLE STRENGTHS

Tablets: 6 mg, 18 mg, 30 mg, and 36 mg
Oral Suspension: 22.75 mg/mL

REFERENCES

- Emflaza [Prescribing Information]. Northbrook, IL: Marathon Pharmaceuticals. June 2021.

Created: 03/17
Effective: 12/15/21 Client Approval: 10/26/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

DELAFLOXACIN

Generic	Brand	HICL	GCN	Exception/Other
DELAFLOXACIN	BAXDELA		43532	

GUIDELINES FOR USE

The guideline named **DELAFLOXACIN (Baxdela)** requires the patient to be at least 18 years of age and have an infection caused by **ANY** of the following pathogens: Staphylococcus aureus (including methicillin-resistant [MRSA] and methicillin susceptible [MSSA] isolates), Staphylococcus haemolyticus, Staphylococcus lugdunensis, Streptococcus agalactiae, Streptococcus anginosus Group (including Streptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus), Streptococcus pyogenes, and Enterococcus faecalis, Escherichia coli, Enterobacter cloacae, Klebsiella pneumoniae, and Pseudomonas aeruginosa.

RATIONALE

Promote appropriate utilization of Baxdela (delafloxacin) based on FDA approved indication and dosing. Inappropriate use of Baxdela could lead to an increase in resistant organisms.

FDA APPROVED INDICATIONS

BAXDELA is indicated in adults for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following:

Gram-positive organisms**:** *Staphylococcus aureus (including methicillin-resistant [MRSA] and methicillin susceptible [MSSA] isolates), Staphylococcus haemolyticus, Staphylococcus lugdunensis, Streptococcus agalactiae, Streptococcus anginosus Group (including Streptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus), Streptococcus pyogenes, and Enterococcus faecalis.*

Gram-negative organisms: *Escherichia coli, Enterobacter cloacae, Klebsiella pneumoniae, and Pseudomonas aeruginosa.*

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DELAFLOXACIN

FDA APPROVED INDICATIONS (CONTINUED)

To reduce the development of drug-resistant bacteria and maintain the effectiveness of BAXDELA and other antibacterial drugs, BAXDELA should be used only to treat infections that are proven or strongly suspected to be caused by bacteria.

DOSAGE AND ADMINISTRATION

Administer BAXDELA for injection 300 mg by intravenous infusion over 60 minutes, every 12 hours, or a 450-mg BAXDELA tablet orally every 12 hours for 5 to 14 days total duration.

DOSAGE FORMS

Injection: 300 mg of delafloxacin (equivalent to 433 mg delafloxacin meglumine) as a lyophilized powder in a single dose vial for reconstitution and further dilution before intravenous infusion.
Oral Tablets: 450 mg delafloxacin (equivalent to 649 mg delafloxacin meglumine).

REFERENCES

- Baxdela [Prescribing Information]. Lincolnshire, Illinois USA Melinta Therapeutics, Inc.; June 2017.

Created: 11/17
Effective: 01/20/18 Client Approval: 11/29/17 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

DENOSUMAB (PROLIA)

Generic	Brand	HICL	GCN	Exception/Other
DENOSUMAB	PROLIA		28656	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline for **DENOSUMAB (Prolia)** requires that the patient has a diagnosis of post-menopausal osteoporosis, osteoporosis in a male patient, glucocorticoid-induced osteoporosis, bone loss in men receiving androgen deprivation therapy for non-metastatic prostate cancer, or bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer. The following criteria must also be met:

For the diagnosis of post-menopausal osteoporosis, approval requires ONE of the following:

- The patient is at high risk for fractures defined as **ONE** of the following:
  - History of osteoporotic (i.e., fragility, low trauma) fracture(s)
  - 2 or more risk factors for fracture (e.g., history of multiple recent low trauma fractures, BMD T-score less than or equal to -2.5, corticosteroid use, or use of gonadotropin-releasing hormone [GnRH] analogs such as nafarelin, etc.)
  - No prior treatment for osteoporosis and FRAX score ≥ 20% for any major fracture OR ≥ 3% for hip fracture
- The patient had a previous trial of or contraindication to bisphosphonates (e.g., Fosamax, Actonel, Boniva, Reclast)
- The patient is unable to use oral therapy (upper gastrointestinal [GI] problems - unable to tolerate oral medication, lower GI problems - unable to absorb oral medications, trouble remembering to take oral medications or coordinating an oral bisphosphonate with other oral medications or their daily routine)

For the diagnosis of osteoporosis in a male patient or glucocorticoid-induced osteoporosis, approval requires all of the following:

- The patient is at high risk for fractures defined as ONE of the following:
  - History of osteoporotic (i.e., fragility, low trauma) fracture(s)
  - 2 or more risk factors for fracture (e.g., history of multiple recent low trauma fractures, BMD T-score less than or equal to -2.5, corticosteroid use, or use of gonadotropin-releasing hormone [GnRH] analogs such as nafarelin, etc.)
- The patient had a previous trial of or contraindication to bisphosphonates (e.g., Fosamax, Actonel, Boniva, Reclast)

For diagnosis of bone loss in men receiving androgen deprivation therapy for non-metastatic prostate cancer, or bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer, approval requires all of the following:

- The patient is at high risk for fracture (e.g., history of osteoporotic fracture, history of multiple recent low trauma fractures, corticosteroid use, or use of GnRH analogs such as nafarelin, etc.)
- The patient had a previous trial of or contraindication to bisphosphonates (e.g., Reclast, Fosamax, Actonel, or Boniva)

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

DENOSUMAB (PROLIA)

RENEWAL CRITERIA

Our guideline for renewal of **DENOSUMAB (Prolia)** requires that the patient has a diagnosis of post-menopausal osteoporosis, osteoporosis in a male patient, or glucocorticoid-induced osteoporosis, the patient is receiving androgen deprivation therapy for non-metastatic prostate cancer, or the patient is receiving adjuvant aromatase inhibitor therapy for breast cancer.

RATIONALE

To ensure appropriate use of PROLIA based on FDA and compendia approved indications and dosing.

PROLIA Dosing:

- Treatment of postmenopausal women with osteoporosis at high risk for fracture: Administer 60mg subcutaneously every 6 months in the upper arm, upper thigh, or abdomen.
- Treatment to increase bone mass in men with osteoporosis at high risk for fracture: Administer 60mg subcutaneously every 6 months in the upper arm, upper thigh, or abdomen.
- Treatment to increase bone mass in men at high risk of fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer: Administer 60mg subcutaneously every 6 months in the upper arm, upper thigh, or abdomen.
- Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer: Administer 60mg subcutaneously every 6 months in the upper arm, upper thigh, or abdomen.
- Instruct patient to take calcium 1000mg daily and at least 400IU vitamin D daily.

PROLIA Dosing (CONTINUED):

Per American Association of Clinical Endocrinologists (AACE) medical guidelines for clinical practice for the diagnosis and treatment of postmenopausal osteoporosis, alendronate, risedronate, zoledronic acid, and denosumab are first line therapy for postmenopausal women with osteoporosis. The Endocrine Society guidelines for the treatment of osteoporosis in men indicate bisphosphonates and denosumab as appropriate therapy for treatment.

National Comprehensive Cancer Network (NCCN) state the use of a bisphosphonate is generally the preferred intervention to improve bone mineral density for female patients receiving aromatase inhibitors. The NCCN also state denosumab, zolderonic acid, or alendronate are recommended for male patients receiving androgen replacement therapy when absolute fracture risk warrants drug therapy.

FDA APPROVED INDICATIONS

PROLIA is a RANK ligand (RANKL) inhibitor indicated for:

- Treatment of postmenopausal women with osteoporosis at high risk for fracture
- Treatment to increase bone mass in men with osteoporosis at high risk for fracture
- Treatment to increase bone mass in men at high risk of fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer
- Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer

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DENOSUMAB (PROLIA)

REFERENCES

- Prolia (denosumab) [prescribing information]. Thousand Oaks, CA: Amgen Inc; April 2019.
- National Comprehensive Cancer Network. Prostate Cancer. Version 1.2015. Accessed online July 12, 2018 at: http://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf
- National Comprehensive Cancer Network. Breast Cancer. Version 3.2015. Accessed online July 12, 2018 at: http://www.nccn.org/professionals/physician_gls/pdf/breast.pdf
- Endocrine Society Clinical Guidelines: Osteoporosis in Men. Accessed online July 12, 2018 at: www.endocrine.org
- American Association of Clinical Endocrinologists (AACE) medical guidelines for clinical practice for the diagnosis and treatment of postmenopausal osteoporosis. Accessed online July 12, 2018 at: www.aace.com

Created: 10/15
Effective: 04/01/20 Client Approval: 02/24/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

DENOSUMAB (XGEVA)

Generic	Brand	HICL	GCN	Exception/Other
DENOSUMAB	XGEVA		29261	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline for **DENOSUMAB (Xgeva)** requires that the patient have a diagnosis of multiple myeloma, bone metastases from solid tumors, giant cell tumor of bone, or hypercalcemia of malignancy. The following criteria must also be met:

For patients with a diagnosis of multiple myeloma OR bone metastases from solid tumors, approval requires BOTH of the following:

- Xgeva is being used to prevent skeletal-related events (e.g., bone fractures or bone pain requiring radiation)
- Previous trial of or contraindication to an IV bisphosphonate (e.g. Zometa or pamidronate)

For patients with a diagnosis of giant cell tumor of bone, approval requires:

- Tumor is unresectable or surgical resection is likely to result in severe morbidity

For patients with a diagnosis of hypercalcemia of malignancy, approval requires:

- Previous trial of or contraindication to an IV bisphosphonate (e.g. Zometa or pamidronate)

RENEWAL CRITERIA

Our guideline for renewal of **DENOSUMAB** (**Xgeva)** requires that the patient have a diagnosis of multiple myeloma, bone metastases from solid tumors, giant cell tumor of the bone, or hypercalcemia of malignancy.

RATIONALE
To ensure appropriate use of denosumab based on FDA approved indication and dosing.

Xgeva Dosing:

- Multiple Myeloma and Bone Metastasis from Solid Tumors: Administer 120 mg every 4 weeks as a subcutaneous injection in the upper arm, upper thigh, or abdomen
- Giant Cell Tumor of Bone: Administer 120 mg every 4 weeks with additional 120 mg doses on Days 8 and 15 of the first month of therapy.
- Hypercalcemia of Malignancy: Administer 120 mg every 4 weeks with additional 120 mg doses on Days 8 and 15 of the first month of therapy.
- Administer subcutaneously in the upper arm, upper thigh, or abdomen
- Administer calcium and vitamin D as necessary to treat or prevent hypocalcemia

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

DENOSUMAB (XGEVA)

FDA APPROVED INDICATIONS

Xgeva is a RANK ligand (RANKL) inhibitor indicated for:

- Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors
- Treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity
- Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy

REFERENCES

- Amgen. Xgeva package insert. Thousand Oaks, CA. June 2018.

Created: 10/15
Effective: 10/01/18 Client Approval: 08/22/18 P&T Approval: 3QTR

EPOETIN
EPOT

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

DESIRUDIN

Generic	Brand	HICL	GCN	Exception/Other
DESIRUDIN	IPRIVASK	19072		

GUIDELINES FOR USE

Approval requires that the patient is receiving Iprivask for the prevention of deep vein thrombosis (DVT) undergoing elective hip replacement surgery.

RATIONALE

To ensure appropriate use of desirudin for the prevention of deep vein thrombosis (DVT) in patients undergoing hip replacement surgery. The desirudin prescribing information states that the average duration of treatment is 9 to 12 days. The 2008 ACCP guidelines recommend venous thromboembolism treatment of up to 35 days.

FDA APPROVED INDICATIONS

Prophylaxis of deep vein thrombosis (DVT) in elective hip replacement surgery.

REFERENCES

- Canyon Pharmaceuticals, Inc. Iprivask package insert. Hunt Valley, MD. January 2010.
- MICROMEDEX® Healthcare Series [database online]. Greenwood Village, CO: Thomson Healthcare. Available at: https://www.thomsonhc.com/hcs/librarian/PFDefaultActionId/pf.LoginAction. [Accessed: August 19, 2010].
- Geerts W, Bergquist D, and Pineo G et al. Prevention of Venous Thromboembolism supplement; The eighth ACCP conference on antithrombotic and thrombolytic therapy. *Chest* 2008; 133 (6 Suppl): 381S-453S.

Created: 06/15
Effective: 07/22/15 Client Approval: 06/15 P&T Approval: 11/13

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

DEUCRAVACITINIB

Generic	Brand	HICL	GCN	Exception/Other
DEUCRAVACITINIB	SOTYKTU	48292		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **DEUCRAVACITINIB (Sotyktu)** requires the following rule(s) be met for approval:
A. You have moderate to severe plaque psoriasis (a type of skin condition)
B. You are 18 years of age or older
C. You have psoriasis covering 10% or more of body surface area (BSA) or psoriatic lesions (rashes) affecting the hands, feet, face, or genital area
D. You have previously tried ONE of the following conventional therapies: PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
E. You have previously tried TWO of the following: Cosentyx, Enbrel, or Humira

RENEWAL CRITERIA

Our guideline named **DEUCRAVACITINIB (Sotyktu)** requires the following rule(s) be met for renewal:
A. You have moderate to severe plaque psoriasis (a type of skin condition)
B. You have experienced or maintained symptomatic improvement while on therapy

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RATIONALE
Ensure appropriate diagnostic, utilization and safety criteria are used for the management of requests for deucravacitinib.

FDA APPROVED INDICATIONS
Sotyktu is a tyrosine kinase 2 (TYK2) inhibitor indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

DOSING
The recommended dosage of Sotyktu is 6 mg orally once daily, with or without food.

REFERENCES

- Sotyktu [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb Company, September 2022.
- Menter A, Strober BE, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72

Created: 10/22
Effective: 11/21/22 Client Approval: 10/21/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

DEUTETRABENAZINE

Generic	Brand	HICL	GCN	Exception/Other
DEUTETRABENAZINE	AUSTEDO	44192		

GUIDELINES FOR USE

Our guideline named **DEUTETRABENAZINE (Austedo)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Chorea (involuntary muscle movements) associated with Huntington's disease
   2. Moderate to severe tardive dyskinesia (uncontrolled body movements)

B. **If you have moderate to severe tardive dyskinesia, approval also requires:**
   1. You are 18 years of age or older
   2. Moderate to severe tardive dyskinesia (uncontrolled body movements) has been present for at least 4 weeks
   3. You have a prior history of antipsychotic medications or dopamine receptor blocking drugs used in the treatment of nausea and gastroparesis (e.g., metoclopramide, prochlorperazine, promethazine) for at least 3 months (or at least 1 month if you are 60 years of age or older) as documented in the medical record or prescription claims history

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RATIONALE

Promote appropriate utilization of **DEUTETRABENAZINE (Austedo)** based on FDA approved indication and dosing.

FDA APPROVED INDICATION

Austedo is indicated for the treatment of chorea associated with Huntington's disease and for the treatment of tardive dyskinesia in adults.

DOSAGE

The dose of Austedo is determined individually for each patient based on reduction of chorea or tardive dyskinesia and tolerability.

Dosing Recommendations to Initiate DEUTETRABENAZINE (Austedo) treatment

When first prescribed to patients who are not being switched from tetrabenazine, the dosing recommendations are as follows:

- The recommended starting dose of Austedo is 6 mg administered orally once daily for patients with Huntington's disease and 12 mg per day (6 mg twice daily) for patients with tardive dyskinesia
- The dose may be increased at weekly intervals in increments of 6 mg per day to a maximum recommended daily dosage of 48 mg
- Administer total daily dosages of 12 mg or above in two divided doses

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DEUTETRABENAZINE

FDA APPROVED INDICATION (CONTINUED)

Initial Dosing Recommendations for Patients Switching from Tetrabenazine to Austedo
Discontinue tetrabenazine and initiate Austedo the following day. The recommended initial dosing regimen of Austedo in patients switching from tetrabenazine to Austedo is as follows:

Current tetrabenazine daily dosage	Initial regimen of Austedo
12.5 mg	6 mg once daily
25 mg	6 mg twice daily
37.5 mg	8 mg twice daily
50 mg	12 mg twice daily
62.5 mg	15 mg twice daily
75 mg	18 mg twice daily
87.5 mg	21 mg twice daily
100 mg	24 mg twice daily

Dosage Adjustment with Strong CYP2D6 Inhibitors
In patients receiving strong CYP2D6 inhibitors (e.g., quinidine, antidepressants such as paroxetine, fluoxetine, and bupropion), the total daily dosage of Austedo should not exceed 36 mg (maximum single dose of 18 mg).

Dosage Adjustment in Poor CYP2D6 Metabolizers
In patients who are poor CYP2D6 metabolizers, the total daily dosage of Austedo should not exceed 36 mg (maximum single dose of 18 mg).

REFERENCES

- Austedo [Prescribing Information]. North Wales, PA. Teva Pharmaceuticals, Inc. June 2021.
- Diagnostic and Statistical Manual of Mental Disorders: DSM-5. Arlington, VA: American Psychiatric Publishing, 2013.

Created: 04/17
Effective: 04/11/22 Client Approval: 03/09/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

DEXTROMETHORPHAN WITH QUINIDINE

Generic	Brand	HICL	GCN	Exception/Other
DEXTROMETHORPHAN / QUINIDINE	NUEDEXTA	37278		

GUIDELINES FOR USE

Our guideline for **DEXTROMETHORPHAN with QUINIDINE** requires a diagnosis of pseudobulbar affect (PBA).

RATIONALE

Ensure that Nuedexta is used solely for its FDA approved indication and in patients for whom it has been determined to be safe and efficacious.

FDA APPROVED INDICATION

Nuedexta is a combination product containing dextromethorphan hydrobromide (an uncompetitive NMDA receptor antagonist and sigma-1 agonist) and quinidine sulfate (a CYP450 2D6 inhibitor) indicated for treatment of pseudobulbar affect (PSA).

DOSING

The recommended starting dose of Nuedexta is one capsule daily by mouth for the initial seven days of therapy. On the eighth day of therapy and thereafter, the daily dose should be a total of two capsules a day, given as one capsule every 12 hours.

REFERENCES

Avanir Pharmaceuticals, Inc. Nuedexta package insert. Aliso Viejo, CA. June 2019.

Created: 06/15
Effective: 08/08/22 Client Approval: 07/13/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

DIABETIC TEST STRIPS

Generic	Brand	HICL	GCN	Exception/Other
BLOOD SUGAR DIAGNOSTIC; BLOOD SUGAR DIAGNOSTIC, DISC; BLOOD SUGAR DIAGNOSTIC, DRUM	DIABETIC TEST STRIPS VARIOUS		25200	

Requests for preferred blood glucose (diabetic) test strips manufactured by Roche or Trividia will adjudicate at the point of service with a quantity limit of 5 test strips per day. Formulary test strip requests for >5 test strips per day will require prior authorization. Non-formulary test strips will also require prior authorization. Below are the preferred test strip NDCs as determined by the state of Indiana:

- **ROCHE**
  - Accu-Chek Guide Test Strips 65702-0711-10
  - Accu-Chek Guide Test Strips 65702-0712-10
- **TRIVIDIA**
  - ReliOn Rx TMX Strips 56151-1461-04
  - ReliOn Rx TMX Strips 56151-1461-01
  - TRUE METRIX Test Strips 56151-1460-04
  - TRUE METRIX Test Strips 56151-1460-01

GUIDELINES FOR USE

Our guideline for **DIABETIC TEST STRIPS** limits testing to no more than 5 times per day unless the patient has a diagnosis of Type I diabetes mellitus or a diagnosis of Type II diabetes and is currently using an insulin pump.

Our guideline for **DIABETIC TEST STRIPS** requires that this product is only covered for patients that have tried the preferred blood glucose (diabetic) meters and test strips or are unable to use the preferred products. Test strips manufactured by Roche or Trividia are the preferred formulary agents. Approval for non-formulary test strips requires documentation of significant visual and/or cognitive impairment or the use of another manufacturer's companion insulin pump. Your provider did not indicate that you are using this product due to either of these conditions and therefore your request was not approved. Data management software is available for the formulary test strip products.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

DIABETIC TEST STRIPS

RATIONALE

The intent of this guideline is to encourage the use of cost-effective formulary preferred glucose testing strips before considering coverage of non-preferred alternatives and to encourage testing frequency in accordance with treatment guidelines.

ADDITIONAL INFORMATION

Below are the preferred test strip NDCs as determined by the state of Indiana:

- **ROCHE**
  - Accu-Chek Guide Test Strips 65702-0711-10
  - Accu-Chek Guide Test Strips 65702-0712-10
- **TRIVIDIA**
  - ReliOn Rx TMX Strips 56151-1461-04
  - ReliOn Rx TMX Strips 56151-1461-01
  - TRUE METRIX Test Strips 56151-1460-04
  - TRUE METRIX Test Strips 56151-1460-01

Eligible meters will reject at POS with the appropriate billing information (BIN and PCN) for the corresponding manufacturer.

- Accu-Chek Guide Care Kit
- Accu-Chek Guide Me Care Kit
- ReliOn Rx TMX Blood Glucose System
- TRUE METRIX Meter
- TRUE METRIX AIR Meter

REFERENCES

- American Diabetes Association. Standards of Medical Care in Diabetes- 2011. Diabetes Care 2011; 34(suppl 1): S11-S61.
- IHCP Bulletin

Created: 10/14
Effective: 02/01/23 Client Approval: 12/29/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

DIABETIC TEST STRIPS

RATIONALE

The intent of this guideline is to encourage the use of cost-effective formulary preferred glucose testing strips before considering coverage of non-preferred alternatives and to encourage testing frequency in accordance with treatment guidelines.

ADDITIONAL INFORMATION

Below are the preferred test strip NDCs as determined by the state of Indiana:

- **ROCHE**
  - Accu-Chek Aviva Plus Test Strips 65702-0407-10
  - Accu-Chek Aviva Plus Test Strips 65702-0408-10
  - Accu-Chek Guide Test Strips 65702-0711-10
  - Accu-Chek Guide Test Strips 65702-0712-10
  - Accu-Chek SmartView Test Strips 65702-0492-10
  - Accu-Chek SmartView Test Strips 65702-0493-10
- **ABBOTT**
  - FreeStyle InsuLinx Test Strips (Retail) 99073-0712-31
  - FreeStyle InsuLinx Test Strips (Retail) 99073-0712-27
  - FreeStyle Lite Test Strips (Retail) 99073-0708-22
  - FreeStyle Lite Test Strips (Retail) 99073-0708-27
  - FreeStyle Test Strips (Retail) 99073-0120-50
  - FreeStyle Test Strips (Retail) 99073-0121-01
- **TRIVIDIA**
  - ReliOn Rx TMX Strips 56151-1461-04
  - ReliOn Rx TMX Strips 56151-1461-01
  - TRUE METRIX Test Strips 56151-1460-04
  - TRUE METRIX Test Strips 56151-1460-01

Eligible meters will reject at POS with the appropriate billing information (BIN and PCN) for the corresponding manufacturer.

- FreeStyle Freedom Lite System Kit
- FreeStyle Lite System Kit
- FreeStyle InsuLinx Meter
- Accu-Chek Guide Retail Care Kit
- Accu-Chek Guide Me Retail Care Kit
- TRUE METRIX Blood Glucose System
- TRUE METRIX AIR Blood Glucose System

REFERENCES

- Drug Facts and Comparisons (online version), Blood Glucose Meters. Available at http://online.factsandcomparisons.com. Accessed January 4, 2011.
- American Diabetes Association. Standards of Medical Care in Diabetes- 2011. Diabetes Care 2011; 34(suppl 1): S11-S61.

Created: 10/14
Effective: 06/15/21 Client Approval: 05/26/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

DICHLORPHENAMIDE

Generic	Brand	HICL	GCN	Exception/Other
DICHLORPHENAMIDE	KEVEYIS	03642		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline for **DICHLORPHENAMIDE** requires that the patient has a diagnosis of primary hypokalemic periodic paralysis, primary hyperkalemic periodic paralysis, or Paramyotonia Congenita. In addition, the following criteria must be met: patient age of at least 18 years, prescription written by or currently supervised by a neurologist, and that the patient does not have hepatic insufficiency, pulmonary obstruction, or a health condition that warrants concurrent use of high-dose aspirin. For primary hypokalemic periodic paralysis, a trial of acetazolamide AND a potassium-sparing diuretic (i.e., spironolactone, triamterene) is also required. For primary hyperkalemic periodic paralysis or Paramyotonia Congenita, a trial of acetazolamide AND a thiazide diuretic (i.e., hydrochlorothiazide) is also required. Renewal of **DICHLORPHENAMIDE** requires that the patient experience at least two fewer attacks per week from their baseline.

RENEWAL CRITERIA

Our guideline for **DICHLORPHENAMIDE** renewal requires that the patient experience at least two fewer attacks per week from their baseline.

RATIONALE

Promote appropriate utilization of **DICHLORPHENAMIDE** based on FDA approved indication, dosing, and contraindications. A step therapy has been implemented to promote cost-effective therapies based on previously available agents. A specialist edit has also been implemented to promote appropriate diagnosis and on-label use due to rare neuromuscular condition.

Keveyis is the first FDA approved treatment for primary hyperkalemic and primary hypokalemic periodic paralysis. The only clinical trials demonstrating a benefit for treatment in periodic paralysis involve the carbonic anhydrase inhibitor, dichlorphenamide. Dichlorphenamide was initially approved in 1958 as the branded drug Daranide for the treatment of elevated intraocular pressure but was discontinued in May 2003. In 2015, it was reintroduced as Keveyis as an orphan drug.

Affecting almost 5,000 people in the United States, periodic paralysis is a rare neuromuscular disorder related to a defect in muscle ion channels, characterized by episodes of painless but debilitating muscle weakness or paralysis (lasting minutes to an hour or two), which may be precipitated by heavy exercise, fasting, or high-carbohydrate meals. Periodic paralysis (PP) is classified as hypokalemic when episodes occur in association with low potassium blood levels or as hyperkalemic when episodes can be induced by elevated potassium. Most cases of periodic paralysis are hereditary, usually with an autosomal dominant inheritance pattern. Acquired cases of hypokalemic PP have been described in association with hyperthyroidism. When there is an established family history, episodes of periodic paralysis often require no further diagnostic evaluation. Otherwise, the diagnosis of PP is suggested by documentation of hypo/hyperkalemia during a typical attack of weakness.

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RATIONALE (CONTINUED)

Even when this is demonstrated, diagnosis is not as easily accomplished, as other testing is required to rule out alternative diagnoses. Genetic testing is available for most, but not all of the mutations underlying hypokalemic PP. Evidence of myotonia (seen in up to 80% with this subtype) during electromyographic (EMG) examination can help support the diagnosis of hyperkalemic PP.

Nonpharmacologic interventions that may be effective for preventing attacks include a low-carbohydrate diet and refraining from vigorous exercise. When attacks continue to be disabling, prophylactic treatment is indicated to avoid morbidity, even mortality, which can be associated with hospitalization and acute treatment. When lifestyle changes are not sufficiently effective, symptomatic potassium supplementation, diuretics, and medications such as carbonic anhydrase inhibitors are used. The mechanism whereby carbonic anhydrase inhibitors are effective in PP is not clear, but appears to be independent of carbonic anhydrase inhibition. Studies in animal models suggest that these agents trigger calcium-activated potassium channels on skeletal muscle. Acetazolamide, another carbonic anhydrase inhibitor, is also commonly reported to be effective in reducing attacks when dosed at 250mg twice daily. However, one retrospective study found that only half of patients respond to acetazolamide therapy. The subset of patients who might find acetazolamide treatment helpful are those who experience mild, fluctuating weakness between attacks. For hypokalemic PP, potassium-sparing diuretics such as spironolactone (100mg daily) or triamterene (150mg daily) can be used as a supplement or as an alternative to a carbonic anhydrase inhibitor in patients who experience worsening or intolerance. For hyperkalemic PP, thiazide diuretics (i.e. hydrochlorothiazide 25-50mg daily) have been reported as helpful in controlling attacks in some patients.

DOSAGE

Initiate dosing at 50 mg twice daily. The initial dose may be increased or decreased based on individual response, at weekly intervals (or sooner in case of adverse reaction). The maximum total daily dose is 200 mg.

Primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, and related variants are a heterogeneous group of conditions, for which the response to Keveyis may vary. Therefore, prescribers should evaluate the patient's response after 2 months of treatment to decide whether Keveyis should be continued.

FDA APPROVED INDICATIONS

Keveyis is an oral carbonic anhydrase inhibitor indicated for the treatment of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, and related variants.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

DICHLORPHENAMIDE

REFERENCES

- Keveyis [Prescribing Information]. Hawthorne, NY: Taro Pharmaceuticals; August 2015.
- UpToDate, Inc. Hypokalemic periodic paralysis. UpToDate [database online]. Waltham, MA. Available at: http://www.uptodate.com/home/index.html. Updated July 23, 2014.
- UpToDate, Inc. Hyperkalemic periodic paralysis. UpToDate [database online]. Waltham, MA. Available at: http://www.uptodate.com/home/index.html. Updated June 13, 2014.
- Jeffrey S. FDA Nod for Keveyis in Primary Periodic Paralysis. Available at: http://www.medscape.com/viewarticle/850050 Updated August 25, 2015.
- Periodic paralysis international. Available at: http://hkpp.org/patients/hyperkpp-FAQ Updated June 25, 2011.

Created: 10/15
Effective: 11/12/15 Client Approval: 11/09/15 P&T Approval: 11/15

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

DICLOFENAC TOPICAL

Generic	Brand	HICL	GCN	Exception/Other
DICLOFENAC EPOLAMINE 1.3%	FLECTOR		97958	
DICLOFENAC 1.5%	PENNSAID		19454	
DICLOFENAC SODIUM 3%	SOLARAZE		86831	
DICLOFENAC SODIUM 1%	VOLTAREN		45680	

GUIDELINES FOR USE

Our guideline named **DICLOFENAC 3% TOPICAL (Solaraze)** requires the following rule(s) be met for approval:

A. The medication is prescribed by or in consultation with a dermatologist (skin doctor) or oncologist
B. You have actinic keratosis
C. You have tried or have a contraindication to topical fluorouracil (for example, Efudex, Fluoroplex, Carac)

RATIONALE

To promote clinically appropriate utilization of Solaraze for actinic keratosis.

FDA APPROVED INDICATIONS

Solaraze (diclofenac sodium) Gel is indicated for the topical treatment of actinic keratoses (AK).

DOSING

Solaraze Gel is applied to lesion areas twice daily. It is to be smoothed onto the affected skin gently. The amount needed depends upon the size of the lesion site. Assure that enough Solaraze Gel is applied to adequately cover each lesion. Normally 0.5 g of gel is used on each 5 cm x 5 cm lesion site. The recommended duration of therapy is from 60 days to 90 days. Complete healing of the lesion(s) or optimal therapeutic effect may not be evident for up to 30 days following cessation of therapy. Lesions that do not respond to therapy should be carefully re-evaluated and management reconsidered.

REFERENCES

PharmaDerm. Solaraze package insert. Melville, NY. December 2011.

Created: 06/15
Effective: 08/08/22 Client Approval: 07/13/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

DIHYDROERGOTAMINE MESYLATE

Generic	Brand	HICL	GCN	Exception/Other
DIHYDROERGOTAMINE MESYLATE	MIGRANAL		24732	ROUTE = INTRANASAL

GUIDELINES FOR USE

Our guideline for **DIHYDROERGOTAMINE MESYLATE (MIGRANAL)** requires a diagnosis of migraine headaches, excluding hemiplegic and basilar migraines. In addition, documentation of trial and failure of **ALL** of the following for migraine is required unless contraindicated:

- Acetaminophen
- Non-steroidal anti-inflammatory agent (NSAID) (e.g., ibuprofen, naproxen)
- **TWO** Selective serotonin agonists (e.g., sumatriptan, rizatriptan)

Chart notes indicating doses and dates of therapy are required in the absence of electronic prescription claims history.

RATIONALE

Ensure appropriate criteria are used for the management of requests for MIGRANAL according to approved indication, dosing, and national treatment guidelines.

FDA APPROVED INDICATIONS

MIGRANAL is an ergot derivative indicated for the acute treatment of migraine headaches with or without aura; not intended for the prophylactic therapy of migraine or for the management of hemiplegic or basilar migraine.

HOW SUPPLIED

INTRANASAL: 4 mg/mL solution

DOSING & ADMINISTRATION

MIGRANAL is for intranasal use only. One spray should be administered in each nostril. Fifteen minutes later, an additional one spray should be administered in each nostril if needed, for a total dosage of four sprays. MIGRANAL should not be used for chronic daily administration.

REFERENCES

- Millea PJ, Brodie JJ. Acute Migraine Headache: Treatment Strategies. Am Fam Physician. 2018 Feb;97(4):243-251.
- Smith, Jonathan H. Acute Treatment of Migraine in Adults. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. https://www.uptodate.com (Accessed on August 19, 2019.)
- Migranal (dihydroergotamine mesylate) [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals North America; November 2014.

Created: 08/19
Effective: 01/01/20 Client Approval: 10/14/19 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

DIMETHYL FUMARATE

Generic	Brand	HICL	GCN	Exception/Other
DIMETHYL FUMARATE	TECFIDERA	40168		

GUIDELINES FOR USE

Our guideline named **DIMETHYL FUMARATE (Tecfidera)** requires the following rules be met for approval:

A. You have multiple sclerosis (MS: an illness where the immune system eats away at the protective covering of the nerves)

RATIONALE

To ensure appropriate use aligned with FDA approved indication.

FDA APPROVED INDICATIONS

Tecfidera is indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

DOSING

The starting dose for Tecfidera is 120 mg twice a day orally. After 7 days, the dose should be increased to the maintenance dose of 240 mg twice a day orally. Temporary dose reductions to 120 mg twice a day may be considered for individuals who do not tolerate the maintenance dose. Within 4 weeks, the recommended dose of 240 mg twice a day should be resumed.
Discontinuation of Tecfidera should be considered for patients unable to tolerate return to the maintenance dose. The incidence of flushing may be reduced by administration of Tecfidera with food. Alternatively, administration of non-enteric coated aspirin (up to a dose of 325 mg) 30 minutes prior to Tecfidera dosing may reduce the incidence or severity of flushing.

REFERENCES

- Tecfidera [Prescribing Information]. Cambridge, MA: Biogen, Idec; January 2021.

Created: 06/15
Effective: 08/16/21 Client Approval: 07/07/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

DIROXIMEL FUMARATE

Generic	Brand	HICL	GCN	Exception/Other
DIROXIMEL FUMARATE	VUMERITY	46164		

GUIDELINES FOR USE

Our guideline named **DIROXIMEL FUMARATE (Vumerity)** requires the following rule(s) be met for approval:

A. You have multiple sclerosis (MS: disease in which the immune system eats away at the protective covering of nerves)
B. You are 18 years of age or older
C. You have previously tried dimethyl fumarate (generic Tecfidera) and ONE of the following medications, unless there is a medical reason why you cannot (contraindication): Aubagio, Avonex, glatiramer (generic Copaxone/Glatopa), or Rebif

(**Please note:** The preferred MS agents may also a require prior authorization)

RATIONALE

To ensure appropriate use of Vumerity consistent with FDA approved indication.

FDA APPROVED INDICATIONS

Vumerity is indicated for the treatment of patients with the relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

DOSING

The starting dose of Vumerity is 231 mg twice a day orally for 7 days. After 7 days, the dosage should be increased to the maintenance dosage of 462 mg (administered as two 231 mg capsules) twice a day orally.

REFERENCES

- Vumerity [Prescribing Information]. Waltham, MA: Alkermes, Inc.; January 2021.

Created: 05/21
Effective: 08/16/21 Client Approval: 07/13/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

DORNASE ALFA

Generic	Brand	HICL	GCN	Exception/Other
DORNASE ALFA	PULMOZYME	08832		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **DORNASE ALFA (Pulmozyme)** requires the following rule(s) be met for approval:

A. You have cystic fibrosis (CF: an inherited disorder that damages lung and digestive system with fluid build-up)
B. You are 5 years of age or older

RENEWAL CRITERIA

Our guideline named **DORNASE ALFA (Pulmozyme)** requires the following rule(s) be met for renewal:

A. You have history of paid claim(s) for the requested medication in the past 90 days
B. You have a previous authorization on file for the requested medication

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RATIONALE
Promote appropriate utilization of Pulmozyme based on FDA approved indication.

FDA APPROVED INDICATION
Pulmozyme is indicated in conjunction with standard therapies in the management of cystic fibrosis patients to improve pulmonary function.

DOSAGE
The recommended dose for use in most cystic fibrosis patients is one 2.5mg single-use ampule inhaled once daily using a recommended nebulizer. Some patients may benefit from twice daily administration.

REFERENCE
Genentech, Inc. Pulmozyme package insert. South San Francisco, CA. July 2021.

Created: 06/15
Effective: 04/11/22 Client Approval: 03/09/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

DROXIDOPA

Generic	Brand	HICL	GCN	Exception/Other
DROXIDOPA	NORTHERA	40936		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

Our guideline named **DROXIDOPA (Northera)** requires the following rules be met for approval:

A. You have neurogenic orthostatic hypotension (a type of low blood pressure)
B. You are 18 years of age or older
C. You have a documented diagnosis of neurogenic orthostatic hypotension caused by primary autonomic failure (Parkinson's disease, multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency (you are missing a type of enzyme), or non-diabetic autonomic neuropathy (nerve pain/damage)
D. You have previously tried midodrine OR fludrocortisone, unless there is a medical reason why you cannot (contraindication)
E. Your doctor performed baseline blood pressure readings while you are sitting and also within 3 minutes of standing from a supine (lying face up) position
F. You have a documented decrease of at least 20 mmHg in systolic blood pressure or 10 mmHg diastolic blood pressure within 3 minutes after standing from a sitting position
G. You have persistent symptoms of neurogenic orthostatic hypotension which includes dizziness, lightheadedness, and the feeling of 'blacking out'

RENEWAL CRITERIA

Our guideline named **DROXIDOPA (Northera)** requires the following rule(s) be met for renewal:

A. You have neurogenic orthostatic hypotension (NOH)
B. You have demonstrated improvement in severity from baseline symptoms of dizziness, lightheadedness, feeling faint, or feeling like you may black out
C. You had an increase in systolic blood pressure from baseline of at least 10mmHg upon standing from a supine (lying face up) position

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

DROXIDOPA

RATIONALE
Promote clinically appropriate utilization of Northera (droxidopa) based on its FDA approved indication and dosing.

FDA APPROVED INDICATIONS
Northera is indicated for the treatment of orthostatic dizziness, lightheadedness, or the "feeling that you are about to black out" in adult patients with symptomatic neurogenic orthostatic hypotension (NOH) caused by primary autonomic failure [Parkinson's disease (PD), multiple system atrophy and pure autonomic failure], dopamine beta-hydroxylase deficiency, and non-diabetic autonomic neuropathy.

Effectiveness of Northera beyond 2 weeks of treatment has not been established. The continued effectiveness of Northera should be assessed periodically.

DOSE
The recommended starting dose of Northera is 100mg orally three times a day, upon arising in the morning, at midday, and in the late afternoon at least 3 hours prior to bedtime (to reduce the potential for supine hypertension during sleep). Titrate to symptomatic response, in increments of 100mg three times daily every 24-48 hours up to a maximum dose of 600mg three times daily (maximum total daily dose of 1800mg).

REFERENCES

- Northera [Prescribing Information]. Charlotte, NC, Chelsea Therapeutics, July 2019.
- Freeman, Roy et al. “Consensus statement on the definition of orthostatic hypotension, neurally mediated syncope and the postural tachycardia syndrome.” Clin Auton Res Clinical autonomic research, 2011, Vol.21(2), p.69-72.

Created: 06/15
Effective: 03/14/22 Client Approval: 02/04/22 P&T Approval: N/A

DUPILUMAB

Generic	Brand	HICL	GCN	Exception/Other
DUPILUMAB	DUPIXENT	44180		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **DUPILIMAB (Dupixent)** requires the following rule(s) be met for approval:

A. You have one of the following diagnoses:
   1. Moderate to severe atopic dermatitis (condition of red, itchy skin)
   2. Moderate to severe asthma with an eosinophilic phenotype
   3. Moderate to severe oral corticosteroid-dependent asthma
   4. Chronic rhinosinusitis with nasal polyposis (inflammation of nasal and sinus ways with small growths in the nose)
   5. Eosinophilic esophagitis
   6. Prurigo nodularis

B. If you have moderate to severe atopic dermatitis, approval also requires:
   1. You are 6 months of age or older
   2. You have had a trial of a high or super-high potency topical corticosteroid (e.g., triamcinolone acetonide, fluocinonide, clobetasol propionate, halobetasol propionate) **AND** one non-steroidal topical immunomodulating agent (e.g., Eucrisa, Opzelura, pimecrolimus, tacrolimus)

C. If you have moderate to severe asthma, approval also requires:
   1. You are 6 years of age or older
   2. You have an eosinophilic phenotype asthma (type of adult inflammatory asthma) OR oral corticosteroid-dependent asthma
   3. You are currently receiving therapy with ONE of the following:
      a. High-dose inhaled corticosteroid (ICS) AND a long-acting beta2 agonist (LABA)
      b. High-dose ICS/LABA combination product
   4. Dupixent will be used as add-on maintenance treatment to one of the above inhaled asthma regimens
   5. You have experienced at least ONE asthma exacerbation within the past 12 months (exacerbation is defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days)

D. If you have chronic rhinosinusitis with nasal polyposis, approval also requires:
   1. You are 18 years of age or older
   2. You had an inadequate response to intranasal corticosteroids

E. **If you have eosinophilic esophagitis, approval also requires ONE of the following:**
   1. You are 18 years of age or older
   2. You are 12 to 17 years of age AND weigh at least 40kg

F. **If you have prurigo nodularis, approval also requires:**
   1. You are 18 years of age or older
   2. You have had a trial of a topical corticosteroid, pimecrolimus, or tacrolimus

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DUPILUMAB

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **DUPILIMAB (Dupixent)** requires the following rule(s) be met for renewal:

A. You have one of the following diagnoses:
   1. Moderate to severe atopic dermatitis (condition of red, itchy skin)
   2. Moderate to severe asthma
   3. Chronic rhinosinusitis with nasal polyposis (inflammation of nasal and sinus ways with small growths in the nose)
   4. Eosinophilic esophagitis
   5. Prurigo nodularis

B. **If you have moderate to severe atopic dermatitis, renewal also requires:**
   1. You have documentation showing that you have experienced or maintained improvement in at least two of the following:
      a. Intractable pruritus (severe itching)
      b. Cracking and oozing/bleeding of affected skin
      c. Impaired activities of daily living

C. **If you have moderate to severe asthma, renewal also requires:**
   1. You will continue to use inhaled corticosteroid (ICS) or ICS-containing combination inhalers
   2. You have shown a clinical response as evidenced by ONE of the following:
      a. Reduction in asthma exacerbation (worsening of symptoms) from baseline
      b. Decreased use of rescue medications
      c. Increase in percent predicted FEV1 (amount of air you can forcefully exhale) from pretreatment baseline
      d. Reduction in severity or frequency of asthma-related symptoms such as less wheezing, shortness of breath, coughing, etc.

D. **If you have chronic rhinosinusitis with nasal polyposis, renewal also requires:**
   1. You had a clinical benefit compared to baseline (such as improvements in nasal congestion, sense of smell or size of polyps)

E. **If you have eosinophilic esophagitis, renewal also requires:**
   1. You had a clinical benefit compared to baseline

F. **If you have prurigo nodularis, renewal also requires:**
   1. You had a clinical benefit compared to baseline

RATIONALE

Ensure appropriate diagnostic, utilization and safety criteria are used for the management of requests for (Dupixent) dupilumab.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

DUPILUMAB

FDA APPROVED INDICATIONS

Dupixent is indicated:

- For the treatment of patients aged 6 months and older with moderate to severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Dupixent can be used with or without topical corticosteroids
- As an add-on maintenance treatment in patients aged 6 years and older with moderate to severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma
- As an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP)
- For the treatment of patients aged 12 years and older, weighing at least 40 kg, with eosinophilic esophagitis (EoE)
- For the treatment of adult patients with prurigo nodularis (PN)

DOSING

Atopic Dermatitis

- The recommended dosage for adults is an initial subcutaneous dose of 600mg (two 300mg injections in different sites), followed by 300mg subcutaneously given every other week.
- The recommended dosage for pediatric patients 6 months to 5 years of age is specified in the table below.

Body Weight	Initial and Subsequent Dosage
5 to less than 15 kg	200 mg (one 200 mg injection) every 4 weeks (Q4W)
15 to less than 30 kg	300 mg (one 300 mg injection) every 4 weeks (Q4W)

- The recommended dosage for pediatric patients 6 to 17 years of age is specified in the table below.

Body Weight	Initial Loading Dose	Subsequent Dosage
15 to less than 30 kg	600 mg (two 300 mg injections)	300 mg every 4 weeks (Q4W)
30 to less than 60 kg	400 mg (two 200 mg injections)	200 mg every other week (Q2W)
60 kg or more	600 mg (two 300 mg injections)	300 mg every other week (Q2W)

Asthma

- The recommended dose in adults and adolescents (12 years and older) is an initial subcutaneous dose of 600mg (two 300mg injections in different sites), followed by 300mg subcutaneously given every other week OR an initial subcutaneous dose of 400mg (two 200mg injections in different sites), followed by 200mg subcutaneously given every other week.
- For patients requiring concomitant oral corticosteroids or with co-morbid moderate-to-severe atopic dermatitis for which Dupixent is indicated, start with an initial dose of 600 mg followed by 300 mg given every other week.
- For pediatric patients (6 to 11 years of age) weighing 15 to less than 30 kg, the recommended dose is 100 mg subcutaneously given every other week OR 300 mg given every 4 weeks.
- For pediatric patients (6 to 11 years of age) weighing greater than 30 kg, the recommended dose is 200 mg subcutaneously given every other week.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

DUPILUMAB

Chronic Rhinosinusitis with Nasal Polyposis
- The recommended dose for adult patients is 300 mg given every other week (QOW).

Eosinophilic Esophagitis
- The recommended dosage for adult and pediatric patients 12 years of age and older, weighing at least 40 kg, is 300 mg given every week (QW).

Prurigo Nodularis
- The recommended dose for adult patients is an initial dose of 600 mg (two 300 mg injections), followed by 300 mg given every other week (Q2W).

REFERENCES

- Dupixent [Prescribing Information]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc. September 2022.
- Sidbury R, et al. Guidelines of care for the management of atopic dermatitis: section 4. Prevention of disease flares and use of adjunctive therapies and approaches. J Am Acad Dermatol 2014;71:1218-1233.
- Wollenberg A, et al. ETFAD/EADV Eczema task force 2015 position paper on diagnosis and treatment of atopic dermatitis in adult and pediatric patients. JEADV 2016;30:729-747.
- Totri CR, et al. Prescribing practices for systemic agents in the treatment of severe pediatric atopic dermatitis in the US and Canada: the PeDRA TREAT survey. J Am Acad Dermatol. 2017 Feb;76(2):281-285.
- Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma. National Heart, Lung, and Blood Institute. August 28, 2007. Available at: https://www.nhlbi.nih.gov/sites/default/files/media/docs/asthgdln_1.pdf.
- Chung KF, Wenzel SE, Brozek JL, et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. Eur Respir J. 2014;43(2):343-73.
- Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention. 2018. Available from: www.ginasthma.org.

Created: 04/17
Effective: 11/07/22 Client Approval: 10/28/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ECALLANTIDE

Generic	Brand	HICL	GCN	Exception/Other
ECALLANTIDE	KALBITOR	36797		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

The guideline named **ECALLANTIDE** requires a diagnosis of hereditary angioedema, documented age of 12 years old or older, and administration of the medication by a healthcare professional.

RATIONALE
Ensure appropriate use of ecallantide based on FDA approved indication and dosing.

The recommended dose of ecallantide is 30mg (3mL) subcutaneously in three 10mg (1mL) injections. If symptoms do not subside, an additional 30mg dose can be given within a 24 hour period.

FDA APPROVED INDICATIONS
Kalbitor (ecallantide) is indicated for the treatment of acute attacks of hereditary angioedema in adults 12 years of age and older.

BOXED WARNING FOR ECALLANTIDE:
Anaphylaxis has occurred after administration of Kalbitor. Because of the risk of anaphylaxis, Kalbitor should only be administered by a healthcare professional with appropriate medical support to manage anaphylaxis and hereditary angioedema. Healthcare professionals should be aware of the similarity of symptoms between hypersensitivity reactions and hereditary angioedema and patients should be monitored closely. Do not administer Kalbitor to patients with known clinical hypersensitivity to Kalbitor.

REFERENCES

- Dyax Corp. Kalbitor product information. Burlington, MA. March 2014.

Created: 12/17
Effective: 02/02/18 Client Approval: 12/28/17 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ECULIZUMAB

Generic	Brand	HICL	GCN	Exception/Other
ECULIZUMAB	SOLIRIS	34618		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline for **ECULIZUMAB** requires a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS), or generalized myasthenia gravis. The following criteria must also be met:

- Eculizumab (Soliris) is NOT being used for Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS)

For patients with generalized Myasthenia gravis (gMG), approval requires:

- The patient is 18 years of age or older
- The patient's diagnosis is confirmed by a positive Anti-acetylcholine receptor (AchR) antibody test
- The patient has failed **TWO** of the following immunosuppressive therapies: corticosteroids, azathioprine, mycophenolate mofetil, cyclosporine

For patients with paroxysmal nocturnal hemoglobinuria (PNH), approval requires:

- The patient is 18 years of age or older
- The patient has confirmed PNH as demonstrated by **ALL** of the following via flow cytometry:
    - At least 2 different GPI-protein deficiencies (e.g., CD55, CD59) on at least 2 cell lineages (e.g., erythrocytes, granulocytes)
    - PNH granulocyte clone size ⩾10%
- The patient meets **ONE** of the following:
    - Transitioning from alternative complement inhibitor therapy (i.e., Ultomiris)
    - Documentation of evidence of intravascular hemolysis (e.g., lactate dehydrogenase [LDH] level ⩾1.5 X ULN, hemoglobinuria) **OR** history of major adverse vascular event from thromboembolism

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ECULIZUMAB

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

The guideline for **ECULIZUMAB** renewal requires a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS), or generalized myasthenia gravis.

For patients with PNH, the following criterion must be met:

- Physician attestation of clinical benefit compared to baseline (e.g., reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase (LDH) and hemoglobin levels)

For patients with aHUS, the following criterion must be met:

- Documentation (i.e., chart notes, lab results) that the patient has experienced clinical improvement (e.g., improved platelet count, serum lactate dehydrogenase levels, reduced serum creatinine, reduced need for dialysis) while receiving Soliris therapy

For patients with generalized myasthenia gravis, the following criterion must be met:

- Documentation (i.e., chart notes) that the patient has experienced an improvement in daily functioning (e.g., reduced muscle weakness, improved swallowing, reduction in double vision, improved grip, improved forced vital capacity) while receiving Soliris therapy

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RATIONALE

To ensure appropriate use of Soliris based on FDA approved indication and prescribing information.

FDA APPROVED INDICATIONS

Soliris is indicated for 1) paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis, 2) atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy, and 3) for the treatment of adult patients with generalized myasthenia gravis (gMG) who are antiacetylcholine receptor (AchR) antibody positive.

Limitation of Use:
Soliris is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).

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ECULIZUMAB

FDA APPROVED INDICATIONS (CONTINUED)

DOSING AND ADMINISTRATION

For patients 18 years of age and older with PNH, Soliris therapy consists of:

- 600 mg weekly for the first 4 weeks, followed by
- 900 mg for the fifth dose 1 week later, then
- 900 mg every 2 weeks thereafter.

For patients 18 years of age and older with aHUS, Soliris therapy consists of:

- 900 mg weekly for the first 4 weeks, followed by
- 1200 mg for the fifth dose 1 week later, then
- 1200 mg every 2 weeks thereafter.

For patients with generalized myasthenia gravis, Soliris therapy consists of:

- 900 mg weekly for the first 4 weeks, followed by
- 1200 mg for the fifth dose 1 week later, then
- 1200 mg every 2 weeks thereafter.

For patients less than 18 years of age, Soliris should be dosed as follows:

For patients less than 18 years of age, administer Soliris based upon body weight, according to the following schedule (Table 1):

Table 1: Dosing recommendations in patients less than 18 years of age

Patient Body Weight	Induction	Maintenance
40 kg and over	900 mg weekly x 4 doses	1200 mg at week 5; then 1200 mg every 2 weeks
30 kg to less than 40 kg	600 mg weekly x 2 doses	900 mg at week 3; then 900 mg every 2 weeks
20 kg to less than 30 kg	600 mg weekly x 2 doses	600 mg at week 3; then 600 mg every 2 weeks
10 kg to less than 20 kg	600 mg weekly x 1 dose	300 mg at week 2; then 300 mg every 2 weeks
5 kg to less than 10 kg	300 mg weekly x 1 dose	300 mg at week 2; then 300 mg every 3 weeks

Soliris should be administered at the recommended dosage regimen time points, or within two days of these time points.

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ECULIZUMAB

FDA APPROVED INDICATIONS (CONTINUED)

BOXED WARNING
Soliris contains a black box warning regarding life-threatening and fatal meningococcal infections that have occurred in patients treated with Soliris. The warning advises prescribers to comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccination in patients with complement deficiencies. Patients should be immunized with a meningococcal vaccine at least 2 weeks prior to administering the first dose of Soliris, unless the risks of delaying Soliris therapy outweigh the risks of developing a meningococcal infection. Patients should be monitored for early signs of meningococcal infections and evaluated immediately if infection is suspected. Soliris is only available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS). Under the Soliris REMS prescribers must enroll in the program. Enrollment in REMS and other information are available at 1-888-SOLIRIS.

HOW SUPPLIED
Soliris (eculizumab) is supplied as 300 mg single-dose vials containing 30 mL of 10 mg/mL sterile, preservative-free Soliris solution per vial.

REFERENCES
Soliris (eculizumab) [Prescribing Information]. New Haven, CT: Alexion Pharmaceuticals, Inc.; February 2018.

Created: 10/15
Effective: 04/11/22 Client Approval: 03/09/22 P&T Approval: N/A

EDARAVONE

Generic	Brand	HICL	GCN	Exception/Other
EDARAVONE	RADICAVA ORS		52318	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **EDARAVONE ORAL (Radicava ORS)** requires the following rule(s) be met for approval:

A. You have amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition)
B. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor) or ALS specialist at an ALS Specialty Center or Care Clinic
C. You have had ALS (from onset of symptoms) for 3 years or less
D. You have a forced vital capacity (FVC: amount of air exhaled from lungs) of greater than 70 percent
E. You have tried riluzole OR are currently taking riluzole
F. You have mild to moderate ALS with a score of 2 or higher in all of the following 12 items of the Amyotrophic Lateral Sclerosis Functional Rating Scale Revised (ALSFRS-R: a tool for evaluating functional status): speech, salivation, swallowing, handwriting, cutting food, dressing and hygiene, turning in bed, walking, climbing stairs, dyspnea (difficulty breathing), orthopnea (shortness of breath while lying down), respiratory insufficiency (a type of breathing condition)

RENEWAL CRITERIA

Our guideline named **EDARAVONE ORAL (Radicava ORS)** requires the following rule(s) be met for renewal:

A. You have amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition)
B. You do not require invasive ventilation (inserting a breathing tube into your throat)
C. You have improved baseline functional ability OR you have maintained a score of 2 or greater in all 12 items of the Amyotrophic Lateral Sclerosis Functional Rating Scale Revised (ALSFRS-R)

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

EDARAVONE

RATIONALE
Ensure appropriate diagnostic, utilization and safety criteria are met for the management of requests for edaravone.

FDA APPROVED INDICATIONS
Edaravone is indicated for the treatment of amyotrophic lateral sclerosis (ALS).

DOSAGE AND ADMINISTRATION
The recommended dosage of Radicava ORS is 105 mg (5 mL) taken orally or via feeding tube in the morning after overnight fasting. Radicava ORS should be administered according to the following schedule:

- An initial treatment cycle with daily dosing for 14 days, followed by a 14-day drug-free period.
- Subsequent treatment cycles with daily dosing for 10 days out of 14-day periods, followed by 14-day drugfree periods.

REFERENCES
Radicava ORS [Prescribing Information]. Jersey City, NJ: Mitsubishi Tanabe Pharma America, Inc.; May 2022.

Created: 06/22
Effective: 07/18/22 Client Approval: 06/20/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

EFINACONAZOLE

Generic	Brand	HICL	GCN	Exception/Other
EFINACONAZOLE	JUBLIA	41184		

GUIDELINES FOR USE

Our guideline for **EFINACONAZOLE** requires a previous trial or contraindication to oral terbinafine or oral itraconazole and ciclopirox topical solution and one of the following: 1) a diagnosis of onychomycosis of the toenails and, 2) presence of complicating factors such as diabetes, peripheral vascular disease, a suppressed immune system, or 3) pain surrounding the nail or soft tissue.

RATIONALE

Promote clinically appropriate utilization of Jublia (efinaconazole) based on its FDA approved indication and dosing.

Jublia is an azole antifungal indicated for the topical treatment of onychomycosis of the toenails due to Trichophyton rubrum and Trichophyton mentagrophyte. Onychomycosis refers to nail infections caused by any fungus, including yeasts and non-dermatophyte molds. Although onychomycosis is usually a cosmetic concern to patients, it also causes physical discomfort for some, particularly with more severe or advanced disease. Patients may experience chronic pain or acute pain exacerbated by nail cutting, footwear, or pressure from bedclothes. Additionally, in patients with diabetes or other immunocompromised states, onychomycosis may increase the risk of bacterial infections such as cellulitis.

Jublia may not be as efficacious as oral antifungals (e.g. terbinafine and itraconazole) in the treatment of onychomycosis, but its safety profile is improved. The most common adverse reactions associated with Jublia are ingrown toenails, application site dermatitis, application site vesicles, and application site pain. Additionally, Jublia neither interacts with cytochrome P450 enzymes nor is associated with hepatotoxicity, as seen with oral antifungals.

DOSE

Apply one drop onto each affected toenail once daily (for the big toenail, also apply a second drop to the end of the toenail) for 48 weeks. Use the brush attached to the bottle to gently spread Jublia to the entire toenail including the cuticle, toenail folds, toenail bed, hyponychium, and the undersurface of the toenail plate.

For topical use only and not for oral, ophthalmic, or intravaginal use.

Note: 1 bottle of 4mL contains 200 applications.

FDA APPROVED INDICATIONS

Topical treatment of onychomycosis of the toenails due to *Trichophyton rubrum* and *Trichophyton mentagrophyte*

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EFINACONAZOLE

REFERENCES (CONTINUED)

- Jublia [Prescribing Information]. Bridgewater, NJ: Valeant Pharmaceuticals; June 2014.
- UpToDate, Inc. Onychomycosis. UpToDate [database online]. Waltham, MA. Available at: http://www.uptodate.com/home/index.html. Updated April 1, 2014.

Created: 06/15
Effective: 07/22/15 Client Approval: 06/15 P&T Approval: 08/14

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ELAGOLIX

Generic	Brand	HICL	GCN	Exception/Other
ELAGOLIX	ORILISSA	45108		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ELAGOLIX (Orilissa)** requires the following rule(s) be met for approval:

A. You have moderate to severe pain associated with endometriosis (disorder where uterus tissue grows outside of the uterus)
B. You are 18 years of age or older
C. You had a previous trial of or contraindication to (a medical reason why you cannot use) a nonsteroidal anti-inflammatory drug (NSAID; such as ibuprofen, meloxicam, naproxen) **AND** hormonal contraceptives/therapy [e.g., oral tablets, vaginal ring, patch, intrauterine contraception (IUD)]

RENEWAL CRITERIA

Our guideline named **ELAGOLIX (Orilissa)** requires the following rule(s) be met for approval:

A. You have history of paid claim(s) for the requested medication in the past 90 day
B. You have a previous authorization on file for the requested medication
C. You will not exceed 24 total months of therapy with Orilissa

Requests will not be approved if you meet any ONE of the following conditions:

- You have received a 6-month course of Orilissa 200 mg twice daily
- You have received a 6-month course of Orilissa 150 mg once daily and you have moderate hepatic (liver) impairment (Child-Pugh Class B)
- You have received a 24-month course of Orilissa 150 mg once daily and you have normal liver function or mild hepatic (liver) impairment (Child-Pugh Class A)

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ELAGOLIX

RATIONALE
Ensure appropriate utilization and safety criteria are used for the management of requests for Orilissa (elagolix).

FDA-APPROVED INDICATION
Orilissa (elagolix) is a gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the management of moderate to severe pain associated with endometriosis.

DOSING AND ADMINISTRATION
Pregnancy should be excluded before starting Orilissa (elagolix), or Orilissa (elagolix) can be prescribed within 7 days from the onset of menses. The lowest effective dose should be used, taking into account the severity of symptoms and treatment objectives. Treatment duration should be limited due to the potential for decreases in bone mineral density that may not be completely reversible.

Orilissa (elagolix) is dosed according to the following table:

Hepatic Function	Dosing Regimen	Maximum Treatment Duration
Normal hepatic function *or* mild hepatic impairment (Child-Pugh Class A)	150 mg once daily	24 months
	200 mg twice daily*	6 months
Moderate hepatic impairment (Child-Pugh Class B)	150 mg once daily	6 months
Severe hepatic impairment (Child-Pugh Class C)	Contraindicated	
*Regimen to be considered for those with coexisting dyspareunia		

REFERENCES

- Orilissa [Prescribing Information]. North Chicago, IL: AbbVie Inc.; August 2021.

Created: 08/18
Effective: 12/15/21 Client Approval: 10/26/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ELAGOLIX/ ESTRADIOL/ NORETHINDRONE

Generic	Brand	HICL	GCN	Exception/Other
ELAGOLIX/ ESTRADIOL/ NORETHINDRONE ACETATE	ORIAHNN	46577		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ELAGOLIX/ ESTRADIOL/ NORETHISTERONE (Oriahnn)** requires the following rule(s) be met for approval:

- The request is for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids: non-cancerous growths in the uterus)
- You are premenopausal
- You are 18 years of age or older
- You have had a previous trial of hormonal contraceptives/therapy [e.g., oral tablets, vaginal ring, patch, intrauterine contraception (IUD)]

RENEWAL CRITERIA

Our guideline named **ELAGOLIX/ESTRADIOL/NORETHISTERONE (Oriahnn)** requires the following rule(s) be met for approval:

A. You have history of paid claim(s) for the requested medication in the past 90 day
B. You have a previous authorization on file for the requested medication
C. You will not exceed 24 total months of therapy with Oriahnn

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RATIONALE

Ensure appropriate diagnostic, utilization and safety criteria are used for the management of requests for Oriahnn.

FDA APPROVED INDICATIONS

Oriahnn is indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women.

DOSING

The recommended dosage of Oriahnn is:

- One elagolix 300 mg, estradiol 1 mg, and norethindrone acetate 0.5 mg capsule in the morning (AM), and
- One elagolix 300 mg capsule in the evening (PM).

The recommended duration of treatment is 24 months.

REFERENCES

- Oriahnn [Prescribing Information]. North Chicago, IL: AbbVie Inc., August 2021.

Created: 07/20
Effective: 12/15/21 Client Approval: 10/26/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ELIGLUSTAT TARTRATE

Generic	Brand	HICL	GCN	Exception/Other
ELIGLUSTAT TARTRATE	CERDELGA		36988	Strength = 84mg Route = ORAL

GUIDELINES FOR USE

Our guideline for **ELIGLUSTAT TARTRATE** requires a diagnosis of type 1 (non-neuronopathic) Gaucher's disease in a patient at least 18 years of age. Twice daily dosing will be approved for patients who are extensive or immediate metabolizers of CYP2D6 inhibitors. Once daily dosing will be approved for patients who are poor metabolizers of CYP2D6. This medication is not approved for the following patients: CYP2D6 ultra-rapid metabolizers or CYP2D6 indeterminate metabolizer.

ELIGLUSTAT TARTRATE

RATIONALE

Promote appropriate utilization and dosing of Cerdelga (eliglustate tartrate) based on the FDA approved indication. Eliglustat is a CYP2D6 and CYP3A substrate. Drugs that inhibit CYP2D6 and CYP3A metabolism pathways may significantly increase the exposure to eliglustat and result in prolongation of the PR, QTc, and/or QRS cardiac intervals that could result in cardiac arrhythmias.

The recommended dosage of CERDELGA is 84 mg twice daily in CYP2D6 extensive metabolizers (EMs), and intermediate metabolizers (IMs). The recommended dosage in CYP2D6 poor metabolizers (PMs) is 84 mg once daily.

Some inhibitors of CYP2D6 and CYP3A are contraindicated with CERDELGA depending on the patient's metabolizer status. Co-administration of CERDELGA with other CYP2D6 and CYP3A inhibitors may require dosage adjustment depending on the patient's CYP2D6 metabolizer status to reduce the risk of potentially significant adverse reactions.

Reduce the dosage of CERDELGA to 84 mg once daily for:
• CYP2D6 EMs and IMs taking strong or moderate CYP2D6 inhibitors
• CYP2D6 EMs taking strong or moderate CYP3A inhibitors

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RATIONALE (CONTINUED)

Table 1. Established and other potentially significant drug interactions: Alteration in Cerdelga Dosage May be Recommended Based on Predicted Interaction in Extensive Metabolizers (EM) and Intermediate Metabolizers (IM)

	Recommended CERDLEGA Dosage, by CYP2D6 Metabolizer Status	
CYP450 Inhibitors	**EM**	**IM**
Strong or Moderate CYP2D6 inhibitors concomitantly with Strong or Moderate CYP3A inhibitors	Contraindicated	Contraindicated
Strong CYP2D6 inhibitors e.g., paroxetine	84 mg once daily	84 mg once daily
Moderate CYP2D6 inhibitors e.g., terbinafine	84 mg once daily	84 mg once daily
Strong CYP3A inhibitors e.g., ketoconazole	84 mg once daily	Contraindicated
Moderate CYP3A inhibitors e.g., fluconazole	84 mg once daily	Not recommended

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ELIGLUSTAT TARTRATE

RATIONALE (CONTINUED)

Table 2. Established and other potentially significant drug interactions: Alteration in Cerdelga Dosage May be Recommended Based on Predicted Interaction in Poor Metabolizers

CYP450 Inhibitors	Recommended CERDELGA Dosage for PMs
Strong CYP3A inhibitors e.g., ketoconazole	Contraindicated
Moderate CYP3A inhibitors e.g., fluconazole	Not recommended
Weak CYP3A inhibitors e.g., ranitidine	Not recommended

FDA APPROVED INDICATIONS

CERDELGA is a glucosylceramide synthase inhibitor indicated for the long term treatment of adult patients with Gaucher disease type 1 who are CYP2D6 extensive metabolizers (EMs), intermediate metabolizers (IMs), or poor metabolizers (PMs) as detected by an FDA-cleared test.

Limitations of Use:

- CYP2D6 ultra-rapid metabolizers may not achieve adequate concentrations of CERDELGA to achieve a therapeutic effect
- A specific dosage cannot be recommended for CYP2D6 indeterminate metabolizers

REFERENCES

- Cerdelga [Prescribing Information]. Waterford, Ireland: Genzyme; August 2014

Created: 06/15
Effective: 07/22/15 Client Approval: 06/15 P&T Approval: 11/14

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ELOSULFASE ALFA

Generic	Brand	HICL	GCN	Exception/Other
ELOSULFASE ALFA	VIMIZIM	40929		

GUIDELINES FOR USE

Our guideline for **ELOSULFASE ALFA** requires a diagnosis of Mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome).

RATIONALE
Promote appropriate utilization of Vimizim based on FDA approved indication.

Vimizim is the first agent approved to treat Morquio A syndrome. Prior to the approval of this medication, complications of Morquio A syndrome, such as, skeletal abnormalities, heart disease, hearing and vision loss, and breathing difficulties, are often treated medically and surgically as needed.

Morquio A syndrome, an autosomal recessive lysosomal storage disease, affects approximately 800 individuals in the United States. Morquio A syndrome is classified within a group of diseases called mucopolysaccharidoses (MPS) as MPS IV. Patients with Morquio A syndrome are deficient in the N-acetylgalactosamine-6-sulfate sulfatase (GALNS) enzyme. The first symptoms usually occur at 2-3 years of age. This enzyme deficiency causes difficulties in skeletal development and growth, and patients will typically exhibit symptoms such as abnormal bone development (including the spine), bell-shaped chest with flared ribs at bottom, coarse facial features, widely spaced teeth, hypermobile joints, knock knees, macrocephaly, and short stature. The patient with Morquio A syndrome may have physical exam abnormalities such as kyphoscoliosis, cloudy cornea, aortic regurgitation, enlarged liver, inguinal hernia, and paralysis below the neck due to underdeveloped upper vertebrae.

The most common adverse events observed in clinical trials (occurring in 10% or greater of Vimizim patients) were nausea, vomiting, abdominal pain, chills, headache, pyrexia, and fatigue. In clinical trials 7.7% of patients had anaphylactic reactions and 18.7% had hypersensitivity reactions during or after Vimizim administration.

Vimizim contains a boxed warning regarding the risk of life-threatening anaphylactic reactions that may occur during infusion. Patients must be observed during and after Vimizim infusion by a health care provider trained to manage medical emergencies. Patients with acute febrile or respiratory conditions may be at increased risk due to potential for respiratory compromise during a hypersensitivity reaction; the healthcare provider must carefully consider the patient's clinical condition prior to infusion and consider delaying treatment with Vimizim when appropriate.

The safety and efficacy of Vimizim have not been established in patients less than 5 years old.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ELOSULFASE ALFA

DOSAGE

The recommended dose of Vimizim is 2mg per kilogram of body weight administered once weekly as an intravenous infusion. Administer Vimizim over a minimum of 3.5 to 4.5 hours (based on infusion volume). Patients should receive pretreatment with antihistamines, with or without antipyretics, 30 to 60 minutes before administration of Vimizim. If a hypersensitivity reaction occurs during the infusion, administration may be slowed, temporarily stopped or discontinued based on the severity of the reaction. Vimizim should be infused using a low-protein binding infusion set with a low-protein binding 0.2 micrometer in-line filter.

FDA APPROVED INDICATIONS

Vimizim is a hydrolytic lysosomal glycosaminoglycan (GAG)-specific enzyme indicated for patients with Mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome).

REFERENCES

- Vimizim [Prescribing Information]. Novato, CA: Biomarin Pharmaceutical Inc; February 2014.
- FDA Press Announcement on 2/14/14: FDA approves Vimizim to treat rare congenital disorder. Available online at: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm386008.htm Accessed February 24, 2014.

Created: 10/15
Effective: 11/12/15 Client Approval: 10/19/15 P&T Approval: 10/15

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ELTROMBOPAG

Generic	Brand	HICL	GCN	Exception/Other
ELTROMBOPAG	PROMACTA	35989		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline for **ELTROMBOPAG (Promacta)** requires you have one of the following diagnoses:

- Chronic immune (idiopathic) thrombocytopenia (low levels of the blood cells that prevent bleeding)
- Thrombocytopenia (low blood platelet count) due to chronic hepatitis C
- Severe aplastic anemia (type of blood disorder)

If you are greater than 12 years of age and the request is for Promacta packets, approval also requires:

- You previously had a trial of Promacta tablets
- You have a medical need for powder packets

If you have chronic immune (idiopathic) thrombocytopenia, approval also requires:

- You are 1 year of age or older
- You have tried corticosteroids or immunoglobulins, or did not have a good enough response to a splenectomy (removal of spleen) – unless there is a medical reason why you cannot (contraindication)

If you have thrombocytopenia due to chronic hepatitis C, approval also requires:

- Your thrombocytopenia does not allow you to start interferon-based therapy (type of drug for hepatitis) or limits your ability to maintain interferon-based therapy

If you have severe aplastic anemia, approval also requires ONE of the following:

- You are 2 years of age or older and Promacta will be used in combination with standard immunosuppressive therapy (treatment that prevents activity from your immune system) as first-line treatment
- You did not have a good enough response to immunosuppressive therapy

RENEWAL CRITERIA
(NOTE: For the diagnoses of thrombocytopenia due to chronic hepatitis C or severe aplastic anemia, please refer to the Initial Criteria section.)

Our guideline named **ELTROMBOPAG (Promacta)** requires the following rules be met for renewal:

- You have a diagnosis of chronic immune (idiopathic) thrombocytopenia (low levels of the blood cells that prevent bleeding)
- You have a clinical response, as defined by an increase in platelet count to at least 50X10(9)/L (at least 50,000 per microliter)

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ELTROMBOPAG

RATIONALE

To ensure safe and appropriate utilization of Promacta per FDA labeling.

FDA APPROVED INDICATIONS

Promacta is a thrombopoietin receptor agonist indicated:

- For the treatment of thrombocytopenia in adult and pediatric patients 1 year and older with chronic immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. Promacta should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding.
- For the treatment of thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy. Promacta should be used only in patients with chronic hepatitis C whose degree of thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy.
- In combination with standard immunosuppressive therapy for the first-line treatment of adult and pediatric patients 2 years and older with sever aplastic anemia.
- For the treatment of patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy.

Limitations of use:

- Promacta is not indicated for the treatment of patients with myelodysplastic syndrome.
- Safety and efficacy have not been established in combination with direct-acting antiviral agents used without interferon for treatment of chronic hepatitis C infection.

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DOSING

Take on empty stomach (1 hour before or 2 hours after a meal).

Chronic Immune (Idiopathic) Thrombocytopenia
Initiate Promacta at 50mg once daily for most adult and pediatric patients 6 years and older, and at 25mg once daily for pediatric patients aged 1 to 5 years. Dose reductions are needed for patients with hepatic impairment and some patients of Asian ancestry. Adjust to maintain platelet count greater than or equal to $50X10^9$/L. Do not exceed 75mg per day.

First-line Severe Aplastic Anemia
Initiate Promacta once daily at 2.5mg/kg (in pediatric patients aged 2 to 5 years old), 75mg (pediatric patients aged 6 to 11 years old), or 150mg for patients aged 12 years and older concurrently with standard immunosuppressive therapy. Reduce initial dose in patients of Asian ancestry. Modify dosage for toxicity or elevated platelet counts.

Refractory Severe Aplastic Anemia
Initiate Promacta at 50mg once daily. Reduce initial dose in patients with hepatic impairment or patients of Asian ancestry. Adjust to maintain platelet count greater than $50X10^9$/L. Do not exceed 150 mg per day.

Chronic Hepatitis C-associated Thrombocytopenia
Initiate Promacta at a dose of 25 mg once daily. Adjust to achieve target platelet count required to initiate antiviral therapy. Do not exceed a dose of 100 mg daily.

HOW SUPPLIED

Tablets: 12.5, 25, 50, 75, and 100mg
Oral suspension: 12.5, and 25mg

REFERENCES

Promacta [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2019.

Created: 06/15
Effective: 05/01/20 Client Approval: 04/14/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ELUXADOLINE

Generic	Brand	HICL	GCN	Exception/Other
ELUXADOLINE	VIBERZI	42445	39355 39354	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline for **ELUXADOLINE (Viberzi)** requires a diagnosis of irritable bowel syndrome with diarrhea (IBS-D). The following criteria must also be met:

- The patient is at least 18 years old
- The patient has had a trial of or contraindication to **ALL** of the following: loperamide **AND** a tricyclic anti-depressant (e.g., amitriptyline, desipramine) **AND** dicyclomine
- The patient has had a trial of or contraindication to Xifaxan (rifaximin)

In addition, the **ELUXADOLINE (Viberzi)** dosage of 75 mg twice daily will only be approved in patients who meet **ONE** of the following criteria:

- Are unable to tolerate the 100 mg dose
- Are receiving concomitant OATP1B1 inhibitors
- Have mild or moderate hepatic impairment
- Have moderate or severe renal impairment, and in patients with end stage renal disease not yet on dialysis

RENEWAL CRITERIA

Our guideline for **ELUXADOLINE (Viberzi)** renewal requires a diagnosis of irritable bowel syndrome with diarrhea (IBS-D). The following criteria must also be met:

- Patient has experienced at least 30% decrease in abdominal pain (on a 0-10 point pain scale)
- Patient has experienced at least 50% reduction in the number of days per week with a stool consistency of mushy stool (Bristol Stool scale type 6) or entirely liquid stool (Bristol Stool scale type 7)

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ELUXADOLINE

RATIONALE
To ensure appropriate utilization of Viberzi for irritable bowel syndrome with diarrhea (IBS-D).

FDA APPROVED INDICATIONS
Viberzi is a mu-opioid receptor agonist, indicated in adults for the treatment of irritable bowel syndrome with diarrhea (IBS-D).

DOSING
The recommended dosage in adults is 100 mg twice daily taken with food.
The recommended dosage is 75 mg twice daily taken with food in patients who:
- Are unable to tolerate the 100 mg dose
- Are receiving concomitant OATP1B1 inhibitors
- Have mild or moderate hepatic impairment
- Have moderate or severe renal impairment; and in patients with end stage renal disease not yet on dialysis

REFERENCES

- Patheon Pharmaceuticals, Inc. Viberzi package insert. Cincinnati, OH 45209. June 2020.
- Salix Pharmaceuticals, Inc. Xifaxan package insert. Raleight, NC. October 2020.
- Task Force on the Management of Functional Bowel Disorders. American College of Gastroenterology Monograph on the Management of Irritable Bowel syndrome and Chronic Idiopathic Constipation. Am J Gastroenterol 2014; 109:S2-S26.

Created: 08/16
Effective: 03/14/22 Client Approval: 02/04/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ENASIDENIB

Generic	Brand	HICL	GCN	Exception/Other
ENASIDENIB	IDHIFA	44450		

GUIDELINES FOR USE

The guideline named **ENSIDENIB (Idhifa)** requires a diagnosis of relapsed or refractory acute myeloid leukemia (AML). In addition, the following criteria must also be met:

- The patient is isocitrate dehydrogenase-2 (IDH2) mutation positive as detected by an FDA-approved diagnostic test
- The patient is 18 years of age or older

RATIONALE
Promote appropriate utilization of **ENASIDENIB** based on FDA approved indication and dosage.

FDA APPROVED INDICATIONS
Idhifa is an isocitrate dehydrogenase-2 inhibitor indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with an isocitrate dehydrogenase-2 (IDH2) mutation as detected by an FDA-approved test.

DOSAGE AND ADMINISTRATION
The recommended dose of Idhifa is 100mg taken orally once daily with of without food. Idhifa tablets should not be split or crushed.

REFERENCES

- Idhifa [Prescribing Information]. Summit, NJ: Celgene Corporation; August 2017.

Created: 08/17
Effective: 02/23/18 Client Approval: 09/01/17 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ENCORAFENIB

Generic	Brand	HICL	GCN	Exception/Other
ENCORAFENIB	BRAFTOVI	45039		

GUIDELINES FOR USE

Our guideline named **ENCORAFENIB (Braftovi)** requires the following rule(s) be met for approval:

D. You have ONE of the following diagnoses:
1. Unresectable or metastatic melanoma (a type of skin cancer that has spread or cannot be completely removed with surgery)
2. Metastatic colorectal cancer (a type of cancer that affects the colon and the rectum and has spread to other parts of the body)

E. If you have unresectable or metastatic melanoma, approval also requires:
1. You have a BRAF V600E or V600K mutation (types of gene mutations) as detected by an FDA (Food and Drug Administration)-approved test
2. The medication will be used in combination with Mektovi (binimetinib)

F. If you have metastatic colorectal cancer, approval also requires:
1. You have a BRAF V600E mutation (types of gene mutation) as detected by an FDA (Food and Drug Administration)-approved test
2. The medication will be used in combination with Erbitux (cetuximab)
3. You have previously received treatment

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ENCORAFENIB

RATIONALE

To promote appropriate utilization of BRAFTOVI based on FDA approved indication and dosing.

FDA APPROVED INDICATION

Braftovi is a kinase inhibitor indicated:

- In combination with Mektovi (binimetinib), for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test.
- In combination with cetuximab, for the treatment of adult patients with metastatic colorectal cancer (CRC) with a BRAF V600E mutation, as detected by an FDA-approved test, after prior therapy.

Limitations of Use: Braftovi is not indicated for treatment of patients with wild-type BRAF melanoma or wild-type BRAF CRC.

DOSAGE & ADMINISTRATION

- Melanoma: The recommended dosage of Braftovi is 450 mg orally taken once daily in combination with Mektovi (binimetinib).
- CRC: The recommended dose is 300 mg orally once daily in combination with cetuximab.

Braftovi may be taken with or without food. Do not take a missed dose of Braftovi within 12 hours of the next dose of Braftovi. Do not take an additional dose if vomiting occurs after Braftovi administration but continue with the next scheduled dose.

REFERENCES

- Braftovi [Prescribing Information]. Boulder, CO: Array BioPharma Inc. April 2020.

Created: 08/18
Effective: 07/27/20 Client Approval: 07/13/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ENDOTHELIN RECEPTOR ANTAGONISTS

Generic	Brand	HICL	GCN	Exception/Other
BOSENTAN	TRACLEER	22990		
AMBRISENTAN	LETAIRIS	34849		
MACITENTAN	OPSUMIT	40677		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

LETAIRIS

Our guideline for **ENDOTHELIN RECEPTOR ANTAGONISTS (Letairis)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (type of high blood pressure in the arteries of the lungs, World Health Organization Group 1)
B. The requested medication is prescribed by or given in consultation with a cardiologist (heart doctor) or pulmonologist (lung doctor)

TRACLEER

Our guideline for **ENDOTHELIN RECEPTOR ANTAGONISTS (Tracleer)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (type of high blood pressure in the arteries of the lungs, World Health Organization Group 1)
B. The requested medication is prescribed by or given in consultation with a cardiologist (heart doctor) or pulmonologist (lung doctor)

OPSUMIT

Our guideline for **ENDOTHELIN RECEPTOR ANTAGONISTS (Opsumit)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (type of high blood pressure in the arteries of the lungs, World Health Organization Group 1)
B. The requested medication is prescribed by or given in consultation with a cardiologist (heart doctor) or pulmonologist (lung doctor)

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ENDOTHELIN RECEPTOR ANTAGONISTS

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline for **ENDOTHELIN RECEPTOR ANTAGONISTS (Letairis, Tracleer, Opsumit)** renewal requires the following rule(s) be met for renewal:

A. You have history of paid claim(s) for the requested medication in the past 90 days
B. You have a previous authorization on file for the requested medication

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RATIONALE

Ensure appropriate utilization of Tracleer, Letairis and Opsumit.

FDA APPROVED INDICATIONS

Letairis is an endothelin receptor antagonist indicated for the treatment of pulmonary arterial hypertension (WHO Group I):

- In adults to improve exercise ability and to decrease clinical worsening. Studies establishing effectiveness included predominantly patients with WHO Functional Class II-IV symptoms and etiologies of idiopathic or heritable PAH (60%), PAH associated with connective tissue diseases (21%), and PAH associated with congenital heart disease with left-to-right shunts (18%)
- In pediatric patients aged 3 years and older with idiopathic or congenital PAH to improve pulmonary vascular resistance (PVR), which is expected to result in an improvement in exercise ability

Tracleer is an endothelin receptor antagonist indicated for the treatment of pulmonary arterial hypertension (WHO Group I):

- In adults to improve exercise ability and decrease clinical worsening.
- In pediatric patients 3 years of age and older with idiopathic or congenital PAH to improve pulmonary vascular resistance (PVR), which is expected to result in an improvement in exercise ability.

Opsumit is an endothelin receptor antagonist indicated for the treatment of pulmonary arterial hypertension (WHO Group I) to reduce the risks of disease progression and hospitalization for PAH.

REFERENCES

- Actelion Pharmaceuticals US, Inc. Tracleer package insert. South San Francisco, CA. January 2021.
- Actelion Pharmaceuticals US, Inc. Opsumit package insert. South San Francisco, CA. May 2021.
- Gilead Sciences, Inc., Letairis package insert. Foster City, CA. March 2011.
- Badesch DB, Abman SH, Simonneau G, Rubin LJ, McLaughlin VV. Medical therapy for pulmonary arterial hypertension: updated ACCP evidence-based clinical practice guidelines. Chest 2007 Jun; 131(6):1917-28.

Created: 06/15
Effective: 12/15/21 Client Approval: 10/21/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ENTRECTINIB

Generic	Brand	HICL	GCN	Exception/Other
ENTRECTINIB	ROZLYTREK	45952		

GUIDELINES FOR USE

The guideline named **ENTRECTINIB (Rozlytrek)** requires a diagnosis of metastatic non-small cell lung cancer (NSCLC) or solid tumor. In addition, the following criteria must be met:

For a diagnosis of metastatic non-small cell lung cancer (NSCLC), approval requires:

- The patient is 18 years of age or older
- The patient has *ROS1*-positive tumors

For a diagnosis of solid tumor, approval requires:

- The patient is 12 years of age or older
- The tumor has a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation
- The tumor is metastatic or surgical resection is likely to result in severe morbidity
- There are no satisfactory alternative treatments, or the patient has progressed following treatment

RATIONALE

For further information, please refer to the Prescribing Information for Rozlytrek.

REFERENCES

Rozlytrek [Prescribing Information]. South San Francisco, CA: Genentech USA, Inc.; August 2019.

Created: 10/19
Effective: 11/08/19 Client Approval: 10/07/19 P&T Approval: 10/19

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ENZALUTAMIDE

Generic	Brand	HICL	GCN	Exception/Other
ENZALUTAMIDE	XTANDI	39580		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: BFOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ENZALUTAMIDE (Xtandi)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
1. Metastatic or non-metastatic castration-resistant prostate cancer (cancer that does or does not spread after being treated with hormone therapy)
2. Metastatic castration-sensitive prostate cancer (cancer that has spread beyond the prostate and responds to hormone therapy)

B. You meet ONE of the following:
1. You previously received a bilateral orchiectomy (both testicles have been surgically removed)
2. The requested medication will be used together with a gonadotropin releasing hormone analog (such as leuprolide, goserelin, histrelin, degarelix)
3. Your blood testosterone levels are less than 50 ng/dL

C. If you have non-metastatic castration-resistant prostate cancer, approval also requires:
1. You have a high-risk prostate cancer (rapidly increasing prostate specific antigen levels)

D. If you have metastatic castration-resistant prostate cancer, approval also requires:
1. You have previously tried Zytiga (abiraterone acetate) unless there is a medical reason why you cannot take it (contraindication)

RENEWAL CRITERIA

Our guideline named **ENZALUTAMIDE (Xtandi)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
1. Metastatic or non-metastatic castration-resistant prostate cancer (cancer that does or does not spread after being treated with hormone therapy)
2. Metastatic castration-sensitive prostate cancer (cancer that has spread beyond the prostate and responds to hormone therapy)

RATIONALE
To ensure appropriate and cost effective use of Xtandi.

FDA APPROVED INDICATIONS
Xtandi is indicated for the treatment of patients with:
- castration-resistant prostate cancer
- metastatic castration-sensitive prostate cancer

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ENZALUTAMIDE

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE

The recommended dosage is 160 mg (two 80 mg tablets or four 40 mg tablets or four 40 mg capsules) administered orally once daily.

Patients receiving Xtandi should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy.

REFERENCES

- Xtandi [Prescribing Information]. Northbrook, IL: Astellas Pharma US, Inc.; October 2020.

Created: 06/22/15
Effective: 05/17/21 Client Approval: 04/19/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

EPOPROSTENOL IV

Generic	Brand	HICL	GCN	Exception/Other
EPOPROSTENOL SODIUM (GLYCINE)	FLOLAN	07323		
EPOPROSTENOL SODIUM (ARGININE)	VELETRI	37762		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline for **EPOPROSTENOL (Flolan, Veletri)** requires a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1). The following criteria must also be met.

- The requested medication is prescribed by or given in consultation with a cardiologist or pulmonologist
- The patient has NYHA/WHO Functional Class III-IV symptoms

RENEWAL CRITERIA

The guideline for **EPOPROSTENOL (Flolan, Veletri)** renewal requires a diagnosis of pulmonary arterial hypertension (PAH). The following criteria must also be met.

- The patient has shown improvement from baseline in the 6-minute walk distance test **OR**
- The patient has a stable 6-minute walk distance test with a stable or improved WHO functional class.

RATIONALE
Ensure appropriate use of Flolan and Veletri based on FDA approved indication.

Diagnosis of PAH involves a logical sequence of steps utilizing different diagnostic tests to assist in confirmation of PAH (chest x-ray, echocardiogram, electrocardiogram, CT angiogram, pulmonary function tests, VQ scan); however, right heart catheterization (RHC) remains the gold standard and is an essential component in the definitive diagnosis, prognosis, and evaluation of PAH. RHC is critical in distinguishing PH due to other etiologies, for example PH due to left heart disease (e.g. diastolic dysfunction) or severe lung disease, which may appear similar to PAH on an echocardiogram. In addition, RHC can be used to monitor the therapeutic and adverse effects of medical interventions, to assess the severity of hemodynamic impairment, and to test the vasoreactivity of the pulmonary circulation.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

EPOPROSTENOL IV

FDA APPROVED INDICATION

Epoprostenol is indicated for the long-term intravenous treatment of primary pulmonary hypertension and pulmonary hypertension associated with the scleroderma spectrum of disease in NYHA/WHO Class III and Class IV patients who do not respond adequately to conventional therapy.

Veletri is indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise capacity. Studies establishing effectiveness included predominantly patients with NYHA Functional Class III-IV symptoms and etiologies of idiopathic or heritable PAH or PAH associated with connective tissue diseases.

REFERENCES

- GlaxoSmithKline. Flolan package insert. Research Triangle Park, NC. April 2015.
- Actelion. Veletri package insert. South San Francisco, CA. June 2012.

Created: 09/18
Effective: 10/01/18 Client Approval: 08/22/18 P&T Approval: 3QTR

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ERDAFITINIB

Generic	Brand	HICL	GCN	Exception/Other
ERDAFITINIB	BALVERSA	45687		

GUIDELINES FOR USE

The guideline named **ERDAFITINIB (Balversa)** requires a diagnosis of locally advanced or metastatic urothelial carcinoma. In addition, the following criteria must be met:

- The patient is 18 years of age or older
- The patient has susceptible Fibroblast growth factor receptor (FGFR3) or (FGFR2) genetic alterations as detected by an Food and Drug Administration (FDA)-approved companion diagnostic test
- The patient meets **ONE** of the following criteria:
  - The patient has progressed during or following at least one line of prior platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
  - The patient has progressed within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Balversa.

REFERENCES

- Balversa [Prescribing Information]. Horsham, PA: Janssen Products, LP; April 2019.

Created: 06/19
Effective: 07/15/19 Client Approval: 06/10/19 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ERENUMAB-AOOE

Generic	Brand	HICL	GCN	Exception/Other
ERENUMAB-AOOE	AIMOVIG	44923		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ERENUMAB-AOOE (Aimovig)** requires the following rules be met for approval:

A. You have migraines
B. You are 18 years of age or older
C. You have previously tried any **THREE** of the following preventative migraine treatments (chart notes required in the absence of electronic prescription claims history):
    1. beta-blocker (such as propranolol, timolol or nadolol)
    2. candesartan
    3. cyproheptadine
    4. lisinopril
    5. tricyclic antidepressant (such as amitriptyline, nortriptyline, or doxepin)
    6. topiramate
    7. valproic acid/divalproex sodium
    8. venlafaxine/desvenlafaxine
    9. verapamil

RENEWAL CRITERIA

Our guideline named **ERENUMAB-AOOE (Aimovig)** requires the following rule(s) be met for renewal:

A. You have history of paid claim(s) for the requested medication in the past 90 days
B. You have a previous authorization on file for the requested medication

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RATIONALE
Ensure appropriate criteria are used for the management of requests for Aimovig according to approved indication, dosing, and national treatment guidelines.

FDA APPROVED INDICATIONS
Aimovig is a calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine in adults.

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ERENUMAB-AOOE

FDA APPROVED INDICATIONS (CONTINUED)

HOW SUPPLIED
Injection: 70 mg/mL solution in a single-dose prefilled SureClick® autoinjector
Injection: 140 mg/mL in a single-dose prefilled SureClick® autoinjector
Injection: 70 mg/mL solution in a single-dose prefilled syringe
Injection: 140 mg/mL solution in a single-dose prefilled syringe

DOSING & ADMINISTRATION
Aimovig is for subcutaneous use only.

The recommended dosage of Aimovig is 70 mg injected subcutaneously once monthly. Some patients may benefit from a dosage of 140 mg injected subcutaneously once monthly.

REFERENCES

- Aimovig [Prescribing Information]. Thousand Oaks, CA: Amgen/Novartis. May 2021.
- Clinical Pharmacology Level of Evidence for Off-Label Indication [Internet]. Tampa (Fl): Elsevier. c2019 [cited June 5, 2019]. Available from https://www-clinicalkey-com.ezproxy.butler.edu/pharmacology/monograph/loe?sectionId=7826&ratingId=782&print=true.
- Cyproheptadine hydrochloride tablet package insert. Middlesex, NJ: CorePharma, LLC; 2015 Aug.
- Guinn, D. Hickenbottom, S. Lee MJ. Headache in pregnant and postpartum women. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed June 11, 2019
- Migraine in adults. In DynaMed Plus [database online]. EBSCO Information Services. http://www.dynamed.com/topics/dmp~AN~T114718/Migraine-in-adults#Prevention-and-Screening. Updated November 30, 2018. Accessed June 10, 2019.
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- Schrader H, Stovner LJ, Helde G, et al. Prophylactic treatment of migraine with angiotensin converting enzyme inhibitor (lisinopril): randomized, placebo controlled, crossover study. BMJ 2001;322:19-22. Accessed June 13, 2019.
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Created: 06/18
Effective: 12/15/21 Client Approval: 10/21/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ERLOTINIB

Generic	Brand	HICL	GCN	Exception/Other
ERLOTINIB	TARCEVA	26745		

GUIDELINES FOR USE

The guideline named **ERLOTINIB (Tarceva)** requires a diagnosis of metastatic non-small cell lung cancer (NSCLC) or locally advanced, unresectable, or metastatic pancreatic cancer. In addition, the following criteria must also be met:

For the diagnosis of metastatic non-small cell lung cancer (NSCLC), approval requires:

- The patient's tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test

For the diagnosis of locally advanced, unresectable, or metastatic pancreatic cancer, approval requires:

- The requested medication will be used in combination with gemcitabine

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RATIONALE

To promote appropriate utilization of erlotinib based on FDA approved indications.

FDA approved dosage of 100 mg daily for pancreatic cancer and 150 mg daily for NSCLC, available as 25 mg, 100 mg, and 150 mg tablets. Dose reduction in 50 mg increments for specific adverse effects and drug interactions. Dose increase in 50 mg increments for drug interactions to a maximum of 450 mg daily.

FDA APPROVED INDICATIONS

Tarceva is a kinase inhibitor indicated for:

- Treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test receiving first-line, maintenance, or second-line or greater treatment
- First-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer, in combination with gemcitabine.

Limitations of Use:

- Tarceva is not recommended for use in combination with platinum-based chemotherapy.
- Safety and efficacy of Tarceva have not been evaluated in patients with metastatic NSCLC whose tumors have EGFR mutations other than exon 19 deletions or exon 21 (L858R) substitution.

DOSAGE & ADMINISTRATION

The recommended daily dose of Tarceva for NSCLC is 150 mg taken on an empty stomach, i.e., at least one hour before or two hours after the ingestion of food. Treatment should continue until disease progression or unacceptable toxicity.

The recommended daily dose of Tarceva for pancreatic cancer is 100 mg taken once daily in combination with gemcitabine. Take Tarceva on an empty stomach, i.e., at least one hour before or two hours after the ingestion of food. Treatment should continue until disease progression or unacceptable toxicity.

REFERENCES

- Tarceva [Prescribing Information]. Northbrook, IL. Astellas Pharma US, Inc. October 2016.

Created: 06/15
Effective: 07/01/17 Client Approval: 05/02/17 P&T Approval: 11/13

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ERYTHROPOIESIS STIMULATING AGENTS

Generic	Brand	HICL	GCN	Exception/Other
DARBEPOETIN	ARANESP	22890		
EPOETIN ALFA	EPOGEN, PROCRIT	04553		
EPOETIN ALFA-EBPX	RETACRIT	44931		
METHOXY PEG-EPOETIN BETA	MIRCERA	35005		

GUIDELINES FOR USE

****Please use the criteria for the specific drug requested ****

INITIAL CRITERIA FOR PROCRIT (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Procrit)** requires BOTH of the following rule(s) be met for approval:

A. You have ONE of the following indications for treatment:
   1. Anemia associated with **ONE** of the following diagnoses:
      a. Chronic kidney disease (CKD)
      b. Congestive heart failure (CHF)
      c. Hepatitis C and receiving treatment with ribavirin plus interferon alfa/peginterferon alfa
      d. HIV-infection and receiving treatment with zidovudine
      e. Multiple myeloma
      f. Myelodysplastic syndrome (MDS)
      g. Myelofibrosis
      h. Neoplastic disease not associated with chemotherapy
      i. Rheumatoid arthritis
      j. Transfusion-dependent beta thalassemia
   2. Anemia associated with radiation therapy
   3. Anemia due to transfusion refusal after trauma or surgery
   4. Anemia of prematurity
   5. Blood unit collection in preparation for autotransfusion
   6. Chemotherapy-induced anemia in patients with nonmyeloid malignancies/neoplastic disease and at least 2 additional months of chemotherapy is planned
   7. Chronic anemia in neoplastic disease not associated with chemotherapy
   8. Iron overload transfusion
   9. Post-partum anemia (during the puerperium)
   10. Reduction in allogenic blood transfusions in anemic surgical patients (e.g., elective noncardiac, nonvascular surgeries) at high risk for perioperative blood loss
B. You have tried Retacrit

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ERYTHROPOIESIS STIMULATING AGENTS

INITIAL CRITERIA (CONTINUED)

ARANESP

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Aranesp)** requires BOTH of the following rule(s) be met for approval:

A. You have ONE of the following indications for treatment:
   1. Anemia associated with **ONE** of the following diagnoses:
      a. Chronic kidney disease (CKD)
      b. Myelodysplastic syndrome (MDS)
   2. Chemotherapy-induced anemia in patients with nonmyeloid malignancies/neoplastic disease and at least 2 additional months of chemotherapy is planned
B. You have tried Retacrit

EPOGEN

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Epogen)** requires BOTH of the following rule(s) be met for approval:

A. You have ONE of the following indications for treatment:
   1. Anemia associated with **ONE** of the following diagnoses:
      a. Chronic kidney disease (CKD)
      b. Congestive heart failure (CHF)
      c. Hepatitis C and receiving treatment with ribavirin plus interferon alfa/peginterferon alfa
      d. HIV-infection and receiving treatment with zidovudine
      e. Multiple myeloma
      f. Myelodysplastic syndrome (MDS)
      g. Myelofibrosis
      h. Neoplastic disease not associated with chemotherapy
      i. Rheumatoid arthritis
      j. Transfusion-dependent beta thalassemia
   2. Anemia associated with radiation therapy
   3. Anemia due to transfusion refusal after trauma or surgery
   4. Anemia of prematurity
   5. Blood unit collection in preparation for autotransfusion
   6. Chemotherapy-induced anemia in patients with nonmyeloid malignancies/neoplastic disease and at least 2 additional months of chemotherapy is planned
   7. Chronic anemia in neoplastic disease not associated with chemotherapy
   8. Iron overload transfusion
   9. Post-partum anemia (during the puerperium)
   10. Reduction in allogenic blood transfusions in anemic surgical patients (e.g., elective noncardiac, nonvascular surgeries) at high risk for perioperative blood loss
B. You have tried Retacrit

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ERYTHROPOIESIS STIMULATING AGENTS

GUIDELINES FOR USE (CONTINUED)

INITIAL CRITERIA FOR RETACRIT (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Retacrit)** requires BOTH of the following rules be met for approval:

A. You have ONE of the following indications for treatment:
   1. Anemia associated with **ONE** of the following diagnoses:
      a. Chronic kidney disease (CKD)
      b. Congestive heart failure (CHF)
      c. Hepatitis C and receiving treatment with ribavirin plus interferon alfa/peginterferon alfa
      d. HIV-infection and receiving treatment with zidovudine
      e. Multiple myeloma
      f. Myelodysplastic syndrome (MDS)
      g. Myelofibrosis
      h. Neoplastic disease not associated with chemotherapy
      i. Rheumatoid arthritis
      j. Transfusion-dependent beta thalassemia
   2. Anemia associated with radiation therapy
   3. Anemia due to transfusion refusal after trauma or surgery
   4. Anemia of prematurity
   5. Blood unit collection in preparation for autotransfusion
   6. Chemotherapy-induced anemia in patients with nonmyeloid malignancies/neoplastic disease and at least 2 additional months of chemotherapy is planned
   7. Chronic anemia in neoplastic disease not associated with chemotherapy
   8. Iron overload transfusion
   9. Post-partum anemia (during the puerperium)
   10. Reduction in allogenic blood transfusions in anemic surgical patients (e.g., elective noncardiac, nonvascular surgeries) at high risk for perioperative blood loss

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ERYTHROPOIESIS STIMULATING AGENTS

GUIDELINES FOR USE (CONTINUED)

INITIAL CRITERIA FOR MIRCERA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Mircera)** requires the following rule(s) be met for approval:

A. You have anemia (low amount of healthy red blood cells) associated with chronic kidney disease
B. You have tried Retacrit

RENEWAL CRITERIA FOR PROCRIT

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Procrit)** requires the following rule(s) be met for renewal:

- You have a history of paid claim(s) for the requested medication in the past 90 days
- You have a previous authorization on file for the requested medication

RENEWAL CRITERIA FOR ARANESP

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Aranesp)** requires the following rule(s) be met for renewal:

A. You have a history of paid claim(s) for the requested medication in the past 90 days
B. You have a previous authorization on file for the requested medication

RENEWAL CRITERIA FOR EPOGEN

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Epogen)** requires the following rule(s) be met for renewal:

A. You have a history of paid claim(s) for the requested medication in the past 90 days
B. You have a previous authorization on file for the requested medication

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ERYTHROPOIESIS STIMULATING AGENTS

GIUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA FOR RETACRIT

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Retacrit)** requires the following rule(s) be met for renewal:

A. You have a history of paid claim(s) for the requested medication in the past 90 days
B. You have a previous authorization on file for the requested medication

RENEWAL CRITERIA FOR MIRCERA

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Mircera)** requires the following rule(s) be met for renewal:

A. You have a history of paid claim(s) for the requested medication in the past 90 days
B. You have a previous authorization on file for the requested medication

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RATIONALE
Ensure appropriate utilization and promote use of preferred ESA treatment.

FDA APPROVED INDICATIONS AND DOSING
Aranesp
For the treatment of anemia due to:

- Chronic Kidney Disease (CKD) in patients on dialysis and patients not on dialysis
- The effects of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy.

Recommended starting dose:

- CKD on dialysis: 0.45mcg/kg IV/SC as a weekly injection or 0.75mcg/kg once every 2 weeks as appropriate
- CKD not on dialysis: 0.45mcg/kg IV/SC given once at 4-week intervals as appropriate
- Cancer chemotherapy:
  - 2.25mcg/kg SC every week until completion of a chemotherapy course
  - 500 mcg every 3 weeks SC until completion of a chemotherapy course

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FDA APPROVED INDICATIONS AND DOSING (CONTINUED)

Mircera

For the treatment of anemia due to Chronic Kidney Disease (CKD) in:

- Adult patients on dialysis and adult patients not on dialysis
- Pediatric patients 5 to 17 years of age on hemodialysis who are converting from another ESA after their hemoglobin level was stabilized with an ESA.

Recommended starting dose:

- Adult patients: 0.6 mcg/kg administered once every 2 weeks
- Pediatric patients for conversion from another ESA: dose once every 4 weeks based on total weekly epoetin alfa or darbepoetin alfa dose at time of conversion

Epogen & Procrit

- Treatment of anemia due to:
  - Chronic Kidney Disease (CKD) in patients on dialysis and not on dialysis
  - Zidovudine in HIV-infected patients
  - The effects of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy
- Reduction of allogeneic RBC transfusions in patients undergoing elective, noncardiac, nonvascular surgery

Recommended starting dose:

- CKD on dialysis:
  - Adults: 50-100 units/kg 3 times weekly
  - Pediatrics: 50 units/kg 3 times weekly
- CKD not on dialysis: adult patients: 50-100 units/kg 3 times weekly
- Zidovudine-treated HIV-infected patients
  - Adults: 100 units/kg 3 times per week
- Cancer chemotherapy:
  - Adults: 150 units/kg SC 3 times per week until completion of a chemotherapy course, or 40,000 units SC weekly until completion of a chemotherapy course
  - Pediatrics: 600 units/kg IV until completion of a chemotherapy course
- Surgery:
  - 300 units/kg per day SC for 15 days total: administered daily for 10 days before surgery, on the day of surgery, and for 4 days after surgery
  - 600 units/kg SC in 4 does administered 21, 14, and 7 days before surgery and on the day of surgery

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ERYTHROPOIESIS STIMULATING AGENTS

FDA APPROVED INDICATIONS AND DOSING (CONTINUED)

Retacrit

- Treatment of anemia due to:
  - Chronic Kidney Disease (CKD) in patients on dialysis and not on dialysis
  - Zidovudine in patients with HIV-infection
  - The effects of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy
- Reduction of allogeneic RBC transfusions in patients undergoing elective, noncardiac, nonvascular surgery

Recommended starting dose:

- Patients with CKD: 50 to 100 Units/kg 3 times weekly (adults) and 50 Units/kg 3 times weekly (pediatric patients). Individualize maintenance dose. Intravenous route recommended for patients on hemodialysis.
- Patients on Zidovudine due to HIV-infection: 100 Units/kg 3 times weekly.
- Patients with Cancer on Chemotherapy: 40,000 Units weekly or 150 Units/kg 3 times weekly (adults); 600 Units/kg intravenously weekly (pediatric patients $\geqslant$ 5 years).
- Surgery Patients: 300 Units/kg per day daily for 15 days or 600 Units/kg weekly.

REFERENCES

- Aranesp [Prescribing Information]. Thousand Oaks, CA: Amgen, January 2019.
- Epogen [Prescribing Information]. Thousand Oaks, CA: Amgen, July 2018.
- Mircera [Prescribing Information]. St. Gallen, Switzerland: Vifor, June 2018.
- Procrit [Prescribing Information]. Thousand Oaks, CA: Amgen, July 2018.
- Retacrit [Prescribing Information]. Lake Forest, IL: Pfizer Inc. August 2020.

Created: 03/15
Effective: 12/15/21 Client Approval: 10/26/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ETANERCEPT

Generic	Brand	HICL	GCN	Exception/Other
ETANERCEPT	ENBREL	18830		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline for **ETANERCEPT (Enbrel)** requires the following rule(s) be met for approval:

A. **You have ONE of the following diagnoses:**
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in joints in children)
   3. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   4. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   5. Chronic moderate to severe plaque psoriasis (PsO: dry, scaly, itchy skin patches)

B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
   1. You have previously tried at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs): methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

C. **If you have chronic moderate to severe plaque psoriasis, approval also requires:**
   1. You have previously tried at least **ONE** of the following preferred conventional therapies: PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

RENEWAL CRITERIA

Our guideline for renewal of **ETANERCEPT (Enbrel)** requires the following rules be met:
   A. You have history of paid claims(s) for the requested medication in the past 90 days
   B. You have a previous authorization on file for the requested medication

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ETANERCEPT

RATIONALE

Ensure that appropriate diagnostic, utilization, and safety criteria are utilized for the management of requests for etanercept.

FDA APPROVED INDICATIONS

Enbrel is a tumor necrosis factor (TNF) blocker indicated for the treatment of:

- Rheumatoid Arthritis (RA)
- Polyarticular Juvenile Idiopathic Arthritis (JIA) in patients aged 2 years or older
- Psoriatic Arthritis (PsA)
- Ankylosing Spondylitis (AS)
- Plaque Psoriasis (PsO) in patients 4 years or older

DOSING

Enbrel is administered by subcutaneous injection.

- Adult RA and PsA: 50 mg once weekly with or without methotrexate (MTX)
- AS: 50 mg once weekly
- Adult PsO: 50 mg twice weekly for 3 months, followed by 50 mg once weekly
- PJIA and Pediatric PsO: 0.8 mg/kg weekly, with a maximum of 50 mg per week

DOSAGE FORMS AND STRENGTHS

- Injection: 25 mg/0.5 mL and 50 mg/mL solution in a single-dose prefilled syringe
- Injection: 50 mg/mL solution in single-dose prefilled SureClick autoinjector
- Injection: 25 mg/0.5 mL solution in a single-dose vial
- For injection: 25 mg lyophilized powder in a multiple-dose vial for reconstitution
- Injection: 50 mg/mL solution in Enbrel Mini single-dose pre-filled cartridge for use with the AutoTouch reusable autoinjector only

REFERENCES

- Immunex Corporation. Enbrel Prescribing Information. Thousand Oaks, CA. March 2020.
- Beukelman T, Patkar NM, et al. 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: Initiation and safety monitoring of therapeutic agents for the treatment of arthritis and systemic features. Arthritis Care Res, 63: 465–482. doi: 10.1002/acr.20460.
- Braun J, Davis J, et al. First update of the international ASAS consensus statement for the use of anti-TNF agents in patients with Ankylosing Spondylitis. Ann Rheum Dis. 2006; 65(3):316-20.
- Menter A, Strober BE, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.
- Singh JA, Guyatt G, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Care & Research. Vol. 71, No. 1, January 2019, pp 2–29DOI 10.1002/acr.2378.
- Singh JA, Saag KG, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. 2016;68(1):1-25. DOI 10.1002/acr.22783.

Created: 03/15
Effective: 08/20/2021 Client Approval: 08/13/2021 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

EVEROLIMUS

Generic	Brand	HICL	GCN	Exception/Other
EVEROLIMUS	AFINITOR		20784, 20844, 28783, 31396	
EVEROLIMUS	AFINITOR DISPERZ		34589, 34590, 34592	

**** Please use the criteria for the specific drug requested ****

GUIDELINES FOR USE

AFINITOR DISPERZ

The guideline named **EVEROLIMUS (Afinitor Disperz)** requires a diagnosis of subependymal giant cell astrocytoma (SEGA) with tuberous sclerosis complex (TSC or TSC-associated partial-onset seizures. In addition, the following criteria must be met:

For diagnosis of subependymal giant cell astrocytoma (SEGA) in tuberous sclerosis complex (TSC), approval requires:
- The patient is 1 year of age or older
- The patient's diagnosis requires therapeutic intervention but cannot be curatively resected

For diagnosis of TSC-associated partial-onset seizures, approval requires:
- The patient is 2 year of age or older
- The medication will be used as adjunctive treatment

AFINITOR

The guideline named **EVEROLIMUS (Afinitor)** requires **ONE** of the following FDA approved indications:
- Advanced renal cell carcinoma (RCC) after failure of or contraindication to treatment with sunitinib (Sutent) or sorafenib (Nexavar), which may also require prior authorization AND the patient is 18 years of age or older
- Subependymal giant cell astrocytoma (SEGA) with tuberous sclerosis complex (TSC) that requires therapeutic intervention but cannot be curatively resected AND the patient is 1 year of age or older
- Progressive neuroendocrine tumor (NET) with unresectable, locally advanced or metastatic disease, either neuroendocrine tumor (NET) of pancreatic origin or well-differentiated, non-functional neuroendocrine tumor (NET) of gastrointestinal or lung origin. The patient must also be 18 years of age or older

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EVEROLIMUS

GUIDELINES FOR USE AFINITOR (CONTINUED)

- Renal angiomyolipoma, and tuberous sclerosis complex (TSC) that does not require immediate surgery AND the patient is 18 years of age or older
- For postmenopausal women with a diagnosis of advanced hormone receptor-positive, HER2-negative breast cancer (defined as IHC less than or equal to 3+ or FISH amplification ratio less than or equal to 2.0) in combination with Aromasin (exemestane) after failure of or contraindication to treatment with Femara (letrozole) or Arimidex (anastrozole)

RATIONALE

Ensure appropriate utilization of everolimus based on FDA approved indication and NCCN guidelines.

DOSAGE AND ADMINISTRATION

Afinitor and Afinitor Disperz are two different dosage forms. Select the recommended dosage form based on the indication. Do not combine Afinitor and Afinitor disperz to achieve the total dose. Modify the dosage for patients with hepatic impairment or for patients taking drugs that inhibit or induce pglycoprotein (P-gp) and CYP3A4.

Advanced HR+ BC, advanced NET, advanced RCC, or renal angiomyolipoma with TSC:

- AFINITOR 10 mg once daily orally until disease progression or unacceptable toxicity

SEGA with TSC:

- AFINITOR/AFINITOR DISPERZ 4.5 mg/m^2 once daily orally until disease progression or unacceptable toxicity
- Titrate the dose to attain trough concentrations of 5-15 ng/mL

TSC-Associated Partial-Onset Seizures

- AFINITOR DISPERZ 5 mg/m^2 once daily orally until disease progression or unacceptable toxicity
- Titrate the dose to attain trough concentrations of 5-15 ng/mL

FDA APPROVED INDICATIONS

AFINITOR is a kinase inhibitor indicated for the treatment of:

- Postmenopausal women with advanced hormone receptor-positive, HER2negative breast cancer (advanced HR+ BC) in combination with exemestane after failure of treatment with letrozole or anastrozole.
- Adults with progressive neuroendocrine tumors of pancreatic origin (PNET) that are unresectable, locally advanced or metastatic. The safety and effectiveness of AFINITOR in the treatment of patients with carcinoid tumors have not been established.
- Adults with advanced renal cell carcinoma (RCC) after failure of treatment with sunitinib or sorafenib.
- Adults with renal angiomyolipoma and tuberous sclerosis complex (TSC), not requiring immediate surgery. The effectiveness of AFINITOR in the treatment of renal angiomyolipoma is based on an analysis of durable objective responses in patients treated for a median of 8.3 months. Further follow-up of patients is required to determine long-term outcomes.

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EVEROLIMUS

FDA APPROVED INDICATIONS (CONTINUED)

AFINITOR and AFINITOR DISPERZ are kinase inhibitors indicated for the treatment of:

- Adult and pediatric patients aged 1 year and older with tuberous sclerosis complex (TSC) who have subependymal giant cell astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected

AFINITOR DISPERZ is a kinase inhibitor indicated for:

- Adjunctive treatment of adult and pediatric patients aged 2 years and older with TSC associated partial-onset seizures

REFERENCES

- Novartis Pharmaceuticals Corporation. Afinitor package insert. East Hanover, NJ. April 2018.

Created: 06/15
Effective: 10/01/19 Client Approval: 09/04/19 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

EVOLOCUMAB

Generic	Brand	HICL	GCN	Exception/Other
EVOLOCUMAB	REPATHA SYRINGE, REPATHA PEN, REPATHA PUSHTRONEX	42378	39363 38178 41834	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

Our guideline named **EVOLOCUMAB (Repatha)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Established cardiovascular disease (health issues related to heart and blood vessels) such as: history of myocardial infarction (heart attack) or other acute coronary syndrome, coronary or other revascularization procedure (restoring blood flow to heart and other areas), transient ischemic attack (short stroke-like attack), ischemic stroke (arteries to your brain become narrowed or blocked), atherosclerotic peripheral arterial disease (arteries get blocked with fats and plaques), coronary atherosclerosis (heart arteries get blocked with fats and plaques), renal atherosclerosis (kidney arteries get blocked with fats and plaques), aortic aneurysm secondary to atherosclerosis (fat and plaque build-up causes enlargement of the aorta), carotid plaque with 50% or more stenosis (narrowing of blood vessel)
   2. Primary hyperlipidemia (high cholesterol) such as heterozygous familial hypercholesterolemia (HeFH, type of inherited high cholesterol)
   3. Homozygous familial hypercholesterolemia (HoFH, type of inherited high cholesterol)

B. You have a baseline LDL (low density lipoprotein) cholesterol level greater than or equal to 70 mg/dL

C. You meet ONE of the following:
   1. You are currently taking a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) AND have been taking it for a duration of at least 8 weeks
   2. You have a documented intolerance to BOTH rosuvastatin and atorvastatin
   3. Your prescriber has provided medical rationale against use of statin therapy

D. You will continue to take statin therapy in combination with Repatha, unless contraindicated or not tolerated

E. **If you have established cardiovascular disease, approval also requires:**
   You are 18 years of age or older

F. **If you have primary hyperlipidemia (such as heterozygous familial hypercholesterolemia [HeFH]), approval also requires:**
   You are 10 years of age or older

G. **If you have homozygous familial hypercholesterolemia (HoFH), approval also requires:**
   You are 10 years of age or older

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EVOLOCUMAB

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **EVOLOCUMAB (Repatha)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Established cardiovascular disease (health issues related to heart and blood vessels)
   2. Primary hyperlipidemia (high cholesterol such heterozygous familial hypercholesterolemia)
   3. Homozygous familial hypercholesterolemia (type of inherited high cholesterol)
B. You have a history of paid claim(s) for the requested medication in the past 90 days
C. You have a previous authorization on file for the requested medication
D. You meet **ONE** of the following:
   1. You have continued concurrent therapy with a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
   2. You have a documented intolerance to statin therapy
   3. Your prescriber has provided medical rationale against use of statin therapy
E. Documentation of reduction in LDL-cholesterol from baseline

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

EVOLOCUMAB

RATIONALE
Promote appropriate utilization of Repatha based on FDA approved indication and appropriate clinical criteria.

FDA APPROVED INDICATIONS
Repatha is a PCSK9 (proprotein convertase subtilisin kexin type 9) inhibitor indicated:
- in adults with established cardiovascular disease (CVD) to reduce the risk of myocardial infarction, stroke, and coronary revascularization
- as an adjunct to diet, alone or in combination with other low-density lipoprotein cholesterol (LDL-C)-lowering therapies, in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce LDL-C
- as an adjunct to diet and other LDL-C-lowering therapies in pediatric patients aged 10 years and older with HeFH, to reduce LDL-C
- as an adjunct to other LDL-C-lowering therapies in adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia (HoFH), to reduce LDL-C

DOSAGE
In adults with established CVD or with primary hyperlipidemia:
- The recommended dosage of Repatha is either 140 mg every 2 weeks OR 420 mg once monthly administered subcutaneously.
- If switching dosage regimens, administer the first dose of the new regimen on the next scheduled date of the prior regimen.

In pediatric patients aged 10 years and older with HeFH:
- The recommended dosage of Repatha is either 140 mg every 2 weeks OR 420 mg once monthly administered subcutaneously.
- If switching dosage regimens, administer the first dose of the new regimen on the next scheduled date of the prior regimen.

In adults and pediatric patients aged 10 years and older with HoFH:
- The initial recommended dosage of Repatha is 420 mg once monthly administered subcutaneously.
- The dosage can be increased to 420 mg every 2 weeks if a clinically meaningful response is not achieved in 12 weeks.
- Patients on lipid apheresis may initiate treatment with 420 mg every 2 weeks to correspond with their apheresis schedule. Administer after the apheresis session is complete.

REFERENCES
Repatha package insert. Thousand Oaks, CA: Amgen, Inc.; September 2021.

Created: 09/15
Effective: 05/16/22 Client Approval: 05/02/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

FEDRATINIB

Generic	Brand	HICL	GCN	Exception/Other
FEDRATINIB	INREBIC	45953		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named **FEDRATINIB (Inrebic)** requires a diagnosis of intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocytemia) myelofibrosis (MF). In addition, the following criteria must be met:

- The patient is 18 years of age or older
- The patient had a trial of or contraindication to Jakafi (ruxolitinib)

RENEWAL CRITERIA

The guideline named **FEDRATINIB (Inrebic)** requires a diagnosis of intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocytemia) myelofibrosis (MF). In addition, the following must be met:

- The patient has had symptom improvement as documented by **ONE** of the following:
  - The patient has a spleen volume reduction of 35% or greater from baseline after 6 months of therapy
  - The patient has a 50% or greater reduction in total symptom score on the modified Myelofibrosis Symptom Assessment Form (MFSAF) v2.0
  - The patient has a 50% or greater reduction in palpable spleen length

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RATIONALE

Promote appropriate utilization of **FEDRATINIB** based on FDA approved indication and appropriate clinical criteria.

FDA APPROVED INDICATIONS

Inrebic is a kinase inhibitor indicated for the treatment of adult patients with intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF)

DOSING

The recommended dosage of Inrebic is 400 mg taken orally once daily for patients with a baseline platelet count of greater than or equal to 50 x 109/L.

REFERENCES

Inrebic [Prescribing Information]. Summit, NJ: Celgene Corporation; August 2019.

Created: 10/19
Effective: 07/01/20 Client Approval: 05/12/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

FENFLURAMINE

Generic	Brand	HICL	GCN	Exception/Other
FENFLURAMINE	FINTEPLA	02116		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **FENFLURAMINE (Fintepla)** requires the following rule(s) be met for approval:

A. You have seizures associated with ONE of the following:
   1. Dravet syndrome (a rare type of seizure)
   2. Lennox- Gastaut syndrome (LGS: a type of seizure disorder in young children)

B. **If you have Dravet syndrome, approval also requires:**
   1. You are 2 years of age or older
   2. You have tried or have a contraindication to (harmful for) TWO of the following: a valproic acid derivative, clobazam, or topiramate

C. If you have Lennox-Gastaut syndrome, approval also requires:
   1. You are 2 years of age or older
   2. You have tried or have a contraindication to (harmful for) valproic acid or a valproic acid derivative
   3. You have tried or have a contraindication to (harmful for) TWO of the following: Epidiolex, rufinamide, felbamate, clobazam, topiramate, lamotrigine, or clonazepam

RENEWAL CRITERIA

Our guideline named **FENFLURAMINE (Fintepla)** requires the following rule(s) be met for approval:

A. You have seizures associated with Dravet syndrome (severe type of seizure disorder that begins during the first year of life)
B. You have shown continued clinical benefit (such as reduction of seizures, reduced length of seizures, seizure control maintained) while on therapy

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

FENFLURAMINE

RATIONALE
To ensure appropriate use of Fintepla based on FDA approved indications and dosing.

INDICATION
Fintepla is indicated for the treatment of seizures associated with Dravet syndrome and Lennox-Gastaut syndrome in patients 2 years of age and older.

DOSING
The initial starting and maintenance dosage is 0.1 mg/kg twice daily, which can be increased weekly based on efficacy and tolerability. Table 1 provides the recommended titration schedule, if needed.

Table 1: Fintepla Recommended Titration Schedule*

	Without concomitant stiripentol*		**With concomitant stiripentol and clobazam**	
	Weight-based Dosage	**Maximum Total Daily Dosage**	**Weight-based Dosage**	**Maximum Total Daily Dosage**
Initial Dosage	0.1 mg/kg twice daily	26 mg	0.1 mg/kg twice daily	17 mg
Day 7	0.2 mg/kg twice daily	26 mg	0.15 mg/kg twice daily	17 mg
Day 14	0.35 mg/kg twice daily	26 mg	0.2 mg/kg twice daily	17 mg

REFERENCES
Fintepla [Prescribing Information]. Emeryville, CA: Zogenix, Inc., June 2022.

Created: 07/20
Effective: 08/15/22 Client Approval: 08/05/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

FENTANYL (BUCCAL, NASAL, SUBLINGUAL)

Generic	Brand	HICL	GCN	Exception/Other
FENTANYL SUBLINGUAL SPRAY	SUBSYS	06438	31187 31596 31597 31189 31188 31192 31193	ROUTE = SUBLINGUAL
FENTANYL CITRATE	ACTIQ, FENTORA, LAZANDA	01747	97280 27648 19193 19194 19204 97281 41539 19206 97283 29146 19191 97284 19192 97285	ROUTE = BUCCAL, NASAL, SUBLINGUAL

GUIDELINES FOR USE

Please use the RENEWAL CRITERIA in the following scenarios only.

- For patients active with MDwise for 90 days or longer AND previous prior authorization approval for the same medication with the same strength AND recent paid pharmacy claims for the requested medication. Chart notes and/or cash pay for opioid use is not accepted.
- For patients new to MDwise within the past 90 days AND chart notes are provided that document the patient is stable on the requested medication.

All other requests must be reviewed with the INITIAL CRITERIA.

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

Our guideline for **FENTANYL (BUCCAL, NASAL, SUBLINGUAL)** for patients with past use of opioid dependency agents (i.e., buprenorphine/naloxone SL tablets/films or buprenorphine SL tablets) requires the buprenorphine/naloxone or buprenorphine prescribing physician be notified about prescribed opiate therapy and must approve the use before the opioid analgesic will be authorized.

Our guideline for **FENTANYL (BUCCAL, NASAL, SUBLINGUAL)** does not permit concurrent use with carisoprodol-containing products.

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FENTANYL (BUCCAL, NASAL, SUBLINGUAL)

INITIAL CRITERIA (CONTINUED)

Our guideline for **FENTANYL (BUCCAL, NASAL, SUBLINGUAL)** requires **ALL** of the following rules to be met:

- **FENTANYL (BUCCAL, NASAL, SUBLINGUAL)** is prescribed for ONE of the following reasons:
  - Cancer
  - Sickle cell disease
  - Palliative care
  - Other terminal diagnosis associated with significant pain
- You are taking a long-acting opioid analgesic at the same time (such as MS Contin, OxyContin, Duragesic), **AND**
- You have had a trial and failure of an oral short-acting opioid analgesic (such as codeine/APAP, hydrocodone/APAP, hydromorphone, morphine sulfate IR, oxycodone/APAP, oxycodone IR) **OR** you have difficulty swallowing, **AND**
- You have had a trial and failure of generic Actiq (fentanyl citrate buccal lozenge)
- Requests for Lazanda nasal spray require failure of generic Actiq AND a fentanyl buccal or sublingual product other than Actiq (e.g., Abstral, Fentora, Subsys)

Please note that additional criteria apply for concurrent use of opioid analgesics and benzodiazepines, including submission of signed prescriber attestation on a state-mandated fax form.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

FENTANYL (BUCCAL, NASAL, SUBLINGUAL)

INITIAL CRITERIA (CONTINUED)

Our guideline for **FENTANYL (BUCCAL, NASAL, SUBLINGUAL)** for patients with claims in history for benzodiazepines requires that the prescriber submit the required fax form documenting **ALL** of the following:

- The diagnosis contributing to the need for benzodiazepine therapy and previous therapy attempted, including dates and doses of prior therapies
  - For generalized anxiety disorder, one of the following is required: Selective serotonin reuptake inhibitor (SSRI, such as sertraline or citalopram), serotonin-noradrenaline reuptake inhibitor (SNRI, such as duloxetine or venlafaxine), or pregabalin (generic for Lyrica)
  - For panic disorder, one of the following is required: SSRI or tricyclic antidepressant (TCA, such as amitriptyline or nortriptyline)
  - For social anxiety disorder (SAD), a trial of an SSRI is required
  - For obsessive compulsive disorder (OCD), a trial of an SSRI is required
  - For post-traumatic stress disorder (PTSD), one of the following is required: mirtazapine, paroxetine, amitriptyline, or phenelzine
  - For insomnia, one of the following is required: ramelteon or a sedating antidepressant (for example, trazodone, amitriptyline, doxepin, mirtazapine)
- The diagnosis contributing to the need for opioid analgesic therapy and previous therapy attempted, including dates and doses of prior therapies. For a diagnosis of moderate to severe cancer-related pain, pain related to sickle cell disease, or pain in patients receiving palliative care, no additional criteria applies
- Your prescriber has signed an attestation as to **ALL** of the following:
  - Your provider will regularly review your controlled substance utilization contained within INSPECT (Indiana controlled substance monitoring program)
  - You have been educated about the risks of using benzodiazepines and opioid analgesics together at the same time
  - Both you and your provider accept the risk of using benzodiazepines and opioid analgesics together at the same time

Please note that additional criteria apply for the benzodiazepine day supply limits. Your benzodiazepine prescription claim must not be greater than a 15-day supply of medication. You cannot receive more than 30 days' supply of benzodiazepine medication in the past 90 days. The current request for medication is also counted as a part of the 30 days' supply in the past 90 days.

Our guideline named **FENTANYL (BUCCAL, NASAL, SUBLINGUAL)** for patients with claims in history for Lybalvi (olanzapine/samidorphan) requires that you have not taken Lybalvi (olanzapine/samidorphan) less than or equal to 5 days prior to initiating opioid therapy.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

FENTANYL (BUCCAL, NASAL, SUBLINGUAL)

RENEWAL CRITERIA

Our guideline for **FENTANYL (BUCCAL, NASAL, SUBLINGUAL)** does not permit concurrent use with carisoprodol-containing products.

Our guideline for renewal of **FENTANYL (BUCCAL, NASAL, SUBLINGUAL)** for patients with claims in history for benzodiazepines requires that the prescriber submit the required fax form documenting **ALL** of the following:

- The diagnosis contributing to the need for benzodiazepine therapy and previous therapy attempted, including dates and doses of prior therapies
  - For generalized anxiety disorder, one of the following is required: Selective serotonin reuptake inhibitor (SSRI, such as sertraline or citalopram), serotonin-noradrenaline reuptake inhibitor (SNRI, such as duloxetine or venlafaxine), or pregabalin (generic for Lyrica)
  - For panic disorder, one of the following is required: SSRI or tricyclic antidepressant (TCA, such as amitriptyline or nortriptyline)
  - For social anxiety disorder (SAD), a trial of an SSRI is required
  - For obsessive compulsive disorder (OCD), a trial of an SSRI is required
  - For post-traumatic stress disorder (PTSD), one of the following is required: mirtazapine, paroxetine, amitriptyline, or phenelzine
  - For insomnia, one of the following is required: ramelteon or a sedating antidepressant (for example, trazodone, amitriptyline, doxepin, mirtazapine)
- The diagnosis contributing to the need for opioid analgesic therapy
- Your prescriber has signed an attestation as to **ALL** of the following:
  - Your provider will regularly review your controlled substance utilization contained within INSPECT (Indiana controlled substance monitoring program)
  - You have been educated about the risks of using benzodiazepines and opioid analgesics together at the same time
  - Both you and your provider accept the risk of using benzodiazepines and opioid analgesics together at the same time

Please note that additional criteria apply for the benzodiazepine day supply limits. Your benzodiazepine prescription claim must not be greater than a 15-day supply of medication. You cannot receive more than 30 days' supply of benzodiazepine medication in the past 90 days. The current request for medication is also counted as a part of the 30 days' supply in the past 90 days.

Our guideline named **FENTANYL (BUCCAL, NASAL, SUBLINGUAL)** for patients with claims in history for Lybalvi (olanzapine/samidorphan) requires that you have not taken Lybalvi (olanzapine/samidorphan) less than or equal to 5 days prior to initiating opioid therapy.

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FENTANYL (BUCCAL, NASAL, SUBLINGUAL)

RATIONALE

To ensure opioid analgesics are used according to FDA approved indications with patient safety in mind, and to encourage the use of more cost-effective analgesics.

From 2000-2014, almost half a million people died due to drug overdose, with 2014 being the highest year for deaths on record. In that time, the number of opioids prescribed, as well as the number of opioid overdoses, has risen exponentially. At least half of all opioid overdose deaths involve a prescription opioid. Indiana was among the states that had a statistically significant increase of overdose deaths from 2013-2014.

According to recent research, the opioid epidemic has a disproportionate impact on Medicaid beneficiaries. Medicaid patients are prescribed opioids at double the rate of non-Medicaid patients, and are subsequently at much higher risk of prescription opioid overdose.
Improving the way that opioids are prescribed can ensure safer and more effective pain treatment, and reduce the addiction, misuse, abuse, and overdose of these drugs. These guidelines are to ensure that the use of opioids is consistent with their FDA approved indications, and to initiate action combating the current opioid epidemic.

Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 morphine milligram equivalents (MME)/day such as 60mg oral morphine/day, 25mcg transdermal fentanyl/hour, 40mg oral oxycodone/day, 15mg oral hydromorphone/day, 60mg oral hydrocodone/day, 400mg oral codeine/day, or an equianalgesic dose of another opioid for a week or longer.

Buprenorphine Conversion Table

Buprenorphine Product	Oral MME Conversion Factor
Belbuca buccal film (mcg/hr)	0.03
buprenorphine, tablet or film for opioid use disorder	30
Butrans transdermal patch (mcg/hr)	12.6

Example: 900 mcg buprenorphine buccal film x (60 films/30 days) x 0.03=54 MME/day
Example: 5 mcg buprenorphine patch x (4 patches/28 days) x 12.6= 9 MME/day

Fentanyl Conversion Table

Fentanyl Product	Oral MME Conversion Factor
fentanyl buccal or SL tablets, or lozenge/troche (mcg)	0.13
fentanyl film or oral spray (mcg)	0.18
fentanyl nasal spray (mcg)	0.16
fentanyl patch (mcg)	7.2

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FENTANYL (BUCCAL, NASAL, SUBLINGUAL)

RATIONALE (CONTINUED)

Opioid Conversion Table

Drug	Oral MME Conversion Factor (1mg of drug to mg morphine)	60mg Morphine Equivalent Dose
benzhydrocodone	1.22	50mg
butorphanol	7	8.5mg
codeine	0.15	400mg
dihydrocodeine	0.25	240mg
hydrocodone	1	60mg
hydromorphone HCl	4	15mg
levorphanol tartrate	11	5.5mg
meperidine HCl	0.1	600mg
morphine	1	60mg
oxycodone HCl	1.5	40mg
oxymorphone HCl	3	20mg
pentazocine HCl	0.37	162mg
tapentadol HCl	0.4	150mg
tramadol HCl	0.1	600mg

Methadone Conversion Table

Methadone daily dose (mg/day)	MME Conversion Factor (1mg of drug to mg morphine)	60mg Morphine Equivalent Dose
>0, <= 20	4	20mg
>20, <=40	8	7.5mg
>40, <=60	10	6mg
>60	12	5mg

Opioid Usage in Chronic Pain Management
Per systematic review in the CDC Guideline for Prescribing Opioids for Chronic Pain, long-term (≥ 1 year) efficacy of opioids in management of chronic pain, function, or quality of life is not established. Most randomized controlled trials present effectiveness within 6 weeks or less. Conversely, significant risks of adverse events are present with chronic opioid therapy, including opioid abuse and dependence, social role withdrawal, and increased risk of CNS depression, and withdrawal emergencies.

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RATIONALE (CONTINUED)

The CDC also recommends re-evaluating and re-establishing treatment goals, including realistic expectation for pain and function, as well as discontinuation strategies when benefits do not outweigh risks. The guideline provides the following recommendations for opioid selection, dosage, duration, follow-up and discontinuation:

- Immediate-release (IR) opioids are preferred over extended-release (ER) forms.
- The lowest effective dosage is preferred with initial opioid use. Caution is warranted at any dose and reassessing benefits and risks is recommended for 50 morphine milligram equivalents (MME) daily or more. 90 MME daily or more should be avoided if possible.
- Within 1 to 4 weeks of therapy, clinicians should evaluate benefits and harms of using opioids to treat chronic pain. Therapy continuation should be evaluated every 3 months or sooner. If benefits do not outweigh harms to continue opioid therapy, other therapies should be optimized and opioid tapering/discontinuation should be considered and encouraged.

Assessing Risk and Addressing Harms of Opioid Use

- Prior to and throughout opioid therapy, adverse events should be evaluated periodically. Factors that increase risk for opioid overdose include history of overdose or substance use disorder, 50 MME daily or more, and concurrent benzodiazepine use.
- Prescription drug monitoring program (PDMP) data (e.g., RXINSPECT) are useful to monitor total opioid dosage. PDMP data is helpful for initial and periodic opioid usage evaluations.
- Prescribing opioids and benzodiazepines concurrently should be avoided.
- For patients with substance use disorder, evidence-based treatment (medication-assisted and behavioral therapy) is recommended.

Analysis performed by the US Department of Health and Human Services Center for Disease Control and Prevention (CDC) determined the risk of harm to individuals increases as their opioid dose increases and as their length of opioid therapy increases. For example:

- Individuals taking opioid doses > 50 morphine milligram equivalents (MMEs) per day had twice the risk of death from an overdose than those taking < 20 MMEs per day.
- Individuals taking opioid doses > 90 (MMEs) per day had 10 times the risk of death from an overdose than those taking < 20 MMEs per day.
- Individuals taking an opioid for > 3 months (even at low doses) had 15 times the risk of addiction to those taking opioids for < 3 months.

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FENTANYL (BUCCAL, NASAL, SUBLINGUAL)

APPENDIX 1: BENZODIAZEPINE/OPIOID CONCURRENT USE FAX FORM
INDIANA HEALTH COVERAGE PROGRAMS (IHCP) PHARMACY BENEFIT
BENZODIAZEPINE AND OPIOID CONCURRENT THERAPY
PRIOR AUTHORIZATION REQUEST FORM

MDwise
Fax to: (858) 790-7100
c/o MedImpact Healthcare Systems, Inc.
Attn: Prior Authorization Department
10181 Scripps Gateway Court, San Diego, CA 92131
Phone: 1-800-788-2949

Today's Date
☐☐ / ☐☐ / ☐☐☐☐

Note: This form must be completed by the prescribing provider.
****All sections must be completed or the request will be denied.****

Patient's Medicaid # ☐☐☐☐☐☐☐☐☐☐☐☐	**Date of Birth** ☐☐ / ☐☐ / ☐☐☐☐
Patient's Name	**Prescriber's Name**
Prescriber's IN License # ☐☐☐☐☐☐☐☐	**Specialty**
Prescriber's NPI # ☐☐☐☐☐☐☐☐☐☐	**Prescriber's Signature: **Required below within attestation section.****
Return Fax # ☐☐☐ - ☐☐☐ - ☐☐☐☐	**Return Phone #** ☐☐☐ - ☐☐☐ - ☐☐☐☐

PA is required for the following:

- **Claim(s) for new opioid(s) to be used concurrently with benzodiazepines and exceeding 7 days within a 180-day period.**
- **Claim(s) for new benzodiazepine(s) to be used concurrently with opioids and exceeding 7 days of therapy within a 180-day period and/or exceeding established benzodiazepine/opioid concurrent therapy quantity limits (see Sedative Hypnotics/Benzodiazepine PA criteria).**

Benzodiazepine Agent(s)	Prescriber Name*	Quantity	Dosage Regimen/Duration

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Opioid Agent(s)	Prescriber Name*	Quantity	Dosage Regimen/Duration

***NOTE: If prescribers of the opioid(s) and benzodiazepine(s) are not the same, please answer the following questions:**

- **Are you requesting PA for: Benzodiazepine Agent(s) □ Opioid Agent(s) □ Both □**
- **Is/are the other prescriber(s) aware of the request for concurrent therapy? □ Yes □ No**
- **Has/have the other prescriber(s) been consulted about the risks associated with concurrent therapy, and do all prescribers involved believe continuing with concurrent therapy is warranted, given the risks associated with concurrent use? □ Yes □ No**

PA Requirements:

Patient diagnosis/diagnoses for use of benzodiazepine therapy:

Prior therapies attempted for the above diagnosis/diagnoses (submission of chart notes required in absence of claims history):

Drug Therapy	Dosage Regimen	Dates of Utilization

Do you plan to continue benzodiazepine therapy for this patient? □ Yes □ No
If no, please provide withdrawal plan:

Patient diagnosis/diagnoses for use of opioid therapy:

Prior therapies (both drug and non-drug) attempted for the above diagnosis/diagnoses (submission of chart notes required in absence of claims history):

Drug/Non-Drug Therapy	Dosage Regimen	Dates of Utilization	Reason for Discontinuation or Failure

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Do you plan to continue opioid therapy for this patient? □ Yes □ No
If no, please provide withdrawal plan:

Attestation:

I, _____, hereby attest to the following:
(Prescriber Name)

The patient's INSPECT report has been evaluated and continues to be evaluated on a regular basis (Per IC 35-48-7-11.1, DO NOT attach a copy of the INSPECT report to this PA request).

I have educated the patient in regards to the risks of concurrent utilization of benzodiazepine and opioid therapy, and the patient accepts these risks.

If applicable, I have consulted other prescriber(s) involved in concurrent therapy and all prescribers involved agree to pursue concurrent opioid and benzodiazepine therapy for this patient.

I acknowledge, as the prescriber initiating or maintaining concurrent benzodiazepine and opioid therapy, the risk of adverse event(s), including respiratory depression, coma, and death, associated with concurrent utilization.

Prescriber Signature:_____

****Prescriber signature is required for consideration. Electronic or stamped signature will not be accepted.****

CONFIDENTIAL INFORMATION

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FENTANYL (BUCCAL, NASAL, SUBLINGUAL)

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Created: 09/19
Effective: 06/13/22 Client Approval: 05/26/22 P&T Approval: N/A

FENTANYL TRANSDERMAL PATCH

Generic	Brand	HICL	GCN	Exception/Other
FENTANYL	DURAGESIC	06438	24635 19200 37952 19201 37947 19202 37948 19203	ROUTE = TRANSDERM STRENGTH = 12MCG/HR 25MCG/HR 37.5MCG/HR 50MCG/HR 62.5MCG/HR 75MCG/HR 87.5MCG/HR 100MCG/HR

GUIDELINES FOR USE

RENEWAL CRITERIA will apply in the following scenarios only:

- For patients active with MDwise for 90 days or longer AND previous prior authorization approval for the same medication with the same strength AND recent paid pharmacy claims for the requested medication. Chart notes and/or cash pay for opioid use is not accepted.
- For patients new to MDwise within the past 90 days AND chart notes are provided that document the patient is stable on the requested medication.

All other requests will be reviewed against the INITIAL CRITERIA.

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

Our guideline for FENTANYL TRANSDERMAL PATCH for patients with past use of opioid dependency agents (such as, buprenorphine/naloxone SL tablets/films or buprenorphine SL tablets) requires the buprenorphine/naloxone or buprenorphine prescribing physician be notified about prescribed opiate therapy and must approve the use before the opioid analgesic will be authorized.

Our guideline for **FENTANYL TRANSDERMAL PATCH** does not permit concurrent use with carisoprodol-containing products.

Our guideline for **FENTANYL TRANSDERMAL PATCH** requires that patients meet **BOTH** of the following criteria:

- The requested medication is prescribed for one of the following indications:
  - Cancer
  - Sickle cell disease
  - Palliative care
  - Another terminal diagnosis associated with significant pain
- You have had a trial of at least 7 days generic MS Contin in the past 120 days (**NOTE:** This requirement does not apply for **FENTANYL TRANSDERMAL PATCH** requests in patients who have difficulty swallowing.)

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MDwise MANAGED MEDICAID
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FENTANYL TRANSDERMAL PATCH

INITIAL CRITERIA (CONTINUED)

Our guideline for **FENTANYL TRANSDERMAL PATCH** requires that patients meet **ALL** of the following criteria:

- You have a diagnosis of moderate to severe pain
- You meet the definition of opioid tolerance [defined as those who are taking, for one week or longer, at least 60 morphine milligram equivalents (MME)/day such as 60mg oral morphine/day, 40mg oral oxycodone/day, 15mg oral hydromorphone/day, 60mg oral hydrocodone/day, 400mg oral codeine/day, or an equianalgesic dose of another opioid]. Your plan requires that for patients active with MDwise for 90 days or longer, only previously paid claims for opioids may be considered for this criterion. If your prescriber indicates that you have been on opioid therapy, it must be verified in claims history. Chart notes and/or cash pay for opioid use is not accepted. For patients active with MDwise less than 90 days, chart notes are required to verify previous opioid use for this criterion You have had a trial of at least 30 days generic MS Contin in the past 120 days (**NOTE:** This requirement does not apply for **FENTANYL TRANSDERMAL PATCH** requests in patients who have difficulty swallowing.)
- Your prescriber has consulted with you regarding the risks of opioid therapy and developed a pain management plan with clear treatment goals
- **FENTANYL TRANSDERMAL PATCH** requests for dosing every 48 hours require a trial of every 72 hours dosing

Please note that additional criteria apply for concurrent use of opioid analgesics and benzodiazepines, including submission of signed prescriber attestation on a state-mandated fax form.

Our guideline for **FENTANYL TRANSDERMAL PATCH** dosed every 48 hours requires a trial of fentanyl transdermal patch dosed every 72 hours.
Please note that additional criteria apply for concurrent use of opioid analgesics and benzodiazepines, including submission of signed prescriber attestation on a state-mandated fax form.

Our guideline named **FENTANYL TRANSDERMAL PATCH** for concurrent use of more than one long-acting opioid analgesic requires your provider to verify that you meet ALL of the following criteria:

- You have a diagnosis of moderate to severe pain
- You experience refractory pain (pain that continues or returns) despite concurrent therapy with one short-acting opioid and one long-acting opioid
- Your prescriber has consulted with you regarding the risks of opioid therapy and developed a pain management plan with clear treatment goals

Exceptions to these criteria may be authorized in patients with moderate to severe pain from cancer or sickle cell disease or those receiving opioids as part of a palliative care (medical care for symptoms related to illness) plan. Please note that additional criteria apply for concurrent use of opioid analgesics and benzodiazepines, including submission of signed prescriber attestation on a state-mandated fax form.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

FENTANYL TRANSDERMAL PATCH

INITIAL CRITERIA (CONTINUED)

Our guideline for FENTANYL TRANSDERMAL PATCH for patients with claims in history for benzodiazepines requires that the prescriber submit the required fax form documenting **ALL** of the following:

- The diagnosis contributing to the need for benzodiazepine therapy and previous therapy attempted, including dates and doses of prior therapies
  - For generalized anxiety disorder, one of the following is required: Selective serotonin reuptake inhibitor (SSRI, such as sertraline or citalopram), serotonin-noradrenaline reuptake inhibitor (SNRI, such as duloxetine or venlafaxine), or pregabalin (generic for Lyrica)
  - For panic disorder, one of the following is required: SSRI or tricyclic antidepressant (TCA, such as amitriptyline or nortriptyline)
  - For social anxiety disorder (SAD), a trial of an SSRI is required
  - For obsessive compulsive disorder (OCD), a trial of an SSRI is required
  - For post-traumatic stress disorder (PTSD), one of the following is required: mirtazapine, paroxetine, amitriptyline, or phenelzine
  - For insomnia, one of the following is required: ramelteon or a sedating antidepressant (for example, trazodone, amitriptyline, doxepin, mirtazapine)
- The diagnosis contributing to the need for opioid analgesic therapy and previous therapy attempted, including dates and doses of prior therapies (if applicable). For a diagnosis of moderate to severe cancer-related pain, pain related to sickle cell disease, or pain in patients receiving palliative care, no additional criteria applies
  - For long-acting opioid therapy requested for chronic moderate to severe pain, **ALL** of the following are required:
    - You meet the definition of opioid tolerance (defined as those who are taking, for one week or longer, at least 60 morphine milligram equivalents (MME)/day such as 60mg oral morphine/day, 40mg oral oxycodone/day, 15mg oral hydromorphone/day, 60mg oral hydrocodone/day, 400mg oral codeine/day, or an equianalgesic dose (a dose of one pain medication that is the same in pain-relieving effects to that of another pain medication) of another opioid). Your plan requires that for patients active with MDwise for 90 days or longer, only previously paid claims for opioids may be considered for this criterion. If your prescriber indicates that you have been on opioid therapy, it must be verified in claims history. Chart notes and/or cash pay for opioid use is not accepted. For patients active with MDwise less than 90 days, chart notes are required to verify previous opioid use for this criterion
    - Your prescriber has consulted with you regarding the risks of opioid therapy and developed a pain management plan with clear treatment goals
    - You have had a trial of at least 30 days generic MS Contin in the past 120 days
- Your prescriber has signed an attestation as to **ALL** of the following:
  - Your provider will regularly review your controlled substance utilization contained within INSPECT (Indiana controlled substance monitoring program)
  - You have been educated about the risks of using benzodiazepines and opioid analgesics together at the same time
  - Both you and your provider accept the risk of using benzodiazepines and opioid analgesics together at the same time

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FENTANYL TRANSDERMAL PATCH

GUIDELINES FOR USE

INITIAL CRITERIA (CONTINUED)

Our guideline named **FENTANYL TRANSDERMAL PATCH** for patients with claims in history for Lybalvi (olanzapine/samidorphan) requires that you have not taken Lybalvi (olanzapine/samidorphan) less than or equal to 5 days prior to initiating fentanyl transdermal patch therapy.

RENEWAL CRITERIA

Our guideline for **FENTANYL TRANSDERMAL PATCH** does not permit concurrent use with carisoprodol-containing products.

Our guideline for renewal of **FENTANYL TRANSDERMAL PATCH** requires your prescriber to verify that you meet **ALL** of the following criteria:

- Opioid therapy has resulted in a meaningful improvement in your pain and/or function
- Your doctor has developed an updated pain management plan with clear treatment goals
- A risk assessment has been performed including review of the state prescription drug monitoring program (PDMP) data (for example, INSPECT)
- Adherence to prescribed opioid regimen has been periodically assessed (for example, urine drug screen, pill counts)

In addition, requests for renewal of concurrent use of (used at the same time with) more than one long-acting opioid requires that you meet **ALL** of the following rules:

- You have a diagnosis of moderate to severe pain
- You experience refractory pain (pain that continues or returns) despite concurrent therapy with one short-acting opioid and one long-acting opioid
- Your prescriber has consulted with you regarding the risks of opioid therapy and developed a pain management plan with clear treatment goals
- Exceptions may be granted if you have moderate to severe pain from cancer, have sickle cell disease (a type of red blood cell disorder) or you are receiving opioids as part of a palliative care plan (treatment for symptoms related to an illness)

Exceptions to these criteria may be authorized in patients with cancer, sickle cell disease, another terminal diagnosis associated with significant pain, or those receiving opioids as part of a palliative care (medical care for symptoms related to illness) plan. Please note that additional criteria apply for concurrent use of opioid analgesics and benzodiazepines, including submission of signed prescriber attestation on a state-mandated fax form.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

FENTANYL TRANSDERMAL PATCH

RENEWAL CRITERIA (CONTINUED)

Our guideline for renewal of **FENTANYL TRANSDERMAL PATCH** for patients with claims in history for benzodiazepines requires that the prescriber submit the required fax form documenting **ALL** of the following:

- The diagnosis contributing to the need for benzodiazepine therapy and previous therapy attempted, including dates and doses of prior therapies
  - For generalized anxiety disorder, one of the following is required: Selective serotonin reuptake inhibitor (SSRI, such as sertraline or citalopram), serotonin-noradrenaline reuptake inhibitor (SNRI, such as duloxetine or venlafaxine), or pregabalin (generic for Lyrica)
  - For panic disorder, one of the following is required: SSRI or tricyclic antidepressant (TCA, such as amitriptyline or nortriptyline)
  - For social anxiety disorder (SAD), a trial of an SSRI is required
  - For obsessive compulsive disorder (OCD), a trial of an SSRI is required
  - For post-traumatic stress disorder (PTSD), one of the following is required: mirtazapine, paroxetine, amitriptyline, or phenelzine
  - For insomnia, one of the following is required: ramelteon or a sedating antidepressant (for example, trazodone, amitriptyline, doxepin, mirtazapine)
- The diagnosis contributing to the need for renewal of the requested opioid analgesic therapy and that you meet the following:
  - Opioid therapy has resulted in a meaningful improvement in your pain and/or function
  - Your doctor has developed an updated pain management plan with clear treatment goals
  - A risk assessment has been performed including review of the state prescription drug monitoring program (PDMP) data (e.g., INSPECT)
  - Adherence to prescribed opioid regimen has been periodically assessed (e.g., urine drug screen, pill counts)
- Your prescriber has signed an attestation as to **ALL** of the following:
  - Your provider will regularly review your controlled substance utilization contained within INSPECT
  - You have been educated about the risks of using benzodiazepines and opioid analgesics together at the same time
  - Both you and your provider accept the of using benzodiazepines and opioid analgesics together at the same time

Please note that additional criteria apply for the benzodiazepine day supply limits. Your benzodiazepine prescription claim must not be greater than a 15-day supply of medication. You cannot receive more than 30 days' supply of benzodiazepine medication in the past 90 days. The current request for medication is also counted as a part of the 30 days' supply in the past 90 days.

Our guideline named **FENTANYL TRANSDERMAL PATCH** for patients with claims in history for Lybalvi (olanzapine/samidorphan) requires that you have not taken Lybalvi (olanzapine/samidorphan) less than or equal to 5 days prior to initiating methadone therapy.

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FENTANYL TRANSDERMAL PATCH

RATIONALE

To ensure opioid analgesics are used according to FDA approved indications with patient safety in mind, and to encourage the use of more cost-effective analgesics.

From 2000-2014, almost half a million people died due to drug overdose, with 2014 being the highest year for deaths on record. In that time, the number of opioids prescribed, as well as the number of opioid overdoses, has risen exponentially. At least half of all opioid overdose deaths involve a prescription opioid. Indiana was among the states that had a statistically significant increase of overdose deaths from 2013-2014.

According to recent research, the opioid epidemic has a disproportionate impact on Medicaid beneficiaries. Medicaid patients are prescribed opioids at double the rate of non-Medicaid patients, and are subsequently at much higher risk of prescription opioid overdose.
Improving the way that opioids are prescribed can ensure safer and more effective pain treatment, and reduce the addiction, misuse, abuse, and overdose of these drugs. These guidelines are to ensure that the use of opioids is consistent with their FDA approved indications, and to initiate action combating the current opioid epidemic.

Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60mg oral morphine/day, 25mcg transdermal fentanyl/hour, 40mg oral oxycodone/day, 15mg oral hydromorphone/day, 60mg oral hydrocodone/day, 400mg oral codeine/day, or an equianalgesic dose of another opioid for a week or longer.

Buprenorphine Conversion Table

Buprenorphine Product	Oral MME Conversion Factor
Belbuca buccal film (mcg/hr)	0.03
buprenorphine, tablet or film for opioid use disorder	30
Butrans transdermal patch (mcg/hr)	12.6

Example: 900 mcg buprenorphine buccal film x (60 films/30 days) x 0.03=54 MME/day
Example: 5 mcg buprenorphine patch x (4 patches/28 days) x 12.6= 9 MME/day

Fentanyl Conversion Table

Fentanyl Product	Oral MME Conversion Factor
fentanyl buccal or SL tablets, or lozenge/troche (mcg)	0.13
fentanyl film or oral spray (mcg)	0.18
fentanyl nasal spray (mcg)	0.16
fentanyl patch (mcg)	7.2

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FENTANYL TRANSDERMAL PATCH

RATIONALE (CONTINUED)

Opioid Conversion Table

Drug	MME Conversion Factor (1mg of drug to mg morphine)	60mg Morphine Equivalent Dose
butorphanol	7	8.5mg
codeine	0.15	400mg
fentanyl citrate	0.12	0.5mg (500mcg)
hydrocodone	1	60mg
hydromorphone HCl	4	15mg
meperidine HCl	0.1	600mg
morphine	1	60mg
oxycodone HCl	1.5	40mg
oxymorphone HCl	3	20mg
pentazocine HCl	0.37	162mg
tapentadol HCl	0.4	150mg
tramadol HCl	0.1	600mg

Methadone Conversion table

Methadone daily dose (mg/day)	MME Conversion Factor (1mg of drug to mg morphine)	60mg Morphine Equivalent Dose
>0, <= 20	4	20mg
>20, <=40	8	7.5mg
>40, <=60	10	6mg
>60	12	5mg

Opioid Usage in Chronic Pain Management
Per systematic review in the CDC Guideline for Prescribing Opioids for Chronic Pain, long-term (≥ 1 year) efficacy of opioids in management of chronic pain, function, or quality of life is not established. Most randomized controlled trials present effectiveness within 6 weeks or less. Conversely, significant risks of adverse events are present with chronic opioid therapy, including opioid abuse and dependence, social role withdrawal, and increased risk of CNS depression, and withdrawal emergencies.

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RATIONALE (CONTINUED)

The CDC also recommends re-evaluating and re-establishing treatment goals, including realistic expectation for pain and function, as well as discontinuation strategies when benefits do not outweigh risks. The guideline provides the following recommendations for opioid selection, dosage, duration, follow-up and discontinuation:

- Immediate-release (IR) opioids are preferred over extended-release (ER) forms.
- The lowest effective dosage is preferred with initial opioid use. Caution is warranted at any dose and reassessing benefits and risks is recommended for 50 morphine milligram equivalents (MME) daily or more. 90 MME daily or more should be avoided if possible.
- Within 1 to 4 weeks of therapy, clinicians should evaluate benefits and harms of using opioids to treat chronic pain. Therapy continuation should be evaluated every 3 months or sooner. If benefits do not outweigh harms to continue opioid therapy, other therapies should be optimized and opioid tapering/discontinuation should be considered and encouraged.

Assessing Risk and Addressing Harms of Opioid Use

- Prior to and throughout opioid therapy, adverse events should be evaluated periodically. Factors that increase risk for opioid overdose include history of overdose or substance use disorder, 50 MME daily or more, and concurrent benzodiazepine use.
- Prescription drug monitoring program (PDMP) data (e.g., RXINSPECT) are useful to monitor total opioid dosage. PDMP data is helpful for initial and periodic opioid usage evaluations.
- Prescribing opioids and benzodiazepines concurrently should be avoided.
- For patients with substance use disorder, evidence-based treatment (medication-assisted and behavioral therapy) is recommended.

Analysis performed by the US Department of Health and Human Services Center for Disease Control and Prevention (CDC) determined the risk of harm to individuals increases as their opioid dose increases and as their length of opioid therapy increases. For example:

- Individuals taking opioid doses > 50 morphine milligram equivalents (MMEs) per day had twice the risk of death from an overdose than those taking < 20 MMEs per day.
- Individuals taking opioid doses > 90 (MMEs) per day had 10 times the risk of death from an overdose than those taking < 20 MMEs per day.
- Individuals taking an opioid for > 3 months (even at low doses) had 15 times the risk of addiction to those taking opioids for < 3 months.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

FENTANYL TRANSDERMAL PATCH

APPENDIX 1: BENZODIAZEPINE/OPIOID CONCURRENT USE FAX FORM
INDIANA HEALTH COVERAGE PROGRAMS (IHCP) PHARMACY BENEFIT
BENZODIAZEPINE AND OPIOID CONCURRENT THERAPY
PRIOR AUTHORIZATION REQUEST FORM

MDwise
Fax to: (858) 790-7100
c/o MedImpact Healthcare Systems, Inc.
Attn: Prior Authorization Department
10181 Scripps Gateway Court, San Diego, CA 92131
Phone: 1-800-788-2949

Today's Date
☐☐ / ☐☐ / ☐☐☐☐

Note: This form must be completed by the prescribing provider.
****All sections must be completed or the request will be denied.****

Patient's Medicaid # ☐☐☐☐☐☐☐☐☐☐☐☐	**Date of Birth** ☐☐ / ☐☐ / ☐☐☐☐
Patient's Name	**Prescriber's Name**
Prescriber's IN License # ☐☐☐☐☐☐☐☐	**Specialty**
Prescriber's NPI # ☐☐☐☐☐☐☐☐☐☐	**Prescriber's Signature: **Required below within attestation section.****
Return Fax # ☐☐☐ - ☐☐☐ - ☐☐☐☐	**Return Phone #** ☐☐☐ - ☐☐☐ - ☐☐☐☐

PA is required for the following:

- **Claim(s) for new opioid(s) to be used concurrently with benzodiazepines and exceeding 7 days within a 180-day period.**
- **Claim(s) for new benzodiazepine(s) to be used concurrently with opioids and exceeding 7 days of therapy within a 180-day period and/or exceeding established benzodiazepine/opioid concurrent therapy quantity limits (see Sedative Hypnotics/Benzodiazepine PA criteria).**

Benzodiazepine Agent(s)	Prescriber Name*	Quantity	Dosage Regimen/Duration

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

Opioid Agent(s)	Prescriber Name*	Quantity	Dosage Regimen/Duration

***NOTE: If prescribers of the opioid(s) and benzodiazepine(s) are not the same, please answer the following questions:**

- **Are you requesting PA for: Benzodiazepine Agent(s) ☐ Opioid Agent(s) ☐ Both ☐**
- **Is/are the other prescriber(s) aware of the request for concurrent therapy? □ Yes □ No**
- **Has/have the other prescriber(s) been consulted about the risks associated with concurrent therapy, and do all prescribers involved believe continuing with concurrent therapy is warranted, given the risks associated with concurrent use? □ Yes □ No**

PA Requirements:

Patient diagnosis/diagnoses for use of benzodiazepine therapy:

Prior therapies attempted for the above diagnosis/diagnoses (submission of chart notes required in absence of claims history):

Drug Therapy	Dosage Regimen	Dates of Utilization

Do you plan to continue benzodiazepine therapy for this patient? □ Yes □ No
If no, please provide withdrawal plan:

Patient diagnosis/diagnoses for use of opioid therapy:

Prior therapies (both drug and non-drug) attempted for the above diagnosis/diagnoses (submission of chart notes required in absence of claims history):

Drug/Non-Drug Therapy	Dosage Regimen	Dates of Utilization	Reason for Discontinuation or Failure

Do you plan to continue opioid therapy for this patient? □ Yes □ No
If no, please provide withdrawal plan:

Attestation:

I, _____, hereby attest to the following:
(Prescriber Name)

The patient's INSPECT report has been evaluated and continues to be evaluated on a regular basis (Per IC 35-48-7-11.1, DO NOT attach a copy of the INSPECT report to this PA request).
I have educated the patient in regards to the risks of concurrent utilization of benzodiazepine and opioid therapy, and the patient accepts these risks.
If applicable, I have consulted other prescriber(s) involved in concurrent therapy and all prescribers involved agree to pursue concurrent opioid and benzodiazepine therapy for this patient.
I acknowledge, as the prescriber initiating or maintaining concurrent benzodiazepine and opioid therapy, the risk of adverse event(s), including respiratory depression, coma, and death, associated with concurrent utilization.

Prescriber Signature:_____

****Prescriber signature is required for consideration. Electronic or stamped signature will not be accepted.****

CONFIDENTIAL INFORMATION
This facsimile transmission (and attachments) may contain protected health information from the Indiana Health Coverage Programs (IHCP), which is intended only for the use of the individual or entity named in this transmission sheet. Any unintended recipient is hereby notified that the information is privileged and confidential, and any use, disclosure, or reproduction of this information is prohibited.

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

FENTANYL TRANSDERMAL PATCH

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Created: 09/19
Effective: 06/13/22 Client Approval: 05/26/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

FINASTERIDE-TADALAFIL

Generic	Brand	HICL	GCN	Exception/Other
FINASTERIDE/TADALAFIL	ENTADFI	47719		

GUIDELINES FOR USE

Our guideline named **FINASTERIDE-TADALAFIL (Entadfi)** requires the following rule(s) be met for approval:

A. You have benign prostatic hyperplasia (BPH: a type of prostate condition)
B. You are 18 years of age or older
C. You have had a trial of or contraindication (harmful for) to TWO alpha blockers (such as terazosin, doxazosin, tamsulosin)
D. You have had a trial of or contraindication (harmful for) to ONE 5-alpha-reductase inhibitor (such as finasteride, dutasteride)
E. You have had a trial of or contraindication (harmful for) to tadalafil 2.5 mg or tadalafil 5 mg

Requests will not be approved if you have already received a 26-week course of Entadfi.

RATIONALE

Promote appropriate utilization of Entadfi based on FDA approved indication.

FDA APPROVED INDICATION

Entadfi is indicated to initiate treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) in men with an enlarged prostate for up to 26 weeks.

Limitations of Use

Entadfi is not recommended for more than 26 weeks because the incremental benefit of tadalafil decreases from 4 weeks until 26 weeks, and the incremental benefit beyond 26 weeks is unknown

DOSAGE

The recommended dosage of Entadfi is one capsule (containing finasteride 5 mg and tadalafil 5 mg) orally once daily at approximately the same time every day for up to 26 weeks.

REFERENCES

Entadfi [Prescribing Information]. Miami, FL: Veru, Inc.; December 2021.

Created: 09/22
Effective: 10/17/22 Client Approval: 09/16/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

FINERENONE

Generic	Brand	HICL	GCN	Exception/Other
FINERENONE	KERENDIA	47487		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **FINERENONE (KERENDIA)** requires the following rule(s) be met for approval:
A. You have chronic kidney disease (CKD) associated with type 2 diabetes (T2D)
B. You are 18 years of age or older
C. You had a trial of or contraindication to (medical reason why you cannot use) BOTH of the following:
   1. A sodium-glucose cotransport-2 (SGLT2) inhibitor (such as Farxiga, Invokana, Jardiance, Steglatro)
   2. Spironolactone or epelerenone

RENEWAL CRITERIA

Our guideline named **FINERENONE (KERENDIA)** requires the following rule(s) be met for renewal:
A. You have chronic kidney disease (CKD) associated with type 2 diabetes (T2D)
B. You have experienced or maintained clinical improvement while on Kerendia

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RATIONALE
To ensure appropriate use of Kerendia consistent with FDA approved indication.

FDA APPROVED INDICATIONS
Kerendia is a non-steroidal mineralocorticoid receptor antagonist (MRA) indicated to reduce the risk of sustained eGFR decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D).

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

FINERENONE

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

The recommended starting dosage of Kerendia is 10 mg or 20 mg orally once daily based on estimated glomerular filtration rate (eGFR) and serum potassium thresholds.

Table 1: Recommended Starting Dosage

eGFR (mL/min/1.73m^2)	Starting Dose
≥ 60	20mg once daily
≥ 25 to < 60	10mg once daily
< 25	Not Recommended

Increase dosage after 4 weeks to the target dose of 20 mg once daily, based on eGFR and serum potassium thresholds.

Table 2: Dose Adjustment Based on Current Serum Potassium Concentration and Current Dose

		Current Kerendia Dose	
		10mg once daily	**20mg once daily**
Current Serum Potassium (mEq/L)	≤ 4.8	Increase the dose to 20 mg once daily.*	Maintain 20mg once daily.
	> 4.8 to 5.5	Maintain 10mg once daily.	Maintain 20mg once daily.
	> 5.5	Withhold Kerendia. Consider restarting at 10 mg once daily when serum potassium ≤ 5.0 mEq/L.	Withhold Kerendia. Restart at 10 mg once daily when serum potassium ≤ 5.0 mEq/L.

*If eGFR has decreased by more than 30% compared to previous measurement, maintain 10 mg dose.

REFERENCES

- Kerendia [Prescribing Information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals, Inc., July 2021.

Created: 08/21
Effective: 09/20/21 Client Approval: 08/20/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

FINGOLIMOD

Generic	Brand	HICL	GCN	Exception/Other
FINGOLIMOD	GILENYA	37180		

GUIDELINES FOR USE

Our guideline named **FINGOLIMOD (Gilenya)** requires the following rule(s) be met for approval:

A. You have multiple sclerosis (MS: an illness where the immune system eats away at the protective covering of the nerves)

RATIONALE

To promote appropriate utilization of fingolimod based on labeled indication.

FDA APPROVED INDICATIONS

Fingolimod is a sphingosine 1-phosphate receptor modulator indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in patients 10 years of age and older.

DOSAGE AND ADMINISTRATION

- Recommended dosage for adults and pediatric patients (10 years of age and older) weighing more than 40 kg: 0.5 mg orally once-daily, with or without food.
- Recommended dosage for pediatric patients (10 years of age and above) weighing less than or equal to 40 kg: 0.25 mg orally once-daily, with or without food.
- First Dose Monitoring (including reinitiation after discontinuation > 14 days and dose increases):
  - Observe all patients for bradycardia for at least 6 hours; monitor pulse and blood pressure hourly. Electrocardiograms (ECGs) prior to dosing and at end of observation period required.
  - Monitor until resolution if heart rate < 45 beats per minute (bpm) in adults, < 55 bpm in patients aged 12 years and above, or < 60 bpm in pediatric patients aged 10 to below 12 years, atrioventricular (AV) block, or if lowest post-dose heart rate is at the end of the observation period.
  - Monitor symptomatic bradycardia with ECG until resolved. Continue overnight if intervention is required; repeat first-dose monitoring for second dose.
  - Observe patients overnight if at higher risk of symptomatic bradycardia, heart block, prolonged QTc interval, or if taking drugs with known risk of torsades de pointes.

AVAILABLE STRENGTHS

- 0.25 mg hard capsules
- 0.5 mg hard capsules

REFERENCES

- Novartis Pharmaceutical Corporation. Gilenya package insert. East Hanover, NJ. December 2019.

Created: 03/15
Effective: 08/16/21 Client Approval: 07/07/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

FINGOLIMOD LAURYL SULFATE

Generic	Brand	HICL	GCN	Exception/Other
FINGOLIMOD LAURYL SULFATE	TASCENSO ODT	48165		

GUIDELINES FOR USE

Our guideline named **FINGOLIMOD LAURYL SULFATE (Tascenso ODT)** requires the following rule(s) be met for approval:

A. You have multiple sclerosis (a type of nerve disorder)
B. You are 10 years of age or older
C. You had a trial of fingolimod capsules
D. You are unable to swallow fingolimod capsules

RATIONALE

To promote appropriate utilization of fingolimod lauryl sulfate based on labeled indication.

FDA APPROVED INDICATIONS

Fingolimod lauryl sulfate is a sphingosine 1-phosphate receptor modulator indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in patients 10 years of age and older.

DOSAGE AND ADMINISTRATION

- In adults and pediatric patients 10 years of age and older weighing more than 40 kg, the recommended dosage of Tascenso ODT is 0.5 mg orally once-daily.
- In pediatric patients 10 years of age and older weighing less than or equal to 40 kg, the recommended dosage of Tascenso ODT is 0.25 mg orally once daily.
- First-Dose Monitoring (including reinitiation after discontinuation greater than 14 days) and dose increases of any fingolimod product approved for use at a higher dose:
  - Observe all patients for bradycardia for at least 6 hours; monitor pulse and blood pressure hourly. Electrocardiograms (ECGs) prior to dosing and at end of observation period required.
  - Monitor until resolution if heart rate < 45 beats per minute (bpm) in adults, < 55 bpm in patients aged 12 years and above, or < 60 bpm in pediatric patients aged 10 to below 12 years, atrioventricular (AV) block, or if lowest post-dose heart rate is at the end of the observation period.
  - Monitor symptomatic bradycardia with ECG until resolved. Continue overnight if intervention is required; repeat first-dose monitoring for second dose.
  - Observe patients overnight if at higher risk of symptomatic bradycardia, heart block, prolonged QTc interval, or if taking drugs with known risk of torsades de pointes.

AVAILABLE STRENGTHS

- 0.25 mg orally disintegrating tablets
- 0.5 mg orally disintegrating tablets

REFERENCES

Tascenso ODT [Prescribing Information]. San Jose, CA: Handa Neuroscience, LLC; December 2022.

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

FOSTAMATINIB

Generic	Brand	HICL	GCN	Exception/Other
FOSTAMATINIB	TAVALISSE	44895		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **FOSTAMATINIB (Tavalisse)** requires the following rule(s) be met for approval:
A. You have chronic immune thrombocytopenia (cITP; Low levels of the blood cells that prevent bleeding)
B. You are 18 years of age or older
C. You had a splenectomy (surgical removal of spleen) **OR** a previous trial of at least **TWO** of the following treatments:
   1. Corticosteroids
   2. IVIG (intravenous immunoglobulin)
   3. Rhogam
   4. Rituxan (rituximab)
   5. Thrombopoietin receptor agonist such as Promacta (eltrombopag), Nplate (romiplostim)

RENEWAL CRITERIA

Our guideline named **FOSTAMATINIB (Tavalisse)** requires the following rule(s) be met for renewal:
A. You have chronic immune thrombocytopenia (cITP; Low levels of the blood cells that prevent bleeding)
B. You are 18 years of age or older
C. You had clinically significant prevention of bleeds while on therapy
D. Your AST (aspartate transaminase) and ALT (alanine transaminase) levels (types of liver enzymes) have remained under 3 times the upper limits of normal per reference range
E. Your total bilirubin level has remained under 2 times the upper limits of normal per reference range
F. Your absolute neutrophil count (ANC; a measure of the number of neutrophils which are a type of white blood cell) has remained within normal limits per reference range
G. Your platelets have reached a level between 50 and 450 x 10^9/L

RATIONALE
To ensure appropriate use of Tavalisse (fostamatinib) consistent with FDA approved indications.

FDA APPROVED INDICATION
Tavalisse is a kinase inhibitor indicated for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

FOSTAMATINIB

DOSAGE AND ADMINISTRATION

Initiate Tavalisse at 100 mg orally twice daily with or without food. After 4 weeks, increase dose to 150 mg twice daily, if needed, to achieve platelet count of at least 50 x 10^9/L. Use the lowest dose of Tavalisse to achieve and maintain a platelet count at least 50 x 10^9/L as necessary to reduce the risk of bleeding. Please refer to the full prescribing information for recommendations on how to manage adverse reactions. Discontinue Tavalisse after 12 weeks of treatment if the platelet count does not increase to a level sufficient to avoid clinically important bleeding.

REFERENCES

Tavalisse [Prescribing Information]. South San Francisco, CA. Rigel Pharmaceuticals, Inc. November 2020.

Created: 06/18
Effective: 03/14/22 Client Approval: 02/14/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

FOSTEMSAVIR

Generic	Brand	HICL	GCN	Exception/Other
FOSTEMSAVIR	RUKOBIA	46684		

GUIDELINES FOR USE

Our guideline named **FOSTEMSAVIR (Rukobia)** requires the following rule(s) be met for approval:

i. You have human immunodeficiency virus type 1 (HIV-1) infection
ii. You are 18 years of age or older
iii. The requested medication will be used in combination with other antiretroviral(s) (class of medication used to treat HIV)
iv. You are heavily treatment experienced (previously treated) and have multidrug-resistant HIV-1 infection
v. You are failing your current antiretroviral regimen due to resistance, intolerance, or safety considerations

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RATIONALE

To ensure appropriate use of Rukobia on FDA approved indications and dosing.

INDICATIONS

Rukobia, a human immunodeficiency virus type 1 (HIV-1) gp120-directed attachment inhibitor, in combination with other antiretroviral(s), is indicated for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug-resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations.

DOSING

The recommended dosage of Rukobia is one 600-mg tablet taken orally twice daily with or without food.

REFERENCES

Rukobia [Prescribing Information]. Research Triangle Park, NC: GlaxoSmithKline; July 2020.

Created: 07/20
Effective: 08/24/20 Client Approval: 07/29/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

FREMANEZUMAB-VFRM

Generic	Brand	HICL	GCN	Exception/Other
FREMANEZUMAB-VFRM	AJOVY	45236		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **FREMANEZUMAB-VFRM (Ajovy)** requires the following rules be met for approval:

A. You have migraines
B. You are 18 years of age or older
C. You have previously tried any **THREE** of the following preventive migraine treatments (chart notes required in the absence of electronic prescription claims history):
   1. beta-blocker (such as propranolol, timolol or nadolol)
   2. candesartan
   3. cyproheptadine
   4. lisinopril
   5. tricyclic antidepressant (such as amitriptyline, nortriptyline, or doxepin)
   6. topiramate
   7. valproic acid/divalproex sodium
   8. venlafaxine/desvenlafaxine
   9. verapamil

RENEWAL CRITERIA

Our guideline named **FREMANEZUMAB-VFRM (Ajovy)** requires the following rules be met for renewal:

A. You have history of paid claim(s) for the requested medication in the past 90 days
B. You have a previous authorization on file for the requested medication

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RATIONALE

Ensure appropriate criteria are used for the management of requests for Ajovy according to approved indication, dosing, and national treatment guidelines.

FDA APPROVED INDICATIONS

Ajovy is a calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine in adults.

HOW SUPPLIED

225 mg/1.5 mL solution in a single-dose prefilled syringe or autoinjector.

DOSING & ADMINISTRATION

Two subcutaneous dosing options of Ajovy are available to administer the recommended dosage:

- 225 mg monthly
- 675 mg every 3 months (quarterly) - administered as 3 consecutive injections of 225 mg each.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

FREMANEZUMAB-VFRM

REFERENCES

- Ajovy [Prescribing Information]. North Wales, PA: Teva Pharmaceuticals USA, Inc. September 2021.
- Clinical Pharmacology Level of Evidence for Off-Label Indication [Internet]. Tampa (Fl): Elsevier. c2019 [cited June 5, 2019]. Available from https://www-clinicalkey-com.ezproxy.butler.edu/pharmacology/monograph/loe?sectionId=7826&ratingId=782&print=true.
- Cyproheptadine hydrochloride tablet package insert. Middlesex, NJ: CorePharma, LLC; 2015 Aug.
- Guinn, D. Hickenbottom, S. Lee MJ. Headache in pregnant and postpartum women. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed June 11, 2019
- Migraine in adults. In DynaMed Plus [database online]. EBSCO Information Services. http://www.dynamed.com/topics/dmp~AN~T114718/Migraine-in-adults#Prevention-and-Screening. Updated November 30, 2018. Accessed June 10, 2019.
- Rao BS, Das DG, Taraknath VR, Sarma Y. A double-blind controlled study of propranolol and cyproheptadine in migraine prophylaxis. Neurol India. 2000 Sep;48(3):223-6.
- Schrader H, Stovner LJ, Helde G, et al. Prophylactic treatment of migraine with angiotensin converting enzyme inhibitor (lisinopril): randomized, placebo controlled, crossover study. BMJ 2001;322:19-22. Accessed June 13, 2019.
- Silberstein SD. Practice parameter: Evidence-Based guidelines for migraine headache (an evidence-based review): Report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology 2000; 55; 754-762.
- Stovner LJ, Linde M, Gravdahl GB, et al. A comparative study of candesartan versus propranolol for migraine prophylaxis: a randomized triple-blind, placebo-controlled, double cross-over study. Cephalagia 2014;24:523-532. Accessed June 13, 2019.
- Tronvik E, Stovner LJ, Helde G, et al. Prophylactic treatment of migraine with an angiotensin II receptor blocker, a randomized controlled trial. JAMA 2003;289(1):65-69. Accessed June 13, 2019.

Created: 11/18
Effective: 12/15/21 Client Approval: 10/21/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

FUTIBATINIB

Generic	Brand	HICL	GCN	Exception/Other
FUTIBATINIB	LYTGOBI	48369		

GUIDELINES FOR USE

Our guideline named **FUTIBATINIB (Lytgobi)** requires the following rule(s) be met for approval:

A. You have unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma (iCCA) (a type of bile duct cancer inside the liver that is unable to be removed by surgery, has spread from where it started to nearby tissue/lymph nodes or to other parts of the body)
B. You are 18 years of age or older
C. You have been previously treated for unresectable, locally advanced or metastatic iCCA
D. You have fibroblast growth factor receptor 2 (FGFR2: a type of protein) gene fusions or other rearrangements

RATIONALE

To ensure appropriate diagnostic, utilization, and safety criteria are used for the management of requests for futibatinib.

INDICATIONS

Lytgobi is a kinase inhibitor indicated for the treatment of adult patients with previously treated, unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements.

DOSAGE

The recommended dose is 20 mg orally (five 4 mg tablets) once daily until disease progression or unacceptable toxicity occurs.

REFERENCES

Lytgobi [Prescribing Information]. Princeton, NJ: Taiho Pharmaceutical Co., Ltd., September 2022.

Created: 11/22
Effective: 12/05/22 Client Approval: 11/21/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

GALCANEZUMAB-GNLM

Generic	Brand	HICL	GCN	Exception/Other
GALCANEZUMAB-GNLM	EMGALITY	45281		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **GALCANEZUMAB-GNLM (Emgality)** requires the following rules be met for approval:

A. You have migraines or you are being treated for episodic cluster headache (very painful headaches that occur in patterns)
B. **If you have migraines, approval requires:**
   1. You are 18 years of age or older
   2. You have previously tried any **THREE** of the following preventive migraine treatments (chart notes required in the absence of electronic prescription claims history):
      - beta-blocker (such as propranolol, timolol or nadolol)
      - candesartan
      - cyproheptadine
      - lisinopril
      - tricyclic antidepressant (such as amitriptyline, nortriptyline, or doxepin)
      - topiramate
      - valproic acid/divalproex sodium
      - venlafaxine/desvenlafaxine
      - verapamil
C. **If you have episodic cluster headaches, approval requires:**
   1. You are 18 years of age or older

RENEWAL CRITERIA

Our guideline named **GALCANEZUMAB-GNLM (Emgality)** requires the following rule(s) be met for renewal:

A. You have a diagnosis of migraines or episodic cluster headache (very painful headaches that occur in patterns)
B. You have history of paid claim(s) for the requested medication in the past 90 days
C. You have a previous authorization on file for the requested medication

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RATIONALE

Ensure appropriate criteria are used for the management of requests for Emgality according to approved indication, dosing, and national treatment guidelines.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

GALCANEZUMAB-GNLM

FDA APPROVED INDICATIONS
Emgality is a calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine in adults and for the treatment of episodic cluster headache in adults.

HOW SUPPLIED
- Injection: 120 mg/mL solution in a single-dose prefilled pen
- Injection: 120 mg/mL solution in a single-dose prefilled syringe
- Injection: 100 mg/mL solution in a single-dose prefilled syringe

DOSING & ADMINISTRATION
Recommended dosage for migraines: 240 mg loading dose (administered as two consecutive injections of 120 mg each), followed by monthly doses of 120 mg.

Recommended dosage for episodic cluster headaches: 300 mg (three consecutive injections of 100 mg each) at the onset of the cluster period, and then monthly until the end of the cluster period.

REFERENCES

- Emgality [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company. December 2019.
- Clinical Pharmacology Level of Evidence for Off-Label Indication [Internet]. Tampa (Fl): Elsevier. c2019 [cited June 5, 2019]. Available from https://www-clinicalkey-com.ezproxy.butler.edu/pharmacology/monograph/loe?sectionId=7826&ratingId=782&print=true.
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- Guinn, D. Hickenbottom, S. Lee MJ. Headache in pregnant and postpartum women. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed June 11, 2019
- Migraine in adults. In DynaMed Plus [database online]. EBSCO Information Services. http://www.dynamed.com/topics/dmp~AN~T114718/Migraine-in-adults#Prevention-and-Screening. Updated November 30, 2018. Accessed June 10, 2019.
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- Schrader H, Stovner LJ, Helde G, et al. Prophylactic treatment of migraine with angiotensin converting enzyme inhibitor (lisinopril): randomized, placebo controlled, crossover study. BMJ 2001;322:19-22. Accessed June 13, 2019.
- Silberstein SD. Practice parameter: Evidence-Based guidelines for migraine headache (an evidence-based review): Report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology 2000; 55; 754-762.
- Stovner LJ, Linde M, Gravdahl GB, et al. A comparative study of candesartan versus propranolol for migraine prophylaxis: a randomized triple-blind, placebo-controlled, double cross-over study. Cephalagia 2014;24:523-532. Accessed June 13, 2019.
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- Weaver-Agostoni J. Cluster headache. *Am Fam Physician*. 2013 Jul 15;88(20):122-128.

Created: 11/18
Effective: 12/15/21 Client Approval: 10/21/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

GANAXOLONE

Generic	Brand	HICL	GCN	Exception/Other
GANAXOLONE	ZTALMY	47912		

GUIDELINES FOR USE

Our guideline named **GANAXOLONE (Ztalmy)** requires the following rule(s) be met for approval:
A. You have seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD: a type of genetic disorder)
B. You are 2 years of age or older
C. You have tried TWO other antiseizure drugs (for example, clobazam, levetiracetam, valproic acid, vigabatrin)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
To ensure safe and appropriate use of ganaxolone per approved indication and dosing.

FDA APPROVED INDICATIONS
Ztalmy is a neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulator indicated for the treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) in patients 2 years of age and older.

DOSAGE AND ADMINISTRATION
Ztalmy is administered three times a day and must be taken with food. The recommended titration schedule and maintenance dosage are based on body weight for patients weighing 28 kg or less. Dosage recommendations for patients weighing 28 kg or less are included in Table 1, and dosage recommendations for patients weighing more than 28 kg are included in Table 2. Dosage should be increased based on tolerability no more frequently than every 7 days. Titration increments should not exceed those shown in Table 1 and Table 2.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

GANAXOLONE

Table 1: Recommended Titration Schedule for Patients Weighing 28 kg or Less

Dosage	Total Daily Dosage	Days
6 mg/kg three times daily	18 mg/kg/day	1 to 7
11 mg/kg three times daily	33 mg/kg/day	8 to 14
16 mg/kg three times daily	48 mg/kg/day	15 to 21
21 mg/kg three times daily	63 mg/kg/day	22 and beyond

Table 2: Recommended Titration Schedule for Patients Weighing More Than 28 kg

Dosage	mL per Dose	Total Daily Dosage	Days
150 mg three times daily	3	450 mg	1 to 7
300 mg three times daily	6	900 mg	8 to 14
450 mg three times daily	9	1350 mg	15 to 21
600 mg three times daily	12	1800 mg	22 and beyond

REFERENCES

Ztalmy [Prescribing Information]. Radnor, PA: Marinus Pharmaceuticals, Inc.; June 2022.

Created: 08/22
Effective: 09/19/22 Client Approval: 08/19/22 P&T Approval: N/A

GEFITINIB

Generic	Brand	HICL	GCN	Exception/Other
GEFITINIB	IRESSA	25178		

GUIDELINES FOR USE

Our guideline for **GEFITINIB** requires that the patient has a diagnosis of metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test.

GEFITINIB

RATIONALE

Promote appropriate utilization of **GEFITINIB** based on FDA approved indication and dosing.

About 85% to 90% of lung cancer is classified as NSCLC and of that population; an estimated 10% is due to an EGFR mutation. Iressa targets a specific subset of this EGFR mutation population. Although Iressa was withdrawn from the market in 2012 due to failure to demonstrate clinical benefit in NSCLC, it is now reapproved due to efficacy findings in a specific population whose tumors have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations.

DOSAGE

The recommended dose of Iressa is 250 mg by mouth daily until disease progression or unacceptable toxicity.

Increase Iressa dose to 500 mg daily when taken concomitantly with a strong CYP3A4 inducer. Return to recommended dose of 250 mg daily 7 days after discontinuation of the strong inducer.

FDA APPROVED INDICATIONS

Iressa is a tyrosine kinase inhibitor indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test.

Limitation of Use: Safety and efficacy of Iressa have not been established in patients whose tumors have EGFR mutations other than exon 19 deletions or exon 21 (L858R) substitution mutations.

REFERENCES

- Iressa [Prescribing Information]. AstraZeneca Pharmaceuticals. Wilmington, DE. July 2015.

Created: 01/16
Effective: 03/01/16 Client Approval: 01/14/16 P&T Approval: 01/16

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

GENERAL QUANTITY EXCEPTION CRITERIA

Generic	Brand	HICL	GCN	Exception/Other
N/A	N/A	N/A	N/A	N/A

NOTE: This guideline does not apply to mental/behavioral health drugs, opioid analgesics, or proton pump inhibitors. Do not use this guideline if the requested medication has a linked guideline.

GUIDELINES FOR USE

GENERAL QUANTITY EXCEPTION CRITERIA (For insulin, see criteria further in this guideline)

The guideline named **GENERAL QUANTITY EXCEPTION CRITERIA** requires the following criteria (rules) be met for approval:

1. The requested medication is being used to treat certain medical conditions that are Food and Drug Administration (FDA) approved.

2. If the requested dose is not higher than the FDA (Food and Drug Administration) or drug manufacturer daily maximum recommendations for your age, we require:
   1. You have tried and failed the requested strength within the allowable formulary quantity limits and it did not work for you.
   2. If applicable, you have tried the highest strength available on formulary to achieve the same total daily dose (e.g. dose consolidation: you take one-10mg tablet vs. two-5mg tablets) **OR** your doctor has provided clinical reasons why you cannot dose consolidate.

3. If the requested dose is higher than the FDA (Food and Drug Administration) or drug manufacturer daily maximum recommendations for your age, we require:
   1. Your provider has submitted two (2) articles from major peer reviewed medical journals that support the safety and efficacy of the requested drug at the intended dosage for the specified indication **OR** the requested dose is supported by drug compendia [e.g., DrugDex, AHFS Drug Information, National Comprehensive Cancer Network (NCCN), Clinical Pharmacology] for the specified indication.
   2. You have tried and failed the requested strength within the allowable formulary quantity limit and it did not work for you.
   3. If applicable, you have tried the highest strength available on formulary to achieve the same total daily dose (e.g. dose consolidation: you take one-10mg tablet vs. two-5mg tablets) **OR** your doctor has provided clinical reasons why you cannot dose consolidate.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

GENERAL QUANTITY EXCEPTION CRITERIA

INSULIN QUANTITY EXCEPTION CRITERIA

For information on how to calculate the required number of pens or vials, please refer to Appendix 1.

The guideline named **GENERAL QUANTITY EXCEPTION CRITERIA** requires the following criteria (rules) be met for approval:

- You have a diagnosis of diabetes mellitus
- Your doctor provided the directions for use for your insulin
- Based on the directions of use provided, you require a larger amount of insulin vials or pens than what is allowed by the plan's limit

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

GENERAL QUANTITY EXCEPTION CRITERIA

APPENDIX 1

How to calculate total monthly dose of insulin with vials

***Vial*:** good for 28 days from initial use once opened
1mL = 100 units
1 vial contains 10mL
1 vial = 10mL x 100 units= 1,000 units/ vial. There are 1,000 units/ vial.

Directions for use:
Ex) 50 units TID before meals (AC) = 150 units/day **OR** 4,200 units/28 days
How many vials are needed to provide the patient at least 4,200 units for 28 days?

1 vial → 1,000 units
X (how many vials needed) → 4,200 units

X (1,000 units) = 1 vial (4,200 units)
X= 4,200 units / 1,000 units = 4.2 vials.

Therefore, the patient would need at least 5 vials.
Decision: Approve 5 vials per 28 days.

How to calculate total monthly dose of insulin with pens

Pen: good for 28 days from initial use
Each pen contains 3mL of insulin
1 pen = 3mL x 100 units = 300 units/ pen
1mL = 100 units [*Exceptions:* Toujeo 300 units/ mL or Tresiba 200 units/ mL]

Directions for use:
Ex) 50 units TID before meals (AC) = 150 units/day OR 4,200 units/28 days
How many pens are needed to provide the patient at least 4,200 units for 28 days?

1 pen → 300 units
X → 4,200 units

X (300 units) = 1 vial (4,200 units)
X = 4,200 units / 300 units = 14 pens.

Therefore, the patient would need at least 14 pens.
Decision: Approve 14 pens per 28 days.

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

GILTERITINIB

Generic	Brand	HICL	GCN	Exception/Other
GILTERITINIB FUMARATE	XOSPATA	45506		

GUIDELINES FOR USE

The guideline named **GILTERITINIB (Xospata)** requires a diagnosis of relapsed or refractory acute myeloid leukemia (AML). In addition, the following criteria must be met.

- The patient is 18 years of age or older
- The patient has FMS-like tyrosine kinase 3 (FLT3) mutation as detected by an FDA-approved test

RATIONALE

For further information, please refer to the Prescribing Information for Xospata.

REFERENCES

Xospata [Prescribing Information]. Northbrook, IL: Astellas Pharma US, Inc., November 2018.

Created: 01/18
Effective: 02/18/19 Client Approval: 01/23/18 P&T Approval: N/A

GLASDEGIB

Generic	Brand	HICL	GCN	Exception/Other
GLASDEGIB MALEATE	DAURISMO	45502		

GUIDELINES FOR USE

The guideline named **GLASDEGIB (Daurismo)** requires a diagnosis of newly-diagnosed acute myeloid leukemia (AML). In addition, the following criteria must be met.

- The requested medication will be used in combination with low-dose cytarabine
- The patient is 75 years of age or older, OR the patient has comorbidities that prevent use of intensive induction chemotherapy

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Daurismo.

REFERENCES

Daurismo [Prescribing Information]. New York, NY: Pfizer Inc.; November 2018.

Created: 01/18
Effective: 02/18/19 Client Approval: 01/23/18 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

GLATIRAMER ACETATE

Generic	Brand	HICL	GCN	Exception/Other
GLATIRAMER ACETATE	COPAXONE, GLATOPA	12810		

GUIDELINES FOR USE

Our guideline named **GLATIRAMER ACETATE (Copaxone/Glatopa)** requires you have multiple sclerosis (MS: an illness where the immune system eats away at the protective covering of the nerves).

RATIONALE

To ensure appropriate use aligned with FDA approved indication.

FDA APPROVED INDICATIONS

Copaxone and Glatopa are indicated for the treatment of relapsing-forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

DOSING

Copaxone and Glatopa are for subcutaneous use only. The dosing schedule depends on the product strength that is selected. The recommended doses are:

- Copaxone/Glatopa 20 mg per mL: administer once per day
- Copaxone/Glatopa 40 mg per mL: administer three times per week and at least 48 hours apart

REFERENCES

- Copaxone [Prescribing Information]. Overland Park, KS: Teva; July 2020.
- Glatopa [Prescribing Information], Princeton, NJ: Sandoz Inc.; July 2020.

Created: 06/15
Effective: 08/16/21 Client Approval: 07/07/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

L-GLUTAMINE

Generic	Brand	HICL	GCN	Exception/Other
GLUTAMINE (L-GLUTAMINE)	ENDARI			NDC = 42457-0420-01, 42457-0420-60

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **L-GLUTAMINE (ENDARI)** requires the following rule(s) be met for approval:

A. You have ONE of the following indications for treatment:
   1. You have a diagnosis of sickle cell disease (type of red blood cell disorder)
   2. You have a diagnosis of short-bowel syndrome
   3. You have mucositis following chemotherapy
   4. The medication is prescribed for the prevention of peripheral neuropathy due to oxaliplatin or high-dose paclitaxel use

B. **If you have sickle cell disease, approval also requires:**
   1. You are 5 years of age or older
   2. ONE of the following:
      a. You are currently receiving hydroxyurea therapy
      b. You have a contraindication or intolerance to hydroxyurea
   3. You have experienced at least 2 sickle cell-related vaso-occlusive crisis events within the previous 12 months while concurrently receiving hydroxyurea therapy (unless you have a contraindication or intolerance to hydroxyurea)

C. **If you have short-bowel syndrome, approval also requires the following:**
   1. You are 18 years of age or older
   2. ONE of the following:
      a. You will be using recombinant human growth hormone concurrently with L-glutamine therapy
      b. The prescriber has provided valid medical rationale against the use of recombinant human growth hormone concurrently with L-glutamine therapy

D. **If you have mucositis following chemotherapy or the medication is prescribed for the prevention of peripheral neuropathy due to oxaliplatin or high-dose paclitaxel use short-bowel syndrome, approval also requires the following:**
   1. You are 18 years of age or older

RENEWAL CRITERIA

Our guideline named **L-GLUTAMINE (Endari)** requires the following rule(s) bet met for renewal:

A. You have a history of paid claim(s) for the requested medication in the past 90 days
B. You have a previous authorization on file for the requested medication
C. ONE of the following:
   1. You are continuing to use required adjunct therapy, if applicable
   2. Your doctor has provided medical rationale for not continuing adjunct therapy

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

L-GLUTAMINE

RATIONALE
Promote appropriate utilization of L-GLUTAMINE based on FDA approved indication and dosing.

FDA APPROVED INDICATIONS
Endari is indicated to reduce the acute complications of sickle cell disease in adult and pediatric patients 5 years of age and older.

DOSING & ADMINISTRATION
Administer Endari orally, twice per day at the dose based on body weight according to the table below.

Weight in kilograms	Weight in pounds	Per dose in grams	Per day in grams	Packets per dose	Packets per day
< 30	< 66	5	10	1	2
30 to 65	66 to 143	10	20	2	4
> 65	> 143	15	30	3	6

REFERENCES
Endari [Prescribing Information]. Torrance, CA: Emmaus Medical, Inc. October 2020.

Created: 06/18
Effective: 03/14/22 Client Approval: 02/04/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

GLYCEROL PHENYLBUTYRATE

Generic	Brand	HICL	GCN	Exception/Other
GLYCEROL PHENYLBUTYRATE	RAVICTI	39990		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named **GLYCEROL PHENYLBUTYRATE (Ravicti)** requires a diagnosis of a urea cycle disorder (UCD). In addition, the following criteria must be met:

- Documentation of confirmation of UCD via enzymatic, biochemical or genetic testing
- The patient is 2 months of age or older
- Physician attestation of **ALL** the following:
  a. Ravicti will be used as adjunctive therapy along with dietary protein restriction
  b. The disorder cannot be managed by dietary protein restriction and/or amino acid supplementation alone
- The patient does **NOT** have a deficiency of N-acetylglutamate synthetase deficiency (NAGS) or acute hyperammonemia
- The patient has tried or has a contraindication to Buphenyl (sodium phenylbutyrate)

RENEWAL CRITERIA

The guideline named **GLYCEROL PHENYLBUTYRATE (Ravicti)** requires a diagnosis of a urea cycle disorder (UCD) and physician attestation of clinical benefit from baseline (e.g., normal fasting glutamine, low-normal fasting ammonia levels, or mental status clarity).

RATIONALE
To ensure appropriate use aligned with FDA approved indication.

Ravicti is supplied as a liquid for oral administration. It should be taken with food and administered directly into the mouth via oral syringe or dosing cup. Ravicti should be given in 3 equally divided dosages, each rounded up to the nearest 0.5 mL. The recommended dosages for patients switching from sodium phenylbutyrate to Ravicti and patients naïve to phenylbutyric acid are different.

Patients switching from sodium phenylbutyrate to Ravicti should receive the dosage of Ravicti that contains the same amount of phenylbutyric acid. The conversion is as follows:
Total daily dosage of Ravicti (mL) = total daily dosage of sodium phenylbutyrate (g) x 0.8

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GLYCEROL PHENYLBUTYRATE

RATIONALE (CONTINUED)

The recommended dosage range in patients naïve to phenylbutyrate (PBA), based upon body surface area, is 4.5 to 11.2 mL/m2/day (5 to 12.4 g/m2/day). For patients with some residual enzyme activity who are not adequately controlled with protein restriction, the recommended starting dosage is 4.5 mL/m2/day.

The maximum total daily dosage is 17.5 mL (19 g).

Ravicti (glycerol phenylbutyrate) joins Buphenyl (sodium phenylbutyrate) as the second FDA approved treatment for UCDs. Ravicti is a nearly tasteless and odorless liquid taken three times a day. In contrast, Buphenyl is poorly tolerated by patients due to its unpleasant taste and odor and along with the need to take up to 40 tablets a day. Over half of UCD patients do not take Buphenyl and it is believed that is largely due to the difficulties in tolerating the drug.

UCDs are genetic metabolic disorders present in an estimated 1 in 10,000 births in the United States. Patients with UCDs are deficient in one of the key enzymes that comprise the urea cycle, the body's primary vehicle for removing ammonia, a potent neurotoxin, from the bloodstream. Onset may occur at any age depending on the severity of the disorder. If left untreated, UCDs can cause dangerously heightened levels of ammonia in the bloodstream (hyperammonemia) resulting in brain damage, coma, and/or death.

Ravicti is a triglyceride containing 3 molecules of phenylbutyrate (PBA). Phenylacetate (PAA), the major metabolite of PBA, is the active moiety of Ravicti. PAA conjugates with glutamine (which contains 2 molecules of nitrogen) via acetylation in the liver and kidneys to form phenylacetylglutamine (PAGN), which is excreted by the kidneys. On a molar basis, PAGN, like urea, contains 2 moles of nitrogen and provides an alternate vehicle for waste nitrogen excretion.

The use of Ravicti in patients <2 months of age is contraindicated. Ravicti is not indicated for the treatment of acute hyperammonemia in patients with UCDs because more rapidly acting interventions are essential to reduce plasma ammonia levels. Warnings and precautions include nausea, vomiting, diarrhea, decreased appetite, hyperammonemia, dizziness, headache, upper abdominal pain, rash and fatigue. The most common adverse reactions (occurring in ⩾10% of patients) reported during short-term treatment with Ravicti were diarrhea, flatulence, and headache. Ravicti is pregnancy category C. A voluntary patient registry will include evaluation of pregnancy outcomes in patients with UCDs.

FDA APPROVED INDICATIONS

Ravicti is indicated for use as a nitrogen-binding agent for chronic management of adult and pediatric patients ⩾2 years of age with urea cycle disorders (UCDs) that cannot be managed by dietary protein restriction and/or amino acid supplementation alone. Ravicti must be used with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements).

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GLYCEROL PHENYLBUTYRATE

FDA APPROVED INDICATIONS (CONTINUED)

Limitations of Use:

- Ravicti is not indicated for treatment of acute hyperammonemia in patients with UCDs.
- The safety and efficacy of Ravicti for the treatment of N-acetylglutamate synthase (NAGS) deficiency has not been established.
- The use of Ravicti in patients <2 months of age is contraindicated.

REFERENCES

- Ravicti [Prescribing Information]. Lake Forest, IL: Horizon Pharma USA, Inc; December 2018.

Created: 06/15
Effective: 07/01/20 Client Approval: 05/12/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

GLYCOPYRRONIUM TOPICAL

Generic	Brand	HICL	GCN	Exception/Other
GLYCOPYRRONIUM 2.4% CLOTH	QBREXZA	45086		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW

The guideline named **GLYCOPYRRONIUM TOPICAL (Qbrexza)** requires that the patient has a diagnosis of primary axillary hyperhidrosis. In addition, the following criteria must be met:

- The patient is 9 years of age or older
- Documentation that the patient has primary axillary hyperhidrosis as evidenced by focal, visible, excessive sweating of at least six months duration with all secondary causes ruled out
- Documentation of at least **TWO** of the following:
  - Symptoms occur bilaterally
  - Symptoms impair daily activities
  - Patient has at least one episode per week
  - Onset occurred prior to patient turning 25 years old
  - Patient has a family history of primary axillary hyperhidrosis
  - Symptoms do not occur during sleep

RENEWAL CRITERIA

The guideline named **GLYCOPYRRONIUM TOPICAL (Qbrexza)** renewal requires that the patient has a diagnosis of primary axillary hyperhidrosis. In addition, documentation (i.e., chart notes) that the patient has experienced symptomatic improvement while on therapy is required.

RATIONALE
Ensure appropriate criteria are used for the management of requests for GLYCOPYRRONIUM TOPICAL (Qbrexza) according to approved indication, dosing, and national guidelines.

FDA APPROVED INDICATIONS
GLYCOPYRRONIUM TOPICAL (Qbrexza) is a topical anticholinergic indicated in adult and pediatric patients 9 years of age and older for the treatment of primary axillary hyperhidrosis.

CONTINUED ON NEXT PAGE

GLYCOPYRRONIUM TOPICAL

FDA APPROVED INDICATIONS (CONTINUED)

HOW SUPPLIED
Single-use cloth pre-moistened with 2.4% glycopyrronium solution packaged in individual pouches.

DOSAGE & ADMINISTRATION
GLYCOPYRRONIUM TOPICAL (Qbrexza) is for topical use in the underarm area only and not for use in other body areas.

A single cloth should be used to apply Qbrexza to both underarms no more than once every 24 hours.

REFERENCES

- Qbrexza [Prescribing Information]. Menlo Park, CA: Dermira, Inc. August 2018.
- Hornberger J, Grimes K, Naumann M, et al. Recognition, diagnosis, and treatment of primary focal hyperhidrosis. *J Am Acad Dermatol* 2004; 51:274-86.
- International Hyperhidrosis Society. Primary Axillary Hyperhidrosis Clinical Guidelines. Available at: https://www.sweathelp.org/pdf/Axillary_IHhS_Algorithm_2018.pdf. Accessed March 18, 2019.

Created: 03/19
Effective: 07/01/20 Client Approval: 05/12/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

GOLIMUMAB - IV

Generic	Brand	HICL	GCN	Exception/Other
GOLIMUMAB - IV	SIMPONI ARIA - IV		34983	

NOTE: For requests for the SQ dosage form of Simponi, please see the GOLIMUMAB SQ Guideline.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **GOLIMUMAB - IV (Simponi Aria)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in joints in children)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. You have previously tried **ONE** of the following DMARDs (disease-modifying antirheumatic drugs): methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   3. You are currently using methotrexate at the same time, unless there is a medical reason why you cannot (contraindication)
   4. You have previously tried **ONE** of the following: Enbrel or Humira

C. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You meet ONE of the following criteria:
      a. You are 2 to 17 years old
      b. You are 18 years of age or older and have previously tried **TWO** of the following: Cosentyx, Enbrel, or Humira
   2. You have previously tried **ONE** of the following DMARDs (disease-modifying antirheumatic drugs): methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

D. **If you have ankylosing spondylitis (AS), approval also requires:**
   1. You are 18 years of age or older
   2. You have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
   3. You have previously tried **TWO** of the following: Cosentyx, Enbrel, or Humira

E. **If you have polyarticular juvenile idiopathic arthritis (PJIA), approval also requires:**
   1. You are 2 years of age or older
   2. You have previously tried **ONE** of the following DMARDs (disease-modifying antirheumatic drugs): methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   3. You have previously tried **ONE** of the following: Enbrel or Humira

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GOLIMUMAB - IV

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **GOLIMUMAB - IV (Simponi Aria)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in joints in children)

B. **If you have moderate to severe rheumatoid arthritis (RA), renewal also requires:**
   1. You have experienced or maintained experienced or maintained clinical improvement while on therapy
   2. You are currently using methotrexate at the same time, unless there is a medical reason why you cannot (contraindication)

C. **If you have psoriatic arthritis (PsA), ankylosing spondylitis (AS), or polyarticular juvenile idiopathic arthritis (PJIA), renewal also requires:**
   1. You have experienced or maintained experienced or maintained clinical improvement while on therapy

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GOLIMUMAB - IV

RATIONALE
Ensure appropriate diagnostic, utilization and safety criteria are met for the management of requests for golimumab.

FDA APPROVED INDICATIONS
Simponi Aria is a tumor necrosis factor (TNF) blocker indicated for the treatment of:

- Adult patients with moderately to severely active Rheumatoid Arthritis (RA) in combination with methotrexate
- Active Psoriatic Arthritis (PsA) in patients 2 years of age and older
- Adult patients with active Ankylosing Spondylitis (AS)
- Active polyarticular Juvenile Idiopathic Arthritis (PJIA) in patients 2 years of age and older

DOSAGE
- Adult patients with Rheumatoid Arthritis, Psoriatic Arthritis, and Ankylosing Spondylitis: 2 mg/kg intravenous infusion over 30 minutes at weeks 0 and 4, and every 8 weeks thereafter.
- Pediatric patients with polyarticular Juvenile Idiopathic Arthritis and Psoriatic Arthritis: 80 mg/m^2 intravenous infusion over 30 minutes at weeks 0 and 4, and every 8 weeks thereafter.

For patients with rheumatoid arthritis (RA), Simponi Aria should be given in combination with methotrexate. For patients with psoriatic arthritis (PsA) or ankylosing spondylitis (AS), Simponi Aria may be given with or without methotrexate or other non-biologic disease-modifying Antirheumatic Drugs (DMARDs). Corticosteroids, nonsteroidal anti-inflammatory drugs (NSAIDs), and/or analgesics may be continued during treatment with Simponi Aria.

The efficacy and safety of switching between intravenous and subcutaneous formulations and routes of administration have not been established.

Available Strengths
Each single-use vial contains 50 mg of Simponi Aria per 4 mL of solution.

REFERENCES

- Simponi Aria [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. February 2021.
- Braun J, Davis J, et al. First update of the international ASAS consensus statement for the use of anti-TNF agents in patients with Ankylosing Spondylitis. Ann Rheum Dis. 2006; 65(3):316-20.
- Singh JA, Guyatt G, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Care & Research. Vol. 71, No. 1, January 2019, pp 2–29DOI 10.1002/acr.2378.
- Singh JA, Saag KG, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. 2016;68(1):1-25. DOI 10.1002/acr.22783.
- Beukelman T, Patkar NM, et al. 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: Initiation and safety monitoring of therapeutic agents for the treatment of arthritis and systemic features. Arthritis Care Res, 63: 465–482. doi: 10.1002/acr.20460.

Created: 02/18
Effective: 04/11/22 Client Approval: 03/10/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

GOLIMUMAB - SQ

Generic	Brand	HICL	GCN	Exception/Other
GOLIMUMAB - SQ	SIMPONI - SQ		22533 22536 34697 35001	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **GOLIMUMAB-SQ (Simponi - SQ)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Moderate to severe ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Moderate to severe ulcerative colitis (UC: type of inflammatory bowel disease that causes inflammation in the digestive tract)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. You have previously tried **ONE** of the following DMARDs (disease-modifying antirheumatic drugs): methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   3. You are currently using methotrexate at the same time as the requested medication, unless there is a medical reason why you cannot (contraindication)
   4. You have previously tried ONE of the following: Enbrel or Humira

C. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. You have previously tried ONE of the following DMARDs (disease-modifying antirheumatic drugs): methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   3. You have previously tried TWO of the following: Cosentyx, Enbrel, or Humira

D. **If you have moderate to severe ankylosing spondylitis (AS), approval also requires:**
   1. You are 18 years of age or older
   2. You have previously tried an NSAID (nonsteroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
   3. You have previously tried TWO of the following: Cosentyx, Enbrel, or Humira

E. **If you have moderately to severely active ulcerative colitis (UC), approval also requires:**
   1. You are 18 years of age or older
   2. You have previously tried at least ONE of the following conventional agents: corticosteroids (e.g., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   3. You have previously tried Humira

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GOLIMUMAB - SQ

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **GOLIMUMAB-SQ (Simponi - SQ)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Moderate to severe ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Moderate to severe ulcerative colitis (UC: inflammatory bowel disease that causes inflammation in the digestive tract)

B. You have experienced or maintained symptomatic improvement while on therapy

C. **If you have moderate to severe rheumatoid arthritis (RA), renewal also requires:**
   1. You are currently using methotrexate at the same time as the requested medication, unless there is a medical reason why you cannot (contraindication)

RATIONALE

Ensure appropriate diagnostic, utilization and safety criteria are used for the management of requests for golimumab.

FDA APPROVED INDICATIONS

Simponi is a tumor necrosis factor (TNF) blocker indicated for the treatment of adult patients with:

- Moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate
- Active psoriatic arthritis (PsA) alone, or in combination with methotrexate
- Active ankylosing spondylitis (AS)
- Moderately to severely active Ulcerative colitis (UC) with an inadequate response or intolerant to prior treatment or requiring continuous steroid therapy
  - Inducing and maintaining clinical response
  - Improving endoscopic appearance of the mucosa during induction
  - Inducing clinical remission
  - Achieving and sustaining clinical remission in induction responders

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GOLIMUMAB - SQ

FDA APPROVED INDICATIONS (CONTINUED)

DOSING

RA, PsA, and AS: 50 mg administered by subcutaneous injection once a month

UC: 200 mg initially administered by subcutaneous injection at Week 0, followed by 100 mg at Week 2 and then 100 mg every 4 weeks

REFERENCES

- Janssen Biotech. Simponi package insert. Horsham, PA. September 2019.
- Braun J, Davis J, et al. First update of the international ASAS consensus statement for the use of anti-TNF agents in patients with Ankylosing Spondylitis. Ann Rheum Dis. 2006; 65(3):316-20.
- Kornbluth A, Sachar DB. Ulcerative colitis practice guidelines in adults: American College of Gastroenterology, Practice Parameters Committee. *Am J Gastroenterol* 2010;105:501-523.
- Singh JA, Guyatt G, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Care & Research. Vol. 71, No. 1, January 2019, pp 2–29DOI 10.1002/acr.2378.
- Singh JA, Saag KG, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. 2016;68(1):1-25. DOI 10.1002/acr.22783.

Created: 03/15
Effective: 04/11/22 Client Approval: 03/10/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

GUSELKUMAB

Generic	Brand	HICL	GCN	Exception/Other
GUSELKUMAB	TREMFYA	44418		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **GUSELKUMAB (Tremfya)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   2. Psoriatic arthritis (PsA: joint pain and swelling)

B **If you have moderate to severe plaque psoriasis (PsO), approval also requires:**
   1. You are 18 years of age or older
   2. You have psoriatic lesions involving greater than or equal to 10% of body surface area (BSA) OR psoriatic lesions (rashes) affecting the face, hands, feet, or genital area
   3. You have previously tried ONE of the following preferred therapies: PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
   4. You have previously tried TWO of the following: Cosentyx, Enbrel, or Humira

C. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. You have previously tried at least ONE of the following DMARDs (disease-modifying antirheumatic drugs): methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   3. You have previously tried TWO of the following: Cosentyx, Enbrel, or Humira

RENEWAL CRITERIA

Our guideline named **GUSELKUMAB (Tremfya)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)

B. You have experienced or maintained symptomatic improvement while on therapy

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GUSELKUMAB

RATIONALE
Ensure appropriate diagnostic, utilization and safety criteria are used for the management of requests for guselkumab.

FDA APPROVED INDICATIONS
Tremfya is indicated for the treatment of adult patients with:
- moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.
- active psoriatic arthritis.

DOSAGE

Tremfya is administered by subcutaneous injection. The recommended dose is 100 mg at Week 0, Week 4, and every 8 weeks thereafter.

REFERENCES
- Tremfya [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. July 2020.
- Menter A, Strober BE, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.
- Singh JA, Guyatt G, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Care & Research. Vol. 71, No. 1, January 2019, pp 2–29DOI 10.1002/acr.2378.

Created: 08/17
Effective: 04/11/22 Client Approval: 03/10/22 P&T Approval: N/A

HIGH-POTENCY BASAL INSULIN STEP THERAPY

Generic	Brand	HICL	GCN	Exception/Other
INSULIN GLARGINE	TOUJEO MAX SOLOSTAR		44561	
INSULIN GLARGINE	TOUJEO SOLOSTAR		37988	
INSULIN DEGLUDEC	TRESIBA FLEXTOUCH U-200		35837	

GUIDELINES FOR USE

Our guideline named **HIGH-POTENCY BASAL INSULIN STEP THERAPY** requires that the patient has had a trial of insulin glargine-yfgn in the past 120 days.

Exceptions may be made for **HIGH-POTENCY BASAL INSULIN STEP THERAPY** if the patient requires a single daily dose of basal insulin greater than or equal to 20 units.

RATIONALE

To promote prudent prescribing of high-potency basal insulin.

FDA APPROVED INDICATIONS

Toujeo is a long-acting human insulin analog indicated to improve glycemic control in adults and pediatric patients 6 years and older with diabetes mellitus.

Tresiba is a long-acting human insulin analog indicated to improve glycemic control in patients 1 year of age and older with diabetes mellitus.

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HIGH-POTENCY BASAL INSULIN STEP THERAPY

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

Toujeo is available in 2 single-patient-use prefilled pens:

- Toujeo SoloStar contains 450 units of Toujeo U-300. It delivers doses in 1-unit increments and can deliver up to 80 units in a single injection.
- Toujeo Max SoloStar contains 900 units of Toujeo U-300. It delivers doses in 2-unit increments and can deliver up to 160 units in a single injection. It is recommended for patients requiring at least 20 units per day.

Inject Toujeo subcutaneously once a day at the same time of day. Individualize and titrate the dosage of Toujeo based on the individual's metabolic needs, blood glucose monitoring results, and glycemic control goal. Titrate the dose of Toujeo no more frequently than every 3 to 4 days.

Tresiba is available in two concentrations as follows:

- Tresiba U-100 concentration is available in 2 presentations, FlexTouch pen and vial.
  - Single-patient-use Tresiba U-100 FlexTouch pen contains 300 units of Tresiba U-100. It delivers doses in 1-unit increments and can deliver up to 80 units in a single injection.
  - Tresiba U-100 multiple-dose vial contains 1,000 units of Tresiba U-100. Use vial only with a U-100 insulin syringe.
- Tresiba U-200 concentration is only available in a FlexTouch pen.
  Single-patient-use Tresiba U-200 FlexTouch pen contains 600 units of Tresiba U-200. It delivers doses in 2-unit increments and can deliver up to 160 units in a single injection.

Inject Tresiba subcutaneously once-daily at any time of day. Individualize and titrate the dose of Tresiba based on the patient's metabolic needs, blood glucose monitoring results, and glycemic control goal. The recommended days between dose increases are 3 to 4 days.

REFERENCES

- Toujeo package insert. Bridgewater, NJ: Sanofi-Aventis U.S. LLC; December 2020.
- Tresiba package insert. Plainsboro, NJ: Novo Nordisk Inc.; November 2019.

Created: 02/22
Effective: 02/28/22 Client Approval: 02/11/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

HYDROCORTISONE

Generic	Brand	HICL	GCN	Exception/Other
HYDROCORTISONE	ALKINDI SPRINKLE		46547 46548 46549 46551	

GUIDELINES FOR USE

Our guideline named **HYDROCORTISONE (Alkindi Sprinkle)** requires the following rule(s) be met for approval:

A. You have adrenocortical insufficiency (your body does not produce enough of certain hormones)
B. You are less than 18 years of age
C. You are unable to take the tablet formulation of hydrocortisone (for example, you need a lower strength, or you have difficulty swallowing)

RATIONALE

Ensure appropriate diagnostic, utilization and safety criteria are met for the management of requests for Alkindi Sprinkle.

FDA APPROVED INDICATIONS

Alkindi Sprinkle is a corticosteroid indicated as replacement therapy in pediatric patients with adrenocortical insufficiency.

DOSAGE AND ADMINISTRATION

The recommended starting replacement dosage is 8 to 10 mg/m2 /day daily. Higher doses may be needed based on patient's age and symptoms of the disease. Round the dose to the nearest 0.5 mg or 1 mg. The contents of more than one capsule may be needed to supply the required dose. Divide the total daily dose in 3 doses and administer 3 times daily. Older pediatric patients may have their daily dose divided by 2 and administered twice daily.

REFERENCES

Alkindi Sprinkle [Prescribing Information]. Baden-Wuerttemberg, Germany: Eton Pharmaceuticals, Inc.; February 2022.

Created: 08/22
Effective: 10/01/22 Client Approval: 08/19/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

IBREXAFUNGERP

Generic	Brand	HICL	GCN	Exception/Other
IBREXAFUNGERP CITRATE	BREXAFEMME	47416		

GUIDELINES FOR USE

Our guideline named **IBREXAFUNGERP (Brexafemme)** requires the following rule(s) be met for approval:

A. You have vulvovaginal candidiasis (VVC: vaginal yeast infection)
B. You are a post-menarchal (you have started having your period) female

RATIONALE

To ensure appropriate use of Brexafemme consistent with FDA approved indication.

FDA APPROVED INDICATIONS

Brexafemme is a triterpenoid antifungal indicated for the treatment of adult and post-menarchal pediatric females with vulvovaginal candidiasis (VVC).

DOSAGE AND ADMINISTRATION

The recommended dosage of Brexafemme in adult and post-menarchal pediatric females is 300 mg (two tablets of 150 mg) twice a day for one day, for a total treatment dosage of 600 mg.

REFERENCES

- Brexafemme [Prescribing Information]. Jersey City, NJ: Scynexis, Inc., June 2021.

Created: 07/21
Effective: 09/20/21 Client Approval: 08/20/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

IBRUTINIB

Generic	Brand	HICL	GCN	Exception/Other
IBRUTINIB	IMBRUVICA	40745		

GUIDELINES FOR USE

Our guideline named **IBRUTINIB (Imbruvica)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Mantle cell lymphoma (a type of blood cancer)
   2. Chronic lymphocytic leukemia (a type of blood cancer)
   3. Small lymphocytic lymphoma (a type of blood cancer)
   4. Waldenström's macroglobulinemia (a type of blood cancer)
   5. Marginal zone lymphoma (a type of blood cancer)
   6. Chronic graft versus host disease (a type of immune disorder)

B. Requests for ibrutinib 140 mg or 280 mg tablets requires you had a trial of or contraindication to (harmful for) ibrutinib 140 mg capsules

C. Requests for ibrutinib 70 mg/mL oral suspension requires you are unable to swallow the tablets or capsules

D. **If you have mantle cell lymphoma, approval also requires:**
   1. You are 18 years of age or older
   2. You have received at least one prior therapy for mantle cell lymphoma

E. **If you have chronic lymphocytic leukemia, small lymphocytic lymphoma, or Waldenström's macroglobulinemia, approval also requires:**
   1. You are 18 years of age or older

F. **If you have marginal zone lymphoma, approval also requires:**
   1. You are 18 years of age or older
   2. You need systemic (treatment spreads through the blood) therapy
   3. You have received at least one prior anti-CD20-based therapy (such as Rituxan)

G. **If you have chronic graft versus host disease, approval also requires:**
   1. You are 1 year of age or older
   2. You have failed one or more lines of systemic therapy (treatment spread through the blood, such as corticosteroids)

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

IBRUTINIB

RATIONALE
To promote appropriate utilization of Imbruvica based on FDA approved indication and dosage.

FDA APPROVED INDICATIONS
Imbruvica is a kinase inhibitor indicated for the treatment of:
- Adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.
- Adult patients with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL).
- Adult patients with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) with 17p deletion.
- Adult patients with Waldenström's macroglobulinemia (WM).
- Adult patients with marginal zone lymphoma (MZL) who require systemic therapy and have received at least one prior anti-CD20-based therapy.
- Adult and pediatric patients 1 year of age and older with chronic graft versus host disease (cGVHD) after failure of one or more lines of systemic therapy.

DOSAGE AND ADMINISTRATION
Administer Imbruvica orally once daily at approximately the same time each day. The dose should be taken orally with a glass of water. Do not open, break, or chew the capsules. Do not cut, crush, or chew the tablets.

MCL, MZL
560 mg taken orally once daily until disease progression or unacceptable toxicity.

CLL, SLL, WM:
The recommended dose for CLL/SLL and WM as a single agent, in combination with rituximab for WM, or in combination with bendamustine and rituximab for CLL/SLL is 420 mg taken orally once daily until disease progression or unacceptable toxicity.

When administering Imbruvica in combination with rituximab, consider administering Imbruvica prior to rituximab when given on the same day.

cGVHD
- Patients 12 years and older: 420 mg taken orally once daily
- Patients 1 to less than 12 years of age: 240 mg/m^2 taken orally once daily (up to a dose of 420 mg)

REFERENCES
Imbruvica [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. August 2022.

Created: 06/15
Effective: 10/17/22 Client Approval: 09/29/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ICATIBANT

Generic	Brand	HICL	GCN	Exception/Other
ICATIBANT	FIRAZYR, SAJAZIR	35962		

GUIDELINES FOR USE

Our guideline named **ICATIBANT (Firazyr, Sajazir)** requires the following rule(s) be met for approval:
A. You have hereditary angioedema (HAE)
B. You are 18 years of age or older
C. The medication is prescribed by or in consultation with a hematologist or allergist/immunologist

RATIONALE

Ensure appropriate use of icatibant based on FDA approved indication and dosing.

FDA APPROVED INDICATION

Icatibant injection (Firazyr, Sajazir) is a bradykinin B2 receptor antagonist is indicated for the treatment of acute attacks of hereditary angioedema (HAE) in adults 18 years of age and older.

DOSING

The recommended dose of icatibant is 30 mg subcutaneously. Additional doses may be administered every 6 hours. Do not administer more than 3 doses in any 24-hour period for a total of 90 mg.

REFERENCES

- Shire Orphan Therapies, Inc. Firazyr package insert. Lexington, MA. April 2020.
- Cycle Pharmaceuticals, Ltd. Sajazir package insert. Cambridge, UK. June 2021.

Created: 06/15
Effective: 08/08/22 Client Approval: 07/13/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

IDELALISIB

Generic	Brand	HICL	GCN	Exception/Other
IDELALISIB	ZYDELIG	41297		

GUIDELINES FOR USE

Our guideline for **IDELALISIB** requires a diagnosis of relapsed chronic lymphocytic leukemia (CLL) with concomitant treatment with rituximab, relapsed follicular B-cell non-Hodgkin lymphoma (FL) or relapsed small lymphocytic lymphoma (SLL) and having received two prior systemic therapies.

Table 1. Chronic Lymphocytic Leukemia (CLL) Treatment Options (please refer to NCCN for most current guideline)

chlorambucil
ibrutinib
Obinutuzumab+chlorambucil
Idelalisib+rituximab
Bendamustine+/-rituximab
ofatumumab
fludarabine
cladribine
rituximab
alemtuzumab IV
alemtuzumab (Campath) SC+/-rituximab
chlorambucil + prednisone
fludarabine+prednisone
fludarabine+cyclophosphamide (FC)
Fludarabine+alemtuzumab
Rituximab+chlorambucil
fludarabine+rituximab
fludarabine+cyclophosphamide rituximab (FCR)
cladribine+mitoxantrone+cyclophosphamide (CMC)
cyclophosphamide+vincristine+prednisone (CVP)
lenalidomide+/-rituximab
pentostatin+cyclophosphamide+rituximab (PCR)
cyclophosphamide+fludarabine+alemtuzumab+rituximab (CFAR)
rituximab+cyclophosphamide+doxorubicin+vincristine+prednisone (RCHOP)
Oxaliplatin+fludarabine+cytarabine+rituximab (OFAR)

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IDELALISIB

RATIONALE
Promote appropriate utilization and dosing of idelalisib based or their FDA approved indication.

DOSAGE
The recommended maximum starting dose of Zydelig is 150 mg administered orally twice daily.

Dose modification may be required for specific toxicities related to Zydelig. If resuming Zydelig after interruption for other severe or life-threatening toxicities, reduce the dose to 100 mg twice daily.

FDA APPROVED INDICATIONS
Zydelig is a kinase inhibitor indicated for the treatment of patients with:

- Relapsed chronic lymphocytic leukemia (CLL), in combination with rituximab, in patients for whom rituximab alone would be considered appropriate therapy due to other co-morbidities.
- Relapsed follicular B-cell non-Hodgkin lymphoma (FL) in patients who have received at least two prior systemic therapies.
- Relapsed small lymphocytic lymphoma (SLL) in patients who have received at least two prior systemic therapies.

Accelerated approval was granted for FL and SLL based on overall response rate. Improvement in patient survival or disease related symptoms has not been established. Continued approval for these indications may be contingent upon verification of clinical benefit in confirmatory trials.

REFERENCES
- Gilead Sciences, Inc. Zydelig package insert. Foster City, CA. July 2014
- NCCN Clinical Practice Guidelines in Oncology. Non-Hodgkin's Lymphomas. Version 4.2014. Available at: http://www.nccn.org/professionals/physician_gls/pdf/nhl.pdf [Accessed October 15, 2014]

Created: 06/15
Effective: 07/22/15 Client Approval: 06/15 P&T Approval: 11/14

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ILOPROST

Generic	Brand	HICL	GCN	Exception/Other
ILOPROST	VENTAVIS	26287		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ILOPROST (Ventavis)** requires the following rule(s) be met for approval:
A. You have pulmonary arterial hypertension (PAH: type of high blood pressure in the arteries from the heart to the lungs; World Health Organization Group 1)
B. Therapy is prescribed by or given in consultation with a cardiologist (heart doctor) or pulmonologist (lung doctor)

RENEWAL CRITERIA

Our guideline named **ILOPROST (Ventavis)** requires the following rule(s) be met for renewal:
A. You have history of paid claim(s) for the requested medication in the past 90 days
B. You have a previous authorization on file for the requested medication

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RATIONALE
Ensure appropriate use of Ventavis.

FDA APPROVED INDICATION
Ventavis is a prostacyclin mimetic indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve a composite endpoint consisting of exercise tolerance, symptoms (NYHA Class), and lack of deterioration.

DOSING
Ventavis is intended to be inhaled using the I-neb® AAD® System. The recommended initial inhaled dose is 2.5 mcg (as delivered at the mouthpiece). If well tolerated, increase dosing to 5.0 mcg and maintain at that dose; otherwise maintain the dose at 2.5 mcg. Ventavis should be taken 6 to 9 times per day (no more than once every 2 hours) during waking hours, according to individual need and tolerability. The maximum daily dose evaluated in clinical studies was 45 mcg (5 mcg 9 times per day).

REFERENCES
Actelion. Ventavis® (iloprost) prescribing information. South San Francisco, CA. December 2019.

Created: 06/15
Effective: 08/08/22 Client Approval: 07/13/22 P&T Approval: N/A

IMATINIB

Generic	Brand	HICL	GCN	Exception/Other
IMATINIB MESYLATE	GLEEVEC	22096		

GUIDELINES FOR USE

The guideline named **IMATINIB (GLEEVEC)** requires a diagnosis of newly diagnosed Philadelphia Positive Chronic Myeloid Leukemia (Ph+ CML) in chronic phase; Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in blast crisis, accelerated phase, or chronic phase after failure of interferon-alpha therapy; Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL); myelodysplastic/myeloproliferative disease associated with PDGFR (platelet-derived growth factor receptor) gene re-arrangements; aggressive systemic mastocytosis without D816V c-Kit mutation or with c-Kit mutational status unknown; hypereosinophilic syndrome and/or chronic eosinophilic leukemia; unresectable, recurrent, and/or metastatic dermatofibrosarcoma protuberans; unresectable and/or metastatic malignant gastrointestinal stromal tumor (GIST) with a Kit (CD117) positive; or adjuvant treatment following complete gross resection of Kit (CD117) positive gastrointestinal stromal tumor (GIST). In addition, the following must be met:

For newly diagnosed Philadelphia Positive Chronic Myeloid Leukemia (Ph+ CML) in chronic phase OR Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in blast crisis, accelerated phase, or chronic phase, approval requires:

- The patient has NOT received previous treatment with another tyrosine kinase inhibitor [e.g., Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Iclusig (ponatinib)]

For the treatment of gastrointestinal stromal tumor (GIST), approval requires:

- For request of Gleevec 400mg twice daily, approval requires a trial of Gleevec 400mg once daily OR a GIST tumor expressing a KIT exon 9 mutation

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IMATINIB

RATIONALE

Ensure appropriate utilization of imatinib based on FDA approved indication and NCCN guidelines.

FDA APPROVED INDICATIONS

Gleevec is a kinase inhibitor indicated for the treatment of:

- Newly diagnosed adult and pediatric patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase.
- Patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in blast crisis (BC), accelerated phase (AP), or in chronic phase (CP) after failure of interferon-alpha therapy.
- Adult patients with relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL).
- Pediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) in combination with chemotherapy.
- Adult patients with myelodysplastic/myeloproliferative diseases (MDS/MPD) associated with PDGFR (platelet-derived growth factor receptor) gene re-arrangements as determined with an FDA-approved test.
- Adult patients with aggressive systemic mastocytosis (ASM) without the D816V c-Kit mutation as determined with an FDA-approved test or with c-Kit mutational status unknown.
- Adult patients with hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL) who have the FIP1L1-PDGFRα fusion kinase (mutational analysis or FISH demonstration of CHIC2 allele deletion) and for patients with HES and/or CEL who are FIP1L1-PDGFRα fusion kinase negative or unknown.
- Adult patients with unresectable, recurrent, and/or metastatic dermatofibrosarcoma protuberans (DFSP).
- Patients with Kit (CD117) positive unresectable and/or metastatic malignant gastrointestinal stromal tumors (GIST).
- Adjuvant treatment of adult patients following resection of Kit (CD117) positive GIST.

REFERENCES

- Novartis Pharmaceuticals Corporation. Gleevec package insert. East Hanover, NJ. September 2019.

Created: 06/15
Effective: 07/01/20 Client Approval: 05/12/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

IMMUNE GLOBULIN

Generic	Brand	HICL	GCN	Exception/Other
IMMUNE GLOBULIN	ASCENIV, BIVIGAM, CARIMUNE NF NANOFILTERED, FLEBOGAMMA DIF, GAMASTAN S-D, GAMMAGARD S-D, GAMMAPLEX, PRIVIGEN, GAMMAGARD LIQUID, HIZENTRA	46208, 04202, 41798		
IMMUNE GLOB, GAM CAPRYLATE	GAMUNEX-C, GAMMAKED	25631		
IMMUNE GLOBULIN / MALTOSE	OCTAGAM	33220		
IGG/HYALURONIDASE, RECOMBINANT	HYQVIA	41391		
IMMUN GLOB G(IGG)/GLY/IGA 0-50	HYQVIA IG COMPONENT	41995		
IMMUN GLOB G(IGG)/GLY/IGA OV50	CUVITRU	41796		
IMMUN GLOB G(IGG)-IFAS/GLYCINE	PANZYGA	45354		
IMMUN GLOB G(IGG), KLHW	XEMBIFY	45891		

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

IMMUNE GLOBULIN

GUIDELINE FOR USE

The guideline named **IMMUNE GLOBULIN** requires that the patient has **ONE** of the following diagnoses:

- Primary Immunodeficiency Disease (PID)
- Idiopathic Thrombocytopenic Purpura (ITP)
- Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
- Multifocal Motor Neuropathy (MMN)
- Kawasaki Syndrome
- B-cell Chronic Lymphocytic Leukemia (CLL) with hypogammaglobulinemia, Autoimmune Hemolytic Anemia (AIHA), Immune Thrombocytopenic Purpura (ITP), or pure Red Cell Blood Aplasia (PRCA)
- Guillain-Barre Syndrome (GBS)
- Myasthenia Gravis
- Autoimmune Graves' Ophthalmopathy
- Cytomegalovirus-induced Pneumonitis related to a solid organ transplant
- Prevention of bacterial infection in an HIV-infected child
- Reduction of secondary infections in pediatric HIV infections
- Dermatomyositis or polymyositis
- Autoimmune uveitis (Birdshot retinochoroidopathy)
- Lambert-Eaton myasthenic syndrome
- IgM anti-myelin-associated glycoprotein paraprotein-associated peripheral neuropathy
- Stiff-man syndrome
- Neonatal sepsis
- Rotaviral enterocolitis
- Toxic shock syndrome
- Enteroviral meningoencephalitis
- Toxic Epidermal Necrolysis or Stevens-Johnson syndrome
- Autoimmune Mucocutaneous Blistering Disease (AMBD) (such as pemphigus vulgaris, bullous pemphigoid, mucous membrane pemphigoid, or epidermolysis bullosa acquisita)

(requirements continued on next page)

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IMMUNE GLOBULIN

GUIDELINE FOR USE (CONTINUED)

For prophylaxis or passive immunization of hepatitis A, measles, varicella, or rubella, only Gamastan S-D will be approved.

For requests of Hizentra, approval requires:
- Only for subcutaneous use
- Diagnosis of primary immunodeficiency disease (PID) OR chronic inflammatory demyelinating polyneuropathy (CIDP)

For requests of Xembify, approval requires:
- Only for subcutaneous use
- Diagnosis of primary immunodeficiency disease (PID)
- Age 2 years or older

For requests of Asceniv, approval requires:
- Diagnosis of primary immunodeficiency disease (PID)
- Age 12 years or older

For requests of Cuvitru or Hyqvia, approval requires:
- Only for subcutaneous use
- Diagnosis of primary immunodeficiency disease (PID)

For requests for subcutaneous use of Gammagard, Gamunex-C, or Gammaked, approval requires:
- Diagnosis of primary immunodeficiency disease (PID)

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IMMUNE GLOBULIN

RATIONALE

Ensure appropriate therapeutic use based on FDA approved indications for subcutaneous immune globulin. Although Gammagard Liquid, Gammaked, Gamunex-C may be given intravenously, these products can only be used administered subcutaneously for the treatment of primary immunodeficiency disease (PID).

Ensure appropriate therapeutic use based on FDA approved indications and recommendations from the various professional practice guidelines that discuss the use of non-self-administered immune globulin.

American Academy of Neurology (AAN) 2012 Intravenous Immunoglobulin in the treatment of neuromuscular disorders

AAN evaluated existing evidence for the efficacy of IVIG in treating neuromuscular disorder and made practice recommendations based on evidence level. They also noted that IVIG benefit is generally temporary and longer studies are needed to assess long-term efficacy.

IVIG is as effective as plasmapheresis for treating Guillain-Barre syndrome (GBS) in adults. However, a combination of plasmapheresis and IVIG is likely not superior to monotherapy with either treatment.

IVIG benefit is uncertain in children with GBS however many experts consider it reasonable treatment given its effectiveness for the same condition in adults. There is insufficient data to recommend an optimal IVIG dosing regimen.

IVIG is effective and should be offered for the long-term treatment of CIDP. Dosing, frequency, and duration of IVIG for CIDP may vary by patient. There is insufficient data to assess the comparative efficacy of other CIDP treatments such as steroids, plasmapheresis and immunosuppressants.

IVIG is probably effective for the treatment of myasthenia gravis (MG) in moderately or severely affected patients. A risk benefit analysis should be performed prior to treatment of patients with mild disease. There is insufficient evidence to compare the effectiveness of IVIG and plasmapheresis for the treatment of MG.

IVIG is probably effective and should be considered for the treatment of multifocal motor neuropathy (MMN). MMN requires ongoing treatment but optimal treatment dosing, interval, and duration have not been established.

IVIG is possibly effective for the treatment of nonresponsive dermatomyositis in adults and Lambert-Eaton myasthenic syndrome. There is insufficient evidence to assess the role of IVIG in treating the following conditions: neuropathy associated with IgM paraprotein, inclusion body myositis and postpolio syndrome.

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RATIONALE (CONTINUED)

American Academy of Allergy, Asthma and Immunology (AAAAI) 2017 evidence review of intravenous immunoglobulin in human disease
AAAAI reviewed evidence supporting the use of standard human immunoglobulin preparation for intravenous administration. Therapeutic uses are categorized by evidence of benefit as follows: definitely beneficial, probably beneficial, might provide benefit, and unlikely to be beneficial. AAAAI also comments that subcutaneous therapy can reduce the occurrence of systemic adverse events in selected patients and can improve quality of life for patients receiving intravenous immune globulin. Adverse events may also be reduced by matching specific products to specific patient characteristics.

Definitely Beneficial Uses of IVIG

Disease	Evidence category	Strength of recommendation
Primary immune defects with absent B cells	IIb	B
Primary immune defects with hypogammaglobulinemia and impaired specific antibody production	IIb	B
Reduction of secondary infections in pediatric HIV infections	Ib	A
CIDP	Ia	A
Graves ophthalmopathy	Ib	A
Immune thrombocytopenic purpura	Ia	A
Guillain-Barre syndrome	Ib	B
Multifocal motor neuropathy	Ib	A
Kawasaki disease	Ia	A
Cytomegalovirus-induced pneumonitis in solid organ transplants	Ib	A

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RATIONALE (CONTINUED)

Probably Beneficial Uses of IVIG

Disease	Evidence category	Strength of recommendation
Chronic lymphocytic leukemia with reduced IgG and history of infections	Ib	A
Prevention of bacterial infection in HIV-infected children	Ib	A
Primary immune defects with normogammaglobulinemia and impaired specific antibody production	III	C
Dermatomyositis and polymyositis	IIa	B
Birdshot Retinochoroidopathy	IIa	B
Henoch-Schönlein purpura	IIb	B
Lambert-Eaton myasthenic syndrome	Ib	B
IgM antimyelin-associated glycoprotein paraprotein-associated peripheral neuropathy	Ib	A
Myasthenia gravis	Ib-IIa	B
Stiff-person syndrome	Ib	B
Neonatal sepsis	Ia	A
Rotaviral enterocolitis	Ib	A
Bacterial infections in lymphoproliferative diseases	Ib	B
Toxic shock Syndrome	III	C
Enteroviral meningoencephalitis	III	C
Toxic epidermal necrolysis and Stevens-Johnson syndrome	IIa	B

Guidelines for the Prevention and Treatment of Opportunistic Infections Among HIV-Exposed and HIV-Infected Children: Recommendations from CDC, the National Institutes of Health, the HIV Medicine Association of the Infectious Diseases Society of America, the Pediatric Infectious Diseases Society, and the American Academy of Pediatrics 2013

IVIG was commonly used prior to the advent of highly active anti-retroviral therapy (HAART) for infection prophylaxis in symptomatic HIV-infected children. However, trimethoprim-sulfamethoxazole is now preferred in this setting. IVIG 400mg/kg every 2-4 weeks is only recommended for primary prevention of serious bacterial infections in HIV-infected children if hypogammaglobulinemia (IgG<400mg/dL) is present or functional antibody deficiency is demonstrated by poor specific antibody titers. IVIG can also be considered for secondary prophylaxis when antibiotic prophylaxis fails to prevent recurrent serious bacterial infections. (Mofenson).

HIV-infected children exposed to varicella and have no history of varicella or zoster; are seronegative for VZV by a sensitive, specific antibody assay; or lack evidence of age-appropriate vaccination should receive passive immunization within 96 hours of exposure. The preferred method of immunization is with human varicella immune globulin (VariZIG), a Canadian product lacking FDA approval that can be used under an IND protocol in the US. If VariZIG is unavailable IVIG 400mg/kg can be administered once as soon as possible, ideally within 96 hours after exposure. If more than 96 hours have passed since exposure, acyclovir 20mg/kg (max 800mg) per dose orally 4 times a day for 5-7 days can also be considered.

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RATIONALE (CONTINUED)

European Federation of Neurological Societies (EFNS) Guidelines for the use of intravenous immunoglobulin in treatment of neurological diseases 2008
The EFNS state that the efficacy of IVIG has been proven for the following immune-mediated neurological diseases: Guillain-Barre syndrome, chronic inflammatory demyelinating polyradiculoneuropathy, multifocal mononeuropathy, and acute exacerbations and short-term treatment of myasthenia gravis.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology Non-Hodgkin's Lymphomas Versions 3.2012
Patients with B-cell chronic lymphocytic leukemia (CLL) are susceptible to infections due to both the underlying disease and immunosuppressive properties of the treatment agents. The main options for decreasing the occurrence of secondary infections for patients with recurrent infections and IgG level <500mg/dL are IVIG, anti-infective prophylaxis, and vaccinations. For patients with serum IVIG <500mg/dL) with recurrent sinopulmonary infections requiring intravenous antibiotic or hospitalization it is recommended that IVIG levels be monitored and IVIG be administered monthly at a dose of 0.3-0.5 g/kg to maintain nadir levels around 500mg/dL.
Autoimmune cytopenias including: autoimmune hemolytic anemia (AIHA), immune thrombocytopenic purpura (ITP), and pure red blood aplasia (PRCA) can occur in patients with CLL. AIHA and ITP can be managed with corticosteroids in most cases. IVIG is an option for steroid-refractory cases. Corticosteroids are typically less effective in PRCA than in AIHA or ITP, however they are still considered a first-line treatment along with IVIG and splenectomy.

The American Society of Hematology 2011 evidence-based practice guideline for immune thrombocytopenia
Initial treatment of pediatric ITP consists of IVIG (0.8-1g/kg) or a short course of corticosteroids. IVIG can also be used if a more rapid increase in the platelet count is desired. For the treatment of adult ITP longer courses of corticosteroids are preferred over shorter courses of corticosteroids or IVIG as first-line treatment. IVIG in combination with corticosteroids can be considered when a more rapid increase in platelet count is required. IVIG dosing is usually 1g/kg for a single dose; however additional doses can be administered if necessary. Pregnant patients with ITP can receive either corticosteroids or IVIG. IVIG should be used as initial treatment of ITP in patients with the hepatitis C virus. Initial treatment of ITP patients with HIV coinfection can include corticosteroids, IVIG, or anti-D immunoglobulin.

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RATIONALE (CONTINUED)

Consensus Statement on the Use of Intravenous Immunoglobulin Therapy in the Treatment of Autoimmune Therapy in the Treatment of Autoimmune Mucocutaneous Blistering Diseases
A consensus statement on the use of IVIG for the treatment of autoimmune mucocutaneous blistering diseases (AMBDs) from a group of physicians was published in the Archives of Dermatology. The consensus group considered 5 distinct types of AMBDs: pemphigus vulgaris, bullous pemphigoid, mucous membrane pemphigoid, and epidermolysis bullosa acquisita. All are typically treated with corticosteroids or immunosuppressive agents. The use of IVIG treatment is recommended when one of the following is present: failure of conventional therapy, significant adverse effects with conventional therapy, contraindications to conventional therapy, disease progression with conventional therapy, uncontrolled rapid debilitating progressive disease, or rapid progressive epidermolysis bullosa acquisita with generalized cutaneous disease. The recommended dose is 2g/kg per cycle, consisting of 3 consecutive daily doses every 3 to 4 weeks. Dosing and frequency may vary among patients depending on severity of disease and response to therapy.

FDA APPROVED INDICATIONS

Drug	PI	ITP	CIDP	Other
Asceniv	IV			
Bivigam	IV			
Carimune NF	IV	IV		
Cuvitru (for SC use only)	SC			
Flebogamma DIF	IV (5%, 10%)	IV (10%)		
Gamastan S-D				Hepatitis A, Measles, Varicella, Rubella (IM)
Gammagard Liquid	IV/SC			Multifocal motor neuropathy (IV)
Gammagard S-D	IV	IV		B-cell CLL, Kawasaki syndrome (IV)
Gammaked	IV/SC	IV	IV	
Gammaplex	IV (5%, 10%)	IV (5%, 10%)		
Gamunex-C	IV/SC	IV	IV	
Hizentra	SC			
Octagam	IV (5%)	IV (10%)		
Panzyga	IV	IV		
Privigen	IV	IV	IV	
Xembify	SC			

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FDA APPROVED INDICATIONS (CONTINUED)

Asceniv is an immune globulin intravenous (human), 10% liquid, indicated for the treatment of:
- Primary humoral immunodeficiency (PI) in adults and adolescents 12 to 17 years of age.

Bivigam is an immune globulin intravenous (human), 10% liquid, indicated for the treatment of:
- Primary humoral immunodeficiency (PI)

Carimune NF is a nanofiltered, immune globulin intravenous (human) indicated for:
- Maintenance treatment of patients with primary immunodeficiencies
- Immune thrombocytopenic purpura (ITP)

Cuvitru is an immune globulin subcutaneous (human), 20% solution indicated as replacement therapy for:
- Primary humoral immunodeficiency (PI) in adult and pediatric patients two years of age and older.

Flebogamma 5% DIF is an immune globulin intravenous (human) indicated for treatment of:
- Primary (inherited) immunodeficiency (PI) in adults and pediatric patients 2 years of age and older

Flebogamma 10% DIF is an immune globulin intravenous (human) indicated for treatment of:
- Primary (inherited) immunodeficiency (PI)
- Chronic primary immune thrombocytopenia (ITP) in patients 2 years of age and older

Gamastan S/D is an immune globulin (human) for intramuscular administration indicated for:
- Hepatitis A
- Measles (rubeola)
- Varicella
- Rubella

Gammagard Liquid is an immune globulin infusion (human) indicated as replacement therapy for:
- Primary humoral immunodeficiency (PI) in adult and pediatric patients two years of age or older. This includes, but is not limited to, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.
- Multifocal motor neuropathy (MMN)

Gammagard S/D is an immune globulin intravenous (human) indicated for:
- Treatment of primary immunodeficiency (PI) in adult and pediatric patients two years of age or older
- Prevention of bacterial infections in hypogammaglobulinemia and/or recurrent bacterial infections associated with B-cell chronic lymphocytic leukemia (CLL)
- Prevention and/or control of bleeding in adult chronic idiopathic thrombocytopenic purpura (ITP) patients
- Prevention of coronary artery aneurysms associated with Kawasaki syndrome in pediatric patients

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FDA APPROVED INDICATIONS (CONTINUED)

Gammaked is an immune globulin injection (human) 10% liquid that is indicated for the treatment of:

- Primary humoral immunodeficiency (PI) in patients 2 years of age and older Idiopathic thrombocytopenic purpura (ITP)
- Chronic Inflammatory demyelinating polyneuropathy (CIDP)

Gammaplex 5% is an immune globulin intravenous (human) 5% liquid that is indicated for the treatment of:

- Primary humoral immunodeficiency (PI) in adults and pediatric patients 2 years of age and older
- Chronic immune thrombocytopenic purpura (ITP)

Gammaplex 10% is an immune globulin intravenous (human) 10% liquid that is indicated for the treatment of:

- Primary humoral immunodeficiency (PI) in adults
- Chronic immune thrombocytopenic purpura (ITP) in adults

Gamunex-C is an immune globulin injection (human) 10% liquid that is indicated for the treatment of:

- Primary Humoral Immunodeficiency (PI) in patients 2 years of age and older
- Idiopathic thrombocytopenic purpura (ITP)
- Chronic inflammatory demyelinating polyneuropathy (CIDP)

Hizentra is an immune globulin subcutaneous (human) (IGSC), 20% Liquid indicated for the treatment of:

- Primary immunodeficiency (PI) in adults and pediatric patients 2 years of age and older
- Maintenance therapy in adults with chronic inflammatory demyelinating polyneuropathy (CIDP)
  Limitations of Use:
  Hizentra maintenance therapy in CIDP has been systematically studied for 6 months and for a further 12 months in a follow-up study. Maintenance therapy beyond these periods should be individualized based upon the patient's response and need for continued therapy

Hyqvia is an immune globulin with a recombinant human hyaluronidase indicated for the treatment of:

- Primary Immunodeficiency (PI) in adults
  Limitation of Use:
  Safety and efficacy of chronic use of recombinant human hyaluronidase in Hyqvia have not been established in conditions other than PI.

- Primary humoral immunodeficiency (PI)

Octagam 10% is an immune globulin intravenous (human), 10% liquid, indicated for treatment of:

- Chronic immune thrombocytopenic purpura (ITP) in adults

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IMMUNE GLOBULIN

FDA APPROVED INDICATIONS (CONTINUED)

Panzyga is an immune globulin intravenous (human) 10% liquid that is indicated for the treatment of:

- Primary humoral immunodeficiency (PI) in patients 2 years of age and older
- Chronic immune thrombocytopenia (ITP) in adults

Privigen is an immune globulin intravenous (human), 10% liquid, indicated for treatment of:

- Primary humoral immunodeficiency (PI)
- Chronic immune thrombocytopenic purpura (ITP) in patients aged 15 years and older
- Chronic inflammatory demyelinating polyneuropathy (CIDP) in adults

Xembify is an immune globulin intravenous (human), 20% liquid, indicated for the treatment of:

- Primary humoral immunodeficiency (PI) in patients 2 years of age and older

DOSAGE AND ADMINISTRATION

Asceniv
Administer intravenously for PI.

Dose	Initial Infusion Rate	Maintenance Infusion Rate (if tolerated)
300-800 mg/kg every 3-4 weeks	0.5 mg/kg/min (0.005 mL/kg/min) for the first 15 minutes	Increase gradually every 15 minutes (if tolerated) up to 8 mg/kg/min (0.8 mL/kg/min).

Bivigam
Administer intravenously for PI.

Indication	Dose	Initial Infusion Rate	Maintenance Infusion Rate (if tolerated)
PI	300-800 mg/kg every 3-4 weeks	0.5 mg/kg/min for the first 10 minutes.	Increase every 20 minutes (if tolerated) by 0.8 mg/kg/min up to 6 mg/kg/min.

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DOSAGE AND ADMINISTRATION (CONTINUED)

Carimune NF
Administer intravenously.

Primary immunodeficiency (PI):

- The recommended dose is 0.4 to 0.8 g/kg of body weight administered once every three to four weeks by intravenous infusion.
- The first infusion must be given as a 3% immunoglobulin solution. Subsequent infusions may be given at higher concentrations if tolerated by the patient.
- An initial infusion rate of 0.5 mg/kg/min is recommended. If tolerated, after 30 minutes the rate may be increased to 1 mg/kg/min for the next 30 minutes. Thereafter, the rate may be gradually increased in a stepwise manner up to a maximum of 3 mg/kg/min as tolerated.

Idiopathic thrombocytopenic purpura (ITP):

- The recommended dose is 0.4 g/kg of body weight administered on 2-5 consecutive days.
- A concentration of immunoglobulin solution of 6% is recommended.
- An initial infusion rate of 0.5 mg/kg/min is recommended. If tolerated, after 30 minutes the rate may be increased to 1 mg/kg/min for the next 30 minutes. Thereafter, the rate may be gradually increased in a stepwise manner up to a maximum of 3 mg/kg/min as tolerated.

Cuvitru
Administer subcutaneously at regular intervals from daily up to every two weeks. Cuvitru may be administered subcutaneously utilizing an infusion pump.

- Weekly: Start Hizentra 1 week after last IGIV or Hyqvia infusion

$$\text{Initial Weekly dose} = \frac{\text{Previous IGIV or HYQVIA dose (in grams)}}{\text{No. of weeks between IGIV or HYQVIA doses.}} \times 1.30$$

- Biweekly: Administer twice the calculated weekly dose.
- Frequent dosing (2 to 7 times per week): Divide the calculated weekly dose by the desired number of administrations per week.
- Adjust the dose based on clinical response and serum IgG trough levels.

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IMMUNE GLOBULIN

DOSAGE AND ADMINISTRATION (CONTINUED)

Flebogamma 5% DIF
Administer intravenously.

Indication	Dose	Initial Infusion Rate	Maintenance Infusion Rate (if tolerated)
PI	300-600 mg/kg given every 3 to 4 weeks	0.5 mg/kg/min	5 mg/kg/min

Flebogamma 10% DIF
Administer intravenously.

Indication	Dose	Initial Infusion Rate	Maintenance Infusion Rate (if tolerated)
PI	300-600 mg/kg given every 3 to 4 weeks	1 mg/kg/min	8 mg/kg/min
ITP	1 g/kg daily for 2 consecutive days	1 mg/kg/min	8 mg/kg/min

Gamastan S/D
Administer only by the intramuscular route. Do not given subcutaneously or intravenously.

Indication	Dose
Hepatitis A (household and institutional contacts)	0.1 mL/kg
Measles	0.25 mL/kg to prevent in a susceptible person exposed fewer than 6 days previously 0.5 mL/kg should be given immediately to a susceptible child who is immunocompromised
Varicella	0.6-1.2 mL/kg
Rubella	0.55 mL/kg

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DOSAGE AND ADMINISTRATION (CONTINUED)

Gammagard Liquid
Prior to switching from intravenous to subcutaneous treatment, obtain the patient's serum IgG trough level to guide subsequent dose adjustments. Start the initial subcutaneous dose approximately one week after the last intravenous infusion.

Indication	Dose	Initial Infusion Rate	Maintenance Infusion Rate (if tolerated)
Intravenous administration			
PI	300-600 mg/kg given every 3 to 4 weeks	0.5 mL/kg/hr	Increase every 30 minutes (if tolerated) up to 5 mL/kg/hr
Multifocal motor neuropathy	0.5-2.4 g/kg/month based on clinical response	0.5 mL/kg/hr	Infusion rate may be increased if tolerated up to 5.4 mL/kg/hr
Subcutaneous administration			
PI	Initial Dose is 1.37 × previous intravenous dose divided by # of weeks between intravenous doses. Maintenance dose is based on clinical response and target IgG trough level.	40 kg BW and greater: 30 mL/site at 20 mL/hr/site. Under 40 kg BW: 20 mL/site at 15 mL/hr/site.	40 kg BW and greater: 30 mL/site at 20 to 30 mL/hr/site. Under 40 kg BW: 20 mL/site at 15 to 20 mL/hr/site.

Gammagard S/D
Administer intravenously.

Indication	Recommended Dosage	Duration	Administration (5% concentration)
PI	300-600 mg/kg	Every 3-4 weeks	Recommended initial rate: 0.5 mL/kg/hr Maximum rate: 4 mL/kg/hr
CLL	400 mg/kg	Every 3-4 weeks	
ITP	1 g/kg	Maximal 3 doses on alternate days	
Kawasaki syndrome	Single 1 g/kg or 400 mg/kg for 4 consecutive days	Begin within 7 days of onset of fever	

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IMMUNE GLOBULIN

DOSAGE AND ADMINISTRATION (CONTINUED)

Gammaked
Administer intravenously for PI, ITP and CIDP. Gammaked may also be administered subcutaneously for the treatment of PI.

Indication	Dose	Initial Infusion Rate	Maintenance Infusion Rate (if tolerated)
Intravenous administration			
ITP	2 g/kg	1 mg/kg/min	8 mg/kg/min
CIDP	Loading dose: 2 g/kg Maintenance dose: 1 g/kg	2 mg/kg/min	8 mg/kg/min every 3 weeks
PI	300-600 mg/kg	1 mg/kg/min	8 mg/kg/min every 3 weeks
Subcutaneous administration			
PI	1.37 x current IV dose in grams/IV dose interval in weeks	Adult: 20 mL/hr/site Pediatric: 10 mL/hr/site (< 25 kg) 15 mL/hr/site (⩾ 25 kg)	Adult: 20 mL/hr/site Pediatric: 10 mL/hr/site (< 25 kg) 20 mL/hr/site (⩾ 25 kg) Weekly

Gammaplex 5%
Administer intravenously.

Indication	Dose	Initial Infusion Rate	Maintenance Infusion Rate (if tolerated)
PI	300-800 mg/kg given every 3 to 4 weeks	0.5 mg/kg/min for 15 minutes	Increase gradually every 15 minutes to 4 mg/kg/min
ITP	1 g/kg for 2 consecutive days	0.5 mg/kg/min for 15 minutes	Increase gradually every 15 minutes to 4 mg/kg/min

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IMMUNE GLOBULIN

DOSAGE AND ADMINISTRATION (CONTINUED)

Gammaplex 10%
Administer intravenously.

Indication	Dose	Initial Infusion Rate	Maintenance Infusion Rate (if tolerated)
PI	300-800 mg/kg given every 3 to 4 weeks	0.5 mg/kg/min for 15 minutes	Increase gradually every 15 minutes to 8 mg/kg/min
ITP	1 g/kg for 2 consecutive days	0.5 mg/kg/min for 15 minutes	Increase gradually every 15 minutes to 8 mg/kg/min

Gamunex-C
Administer intravenously for PI, ITP and CIDP. Gamunex-C may also be administered subcutaneously for the treatment of PI.

Indication	Dose	Initial Infusion Rate	Maintenance Infusion Rate (if tolerated)
Intravenous administration			
ITP	2 g/kg	1 mg/kg/min	8 mg/kg/min
CIDP	Loading dose: 2 g/kg Maintenance dose: 1 g/kg	2 mg/kg/min	8 mg/kg/min every 3 weeks
PI	300-600 mg/kg	1 mg/kg/min	8 mg/kg/min every 3 weeks
Subcutaneous administration			
PI	1.37 x current IV dose in grams/IV dose interval in weeks	Adult: 20 mL/hr/site Pediatric: 10 mL/hr/site (< 25 kg) 15 mL/hr/site (≥ 25 kg)	Adult: 20 mL/hr/site Pediatric: 10 mL/hr/site (< 25 kg) 20 mL/hr/site (≥ 25 kg) weekly

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DOSAGE AND ADMINISTRATION (CONTINUED)

Hizentra
For subcutaneous infusion only. Do not inject into a blood vessel. Administer weekly or biweekly (every two weeks).
Primary immunodeficiency (PI):

- Before switching to Hizentra, obtain the patient's serum IgG trough level to guide subsequent dose adjustments.
- Weekly: Start Hizentra 1 week after last IGIV or IGSC infusion

$$\text{Initial HIZENTRA dose} = \frac{\text{Previous IGIV dose (in grams)}}{\text{Number of weeks between IGIV doses}} \times 1.37$$

- Biweekly: Start Hizentra 1 or 2 weeks after the last IGIV infusion or 1 week after the last weekly IGSC infusion. Administer twice the calculated weekly dose.
- Frequent dosing (2 to 7 times per week): Start Hizentra 1 week after last IGIV/IGSC infusion. Divide the calculated weekly dose by the desired number of administrations per week.
- Adjust the dose based on clinical response and serum IgG trough levels.

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP):

- Initiate therapy with Hizentra 1 week after the last IGIV infusion.
- The recommended subcutaneous dose is 0.2 g/kg (1 mL/kg) body weight per week, administered in 1 or 2 sessions over 1 or 2 consecutive days.
- If symptoms worsen, consider re-initiating treatment with an IGIV approved for the treatment of CIDP, while discontinuing Hizentra.
  Monitor the patient's clinical response and adjust the duration of therapy based on patient

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IMMUNE GLOBULIN

DOSAGE AND ADMINISTRATION (CONTINUED)

Hyqvia
For subcutaneous use only.

- For patients previously on another IgG treatment, give the first dose approximately one week after the last infusion of their previous treatment.
- Increase the dose and frequency from a 1-week dose to a 3- or 4-week dose:

Initial Treatment Interval/Dosage Ramp-Up Schedule

Week	Infusion Number	Dose Interval	Example for 30 grams per 4 weeks
1	1st infusion	1-week-dose	7.5 grams
2	2nd infusion	2-week-dose	15 grams
3	No infusion		
4	3rd infusion	3-week-dose	22.5 grams
5	No infusion		
6	No infusion		
7	4th infusion (if required)	4-week-dose	30 grams

- For patients switching from IGIV, given Hyqvia at the same dose and frequency as the previous intravenous treatment, after the initial dose ramp-up.
- For patients naïve to IGSC treatment or switching from IGSC, give Hyqvia at a dose of 300-600 mg/kg at 3- to 4-week intervals, after initial ramp-up.

Octagam 5%
For intravenous use only.

Indication	Dose	Initial Infusion Rate	Maintenance Infusion Rate (if tolerated)
PI	300-600 mg/kg every 3-4 weeks	0.5 mg/kg/min	3.33 mg/kg/min

Octagam 10%
For intravenous use only.

Indication	Dose	Initial Infusion Rate	Maintenance Infusion Rate (if tolerated)
Chronic ITP	1 g/kg daily for 2 consecutive days	1 mg/kg/min	Up to 12 mg/kg/min

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IMMUNE GLOBULIN

DOSAGE AND ADMINISTRATION (CONTINUED)

Panzyga
For intravenous use only.

Indication	Dose	Initial Infusion Rate	Maintenance Infusion Rate (if tolerated)
PI	300-600 mg/kg every 3-4 weeks	1 mg/kg/min	Increase to 8 to 14 mg/kg/min
Chronic ITP	1 g/kg daily for 2 consecutive days	1 mg/kg/min	Increase to 8 mg/kg/min

Privigen
For intravenous use only.

Indication	Dose	Initial Infusion Rate	Maintenance Infusion Rate (if tolerated)
PI	200-800 mg/kg every 3-4 weeks	0.5 mg/kg/min	Increase to 8 mg/kg/min
Chronic ITP	1 g/kg daily for 2 consecutive days	0.5 mg/kg/min	Increase to 4 mg/kg/min
CIDP	Loading dose: 2 g/kg in divided doses over 2 to 5 consecutive days Maintenance dose: 1 g/kg administered in 1 to 2 infusions on consecutive days, every 3 weeks	0.5 mg/kg/min	Increase to 4 mg/kg/min

Xembify
For subcutaneous infusion only.
Before switching to Xembify, obtain the patient's serum IgG trough level to guide subsequent dose adjustments.

- Switching from immune globulin intravenous (human), 10% (IVIG) to XEMBIFY: calculate the dose by using a dose adjustment factor (1.37)
  - Weekly: Begin XEMBIFY one week after last IVIG infusion. Establish initial weekly dose by converting the monthly (or every 3 weeks) IVIG dose into an equivalent weekly dose and increasing it using a dose adjustment factor (1.37)
  - Frequent dosing (2-7 times per week): Divide the calculated weekly dose by the desired number of times per week.
- Switching from immune globulin subcutaneous (human) treatment (IGSC):
  - Weekly dose (grams) should be the same as the weekly dose of prior IGSC treatment (grams).

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

IMMUNE GLOBULIN

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Created: 06/15
Effective: 02/03/20 Client Approval: 01/02/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

IMMUNE GLOBULIN G(IGG)-HIPP/MALTOSE

Generic	Brand	HICL	GCN	Exception/Other
IMMUN GLOB G(IGG)-HIPP/MALTOSE	CUTAQUIG	45734		

GUIDELINES FOR USE

The guideline named **CUTAQUIG** requires a diagnosis of primary humoral immunodeficiency (i.e., primary immunodeficiency disease [PID]. In addition, the following criterion must be met:

- The patient is 18 years of age or older

RATIONALE

To ensure the appropriate usage of Cutaquig according to diagnosis.

INDICATION

Cutaquig is a 16.5% immune globulin solution for subcutaneous infusion (IGSC) indicated for replacement therapy for primary humoral immunodeficiency (PI) in adults. This includes, but is not limited to, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

REFERENCES

Cutaquig Prescribing Information]. Hoboken, NJ: Octapharma USA, Inc. May 2019.

Created: 07/19
Effective: 08/19/19 Client Approval: 08/05/19 P&T Approval: N/A

INFIGRATINIB

Generic	Brand	HICL	GCN	Exception/Other
INFIGRATINIB PHOSPHATE	TRUSELTIQ	47404		

GUIDELINES FOR USE

Our guideline named **INFIGRATINIB (Truseltiq)** requires the following rule(s) be met for approval:

A. You have unresectable locally advanced or metastatic cholangiocarcinoma (bile duct cancer that has grown outside the organ but has not yet spread to other parts of the body and cannot be removed by surgery, or bile duct cancer that has spread to other parts of the body)
B. You are 18 years of age or older
C. You have previously been treated for unresectable locally advanced or metastatic cholangiocarcinoma
D. You have a fibroblast growth factor receptor 2 (FGFR2: type of protein) fusion or other rearrangement, as detected by a Food and Drug Administration (FDA)-approved test

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Truseltiq.

REFERENCES

- Truseltiq [Prescribing Information]. Brisbane, CA: QED Therapeutics, Inc.; May 2021.

Created: 07/21
Effective: 08/23/21 Client Approval: 07/16/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

INFLIXIMAB

Generic	Brand	HICL	GCN	Exception/Other
INFLIXIMAB	REMICADE	18747		
INFLIXIMAB-ABDA	RENFLEXIS	44432		
INFLIXIMAB-DYYB	INFLECTRA	43249		
INFLIXIMAB-AXXQ	AVSOLA	46242		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: USE INITIAL CRITERIA FOR ALL PATIENTS NEW TO INFLIXIMAB THERAPY. USE RENEWAL CRITERIA FOR CONTINUATION OF INFLIXIMAB THERAPY, REGARDLESS OF WHICH AGENT IS REQUESTED. FOR RENEWAL CRITERIA, SEE BELOW.)

The guideline named **INFLIXIMAB (Avsola, Remicade, Renflexis or Inflectra)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Severe plaque psoriasis (PsO: dry, itchy scaly skin patches)
   5. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   6. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   - You are 18 years of age or older
   - You have previously tried ONE of the following DMARDs (disease-modifying antirheumatic drugs): methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   - You are currently using or have a contraindication (a medical reason why you cannot use) to methotrexate
   - You have previously tried ONE of the following: Enbrel or Humira
   - If the request is for Remicade, Renflexis, or Inflectra: you have previously tried Avsola

C. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. You have previously tried ONE of the following DMARDs (disease-modifying antirheumatic drugs): methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   3. You have previously tried TWO of the following: Cosentyx, Enbrel, or Humira
   4. If the request is for Remicade, Renflexis, or Inflectra: you have previously tried Avsola

D. **If you have ankylosing spondylitis (AS), approval also requires:**
   1. You are 18 years of age or older
   2. You have previously tried or have a contraindication (a medical reason why you cannot use) to a non-steroidal anti-inflammatory agent (NSAID)
   3. You have previously tried TWO of the following: Cosentyx, Enbrel, or Humira
   4. If the request is for Remicade, Renflexis, or Inflectra: you have previously tried Avsola

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INITIAL CRITERIA (CONTINUED)

E. **If you have severe plaque psoriasis (PsO), approval also requires:**
   1. You are 18 years of age or older
   2. You have psoriatic lesions (rashes) involving at least 10% body surface area (BSA) or psoriatic lesions (rashes) affecting the face, hands, feet, or genital area
   3. You have previously tried ONE of the following conventional therapies: PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
   4. You have previously tried TWO of the following: Cosentyx, Enbrel, or Humira
   5. If the request is for Remicade, Renflexis, or Inflectra: you have previously tried Avsola

F. **If you have moderate to severe Crohn's disease (CD), approval also requires:**
   1. You are 6 years of age or older
   2. You have previously tried ONE of the following conventional therapies: corticosteroids (e.g., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   3. You have previously tried Humira
   4. If the request is for Remicade, Renflexis, or Inflectra: you have previously tried Avsola

G. **If you have moderate to severe ulcerative colitis (UC), approval also requires:**
   1. You are 6 years of age or older
   2. You have previously tried ONE of the following conventional therapies: corticosteroids (e.g., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   3. You have previously tried Humira
   4. If the request is for Remicade, Renflexis, or Inflectra: you have previously tried Avsola

RENEWAL CRITERIA

Our guideline named **INFLIXIMAB (Avsola, Remicade, Renflexis or Inflectra)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Severe plaque psoriasis (PsO: dry, itchy scaly skin patches)
   5. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   6. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)

B. You have experienced or maintained symptomatic improvement while on therapy.

C. **If you have moderate to severe rheumatoid arthritis (RA), renewal also requires:**
   1. You are currently using methotrexate or have a medical reason why you cannot (contraindication)

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INFLIXIMAB

RATIONALE

Ensure appropriate diagnostic, utilization and safety criteria are used for the management of requests for infliximab.

FDA APPROVED INDICATIONS

Infliximab (Avsola, Remicade, Renflexis or Inflectra) is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in adult and pediatric patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy. It is also indicated for reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing Crohn's disease.

Infliximab (Avsola, Remicade, Renflexis or Inflectra) is indicated for reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in patients with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy. Remicade is indicated for this use in both adults and children, while Inflectra and Renflexis are only indicated for this use in adults.

Infliximab (Avsola, Remicade, Renflexis or Inflectra), in combination with methotrexate, is indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis.

Infliximab (Avsola, Remicade, Renflexis or Inflectra) is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis.

Infliximab (Avsola, Remicade, Renflexis or Inflectra) is indicated for reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in patients with psoriatic arthritis.

Infliximab (Avsola, Remicade, Renflexis or Inflectra) is indicated for the treatment of adult patients with chronic severe (i.e., extensive and /or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate. It should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician.

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INFLIXIMAB

FDA APPROVED INDICATIONS (CONTINUED)

DOSING

Crohn's Disease: 5 mg/kg at 0, 2, and 6 weeks, then every 8 weeks. Some adult patients who initially respond to treatment may benefit from increasing the dose to 10 mg/kg if they later lose their response.
Ulcerative Colitis: 5 mg/kg at 0, 2, and 6 weeks, then every 8 weeks.
Rheumatoid Arthritis: In conjunction with methotrexate, 3 mg/kg at 0, 2, and 6 weeks, then every 8 weeks. Some patients may benefit from increasing the dose up to 10 mg/kg or treating as often as every 4 weeks.
Ankylosing Spondylitis: 5 mg/kg at 0, 2, and 6 weeks, then every 6 weeks.
Psoriatic Arthritis: 5 mg/kg at 0, 2, and 6 weeks, then every 8 weeks.
Plaque Psoriasis: 5 mg/kg at 0, 2, and 6 weeks, then every 8 weeks.

REFERENCES

- Remicade [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. May 2020.
- Renflexis [Prescribing Information]. Whitehouse Station, NY: Merck & Co., Inc. February 2021.
- Inflectra [Prescribing Information]. New York NY: Pfizer, Inc. June 2021.
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- Lichtenstein G, Loftus EV, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. American Journal of Gastroenterology: April 2018, Volume 113, Issue 4, pp 481-517. doi: 10.1038/ajg.2018.27
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Created: 02/18
Effective: 04/11/22 Client Approval: 03/10/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

INHALED INSULIN

Generic	Brand	HICL	GCN	Exception/Other
INSULIN REGULAR, HUMAN	AFREZZA	00768		ROUTE = INHALATION

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline for **INHALED INSULIN (Afrezza)** requires that you have type 1 or type 2 diabetes, you are 18 years of age or older, and your prescriber did a baseline spirometry to measure FEV1. In addition, the following criteria must be met:

If you have Type 1 diabetes, approval requires:

- You are using a long-acting insulin at the same time
- You have tried the preferred rapid acting insulin (e.g., Ademlog)

If you have Type 2 diabetes, approval requires:

- You have tried the preferred rapid acting insulin (e.g., Ademlog)
- Your prescriber has told us that you are physically unable to or unwilling to administer insulin

Afrezza will NOT be approved if you have any of the following conditions:

- Chronic lung disease
- Active lung cancer
- You are currently in diabetic ketoacidosis
- You are currently smoking or have quit smoking within the past 6 months

RENEWAL CRITERIA

Our guideline for **INHALED INSULIN (Afrezza)** renewal requires that you have type 1 or type 2 diabetes and, documentation of follow up spirometry to measure FEV1 after 6 months of treatment and annually thereafter. In addition, the following criteria must be met for renewal:

- **If you have type 1 diabetes,** approval requires that you are using a long-acting insulin at the same time
- **Afrezza will NOT be approved** for patients with a FEV1 that has declined 20% or more from baseline

RATIONALE

To ensure appropriate use of Afrezza according to FDA approved indication. Afrezza should not be used as first line therapy. Apply quantity limits for maximum daily insulin requirements (total daily insulin requirements 1.5 units/per kg with rapid insulin requirements of 70% of total daily insulin requirements in a 100 kg patient).

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

INHALED INSULIN

FDA APPROVED INDICATIONS

Afrezza is a rapid acting inhaled insulin indicated to improve glycemic control in adult patients with diabetes mellitus.

Patients with type 1 diabetes, must use Afrezza with a long-acting insulin. Afrezza is not recommended for the treatment of diabetic ketoacidosis or in patients who smoke.

DOSAGE AND ADMINISTRATION

Afrezza should be administered at the beginning of the meal and is administered using a single inhalation per cartridge. Dosing should be individualized. Dose adjustments may be needed when switching from another insulin to Afrezza.

Afrezza is available in 3 strengths (4 units of insulin in the blue cartridge, 8 units of insulin in the green cartridge, and 12 units of insulin in the yellow cartridge). Three cartridges are contained in a single cavity of a blister strip. Each card contains 5 blister strips separated by perforations for a total of 15 cartridges. Two inhalers are included in each unit. Each inhaler may be used up to 15 days from the date of the first use.

Starting Mealtime Dose:

- *Insulin Naïve Individuals*: Start on 4 units of Afrezza at each meal.
- *Individuals Using Subcutaneous Mealtime (Prandial) Insulin*: Determine the appropriate Afrezza dose for each meal by converting from the injected dose using Table 4.
- *Individuals Using Subcutaneous Pre-mixed Insulin*: Estimate the mealtime injected dose by dividing half of the total daily injected pre-mixed insulin dose equally among the three meals of the day. Convert each estimated injected mealtime dose to an appropriate Afrezza dose using Table 4. Administer half of the total daily injected pre-mixed dose as an injected basal insulin dose.

Table 1. Mealtime Afrezza Dose Conversion

Injected Mealtime Insulin Dose	Afrezza Dose	Number of cartridges needed		
		4 unit (blue cartridge)	8 unit (green cartridge)	12 unit (yellow cartridge)
Up to 4 units	4 units	1	0	0
5 - 8 units	8 units	0	1	0
9-12 units	12 units	1	1	1* (*if not using 4 and 8 unit cartridge)
13-16 units	16 units	0	2	0
17-20 units	20 units	0	1	1
21-24 units	24 units	0	0	2

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INHALED INSULIN

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

Mealtime Dose Adjustment

Similar to other mealtime insulin products, doses of Afrezza should be adjusted based on the individual's metabolic needs, blood glucose monitoring results and glycemic control goal. In addition, dosages may need to be adjusted, changes in physical activity, changes in meal patterns (i.e., macronutrient content or timing of food intake), changes in renal or hepatic function or during acute illness.

In patients on high doses of Afrezza, the use of subcutaneous mealtime insulin should be considered if blood glucose control is not achieved.

REFERENCES

Afrezza [Prescribing Information]. Danbury, CT: Mankind Corporation. February 2020.

Created: 10/15
Effective: 05/13/22 Client Approval: 04/22/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

INOSITOL

Generic	Brand	HICL	GCN	Exception/Other
INOSITOL	INOSITOL		25383 25384	

GUIDELINES FOR USE

Our guideline for **INOSITOL** requires that both the patient and the prescriber are participating in the Genomind genetic testing pilot study and that the prescriber has stated that genetic testing results demonstrate the need for Inositol therapy.

RATIONALE

The intent of this prior authorization is to allow members participating in the Genomind genetic testing pilot study to receive Inositol based upon genetic test results.

Created: 05/16
Effective: 06/01/16 Client Approval: 05/18/16 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

INOTERSEN

Generic	Brand	HICL	GCN	Exception/Other
INOTERSEN SODIUM	TEGSEDI	45353		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **INOTERSEN (Tegsedi)** requires the following rule(s) be met for approval:

A. You have hereditary transthyretin-mediated amyloidosis (hATTR: a disorder with build-up of a type of protein causing your body to not work properly) with polyneuropathy (widespread nerve pain/damage)
B. You are 18 years of age or older
C. You have stage 1 or 2 polyneuropathy
D. You have a documented diagnosis of hereditary TTR amyloidosis (hATTR) as confirmed by **ONE** of the following:
    1. Biopsy (surgical sample) of tissue/organ to confirm amyloid presence **AND** chemical typing to confirm presence of TTR (Transthyretin) protein
    2. DNA genetic sequencing to confirm hATTR mutation

RENEWAL CRITERIA

Our guideline named **INOTERSEN (Tegsedi)** requires the following rule(s) be met for renewal:

A. You have hereditary transthyretin-mediated amyloidosis (hATTR: a disorder with build-up of a type of protein causing your body to not work properly) with polyneuropathy (widespread nerve pain/damage)
B. You have not progressed to stage 3 polyneuropathy (widespread nerve pain/damage) as shown by functional decline such as being wheelchair-bound or bedridden

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RATIONALE
Promote appropriate utilization of INOTERSEN based on clinical trial patient inclusion and FDA approved indication and dosing.

FDA APPROVED INDICATIONS
TEGSEDI is a transthyretin-directed antisense oligonucleotide indicated for treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.

NOTE: Tegsedi is available only through a restricted distribution program called the TEGSEDI REMS Program. Prescribers must be certified within the program by enrolling and completing training. Patients must enroll in the program and comply with ongoing monitoring requirements (platelet count and kidney function every 1 to 2 weeks or more frequently). Pharmacies must be certified with the program and must only dispense to patients who are authorized to receive Tegsedi.

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INOTERSEN

FDA APPROVED INDICATIONS (CONTINUED)

DOSING AND ADMINISTRATION
The recommended dosage is 284 mg administered by subcutaneous injection once weekly. Laboratory tests must be measured prior to treatment, continue to be monitored after treatment initiation, and for 8 weeks following discontinuation of treatment, as directed.

REFERENCES
Inotersen [Prescribing Information]. Carlsbad, CA: Ionis Pharmaceuticals, Inc.; May 2021.

Created: 12/18
Effective: 03/21/22 Client Approval: 02/17/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

INTERFERON AGENTS

Generic	Brand	HICL	GCN	Exception/Other
PEGINTERFERON ALFA-2A	PEGASYS PEGASYS PROCLICK	24035		
INTERFERON ALFA-2B,RECOMB	INTRON A	04528		

These requests require These requests will be reviewed by a pharmacist.

GUIDELINES FOR USE

The guideline for **INTERFERON AGENTS** excludes treatment for hepatitis C. Coverage will be provided for INTRON A for the following diagnoses: hairy cell leukemia; condylomata acuminate; AIDS-related Kaposi's sarcoma; chronic hepatitis B; malignant melanoma; and follicular lymphoma. Coverage will be provided for Pegasys for patients aged 18 years and older with chronic hepatitis B infection currently supervised by a gastroenterologist, infectious disease specialist or a physician specializing in the treatment of hepatitis (e.g. hepatologist).

FDA APPROVED INDICATIONS

INTRON A (Interferon alfa-2b) is indicated for treatment of hairy cell leukemia, condylomata acuminata, AIDS-related Kaposi's sarcoma, hepatitis C (in combination), malignant melanoma, follicular lymphoma and chronic hepatitis B.

PEGASYS (peg-interferon alfa-2a) alone or in combination with COPEGUS (ribavirin) is indicated for the treatment of adults with chronic hepatitis C virus infection who have compensated liver disease and have not been previously treated with interferon or peginterferon alfa.

PEGASYS is also indicated for treatment of adults with chronic hepatitis C virus infection in patients with HIV/HCV co-infection.

PEGASYS is also indicated for treatment of adults with HBeAg positive and negative chronic hepatitis B who have compensated liver disease and evidence of viral replication and inflammation.

REFERENCES

- Intron A Product Information. Whitehouse Station, NJ: Merck & Co., Inc. February 2016.
- Pegasys Product Information. Nutley, NJ: Hoffman-La Roche, Inc. March 2015.

Created: 06/15
Effective: 06/17/17 Client Approval: 05/16/17 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

INTERFERON GAMMA-1B, RECOMB

Generic	Brand	HICL	GCN	Exception/Other
INTERFERON GAMMA-1B,RECOMB.	ACTIMMUNE	06068		

GUIDELINES FOR USE

Our guideline named **INTERFERON GAMMA-1B, RECOMB (Actimmune)** requires the following rules be met for approval:

A. You have ONE of the following diagnoses:
   1. Chronic granulomatous disease (CGD: inherited immune system disorder that occurs when a type of white blood cells that usually helps your body fight infections does not work properly)
   2. Severe malignant osteopetrosis (SMO: a bone disease that makes bone abnormally thick and prone to breakage/fracture)
   3. Mycosis fungoides/Sezary syndrome (MF/SS)

B. **If you have mycosis fungoides/Sezary syndrome (MF/SS), approval also requires:**
   1. You have not responded to skin-directed therapy (e.g., ultraviolet therapy, topical corticosteroids, topical retinoids, topical imiquimod)

RATIONALE

To ensure appropriate use of Actimmune based on FDA approved indications as well as clinical guidelines.

The National Comprehensive Cancer Network Practice Guidelines in Oncology recommend IFN-gamma as a Category A systemic treatment for mycosis fungoides/Sezary syndrome.

FDA APPROVED INDICATIONS

Actimmune is a recombinant form of interferon gamma indicated for:

- Reducing the frequency and severity of serious infections associated with Chronic Granulomatous Disease (CGD)
- Delaying time to disease progression in patients with severe, malignant osteopetrosis (SMO)

DOSAGE AND ADMINISTRATION

The recommended dose of Actimmune is 50 mcg/m^2 for patients whose body surface area is greater than 0.5 m^2 and 1.5 mcg/kg/dose for patients whose body surface area is equal to or less than 0.5 m^2 three times weekly. Higher doses (i.e., greater than 50 mcg/m^2) are not recommended.

REFERENCES

- Actimmune [Prescribing Information]. Lake Forest, IL: Horizon Pharma USA, Inc. March 2021.
- National Comprehensive Cancer Network. NCCN Practice Guidelines in Oncology. Non-Hodgkin's Lymphoma. Version 4.2014. Accessed February 20, 2018.

Created: 02/18
Effective: 04/11/22 Client Approval: 03/09/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

INTERFERONS FOR MULTIPLE SCLEROSIS

Generic	Brand	HICL	GCN	Exception/Other
INTERFERON BETA-1A	AVONEX, AVONEX PEN	11253		
INTERFERON BETA-1A/ALBUMIN	AVONEX ADMINISTRATION PACK, REBIF, REBIF REBIDOSE		23230, 15914, 15918, 24286, 34166, 34167, 34168	
INTERFERON BETA-1B	BETASERON, EXTAVIA	08537		
PEGINTERFERON BETA-1A	PLEGRIDY	41331		

GUIDELINES FOR USE

Our guideline for **INTERFERONS FOR MULTIPLE SCLEROSIS** requires a diagnosis of multiple sclerosis (MS).
For Betaseron, Extavia, and Plegridy, our guideline also requires ALL of the following:

- The patient has a relapsing form of multiple sclerosis to include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease
- The patient is 18 years of age or older
- The patient has had a previous trial of any **TWO** of the following preferred agents for MS: Avonex, Rebif, Copaxone, Tecfidera, Gilenya, or Aubagio

RATIONALE

Ensure appropriate utilization criteria are met for the management of requests for interferons used in the treatment of multiple sclerosis.

FDA APPROVED INDICATIONS

Avonex, Betaseron, Extavia, Plegridy, and Rebif are indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

DOSING

The recommended dose of Avonex is 30 micrograms once a week. To reduce the incidence and severity of flu-like symptoms that may occur when initiating Avonex therapy at a dose of 30 micrograms, Avonex may be started at a dose of 7.5 micrograms and the dose may be increased by 7.5 micrograms each week for the next three weeks until the recommended dose of 30 micrograms is achieved.

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INTERFERONS FOR MULTIPLE SCLEROSIS

FDA APPROVED INDICATIONS (CONTINUED)

DOSING

The recommended starting dose of Betaseron is 0.0625 mg (0.25 mL) subcutaneously every other day, with dose increases over a six-week period to the recommended dose of 0.25 mg (1 mL) every other day.

The recommended starting dose of Extavia is 0.0625 mg (0.25 mL) subcutaneously every other day, with dose increases over a six-week period to the recommended dose of 0.25 mg (1 mL) every other day.

After initial titration, the recommended dosage of Plegridy is 125 micrograms injected every 14 days. Patients using Plegridy for the first time should start treatment with 63 micrograms on day 1. On day 15 (14 days later), the dose is increased to 94 micrograms, reaching the full dose of 125 micrograms on day 29 (after another 14 days). Patients continue with the full dose (125 micrograms) every 14 days thereafter.

The recommended dose of Rebif is either 22 mcg or 44 mcg injected subcutaneously three times per week. Generally, patients should be started at 20% of the prescribed dose three times per week and increased over a 4-week period to the targeted dose, either 22 mcg three times per week or 44 mcg three times per week.

REFERENCES

- Rebif [Prescribing Information]. Rockland, MA: EMD Serono; October 2020.
- Avonex [Prescribing Information]. Cambridge, MA: Biogen Idec; March 2020.
- Betaseron [Prescribing Information]. Whippany, NJ: Bayer; March 2021.
- Extavia [Prescribing Information]. East Hanover, NJ: EMD Novartis; October 2020.
- Plegridy [Prescribing Information]. Cambridge, MA: Biogen Idec; March 2022.

Created: 03/15
Effective: 08/08/22 Client Approval: 07/13/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ISTRADEFYLLINE

Generic	Brand	HICL	GCN	Exception/Other
ISTRADEFYLLINE	NOURIANZ	45994		

GUIDELINES FOR USE

The guideline named **ISTRADEFYLLINE (Nourianz)** requires a diagnosis of Parkinson's disease (PD). In addition, the following criteria must be met:

- The patient is 18 years of age or older
- The patient is experiencing "off" episodes
- Nourianz will be used as adjunctive treatment to levodopa/carbidopa in patients experiencing "off" episodes
- The patient had a previous trial of, or contraindication to **TWO** Parkinson's agents from two different therapeutic classes: dopamine agonists (e.g., ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitors (e.g., selegiline, rasagiline), or catechol-O-methyl transferase inhibitors (e.g., entacapone, tolcapone)

RATIONALE

To ensure safe and appropriate use of istradefylline per approved indication and dosing.

FDA APPROVED INDICATIONS

Istradefylline is an adenosine receptor antagonist indicated as adjunctive treatment to levodopa/carbidopa in adult patients with Parkinson's disease (PD) experiencing "off" episodes.

DOSAGE AND ADMINISTRATION

The recommended dosage of istradefylline is 20 mg orally once daily. The dosage may be increased to a maximum of 40 mg once daily if needed.

REFERENCES

Nourianz [Prescribing Information]. Bedminster, NJ: Kyowa Kirin, Inc.; September 2019.

Created: 11/19
Effective: 07/01/20 Client Approval: 05/12/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ITRACONAZOLE - TOLSURA

Generic	Brand	HICL	GCN	Exception/Other
ITRACONAZOLE	TOLSURA		45848	

GUIDELINES FOR USE

Our guideline for **ITRACONAZOLE (Tolsura)** requires that the patient is 18 years of age or older. In addition, the patient must have **ONE** of the following diagnoses:

- Blastomycosis, pulmonary and extrapulmonary
- Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, nonmeningeal histoplasmosis
- Aspergillosis, pulmonary and extrapulmonary, AND the patient is intolerant or refractory to amphotericin B therapy

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tolsura.

REFERENCES

Tolsura [Prescribing Information]. Greenville, NC: Mayne Pharma; December 2018.

Created: 01/19
Effective: 03/18/19 Client Approval: 02/15/19 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

IVABRADINE

Generic	Brand	HICL	GCN	Exception/Other
IVABRADINE	CORLANOR	33396	26238, 26239, 46204	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline for **IVABRADINE** requires a diagnosis of heart failure. In addition, the following criteria must also be met:

For patients with heart failure:

- Patient is 18 years of age or older
- NYHA Class II - IV Heart failure
- Left ventricular ejection fraction of 35% or less
- Patient is in sinus rhythm (e.g., patient does not have atrial fibrillation, sick sinus syndrome, sinoatrial block, or 2nd or 3rd degree AV block unless a functioning demand pacemaker is present)
- Resting heart rate $\geqslant$ 70 beats per minute
- Patient does not have a demand pacemaker that is set to a rate of 60 beats per minute or greater
- Patient is currently being treated with or has an intolerance to one of the following beta-blockers: metoprolol succinate, bisoprolol, or carvedilol

For patients with heart failure due to dilated cardiomyopathy:

- Patient is 6 months to 18 years of age
- Patient is in sinus rhythm (e.g., patient does not have atrial fibrillation, sick sinus syndrome, sinoatrial block)
- Patient has an elevated resting heart rate

In addition, requests for Corlanor solution in patients greater than 12 years of age require **BOTH** of the following:

- The patient has had a trial of Corlanor tablets
- Physician attestation of medical need for Corlanor solution

RENEWAL CRITERIA

Our guideline for **IVABRADINE** renewal requires a diagnosis of heart failure. In addition, the following criteria must also be met:

- Patient is in sinus rhythm (for example, patient does not have atrial fibrillation, sick sinus syndrome, sinoatrial block, or 2nd or 3rd degree AV block unless a functioning demand pacemaker is present)

In addition, requests for Corlanor solution in patients greater than 12 years of age require **BOTH** of the following:

- The patient has had a trial of Corlanor tablets
- Physician attestation of medical need for Corlanor solution

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

IVABRADINE

RATIONALE
Promote appropriate utilization of ivabradine based on FDA approved indication.

FDA APPROVED INDICATIONS
Corlanor (ivabradine) is a hyperpolarization-activated cyclic nucleotide-gated channel blocker indicated:
- To reduce the risk of hospitalization for worsening heart failure in adult patients with stable, symptomatic chronic heart failure with a reduced left ventricular ejection fraction
- For the treatment of stable symptomatic heart failure due to dilated cardiomyopathy in pediatric patients ages 6 months and older

DOSING
Adult and pediatric patients greater than 40 kg:
Starting dose is 2.5 (pediatrics and vulnerable adults) or 5 mg twice daily with food. After 2 weeks of treatment, adjust dose based on heart rate. The maximum dose is 7.5 mg twice daily.

Pediatric patients less than 40 kg:
Starting dose is 0.05 mg/kg twice daily with food. Adjust dose at two-week intervals by 0.05 mg/kg based on heart rate. Maximum dose is 0.2 mg/kg (patients 6 months to less than 1 year old) or 0.3 mg/kg (patients 1 year old and older), up to a total of 7.5 mg twice daily.

REFERENCES

- Corlanor [Prescribing Information]. Thousand Oaks, California. Amgen, Inc. August 2021.
- Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: A report of the American College of Cardiology Foundation/American Heart Association task force on practice guidelines. Circulation. 2013;128:e240-e327.

Created: 01/16
Effective: 03/14/22 Client Approval: 02/04/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

IVOSIDENIB

Generic	Brand	HICL	GCN	Exception/Other
IVOSIDENIB	TIBSOVO	45096		

GUIDELINES FOR USE

Our guideline named **IVOSIDENIB (Tibsovo)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Acute myeloid leukemia (AML: blood and bone marrow cancer with too many white blood cells)
   2. Locally advanced or metastatic cholangiocarcinoma (bile duct cancer that spreads or returns after treatment)

B. **If you have relapsed or refractory acute myeloid leukemia (AML: type of blood and bone marrow cancer that returns after treatment), approval also requires:**
   1. You have a susceptible isocitrate dehydrogenase-1 (IDH1; type of enzyme) mutation as detected by an FDA (Food and Drug Administration)-approved diagnostic test
   2. You are 18 years of age or older

C. **If you have a new diagnosis of acute myeloid leukemia (AML: type of blood and bone marrow cancer), approval also requires:**
   1. You have a susceptible isocitrate dehydrogenase-1 (IDH1; type of enzyme) mutation as detected by an FDA (Food and Drug Administration)-approved diagnostic test
   2. You meet **ONE** of the following criteria:
      a. You are 75 years of age or older
      b. You are 18 years of age or older **AND** have comorbidities (additional diseases) that prevent the use of intensive induction chemotherapy

D. **If you have locally advanced or metastatic cholangiocarcinoma (bile duct cancer that spreads or returns after treatment), approval also requires:**
   1. You have a susceptible isocitrate dehydrogenase-1 (IDH1; type of enzyme) mutation as detected by an FDA (Food and Drug Administration)-approved diagnostic test
   2. You are 18 years of age or older
   3. You have previously been treated for cholangiocarcinoma (bile duct cancer)

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

IVOSIDENIB

RATIONALE
Promote appropriate utilization of **IVOSIDENIB** based on FDA approved indication and dosage.

FDA APPROVED INDICATIONS
Tibsovo is an isocitrate dehydrogenase-1 (IDH1) inhibitor indicated for the treatment of adult patients with a susceptible IDH1 mutation as detected by an FDA-approved test with:

Acute Myeloid Leukemia (AML)
- Newly-diagnosed AML who are ≥ 75 years old or who have comorbidities that preclude use of intensive induction chemotherapy
- Relapsed or refractory AML

Locally Advanced or Metastatic Cholangiocarcinoma
- Locally advanced or metastatic cholangiocarcinoma who have previously been treated

DOSAGE AND ADMINISTRATION
The recommended dose of Tibsovo is 500 mg orally once daily with or without food until disease progression or unacceptable toxicity. Patients taking Tibsovo should avoid a high-fat meal with dose.

REFERENCES

- Tibsovo [Prescribing Information]. Cambridge, MA: Agios Pharmaceuticals; August 2021.

Created: 08/18
Effective: 09/27/21 Client Approval: 09/13/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

IXAZOMIB

Generic	Brand	HICL	GCN	Exception/Other
IXAZOMIB	NINLARO	42826		

GUIDELINES FOR USE

Our guideline for **IXAZOMIB** (Ninlaro) requires a diagnosis of multiple myeloma and that it be used in combination with lenlidomide and dexamethasone in patients who have received at least one prior therapy such as bortezomid, carfilzomib, thalidomide, lenalidomide, melphalan or stem cell transplantation.

RATIONALE

Promote appropriate utilization of ixazomib (Ninlaro) based on FDA approved indication.

Ninlaro, in combination with lenalidomide and dexamethasone offers the first all-oral treatment option for patients with relapsed and/or refractory multiple myeloma (RRMM). According to the National Cancer Institute (NCI), MM is the third most common blood cancer (after lymphoma and leukemia) in the United States. NCI estimates there will be 26,850 new cases of multiple myeloma and 11,240 related deaths in the US this year.

Standard treatment options for MM include proteasome inhibitors (Velcade [bortezomib], Kyprolis [carfilzomib]), immunomodulators (IMiDs) (Revlimid [lenalidomide], Thalomid [thalidomide], Pomalyst [pomalidomide]), alkylating agents (Alkeran [melphalan], Cytoxan [cyclophosphamide]), anthracyclines (Doxil [liposomal doxorubicin]), and corticosteroids (dexamethasone). Regimens may contain two or three drug combinations, with selected patients undergoing hematopoietic cell transplantation (HCT).

The most recent NCCN guidelines do not yet address the use of Ninlaro for the treatment of RRMM. While ongoing studies are evaluating Ninlaro for newly diagnosed MM, current labeling for Ninlaro requires at least one prior line of therapy, as the FDA approval was based only on patients with RRMM. Although Ninlaro has the convenience of an all-oral regimen, it should be reserved for patients who have progressed on currently recommended regimens.

The efficacy of Ninlaro was evaluated in a phase 3, randomized, double-blind, placebo-controlled, multicenter trial (Tourmaline-MM1) in 722 patients with RRMM. Patients had to receive at least one prior line of therapy (60-62% received one, 38-40% received two or three), but patients who were refractory to lenalidomide or PIs (e.g., Velcade) were excluded from the study. The most common types of prior therapy included melphalan-containing (80-81%), bortezomib-containing (69%), thalidomide-containing (44-47%), and stem cell transplantation (55-59%). Other prior therapies included lenalidomide-containing and carfilzomib containing regimens.

FDA APPROVED INDICATION

Indicated in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

IXAZOMIB

DOSAGE

The recommended starting dose of Ninlaro (ixazomib) is 4mg taken orally on Days 1, 8, and 15 of a 28-day cycle. Treatment should be continued until disease progression or unacceptable toxicity.

The dose may be reduced due to adverse reactions as shown in the table below.

Recommended starting dose	First reduction to	Second reduction to	Discontinue
4mg	3mg	2.3mg	

REFERENCES

Ninlaro [Prescribing Information]. Takeda Pharmaceutical Company Limited. Cambridge, MA 02139

Created: 01/16
Effective: 02/04/16 Client Approval: 01/15/16 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

IXEKIZUMAB

Generic	Brand	HICL	GCN	Exception/Other
IXEKIZUMAB	TALTZ	43193		

GUIDELINES FOR USE
INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **IXEKIZUMAB (Taltz)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Non-radiographic axial spondyloarthritis (nr-axSpA: type of inflammation in the spine that does not show any visible damage on X-rays)

B. **If you have moderate to severe plaque psoriasis (PsO), approval also requires:**
   1. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
   2. You have previously tried ONE of the following preferred therapies: PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
   3. ONE of the following:
      a. You are 6 to 17 years of age and you have previously tried Cosentyx or Enbrel
      b. You are 18 years of age or older and you have previously tried TWO of the following: Cosentyx, Enbrel, or Humira

C. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. You have previously tried at least ONE of the following DMARDs (disease-modifying antirheumatic drugs): methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   3. You have previously tried TWO of the following: Cosentyx, Enbrel, or Humira

D. **If you have ankylosing spondylitis (AS), approval also requires:**
   1. You are 18 years of age or older
   2. You have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
   3. You have previously tried TWO of the following: Cosentyx, Enbrel, or Humira

E. **If you have non-radiographic axial spondyloarthritis (nr-axSpA), approval also requires:**
   1. You are 18 years of age or older
   2. You have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
   3. You have previously tried Cosentyx
   4. You have ONE of the following signs of inflammation:
      a. C-reactive protein (CRP; a measure of how much inflammation you have) levels above the upper limit of normal
      b. Sacroiliitis (type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI)

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IXEKIZUMAB

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **IXEKIZUMAB (Taltz)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Non-radiographic axial spondyloarthritis (nr-axSpA: type of inflammation in the spine that does not show any visible damage on X-rays)

B. You have experienced or maintained symptomatic improvement while on therapy

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RATIONALE

Ensure appropriate diagnostic, utilization and safety criteria are used for the management of requests for ixekizumab.

INDICATIONS

Taltz is indicated for the treatment of:

- Patients 6 years of age and older with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.
- Adult patients with active psoriatic arthritis.
- Adult patients with active ankylosing spondylitis.
- Adult patients with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation.

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IXEKIZUMAB

RATIONALE (CONTINUED)

DOSING

Adult Plaque Psoriasis

- Administer by subcutaneous injection.
- The recommended dose is 160 mg (two 80 mg injections) at Week 0, followed by 80 mg at Weeks 2, 4, 6, 8, 10, and 12, then 80 mg every 4 weeks.

Pediatric Plaque Psoriasis

- Administer by subcutaneous injection every 4 weeks.
- The recommended dose is based on the weight categories in Table 1.

Table 1: Recommended Dosing and Administration for Pediatric Patients

Patient Weight	Starting Dose (Week 0)	Dose Every 4 Weeks (Q4W) Thereafter
Greater than 50 kg	160 mg (two 80 mg injections)	80 mg
25 to 50 kg	80 mg	40 mg
Less than 25 kg	40 mg	20 mg

Psoriatic Arthritis

- The recommended dose is 160 mg by subcutaneous injection (two 80 mg injections) at Week 0, followed by 80 mg every 4 weeks.
- For psoriatic arthritis patients with coexistent moderate-to-severe plaque psoriasis, use the dosing regimen for plaque psoriasis.
- Taltz may be administered alone or in combination with a conventional DMARD (e.g., methotrexate).

Ankylosing Spondylitis

- The recommended dose is 160 mg by subcutaneous injection (two 80 mg injections) at Week 0, followed by 80 mg every 4 weeks.

Non-radiographic Axial Spondyloarthritis

- The recommended dose is 80 mg by subcutaneous injection every 4 weeks.

DOSAGE FORMS AND STRENGTHS

Taltz prefilled autoinjector:

- NDC 00002-1445-11: Carton of one 80 mg/mL single-dose prefilled autoinjector
- NDC 00002-1445-27: Carton of two 80 mg/mL single-dose prefilled autoinjector
- NDC 00002-1445-09: Carton of three 80 mg/mL single-dose prefilled autoinjector

Taltz prefilled syringe:

- NDC 00002-7724-11: Carton of one 80 mg/mL single-dose prefilled syringe

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

IXEKIZUMAB

REFERENCES

- Taltz [Prescribing Information]. Eli Lilly and Company: Indianapolis, IN: May 2020.
- Braun J, Davis J, et al. First update of the international ASAS consensus statement for the use of anti-TNF agents in patients with Ankylosing Spondylitis. Ann Rheum Dis. 2006; 65(3):316-20.
- Menter A, Strober BE, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.
- Singh JA, Guyatt G, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Care & Research. Vol. 71, No. 1, January 2019, pp 2–29DOI 10.1002/acr.2378.

Created: 05/16
Effective: 04/11/22 Client Approval: 03/09/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

LANADELUMAB

Generic	Brand	HICL	GCN	Exception/Other
LANADELUMAB-FLYO	TAKHZYRO	45177		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named **LANADELUMAB (Takhzyro)** requires a diagnosis of hereditary angioedema (HAE). Additionally, the following criteria must be met:

- Diagnosis of HAE is confirmed via complement testing
- The medication is being used for prophylaxis to prevent HAE attacks
- The patient is 12 years of age or older
- The medication is prescribed by or in consultation with an allergist/immunologist or hematologist

RENEWAL CRITERIA

The guideline named **LANADELUMAB (Takhzyro)** requires a diagnosis of hereditary angioedema (HAE) for renewal. The following criteria must also be met.

- Physician attestation of improvement (i.e., reductions in attack frequency or attack severity) compared to baseline in HAE attacks with routine prophylaxis

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RATIONALE

Ensure appropriate utilization of LANADELUMAB (Takhzyro) based on FDA-approved indication and clinical trial design.

FDA APPROVED INDICATION

Takhzyro is a plasma kallikrein inhibitor (monoclonal antibody) indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in patients 12 years and older.

DOSING & ADMINISTRATION

The recommended starting dosage of Takhzyro is 300 mg given subcutaneously every 2 weeks. A dosing interval of 300 mg every 4 weeks is also effective and may be considered if the patient is well-controlled (e.g., attack-free) for more than 6 months.

Takhzyro should be administered subcutaneously into the abdomen, thigh, or upper arm and is provided as a ready-to-use solution in a single-dose vial that does not require additional reconstitution or dilution for administration. Takhzyro is intended for self-administration or administration by a caregiver, following training by a healthcare professional. In clinical studies, the majority of patients self-administered Takhzyro over 10 to 60 seconds.

REFERENCES

- Takhzyro [Prescribing Information]. Lexington, MA: Dyax Corp.; August 2018.

Created: 11/18
Effective: 11/23/18 Client Approval: 11/06/18 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

LANREOTIDE ACETATE

Generic	Brand	HICL	GCN	Exception/Other
LANREOTIDE ACETATE	SOMATULINE DEPOT	10781		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

Approval for Somatuline Depot requires a diagnosis of acromegaly with the failure to be treated with one of the following or the inability to be treated with any of the following: surgical resection, pituitary irradiation, or bromocriptine mesylate at maximally tolerated doses; a diagnosis of unresectable, well- or moderately-differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs); or a diagnosis of carcinoid syndrome.

LANREOTIDE ACETATE

RATIONALE
To ensure appropriate use of Somatuline Depot based on FDA approved indications and dosing.

FDA APPROVED INDICATIONS
SOMATULINE DEPOT mimics natural somatostatin and is indicated for:

- The long-term treatment of acromegalic patients who have had an inadequate response to or cannot be treated with surgery and/or radiotherapy.
- The treatment of adult patients with unresectable, well- or moderately-differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival.
- The treatment of adults with carcinoid syndrome: when used, it reduces the frequency of short-acting somatostatin analog rescue therapy.

DOSING
Acromegaly: 90 mg every 4 weeks for 3 months. Adjust thereafter based on GH and/or IGF-1 levels. After 3 months, the dosage may be adjusted as follows:

- GH greater than 1 ng/mL to less than or equal to 2.5 ng/mL, IGF-1 normal, and clinical symptoms controlled: maintain SOMATULINE DEPOT dosage at 90 mg every 4 weeks.
- GH greater than 2.5 ng/mL, IGF-1 elevated, and/or clinical symptoms uncontrolled: increase SOMATULINE DEPOT dosage to 120 mg every 4 weeks.
- GH less than or equal to 1 ng/mL, IGF-1 normal, and clinical symptoms controlled: reduce SOMATULINE DEPOT dosage to 60 mg every 4 weeks.
- Thereafter, the dosage should be adjusted according to the response

GEP-NETs: 120 mg every 4 weeks.

Carcinoid Syndrome: 120 mg every 4 weeks. If patients are already being treated with SOMATULINE DEPOT for GEP-NET, do not administer an additional dose for carcinoid syndrome.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

LANREOTIDE

DOSAGE FORMS AND STRENGTHS

Somatuline Depot is supplied as 60mg/0.2mL, 90mg/0.3mL, and 120mg/0.5mL single dose prefilled syringes.

REFERENCES

- Somatuline Depot [package insert]. Basking Ridge, NJ: Ipsen Pharma Biotech. September 2017.

Created: 02/18
Effective: 06/01/18 Client Approval: 04/10/18 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

LAPATINIB

Generic	Brand	HICL	GCN	Exception/Other
LAPATINIB DITOSYLATE	TYKERB	34541		

GUIDELINES FOR USE

Approval criteria require concurrent treatment with Xeloda (capecitabine), Herceptin (trastuzumab), or Femara (letrozole) for patients with a diagnosis of HER2-positive breast cancer with estrogen/progesterone receptor-positive breast cancer; or a diagnosis of HER2-positive breast cancer in a patient with a previous trial of Herceptin (trastuzumab).

RATIONALE

To ensure that lapatinib is used in the appropriate patient population with HER2 positive breast cancer. Lapatinib in combination with capecitabine or trastuzumab is recommended for trastuzumab-exposed HER2 positive breast cancer. Lapatinib is recommended in combination with other chemotherapy for HER2 positive breast cancer that is either estrogen or progesterone receptor-positive or negative.

FDA APPROVED INDICATIONS

Tykerb is indicated in combination with:

- Capecitabine, for the treatment of patients with advanced or metastatic breast cancer whose tumors over express HER2 and who have received prior therapy including an anthracycline, a taxane, and trastuzumab.
- Letrozole, for the treatment of postmenopausal women with hormone receptor positive metastatic breast cancer that over expresses the HER2 receptor for whom hormonal therapy is indicated.

REFERENCES

- GlaxoSmithKline. Tykerb package insert. Research Triangle Park, NC. April, 2010.
- National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Breast Cancer v.2.2011
- Thomson Healthcare. Monograph Name. DRUGDEX® System [database online]. Greenwood Village, CO. Available at: https://www.thomsonhc.com/hcs/librarian/PFDefaultActionId/pf.LoginAction. [Accessed: June 27, 2011].

Created: 06/15
Effective: 07/22/15 Client Approval: 06/15 P&T Approval: 08/13

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

LAROTRECTINIB

Generic	Brand	HICL	GCN	Exception/Other
LAROTRECTINIB	VITRAKVI	45494		

GUIDELINES FOR USE
The guideline named **LAROTRECTINIB (Vitrakvi)** requires a diagnosis of a solid tumor. In addition, the following criteria must be met:

- The tumor has a neurotrophic receptor tyrosine kinase (*NTRK*) gene fusion without a known acquired resistance mutation
- The tumor is metastatic or surgical resection is likely to result in severe morbidity
- There are no satisfactory alternative treatments or the patient progressed following treatment

Requests for Vitrakvi oral solution also require that ONE of the following is met:

- The request is for a pediatric patient
- Physician attestation that the patient is unable to take Vitrakvi capsules due to difficulty swallowing or dysphagia
- Physician attestation that the patient has other medical need for the oral solution

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RATIONALE
Promote appropriate utilization and dosing of Vitrakvi for its FDA approved indication.

FDA APPROVED INDICATIONS
Vitrakvi is a kinase inhibitor indicated for the treatment of adult and pediatric patients with solid tumors that:

- Have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation
- Are metastatic or where surgical resection is likely to result in severe morbidity
- Have no satisfactory alternative treatments or that have progressed following treatment

This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

DOSAGE AND ADMINISTRATION

- Recommended dosage in adult and pediatric patients with body surface area of at least $1.0 m^2$: 100 mg orally twice daily
- Recommended dosage in pediatric patients with body surface area of less than $1.0 m^2$: 100 mg/m^2 orally twice daily

AVAILABLE STRENGTHS
Capsules: 25mg, 100mg Oral Solution: 20 mg/mL

REFERENCES
Vitrakvi [Prescribing Information]. Stamford, CT: Loxo Oncology, Inc: November 2018.

Created: 01/18
Effective: 01/01/20 Client Approval: 10/14/19 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

LASMIDITAN

Generic	Brand	HICL	GCN	Exception/Other
LASMIDITAN SUCCINATE	REYVOW	46082		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **LASMIDITAN (Reyvow)** requires the following rule(s) be met for approval:

- You are being treated for acute (quick onset) migraine
- You are 18 years of age or older
- You had a trial of TWO triptans (such as sumatriptan, rizatriptan), unless there is a medical reason why you cannot (contraindication)

RENEWAL CRITERIA

Our guideline named **LASMIDITAN (Reyvow)** requires the following rule(s) be met for renewal:

- You are being treated for acute (quick onset) migraine
- You have history of paid claim(s) for the requested medication in the past 90 days
- You have a previous authorization on file for the requested medication

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RATIONALE
To ensure appropriate diagnostic, utilization and safety criteria are used for the management of requests for lasmiditan.

FDA APPROVED INDICATIONS
Reyvow is a serotonin (5-HT) 1F receptor agonist indicated for the acute treatment of migraine with or without aura in adults.

DOSING
The recommended dose is 50 mg, 100 mg, or 200 mg taken orally as needed. No more than one dose should be taken in 24 hours, and Reyvow should not be taken unless the patient can wait at least 8 hours between dosing and driving or operating machinery. The maximum dose in a 24-hour period is 200 mg.

REFERENCES

- Reyvow [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC, January 2021.

Created: 03/20
Effective: 12/15/21 Client Approval: 10/21/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

LEFAMULIN

Generic	Brand	HICL	GCN	Exception/Other
LEFAMULIN	XENLETA		46826	

GUIDELINES FOR USE

The guideline named **LEFAMULIN (Xenleta)** requires a diagnosis of community-acquired bacterial pneumonia (CABP). In addition, the following criteria must be met:

- The patient is 18 years of age or older
- Infection is caused by any of the following susceptible microorganisms: *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae, Legionella pneumophila, Mycoplasma pneumoniae,* or *Chlamydophila pneumoniae*
- The patient meets **ONE** of the following criteria:
  - Therapy is prescribed by or given in consultation with an Infectious Disease (ID) specialist
  - Antimicrobial susceptibility test is available, and the infection site culture results indicate pathogenic organism(s) with 1) resistance to at least **TWO** standard of care agents for CABP (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone), **AND** 2) the culture is susceptible to Xenleta
  - Antimicrobial susceptibility test is unavailable, and the patient has had a trial of or contraindication to at least **TWO** standard of care agents for CABP (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid)

RATIONALE

To ensure safe and appropriate use of lefamulin per approved indication and dosing.

FDA APPROVED INDICATIONS

Lefamulin is a pleuromutilin antibacterial indicated for the treatment of adults with community-acquired bacterial pneumonia (CABP) caused by susceptible microorganisms. To reduce the development of drug resistant bacteria and maintain the effectiveness of Xenleta and other antibacterial drugs, Xenleta should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

DOSAGE AND ADMINISTRATION

For treatment of adults with CABP, the recommended dosage of XENLETA is as follows:

Dosage	Treatment Duration
150 mg every 12 hours by intravenous infusion over 60 minutes*	5 to 7 days
600 mg orally every 12 hours.	5 days

*With the option to switch to XENLETA Tablets 600 mg every 12 hours to complete treatment course.

REFERENCES

Xenleta [Prescribing Information]. Ireland DAC: Nabriva Therapeutics US, Inc.; August 2019.

Created: 11/19
Effective: 11/29/19 Client Approval: 11/06/19 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

LENALIDOMIDE

Generic	Brand	HICL	GCN	Exception/Other
LENALIDOMIDE	REVLIMID	33412		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

Our guideline for **LENALIDOMIDE (Revlimid)** requires one of the following diagnoses: multiple myeloma (MM), anemia due to a myelodysplastic syndrome (MDS), mantle cell lymphoma (MCL), follicular lymphoma (FL), or marginal zone lymphoma (MZL). The patient also must be 18 years of age or older. In addition, the following criteria must be met:

For patients with myelodysplastic syndrome (MDS), approval requires:

- The patient's MDS is associated with a deletion 5q abnormality

For patients with mantle cell lymphoma (MCL), approval requires:

- The patient has relapsed or progressed after at least two prior therapies, one of which included Velcade (bortezomib).

For patients with follicular lymphoma (FL), approval requires:

- The patient has previously been treated for follicular lymphoma (FL)
- The requested drug is being taken in combination with a rituximab product

For patients with marginal zone lymphoma (MZL), approval requires:

- The patient has previously been treated for marginal zone lymphoma (MZL)
- The requested drug is being taken in combination with a rituximab product

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RATIONALE

To ensure appropriate use aligned with FDA approved indications.

FDA APPROVED INDICATIONS

Revlimid is a thalidomide analogue indicated for the treatment of patients with:

- Multiple myeloma (MM), in combination with dexamethasone.
- Multiple Myeloma (MM) as maintenance following autologous hematopoietic stem cell transplantation (auto-HSCT).
- Transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q abnormality with or without additional cytogenetic abnormalities.
- Mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib.
- Previously treated follicular lymphoma (FL), in combination with a rituximab product.
- Previously treated marginal zone lymphoma (MZL), in combination with a rituximab product

Limitations of Use:
REVLIMID is not indicated and is not recommended for the treatment of patients with chronic lymphocytic leukemia (CLL) outside of controlled clinical trials.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

LENALIDOMIDE

DOSAGE AND ADMINISTRATION

- Multiple Myeloma (MM) combination therapy: 25 mg once daily orally on Days 1-21 of repeated 28-day cycles..
- Multiple Myeloma (MM) maintenance therapy following auto-HSCT: 10mg once daily continuously on Days 1-28 of repeated 28 day cycles.
- Myelodysplastic Syndrome (MDS): 10 mg once daily.
- Mantle Cell Lymphoma (MCL): 25 mg once daily orally on Days 1-21 of repeated 28-day cycles.
- Follicular Lymphoma (FL) or Marginal Zone Lymphoma (MZL): 20 mg once daily orally on Days 1-21 of repeated 28-day cycles for up to 12 cycles

REFERENCES

- Celgene Corporation. Revlimid package insert. Summit, NJ. May 2019.

Created: 06/15
Effective: 11/01/19 Client Approval: 10/17/19 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

LENVATINIB

Generic	Brand	HICL	GCN	Exception/Other
LENVATINIB MESYLATE	LENVIMA	41756		ROUTE = ORAL

GUIDELINES FOR USE

Our guideline named **LENVATINIB (Lenvima)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Differentiated thyroid cancer (DTC: cancer cells look/act like normal thyroid cells)
   2. Advanced renal cell cancer (RCC: kidney cancer)
   3. Unresectable hepatocellular carcinoma (HCC: liver cancer that cannot be removed by surgery)
   4. Advanced endometrial carcinoma (EC: type of cancer that starts in the uterus)

B. **If you have differentiated thyroid cancer (DTC), approval also requires:**
   1. Your thyroid cancer is locally recurrent or metastatic (cancer that has spread to other parts of the body)
   2. Your thyroid cancer is progressive (getting worse)
   3. You have tried radioactive iodine therapy, unless there is medical reason why you cannot (contraindication)

C. **If you have advanced renal cell cancer (RCC), approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. Lenvima will be used as first-line treatment in combination with pembrolizumab (Keytruda)
      b. Lenvima is used in combination with everolimus AND You have tried one prior anti-angiogenic therapy (treatment that stop tumors from growing their own blood vessels, such as Sutent [sunitinib], Votrient [pazopanib], Inlyta [axitinib], Nexavar [sorafenib])

D. **If you have unresectable hepatocellular carcinoma (HCC), approval also requires:**
   1. Lenvima is being used as a first-line treatment

E. **If you have advanced endometrial carcinoma (EC), approval also requires:**
   1. Lenvima is used in combination with pembrolizumab (Keytruda)
   2. You do not have microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) biomarkers (characteristics that help determine what type of cancer you have and what treatment options there are for it)
   3. You have experienced disease progression following prior systemic therapy (disease has worsened after previous therapy)
   4. You are not a candidate for curative surgery or radiation

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

LENVATINIB

RATIONALE
Promote appropriate utilization of Lenvima based on FDA approved indication and dosing.

FDA APPROVED INDICATIONS
LENVIMA is a kinase inhibitor that is indicated:

- For the treatment of patients with locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer (DTC)
- In combination with pembrolizumab, for the first line treatment of adult patients with advanced renal cell carcinoma (RCC)
- In combination with everolimus, for the treatment of patients with advanced renal cell carcinoma (RCC) following one prior anti-angiogenic therapy
- For the first-line treatment of patients with unresectable hepatocellular carcinoma (HCC)
- For the treatment of patients with advanced endometrial carcinoma (EC) that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) who have disease progression following prior systemic therapy and are not candidates for curative surgery or radiation

DOSAGE AND ADMINISTRATION
Single Agent Therapy:

- DTC: The recommended dosage is 24 mg orally once daily.
- HCC: The recommended dosage is based on actual body weight: 12 mg orally once daily for patients greater than or equal to 60 kg or 8 mg orally once daily for patients less than 60 kg.

Combination Therapy:

- EC: The recommended dosage is 20 mg orally once daily in combination with pembrolizumab 200 mg administered as an intravenous infusion over 30 minutes every 3 weeks.
- RCC: The recommended dosage is:
  - 20 mg orally once daily with pembrolizumab 200 mg administered as an intravenous infusion over 30 minutes every 3 weeks.
  - 18 mg orally once daily with everolimus 5 mg orally once daily

REFERENCES

- Lenvima [Prescribing Information]. Woodcliff Lake, NJ: Eisai, Inc. August 2021.

Created: 05/15
Effective: 01/01/22 Client Approval: 11/30/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

LETERMOVIR

Generic	Brand	HICL	GCN	Exception/Other
LETERMOVIR	PREVYMIS		44049 44061	

GUIDELINES FOR USE

The guideline named **LETERMOVIR PO (Prevymis)** requires the patient to be undergoing an allogeneic hematopoietic stem cell transplant (HSCT). In addition, the following criteria must also be met.

- The patient is at least 18 years of age or older.
- The patient is CMV-seropositive [R+]
- Prevymis will be used for prophylaxis of cytomegalovirus (CMV) infection and disease.
- Prevymis will be initiated between Day 0 and Day 28 post-transplantation (before or after engraftment)
- Patient is not receiving the medication beyond 100 days post-transplantation

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RATIONALE
Promote appropriate utilization of **LETERMOVIR** based on FDA approved indication and dosing.

FDA APPROVED INDICATION
Prevymis is indicated for prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT).

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

LETERMOVIR

DOSAGE AND ADMINISTRATION

The recommended dosage of Prevymis is 480 mg administered orally or intravenously once daily. Prevymis is recommended to be initiated between Day 0 and Day 28 post-transplantation (before or after engraftment), and continue through Day 100 post-transplantation. Dosage of Prevymis should be decreased to 240mg once daily when co-administered with cyclosporine.

- If cyclosporine is initiated after starting Prevymis, the next dose of Prevymis should be decreased to 240mg once daily.
- If cyclosporine is discontinued after starting Prevymis, the next dose of Prevymis should be increased to 480mg once daily.
- If cyclosporine dosing is interrupted due to high cyclosporine levels, no dose adjustment of Prevymis is needed.

Prevymis injection, which contains hydroxypropyl betadex, should be used only in patients unable to take oral therapy. Patients should be switched to oral Prevymis as soon as they are able to take oral medications. Prevymis tablet and injection may be used interchangeably at the discretion of the physician, and no dosage adjustment is necessary when switching formulations.

AVAILABLE STRENGTHS

Tablet: 240mg, 480mg tablets; Injection: 240mg/12 mL (20mg/mL), 480mg/24mL (20mg/mL) single dose vials

REFERENCES

- Prevymis [Prescribing Information]. Merck & Co, Inc.; Whitehouse Station, NJ. November 2017.

Created: 12/17
Effective: 02/02/18 Client Approval: 12/28/17 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

LEVODOPA

Generic	Brand	HICL	GCN	Exception/Other
LEVODOPA	INBRIJA	01897		ROUTE = INHALATION

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named **LEVODOPA INHALATION (Inbrija)** requires the following rule(s) be met for approval:

A. You have Parkinson's disease (a nerve system disorder that affects movement)
B. Inbrija is being used for intermittent treatment of OFF episodes (times when you have symptoms return due to medication wearing off) associated with Parkinson's disease
C. You are currently being treated with carbidopa/levodopa
D. You are **NOT** currently taking more than 1600mg of levodopa per day
E. Your doctor has optimized drug therapy as evidenced by **BOTH** of the following:
    1. Change in levodopa/carbidopa dosing strategy or formulation
    2. Trial of or contraindication to (medical reason why you cannot use) at least **TWO** Parkinson's agents from **TWO** different classes of the following: dopamine agonist (such as ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitors (MAO-I) (such as selegiline, rasagiline), catechol-O-methyl transferase (COMT) inhibitors (such as entacapone, tolcapone), adenosine receptor antagonist A_{2A} (such as istradefylline)

RENEWAL CRITERIA
Our guideline named **LEVODOPA INHALATION (Inbrija)** requires the following rule(s) be met for renewal approval:

A. You have Parkinson's disease (a nerve system disorder that affects movement)
B. You had improvement with motor fluctuations during OFF episodes (times when you have symptoms return due to medication wearing off) with the use of Inbrija. Improvements can be in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair.

RATIONALE
To ensure safe and appropriate use of levodopa per approved indication and dosing and national treatment guidelines.

FDA APPROVED INDICATIONS
Inbrija is an aromatic amino acid indicated for the intermittent treatment of OFF episodes in patients with Parkinson's disease treated with carbidopa/levodopa.

DOSAGE AND ADMINISTRATION
Inbrija should be taken when symptoms of an OFF period start to return. The recommended dosage of Inbrija is oral inhalation of the contents of two 42 mg capsules (84 mg) as needed, up to 5 times a day. The maximum dose per OFF period is 84 mg, and the maximum daily dosage is 420 mg. Inbrija has been shown to be effective only in combination with carbidopa/levodopa.

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LEVODOPA

REFERENCES

Inbrija [Prescribing Information]. Ardsley, NY: Acorda Therapeutics, Inc., August 2020.

Created: 03/19
Effective: 03/14/22 Client Approval: 02/14/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

LEVOKETOCONAZOLE

Generic	Brand	HICL	GCN	Exception/Other
LEVOKETOCONAZOLE	RECORLEV	47743		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **LEVOKETOCONAZOLE (Recorlev)** requires the following rule(s) be met for approval:

A. You have Cushing's syndrome (a type of hormone disorder)
B. You are 18 years of age or older
C. You are not a candidate for surgery or surgery has not been curative
D. You have tried or have a contraindication (harmful for) to oral ketoconazole

RENEWAL CRITERIA

Our guideline named **LEVOKETOCONAZOLE (Recorlev)** requires the following rule(s) be met for renewal:

A. You have Cushing's syndrome (a type of hormone disorder)
B. You continue to have improvement of Cushing's syndrome (such as clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of your disease)

RATIONALE

Ensure appropriate diagnostic, utilization and safety criteria are met for the management of requests for levoketoconazole.

FDA APPROVED INDICATIONS

Recorlev is a cortisol synthesis inhibitor indicated for the treatment of endogenous hypercortisolemia in adult patients with Cushing's syndrome for whom surgery is not an option or has not been curative.

DOSING

Initiate dosage at 150 mg orally twice daily, with or without food. Titrate the dosage by 150 mg daily, no more frequently than every 2-3 weeks based on 24-hour urine free cortisol levels and patient tolerability. Monitor cortisol levels from at least two 24-hour urine free cortisol collections every 2-3 weeks until an adequate clinical response is achieved. The maximum recommended dosage is 1200 mg per day, administered as 600 mg twice daily. The dosage may be reduced to 150 mg once daily if needed for reasons of tolerability.

REFERENCES

Recorlev [Prescribing Information]. Chicago, IL: Xeris Pharmaceuticals, Inc.; January 2022.

Created: 02/22
Effective: 03/21/22 Client Approval: 02/18/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

LOMITAPIDE

Generic	Brand	HICL	GCN	Exception/Other
LOMITAPIDE	JUXTAPID	39883		

GUIDELINES FOR USE

INITIAL CRITERIA

The guideline named **LOMITAPIDE (Juxtapid)** requires a diagnosis of homozygous familial hypercholesterolemia (HoFH). The following criteria must also be met:

- The patient has a LDL-cholesterol level greater than or equal to 70 mg/dL while on maximally tolerated drug treatment
- The patient has had a previous trial of Repatha (evolocumab) unless the patient lacks functional LDL receptors

For statin tolerant patients, approval also requires the following:

- The patient meets **ONE** of the following criteria:
  - The patient has been taking a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) for a duration of at least 8 weeks, **OR**
  - The patient has been taking a maximally tolerated dose of any statin for a duration of at least 8 weeks given that the patient cannot tolerate a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
- The patient will continue statin treatment in combination with Juxtapid

For statin intolerant patients, approval also requires ONE of the following:

- The patient has an absolute contraindication to statin therapy (e.g., active decompensated liver disease, nursing female, pregnancy or plans to become pregnant, hypersensitivity reaction)
- The patient has complete statin intolerance as defined by severe and intolerable adverse effects (e.g., creatine kinase elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis, severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group) that have occurred with trials of at least two separate statins and have improved with the discontinuation of each statin

RENEWAL CRITERIA

The guideline named **LOMITAPIDE (Juxtapid)** renewal requires that the patient has had a LDL reduction of at least 30% from baseline after lomitapide therapy for 26 weeks. Patient must also be adherent to Juxtapid (lomitapide) and statin therapy (or Juxtapid and other lipid-lowering agent, if the patient is statin intolerant).

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

LOMITAPIDE

RATIONALE
To ensure appropriate use of Juxtapid based on FDA approved indication and current recommendations of experts and national treatment guidelines.

FDA APPROVED INDICATIONS
Juxtapid is indicated as an adjunct to a low-fat diet and other lipid lowering treatments, including LDL apheresis where available, to reduce low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apoB), and non-high-density lipoprotein cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH).

Limitations of Use:
- The safety and effectiveness of JUXTAPID have not been established in patients with hypercholesterolemia who do not have HoFH.
- The effect of JUXTAPID on cardiovascular morbidity and mortality has not been determined.

DOSAGE AND ADMINISTRATION
Initiate treatment at 5 mg once daily. Titrate dose based on acceptable safety/tolerability: increase to 10 mg daily after at least 2 weeks; and then, at a minimum of 4-week intervals, to 20 mg, 40 mg, and up to the maximum recommended dose of 60 mg daily.

Take once daily, whole, with water and without food, at least 2 hours after evening meal.

REFERENCES
Juxtapid [Prescribing Information]. Cambridge, MA: Aegerion Pharmaceuticals, Inc.; August 2017.

Created: 06/15
Effective: 03/04/22 Client Approval: 02/03/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

LOMUSTINE

Generic	Brand	HICL	GCN	Exception/Other
LOMUSTINE	GLEOSTINE	03900		

GUIDELINES FOR USE

The guideline named **LOMUSTINE (Gleostine)** requires a diagnosis of Hodgkin's Lymphoma or that the request is being used for the treatment of primary or metastatic brain tumors in patients who previously received appropriate surgical and/or radiotherapeutic procedures.

RATIONALE

To promote appropriate utilization of Gleostine based on FDA approved indication and NCCN guidelines

FDA APPROVED INDICATIONS

Gleostine is an alkylating drug indicated for the treatment of patients with: Brain tumors, primary and metastatic, following appropriate surgical and/or radiotherapeutic procedures and Hodgkin's lymphoma in combination with other chemotherapies, following disease progression with initial chemotherapy.

DOSING

The recommended dose of Gleostine in adult and pediatric patients is 130 mg/m^2 taken as a single oral dose every 6 weeks. Round doses to the nearest 5 mg. Give as a single oral dose and do not repeat for at least 6 weeks. Reduce dose to 100 mg/m^2 every 6 weeks in patients with compromised bone marrow function. Also reduce dose accordingly when using with other myelosuppressive drugs.

Perform weekly complete blood counts and withhold each subsequent dose for more than 6 weeks if needed until platelet counts recover to 100,000/mm^3 or greater and leukocytes recover to 4000/mm^3 or greater. Modify each dose of Gleostine according to the hematologic response of the preceding dose as described in the table below.

DOSING

Nadir After Prior Dose		Dose Adjustment
Leukocytes (/mm^3)	Platelets	
≥ 4,000	≥ 100,000	None
3,000-3,999	75,000-99,999	None
2,000-2,999	25,000-74,999	Reduce dose by 30%
<2,000	< 25,000	Reduce dose by 50%

REFERENCES

- Gleostine [Prescribing Information]. NextSource Biotechnology, LLC: Miami, FL; September 2018.
- National Comprehensive Cancer Network. NCCN Guidelines: Central Nervous System Cancers Version 1. 2017. Updated September 25, 2017. Available at: https://www.nccn.org/professionals/physician_gls/pdf/all.pdf. Accessed February 16, 2018.

Created: 05/20
Effective: 07/01/20 Client Aproval: 05/12/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

LONAPEGSOMATROPIN-TCGD

Generic	Brand	HICL	GCN	Exception/Other
LONAPEGSOMATROPIN-TCGD	SKYTROFA	47565		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **LONAPEGSOMATROPIN-TCGD (Skytrofa)** requires the following rule(s) be met for approval:

A. You have growth failure due to an inadequate secretion of endogenous (from your own body) growth hormone
B. You are 1 year of age or older and weigh at least 11.5 kg
C. If you are 10 to 17 years of age, your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) or written documentation
D. Your bone age is 15 years or less if you are female OR 17 years or less if you are male (as confirmed by radiograph or written documentation)

RENEWAL CRITERIA

Our guideline named **LONAPEGSOMATROPIN-TCGD (Skytrofa)** requires the following rule(s) be met for renewal:

A. You have growth failure due to an inadequate secretion of endogenous (from your own body) growth hormone
B. If 10 to 17 years of age, your epiphyses are NOT closed (as confirmed by radiograph or written documentation)
C. Your bone age is 15 years or less if you are female OR 17 years or less if you are male (as confirmed by radiograph or written documentation)

RATIONALE

Ensure appropriate diagnostic, utilization and safety criteria are met for the management of requests for lonapegsomatropin-tcgd.

FDA APPROVED INDICATIONS

Skytrofa is a human growth hormone indicated for the treatment of pediatric patients 1 year and older who weigh at least 11.5 kg and have growth failure due to inadequate secretion of endogenous growth hormone (GH).

DOSING

The recommended dose of Skytrofa is 0.24 mg/kg body weight once-weekly.

REFERENCES

Skytrofa [Prescribing Information]. Palo Alto, CA: Ascendis Pharma US, Inc., August 2021.

Created: 02/22
Effective: 03/21/22 Client Approval: 02/18/22 P&T Approval: N/A

LONG-ACTING OPIOID ANALGESICS

Generic	Brand	HICL	GCN	Exception/Other
HYDROCODONE BITARTRATE ER	ZOHYDRO ER, HYSINGLA ER	01731	35365 35504 35505 35506 35507 35525 37539 37541 37543 37544 37545 37546 37547 38057 38058 38059 38061 38062 38063	
HYDROMORPHONE HCL ER	EXALGO	01695	22056 22098 28427 33088	
MORPHINE SULFATE ER	KADIAN, MS CONTIN, ARYMO ER, MORPHABOND ER	01694	15868 16078 16212 16213 16640 16641 16642 16643 17189 17191 17192 17193 26490 26494 33158 97508 97534 98135 97535 26492 42932 42933 42934	

			39856 39853 39855	
OXYCODONE HCL ER	OXYCONTIN	01742	37158 37161 37163 37165 99238 99239 99240	
OXYCODONE MYRISTATE ER	XTAMPZA ER	43376	41272 41273 41274 41275 41276	
OXYMORPHONE ER HCL	OPANA ER	01696	27247 27248 27249 27253 99492 99493 99494	
TAPENTADOL HCL ER	NUCYNTA ER	36411	29787 29788 29789 29791 29792	
TRAMADOL HCL ER	ULTRAM ER, CONZIP ER	08317	26387 50417 50427 99151 99152 99153 30382 30383 30384 31556 30382 30383 30384	

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

LONG-ACTING OPIOID ANALGESICS

GUIDELINES FOR USE

RENEWAL CRITERIA will apply in the following scenarios only:

- For patients active with MDwise for 90 days or longer AND previous prior authorization approval for the same medication with the same strength AND recent paid pharmacy claims for the requested medication. Chart notes and/or cash pay for opioid use is not accepted.
- For patients new to MDwise within the past 90 days AND chart notes are provided that document the patient is stable on the requested medication.

All other requests will be reviewed against the INITIAL CRITERIA.

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

Our guideline for **LONG-ACTING OPIOID ANALGESICS** for patientswith past use of opioid dependency agents (such as, buprenorphine/naloxone SL tablets/films or buprenorphine SL tablets) requires the buprenorphine/naloxone or buprenorphine prescribing physician be notified about prescribed opiate therapy and must approve the use before the opioid analgesic will be authorized.

Our guideline for **LONG-ACTING OPIOID ANALGESICS** does not permit concurrent use with carisoprodol-containing products.

Our guideline named **LONG-ACTING OPIOID ANALGESICS** (reviewed for Opana ER) requires you to meet **ALL** of the following criteria:

- Opana ER is prescribed for one of the following indications:
  - Cancer
  - Sickle cell disease
  - Palliative care
  - Another terminal diagnosis associated with significant pain
- You have had a trial of generic MS Contin and **TWO** non-preferred long-acting opioid analgesics other than methadone (such as Duragesic, Nucynta, OxyContin or Zohydro)

Please note that additional criteria apply for concurrent use of opioid analgesics and benzodiazepines, including submission of signed prescriber attestation on a state-mandated fax form.

Our guideline for **LONG-ACTING OPIOID ANALGESICS** requires you to meet **BOTH** of the following criteria:

- The requested medication is prescribed for one of the following indications:
  - Cancer
  - Sickle cell disease
  - Palliative care
  - Another terminal diagnosis associated with significant pain
- You have had a trial of at least 7 days generic MS Contin in the past 120 days

Please note that additional criteria apply for concurrent use of opioid analgesics and benzodiazepines, including submission of signed prescriber attestation on a state-mandated fax form.

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LONG-ACTING OPIOID ANALGESICS

INITIAL CRITERIA (CONTINUED)

Our guideline named **LONG-ACTING OPIOID ANALGESICS** (reviewed for Opana ER) requires you to meet **ALL** of the following criteria:

- You have a diagnosis of moderate to severe pain
- You meet the definition of opioid tolerance [defined as those who are taking, for one week or longer, at least 60 morphine milligram equivalents (MME)/day such as 60mg oral morphine/day, 40mg oral oxycodone/day, 15mg oral hydromorphone/day, 60mg oral hydrocodone/day, 400mg oral codeine/day, or an equianalgesic dose of another opioid]. Your plan requires that for patients active with MDwise for 90 days or longer, only previously paid claims for opioids may be considered for this criterion. If your prescriber indicates that you have been on opioid therapy, it must be verified in claims history. Chart notes and/or cash pay for opioid use is not accepted. For patients active with MDwise less than 90 days, chart notes are required to verify previous opioid use for this criterion
- Your prescriber has consulted with you regarding the risks of opioid therapy and developed a pain management plan with clear treatment goals
- You have had a trial of generic MS Contin and **TWO** non-preferred long-acting opioid analgesics other than methadone (such as Duragesic, Nucynta, OxyContin or Zohydro)

Please note that additional criteria apply for concurrent use of opioid analgesics and benzodiazepines, including submission of signed prescriber attestation on a state-mandated fax form.

Our guideline for **LONG-ACTING OPIOID ANALGESICS** requires patient to meet **ALL** of the following criteria:

- You have a diagnosis of moderate to severe pain
- You meet the definition of opioid tolerance [defined as those who are taking, for one week or longer, at least 60 morphine milligram equivalents (MME)/day such as 60mg oral morphine/day, 40mg oral oxycodone/day, 15mg oral hydromorphone/day, 60mg oral hydrocodone/day, 400mg oral codeine/day, or an equianalgesic dose of another opioid]. Your plan requires that for patients active with MDwise for 90 days or longer, only previously paid claims for opioids may be considered for this criterion. If your prescriber indicates that you have been on opioid therapy, it must be verified in claims history. Chart notes and/or cash pay for opioid use is not accepted. For patients active with MDwise less than 90 days, chart notes are required to verify previous opioid use for this criterion
- You have had a trial of at least 30 days generic MS Contin in the past 120 days
- Your prescriber has consulted with you regarding the risks of opioid therapy and developed a pain management plan with clear treatment goals

Please note that additional criteria apply for concurrent use of opioid analgesics and benzodiazepines, including submission of signed prescriber attestation on a state-mandated fax form.

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LONG-ACTING OPIOID ANALGESICS

INITIAL CRITERIA (CONTINUED)

Our guideline named **LONG-ACTING OPIOID ANALGESICS** for concurrent use of more than one long-acting opioid requires patients to meet **ALL** of the following criteria:

- You have a diagnosis of moderate to severe pain
- You have a pain that is not responding to treatment despite concurrent (used at the same time) therapy with one short-acting opioid and one long-acting opioid, as documented in claim history or chart notes
- Your prescriber has consulted with you regarding the risks of opioid therapy and developed a pain management plan with clear treatment goals

Exceptions to these criteria may be authorized in patients with cancer, sickle cell disease, another terminal diagnosis associated with significant pain, or those receiving opioids as part of a palliative care (medical care for symptoms related to illness) plan.

Please note that additional criteria apply for concurrent use of opioid analgesics and benzodiazepines, including submission of signed prescriber attestation on a state-mandated fax form.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

LONG-ACTING OPIOID ANALGESICS

INITIAL CRITERIA (CONTINUED)

Our guideline for **LONG-ACTING OPIOID ANALGESICS** for patients with claims in history for benzodiazepines requires that the prescriber submit the required fax form documenting **ALL** of the following:

- The diagnosis contributing to the need for benzodiazepine therapy and previous therapy attempted, including dates and doses of prior therapies
  - For generalized anxiety disorder, one of the following is required: Selective serotonin reuptake inhibitor (SSRI, such as sertraline or citalopram), serotonin-noradrenaline reuptake inhibitor (SNRI, such as duloxetine or venlafaxine), or pregabalin (generic for Lyrica)
  - For panic disorder, one of the following is required: SSRI or tricyclic antidepressant (TCA, such as amitriptyline or nortriptyline)
  - For social anxiety disorder (SAD), a trial of an SSRI is required
  - For obsessive compulsive disorder (OCD), a trial of an SSRI is required
  - For post-traumatic stress disorder (PTSD), one of the following is required: mirtazapine, paroxetine, amitriptyline, or phenelzine
  - For insomnia, one of the following is required: ramelteon or a sedating antidepressant (for example, trazodone, amitriptyline, doxepin, mirtazapine)
- The diagnosis contributing to the need for opioid analgesic therapy and previous therapy attempted, including dates and doses of prior therapies (if applicable)
  - For long-acting opioid therapy requested for chronic moderate to severe pain, **ALL** of the following are required:
    - You meet the definition of opioid tolerance (defined as those who are taking, for one week or longer, at least 60 morphine milligram equivalents (MME)/day such as 60mg oral morphine/day, 40mg oral oxycodone/day, 15mg oral hydromorphone/day, 60mg oral hydrocodone/day, 400mg oral codeine/day, or an equianalgesic dose (a dose of one pain medication that is the same in pain-relieving effects to that of another pain medication) of another opioid). Your plan requires that for patients active with MDwise for 90 days or longer, only previously paid claims for opioids may be considered for this criterion. If your prescriber indicates that you have been on opioid therapy, it must be verified in claims history. Chart notes and/or cash pay for opioid use is not accepted. For patients active with MDwise less than 90 days, chart notes are required to verify previous opioid use for this criterion. (**NOTE:** For a diagnosis of moderate to severe cancer-related pain, pain related to sickle cell disease, or pain in patients receiving palliative care, this criterion does not apply.)
    - For any long-acting opioid other than MS Contin, the patient has had a trial of at least 30 days generic MS Contin in the past 120 days

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

LONG-ACTING OPIOID ANALGESICS

INITIAL CRITERIA (CONTINUED)

- Your prescriber has signed an attestation as to **ALL** of the following:
  - Your prescriber will regularly review your controlled substance utilization contained within INSPECT (Indiana controlled substance monitoring program)
  - You have been educated about the risks of using benzodiazepines and opioid analgesics together at the same time
  - Both you and your provider accept the risk of using benzodiazepines and opioid analgesics together at the same time

Please note that additional criteria apply for the benzodiazepine day supply limits. Your benzodiazepine prescription claim must not be greater than a 15-day supply of medication. You cannot receive more than 30 days' supply of benzodiazepine medication in the past 90 days. The current request for medication is also counted as a part of the 30 days' supply in the past 90 days.

Our guideline named **LONG-ACTING OPIOID ANALGESICS** for patients with claims in history for Lybalvi (olanzapine/samidorphan) requires that you have not taken Lybalvi (olanzapine/samidorphan) less than or equal to 5 days prior to initiating opioid therapy.

RENEWAL CRITERIA

Our guideline for **LONG-ACTING OPIOID ANALGESICS** does not permit concurrent use with carisoprodol-containing products.

Our renewal guideline for **LONG-ACTING OPIOID ANALGESICS** requires your prescriber to verify that you meet **ALL** of the following criteria:

- Opioid therapy has resulted in a meaningful improvement in your pain and/or function
- Your doctor has developed an updated pain management plan with clear treatment goals
- A risk assessment has been performed including review of the state prescription drug monitoring program (PDMP) data (for example, INSPECT)
- Adherence to prescribed opioid regimen has been periodically assessed (for example, urine drug screen, pill counts)

In addition, requests for renewal of concurrent use of (used at the same time with) more than one short-acting opioid or more than one long-acting opioid requires that you meet **ALL** of the following rules:

- You have a diagnosis of moderate to severe pain
- You experience refractory pain (pain that continues or returns) despite concurrent therapy with one short-acting opioid and one long-acting opioid
- Your prescriber has consulted with you regarding the risks of opioid therapy and developed a pain management plan with clear treatment goals

Exceptions to these criteria may be authorized in patients with cancer, sickle cell disease, another terminal diagnosis associated with significant pain, or those receiving opioids as part of a palliative care (medical care for symptoms related to illness) plan.

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LONG-ACTING OPIOID ANALGESICS

RENEWAL CRITERIA (CONTINUED)

Our renewal guideline for **LONG-ACTING OPIOID ANALGESICS** for patients with claims in history for benzodiazepines requires that the prescriber submit the required fax form documenting **ALL** of the following:

- The diagnosis contributing to the need for benzodiazepine therapy and previous therapy attempted, including dates and doses of prior therapies
  - For generalized anxiety disorder, one of the following is required: Selective serotonin reuptake inhibitor (SSRI, such as sertraline or citalopram), serotonin-noradrenaline reuptake inhibitor (SNRI, such as duloxetine or venlafaxine), or pregabalin (generic for Lyrica)
  - For panic disorder, one of the following is required: SSRI or tricyclic antidepressant (TCA, such as amitriptyline or nortriptyline)
  - For social anxiety disorder (SAD), a trial of an SSRI is required
  - For obsessive compulsive disorder (OCD), a trial of an SSRI is required
  - For post-traumatic stress disorder (PTSD), one of the following is required: mirtazapine, paroxetine, amitriptyline, or phenelzine
  - For insomnia, one of the following is required: ramelteon or a sedating antidepressant (for example, trazodone, amitriptyline, doxepin, mirtazapine)
- The diagnosis contributing to the need for renewal of the requested opioid analgesic therapy and that you meet the following:
  - Opioid therapy has resulted in a meaningful improvement in your pain and/or function
  - Your doctor has developed an updated pain management plan with clear treatment goals
  - A risk assessment has been performed including review of the state prescription drug monitoring program (PDMP) data (e.g., INSPECT)
  - Adherence to prescribed opioid regimen has been periodically assessed (e.g., urine drug screen, pill counts)
- Your prescriber has signed an attestation as to **ALL** of the following:
  - Your provider will regularly review your controlled substance utilization contained within INSPECT
  - You have been educated about the risks of using benzodiazepines and opioid analgesics together at the same time
  - Both you and your provider accept the risks of using benzodiazepines and opioid analgesics together at the same time

Please note that additional criteria apply for the benzodiazepine day supply limits. Your benzodiazepine prescription claim must not be greater than a 15-day supply of medication. You cannot receive more than 30 days' supply of benzodiazepine medication in the past 90 days. The current request for medication is also counted as a part of the 30 days' supply in the past 90 days.

Our guideline named **LONG-ACTING OPIOID ANALGESICS** for patients with claims in history for Lybalvi (olanzapine/samidorphan) requires that you have not taken Lybalvi (olanzapine/samidorphan) less than or equal to 5 days prior to initiating opioid therapy.

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LONG-ACTING OPIOID ANALGESICS

RATIONALE

To ensure opioid analgesics are used according to FDA approved indications with patient safety in mind, and to encourage the use of more cost-effective analgesics.

From 2000-2014, almost half a million people died due to drug overdose, with 2014 being the highest year for deaths on record. In that time, the number of opioids prescribed, as well as the number of opioid overdoses, has risen exponentially. At least half of all opioid overdose deaths involve a prescription opioid. Indiana was among the states that had a statistically significant increase of overdose deaths from 2013-2014.

According to recent research, the opioid epidemic has a disproportionate impact on Medicaid beneficiaries. Medicaid patients are prescribed opioids at double the rate of non-Medicaid patients, and are subsequently at much higher risk of prescription opioid overdose.
Improving the way that opioids are prescribed can ensure safer and more effective pain treatment, and reduce the addiction, misuse, abuse, and overdose of these drugs. These guidelines are to ensure that the use of opioids is consistent with their FDA approved indications, and to initiate action combating the current opioid epidemic.

Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 morphine milligram equivalents (MME)/day such as 60mg oral morphine/day, 25mcg transdermal fentanyl/hour, 40mg oral oxycodone/day, 15mg oral hydromorphone/day, 60mg oral hydrocodone/day, 400mg oral codeine/day, or an equianalgesic dose of another opioid for a week or longer.

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RATIONALE (CONTINUED)

Buprenorphine Conversion Table

Buprenorphine Product	Oral MME Conversion Factor
Belbuca buccal film (mcg/hr)	0.03
buprenorphine, tablet or film for opioid use disorder	30
Butrans transdermal patch (mcg/hr)	12.6

Example: 900 mcg buprenorphine buccal film x (60 films/30 days) x 0.03=54 MME/day
Example: 5 mcg buprenorphine patch x (4 patches/28 days) x 12.6= 9 MME/day

Fentanyl Conversion Table

Fentanyl Product	Oral MME Conversion Factor
fentanyl buccal or SL tablets, or lozenge/troche (mcg)	0.13
fentanyl film or oral spray (mcg)	0.18
fentanyl nasal spray (mcg)	0.16
fentanyl patch (mcg)	7.2

Opioid Conversion Table

Drug	Oral MME Conversion Factor (1mg of drug to mg morphine)	60mg Morphine Equivalent Dose
benzhydrocodone	1.22	50mg
butorphanol	7	8.5mg
codeine	0.15	400mg
dihydrocodeine	0.25	240mg
hydrocodone	1	60mg
hydromorphone HCl	4	15mg
levorphanol tartrate	11	5.5mg
meperidine HCl	0.1	600mg
morphine	1	60mg
oxycodone HCl	1.5	40mg
oxymorphone HCl	3	20mg
pentazocine HCl	0.37	162mg
tapentadol HCl	0.4	150mg
tramadol HCl	0.1	600mg

Methadone Conversion Table

Methadone daily dose (mg/day)	MME Conversion Factor (1mg of drug to mg morphine)	60mg Morphine Equivalent Dose
>0, <= 20	4	20mg
>20, <=40	8	7.5mg
>40, <=60	10	6mg
>60	12	5mg

RATIONALE (CONTINUED)

Opioid Usage in Chronic Pain Management
Per systematic review in the CDC Guideline for Prescribing Opioids for Chronic Pain, long-term (≥ 1 year) efficacy of opioids in management of chronic pain, function, or quality of life is not established. Most randomized controlled trials present effectiveness within 6 weeks or less. Conversely, significant risks of adverse events are present with chronic opioid therapy, including opioid abuse and dependence, social role withdrawal, and increased risk of CNS depression, and withdrawal emergencies.

The CDC also recommends re-evaluating and re-establishing treatment goals, including realistic expectation for pain and function, as well as discontinuation strategies when benefits do not outweigh risks. The guideline provides the following recommendations for opioid selection, dosage, duration, follow-up and discontinuation:

- Immediate-release (IR) opioids are preferred over extended-release (ER) forms.
- The lowest effective dosage is preferred with initial opioid use. Caution is warranted at any dose and reassessing benefits and risks is recommended for 50 morphine milligram equivalents (MME) daily or more. 90 MME daily or more should be avoided if possible.
- Within 1 to 4 weeks of therapy, clinicians should evaluate benefits and harms of using opioids to treat chronic pain. Therapy continuation should be evaluated every 3 months or sooner. If benefits do not outweigh harms to continue opioid therapy, other therapies should be optimized and opioid tapering/discontinuation should be considered and encouraged.

Assessing Risk and Addressing Harms of Opioid Use

- Prior to and throughout opioid therapy, adverse events should be evaluated periodically. Factors that increase risk for opioid overdose include history of overdose or substance use disorder, 50 MME daily or more, and concurrent benzodiazepine use.
- Prescription drug monitoring program (PDMP) data (e.g., RXINSPECT) are useful to monitor total opioid dosage. PDMP data is helpful for initial and periodic opioid usage evaluations.
- Prescribing opioids and benzodiazepines concurrently should be avoided.
- For patients with substance use disorder, evidence-based treatment (medication-assisted and behavioral therapy) is recommended.

Analysis performed by the US Department of Health and Human Services Center for Disease Control and Prevention (CDC) determined the risk of harm to individuals increases as their opioid dose increases and as their length of opioid therapy increases. For example:

- Individuals taking opioid doses > 50 morphine milligram equivalents (MMEs) per day had twice the risk of death from an overdose than those taking < 20 MMEs per day.
- Individuals taking opioid doses > 90 (MMEs) per day had 10 times the risk of death from an overdose than those taking < 20 MMEs per day.
- Individuals taking an opioid for > 3 months (even at low doses) had 15 times the risk of addiction to those taking opioids for < 3 months.

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APPENDIX 1: Long-Acting Opioid Analgesic Quantity Limits

GPID	Generic Name	Dosage Form	Strength	Quantity Limit
15868	morphine sulfate	capsule	50 mg	2 per day
16078	morphine sulfate	tablet	200 mg	3 per day
16212	morphine sulfate	capsule	45 mg	1 per day
16213	morphine sulfate	capsule	75 mg	1 per day
16640	morphine sulfate	tablet	30 mg	3 per day
16641	morphine sulfate	tablet	60 mg	3 per day
16642	morphine sulfate	tablet	100 mg	3 per day
16643	morphine sulfate	tablet	15 mg	3 per day
17189	morphine sulfate	capsule	120 mg	2 per day
17191	morphine sulfate	capsule	90 mg	1 per day
17192	morphine sulfate	capsule	60 mg	1 per day
17193	morphine sulfate	capsule	30 mg	1 per day
19200	fentanyl	patch	25 mcg/ hr	1 per 3 days
19201	fentanyl	patch	50 mcg/ hr	1 per 3 days
19202	fentanyl	patch	75 mcg/ hr	1 per 3 days
19203	fentanyl	patch	100 mcg/ hr	1 per 3 days
22056	hydromorphone HCl	tablet	8 mg	1 per day
22098	hydromorphone HCl	tablet	16 mg	1 per day
24635	fentanyl	patch	12 mcg/ hr	1 per 3 days
25308	buprenorphine	patch	5 mcg/ hr	1 per 7 days
25309	buprenorphine	patch	10 mcg/ hr	1 per 7 days
25312	buprenorphine	patch	20 mcg/ hr	1 per 7 days
26387	tramadol HCl	tablet	100 mg	1 per day
26490	morphine sulfate	capsule	10 mg	2 per day
26492	morphine sulfate	capsule	20 mg	2 per day
26494	morphine sulfate	capsule	100 mg	2 per day
27247	oxymorphone HCl	tablet	5 mg	2 per day
27248	oxymorphone HCl	tablet	10 mg	2 per day
27249	oxymorphone HCl	tablet	20 mg	2 per day
27253	oxymorphone HCl	tablet	40 mg	4 per day
28427	hydromorphone HCl	tablet	12 mg	1 per day
29787	tapentadol HCl	tablet	50 mg	2 per day
29788	tapentadol HCl	tablet	100 mg	2 per day
29789	tapentadol HCl	tablet	150 mg	2 per day
29791	tapentadol HCl	tablet	200 mg	2 per day
29792	tapentadol HCl	tablet	250 mg	2 per day
30382	tramadol HCl	capsule	100 mg	1 per day

30383	tramadol HCl	capsule	200 mg	1 per day
30384	tramadol HCl	capsule	300 mg	1 per day
31556	tramadol HCl	capsule	150 mg	1 per day
33088	hydromorphone HCl	tablet	32 mg	2 per day
33158	morphine sulfate	capsule	40 mg	2 per day
35214	buprenorphine	patch	15 mcg/ hr	1 per 7 days
36946	buprenorphine	patch	7.5 mcg/ hr	1 per 7 days
37158	oxycodone HCl	tablet	10 mg	2 per day
37161	oxycodone HCl	tablet	20 mg	2 per day
37163	oxycodone HCl	tablet	40 mg	2 per day
37165	oxycodone HCl	tablet	80 mg	4 per day
37539	hydrocodone bitartrate	tablet	20 mg	1 per day
37541	hydrocodone bitartrate	tablet	30 mg	1 per day
37543	hydrocodone bitartrate	tablet	40 mg	1 per day
37544	hydrocodone bitartrate	tablet	60 mg	1 per day
37545	hydrocodone bitartrate	tablet	80 mg	1 per day
37546	hydrocodone bitartrate	tablet	100 mg	1 per day
37547	hydrocodone bitartrate	tablet	120 mg	1 per day
37947	fentanyl	patch	62.5 mcg/ hr	1 per 3 days
37948	fentanyl	patch	87.5 mcg/ hr	1 per 3 days
37952	fentanyl	patch	37.5 mcg/ hr	1 per 3 days
38057	hydrocodone bitartrate	capsule	10 mg	2 per day
38058	hydrocodone bitartrate	capsule	15 mg	2 per day
38059	hydrocodone bitartrate	capsule	20 mg	2 per day
38061	hydrocodone bitartrate	capsule	30 mg	2 per day
38062	hydrocodone bitartrate	capsule	40 mg	2 per day
38063	hydrocodone bitartrate	capsule	50 mg	2 per day
39853	morphine sulfate	tablet	15 mg	3 per day
39855	morphine sulfate	tablet	60 mg	3 per day
39856	morphine sulfate	tablet	100 mg	3 per day
39959	buprenorphine HCl	film	75 mcg	2 per day
39965	buprenorphine HCl	film	150 mcg	2 per day
39966	buprenorphine HCl	film	300 mcg	2 per day
39967	buprenorphine HCl	film	450 mcg	2 per day
39968	buprenorphine HCl	film	600 mcg	2 per day
39969	buprenorphine HCl	film	750 mcg	2 per day
39975	buprenorphine HCl	film	900 mcg	2 per day
41272	oxycodone myristate	capsule	9 mg	2 per day
41273	oxycodone myristate	capsule	13.5 mg	2 per day

41274	oxycodone myristate	capsule	18 mg	2 per day
41275	oxycodone myristate	capsule	27 mg	4 per day
41276	oxycodone myristate	capsule	36 mg	8 per day
42932	morphine sulfate	tablet	15 mg	3 per day
42933	morphine sulfate	tablet	30 mg	3 per day
42934	morphine sulfate	tablet	60 mg	3 per day
50417	tramadol HCl	tablet	200 mg	1 per day
50427	tramadol HCl	tablet	300 mg	1 per day
97508	morphine sulfate	capsule	80 mg	2 per day
97534	morphine sulfate	capsule	30 mg	2 per day
97535	morphine sulfate	capsule	60 mg	2 per day
98135	morphine sulfate	capsule	200 mg	4 per day
99151	tramadol HCl	tablet	100 mg	1 per day
99152	tramadol HCl	tablet	200 mg	1 per day
99153	tramadol HCl	tablet	300 mg	1 per day
99238	oxycodone HCl	tablet	15 mg	2 per day
99239	oxycodone HCl	tablet	30 mg	2 per day
99240	oxycodone HCl	tablet	60 mg	2 per day
99492	oxymorphone HCl	tablet	7.5 mg	2 per day
99493	oxymorphone HCl	tablet	15 mg	2 per day
99494	oxymorphone HCl	tablet	30 mg	4 per day

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LONG-ACTING OPIOID ANALGESICS

APPENDIX 2: BENZODIAZEPINE/OPIOID CONCURRENT USE FAX FORM
INDIANA HEALTH COVERAGE PROGRAMS (IHCP) PHARMACY BENEFIT
BENZODIAZEPINE AND OPIOID CONCURRENT THERAPY
PRIOR AUTHORIZATION REQUEST FORM

MDwise
Fax to: (858) 790-7100
c/o MedImpact Healthcare Systems, Inc.
Attn: Prior Authorization Department
10181 Scripps Gateway Court, San Diego, CA 92131
Phone: 1-800-788-2949

Today's Date
☐☐ / ☐☐ / ☐☐☐☐

Note: This form must be completed by the prescribing provider.
****All sections must be completed or the request will be denied.****

Patient's Medicaid # ☐☐☐☐☐☐☐☐☐☐☐☐	**Date of Birth** ☐☐ / ☐☐ / ☐☐☐☐
Patient's Name	**Prescriber's Name**
Prescriber's IN License # ☐☐☐☐☐☐☐☐	**Specialty**
Prescriber's NPI # ☐☐☐☐☐☐☐☐☐☐	**Prescriber's Signature: **Required below within attestation section.****
Return Fax # ☐☐☐ - ☐☐☐ - ☐☐☐☐	**Return Phone #** ☐☐☐ - ☐☐☐ - ☐☐☐☐

PA is required for the following:

- **Claim(s) for new opioid(s) to be used concurrently with benzodiazepines and exceeding 7 days within a 180-day period.**
- **Claim(s) for new benzodiazepine(s) to be used concurrently with opioids and exceeding 7 days of therapy within a 180-day period and/or exceeding established benzodiazepine/opioid concurrent therapy quantity limits (see Sedative Hypnotics/Benzodiazepine PA criteria).**

Benzodiazepine Agent(s)	Prescriber Name*	Quantity	Dosage Regimen/Duration

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Opioid Agent(s)	Prescriber Name*	Quantity	Dosage Regimen/Duration

***NOTE: If prescribers of the opioid(s) and benzodiazepine(s) are not the same, please answer the following questions:**

- **Are you requesting PA for: Benzodiazepine Agent(s) ☐ Opioid Agent(s) ☐ Both ☐**
- **Is/are the other prescriber(s) aware of the request for concurrent therapy? □ Yes □ No**
- **Has/have the other prescriber(s) been consulted about the risks associated with concurrent therapy, and do all prescribers involved believe continuing with concurrent therapy is warranted, given the risks associated with concurrent use? □ Yes □ No**

PA Requirements:

Patient diagnosis/diagnoses for use of benzodiazepine therapy:

Prior therapies attempted for the above diagnosis/diagnoses (submission of chart notes required in absence of claims history):

Drug Therapy	Dosage Regimen	Dates of Utilization

Do you plan to continue benzodiazepine therapy for this patient? □ Yes □ No
If no, please provide withdrawal plan:

Patient diagnosis/diagnoses for use of opioid therapy:

Prior therapies (both drug and non-drug) attempted for the above diagnosis/diagnoses (submission of chart notes required in absence of claims history):

Drug/Non-Drug Therapy	Dosage Regimen	Dates of Utilization	Reason for Discontinuation or Failure

Do you plan to continue opioid therapy for this patient? □ Yes □ No
If no, please provide withdrawal plan:

Attestation:

I, _____, hereby attest to the following:
(Prescriber Name)

The patient's INSPECT report has been evaluated and continues to be evaluated on a regular basis (Per IC 35-48-7-11.1, DO NOT attach a copy of the INSPECT report to this PA request).
I have educated the patient in regards to the risks of concurrent utilization of benzodiazepine and opioid therapy, and the patient accepts these risks.
If applicable, I have consulted other prescriber(s) involved in concurrent therapy and all prescribers involved agree to pursue concurrent opioid and benzodiazepine therapy for this patient.
I acknowledge, as the prescriber initiating or maintaining concurrent benzodiazepine and opioid therapy, the risk of adverse event(s), including respiratory depression, coma, and death, associated with concurrent utilization.

Prescriber Signature:_____

****Prescriber signature is required for consideration. Electronic or stamped signature will not be accepted.****

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LONG-ACTING OPIOID ANALGESICS

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Created: 09/19
Effective: 06/13/22 Client Approval: 05/26/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

LORLATINIB

Generic	Brand	HICL	GCN	Exception/Other
LORLATINIB	LORBRENA	45448		

GUIDELINES FOR USE

Our guideline named **LORLATINIB (Lorbrena)** requires the following rule(s) be met for approval:

A. You have metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
B. You are 18 years of age or older
C. Your tumors are anaplastic lymphoma kinase (ALK: type of enzyme) - positive which is shown by an FDA (Federal and Drug Administration) approved test

RATIONALE

Promote appropriate utilization and dosing of Lorbrena for its FDA approved indication.

FDA APPROVED INDICATIONS

Lorbrena is a kinase inhibitor indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test.

DOSAGE AND ADMINISTRATION

The recommended dosage is 100 mg orally once daily.

AVAILABLE STRENGTHS

Tablets: 25 mg or 100 mg

REFERENCES

- Lorbrena [Prescribing Information]. New York, NY: Pfizer, Inc; March 2021.

Created: 09/19
Effective: 10/01/21 Client Approval: 08/26/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

LUSUTROMBOPAG

Generic	Brand	HICL	GCN	Exception/Other
LUSUTROMBOPAG	MULPLETA	45127		

GUIDELINES FOR USE

The guideline named **LUSUTROMBOPAG (Mulpleta)** requires a diagnosis of thrombocytopenia. In addition, the following criteria must be met.

- The patient is 18 years of age or older
- The patient has chronic liver disease
- The patient is scheduled to undergo a procedure 8 to 14 days following initiation of Mulpleta (lusutrombopag) therapy

RATIONALE

To ensure appropriate utilization of **Mulpleta** based on FDA-approved indication and dosing.

FDA APPROVED INDICATION

Mulpleta (lusutrombopag) is a thrombopoietin receptor agonist indicated for the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.

DOSAGE AND ADMINISTRATION

Begin Mulpleta therapy 8 to 14 days before the scheduled procedure. The recommended dose is 3 mg once per day with or without food for 7 consecutive days. Patients should undergo their procedure 2 to 8 days after the last dose of Mulpleta.

REFERENCES

- Mulpleta [Prescribing Information]. Florham Park, NJ: Shionogi & Co, Ltd. July 2018.

Created: 11/18
Effective: 11/23/18 Client Approval: 11/06/18 P&T Approval: N/

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

MARALIXIBAT

Generic	Brand	HICL	GCN	Exception/Other
MARALIXIBAT CHLORIDE	LIVMARLI	47604		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **MARALIXIBAT (Livmarli)** requires the following rule(s) be met for approval:

A. You have cholestatic pruritus (a type of skin condition) associated with Alagille syndrome (ALGS: a type of genetic disorder)
B. You are 1 year of age or older
C. You have tried ONE of the following conventional treatments for cholestatic pruritus: rifampin, ursodeoxycholic acid, cholestyramine, or colesevelam

RENEWAL CRITERIA

Our guideline for **MARALIXIBAT (Livmarli)** requires the following rule(s) be met for renewal:

- You have cholestatic pruritus (a type of skin condition) associated with Alagille syndrome (ALGS: a type of genetic disorder)
- You have experienced or maintained symptomatic improvement while on therapy

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RATIONALE

Ensure appropriate diagnostic, utilization and safety criteria are met for the management of requests for maralixibat.

INDICATIONS

Livmarli is an ileal bile acid transporter (IBAT) inhibitor indicated for the treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) 1 year of age and older.

DOSAGE

The recommended dosage of Livmarli is 380 mcg/kg once daily, taken 30 minutes before the first meal of the day. Starting dose is 190 mcg/kg orally once daily and should be increased to 380 mcg/kg once daily after one week, as tolerated.

REFERENCES

Livmarli [Prescribing Information]. Foster City, CA: Mirum Pharmaceuticals, Inc., September 2021.

Created: 02/22
Effective: 03/21/22 Client Approval: 02/18/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

MAVACAMTEN

Generic	Brand	HICL	GCN	Exception/Other
MAVACAMTEN	CAMZYOS	47972		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **MAVACAMTEN (Camzyos)** requires the following rule(s) be met for approval:
A. You have symptomatic obstructive hypertrophic cardiomyopathy (HCM: a type of heart condition)
B. You are 18 years of age or older
C. You have New York Heart Association (NYHA) class II-III (classification system for heart failure) symptoms
D. You have a left ventricular outflow track gradient (a predictor of heart failure and cardiovascular death) of 50 mmHg or higher
E. You have tried a beta-blocker (such as metoprolol, carvedilol) AND a non-dihydropyridine calcium channel blocker (such as verapamil, diltiazem)

RENEWAL CRITERIA

Our guideline named **MAVACAMTEN (Camzyos)** requires the following rule(s) be met for renewal:
A. You have symptomatic obstructive hypertrophic cardiomyopathy (HCM: a type of heart condition)
B. You have experienced continued clinical benefit (such as reduction of symptoms, NYHA classification improvement)

RATIONALE
To ensure appropriate use of Camzyos consistent with FDA approved indication.

FDA APPROVED INDICATIONS
Camzyos is a cardiac myosin inhibitor indicated for the treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms.

DOSAGE AND ADMINISTRATION
The recommended starting dose of Camzyos is 5 mg once daily without regard to food; allowable subsequent doses with titration are 2.5, 5, 10, or 15 mg once daily.

REFERENCES
Camzyos [Prescribing Information]. Brisbane, CA: MyoKardia, Inc.; May 2022.

Created: 06/22
Effective: 07/18/22 Client Approval: 06/20/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

MEBENDAZOLE

Generic	Brand	HICL	GCN	Exception/Other
MEBENDAZOLE	EMVERM	04167		

GUIDELINES FOR USE

Our guideline for **MEBENDAZOLE** indicates it will be approved for treatment of *Enterobius vermicularis* (pinworm), *Trichuris trichiura* (whipworm), *Ascaris lumbricoides* (common roundworm), *Ancylostoma duodenale* (common hookworm), or *Necator americanus* (American hookworm). Additional criteria are required for the four aforementioned parasitic worm infections:

- Documented confirmed diagnosis of *Trichuris trichiura* (whipworm), *Ascaris lumbricoides* (common roundworm), *Ancylostoma duodenale* (common hookworm), or *Necator americanus* (American hookworm).

RATIONALE

To ensure appropriate use of **MEBENDAZOLE** consistent with FDA approved use and CDC treatment guidelines.

Emverm is a member of the benzimidazole drug class, which also includes the branded product, Albenza (albendazole). Besides Emverm and Albenza, other anthelmintics include ivermectin and pyrantel pamoate. Ivermectin does not share any of the same indications as Emverm but could be considered as an equally efficacious off-label treatment alternative for roundworm. Pyrantel pamoate is only approved for the treatment of pinworms and is the standard of care due to its low cost and over-the-counter (OTC) availability. Alternatively, Emverm and Albenza may also be used for pinworm due to comparable efficacy; however, of the two benzimidazoles, only Emverm is FDA approved for this indication. For whipworm and roundworm, Emverm is the drug of choice for treatment; however, Albenza may be used off-label. Finally, for hookworm, Albenza has the highest cure rate and is the preferred treatment regimen despite not being FDA approved for this indication.

Enterobius vermicularis (pinworm)

Pinworm is the most common helminthic parasite infection in the United States with an estimated prevalence of 40 million cases each year. Infection most commonly occurs among children aged 5-10 years, institutionalized persons, and within families. Transmission usually occurs through the fecal-oral route but may also spread through contaminated surfaces (including clothing and bedding) or airborne transmission. Due to the ease of transmission, all members of a family should be treated if one member has a confirmed infection. While infections are usually asymptomatic, the worms, eggs, and larvae may also cause perianal itching. Treatment options include, Albenza (albendazole), Emverm (mebendazole) and pyrantel pamoate. All of these agents are comparable in efficacy and have high cure rates, with a near 100% cure rate with two doses. **Reinfection is frequent; the CDC recommends a second dose of any of the three treatment options to prevent re-infection by adult worms that hatch from any eggs not killed by the first treatment.**

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RATIONALE (CONTINUED)

Soil-transmitted helminth (STH) infections
Trichuris trichiura (whipworm), *Ascaris lumbricoides* (common roundworm), *Ancylostoma duodenale* (common hookworm), and *Necator americanus* (American hookworm) are soil-transmitted helminths that are seen primarily in tropical climates. Infections with these organisms are rare overall in the United States but are more common in the rural Southeast. Infection is associated with poor hygiene and is more common in children due to high exposure to soil compared to adults. STH infections are usually asymptomatic. Patients may experience abdominal discomfort, loose stools with blood or mucus, and episodes of nocturnal stools. Rarely, heavy infections with high worm burden can progress to colitis, intestinal blockage, rectal inflammation, cough, peripheral eosinophilia, impaired growth in children, and secondary anemia. Also, hookworm infections may cause rash at the site of cutaneous penetration.

According to the CDC, Albenza (albendazole) and Emverm (mebendazole) are the drugs of choice for whipworm and roundworm infection. Multiple studies have demonstrated that higher cure rates are achieved with the use of Albenza (albendazole) compared to Emverm (mebendazole) when treating hookworm infection. With all agents, three day treatment is required to achieve significant cure rates.

FDA APPROVED INDICATION
Emverm (mebendazole) is indicated for the treatment of *Enterobius vermicularis* (pinworm), *Trichuris trichiura* (whipworm), *Ascaris lumbricoides* (common roundworm), *Ancylostoma duodenale* (common hookworm), *Necator americanus* (American hookworm) in single or mixed infections.

DOSAGE
- Treatment of *Enterobius vermicularis* (pinworm)
  - 1 tablet (100mg), once.
  - If the patient is not cured three weeks after treatment, a second course of treatment is advised.
- Treatment of *Trichuris trichiura* (whipworm), *Ascaris lumbricoides* (common roundworm), *Ancylostoma duodenale* (common hookworm), *Necator americanus* (American hookworm)
  - 1 tablet (100mg) twice daily for three consecutive days.
  - If the patient is not cured three weeks after treatment, a second course of treatment is advised.

AVAILABLE STRENGTHS:
- Mebendazole 100mg chewable tablet

REFERENCES
- Emverm [Prescribing Information]. Amedra Pharmaceuticals: Horsham, PA; July 2015.
- Impax [Press Release]. Impax Receives Approval of EMVERM™ (mebendazole) Chewable Tablets, 100 mg. [Accessed 3/28/16]. Available at: http://investors.impaxlabs.com/Media-Center/Press-Releases/Press-Release-Details/2016/Impax-Receives-Approval-of-EMVERM-mebendazole-Chewable-Tablets-100-mg/default.aspx. Updated 1/15/16.
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MEBENDAZOLE

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Created: 05/16
Effective: 05/12/16 Client Approval: 04/26/16 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

MECAMYLAMINE HYDROCHLORIDE

Generic	Brand	HICL	GCN	Exception/Other
MECAMYLAMINE HCL	VECAMYL		1471	

GUIDELINES FOR USE

Our guideline for approval requires that Vecamyl be used for the management of moderately severe to severe essential (or primary) hypertension or in uncomplicated cases of malignant hypertension; and a trial or a contraindication to at least three of the following: angiotensin converting enzyme (ACE) inhibitor or ACE-I combination, angiotensin receptor blocker (ARB) or ARB combination, Beta Blocker, or Calcium Channel Blocker, such as benazepril, benazepril-HCTZ, captopril, captopril-HCTZ, enalapril, enalapril-HCTZ, fosinopril, fosinopril-HCTZ, lisinopril, lisinopril-HCTZ, quinapril, ramipril, moexipril, moexipril-HCTZ, perindopril erbumine, quinapril, quinapril-HCTZ, trandolapril, trandolapril/verapamil, losartan, losartan-HCTZ, irbesartan, irbesartan-HCTZ, olmesartan, olmesartan-HCTZ, olmesartan-amlodipine-HCTZ, valsartan, valsartan-HCTZ, diltiazem HCL, diltiazem sustained release (generics only), verapamil, verapamil sustained release (generics only), atenolol, atenolol-chlorthalidone, bisoprolol, bisoprolol-HCTZ, carvedilol, metoprolol tartrate, nadolol, acebutolol, betaxolol, labetalol, metoprolol succinate, metoprolol-HCTZ, pindolol, propranolol, propranolol-HCTZ, sotalol, timolol maleate, or nebivolol.

MECAMYLAMINE HYDROCHLORIDE

RATIONALE

To ensure appropriate use aligned with FDA approved indication.

Therapy is usually started with one 2.5 mg tablet of Vecamyl twice a day. This initial dosage should be modified by increments of one 2.5 mg tablet at intervals of not less than 2 days until the desired blood pressure response occurs (the criterion being a dosage just under that which causes signs of mild postural hypotension).

The average total daily dosage of Vecamyl is 25 mg, usually in three divided doses. However, as little as 2.5 mg daily may be sufficient to control hypertension in some patients. Since the blood pressure response to antihypertensive drugs is increased in the early morning, the larger dose should be given at noontime and perhaps in the evening.

Vecamyl joins several different agents used in the treatment of hypertension. The most commonly prescribed drug classes for primary hypertension include thiazide-type diuretics, angiotensin-converting enzyme (ACE) inhibitors, angiotensin II receptor blockers (ARBs), calcium channel blockers, and beta blockers; all of which have generic formulations available. Each category of antihypertensive agent has similar levels of efficacy in lowering the blood pressure, producing a good antihypertensive response in 30 to 50 percent of patients. Malignant hypertension most often occurs in patients with long-standing uncontrolled hypertension, many of whom have discontinued antihypertensive therapy. The oral drug of choice in uncomplicated malignant hypertension is the ACE inhibitor, captopril, since it can substantially lower the BP within 10 to 30 minutes for most patients and has a relatively short duration that facilitates dose titration.

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RATIONALE (CONTINUED)

In more recent years, there has been considerable interest in evaluating Vecamyl for the treatment of other clinical indications, including smoking cessation and depression. The principal focus of research on other clinical indications largely involves Vecamyl's potent blockade of brain nicotinic receptors at doses that do not have a significant effect on parasympathetic function (2.5-10 mg/day). Recently Vecamyl was studied as an add-on treatment to existing anti-depressants. However, it failed two short-term Phase 3 clinical trials in 2011, showing no significant difference in patients when compared to a placebo.

The package insert for Vecamyl does not include any clinical trials as it was approved using an abbreviated new drug application (ANDA) of the innovator product, Inversine (mecamylamine). The distribution of Inversine was discontinued in 2009. Approved on March 1, 1956, Inversine was available prior to the 1962 amendments to the Federal Food, Drug, and Cosmetic Act (commonly referred to as the Kefauver-Harris Amendments) which established a framework requiring drug manufacturers to prove scientifically that a medication was not only safe, but effective. Since drugs approved between 1938 and 1962 were approved only on the grounds of safety, the FDA's Drug Efficacy Study Implementation (DESI) program has been retrospectively evaluating the effectiveness of these medications.

The Journal of the American Medical Association published a study in 1957 examining the effects of mecamylamine alone on 17 patients with sustained blood pressure above 150/100 mm Hg. Each patient was initiated on mecamylamine 2.5mg twice daily before undergoing a set dose titration. Treatment response was defined as a decrease in mean blood pressure by at least 20 mm Hg or a reduction of blood pressure to the normotensive level (defined by the investigators as less than 150/100 mm Hg). A little more than half of this small group responded to mecamylamine alone. Among the responders, the average dose was 34mg daily. However, there were some patients, who despite doubling this average dose, did not respond satisfactorily to mecamylamine.

Vecamyl is contraindicated in those with coronary insufficiency or recent myocardial infarction, uremia, glaucoma, organic pyloric stenosis as well as patients with hypersensitivity to the product.

Vecamyl should be given with great discretion, if at all, in patients with renal insufficiency. Patients receiving antibiotics and sulfonamides should generally not be treated with ganglion blockers such as Vecamyl.

Vecamyl should not be used in mild, moderate, labile hypertension and may prove unsuitable in uncooperative patients. When ganglion blockers or other potent antihypertensive drugs are discontinued suddenly, hypertensive levels return. For some patients, particularly those with malignant hypertension, this may occur abruptly and may cause fatal cerebral vascular accidents or acute congestive heart failure. Vecamyl should be gradually discontinued and substituted with other antihypertensive therapy.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

MECAMYLAMINE HYDROCHLORIDE

RATIONALE (CONTINUED)

At therapeutic antihypertensive doses (30 to 90 mg per day), Vecamyl has parasympathetic-blocking activity which results in side effects such as constipation, urinary retention, dryness of the mouth and skin, dilation of the pupils, and loss of visual accommodation in some patients. Since urinary retention may occur, caution is required in patients with prostatic hypertrophy, bladder neck obstruction, and urethral stricture. Vecamyl should be discontinued immediately if a patient is showing signs of paralytic ileus (for example frequent loose bowel movements with abdominal distention and decreased bowel sounds).

Since Vecamyl readily penetrates into the brain, it can cause central nervous system effects such as tremor, choreiform movements, mental aberrations, and convulsions. Although rare in nature, these effects have occurred most often when large doses of Vecamyl were used, especially in patients with cerebral or renal insufficiency.

Vecamyl is pregnancy category C. Because of the potential for serious adverse reactions in nursing infants from Vecamyl, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

FDA APPROVED INDICATIONS

For the management of moderately severe to severe essential (or primary) hypertension and in uncomplicated cases of malignant hypertension.

REFERENCES

- Vecamyl [Prescribing Information]. Fort Collins, CO: Manchester Pharmaceuticals; February 2012.
- UpToDate, Inc. Choice of therapy in primary (essential) hypertension: Recommendations. UpToDate [database online]. Waltham, MA. Available at http://www.uptodate.com/home/index.html. Updated March 25, 2013.
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Created: 06/15
Effective: 07/22/15 Client Approval: 06/15 P&T Approval: 08/13

MECHLORETHAMINE GEL

Generic	Brand	HICL	GCN	Exception/Other
MECHLORETHAMINE HCL	VALCHLOR		35387	

GUIDELINES FOR USE

Approval requires a diagnosis of stage IA and IB mycosis fungoides-type cutaneous T-cell lymphoma (CTCLs) and prior skin-directed therapy (such as corticosteroids, carmustine, topical retinoids (Targretin, Tazorac), imiquimod, or local radiation therapy).

MECHLORETHAMINE GEL

RATIONALE

To promote appropriate utilization of Valchlor based on FDA approved indication and NCCN guidelines.

Valchlor is for topical dermatological use only. Apply a thin film of Valchlor gel once daily to affected areas of the skin. Stop treatment with Valchlor for any grade of skin ulceration, blistering, or moderately‐severe or severe dermatitis (i.e., marked skin redness with edema). Upon improvement, treatment with Valchlor can be restarted at a reduced frequency of once every 3 days. If reintroduction of treatment is tolerated for at least one week, the frequency of application can be increased to every other day for at least one week and then to once daily application if tolerated.

Warnings and precautions include: mucosal or eye injury; secondary exposure to Valchlor; dermatitis; non-melanoma skin cancer; embryo-fetal toxicity; and flammable gel. The most common adverse reactions (≥5%) are dermatitis, pruritus, bacterial skin infection, skin ulceration or blistering, and hyperpigmentation. Valchlor is contraindicated in patients with severe hypersensitivity to mechlorethamine.

Valchlor is pregnancy category D. No drug interaction studies have been performed with Valchlor. Systemic exposure has not been observed with topical administration of Valchlor; therefore, systemic drug interactions are not likely.

Valchlor is a gel formulation of mechlorethamine (nitrogen mustard), an alkylating agent which inhibits rapidly proliferating cells. Mechlorethamine was previously approved as an intravenous formulation for the treatment of mycosis fungoides. Prior to the approval of Valchlor, there were no FDA-approved topical mechlorethamine products; only pharmacy-compounded petroleum ointment or aqueous-based topical preparations were available.

Developed primarily in the skin, CTCLs may progress to involve lymph nodes, blood and visceral organs. They account for about 5 percent of all non-Hodgkin lymphomas (NHL). There will be an estimated 69,740 new cases of NHL and 19,020 deaths from NHL in 2013. The overall 5-year relative survival rate for patients with NHL is 68 percent.

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RATIONALE (CONTINUED)

The National Comprehensive Cancer Network (NCCN) recommends skin-directed therapies for the initial treatment of patients with patch/plaque mycosis fungoides-type CTCL with the addition of milder systemic therapy. Localized skin-directed therapies include topical therapy with corticosteroids, mechlorethamine (previously compounded formulations and now Valchlor), carmustine, topical retinoids (Targretin, Tazorac), imiquimod, or local radiation therapy. Generalized skin directed therapies such as phototherapy (UVB or PUVA) and total skin electronic beam therapy are indicated for patients with widespread skin involvement. Systemic therapies with extracorporeal photopheresis, interferons, systemic retinoids, or histone deacetylase inhibitors are preferred over traditional chemotherapy for patients who do not respond to initial skin-directed therapies. They include oral Targretin and intravenous formulations Istodax and Ontak.

The efficacy of Valchlor was assessed in a randomized, active-controlled, non-inferiority clinical trial of 260 patients with Stage IA, IB, and IIA mycosis fungoides-type cutaneous T-cell lymphoma (CTCL) who had received at least one prior skin‐directed therapy. Qualifying prior therapies included topical corticosteroids, phototherapy, Targretin gel, and topical nitrogen mustard. Patients were not required to be refractory to or intolerant of prior therapies.

Patients were stratified based on Stage (IA vs. IB and IIA) and then randomized to receive Valchlor 0.016% (equivalent to 0.02% mechlorethamine HCL) or Aquaphor‐based Mechlorethamine HCL 0.02% ointment (comparator). Eighteen patients were excluded from the efficacy analysis due to protocol violations involving randomization at a single site. Study drug was to be applied topically on a daily basis for 12 months. Concomitant use of topical corticosteroids was not permitted during the study. Dosing could be suspended or continued with reduced frequency for dermatitis. The mean daily usage of Valchlor gel was 2.8 g (1 to 2 tubes per month). The maximum daily usage was 10.5 g (5 to 6 tubes per month).Patients were evaluated for a response on a monthly basis for the first 6 months and then every 2 months for the last 6 months using the Composite Assessment of Index Lesion Severity (CAILS) score. The CAILS score is obtained by adding the severity score of each of the following categories for up to 5 index lesions: erythema, scaling, plaque elevation, and surface area. Severity was graded from 0 (none) to 8 (severe) for erythema and scaling; 0 to 3 for plaque elevation; and 0 to 9 for surface area. A response was defined as greater than or equal to 50% reduction in baseline CAILS score which was confirmed at the next visit at least 4 weeks later. A complete response was defined as a confirmed CAILS score of 0. Non‐inferiority was considered to have been demonstrated if the lower bound of the 95% confidence interval (CI) around the ratio of response rates (Valchlor/Comparator) was greater than or equal to 0.75.Patients were also evaluated using the Severity Weighted Assessment Tool (SWAT). The SWAT score is derived by measuring each involved area as a percentage of total body surface area (%BSA) and multiplying it by a severity weighting factor (1=patch, 2=plaque, 3=tumor or ulcer). A response was defined as greater than or equal to 50% reduction in baseline SWAT score which was confirmed at the next visit at least 4 weeks later. The baseline demographics and disease characteristics were balanced between treatment arms. The median age was 57 years in the Valchlor arm and 58 years in the comparator arm. The majority of the patients were male (60% in Valchlor arm, 59% in Comparator arm) and white (75% in both treatment arms).

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

MECHLORETHAMINE GEL

RATIONALE (CONTINUED)

The median number of prior therapies was 2 in both treatment arms. The most common prior therapy was topical corticosteroids (used in 86% of patients in both treatment arms). The median body surface area (BSA) involvement at baseline was 8.5% (range 1%, 61%) in the Valchlor arm and 9% (range 1%, 76%) in the comparator arm.

Sixty percent (60%) of the patients on the Valchlor arm and 48% of patients on the comparator arm achieved a response based on the CAILS score. Valchlor was non-inferior to the comparator based on a CAILS overall response rate ratio of 1.24 (95% CI 0.98, 1.58). Complete responses constituted a minority of the CAILS or SWAT overall responses. The onset of CAILS overall response for both treatment arms showed a wide range from 1 to 11 months.

Efficacy in Patients with Mycosis Fungoides‑Type CTCL (From Valchlor Prescribing Information)

Response Rates	**VALCHLOR N=119**	**Comparator N=123**
CAILS Overall Response (CR+PR), %(N)	**60%**	**48%**
Complete Response (CR)	14%	11%
Partial Response (PR)	45%	37%
SWAT Overall Response (CR+PR), %(N)	**50%**	**46%**
Complete Response (CR)	7%	3%
Partial Response (PR)	43%	43%

FDA APPROVED INDICATIONS

Valchlor (mechlorethamine) is an alkylating drug indicated for the topical treatment of Stage IA and IB mycosis fungoides-type cutaneous T-cell lymphoma (CTCLs) in patients who have received prior skin‑directed therapy.

REFERENCES

- Ceptaris Therapeutics, Inc. Valchlor [Prescribing Information]. August 2013. Available at: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory#labelinfo [Accessed October 21, 2013]
- NCCN Clinical Practice Guidelines in Oncology. Non-Hodgkin's Lymphomas. Version 2.2013. Available at: http://www.nccn.org/professionals/physician_gls/pdf/nhl.pdf [Accessed October 21, 2013]
- American Cancer Society. Lymphoma of the Skin Detail Guide. Available at: http://www.cancer.org/cancer/lymphomaoftheskin/detailedguide/lymphoma-of-the-skin-detailed-guide-toc [Accessed October 21, 2013]

Created: 06/15
Effective: 07/22/15 Client Approval: 06/15 P&T Approval: 11/13

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

MEPOLIZUMAB

Generic	Brand	HICL	GCN	Exception/Other
MEPOLIZUMAB	NUCALA	42775		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **MEPOLIZUMAB (Nucala)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Severe asthma with an eosinophilic phenotype (inflammatory type)
   2. Eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome (inflammation of blood vessels with high levels of a type of white blood cell)
   3. Hypereosinophilic syndrome (HES)
   4. Chronic rhinosinusitis with nasal polyps (CRSwNP, inflammation of nasal and sinus ways with small growths in the nose)

B. **If you have severe asthma with an eosinophilic phenotype, approval also requires:**
   1. You are 6 years of age or older
   2. You are currently receiving therapy with **ONE** of the following:
      a. High-dose inhaled corticosteroid (ICS) AND a long-acting beta2 agonist (LABA)
      b. High-dose ICS/LABA combination product
   3. Nucala will be used as add-on maintenance treatment to one of the above inhaled asthma regimens
   4. You have experienced at least ONE asthma exacerbation (worsening of symptoms) within the past 12 months. Exacerbation is defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days

C. **If you have eosinophilic granulomatosis with polyangiitis (EGPA), approval also requires:**
   1. You are 18 years of age or older

A. **If you have hypereosinophilic syndrome (HES), approval also requires:**
   1. You are 12 years of age or older

E. **If you have chronic rhinosinusitis with nasal polyps (CRSwNP), approval also requires:**
   1. You are 18 years of age or older
   2. You had an inadequate response to intranasal corticosteroids

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MEPOLIZUMAB

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

A. You have ONE of the following diagnoses:
   1. Severe asthma with an eosinophilic phenotype
   2. Eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome (inflammation of blood vessels with high levels of a type of white blood cell)
   3. Hypereosinophilic syndrome (HES)
   4. Chronic rhinosinusitis with nasal polyps (CRSwNP)

B. **If you have severe asthma with an eosinophilic phenotype, renewal also requires:**
   1. You will continue to use inhaled corticosteroid (ICS) or ICS-containing combination inhalers
   2. You have shown a clinical response as evidenced by ONE of the following:
      a. Reduction in asthma exacerbation (worsening of symptoms) from baseline
      b. Decreased use of rescue medications
      c. Increase in percent predicted FEV1 (amount of air you can forcefully exhale) from pretreatment baseline
      d. Reduction in severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing, etc.)

C. **If you have chronic rhinosinusitis with nasal polyps, renewal also requires:**
   1. You have had clinical benefit compared to baseline (e.g., improvements in nasal congestion, sense of smell or size of polyps)

RATIONALE
Promote appropriate utilization of Nucala (mepolizumab) based on FDA approved indication.

FDA APPROVED INDICATIONS
Nucala (mepolizumab) is indicated for:

- the add-on maintenance treatment of patients with severe asthma aged 6 years and older, and with an eosinophilic phenotype
- the add-on maintenance treatment of adult patients 18 years and older with chronic rhinosinusitis with nasal polyps (CRSwNP)
- the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA)
- the treatment of adult and pediatric aged 12 years and older with hypereosinophilic syndrome (HES) for ⩾6 months without an identifiable non-hematologic secondary cause

Limitation of use: Nucala is not indicated for the relief of acute bronchospasm or status asthmaticus.

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MEPOLIZUMAB

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE

Asthma:
Adults and Adolescents Aged 12 Years and Older:
The recommended dosage of Nucala is 100mg given by subcutaneous injection every four weeks into the upper arm, thigh, or abdomen.

Pediatric Patients Aged 6 to 11 Years:
The recommended dosage of Nucala in children aged 6 to 11 years is 40 mg administered once every four weeks by subcutaneous injection into the upper arm, thigh, or abdomen.

Chronic rhinosinusitis with nasal polyps (CRSwNP):
The recommended dosage of Nucala is 100 mg administered once every 4 weeks by subcutaneous injection into the upper arm, thigh, or abdomen.

Eosinophilic granulomatosis with polyangiitis (EGPA):
The recommended dosage of Nucala is 300mg given every four weeks by subcutaneous injection as three separate 100mg injections into the upper arm, thigh, or abdomen.

Hyperesoinophilc Syndrome (HES):
The recommended dosage of Nucala is 300mg administered once every four weeks by subcutaneous injection as three separate 100mg injections into the upper arm, thigh, or abdomen.

HOW SUPPLIED

- 100 mg of lyophilized powder in a single-dose vial for reconstitution
- 100 mg/mL, single-dose, prefilled autoinjector or single-dose prefilled syringe

REFERENCES

- Nucala [Prescribing Information]. Philadelphia, PA. GlaxoSmithKline, LLC. July 2021.
- Chung KF, Wenzel SE, Brozek JL, et al. International ERS/ATS guidelines on definition, evaluation, and treatment of severe asthma. Eur Respir J. 2014;43(2):343-73.

Created: 01/16
Effective: 04/18/22 Client Approval: 03/15/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

METHADONE

Generic	Brand	HICL	GCN	Exception/Other
METHADONE	METHADOSE, DOLOPHINE, DISKETS	01745		ROUTE = ORAL

GUIDELINES FOR USE

RENEWAL CRITERIA will apply in the following scenarios only:
- For patients active with MDwise for 90 days or longer AND previous prior authorization approval for the same medication with the same strength AND recent paid pharmacy claims for the requested medication. Chart notes and/or cash pay for opioid use is not accepted.
- For patients new to MDwise within the past 90 days AND chart notes are provided that document the patient is stable on the requested medication.
  All other requests will be reviewed against the INITIAL CRITERIA.

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

Our guideline named **METHADONE** for patients with past use of opioid dependency agents (i.e., buprenorphine/naloxone SL tablets/films or buprenorphine SL tablets) requires the buprenorphine/naloxone or buprenorphine prescribing physician be notified about prescribed opiate therapy and must approve the use before the opioid analgesic will be authorized.

Our guideline named **METHADONE** does not permit concurrent use with carisoprodol-containing products.

Our guideline named **METHADONE** requires its use be for the treatment of pain or pain management only, and not for opioid dependence therapy. Our guideline does not allow for approval of methadone 40mg tablet for oral suspension (Diskets dispersible tablet) and methadone oral concentrate 10mg/mL as they are FDA (Food and Drug Administration)-indicated for opioid dependence therapy only.

Our guideline named **METHADONE** requires its use be for the treatment of pain or pain management only, and not for opioid dependence therapy. In addition, **BOTH** of the following criteria must be met:
- Methadone is prescribed for one of the following indications:
  - Cancer
  - Sickle cell disease
  - Palliative care
  - Another terminal diagnosis associated with significant pain
- You have had a trial and failure of generic MS Contin and **TWO** non-preferred long-acting opioid analgesics (such as Duragesic, Nucynta, OxyContin, Zohydro)

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

METHADONE

INITIAL CRITERIA (CONTINUED)

Our guideline named **METHADONE** requires its use be for the treatment of pain or pain management only, and not for opioid dependence therapy. In addition, **ALL** of the following criteria must be met:

- You have a diagnosis of moderate to severe pain
- You have had a trial and failure of generic MS Contin and **TWO** non-preferred long-acting opioid analgesics (such as Duragesic, Nucynta, OxyContin, Zohydro)
- You meet the definition of opioid tolerance [defined as those who are taking, for one week or longer, at least 60 morphine milligram equivalents (MME)/day such as 60mg oral morphine/day, 40mg oral oxycodone/day, 15mg oral hydromorphone/day, 60mg oral hydrocodone/day, 400mg oral codeine/day, or an equianalgesic dose of another opioid]. Your plan requires that for patients active with MDwise for 90 days or longer, only previously paid claims for opioids may be considered for this criterion. If your prescriber indicates that you have been on opioid therapy, it must be verified in claims history. Chart notes and/or cash pay for opioid use is not accepted.
- Your prescriber has consulted with you regarding the risks of opioid therapy and developed a pain management plan with clear treatment goals

Please note that additional criteria apply for concurrent use of opioid analgesics and benzodiazepines, including submission of signed prescriber attestation on a state-mandated fax form.

Our guideline named **METHADONE** for concurrent use of more than one long-acting opioid requires patients to meet **ALL** of the following criteria:

- You have a diagnosis of moderate to severe pain
- You experience refractory pain (pain that continues or returns) despite concurrent therapy with one short-acting opioid and one long-acting opioid as documented in chart notes or claim history
- Your prescriber has consulted with you regarding the risks of opioid therapy and developed a pain management plan with clear treatment goals

Exceptions to these criteria may be authorized in patients with moderate to severe pain from cancer or sickle cell disease or those receiving opioids as part of a palliative care (medical care for symptoms related to illness) plan. Please note that additional criteria apply for concurrent use of opioid analgesics and benzodiazepines, including submission of signed prescriber attestation on a state-mandated fax form.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

METHADONE

INITIAL CRITERIA (CONTINUED)

Our guideline named **METHADONE** for patients with claims in history for benzodiazepines requires that the prescriber submit the required fax form documenting **ALL** of the following:

- The diagnosis contributing to the need for benzodiazepine therapy and previous therapy attempted, including dates and doses of prior therapies
  - For generalized anxiety disorder, one of the following is required: Selective serotonin reuptake inhibitor (SSRI, such as sertraline or citalopram), serotonin-noradrenaline reuptake inhibitor (SNRI, such as duloxetine or venlafaxine), or pregabalin (generic for Lyrica)
  - For panic disorder, one of the following is required: SSRI or tricyclic antidepressant (TCA, such as amitriptyline or nortriptyline)
  - For social anxiety disorder (SAD), a trial of an SSRI is required
  - For obsessive compulsive disorder (OCD), a trial of an SSRI is required
  - For post-traumatic stress disorder (PTSD), one of the following is required: mirtazapine, paroxetine, amitriptyline, or phenelzine
  - For insomnia, one of the following is required: ramelteon or a sedating antidepressant (for example, trazodone, amitriptyline, doxepin, mirtazapine)
- The diagnosis contributing to the need for opioid analgesic therapy and previous therapy attempted, including dates and doses of prior therapies (if applicable)
  - For long-acting opioid therapy requested for chronic moderate to severe pain, ALL of the following are required:
    - You meet the definition of opioid tolerance (defined as those who are taking, for one week or longer, at least 60mg oral morphine/day, 40mg oral oxycodone/day, 15mg oral hydromorphone/day, 60mg oral hydrocodone/day, 400mg oral codeine/day, or an equianalgesic dose (a dose of one pain medication that is the same in pain-relieving effects to that of another pain medication) of another opioid). Your plan requires that for patients active with MDwise for 90 days or longer, only previously paid claims for opioids may be considered for this criterion. If your prescriber indicates that you have been on opioid therapy, it must be verified in claims history. Chart notes and/or cash pay for opioid use is not accepted. For patients active with MDwise less than 90 days, chart notes are required to verify previous opioid use for this criterion. (**NOTE:** For a diagnosis of moderate to severe cancer-related pain, pain related to sickle cell disease, or pain in patients receiving palliative care, this criterion does not apply.)
    - You have had a trial and failure of generic MS Contin and **TWO** non-preferred long-acting opioid analgesics (e.g., Duragesic, Nucynta, OxyContin, Zohydro)

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

METHADONE

INITIAL CRITERIA (CONTINUED)

- Your prescriber has signed an attestation as to **ALL** of the following:
  - Your prescriber will regularly review the patient's controlled substance utilization contained within INSPECT
  - You have been educated about the risks of using benzodiazepines and opioid analgesics together at the same time
  - Both you and your provider accept the of using benzodiazepines and opioid analgesics together at the same time

Please note that additional criteria apply for the benzodiazepine day supply limits. Your benzodiazepine prescription claim must not be greater than a 15-day supply of medication. You cannot receive more than 30 days' supply of benzodiazepine medication in the past 90 days. The current request for medication is also counted as a part of the 30 days' supply in the past 90 days.

Our guideline named **METHADONE** for patients with claims in history for Lybalvi (olanzapine/samidorphan) requires that you have not taken Lybalvi (olanzapine/samidorphan) less than or equal to 5 days prior to initiating methadone therapy.

RENEWAL CRITERIA

Our guideline named **METHADONE** does not permit concurrent use with carisoprodol-containing products.

Our guideline named **METHADONE** for renewal of therapy requires your prescriber to verify that you meet **ALL** of the following criteria:

- Opioid therapy has resulted in a meaningful improvement in your pain and/or function
- Your doctor has developed an updated pain management plan with clear treatment goals
- A risk assessment has been performed including review of the state prescription drug monitoring program (PDMP) data (e.g., INSPECT)
- Adherence to prescribed opioid regimen has been periodically assessed (e.g., urine drug screen, pill counts)

In addition, requests for renewal of concurrent use of (used at the same time with) more than one long-acting opioid requires that you meet **ALL** of the following rules:

- You have a diagnosis of moderate to severe pain
- You experience refractory pain (pain that continues or returns) despite concurrent therapy with one short-acting opioid and one long-acting opioid
- Your prescriber has consulted with you regarding the risks of opioid therapy and developed a pain management plan with clear treatment goals
- Exceptions may be granted if you have cancer, sickle cell disease (a type of red blood cell disorder), another terminal diagnosis associated with significant pain, or you are receiving opioids as part of a palliative care plan (treatment for symptoms related to an illness).

Please note that additional rules apply for concurrent use of opioid analgesics and benzodiazepines, including submission of signed prescriber attestation on a state-mandated fax form.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

METHADONE

RENEWAL CRITERIA (CONTINUED)

Our guideline named **METHADONE** for patients with claims in history for benzodiazepines requires that your doctor submit the required fax form documenting **ALL** of the following:

- The diagnosis contributing to the need for benzodiazepine therapy and previous therapy attempted, including dates and doses of prior therapies
  - For generalized anxiety disorder, one of the following is required: Selective serotonin reuptake inhibitor (SSRI, such as sertraline or citalopram), serotonin-noradrenaline reuptake inhibitor (SNRI, such as duloxetine or venlafaxine), or pregabalin (generic for Lyrica)
  - For panic disorder, one of the following is required: SSRI or tricyclic antidepressant (TCA, such as amitriptyline or nortriptyline)
  - For social anxiety disorder (SAD), a trial of an SSRI is required
  - For obsessive compulsive disorder (OCD), a trial of an SSRI is required
  - For post-traumatic stress disorder (PTSD), one of the following is required: mirtazapine, paroxetine, amitriptyline, or phenelzine
  - For insomnia, one of the following is required: ramelteon or a sedating antidepressant (for example, trazodone, amitriptyline, doxepin, mirtazapine)
- The diagnosis contributing to the need for renewal of the requested opioid analgesic therapy and that you meet the following:
  - Opioid therapy has resulted in a meaningful improvement in your pain and/or function
  - Your doctor has developed an updated pain management plan with clear treatment goals
  - A risk assessment has been performed including review of the state prescription drug monitoring program (PDMP) data (e.g., INSPECT)
  - Adherence to prescribed opioid regimen has been periodically assessed (e.g., urine drug screen, pill counts)
- Your prescriber has signed an attestation as to **ALL** of the following:
  - Your provider will regularly review your controlled substance utilization contained within INSPECT
  - You have been educated about the risks of using benzodiazepines and opioid analgesics together at the same time
  - Both you and your provider accept the of using benzodiazepines and opioid analgesics together at the same time

Please note that additional criteria apply for the benzodiazepine day supply limits. Your benzodiazepine prescription claim must not be greater than a 15-day supply of medication. You cannot receive more than 30 day's supply of benzodiazepine medication in the past 90 days. The current request for medication is also counted as a part of the 30 days' supply in the past 90 days.

Our guideline named **METHADONE** for patients with claims in history for Lybalvi (olanzapine/samidorphan) requires that you have not taken Lybalvi (olanzapine/samidorphan) less than or equal to 5 days prior to initiating methadone therapy.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

METHADONE

RATIONALE

To ensure opioid analgesics are used according to FDA approved indications with patient safety in mind, and to encourage the use of more cost-effective analgesics.

From 2000-2014, almost half a million people died due to drug overdose, with 2014 being the highest year for deaths on record. In that time, the number of opioids prescribed, as well as the number of opioid overdoses, has risen exponentially. At least half of all opioid overdose deaths involve a prescription opioid. Indiana was among the states that had a statistically significant increase of overdose deaths from 2013-2014.

According to recent research, the opioid epidemic has a disproportionate impact on Medicaid beneficiaries. Medicaid patients are prescribed opioids at double the rate of non-Medicaid patients, and are subsequently at much higher risk of prescription opioid overdose.

Improving the way that opioids are prescribed can ensure safer and more effective pain treatment, and reduce the addiction, misuse, abuse, and overdose of these drugs. These guidelines are to ensure that the use of opioids is consistent with their FDA approved indications, and to initiate action combating the current opioid epidemic.

Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60mg oral morphine/day, 25mcg transdermal fentanyl/hour, 40mg oral oxycodone/day, 15mg oral hydromorphone/day, 60mg oral hydrocodone/day, 400mg oral codeine/day, or an equianalgesic dose of another opioid for a week or longer.

Buprenorphine Conversion Table

Buprenorphine Product	Oral MME Conversion Factor
Belbuca buccal film (mcg/hr)	0.03
buprenorphine, tablet or film for opioid use disorder	30
Butrans transdermal patch (mcg/hr)	12.6

Example: 900 mcg buprenorphine buccal film x (60 films/30 days) x 0.03=54 MME/day
Example: 5 mcg buprenorphine patch x (4 patches/28 days) x 12.6= 9 MME/day

Fentanyl Conversion Table

Fentanyl Product	Oral MME Conversion Factor
fentanyl buccal or SL tablets, or lozenge/troche (mcg)	0.13
fentanyl film or oral spray (mcg)	0.18
fentanyl nasal spray (mcg)	0.16
fentanyl patch (mcg)	7.2

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

METHADONE

RATIONALE (CONTINUED)

Opioid Conversion Table

Drug	Oral MME Conversion Factor (1mg of drug to mg morphine)	60mg Morphine Equivalent Dose
benzhydrocodone	1.22	50mg
Butorphanol	7	8.5mg
Codeine	0.15	400mg
Dihydrocodeine	0.25	240mg
Hydrocodone	1	60mg
hydromorphone HCl	4	15mg
levorphanol tartrate	11	5.5mg
meperidine HCl	0.1	600mg
Morphine	1	60mg
oxycodone HCl	1.5	40mg
oxymorphone HCl	3	20mg
pentazocine HCl	0.37	162mg
tapentadol HCl	0.4	150mg
tramadol HCl	0.1	600mg

Methadone Conversion Table

Methadone daily dose (mg/day)	MME Conversion Factor (1mg of drug to mg morphine)	60mg Morphine Equivalent Dose
>0, <= 20	4	20mg
>20, <=40	8	7.5mg
>40, <=60	10	6mg
>60	12	5mg

Opioid Usage in Chronic Pain Management
Per systematic review in the CDC Guideline for Prescribing Opioids for Chronic Pain, long-term (≥ 1 year) efficacy of opioids in management of chronic pain, function, or quality of life is not established. Most randomized controlled trials present effectiveness within 6 weeks or less. Conversely, significant risks of adverse events are present with chronic opioid therapy, including opioid abuse and dependence, social role withdrawal, and increased risk of CNS depression, and withdrawal emergencies.

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RATIONALE (CONTINUED)

The CDC also recommends re-evaluating and re-establishing treatment goals, including realistic expectation for pain and function, as well as discontinuation strategies when benefits do not outweigh risks. The guideline provides the following recommendations for opioid selection, dosage, duration, follow-up and discontinuation:

- Immediate-release (IR) opioids are preferred over extended-release (ER) forms.
- The lowest effective dosage is preferred with initial opioid use. Caution is warranted at any dose and reassessing benefits and risks is recommended for 50 morphine milligram equivalents (MME) daily or more. 90 MME daily or more should be avoided if possible.
- Within 1 to 4 weeks of therapy, clinicians should evaluate benefits and harms of using opioids to treat chronic pain. Therapy continuation should be evaluated every 3 months or sooner. If benefits do not outweigh harms to continue opioid therapy, other therapies should be optimized and opioid tapering/discontinuation should be considered and encouraged.

Assessing Risk and Addressing Harms of Opioid Use

- Prior to and throughout opioid therapy, adverse events should be evaluated periodically. Factors that increase risk for opioid overdose include history of overdose or substance use disorder, 50 MME daily or more, and concurrent benzodiazepine use.
- Prescription drug monitoring program (PDMP) data (e.g., RXINSPECT) are useful to monitor total opioid dosage. PDMP data is helpful for initial and periodic opioid usage evaluations.
- Prescribing opioids and benzodiazepines concurrently should be avoided.
- For patients with substance use disorder, evidence-based treatment (medication-assisted and behavioral therapy) is recommended.

Analysis performed by the US Department of Health and Human Services Center for Disease Control and Prevention (CDC) determined the risk of harm to individuals increases as their opioid dose increases and as their length of opioid therapy increases. For example:

- Individuals taking opioid doses > 50 morphine milligram equivalents (MMEs) per day had twice the risk of death from an overdose than those taking < 20 MMEs per day.
- Individuals taking opioid doses > 90 (MMEs) per day had 10 times the risk of death from an overdose than those taking < 20 MMEs per day.
- Individuals taking an opioid for > 3 months (even at low doses) had 15 times the risk of addiction to those taking opioids for < 3 months.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

METHADONE

APPENDIX 1: BENZODIAZEPINE/OPIOID CONCURRENT USE FAX FORM
INDIANA HEALTH COVERAGE PROGRAMS (IHCP) PHARMACY BENEFIT
BENZODIAZEPINE AND OPIOID CONCURRENT THERAPY
PRIOR AUTHORIZATION REQUEST FORM

MDwise
Fax to: (858) 790-7100
c/o MedImpact Healthcare Systems, Inc.
Attn: Prior Authorization Department
10181 Scripps Gateway Court, San Diego, CA 92131
Phone: 1-800-788-2949

Today's Date
☐☐ / ☐☐ / ☐☐☐☐

Note: This form must be completed by the prescribing provider.
****All sections must be completed or the request will be denied.****

Patient's Medicaid # ☐☐☐☐☐☐☐☐☐☐☐☐	**Date of Birth** ☐☐ / ☐☐ / ☐☐☐☐
Patient's Name	**Prescriber's Name**
Prescriber's IN License # ☐☐☐☐☐☐☐☐	**Specialty**
Prescriber's NPI # ☐☐☐☐☐☐☐☐☐☐	**Prescriber's Signature: **Required below within attestation section.****
Return Fax # ☐☐☐ - ☐☐☐ - ☐☐☐☐	**Return Phone #** ☐☐☐ - ☐☐☐ - ☐☐☐☐

PA is required for the following:

- **Claim(s) for new opioid(s) to be used concurrently with benzodiazepines and exceeding 7 days within a 180-day period.**
- **Claim(s) for new benzodiazepine(s) to be used concurrently with opioids and exceeding 7 days of therapy within a 180-day period and/or exceeding established benzodiazepine/opioid concurrent therapy quantity limits (see Sedative Hypnotics/Benzodiazepine PA criteria).**

Benzodiazepine Agent(s)	Prescriber Name*	Quantity	Dosage Regimen/Duration

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Opioid Agent(s)	Prescriber Name*	Quantity	Dosage Regimen/Duration

***NOTE: If prescribers of the opioid(s) and benzodiazepine(s) are not the same, please answer the following questions:**

- **Are you requesting PA for: Benzodiazepine Agent(s) ☐ Opioid Agent(s) ☐ Both ☐**
- **Is/are the other prescriber(s) aware of the request for concurrent therapy? □ Yes □ No**
- **Has/have the other prescriber(s) been consulted about the risks associated with concurrent therapy, and do all prescribers involved believe continuing with concurrent therapy is warranted, given the risks associated with concurrent use? □ Yes □ No**

PA Requirements:

Patient diagnosis/diagnoses for use of benzodiazepine therapy:

Prior therapies attempted for the above diagnosis/diagnoses (submission of chart notes required in absence of claims history):

Drug Therapy	Dosage Regimen	Dates of Utilization

Do you plan to continue benzodiazepine therapy for this patient? □ Yes □ No
If no, please provide withdrawal plan:

Patient diagnosis/diagnoses for use of opioid therapy:

Prior therapies (both drug and non-drug) attempted for the above diagnosis/diagnoses (submission of chart notes required in absence of claims history):

Drug/Non-Drug Therapy	Dosage Regimen	Dates of Utilization	Reason for Discontinuation or Failure

Do you plan to continue opioid therapy for this patient? □ Yes □ No
If no, please provide withdrawal plan:

Attestation:

I, _____, hereby attest to the following:
(Prescriber Name)

The patient's INSPECT report has been evaluated and continues to be evaluated on a regular basis (Per IC 35-48-7-11.1, DO NOT attach a copy of the INSPECT report to this PA request).
I have educated the patient in regards to the risks of concurrent utilization of benzodiazepine and opioid therapy, and the patient accepts these risks.
If applicable, I have consulted other prescriber(s) involved in concurrent therapy and all prescribers involved agree to pursue concurrent opioid and benzodiazepine therapy for this patient.
I acknowledge, as the prescriber initiating or maintaining concurrent benzodiazepine and opioid therapy, the risk of adverse event(s), including respiratory depression, coma, and death, associated with concurrent utilization.

Prescriber Signature:_____

****Prescriber signature is required for consideration. Electronic or stamped signature will not be accepted.****

CONFIDENTIAL INFORMATION
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PRIOR AUTHORIZATION GUIDELINES

METHADONE

REFERENCES

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Created: 09/19
Effective: 06/13/22 Client Approval: 05/26/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

METHOTREXATE ORAL SOLUTION

Generic	Brand	HICL	GCN	Exception/Other
METHOTREXATE ORAL SOLUTION	XATMEP		43319	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **METHOTREXATE ORAL SOLUTION (Xatmep)** requires ONE of the following rule(s) be met for approval:

A. You are less than 18 years of age
B. You are unable to swallow methotrexate tablets

RENEWAL CRITERIA

Our guideline named **METHOTREXATE ORAL SOLUTION (Xatmep)** requires the following rule(s) be met for renewal:

A. You have history of paid claim(s) for the requested medication in the past 90 days
B. You have a previous authorization on file for the requested medication

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RATIONALE

Promote appropriate utilization of Xatmep based on FDA approved indication.

FDA APPROVED INDICATIONS

Xatmep is a folate analog metabolic inhibitor indicated for:

- The treatment of pediatric patients with acute lymphoblastic leukemia (ALL) as a component of a combination chemotherapy maintenance regimen
- Management of pediatric patients with active polyarticular juvenile idiopathic arthritis (pJIA) who are intolerant of or had an inadequate response to first-line therapy including full dose non-steroidal anti-inflammatory agents (NSAIDs)

DOSAGE AND ADMINISTRATION

Xatmep is intended for oral use only. Use another formulation of methotrexate for alternative dosing in patients who require dosing via other routes of administration. Instruct patients and caregivers that the recommended dose should be taken weekly, as directed, and that mistaken daily use of the recommended dose has led to fatal toxicity.

REFERENCES

- Xatmep [Prescribing Information]. Greenwood Village, CO. Silvergate Pharmaceuticals: April 2017.

Created: 06/17
Effective: 12/15/21 Client Approval: 10/26/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

METHYLNALTREXONE

Generic	Brand	HICL	GCN	Exception/Other
METHYLNALTREXONE BROMIDE	RELISTOR	35611		

GUIDELINES FOR USE

Our guideline for **METHYLNALTREXONE (Relistor)** requires that the patient have a diagnosis of opioid-induced constipation. For patients receiving palliative care for an advanced (terminal) illness, only Relistor injection may be approved. In addition, the following criteria must be met.

For patients with chronic non-cancer pain, approval requires all of the following criteria:

- The patient has been taking opioids for at least four weeks
- The patient had a previous trial of or contraindication to naloxegol (Movantik) AND lubiprostone (Amitiza)

METHYLNALTREXONE

RATIONALE

Promote cost-effective and clinically appropriate utilization of methylnaltrexone for its FDA approved indications and dosing. In pivotal trials, methylnaltrexone was studied in patients with advanced illness with a life expectancy of less than 6 months who were receiving care to control their symptoms.

FDA APPROVED INDICATIONS

- Treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain.
- Treatment of opioid-induced constipation (OIC) in adult patients with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient.
- Limitation of Use: Use beyond four months has not been studied in the advanced illness population.

DOSING

Opioid-induced constipation in adult patients with chronic non-cancer pain

- The recommended dosage of Relistor tablets is 450 mg taken orally once daily in the morning.
- The recommended dosage of Relistor injection is 12 mg administered subcutaneously once daily.

Opioid-induced constipation in adult patients with advanced illness

- The pre-filled syringe is only for patients who require a Relistor injection dose of 8 mg or 12 mg. Use the vial for patients who require other doses of Relistor injection.
- The recommended dosage regimen is one administered subcutaneously every other day, as needed (see Table 1). Do not administer more frequently than one dose per 24-hour period.

Table 1. Weight-based dosing of Relistor injection and corresponding injection volume for adult patients with OIC and advanced illness

Weight of adult patient	Subcutaneous dose	Injection volume
Less than 38 kg	0.15 mg/kg	**See below***
38 kg to less than 62 kg	8 mg	0.4 mL
62 kg to 114 kg	12 mg	0.6 mL
More than 114 kg	0.15 mg/kg	**See below***

*Calculate the injection volume for these patients by multiplying the patient weight in kilograms by 0.0075 and then rounding up the volume to the nearest 0.1 mL.

REFERENCES

- Relistor [package insert]. Bridgewater, NJ: Salix Pharmaceuticals. July 2016.

Created: 05/15
Effective: 10/20/17 Client Approval: 09/26/17 P&T Approval: 05/15

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

MIDOSTAURIN

Generic	Brand	HICL	GCN	Exception/Other
MIDOSTAURIN	RYDAPT	44227		

GUIDELINES FOR USE

The guideline named **MIDOSTAURIN (Rydapt)** requires a diagnosis of newly diagnosed acute myeloid leukemia (AML), aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL). The following criteria must also be met:

For newly diagnosed acute myeloid leukemia (AML), approval requires all of the following:

- The patient is FLT3 mutation-positive as detected by an FDA-approved diagnostic test
- The requested medication will be used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation
- The requested medication will not be used as a single-agent induction therapy for the treatment of patients with AML

RATIONALE

Promote appropriate utilization of **MIDOSTAURIN** based on FDA approved indication and dosage.

FDA APPROVED INDICATIONS

Rydapt is a kinase inhibitor indicated for the treatment of adult with:

- Newly diagnosed acute myeloid leukemia (AML) that is FLT3 mutation-positive as detected by an FDA-approved test, in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation
- Aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL)

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MIDOSTAURIN

FDA APPROVED INDICATIONS (CONTINUED)

Limitations of Use:
Rydapt is not indicated as a single-agent induction therapy for the treatment of patients with AML.

DOSAGE AND ADMINISTRATION

Rydapt is available as 25 mg capsules. Rydapt should be taken twice daily with food. Rydapt capsules should not be opened or crushed.

Recommended Dosage in Acute Myeloid Leukemia
The recommended dose of Rydapt for patients with acute myeloid leukemia is 50 mg orally twice daily with food on Days 8 to 21 of each cycle of induction with cytarabine and daunorubicin and on Days 8 to 21 of each cycle of consolidation with high-dose cytarabine.

FLT3 mutation status must be reported using the FDA-approved, in-vitro companion diagnostic LeukoStrat® CDx FLT3 Mutation Assay to ensure correct selection of patients eligible to be treated with Rydapt.

Recommended Dosage in ASM, SM-AHN, and MCL
The recommended dose of Rydapt for patients with ASM, SM-AHN, and MCL is 100 mg orally twice daily with food. Continue treatment until disease progression or unacceptable toxicity occurs. Dose modifications for therapy-related toxicities can be found in the prescribing information.

REFERENCES

- Rydapt [Prescribing Information]. East Hanover, New Jersey: Novartis Pharmaceuticals; April 2017.

Created: 05/17
Effective: 07/22/17 Client Approval: 05/30/17 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

MIFEPRISTONE

Generic	Brand	HICL	GCN	Exception/Other
MIFEPRISTONE	KORLYM		31485	

GUIDELINES FOR USE

INITIAL CRITERIA

The guideline named **MIFEPRISTONE (Korlym)** requires the following rule(s) be met for approval:
A. You have a diagnosis of endogenous Cushing's syndrome
B. You also have a diagnosis of type 2 diabetes mellitus **OR** glucose intolerance
C. You have failed surgical treatment for Cushing's syndrome **OR** you are not a candidate for surgery

RENEWAL CRITERIA

The guideline named **MIFEPRISTONE (Korlym)** requires the following rule(s) be met for renewal approval:
A. You have a diagnosis of endogenous Cushing's syndrome
B. You meet **BOTH** of the following criteria:
    1. You also have a diagnosis of type 2 diabetes mellitus **OR** glucose intolerance
    2. You have shown improvement in HgA1c from baseline

RATIONALE
To ensure appropriate use of Korlym.

FDA APPROVED INDICATIONS
- Korlym is a cortisol receptor antagonist indicated to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery.
- Korlym should not be used for the treatment of diabetes type 2 unrelated to endogenous Cushing's syndrome.

REFERENCE

- Korlym [Prescribing Information]. Menlo Park, CA: Corcept Therapeutics; November 2019.

Created: 06/15
Effective: 07/01/20 Client Approval: 05/12/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

MIGALASTAT

Generic	Brand	HICL	GCN	Exception/Other
MIGALASTAT	GALAFOLD	44433		

GUIDELINES FOR USE

The guideline named **MIGALASTAT (GALAFOLD)** requires a diagnosis of Fabry disease. In addition, the following criteria must be met.

- The patient is 18 years of age or older
- The patient has an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data

RATIONALE

To ensure appropriate use of Galafold (migalastat) consistent with FDA-approved indications.

FDA-APPROVED INDICATIONS

Galafold is an alpha-galactosidase A (a-Gal A) pharmacological chaperone indicated for the treatment of adults with a confirmed diagnosis of Fabry disease and an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data.

This indication is approved under accelerated approval based on reduction in kidney interstitial capillary cell globotriaosylceramide (KIC GL-3) substrate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

DOSAGE AND ADMINISTRATION

Galafold is dosed at 123 mg orally once every other day at the same time of day. Galafold should not be taken on two consecutive days. Doses should be taken on an empty stomach. Food should not be consumed for at least two hours before and two hours after taking Galafold, to give a minimum 4-hour fast. However, clear liquids can be consumed during this fasting window.

REFERENCES

- Galafold [Prescribing Information]. Cranbury, NJ: Amicus Therapeutics; August 2018.

Created: 11/18
Effective: 11/23/18 Client Approval: 11/06/18 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

MIGLUSTAT

Generic	Brand	HICL	GCN	Exception/Other
MIGLUSTAT	ZAVESCA	25098		

GUIDELINES FOR USE

Approval requires a diagnosis of type 1 Gaucher disease in patients 18 years of age or older for whom enzyme replacement therapy is not an option.

RATIONALE
Ensure that Zavesca is being used to treat patients with type 1 Gaucher disease.

FDA APPROVED INDICATION
ZAVESCA® is indicated for the treatment of adult patients with mild to moderate type 1 Gaucher disease for whom enzyme replacement therapy is not a therapeutic option (e.g., due to constraints such as allergy, hypersensitivity, or poor venous access).

REFERENCES

- Actelion Pharmaceuticals. Zavesca package insert. South San Francisco. November 2010.
- Elstein D, Dweck A, Attias D et al. Oral maintenance clinical trial with miglustat for type I Gaucher disease: switch from or combination with intravenous enzyme replacement. Blood. 2007;110:2296-2301

Created: 06/15
Effective: 07/22/15 Client Approval: 06/15 P&T Approval: 08/12

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

MIPOMERSEN SODIUM

Generic	Brand	HICL	GCN	Exception/Other
MIPOMERSEN SODIUM	KYNAMRO	40041		

GUIDELINES FOR USE

INITIAL CRITERA

The guideline named **MIPOMERSEN SODIUM (Kynamro)** requires a diagnosis of homozygous familial hypercholesterolemia (HoFH). The following criteria must also be met:

- The patient has a LDL-cholesterol level greater than or equal to 70 mg/dL while on maximally tolerated drug treatment
- The patient has had a previous trial of Repatha (evolocumab) unless the patient lacks functional LDL receptors

For statin tolerant patients, approval also requires the following:

- The patient meets **ONE** of the following criteria:
  - The patient has been taking a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) for a duration of at least 8 weeks, **OR**
  - The patient has been taking a maximally tolerated dose of any statin for a duration of at least 8 weeks given that the patient cannot tolerate a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
- The patient will continue statin treatment in combination with Kynamro

For statin intolerant patients, approval also requires ONE of the following:

- The patient has an absolute contraindication to statin therapy (e.g., active decompensated liver disease, nursing female, pregnancy or plans to become pregnant, hypersensitivity reaction)
- The patient has complete statin intolerance as defined by severe and intolerable adverse effects (e.g., creatine kinase elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis, severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group) that have occurred with trials of at least two separate statins and have improved with the discontinuation of each statin

RENEWAL CRITERIA

The guideline named **MIPOMERSEN SODIUM (Kynamro)** renewal requires that the patient has had at least 26 weeks of therapy, with a LDL reduction of at least 20% from baseline after Kynamro (mipomersen) therapy for 26 weeks. Patient must also be adherent to Kynamro (mipomersen) and statin therapy (or Kynamro and other lipid-lowering agent, if the patient is statin intolerant).

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

MIPOMERSEN SODIUM

RATIONALE
To ensure appropriate use of Kynamro based on FDA approved indication dosing, and national treatment guidelines.

FDA APPROVED INDICATION
Kynamro (mipomersen) is indicated as an adjunct to lipid-lowering medications and diet to reduce low density lipoprotein-cholesterol (LDL-C), apolipoprotein B (apo B), total cholesterol (TC), and non-high density lipoprotein-cholesterol (non HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH).

Limitations of Use:
- The safety and effectiveness of Kynamro have not been established in patients with hypercholesterolemia who do not have HoFH.
- The effect of Kynamro on cardiovascular morbidity and mortality has not been determined.
- The use of Kynamro as an adjunct to LDL apheresis is not recommended.

DOSAGE AND ADMINISTRATION
The recommended dose of Kynamro is 200 mg once weekly as a subcutaneous injection.

Kynamro is intended for subcutaneous use only. Do not administer intramuscularly or intravenously. The injection should be given on the same day every week, but if a dose is missed, the injection should be given at least 3 days from the next weekly dose.

REFERENCES
Kynamro (mipomersen) [Prescribing Information]. Cambridge, MA: Genzyme Corp.; May 2016.

Created: 06/15
Effective: 03/04/22 Client Approval: 02/03/22 P&T Approval: N/A

MOBOCERTINIB

Generic	Brand	HICL	GCN	Exception/Other
MOBOCERTINIB SUCCINATE	EXKIVITY	47578		

GUIDELINES FOR USE

Our guideline named **MOBOCERTINIB (Exkivity)** requires the following rule(s) be met for approval:

A. You have locally advanced or metastatic (cancer that has spread from where it started to nearby tissue or has spread to other parts of the body) non-small cell lung cancer (NSCLC: type of lung cancer)
B. You are 18 years of age or older
C. You have epidermal growth factor receptor (EGFR) exon 20 insertion mutations (type of gene mutation), as detected by a Food and Drug Administration (FDA)-approved test
D. Your disease progressed (disease has gotten worse) on or after platinum-based chemotherapy such as cisplatin, carboplatin, oxaliplatin

RATIONALE

Ensure appropriate use of Exkivity based on FDA approved indications and dosing.

FDA APPROVED INDICATIONS

Exkivity is a kinase inhibitor indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy.

DOSAGE AND ADMINISTRATION

The recommended dose of Exkivity is 160mg orally once daily.

REFERENCES

- Exkivity [Prescribing Information]. Lexington, MA: Takeda Pharmaceuticals America, Inc., September 2021.

Created: 10/21
Effective: 12/20/21 Client Approval: 11/19/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

MODAFANIL

Generic	Brand	HICL	GCN	Exception/Other
MODAFANIL	PROVIGIL	10865		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named **MODAFANIL (Provigil)** requires that the patient is greater than or equal to 6 years of age and has a diagnosis of **ONE** of the following:

- Narcolepsy
- Excessive daytime sleepiness
- Obstructive sleep apnea/hypopnea syndrome
- Shift work sleep disorder
- Attention Deficit Hyperactivity Disorder
- Unipolar and bipolar depression
- Depression-related fatigue
- Sleep deprivation
- Steinert Myotonic Dystrophy Syndrome

RENEWAL CRITERIA

Our guideline for **MODAFINIL (Provigil)** renewal requires that the patient has a previous authorization on file for the requested medication **AND** there is history of paid claims for 90 of the past 120 days.

RATIONALE
Promote prudent prescribing of agents for the treatment of narcolepsy.

INDICATIONS
Provigil is indicated to improve wakefulness in adult patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea (OSA), or shift work disorder (SWD).

DOSING
The recommended dosage of Provigil for each indication is as follows:

- Narcolepsy or OSA: 200 mg once a day in the morning.
- SWD: 200 mg once a day, taken approximately one hour prior to start of the work shift.

REFERENCES
Provigil [Prescribing Information]. North Wales, PA: Teva Pharmaceuticals, USA, Inc.; November 2018.

Created: 03/20
Effective: 05/01/20 Client Approval: 03/13/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

MONOMETHYL FUMARATE

Generic	Brand	HICL	GCN	Exception/Other
MONOMETHYL FUMARATE	BAFIERTAM	46576		

GUIDELINES FOR USE

Our guideline named **MONOMETHYL FUMARATE (Bafiertam)** requires the following rule(s) be met for approval:

A. You have multiple sclerosis (MS: disease in which the immune system eats away at the protective covering of the nerves)
B. You are 18 years of age or older
C. You have previously tried or have a contraindication (medical reason why you cannot take) to dimethyl fumarate (generic Tecfidera) and ONE of the following: Aubagio, Avonex, glatiramer (generic Copaxone/Glatopa), or Rebif

(**Please note:** Other multiple sclerosis medications may also require prior authorization)

RATIONALE

To ensure appropriate use of Bafiertam consistent with FDA approved indication.

FDA APPROVED INDICATIONS

Bafiertam is indicated for the treatment of patients with the relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

DOSING

The starting dose of Bafiertam is 95 mg twice a day orally for 7 days. After 7 days, the dosage should be increased to the maintenance dosage of 190 mg (administered as two 95 mg capsules) twice a day orally.

REFERENCES

- Bafiertam [Prescribing Information]. High Point, NC: Banner Life Sciences LLC; May 2021.

Created: 05/21
Effective: 08/16/21 Client Approval: 07/13/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

NALOXONE

Generic	Brand	HICL	GCN	Exception/Other
NALOXONE AUTOINJECTOR	EVZIO		36342 42502	ROUTE = INJECTION

GUIDELINES FOR USE

Our guideline for **EVZIO** requires current use of an opioid, a medical reason (other than rhinorrhea) why Narcan Nasal Spray cannot be used, and one of the following risk factors for overdose:

- History of emergency medical care involving opioid overdose
- History of substance abuse
- Daily prescription opioid doses ≥ 60 mg morphine equivalents
- Concomitant use with benzodiazepines, antidepressants, alcohol, or muscle relaxants
- Chronic pulmonary disease (e.g., emphysema, chronic bronchitis, asthma)
- Sleep apnea
- Renal impairment
- Chronic cirrhosis or hepatitis
- Mental illness (e.g., bipolar disorder, schizophrenia)
- Cognitive impairment

NALOXONE

RATIONALE

To ensure use of EVZIO is consistent with indication.

FDA APPROVED INDICATIONS

EVZIO is an opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.

DOSING AND ADMINISTRATION

EVZIO is intended for immediate administration as emergency therapy in settings where opioids may be present. Because treatment of suspected opioid overdose must be performed by someone other than the patient, instruct the prescription recipient to inform those around them about the presence of EVZIO and its instructions for use. Each EVZIO autoinjector contains a single dose of naloxone, either as 0.4mg/0.4mL or 2mg/0.4mL. EVZIO is administered intramuscularly or subcutaneously into the thigh.

REFERENCES

- Kaleo, Inc. Evzio package insert. Richmond, VA. October 2016.
- Zedler B, Xie L, Wang L, et al. Risk factors for serious prescription opioid-related toxicity or overdose among veterans health administration patients. Pain Med 2014. Published online: 14 Jun 2014.

Created: 04/16
Effective: 02/16/17 Client Approval: 02/02/17 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

NATALIZUMAB

Generic	Brand	HICL	GCN	Exception/Other
NATALIZUMAB	TYSABRI	26750		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **NATALIZUMAB (Tysabri)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects the lining of the digestive tract)
   2. A relapsing form of multiple sclerosis (MS: an illness where the immune system eats away at the protective covering of the nerves), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)

B. **If you have moderate to severe Crohn's disease (CD), approval also requires:**
   1. You are 18 years of age or older
   2. You have previously tried ONE of the following conventional agents: corticosteroids (e.g., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   3. You have previously tried Humira

C. **If you have a relapsing form of multiple sclerosis (MS), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is being used as monotherapy (used by itself)
   3. You have previously tried at least **ONE** drug indicated for the treatment of multiple sclerosis (MS) (e.g., Avonex, Rebif, Copaxone, Tecfidera, Gilenya, Aubagio)

RENEWAL CRITERIA

Our guideline named **NATALIZUMAB (Tysabri)** requires the following rule(s) be met for renewal:

A. You have a diagnosis of moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
B. You have experienced or maintained symptomatic improvement while on therapy

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RATIONALE
Ensure appropriate diagnostic, utilization, and safety criteria are used for the management of requests for Tysabri.

FDA APPROVED INDICATIONS
Multiple Sclerosis
Tysabri is indicated as monotherapy for the treatment of adult patients with relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.

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FDA APPROVED INDICATIONS (CONTINUED)

Crohn's Disease
Tysabri is indicated for inducing and maintaining clinical response and remission in adult patients with moderately to severely active Crohn's disease (CD) with evidence of inflammation who have had an inadequate response to, or are unable to tolerate, conventional CD therapies and inhibitors of TNF-α. Tysabri should not be used in combination with immunosuppressants (e.g., 6-mercaptopurine, azathioprine, cyclosporine, or methotrexate) or inhibitors of TNF-α.

Tysabri increases the risk of progressive multifocal leukoencephalopathy (PML), an opportunistic viral infection of the brain that usually leads to death or severe disability. Risk factors for the development of PML include duration of therapy, prior use of immunosuppressants, and presence of anti-JCV antibodies. These factors should be considered in the context of expected benefit when initiating and continuing treatment with Tysabri. Monitor patients and withhold Tysabri immediately at the first sign or symptom suggestive of PML.

DOSING
Multiple Sclerosis
The recommended dose of Tysabri for multiple sclerosis is 300 mg intravenous infusion over one hour every four weeks.

Crohn's Disease
The recommended dose of Tysabri for Crohn's disease is 300 mg intravenous infusion over one hour every four weeks. Although Tysabri should not be used with concomitant immunosuppressants (e.g., 6-mercaptopurine, azathioprine, cyclosporine, or methotrexate) or concomitant inhibitors of TNF-α, aminosalicylates may be continued during treatment with Tysabri.

If the patient with Crohn's disease has not experienced therapeutic benefit by 12 weeks of induction therapy, discontinue Tysabri. For patients with Crohn's disease that start TYSABRI while on chronic oral corticosteroids, commence steroid tapering as soon as a therapeutic benefit of Tysabri has occurred; if the patient with Crohn's disease cannot be tapered off oral corticosteroids within six months of starting Tysabri, discontinue Tysabri. Other than the initial six-month taper, prescribers should consider discontinuing Tysabri for patients who require additional steroid use that exceeds three months in a calendar year to control their Crohn's disease.

REFERENCES
- Biogen Idec Inc. Tysabri Product Information, Cambridge, MA. June 2020.
- Lichtenstein G, Loftus EV, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. American Journal of Gastroenterology: April 2018, Volume 113, Issue 4, pp 481-517. doi: 10.1038/ajg.2018.27

Created: 02/18
Effective: 04/11/22 Client Approval: 03/09/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

NERATINIB

Generic	Brand	HICL	GCN	Exception/Other
NERATINIB	NERLYNX	44421		

GUIDELINES FOR USE

Our guideline named **NERATINIB (Nerlynx)** requires you have early stage (stage I-III) breast cancer OR advanced or metastatic breast cancer

For early stage (stage I-III) breast cancer, approval also requires:
- You are 18 years of age or older
- The tumor is HER2-overexpressed/amplified (i.e., HER2-positive)
- The tumor is hormone-receptor positive
- The requested medication will be used as extended adjuvant therapy following Herceptin-(trastuzumab-) based therapy
- The medication is being requested within 2 years of completing the last trastuzumab dose

For advanced or metastatic breast cancer, approval also requires:
- You are 18 years of age or older
- The tumor is HER2-overexpressed/amplified (i.e., HER2-positive)
- The requested medication will be used in combination with capecitabine
- You have received two or more prior anti-HER2 based regimens in the metastatic setting

RATIONALE
Promote appropriate utilization of **NERATINIB** based on FDA approved indication and dosage.

FDA APPROVED INDICATIONS
Nerlynx is a kinase inhibitor indicated:

As a single agent, for the extended adjuvant treatment of adult patients with early-stage HER2-positive breast cancer, to follow adjuvant trastuzumab-based therapy.
In combination with capecitabine, for the treatment of adult patients with advanced or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 based regimens in the metastatic setting.

DOSAGE AND ADMINISTRATION
Extended Adjuvant Treatment of Early Stage Breast Cancer: The recommended dose of Nerlynx is 240 mg (six tablets) orally once daily, with food, continuously until disease recurrence or for up to one year.

Advanced or Metastatic Breast Cancer: The recommended dose of Nerlynx is 240 mg (six tablets) given orally once daily with food on Days 1-21 of a 21-day cycle plus capecitabine (750 mg/m^2 given orally twice daily) on Days 1-14 of a 21-day cycle until disease progression or unacceptable toxicities.

REFERENCES
Nerlynx [Prescribing Information]. Los Angeles, CA: Puma Biotechnology; February 2020.

Created: 08/17
Effective: 05/01/20 Client Approval: 04/17/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

NILOTINIB

Generic	Brand	HICL	GCN	Exception/Other
NILOTINIB HCL	TASIGNA	35149		

GUIDELINES FOR USE

Our guideline named **NILOTINIB (Tasigna)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML: a type of blood cell cancer) in chronic phase
   2. Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia in chronic or accelerated phase

B. **If you have newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase (PH+CML-CP), approval also requires:**
   1. You are 1 year of age or older

C. **If you have Philadelphia chromosome-positive chronic myeloid leukemia in chronic or accelerated phase (PH+CML-CP or Ph+CML-AP), approval also requires:**
   1. You are 18 years of age or older
   2. You are resistant or intolerant to prior therapy including Gleevec (imatinib)
   3. You have a Breakpoint Cluster Region Abelson Murine Leukemia (BCR-ABL) mutational analysis (a type gene testing) confirming that the following mutations (a permanent change in your DNA that make up your gene) are NOT present: T315I, Y253H, E255K/V, F359V/C/I, or G250E

D. **If you have Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase or accelerated phase (PH+CML-CP or Ph+CML-AP), approval also requires:**
   1. You are 1 to 17 years of age
   2. You are resistant or intolerant to prior therapy with other tyrosine kinase inhibitors (TKI) such as Gleevec (imatinib), Sprycel (dasatinib), Bosulif (bosutinib)
   3. You have a Breakpoint Cluster Region Abelson Murine Leukemia (BCR-ABL) mutational analysis (type of gene testing) confirming that the following mutations (a permanent change in your DNA that make up your gene) are NOT present: T315I, Y253H, E255K/V, F359V/C/I, or G250E

RATIONALE

Ensure appropriate utilization of nilotinib based on its FDA approved indications.

FDA APPROVED INDICATIONS

Tasigna is a kinase inhibitor indicated for the following:

- Adult and pediatric patients greater than or equal to 1 year of age with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase.
- Adult patients with chronic phase (CP) and accelerated phase (AP) Ph+ CML resistant or intolerant to prior therapy that included imatinib.
- Pediatric patients greater than or equal to 1 year of age with Ph+ CML-CP and CML-AP resistant or intolerant to prior tyrosine-kinase inhibitor (TKI) therapy

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NILOTINIB

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

Tasigna should be taken twice daily at approximately 12-hour intervals and must be taken on an empty stomach. No food should be consumed for at least 2 hours before the dose is taken and for at least 1 hour after the dose is taken. Advise patients to swallow the capsules whole with water.

For patients who are unable to swallow capsules, the contents of each capsule may be dispersed in 1 teaspoon of applesauce (puréed apple). The mixture should be taken immediately (within 15 minutes) and should not be stored for future use.

Adult patients with Newly diagnosed Ph+ CML in chronic phase

- The recommended dose of Tasigna is 300 mg orally twice daily.

Adult Patients with Resistant or Intolerant Ph+ CML-CP and CML-AP

- The recommended dose of Tasigna is 400 mg orally twice daily.

Pediatric Patients with Newly Diagnosed Ph+ CML-CP or Resistant or Intolerant Ph+ CML-CP

- The recommended dose of Tasigna for pediatric patients is 230 mg/m^2 orally twice daily, rounded to the nearest 50 mg dose (to a maximum single dose of 400 mg).
- If needed, attain the desired dose by combining different strengths of Tasigna capsules. Continue treatment as long as clinical benefit is observed or until unacceptable toxicity occurs.

REFERENCE

- Tasigna [prescribing information]. Novartis Pharmaceuticals Corporation. East Hanover, NJ. September 2021.

Created: 06/15
Effective: 01/01/22 Client Approval: 11/30/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

NIMODIPINE SOLUTION

Generic	Brand	HICL	GCN	Exception/Other
NIMODIPINE	NYMALIZE		34794 43848 47984 47985 48405	

GUIDELINES FOR USE

Our guideline named **NIMODIPINE SOLUTION (Nymalize)** requires the following rule(s) be met for approval:

A. You have a history of subarachnoid hemorrhage (SAH: bleeding in the space surrounding your brain) from a ruptured intracranial berry aneurysm (an area of an artery wall in your brain ballooned and burst) within the past 21 days
B. You are 18 years of age or older
C. You are unable to swallow nimodipine oral capsules

RATIONALE

To ensure appropriate diagnostic, utilization, and safety criteria are used for the management of requests for nimodipine solution.

INDICATIONS

Nymalize is a dihydropyridine calcium channel blocker indicated for the improvement of neurological outcome by reducing the incidence and severity of ischemic deficits in adult patients with subarachnoid hemorrhage (SAH) from ruptured intracranial berry aneurysms regardless of their post-ictus neurological condition (i.e., Hunt and Hess Grades I-V).

DOSAGE

The recommended oral dosage of nimodipine solution is 10 mL (60 mg) every 4 hours for 21 consecutive days.

REFERENCES

- Nymalize [Prescribing Information]. Atlanta, GA: Arbor Pharmaceuticals, Inc. November 2020.

Created: 06/15
Effective: 08/06/21 Client Approval: 07/20/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

NINTEDANIB

Generic	Brand	HICL	GCN	Exception/Other
NINTEDANIB	OFEV	41489		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **NINTEDANIB (Ofev)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
1. Idiopathic pulmonary fibrosis (IPF: scarring of the lungs with an unknown cause)
2. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: disorder that causes hardening of lung tissue)
3. Chronic fibrosing interstitial lung disease (ILDs) with a progressive phenotype (PF-ILD: scarring of the lungs caused by different underlying diseases or conditions that worsens over time)

B. If you have idiopathic pulmonary fibrosis (IPF), approval also requires:
1. You are 18 years of age or older
2. You have a usual interstitial pneumonia pattern as evidenced by high-resolution computed tomography (HRCT: type of imaging test) alone or via a combination of surgical lung biopsy and HRCT
3. You do NOT have other known causes of interstitial lung disease such as connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis (lung inflammation from inhaled substances), systemic sclerosis (an immune system disorder), rheumatoid arthritis (joint pain and inflammation), radiation, sarcoidosis (growth of inflammatory cells in the body), bronchiolitis obliterans organizing pneumonia (type of lung infection), human immunodeficiency virus infection, viral hepatitis (type of liver inflammation), or cancer
4. You have a predicted forced vital capacity (FVC: amount of air that can be forcefully exhaled) of at least 50% at baseline
5. You are NOT receiving treatment with Esbriet

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NINTEDANIB

INITIAL CRITERIA (CONTINUED)

C. If you have systemic sclerosis-associated interstitial lung disease (SSc-ILD), approval also requires:
1. You have Systemic Sclerosis (SSc) according to the American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR)
2. You are 18 years of age or older
3. You have at least 10% fibrosis (tissue scarring) on a chest high resolution computed tomography (HRCT)
4. You have a baseline forced vital capacity (FVC: amount of air that can be forcefully exhaled) of at least 40% of predicted value
5. Other causes of interstitial lung disease are ruled out. Other causes may include heart failure/fluid overload, drug-induced lung toxicity [cyclophosphamide, methotrexate, ACE-inhibitors (class of blood pressure medications)], recurrent aspiration (inhaling) such as from GERD (acid reflux), pulmonary vascular disease (affecting blood vessels in lungs), pulmonary edema (excess fluid in the lungs), pneumonia (type of lung infection), chronic pulmonary thromboembolism (blood clot in lungs), alveolar hemorrhage (bleeding of a part of the lungs) or interstitial lung disease caused by another rheumatic (inflammatory) disease, such as mixed connective tissue disease (MCTD)

D. If you have chronic fibrosing interstitial lung disease with progressive phenotype (PF-ILD), approval also requires that you are 18 years of age or older

RENEWAL CRITERIA

Our guideline named **NINTEDANIB (Ofev)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
1. Idiopathic pulmonary fibrosis (IPF: scarring of the lungs with an unknown cause)
2. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: disorder that causes hardening of lung tissue)
3. Chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype (PF-ILD: scarring of the lungs caused by different underlying diseases or conditions that worsens over time)

B. You have experienced a clinically meaningful improvement or maintenance in annual rate of decline

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

NINTEDANIB

RATIONALE
Promote appropriate utilization of Ofev based on FDA approved indication and dosage.

FDA APPROVED INDICATIONS
Ofev is a kinase inhibitor indicated for:
- Treatment of idiopathic pulmonary fibrosis (IPF).
- Treatment of chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype.
- Slowing the rate of decline in pulmonary function in patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD).

DOSAGE
The recommended dosage of Ofev is 150 mg twice daily administered approximately 12 hours apart. Do not exceed the recommended maximum daily dosage of 300 mg.

Dose reduction (100mg twice daily) or temporary interruption maybe necessary for management of adverse events until the specific adverse reaction resolves to levels that allow continuation of therapy. If a patient cannot tolerate 100 mg twice daily treatment with Ofev should be discontinued. In patients with aminotransferase (AST) or alanine aminotransferase (ALT) >3 times to <5 times the upper limit of normal (ULN) without signs of severe liver damage, interrupt treatment or reduce Ofev to 100 mg twice daily. Discontinue Ofev for AST or ALT elevations >5 times ULN or >3 times ULN with signs or symptoms of severe liver damage.

REFERENCES
Ofev [Prescribing Information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; October 2020.

Created: 06/15
Effective: 03/14/22 Client Approval: 02/04/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

NIRAPARIB

Generic	Brand	HICL	GCN	Exception/Other
NIRAPARIB TOSYLATE	ZEJULA	44177		

GUIDELINES FOR USE

Our guideline named **NIRAPARIB (Zejula)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Advanced epithelial ovarian (cancer that forms on the surface of the ovary), fallopian tube, or primary peritoneal cancer (type of abdominal cancer)
   2. Recurrent (returning) epithelial ovarian cancer (cancer that forms on the surface of the ovary), fallopian tube cancer, or primary peritoneal cancer (type of abdominal cancer)

B. **If you have advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You are in complete or partial response to first-line platinum-based chemotherapy
   3. The requested medication will be used for maintenance treatment (treatment to prevent cancer from coming back after it has disappeared after initial therapy)
   4. The requested medication will be started no later than 12 weeks after your most recent platinum-containing regimen

C. **If you have recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   a. You are 18 years of age or older
   b. You are in complete or partial response to your most recent platinum-based chemotherapy
   c. The requested medication will be used for maintenance treatment (treatment to prevent cancer from coming back after it has disappeared after initial therapy)
   d. Your cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either a deleterious or suspected deleterious BRCA mutation
   e. The requested medication will be started no later than 8 weeks after your most recent platinum-containing regimen

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

NIRAPARIB

RATIONALE
Promote appropriate utilization of **NIRAPARIB** based on FDA approved indication and dosage.

FDA APPROVED INDICATIONS
Zejula is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated:
- For the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response first-line to platinum-based chemotherapy.
- For the maintenance treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.

DOSAGE AND ADMINISTRATION
First-Line Maintenance Treatment of Advanced Ovarian Cancer
- For patients weighing less than 77 kg (170 lbs) OR with a platelet count of less than 150,000/µL, the recommended dose is 200 mg (two 100-mg capsules) taken orally once daily.
- For patients weighing greater than or equal to 77 kg (170 lbs) AND who have a platelet count greater than or equal to 150,000/µL, the recommended dose is 300 mg (three 100-mg capsules) taken orally once daily.

For the maintenance treatment of advanced ovarian cancer, patients should start treatment with Zejula no later than 12 weeks after their most recent platinum-containing regimen.

Maintenance Treatment of Recurrent Ovarian Cancer
The recommended dose of Zejula is 300 mg (three 100-mg capsules) taken orally once daily.

For the maintenance treatment of recurrent ovarian cancer, patients should start treatment with Zejula no later than 8 weeks after their most recent platinum-containing regimen.

REFERENCES
Zejula [Prescribing Information]. Waltham, MA: Tesaro; December 2022.

Created: 05/17
Effective: 01/30/23 Client Approval: 01/05/23 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

NITISINONE

Generic	Brand	HICL	GCN	Exception/Other
NITISINONE	ORFADIN, NITYR	23253		ROUTE = ORAL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **NITISINONE (Orfadin, Nityr)** requires the following rule(s) be met for approval:

A. You have hereditary tyrosinemia type 1 (HT-1: a type of genetic disorder where you cannot breakdown an important component in proteins)
B. Your diagnosis is confirmed by elevated urinary or plasma succinylacetone levels (a chemical that is present in hereditary tyrosinemia) OR a mutation in the fumarylacetoacetate hydrolase gene
C. You have been counseled on maintaining dietary restriction of tyrosine and phenylalanine
D. **If you are requesting Nityr tablets or Orfadin oral suspension, approval also requires:**
    1. You have previously tried generic nitisinone capsules

RENEWAL CRITERIA

Our guideline named **NITISINONE (Orfadin, Nityr)** requires the following rule(s) be met for renewal:

A. You have hereditary tyrosinemia type 1 (HT-1: a type of genetic disorder where you cannot breakdown an important component in proteins)
B. Your urinary or plasma succinylacetone levels (a chemical that is present in hereditary tyrosinemia) have decreased from baseline while on treatment with nitisinone

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RATIONALE

Promote appropriate utilization of **NITISINONE** based on FDA approved indication.

FDA APPROVED INDICATION

Nitisinone (Orfadin and Nityr) is a hydroxyphenyl-pyruvate dioxygenase inhibitor indicated for the treatment of adult and pediatric patients with hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine.

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NITISINONE

FDA APPROVED INDICATION (CONTINUED)

DOSAGE

Recommended Dosage:

- The recommended initial dosage is 0.5 mg/kg orally twice daily.
- In patients 5 years of age and older who have undetectable serum and urine succinylacetone concentrations after a minimum of 4 weeks on a stable dosage of nitisinone, the total daily dose may be given once daily.
- Titrate the dose based on biochemical and/or chemical response, as described in the full prescribing information.
- The maximum daily dosage is 2 mg/kg orally.

Preparation and Administration Instructions for Orfadin:

- For instructions on preparing, measuring and administering the oral suspension, see the full prescribing information.
- Maintain dietary restriction of tyrosine and phenylalanine.
- Take Orfadin capsules at least one hour before, or two hours after a meal.
- For patients who have difficulties swallowing capsules and who are intolerant to the oral suspension, the capsules may be opened and the contents suspended in a small amount of water, formula or applesauce immediately before use.
- Take Orfadin oral suspension without regard to meals.

Preparation and Administration Instructions for Nityr:

- Take with or without food.
- For patients who have difficulties swallowing intact tablets, including pediatric patients, the tablets can be disintegrated in water and administered using an oral syringe. If patients can swallow semi-solid foods, the tablets can also be crushed and mixed with applesauce. For preparation and administration instructions, see the full prescribing information.

DOSAGE FORMS AND STRENGTHS

Orfadin:

- Capsules: 2 mg, 5 mg, 10 mg, 20 mg
- Oral suspension: 4 mg/mL

Nityr:

- Tablets: 2 mg, 5 mg, 10 mg

REFERENCES

- Orfadin [Prescribing Information]. Waltham, MA: Sobi, Inc. May 2019.
- Nityr [Prescribing Information]. Cambridge, UK: Cycle Pharmaceuticals Ltd. June 2021.

Created: 09/16
Effective: 03/21/22 Client Approval: 02/17/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

OBETICHOLIC ACID

Generic	Brand	HICL	GCN	Exception/Other
OBETICHOLIC ACID	OCALIVA	43438		ROUTE = ORAL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **OBETICHOLIC ACID (Ocaliva)** requires the following rule(s) be met for approval:

A. You have primary biliary cholangitis (type of liver disease), as confirmed by TWO of the following:
   1. An alkaline phosphatase level (indicator of possible liver/gallbladder problems) of at least 1.5 times the upper limit of normal
   2. The presence of antimitochondrial antibodies (indicator of body attacking its own cells) at a titer (concentration) of 1:40 or higher
   3. Histologic evidence of non-suppurative destructive cholangitis and destruction of interlobular bile ducts (you have lab data that shows you have certain symptoms of liver disease)
B. You are 18 years of age or older
C. You meet ONE of the following:
   1. You have had an inadequate response to ursodeoxycholic acid (such as Ursodiol, Urso 250, Urso Forte) at a dosage of 13-15 mg/kg/day for at least 1 year and the requested medication will be used in combination with ursodeoxycholic acid
   2. You are unable to tolerate ursodeoxycholic acid and the requested medication will be used as monotherapy (only drug used for treatment)
D. You do not have complete biliary obstruction (blockage of bile ducts)

RENEWAL CRITERIA

Our guideline named **OBETICHOLIC ACID (Ocaliva)** requires the following rule(s) be met for renewal:

A. You have primary biliary cholangitis (type of liver disease)
B. Your alkaline phosphatase levels (indicator of possible liver/gallbladder problems) are less than 1.67-times the upper limit of normal or have decreased by at least 15% from baseline while on treatment with obeticholic acid
C. You have not developed complete biliary obstruction (blockage of bile ducts)

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

OBETICHOLIC ACID

RATIONALE
Promote appropriate utilization of **OBETICHOLIC ACID** based on FDA approved indication.

DOSAGE
- Starting Dosage: The recommended starting dosage of Ocaliva is 5 mg orally once daily in adults who have not achieved an adequate response to an appropriate dosage of UDCA for at least 1 year or are intolerant to UDCA.
- Dosage Titration: If adequate reduction in ALP and/or total bilirubin has not been achieved after 3 months of Ocaliva 5 mg once daily and the patient is tolerating Ocaliva, increase dosage to 10 mg once daily.
- Maximum Dosage: 10 mg once daily
- Administration Instructions: Take with or without food. For patients taking bile acid binding resins (e.g., cholestyramine, colestipol, colesevelam), take Ocaliva at least 4 hours before or 4 hours after taking a bile acid binding resin, or at as great an interval as possible.

FDA APPROVED INDICATION
Ocaliva (obeticholic acid), a farnesoid X receptor (FXR) agonist, is indicated for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA.

REFERENCES
Ocaliva [Prescribing Information]. New York, NY: Intercept Pharmaceuticals, Inc. May 2021.

Created: 05/17
Effective: 03/28/22 Client Approval: 02/24/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

OCRELIZUMAB

Generic	Brand	HICL	GCN	Exception/Other
OCRELIZUMAB	OCREVUS	44178		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named **OCRELIZUMAB (Ocrevus)** requires a diagnosis of primary progressive multiple sclerosis (PPMS) or a relapsing form of multiple sclerosis (MS). In addition, the following criteria must be met:

For the diagnosis of primary progressive multiple sclerosis (PPMS), approval requires:

- The patient is 18 years of age or older

For the diagnosis of a relapsing form of multiple sclerosis (MS), approval requires:

- The patient is 18 years of age or older
- The patient meets **ONE** of the following:
  - The patient had a previous trial of any **TWO** of the following preferred MS agents: Aubagio, Avonex, Copaxone, Gilenya, Rebif, or Tecfidera
  - Physician attestation that the patient shows signs of severe disease requiring high-efficacy disease modifying therapy (DMT) (e.g., high lesion volume and/or count, walking disability, or rapid decline)

RENEWAL CRITERIA

The guideline named **OCRELIZUMAB (Ocrevus)** renewal requires patient age of 18 years or older AND a diagnosis of primary progressive multiple sclerosis (PPMS) or a relapsing form of multiple sclerosis (MS).

RATIONALE

Promote appropriate utilization of Ocrevus (ocrelizumab) based on FDA approved indication and dosing.

FDA APPROVED INDICATIONS

Ocrevus is a CD20-directed cytolytic antibody indicated for the treatment of:

- Relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults
- Primary progressive MS, in adults

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OCRELIZUMAB

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

Administer Ocrevus under the close supervision of an experienced healthcare professional with access to appropriate medical support to manage severe reactions such as serious infusion reactions.

- Initial dose: 300 mg intravenous infusion, followed two weeks later by a second 300 mg intravenous infusion.
- Subsequent doses: single 600 mg intravenous infusion every 6 months.

HOW SUPPLIED

Injection: 300 mg/10 mL (30 mg/mL) in a single-dose vial.

REFERENCES

- Ocrevus [Prescribing Information]. Genentech, Inc.: San Francisco, CA. July 2019.

Created: 02/18
Effective: 11/29/19 Client Approval: 11/06/19 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

OCTREOTIDE ACETATE

Generic	Brand	HICL	GCN	Exception/Other
OCTREOTIDE ACETATE	BYNFEZIA		47454	
OCTREOTIDE ACETATE	SANDOSTATIN	02826	24221 26542 26541 24220 24222 29746 29747 29748 21767 21765 21766	
OCTREOTIDE ACETATE, MI-SPHERES	SANDOSTATIN LAR DEPOT	19000	21307 21308 21309	

****Please use the criteria for the specific drug requested ****

INITIAL CRITERIA FOR SANDOSTATIN/ SANDOSTATIN LAR (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named **OCTREOTIDE ACETATE (SANDOSTATIN/ SANDOSTATIN LAR)** requires the following rule(s) be met for approval:

A. You have ONE of the following indications for treatment:
   1. Acromegaly (a disorder in which the pituitary gland produces too much growth hormone)
   b. Acquired immunodeficiency syndrome (AIDS)-associated diarrhea
   c. Bleeding associated with esophageal varices
   d. Chemotherapy-induced diarrhea
   e. Chylothorax in pediatric members post-heart surgery
   f. Cryptosporidiosis
   g. Insulin-dependent diabetes mellitus as adjunct therapy
   h. Metastatic carcinoid tumor (a type of slow growing cancer that has spread to different parts of the body)-associated symptoms
   i. Necrotizing pancreatitis with pulmonary failure
   j. Neuroendocrine tumor
   k. Persistent ileostomy diarrhea
   l. Pituitary adenoma
   m. Polycystic ovary syndrome
   n. Polyostotic fibrous dysplasia of bone
   o. Post-gastrectomy dumping syndrome
   p. Post-surgical lymphorrhea
   q. Radiation-induced diarrhea
   r. Sulfonylurea-induced hypoglycemia
   s. Vasoactive intestinal peptide-secreting tumor (VIPomas: a type of cancer that starts from hormone producing cells)-associated diarrhea
   t. Zollinger-Ellison syndrome-associated gastrinoma

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OCTREOTIDE ACETATE

GUIDELINES FOR USE (CONTINUED)

INITIAL CRITERIA FOR BYNFEZIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **OCTREOTIDE ACETATE (BYNFEZIA)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Acromegaly (a disorder in which the pituitary gland produces too much growth hormone)
   2. Metastatic carcinoid tumors (a type of slow growing cancer that has spread to different parts of the body)
   3. Vasoactive intestinal peptide tumors (VIPomas: a type of cancer that starts from hormone producing cells)

B. **If you have acromegaly, approval also requires ONE of the following:**
   1. You had an inadequate response to **ALL** of the following:
      a. Surgical resection (removal by surgery)
      b. Pituitary irradiation (radiation therapy directed at the pituitary)
      c. Bromocriptine mesylate at maximally tolerated doses
   2. You cannot be treated with **ANY** of the following:
      a. Surgical resection (removal by surgery)
      b. Pituitary irradiation (radiation therapy directed at the pituitary)
      c. Bromocriptine mesylate at maximally tolerated doses

C. **If you have metastatic carcinoid tumors, approval also requires:**
   1. You are 18 years of age or older
   2. You are being treated for severe diarrhea and flushing episodes associated with metastatic carcinoid tumors

D. **If you have vasoactive intestinal peptide tumors (VIPomas), approval also requires:**
   1. You are 18 years of age or older
   2. You are being treated for profuse watery diarrhea associated with VIP-secreting tumors

RENEWAL CRITERIA FOR ALL AGENTS

Our guideline named **OCTREOTIDE ACETATE** requires the following rule(s) be met for renewal:

A. You have history of paid claim(s) for the requested medication in the past 90 days
B. You have previous authorization on file for the requested medication

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

OCTREOTIDE ACETATE

RATIONALE
To ensure appropriate use of octreotide acetate based on FDA approved indications and dosing.

FDA APPROVED INDICATIONS
Octreotide acetate (Sandostatin and Bynfezia) mimics natural somatostatin and is indicated:

- to reduce blood levels of growth hormone and IGF-I (somatomedin C) in acromegaly patients who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses
- for the symptomatic treatment of patients with metastatic carcinoid tumors where it suppresses or inhibits the severe diarrhea and flushing episodes associated with the disease.
- for the treatment of the profuse watery diarrhea associated with VIP-secreting tumors

Sandostatin LAR is indicated for treatment in patients who have responded to and tolerated Sandostatin subcutaneous injection for acromegaly, severe diarrhea/flushing episodes associated with metastatic carcinoid tumors, or profuse watery diarrhea associated with VIP-secreting tumors

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OCTREOTIDE ACETATE

FDA APPROVED INDICATIONS (CONTINUED)

INITIAL DOSAGE
Acromegaly: SubQ: Initial 50mcg SubQ, IV 3 times per day. IM Depot: 20mg IM Depot intragluteally every 4 weeks for 3 months.

Carcinoid Tumors: SubQ: 100-600mcg/day SubQ, IV in 2 to 4 divided doses for initial 2 weeks. IM Depot: 20mg IM intragluteally every 4 weeks for 2 months.

Vasoactive Intestinal Peptide Tumors: SubQ: 200-300mcg/day in 2 to 4 divided doses for initial 2 weeks. IM Depot: 20mg IM Depot intragluteally every 4 weeks for 2 months.

DOSAGE ADJUSTMENTS
Acromegaly
- SubQ: titrate initial 50mcg 3 times/day to achieve growth hormone levels <5ng/mL or IGF-I (somatostatin C) levels <1.9units/mL in males and <2.2 units/mL in females
  - Should be withdrawn yearly for a 4-week interval (8 weeks for depot injection) in patients who have received irradiation
- Depot dose adjustments: After 3 months of depot injections, the dosage may be continued or modified as follows:
  - GH ≤1 ng/mL, IGF-1 normal, and symptoms controlled: Reduce octreotide depot to 10 mg IM every 4 weeks
  - GH ≤2.5 ng/mL, IGF-1 normal, and symptoms controlled: Maintain octreotide depot at 20 mg IM every 4 weeks
  - GH >2.5 ng/mL, IGF-1 elevated, and/or symptoms uncontrolled: Increase octreotide depot to 30 mg IM every 4 weeks

Carcinoid tumors
- After 2 months of depot injections, the dosage may be continued or modified as follows:
  - Increase to 30 mg IM every 4 weeks if symptoms are inadequately controlled
  - Decrease to 10 mg IM every 4 weeks, for a trial period, if initially responsive to 20 mg dose
  - Dosage >30 mg is not recommended

Vasoactive intestinal peptide tumors
- After 2 months of depot injections, the dosage may be continued or modified as follows:
  - Increase to 30 mg IM every 4 weeks if symptoms are inadequately controlled
  - Decrease to 10 mg IM every 4 weeks, for a trial period, if initially responsive to 20 mg dose
  - Dosage >30 mg is not recommended

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OCTREOTIDE ACETATE

FDA APPROVED INDICATIONS (CONTINUED)

HOW SUPPLIED

Bynfezia (octreotide acetate) injection is available as a 2.8 mL single 2,500 mcg/mL patient-use pen.

Sandostatin (octreotide acetate) Injection is available in 1 mL ampules and 5-mL multi-dose vials as follows:
Ampules

- 50 mcg/mL octreotide (as acetate), package of 10 ampules
- 100 mcg/mL octreotide (as acetate), package of 10 ampules
- 500 mcg/mL octreotide (as acetate), package of 10 ampules

Multi-Dose Vials

- 200 mcg/mL octreotide (as acetate), box of one
- 1000 mcg/mL octreotide (as acetate), box of one

Sandostatin LAR Depot is available in single-use kits containing a 6-mL vial of 10 mg, 20 mg or 30 mg strength, a syringe containing 2 mL of diluent, one vial adapter, and one sterile safety injection needle.

REFERENCES

- Sandostatin [prescribing information]. East Hanover, NJ: June 2020.
- Sandostatin LAR Depot [prescribing information]. East Hanover, NJ: Novartis; April 2019.
- Bynfezia [Prescribing Information]. Cranbury, NJ: Sun Pharmaceuticals Industries Inc., January 2020.

Created: 10/15
Effective: 12/15/21 Client Approval: 10/26/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ODEVIXIBAT

Generic	Brand	HICL	GCN	Exception/Other
ODEVIXIBAT	BYLVAY	47501		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ODEVIXIBAT (Bylvay)** requires the following rule(s) be met for approval:

A. You have pruritus (itching) associated with progressive familial intrahepatic cholestasis (PFIC: an inherited liver condition)
B. You are 3 months of age or older
C. You have tried ONE of the following conventional treatments for cholestatic pruritus: rifampin, ursodeoxycholic acid, cholestyramine, or colesevelam

RENEWAL CRITERIA

Our guideline for **ODEVIXIBAT (Bylvay)** requires the following rule(s) be met for renewal:

A. You have pruritus (itching) associated with progressive familial intrahepatic cholestasis (PFIC: an inherited liver condition)
B. You have experienced or maintained symptomatic improvement while on therapy

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RATIONALE

Ensure appropriate diagnostic, utilization and safety criteria are met for the management of requests for odevixibat.

INDICATIONS

Bylvay is an ileal bile acid transporter (IBAT) inhibitor indicated for the treatment of pruritus in patients 3 months of age and older with progressive familial intrahepatic cholestasis (PFIC).

DOSAGE

The recommended dosage of Bylvay is 40 mcg/kg once daily in the morning with a meal. If there is no improvement in pruritus after 3 months, the dosage may be increased in 40 mcg/kg increments up to 120 mcg/kg once daily not to exceed a total daily dose of 6 mg.

REFERENCES

Bylvay [Prescribing Information]. Boston, MA: Albireo Pharma, Inc., July 2021.

Created: 02/22
Effective: 03/21/22 Client Approval: 02/18/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

OFATUMUMAB-SQ

Generic	Brand	HICL	GCN	Exception/Other
OFATUMUMAB	KESIMPTA		48513	

GUIDELINES FOR USE

Our guideline named **OFATUMUMAB-SQ (Kesimpta)** requires the following rules be met for approval:

A. You have a relapsing form of multiple sclerosis (MS: an illness where the immune system eats away at the protective covering of the nerves), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
B. You are 18 years of age or older
C. You meet ONE of the following criteria:
   1. You previously had a trial of ONE of the following therapies (type of medication for multiple sclerosis): Avonex, Aubagio, Copaxone 40mg, Glatopa, Rebif, Tecfidera
   2. You show signs of high-severity disease (such as high frequency or intensity of relapses) which merit (justify) immediate progression to high-efficacy disease-modifying therapies (type of medication for multiple sclerosis)
D. You previously had a trial of or contraindication (medical reason why you cannot) to the high-efficacy disease-modifying therapy (type of medication for multiple sclerosis): Gilenya

Please note: Other multiple sclerosis agents may also require prior authorization.

RATIONALE
Ensure appropriate diagnostic, utilization and safety criteria are met for the management of requests for Kesimpta.

FDA APPROVED INDICATIONS
Kesimpta is a CD20-directed cytolytic antibody indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

DOSING
The recommended dosage of Kesimpta is initial dosing of 20 mg by subcutaneous injection at Weeks 0, 1, and 2, followed by subsequent dosing of 20 mg by subcutaneous injection once monthly starting at Week 4.

REFERENCES

- Kesimpta [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2020.

Created: 10/20
Effective: 11/16/20 Client Approval: 10/16/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

OLAPARIB

Generic	Brand	HICL	GCN	Exception/Other
OLAPARIB	LYNPARZA	41642		ROUTE = ORAL

GUIDELINES FOR USE

Our guideline named **OLAPARIB (Lynparza)** requires the following rule(s) be met for approval:

A You have ONE of the following diagnoses:
1. Recurrent (returning) or advanced epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer (types of reproductive system cancers)
2. HER2 (a type of protein)-negative high risk early breast cancer (a type of breast cancer)
3. HER2-negative metastatic breast cancer (a type of breast cancer that has spread to other parts of the body)
4. Metastatic pancreatic adenocarcinoma (a type of pancreas cancer that has spread to other parts of the body)
5. Metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and does not respond to hormone therapy)

B. **If you have advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
1. You are 18 years of age or older
2. The requested medication will be used for maintenance treatment
3. You are in complete or partial response to first-line platinum-based chemotherapy (a type of therapy to treat cancer)
4. Your diagnosis is confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
5. ONE of the following:
   a. Your cancer has a deleterious or suspected deleterious germline or somatic BRCA mutation (a type of gene mutation)
   b. Your cancer is associated with a homologous recombination deficiency (HRD: type of gene mutation) positive status as defined by either a deleterious or suspected deleterious BRCA mutation (type of gene mutation), and/or genomic instability (high rate of gene mutation), AND Lynparza will be used in combination with bevacizumab

C. **If you have recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
1. You are 18 years of age or older
2. You are in complete or partial response to your most recent platinum-based chemotherapy (a type of therapy to treat cancer)
3. You have completed at least two or more lines of platinum-based chemotherapy
4. The requested medication will be used alone for maintenance treatment

D. **If you have HER2-negative high risk early breast cancer, approval also requires:**
1. You are 18 years of age or older
2. The requested medication will be used as adjuvant (add-on) treatment
3. Your cancer has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm: a type of gene mutation) as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
4. You have been treated with neoadjuvant or adjuvant chemotherapy (cancer treatment given before main treatment or as add-on therapy)

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OLAPARIB

GUIDELINES FOR USE (CONTINUED)

E. **If you have HER2-negative metastatic breast cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm: a type of gene mutation) as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   3. You have been treated with chemotherapy in the neoadjuvant (given before main treatment), adjuvant (add-on to main treatment), or metastatic setting (to treat disease that has spread to other parts of the body)
   4. ONE of the following:
      a. You do not have hormone receptor (HR)-positive breast cancer
      b. You have hormone receptor (HR)-positive breast cancer and you have been treated with a prior endocrine (hormone) therapy or endocrine therapy is considered inappropriate for you

F. **If you have metastatic pancreatic adenocarcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication will be used for maintenance treatment
   3. Your cancer has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm: a type of gene mutation) as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   4. Your disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen (a type of therapy to treat cancer)

G. **If you have metastatic castration-resistant prostate cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer has a deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene mutation (type of mutation) as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   3. Your disease has worsened following prior treatment with enzalutamide or abiraterone
   4. ONE of the following:
      a. You previously had a bilateral orchiectomy (both testicles have been surgically removed)
      b. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
      c. The requested medication will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as leuprolide, goserelin, histrelin, degarelix)

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

OLAPARIB

RATIONALE
Promote appropriate utilization of **OLAPARIB** based on FDA approved indications.

FDA APPROVED INDICATIONS
Lynparza is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated for:
Ovarian cancer
- for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.
- in combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either a deleterious or suspected deleterious BRCA mutation and/or genomic instability. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.
- for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in complete or partial response to platinum-based chemotherapy.

Breast cancer
- for the adjuvant treatment of adult patients with deleterious or suspected deleterious gBRCAm human epidermal growth factor receptor 2 (HER2)-negative high risk early breast cancer who have been treated with neoadjuvant or adjuvant chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.
- for the treatment of adult patients with deleterious or suspected deleterious gBRCAm, HER2-negative metastatic breast cancer who have been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine therapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.

Pancreatic cancer
- for the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.

Prostate cancer
- for the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with enzalutamide or abiraterone. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

OLAPARIB

DOSAGE AND ADMINISTRATION

The recommended dose is 300 mg (two 150 mg tablets) taken orally twice daily, with or without food, for a total daily dose of 600 mg. Continue treatment until disease progression or unacceptable toxicity. When used for first-line maintenance treatment of BRCA-mutated advanced ovarian cancer, patients should be re-evaluated for treatment response at 2 years. Patients with a complete response (no radiological evidence of disease) at 2 years should stop treatment. Patients with evidence of disease at 2 years, who in the opinion of the treating healthcare provider can derive further benefit from continuous treatment, can be treated beyond 2 years.

To manage adverse reactions, the dosage can be reduced to 250 mg (one 150 mg tablet and one 100 mg tablet) taken twice daily, for a total daily dose of 500 mg. If a further dose reduction is required, then reduce to 200 mg (two 100 mg tablets) taken twice daily, for a total daily dose of 400 mg.

If concurrent use with a CYP3A inhibitor cannot be avoided, reduce the Lynparza dose to 100 mg (one 100 mg tablet) taken twice daily for a strong CYP3A inhibitor or 150 mg (one 150 mg tablet) taken twice daily for a moderate CYP3A inhibitor.

In patients with moderate renal impairment (CrCl 31-50 mL/min) the recommended dose reduction is to 200 mg (two 100 mg tablets) twice daily, for a total daily dose of 400 mg. Patients with mild renal impairment (CrCl 51-80 mL/min) do not require an adjustment in Lynparza dosing.

REFERENCES

Lynparza Tablets [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals. October 2022.

Created: 06/15
Effective: 01/30/23 Client Approval: 01/04/23 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

OMADACYCLINE

Generic	Brand	HICL	GCN	Exception/Other
OMADACYCLINE	NUZYRA		45478	

GUIDELINES FOR USE

The guideline named **OMADACYCLINE (Nuzyra)** requires a diagnosis of community-acquired bacterial pneumonia (CABP) or acute bacterial skin or skin structure infection (ABSSSI). In addition, the following criteria must also be met:

For the diagnosis of community-acquired bacterial pneumonia (CABP), approval requires:

- The patient is 18 years of age or older
- The infection is caused by any of the following susceptible microorganisms: Streptococcus pneumoniae, Staphylococcus aureus (methicillin-susceptible isolates), Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Legionella pneumoniae, Mycoplasma pneumoniae, or Chlamydophila pneumoniae
- The patient meets **ONE** of the following criteria:
  - **A.** Therapy is prescribed by or given in consultation with an Infectious Disease (ID) specialist
  - **B.** Antimicrobial susceptibility test is available, and the infection site culture results indicate pathogenic organism(s) with 1) resistance to at least **TWO** standard of care agents for CABP (e.g. azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone), **AND** 2) the culture is susceptible to Nuzyra
  - **C.** Antimicrobial susceptibility test is unavailable, and the patient has had a trial of or contraindication to at least TWO standard of care agents for CABP (e.g. azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone)

For the diagnosis of acute bacterial skin or skin structure infection (ABSSSI), approval also requires all of the following:

- The patient is 18 years of age or older
- The infection is caused by any of the following susceptible microorganisms:
- Staphylococcus aureus (methicillin-susceptible and -resistant isolates), Staphylococcus lugdunensis, Streptococcus pyogenes, Streptococcus anginosus grp. (Includes S. anginosus, S. intermedius, and S. constellatus), Enterococcus faecalis, Enterobacter cloacae, or Klebsiella pneumoniae
- The patient meets **ONE** of the following criteria:
  - **D.** Therapy is prescribed by or given in consultation with an Infectious Disease (ID) specialist
  - **E.** Antimicrobial susceptibility test is available, and the infection site culture results indicate pathogenic organism(s) with 1) resistance to at least **TWO** standard of care agents for ABSSSI (e.g. linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, amoxicillin, nafcillin, ceftriaxone, cephalexin, cefazolin), **AND** 2) the culture is susceptible to Nuzyra
  - **F.** Antimicrobial susceptibility test is unavailable, and the patient has had a trial of or contraindication to at least **TWO** standard of care agents for ABSSI (e.g. linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, amoxicillin, nafcillin, ceftriaxone, cephalexin, cefazolin)

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OMADACYCLINE

RATIONALE
For further information, please refer to the Prescribing Information for Nuzyra.

REFERENCES
Nuzyra [Prescribing Information]. Boston, MA: Paratek Pharmaceuticals, Inc.; October 2018.

Created: 11/19
Effective: 04/01/20 Client Approval: 02/24/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

OMALIZUMAB

Generic	Brand	HICL	GCN	Exception/Other
OMALIZUMAB	XOLAIR	25399		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **OMALIZUMAB (Xolair)** requires the following rule(s) be met for approval:

A. You have one of the following diagnoses:
   1. Chronic idiopathic urticaria (CIU)
   2. Moderate to severe persistent asthma
   3. Nasal polyps (small growths in the nose)

B. If you have chronic idiopathic urticaria (CIU), approval also requires:
   1. You are 12 years of age or older
   2. You have had at least 6 weeks of symptoms
   3. You have tried at least two weeks treatment with THREE of the following:
      - First generation H1 antihistamine (e.g., diphenhydramine, hydroxyzine)
      - Second generation H1 antihistamine (e.g., loratadine, fexofenadine, levocetirizine)
      - H2 receptor antagonist (e.g., ranitidine, famotidine)
      - Leukotriene receptor antagonist
      - Cyclosporine

C. If you have moderate to severe persistent asthma, approval also requires:
   1. You are 6 years of age or older
   2. You have had positive skin prick or RAST test to a perennial aeroallergen
   3. You are currently receiving therapy with ONE of the following:
      a. High-dose inhaled corticosteroid (ICS) AND a long-acting beta2 agonist (LABA)
      b. High-dose ICS/LABA combination product
   4. Xolair will be used as add-on maintenance treatment to one of the above inhaled asthma regimens
   5. You have experienced at least one asthma exacerbation within the past 12 months (exacerbation is defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days)

D. If you have nasal polyps, approval also requires:
   1. You are 18 years of age or older
   2. You had an inadequate response to intranasal corticosteroids

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OMAILZUMAB

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **OMALIZUMAB (Xolair)** requires the following rule(s) be met for renewal:

A. You have one of the following diagnoses:
   1. Chronic idiopathic urticaria (CIU)
   2. Moderate to severe persistent asthma
   3. Nasal polyps (small growths in the nose)

B. If you have chronic idiopathic urticaria, renewal also requires:
   1. You had a clinical benefit compared to baseline (such as reduction in frequency or severity of hives)

C. If you have moderate to severe persistent asthma, renewal also requires:
   1. You had a clinical benefit compared to baseline (such as reduction in asthma exacerbations, reduction in use of rescue inhalers, reduced need for systemic corticosteroid therapy)

D. If you have nasal polyps, renewal also requires:
   1. You had a clinical benefit compared to baseline (such as improvements in nasal congestion, sense of smell, or size of polyps)

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

OMALIZUMAB

RATIONALE
Ensure appropriate diagnostic and utilization criteria.

FDA APPROVED INDICATIONS
Xolair is an anti-IgE antibody indicated for:
- Moderate to severe persistent asthma in patients 6 years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids
- Nasal polyps in adult patients 18 years of age and older with inadequate response to nasal corticosteroids, as add-on maintenance treatment
- Chronic idiopathic urticaria in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment

DOSAGE
Chronic Idiopathic Urticaria: Xolair 150 or 300 mg SC every 4 weeks. Dosing in CIU is not dependent on serum IgE level or body weight.

Asthma: Xolair 150 to 375 mg SC every 2 or 4 weeks. Determine dose (mg) and dosing frequency by serum total IgE level (IU/mL), measured before the start of treatment, and body weight (kg). See Tables 1 and 2 for dose determination.

Table 1
Xolair Doses (milligrams) Administered by Subcutaneous Injection Every 2 or 4 Weeks for Patients 12 Years of Age and Older with Asthma

Pretreatment Serum IgE (IU/mL)	Dosing Freq.	Body Weight			
		30–60 kg	>60–70 kg	>70–90 kg	>90–150 kg
		Dose (mg)			
≥30–100	Every	150	150	150	300
>100–200	4	300	300	300	225
>200–300	weeks	300	225	225	300
>300–400	Every	225	225	300	
>400–500	2	300	300	375	
>500–600	weeks	300	375	**Insufficient Data**	
>600–700		375		**to Recommend a Dose**	

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OMALIZUMAB

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE

Table 2
Xolair Doses (milligrams) Administered by Subcutaneous Injection Every 2 or 4 Weeks for Pediatric Patients with Asthma Who Begin Xolair Between the Ages of 6 to <12 Years

Pre-treatment Serum IgE (IU/mL)	Dosing Freq.	Body Weight									
		20-25 kg	>25-30 kg	>30-40 kg	>40-50 kg	>50-60 kg	>60-70 kg	>70-80 kg	>80-90 kg	>90-125 kg	>125-150 kg
		Dose (mg)									
30-100	Every 4 weeks	75	75	75	150	150	150	150	150	300	300
>100-200		150	150	150	300	300	300	300	300	225	300
>200-300		150	150	225	300	300	225	225	225	300	375
>300-400		225	225	300	225	225	225	300	300		
>400-500		225	300	225	225	300	300	375	375		
>500-600		300	300	225	300	300	375				
>600-700		300	225	225	300	375					
>700-800	Every 2 weeks	225	225	300	375						
>800-900		225	225	300	375						
>900-1000		225	300	375	Insufficient Data to Recommend a Dose						
>1000-1100		225	300	375							
>1100-1200		300	300								
>1200-1300		300	375								

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OMALIZUMAB

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE
Nasal Polyps: Xolair 75 mg to 600 mg by subcutaneous injection every 2 or 4 weeks based on serum total IgE level (IU/mL) measure before the start of treatment and by body weight (kg). See Table 3 for dose determination.

Table 3
Xolair Doses (milligrams) Administered by Subcutaneous Injection Every 2 or 4 Weeks for Adult Patients with Nasal Polyps

Pretreatment Serum IgE (IU/mL)	Dosing Freq.	Bodyweight							
		>30-40 kg	>40-50 kg	>50-60 kg	>60-70 kg	>70-80 kg	>80-90 kg	>90-125 kg	> 125-150 kg
		Dose (mg)							
30 - 100	Every 4 Weeks	75	150	150	150	150	150	300	300
>100 - 200		150	300	300	300	300	300	450	600
>200 - 300		225	300	300	450	450	450	600	375
>300 - 400		300	450	450	450	600	600	450	525
>400 - 500		450	450	600	600	375	375	525	600
>500 - 600		450	600	600	375	450	450	600	
>600 - 700		450	600	375	450	450	525		
>700 - 800	Every 2 Weeks	300	375	450	450	525	600		
>800 - 900		300	375	450	525	600			
>900 - 1000		375	450	525	600				
>1000 - 1100		375	450	600					
>1100 - 1200		450	525	600	Insufficient Data to Recommend a Dose				
>1200 - 1300		450	525						
>1300 - 1500		525	600						

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

OMALIZUMAB

REFERENCES

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- 2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group. National Institutes of Health. Available from https://www.nhlbi.nih.gov/health-topics/all-publications-and-resources/2020-focused-updates-asthma-management-guidelines.
- Genentech, INC. Xolair package insert. South San Francisco, CA. December 2020.
- Zuberbier T, et al. Dermatology Section of the European Academy of Allergology and Clinical Immunology; Global Allergy and Asthma European Network; European Dermatology Forum; World Allergy Organization. EAACI/GA(2)LEN/EDF/WAO guideline: management of urticaria. Allergy. 2009 Oct;64(10):1427-43. doi: 10.1111/j.1398-9995.2009.02178.x. PMID: 19772513.
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- Hamilos D, Holbrook E. Chronic rhinosinusitis: Clinical manifestations, pathophysiology, and diagnosis. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed June 27, 2019.

Created: 10/15
Effective: 04/18/22 Client Approval: 03/15/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

OMNIPOD/OMNIPOD DASH INSULIN DEVICES

Generic	Brand	HICL	GCN	Exception/Other
INSULIN PUMP CART, AUTO, BT/CNTR	OMNIPOD 5 G6 INTRO KIT (GEN 5)	47922		
INSULIN PUMP CART, CONT BT/CNTR	OMNIPOD DASH INTRO KIT (GEN 4)	47923		
INSULIN PUMP CONTROLLER	OMNIPOD DASH PDM KIT (GEN 4)	40278		
INSULIN PUMP CONTROLLER, RF	OMNIPOD CLASSIC PDM KIT (GEN 3)	47929		

GUIDELINES FOR USE

Our guideline named **OMNIPOD/OMNIPOD DASH INSULIN DEVICES** requires the following rule(s) be met for approval:

A. The requested pump is prescribed by or given in consultation with an endocrinologist (hormone doctor)
B. You have completed a comprehensive diabetes education program within the previous 24 months
C. You follow a maintenance program of at least 3 injections of insulin per day and have required frequent self-adjustments of insulin dose in the previous 6 months
D. You require glucose (blood sugar) self-testing at least 4 times per day on average in the previous 2 months
E. You have not received a device (personal diabetes manager [PDM]) within the last 4 years (Exception: your device is malfunctioning, not repairable, and not under warranty.)
F. You are on a multiple daily insulin injection regimen and meet ONE of the following:
    1. You have a glycosylated hemoglobin level (HbA1c: measure of how well controlled your blood sugar has been over a period of about 3 months) greater than 7 percent
    2. You have a history of recurring hypoglycemia (low blood sugar)
    3. You have wide fluctuations in blood sugar before mealtime
    4. You experience the dawn phenomenon (abnormal early morning increase in blood sugar, usually between 2 a.m. and 8 a.m.) with fasting blood glucose levels frequently exceeding 200 mg/dL
    5. You have a history of severe glycemic excursions (sudden spikes in blood sugar levels)

RATIONALE
To ensure appropriate use of Omnipod/Omnipod Dash insulin pumps and devices consistent with FDA approved indications, treatment guidelines, and current literature.

REFERENCES
Omnipod/Omnipod Dash. Insulet Corporation. Indications and Safety Information. Available at: https://www.omnipod.com/hcp/products.

Created: 02/22
Effective: 06/20/22 Client Approval: 06/07/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

OPICAPONE

Generic	Brand	HICL	GCN	Exception/Other
OPICAPONE	ONGENTYS	45536		

GUIDELINES FOR USE

Our guideline named **OPICAPONE (Ongentys)** requires the following rule(s) be met for approval:

A. You have Parkinson's disease (PD: a nerve system disorder that affects movement)
B. You are 18 years of age or older
C. You are experiencing "OFF" episodes (times when you have symptoms return due to medication wearing off)
D. You are currently being treated with carbidopa/levodopa
E. You have tried or have a contraindication (medical reason why you cannot use) to TWO Parkinson's disease medications from TWO different classes of medications:
    1. Dopamine agonist (such as ropinirole, pramipexole, rotigotine)
    2. Monoamine oxidase-inhibitors (MAO-I) (such as selegiline, rasagiline)
    3. Adenosine receptor antagonist A2A (such as istradefylline)

RATIONALE

Ensure appropriate use of Ongentys.

FDA APPROVED INDICATION

Ongentys is a catechol-O-methyltransferase (COMT) inhibitor indicated as adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease (PD) experiencing "off" episodes.

DOSING

The recommended dose is 50 mg administered orally once daily at bedtime.

REFERENCES

- Ongentys [Prescribing Information]. San Diego, CA: Neurocrine Biosciences, Inc.; April 2020.

Created: 10/20
Effective: 11/16/20 Client Approval: 10/16/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

OPIOID CUMULATIVE DOSING

The guideline named **OPIOID CUMULATIVE DOSING OVERRIDE** will cause a claim for a pain medication to deny when an opioid agent is prescribed for a patient who is receiving a high total daily opioid dose. This guideline will allow you to receive a higher quantity of an opioid medication if certain criteria are met. The safety edit allows for an override for an opioid product equal to or exceeding hard-stop threshold (751 morphine milligram equivalent [MME]).

An approval will be provided for patients with at least **ONE** of the following conditions:

- You have a diagnosis of cancer
- You have a diagnosis of sickle cell disease
- You are receiving palliative care
- You have another terminal diagnosis that causes significant pain

For all other patients, **ONE** of the following criteria must be met:

- You provider has submitted an alternate taper plan with specific doses and durations
- **ALL** of the following:
  - You have attempted a reduction in your total opioid daily dose in the past 12 months
  - Your attempt at opioid dose reduction can be identified by chart notes or claims history
  - You provider has submitted chart notes demonstrating adverse outcomes experienced with the attempted taper

Please consult your physician if you have any questions about this safety edit on prescription opioid medications and the requirements needed for you to obtain an approval for higher quantities of these agents.

RATIONALE

To positively impact the opioid epidemic affecting Indiana Hoosiers, to meet the requirements of federal legislation, and to ensure appropriate use of opioids, while preserving patient access to medically necessary drug regimens.

Prior authorization will be required for opioid claims exceeding the maximum allowable daily MME limits as follows:

- Beginning April 1, 2022, the maximum allowable limit will be 1,000 MME/ day.
- Subsequently, the maximum allowable daily MME limits will decrease by no more than 10% on a quarterly basis, ending with a final limit of 90 MME/ day.
- See Table 1 for planned taper schedule.

Providers should take steps now to review and evaluate medication regimens for their patients currently prescribed opioids, including opioid prescriptions displayed in Indiana's prescription drug monitoring program, INSPECT. To avoid delays in therapy, please consider initiating opioid tapering or proactively submitting prior authorization requests for your patients prescribed opioids exceeding initial and planned subsequent quarterly reductions in the maximum allowable daily MME limit.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

OPIOID CUMULATIVE DOSING

Claims exceeding the maximum allowable MME limit will deny at point-of-sale.

- Dispensing pharmacies may utilize a one-time override per member for opioid claims exceeding the limit. The override may only be utilized once in a six-month period of time.
- Pharmacy providers utilizing the override should take steps to notify the prescriber so the prescriber is aware that further treatment consideration may be necessary.

TABLE 1: PLANNED TAPER SCHEDULE FOR MME LIMIT REDUCTION (2022-2023)

Date of Reduction	MME Daily Limit
April 1, 2022	1,000
July 1, 2022	900
October 1, 2022	825
January 1, 2023	750
April 1, 2023	675
July 1, 2023	625
October 1, 2023	575

REFERENCES

- Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain - United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1-49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1.Available at http://www.cdc.gov/drugoverdose/prescribing/guideline.html.
- CMS 2482 Final Rule - SUPPORT II: Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third-Party Liability (TPL) Requirements. Available at: https://www.cms.gov/files/document/122120-cms-2482-f-medicaid-dur- ofr-master-webposting-508.pdf.
- U.S. Department of Health and Human Services. Centers for Disease Control and Prevention. Pocket Guide: Tapering Opioids for Chronic Pain. Available at: https://www.cdc.gov/drugoverdose/pdf/clinical_pocket_guide_tapering-a.pdf.

Created: 03/22
Effective: 01/01/23 Client Approval: 08/25/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

OSILODROSTAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OSILODROSTAT	ISTURISA	46396			

GUIDELINES FOR USE

Our guideline named **OSILODROSTAT (Isturisa)** requires the following rule(s) be met for approval:

A. You have Cushing's disease (a condition due to a tumor in the pituitary gland causing an excess release of the hormone cortisol in the blood)
B. You are 18 years of age or older
C. Pituitary surgery is not an option or has not cured your condition

RATIONALE

To ensure appropriate diagnostic, utilization, and safety criteria are used for the management of requests for osilodrostat.

INDICATIONS

Isturisa is indicated for the treatment of Cushing disease in adults for whom pituitary surgery is not an option or has not been curative.

DOSAGE

Initiate dosing at 2 mg orally twice daily, with or without food. Then, titrate the dosage by 1 to 2 mg twice daily, no more frequently than every 2 weeks based on the rate of cortisol changes, individual tolerability and improvement in signs and symptoms of Cushing's disease. If a patient tolerates ISTURISA dosage of 10 mg twice daily and continues to have elevated 24-hour urine free cortisol (UFC) levels above upper normal limit, the dosage can be titrated further by 5 mg twice daily every 2 weeks. Monitor cortisol levels from at least two 24-hour urine free cortisol collections every 1-2 weeks until adequate clinical response is maintained.

REFERENCES

Isturisa [Prescribing Information]. Lebanon, NJ: Recordati Rare Diseases, Inc.; March 2020.

Created: 06/20
Effective: 07/01/20 Client Aproval: 06/05/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

OSIMERTINIB

Generic	Brand	HICL	GCN	Exception/Other
OSIMERTINIB	TAGRISSO	42803		

GUIDELINES FOR USE

The guideline named **OSIMERTINIB (Tagrisso)** requires a diagnosis of non-small cell lung cancer (NSCLC). In addition, **ONE** of the following criteria must be met:

- The patient has metastatic NSCLC and is positive for an epidermal growth factor receptor (EGFR) T790M mutation as confirmed by an FDA-approved test AND meets all of the following:
  - The patient has progressed while on or after epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor therapy (e.g., Tarceva [erlotinib], Iressa [gefitinib], or Gilotrif [afatinib dimaleate])
  - The patient is **NOT** receiving concurrent therapy with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (e.g., Tarceva [erlotinib], Iressa [gefitinib], or Gilotrif [afatinib dimaleate])

- The patient has metastatic NSCLC and is positive for an epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations as confirmed by an FDA-approved test **AND** meets the following:
  - The patient has not received prior systemic treatment for metastatic non-small cell lung cancer (NSCLC)

- The patient is positive for epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations as confirmed by an FDA-approved test **AND** meets the following:
  - The requested medication will be used as adjuvant therapy after tumor resection

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

OSIMERTINIB

RATIONALE
To ensure appropriate use of osimertinib (Tagrisso) consistent with FDA-approved indications.

DOSAGE
Recommended dose is 80 mg orally once daily, with or without food.

FDA-APPROVED INDICATIONS
Osimertinib (Tagrisso) is a kinase inhibitor indicated:
- as adjuvant therapy after tumor resection in adult patients with non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.
- for the first-line treatment of adult patients with metastatic NSCLC whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.
- for the treatment of adult patients with metastatic EGFR T790M mutation-positive NSCLC, as detected by an FDA-approved test, whose disease has progressed on or after EGFR tyrosine kinase inhibitor (TKI) therapy.

AVAILABLE STRENGTHS
- 40 mg tablets
- 80 mg tablets

REFERENCES

- Tagrisso [Prescribing Information]; Wilmington, DE: AstraZeneca Pharmaceuticals LP; December 2020.

Created: 01/16
Effective: 01/18/21 Client Approval: 01/04/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

OTESECONAZOLE

Generic	Brand	HICL	GCN	Exception/Other
OTESECONAZOLE	VIVJOA	47976		

GUIDELINES FOR USE

Our guideline named **OTESECONAZOLE (Vivjoa)** requires the following rule(s) be met for approval:
A. You have recurrent vulvovaginal candidiasis (RVVC: a repeating vaginal fungal infection)
B. You are not able to reproduce, which means you are a biological female and are postmenopausal (after menopause) or you have another reason for permanent infertility (such as tubal ligation [having tubes tied], hysterectomy [removal of the uterus], salpingo-oophorectomy [removal of an ovary and its fallopian tube])
C. You have experienced 3 or more episodes of RVVC in the past 12 months

RATIONALE

Promote appropriate utilization of Vivjoa based on FDA approved indication and dosing.

FDA APPROVED INDICATION

Vivjoa is an azole antifungal indicated to reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are NOT of reproductive potential.

DOSAGE

There are two recommended Vivjoa dosage regimens: a Vivjoa-only regimen and a fluconazole/ Vivjoa regimen.

For the Vivjoa-only dosage regimen:
- On Day 1: Administer Vivjoa 600 mg (as a single dose), then
- On Day 2: Administer Vivjoa 450 mg (as a single dose), then
- Beginning on Day 14: Administer Vivjoa 150 mg once a week (every 7 days) for 11 weeks (Weeks 2 through 12).

For the fluconazole/Vivjoa dosage regimen, prescribe fluconazole and:
- On Day 1, Day 4, and Day 7: Administer fluconazole 150 mg orally, then
- On Days 14 through 20: Administer Vivjoa 150 mg once daily for 7 days, then
- Beginning on Day 28: Administer Vivjoa 150 mg once a week (every 7 days) for 11 weeks (Weeks 4 through 14).

REFERENCES

Vivjoa [Prescribing Information]. Durham, NC: Mycovia Pharmaceuticals, Inc.; April 2022.

Created: 08/22
Effective: 09/19/22 Client Approval: 08/19/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

OZANIMOD

Generic	Brand	HICL	GCN	Exception/Other
OZANIMOD	ZEPOSIA	46431		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **OZANIMIOD (Zeposia)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. A relapsing form of multiple sclerosis (type of disease where body attacks its own nerves and symptoms return after treatment) such as clinically isolated syndrome (occurs once), relapsing-remitting disease (periods of symptoms and no symptoms), or active secondary progressive disease (advanced disease)
   2. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)

B. **If you have multiple sclerosis (MS), approval also requires:**
   1. You are 18 years of age or older
   2. You have previously tried ONE agent indicated for the treatment of multiple sclerosis (MS) (e.g., Avonex, Rebif, Copaxone, Tecfidera, Gilenya, Aubagio)

C. **If you have moderate to severe ulcerative colitis (UC), approval also requires:**
   1. You are 18 years of age or older
   2. You have previously tried at least ONE of the following conventional agents: corticosteroids (e.g., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   3. You have previously tried Humira

RENEWAL CRITERIA

Our guideline for **OZANIMOD (Zeposia)** requires the following rule(s) be met for renewal:

A. You have a diagnosis of moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)
B. You have experienced or maintained symptomatic improvement while on therapy

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

OZANIMOD

RATIONALE
Ensure appropriate diagnostic, utilization and safety criteria are used for the management of requests for ozanimod.

FDA APPROVED INDICATIONS
Zeposia is indicated for the treatment of:
- Relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults
- Moderately to severely active ulcerative colitis in adults

DOSING
Initiate Zeposia with a 7-day titration, as follows:

Days 1 - 4	0.23 mg once daily
Days 5 - 7	0.46 mg once daily
Day 8 and thereafter	0.92 mg once daily

After initial titration, the recommended maintenance dosage of Zeposia is 0.92 mg taken orally once daily starting on Day 8.

REFERENCES

- Zeposia [Prescribing Information]. Summit, NJ: Celgene Corporation, May 2021.
- Kornbluth A, Sachar DB. Ulcerative colitis practice guidelines in adults: American College of Gastroenterology, Practice Parameters Committee. Am J Gastroenterol 2010;105:501-523.

Created: 07/20
Effective: 04/11/22 Client Approval: 03/09/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

PACRITINIB

Generic	Brand	HICL	GCN	Exception/Other
PACRITINIB CITRATE	VONJO	47850		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **PACRITINIB (Vonjo)** requires the following rule(s) be met for approval:
A. You have intermediate- or high-risk primary or secondary (post-polycythemia vera [type of blood cell disorder] or post-essential thrombocythemia [type of blood cell disorder]) myelofibrosis (type of bone marrow cancer)
B. You are 18 years of age or older

RENEWAL CRITERIA

Our guideline named **PACRITINIB (Vonjo)** requires the following rule(s) be met for renewal:
A. You have intermediate- or high-risk primary or secondary (post-polycythemia vera [type of blood cell disorder] or post-essential thrombocythemia [type of blood cell disorder]) myelofibrosis (type of bone marrow cancer)
B. You have shown symptom improvement by meeting ONE of the following:
   1. You have a spleen volume reduction of 35% or greater from baseline
   2. You have a 50% or greater reduction in total symptom score (such as Myeloproliferative Neoplasm Symptom Assessment Form [MPN-SAF TSS], modified Myelofibrosis Symptom Assessment Form [MFSAF] v2.0)
   3. You have a 50% or greater reduction in palpable (can be felt by external examination) spleen length

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RATIONALE
Promote appropriate utilization of **PACRITINIB** based on FDA approved indication and appropriate clinical criteria.

FDA APPROVED INDICATIONS
Vonjo is a kinase inhibitor indicated for the treatment of adult patients with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF) with a platelet count below 50 x 10^9/L.

DOSING
The recommended dosage of Vonjo is 200mg orally twice daily.

REFERENCES
Vonjo [Prescribing Information]. Seattle, WA: CTI BioPharma Corp.; February 2022.

Created: 05/22
Effective: 07/01/22 Client Approval: 05/20/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

PALBOCICLIB

Generic	Brand	HICL	GCN	Exception/Other
PALBOCICLIB	IBRANCE	41725		ROUTE = ORAL

GUIDELINES FOR USE

Our guideline named **PALBOCICLIB (Ibrance)** requires the following rule(s) be met for approval:

A. You have hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer (cancer that is in the advanced stage or that has spread to other parts of the body)
B. You are 18 years of age or older
C. You meet ONE of the following:
    - The requested medication will be used with an aromatase inhibitor (type of cancer drug such as anastrozole, letrozole, or exemestane) AND you meet ALL of the following:
        - You are a postmenopausal female or a male
        - You have NOT received endocrine (hormone)-based therapy (such as letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
        - Your disease has NOT worsened after cyclin-dependent kinase (CDK) inhibitor therapy (this type of therapy is used to treat cancer by preventing the cancer cells from multiplying)
    - The requested medication will be used in combination with Faslodex (fulvestrant) AND you meet ALL of the following:
        - Your disease has worsened after endocrine (hormone) therapy (such as letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
        - Your disease has NOT worsened after cyclin-dependent kinase (CDK) inhibitor therapy (this type of therapy is used to treat cancers by preventing the cancer cells from multiplying)

RATIONALE

Promote appropriate utilization of Ibrance based on FDA approved indication.

FDA APPROVED INDICATIONS

Ibrance is a kinase inhibitor indicated in combination with letrozole for the treatment of postmenopausal women with estrogen receptor (ER) positive, human epidermal growth factor receptor 2 (HER2) negative advanced breast cancer in combination with:

- An aromatase inhibitor as initial endocrine based therapy in postmenopausal women or in men
- Fulvestrant in patients with disease progression following endocrine therapy

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

PALBOCICLIB

DOSAGE

The recommended starting dose is 125 mg once daily taken with food for 21 days followed by 7 days off treatment (for complete 28 days cycle).

Ibrance is taken orally with food in combination with the recommended dose of an aromatase inhibitor or fulvestrant.

Dosing interruption and/or dose reductions are recommended based on individual safety and tolerability.

Dose Level	Dose
Recommended starting dose	125 mg/day
First dose reduction	100 mg/day
Second dose reduction	75 mg/day*

*If further dose reduction below 75 mg/day is required, discontinue the treatment.

Avoid concomitant use of strong CYP3A inhibitors; if must be co-administered with strong CYP3A inhibitor reduce dose to 75 mg daily.

REFERENCE

- Ibrance [Prescribing Information]. New York, NY: Pfizer Laboratories. November 2019.

Created: 05/15
Effective: 08/03/20 Client Approval: 07/22/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

PALIVIZUMAB

Generic	Brand	HICL	GCN	Exception/Other
PALIVIZUMAB	SYNAGIS	18564		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **PALIVIZUMAB (Synagis)** requires the following rule(s) be met for approval:

A. You are less than 12 months old or less than 24 months at the start of respiratory syncytial virus (RSV: type of lung and respiratory tract infection) season (mid-September to mid-May)
B. **If you are less than 12 months old, you must meet ONE of the following**:
   1. You have chronic lung disease of prematurity (a condition where you were born at less than 32 weeks and required more than 21% of additional oxygen for at least the first 28 days after birth)
   2. You are profoundly immunocompromised during RSV season (your body cannot fight off infections)
   3. You have received a solid-organ transplant during RSV season
   4. You have congenital (starting from birth) heart disease conditions at birth, such as acyanotic heart disease (blood from the left side to the right side of the heart due to a hole in the heart walls) where you need medication to control chronic heart failure and will require heart surgical procedures; moderate to severe pulmonary hypertension (high blood pressure in the lungs); or cyanotic heart defect (low blood oxygen level) and the requested medication is prescribed by or given in consultation with a pediatric cardiologist (a heart doctor for children)
   5. You have congenital (starting from birth) abnormalities of the lung airways or a neuromuscular (nerve-muscle) disorder that affects respiratory (lung/breathing) secretions
   6. You were born premature at less than 29 weeks (gestational age)
   7. You are an American Navajo, American White Mountain Apache, or Alaska Native infant born prematurely
C. **If you are less than 24 months old, you must meet ONE of the following:**
   1. You are profoundly immunocompromised during RSV season (a condition where your body cannot fight off infections)
   2. You have chronic lung disease of prematurity and need medical support within 6 months before the start of the second respiratory syncytial virus (RSV) season. Medical support includes oxygen, bronchodilator (drug that helps you breathe), diuretic (drug that makes you urinate), or chronic steroid therapy.
   3. You have received a solid-organ transplant during RSV season

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PALIVIZUMAB

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **PALIVIZUMAB (Synagis)** requires the following rule(s) be met for renewal:

A. You are under 24 months old
B. You meet **ONE** of the following:
    1. You received cardiopulmonary bypass surgery (type of heart and lung surgery) during respiratory syncytial virus (RSV: type of lung and respiratory tract infection) prevention season (mid-September to mid-May)
    2. This request is for a second year of coverage and you have chronic lung disease of prematurity and need medical support during the 6 months before the start of the second RSV season. Medical support includes oxygen, bronchodilator (drug that helps you breathe), diuretic (drug that makes you urinate), or chronic steroid therapy

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

PALIVIZUMAB

RATIONALE

To ensure the optimal use of palivizumab in high-risk patients for the prophylaxis of RSV by following the most recent American Academy of Pediatrics guidelines for the use of palivizumab for the prevention of serious RSV infections. Variations in the onset and offset of the RSV season in different regions may affect the timing of palivizumab administration. A maximum of five monthly doses of palivizumab should be adequate for qualifying infants for most RSV seasons. RSV seasons within the continental United States typically start in October/November and end in March/April.

The Indiana RSV Season is defined as November 1st through March 31st. The season may be initiated early or extended at the discretion of the Office of Medicaid Policy and Planning (OMPP) based upon statewide virology data.

FDA APPROVED INDICATIONS

Synagis is a respiratory syncytial virus (RSV) F protein inhibitor monoclonal antibody indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients:

- with a history of premature birth (less than or equal to 35 weeks gestational age) and who are 6 months of age or younger at the beginning of RSV season
- with bronchopulmonary dysplasia (BPD) that required medical treatment within the previous 6 months and who are 24 months of age or younger at the beginning of RSV season
- with hemodynamically significant congenital heart disease (CHD) and who are 24 months of age or younger at the beginning of RSV season.

REFERENCES

- Synagis package insert. MedImmune, Inc., Gaithersburg, MD. November 2020.
- American Academy of Pediatrics, Committee on Infectious Diseases and Committee on Fetus and Newborn. Revised indications for the use of palivizumab and respiratory syncytial virus immune globulin intravenous for the prevention of respiratory syncytial virus infections. Pediatrics 2003; 112(6):1442-1446.
- American Academy of Pediatrics. Policy statement - modified recommendations for use of palivizumab for prevention of respiratory syncytial virus infections. Pediatrics 2009;124:1694-1701.
- American Academy of Pediatrics, Subcommittee on Diagnosis and Management of Bronchiolitis. Pediatrics 2006; 118; 1774-1798.
- American Academy of Pediatrics, Committee on Infectious Diseases and Bronchiolitis Guidelines Committee. Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infections. Pediatrics 2014:134:415-420
- Reducing RSV hospitalizations. AAP modifies recommendations for use of palivizumab in high-risk infants, young children. AAP News 2009; 30:1.
- American Academy of Pediatrics. Interim Guidance for Use of Palivizumab Prophylaxis to Prevent Hospitalization From Severe Respiratory Syncytial Virus Infection During the Current Atypical Interseasonal RSV Spread. https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/clinical-guidance/interim-guidance-for-use-of-palivizumab-prophylaxis-to-prevent-hospitalization/. Accessed September 3, 2021.

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

PAMIDRONATE

Generic	Brand	HICL	GCN	Exception/Other
PAMIDRONATE	AREDIA	06250		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline for **PAMIDRONATE (Aredia)** requires that the patient have a diagnosis of moderate to severe hypercalcemia of malignancy, osteolytic bone metastases of breast cancer, osteolytic bone lesions of multiple myeloma, Paget's disease. Aredia will not be approved for use in hyperparathyroidism or non-tumor-related hypercalcemia. The following criteria must also be met:

For patients with a diagnosis of Paget's disease, approval requires:

- Previous trial of or contraindication to an oral bisphosphonate (e.g. Fosamax, Actonel, Boniva)

RENEWAL CRITERIA

Our guideline for renewal of **PAMIDRONATE (Aredia)** requires that the patient have a diagnosis of hypercalcemia of malignancy, osteolytic bone metastases of breast cancer, osteolytic bone lesions of multiple myeloma, or Paget's disease.

RATIONALE
To ensure appropriate use of pamidronate based on FDA approved indications and dosing.

Aredia Dosing:

- Hypercalcemia of malignancy:
  - Moderate hypercalcemia (12-13.5mg/dL): Administer 60 to 90mg single dose IV infusion over 2 to 24 hours.
  - Severe hypercalcemia (>13.5mg/dL): Administer 90mg single dose IV infusion over 2 to 24 hours.
- Osteolytic bone metastases of breast cancer: Administer 90mg IV infusion over 2 hours once every 3 to 4 weeks.
- Osteolytic bone lesions of multiple myeloma: Administer 90mg IV infusion over 4 hours once monthly.
- Paget Disease: Administer 30mg IV infusion over 4 hours for 3 consecutive days (Maximum total dose is 90mg).

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

PAMIDRONATE

FDA APPROVED INDICATIONS

Aredia is an injectable bisphosphonate indicated for:

- Hypercalcemia of malignancy
- Osteolytic bone metastases of breast cancer
- Osteolytic bone lesions of multiple myeloma
- Paget Disease

REFERENCES

- Pamidronate disodium [prescribing information]. Lake Forest, IL: Hospira Inc; August 2012.
- Pamidronate disodium. Drug Facts and Comparisons. Facts & Comparisons eAnswers. Wolters Kluwer Health, Inc. Philadelphia, PA. Available at: http://factsandcomparisons.com. Accessed July 16, 2018.

Created: 10/15
Effective: 10/01/18 Client Approval: 08/22/18 P&T Approval: 3QTR

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

PANOBINOSTAT

Generic	Brand	HICL	GCN	Exception/Other
PANOBINOSTAT	FARYDAK	41794		ROUTE = ORAL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline for **PANOBINOSTAT** requires the patient to have a diagnosis of multiple myeloma. Additional guideline requirements apply.

- Previously treated with at least 2 prior regimens; the patient must have had tried Velcade (bortezomib) and one of the following immunomodulatory agents: Thalomid, Revlimid, Pomalyst.
- Farydak to be used concurrently with Velcade (bortezomib) and dexamethasone.

RENEWAL CRITERIA

Our guideline for **PANOBINOSTAT** renewal permits patients with clinical benefit who do not experience unresolved severe or medically significant toxicity.

PANOBINOSTAT

RATIONALE

Promote appropriate utilization of **Farydak (panobinostat)** based on FDA approved indication. Initial dosing for up to 8 cycles. Renewal provided for patients with clinical benefit who do not experience unresolved severe or medically significant toxicity (maximum duration of therapy up to 16 cycles which allows up to 96 capsules in 48 weeks).

The most common prior antineoplastic therapies in the PANORAMA-1 (Panobinostat Oral in Multiple Myeloma) trial were corticosteroids (90%), melphalan (80%), thalidomide (53%), cyclophosphamide (47%), bortezomib (44%), and lenalidomide (19%).

Given the toxicity concerns, a regimen containing Farydak may be less preferred over other regimens for relapsed/refractory MM. As of March 2015, the NCCN lists the following as Category 1 recommendations (please check NCCN treatment guidelines for other possible regimens):

- Velcade
- Velcade with liposomal doxorubicin (i.e. Doxil, Lipodox)
- Revlimid/dexamethasone
- Kyprolis (carfilzomib)/Revlimid/dexamethasone

Farydak might also be reserved for patients less than 65 years of age with good performance status who either have not been exposed to or have been exposed to, but are not refractory to, proteasome inhibitors (i.e. Velcade and Kyprolis).

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

PANOBINOSTAT

DOSAGE

The recommended starting dose of Farydak is 20 mg, taken orally once every other day for 3 doses per week in Weeks 1 and 2 of each 21-day cycle for up to 8 cycles. Consider continuing treatment for an additional 8 cycles for patients with clinical benefit who do not experience unresolved severe or medically significant toxicity. The total duration of treatment may be up to 16 cycles (48 weeks). Farydak is administered in combination with bortezomib and dexamethasone.

21-Day Cycle														
Cycles 1 to 8 (3-Week cycles)	Week 1 Days							Week 2 Days						Week 3
FARYDAK	1		3		5			8		10		12		Rest period
Bortezomib	1			4				8			11			Rest period
Dexamethasone	1	2		4	5			8	9		11	12		Rest period

FDA APPROVED INDICATIONS

Indicated in combination with bortezomib and dexamethasone for the treatment of patients with multiple myeloma who have received at least 2 prior regimens, including bortezomib and an immunomodulatory agent.

REFERENCES

- Farydak [Prescribing Information]. East Hanover, NJ: Novartis; February 2015.
- NCCN Clinical Practice Guideline in Oncology: Multiple Myeloma Version 3.2015. National Comprehensive Cancer Network. Available at: http://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf [Accessed February 23, 2015].

Created: 05/15
Effective: 11/01/15 Client Approval: 09/15 P&T Approval: 05/15

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

PARATHYROID HORMONE

Generic	Brand	HICL	GCN	Exception/Other
PARATHYROID HORMONE	NATPARA	34000		ROUTE = SUBCUTANE.

GUIDELINES FOR USE

Our guideline for **PARATHYROID HORMONE** requires the following rule(s) be met for approval:

A. You have hypocalcemia secondary to hypoparathyroidism (low blood calcium due to low levels of a type of hormone)
B. You have previously tried activated vitamin D (calcitriol) and calcium
C. Your hypoparathyroidism (low levels of a type of hormone) is not due to a calcium sensing receptor (CSR) mutation (changes in your DNA that make up your gene)
D. Your hypoparathyroidism is not considered acute post-surgical hypoparathyroidism (not sudden and severe due to surgery in past 30 days)

RATIONALE

Promote appropriate utilization of parathyroid hormone based on FDA approved indication, dosing and best practices.

DOSAGE

The starting dose of Natpara is 50 mcg injected once daily in the thigh.

The dose of Natpara may be increased in increments of 25 mcg every four weeks up to a maximum daily dose of 100 mcg if serum calcium cannot be maintained above 8 mg/dL without an active form of vitamin D and/or oral calcium supplementation.

FDA APPROVED INDICATIONS

Natpara is a parathyroid hormone indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism.

Limitations of Use

- Because of the potential risk of osteosarcoma, Natpara is recommended only for patients who cannot be well-controlled on calcium supplements and active forms of vitamin D alone.
- Natpara was not studied in patients with hypoparathyroidism caused by calcium-sensing receptor mutations.
- Natpara was not studied in patients with acute post-surgical hypoparathyroidism.

REFERENCES

Natpara [Prescribing Information]. Bedminster, NJ: NPS Pharmaceuticals, Inc. December 2018.

Created: 05/15
Effective: 04/11/22 Client Approval: 03/09/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

PASIREOTIDE

Generic	Brand	HICL	GCN	Exception/Other
PASIREOTIDE	SIGNIFOR	39866		

GUIDELINES FOR USE

Approval requires a diagnosis of Cushing's disease for which the patient has undergone pituitary surgery or pituitary surgery is not an option, and a trial of ketoconazole, metyrapone, or cabergoline.

RATIONALE

To ensure appropriate use of Signifor consistent with FDA approved indication and dose.

Signifor's recommended dosage range is 0.3 mg to 0.9 mg twice a day. The recommended initial dose is either 0.6 mg or 0.9 mg injected subcutaneously twice a day. For patients with moderate hepatic impairment (Child Pugh B), the recommended initial dosage is 0.3 mg twice a day and the maximum dosage is 0.6 mg twice a day. Avoid the use of SIGNIFOR in patients with severe hepatic impairment (Child Pugh C).

Cushing's disease is caused by a pituitary gland tumor that produces adrenocorticotropic hormone (ACTH). This additional ACTH acts as a signal to the adrenal glands to make excess cortisol. Signifor binds and activates the human somatostatin receptor subtype 5 resulting in inhibition of ACTH secretion by the pituitary tumor cells, which leads to decreased cortisol secretion. First line treatment for Cushing's disease is transsphenoidal surgery and resection of the pituitary tumor. If surgery is delayed, contraindicated, or unsuccessful, adjunct medical therapy is usually required. Adrenal enzyme inhibitors, ketoconazole, and metyrapone (not FDA approved for this indication) are most commonly prescribed, followed by cabergoline (also not FDA approved for this indication) which targets the corticotrophin tumor. Combination therapy, such as Signifor, cabergoline, and/or ketoconazole, may be necessary to achieve an acceptable response.

A total of 162 patients were enrolled in a Phase III, multicenter, randomized study over a 6-month treatment period to evaluate the safety and efficacy of Signifor in patients with Cushing's disease. The majority of clinical trial subjects (83%) had persistent or recurrent disease despite pituitary surgery whereas surgery was not indicated or surgery was refused in the remaining subjects. Patients with a baseline 24-hour urine free cortisol (UFC) >1.5 x upper limit of normal (ULN) were randomized to receive a twice-daily, subcutaneous injection of either Signifor 0.6 mg or 0.9 mg. The primary efficacy endpoint was the proportion of patients who achieved normalization of mean 24-hour UFC levels after six months of treatment and did not dose increase during this period. At Month 6, the percentages of responders for the primary endpoint were 15% and 26% in the 0.6 mg twice daily and 0.9 mg twice daily groups, respectively. Signifor resulted in a decrease in the mean 24-hour UFC after 1 month of treatment. For patients (n=78) who stayed in the trial, similar UFC lowering was observed at Month 12.

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PASIREOTIDE

RATIONALE (CONTINUED)
Most common adverse reactions occurring in ≥20% of patients are diarrhea, nausea, hyperglycemia, cholelithiasis, headache, abdominal pain, fatigue, and diabetes mellitus.

Other clinically significant adverse reactions include hypocortisolism, bradycardia and QT prolongation, liver test elevations, and pituitary hormone deficiency.

Treatment with Signifor leads to suppression of adrenocorticotropic hormone (ACTH) secretion in Cushing's disease. Suppression of ACTH may lead to a decrease in circulating levels of cortisol and potentially hypocortisolism. Pituitary hormones other than ACTH may also be inhibited since Signifor mimics the acts of somatostatin. Monitoring of pituitary function (e.g., TSH/free T4, GH/IGF-1) should occur prior to initiation of therapy with Signifor and periodically during treatment. Patients who have undergone transsphenoidal surgery and pituitary irradiation are particularly at increased risk for deficiency of pituitary hormones.

Drug interactions include cyclosporine (decreased cyclosporine levels), bromocriptine (increased bromocriptine levels), and anti-arrhythmic drugs or other medications that prolong QT interval (additive effects on QT interval prolongation).

Signifor is Pregnancy Category C.

FDA APPROVED INDICATIONS
Signifor is a somatostatin analog indicated for the treatment of adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative.

REFERENCES

- Signifor [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2012.
- UpToDate, Inc. Overview of the treatment of Cushing's syndrome. UpToDate [database online]. Waltham, MA. Available at http://www.uptodate.com/home/index.html. Updated January 17, 2013.
- UpToDate, Inc. Medical therapy of hypercortisolism (Cushing's syndrome). UpToDate [database online]. Waltham, MA. Available at http://www.uptodate.com/home/index.html. Updated January 18, 2013.

Created: 06/15
Effective: 07/22/15 Client Approval: 06/15 P&T Approval: 05/13

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

PATIROMER

Generic	Brand	HICL	GCN	Exception/Other
PATIROMER CALCIUM SORBITEX	VELTASSA	42767		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **PATIROMER (Veltassa)** requires the following rule(s) be met for approval:

A. You have a diagnosis of hyperkalemia (high levels of potassium in blood)
B. The requested drug is NOT being used as an emergency treatment for life-threatening hyperkalemia (high levels of potassium in blood)
C. The requested drug will NOT be used if you are currently receiving dialysis.
D. You have tried **ONE** of the following to lower the risks for hyperkalemia:
   - Limit to taking no more than one of the following drugs at any given time: angiotensin converting enzyme inhibitor (ACE-I, such as lisinopril, benazepril) or angiotensin receptor blocker (ARB, such as valsartan, losartan)
   - Your prescriber has considered lowering the dose of renin-angiotensin-aldosterone system (RAAS) inhibitors (such as ACE-I's, ARB's, aldosterone antagonists like spironolactone)
E. If estimated glomerular filtration rate (eGFR) is below 30 mL/min/1.73 m^2: you have tried to treat hyperkalemia with a loop diuretic such as bumetanide, ethacrynic acid, furosemide, torsemide
F. If estimated glomerular filtration rate (eGFR) is 30 mL/min/1.73 m^2 or above: you have tried to treat hyperkalemia with a loop diuretic such as bumetanide, ethacrynic acid, furosemide, torsemide OR a thiazide diuretic such as chlorthalidone, hydrochlorothiazide, metolazone

RENEWAL CRITERIA

Our guideline named **PATIROMER (Veltassa)** requires the following rule(s) be met for renewal approval:

A. You have a diagnosis of hyperkalemia (high levels of potassium in blood)
B. The requested drug is NOT being used as an emergency treatment for life-threatening hyperkalemia (high levels of potassium in blood)
C. The requested drug will NOT be used if you are currently receiving dialysis
D. Documentation has been provided that your blood potassium level has improved since you started taking Veltassa

RATIONALE
Promote appropriate utilization of PATIROMER based on FDA approved indication.

FDA APPROVED INDICATION
Veltassa is a potassium binder indicated for the treatment of hyperkalemia. Veltassa should not be used as an emergency treatment for life-threatening hyperkalemia because of its delayed onset of action.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

PATIROMER

DOSAGE
The recommended starting dose of Veltassa is 8.4 grams administered orally once daily with food. Based on serum potassium levels, the dose can be increased or decreased to reach the target range. The dose can be increased at one-week intervals in increments of 8.4g up to a maximum dose of 25.2g once daily.

AVAILABLE STRENGTHS:
- 8.4g powder for oral suspension packet
- 16.8g powder for oral suspension packet
- 25.2g powder for oral suspension packet

REFERENCES
Veltassa [Prescribing Information]. Relypsa, Inc.: Redwood City, CA; December 2021.

Created: 11/17
Effective: 03/21/22 Client Approval: 02/17/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

PAZOPANIB

Generic	Brand	HICL	GCN	Exception/Other
PAZOPANIB	VOTRIENT	36709		

GUIDELINES FOR USE

Approval requires a diagnosis of advanced renal cell carcinoma (RCC) or advanced soft tissue sarcoma (STS) and previous chemotherapy. Votrient is not covered for adipocytic soft tissue sarcoma (STS) and gastrointestinal stromal tumors (GIST).

PAZOPANIB

RATIONALE

Ensure appropriate utilization of pazopanib based on FDA approved indication and NCCN guidelines.

FDA APPROVED INDICATIONS

Pazopanib is indicated for the treatment of advanced renal cell carcinoma and advanced soft tissue sarcoma (STS) in patients who have received prior chemotherapy.

Limitation of use: the efficacy of pazopanib for the treatment of patients with adipocytic STS or gastrointestinal stromal tumors (GIST) has not been demonstrated.

REFERENCES

- GlaxoSmithKline. Votrient package insert. Research Triangle Park, NC. April, 2012.
- National Comprehensive Cancer Network, Inc. The NCCN Clinical Practice Guidelines in Oncology. Kidney Cancer. (Version 2.2011).

Created: 06/15
Effective: 07/22/15 Client Approval: 06/15 P&T Approval: 11/12

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION

Generic	Brand	HICL	GCN	Exception/Other
SILDENAFIL	REVATIO		24758 33186	
TADALAFIL	ADCIRCA, ALYQ, TADLIQ		26587 52585	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline for **PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: type of high blood pressure that affects arteries in the lungs and in the heart) World Health Organization (WHO Group I: a way to classify the severity of disease)
B. The medication is prescribed by or in consultation with a cardiologist (heart doctor) or pulmonologist (lung/breathing doctor)
C. In addition to the above requirements, the following criteria apply to the specific agents listed:
    1. Requests for Revatio (sildenafil) oral suspension require that you are unable to swallow tablets and you have tried crushed sildenafil tablets
    2. Requests for Tadliq (tadalafil) oral suspension require that you are unable to swallow tablets and you have tried crushed tadalafil tablets

RENEWAL CRITERIA

Our guideline named **PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION (Revatio, Adcirca/Alyq, Tadliq)** requires the following rule(s) be met for renewal:

A. You have history of paid claim(s) for the requested medication in the past 90 days
B. You have a previous authorization on file for the requested medication

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RATIONALE
Ensure appropriate utilization of PDE5 inhibitors, sildenafil and tadalafil.

FDA APPROVED INDICATIONS
Adcirca, Alyq, and Tadliq are phosphodiesterase 5 (PDE5) inhibitors indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise ability.

Revatio is a phosphodiesterase-5 (PDE-5) inhibitor indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group I) in adults to improve exercise ability and delay clinical worsening.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION

DOSING

The recommended dose of Adcirca or Alyq is 40 mg taken once daily with or without food. Dividing the dose (40 mg) over the course of the day is not recommended.

The recommended dose of Tadliq is 40 mg (10 mL) taken once daily with or without food.

The recommended dose of Revatio is 5 mg or 20 mg three times a day. Administer Revatio doses 4 to 6 hours apart. Treatment with doses higher than 20 mg three times a day is not recommended.

REFERENCES

- Revatio [Prescribing Information] New York, NY: Pfizer Inc.; February 2020.
- Adcirca [Prescribing Information] Indianapolis, IN: Eli Lilly and Company; September 2020.
- Alyq [Prescribing Information] North Wales, PA: Teva Pharmaceuticals USA, Inc., July 2021.
- Tadliq [Prescribing Information]. Farmville, NC: CMP Pharma, Inc., June 2022.

Created: 09/15
Effective: 11/21/22 Client Approval: 10/21/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

PEANUT ALLERGEN POWDER-DNFP

Generic	Brand	HICL	GCN	Exception/Other
PEANUT (ARACHIS HYPOGAEA) ALLERGEN POWDER-DNFP	PALFORZIA	46332		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **PEANUT ALLERGEN POWDER-DNFP (Palforzia)** requires the following rule(s) be met for approval:
A. You have a diagnosis of peanut allergy
B. You are 4 to 17 years of age

RENEWAL CRITERIA

Our guideline named **PEANUT ALLERGEN POWDER-DNFP (Palforzia)** requires the following rule(s) be met for renewal:
A. You have history of paid claim(s) for the requested medication in the past 90 day
B. You have a previous authorization on file for the requested medication

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RATIONALE
Promote appropriate utilization of Palforzia based on FDA approved indication, dosage, and guidelines adopted from ARIA (Allergic Rhinitis and its Impact on Asthma) as well as the AAAAI (American Academy of Allergy, Asthma & Immunology) Practice Parameter on Allergen Immunotherapy.

INDICATIONS
Palforzia is an oral immunotherapy indicated for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut. Palforzia is approved for use in patients with a confirmed diagnosis of peanut allergy.

DOSING
Treatment with Palforzia is administered in 3 sequential phases: Initial Dose Escalation, Up-Dosing, and Maintenance. The final maintenance dose is 300mg once daily.

REFERENCES

- Palforzia [Prescribing Information]. Brisbane, CA: Aimmune Therapeutics, Inc.; January 2020.

Created: 10/21
Effective: 03/04/22 Client Aproval: 02/03/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

PEGCETACOPLAN

Generic	Brand	HICL	GCN	Exception/Other
PEGCETACOPLAN	EMPAVELI	47380		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **PEGCETACOPLAN (Empaveli)** requires the following rule(s) be met for approval:

A. You have paroxysmal nocturnal hemoglobinuria (PNH: a rare disorder that causes red blood cells break)
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with a hematologist (blood specialist)
D. You have documented confirmation of PNH by flow cytometry (type of measurement of physical and chemical qualities of cells) demonstrating ALL of the following:
    1. At least 2 different GPI-protein deficiencies (missing a certain type of protein such as CD55, CD59) on at least 2 cell lineages (types of cells such as erythrocytes, granulocytes)
    2. PNH granulocyte clone size of 10% or greater
E. You have tried and failed Soliris or Ultomiris as evidenced by hemoglobin (type of protein in red blood cells) levels less than 10.5 g/dL, directly following at least 3 months of stable dosing
F. You are not using concurrent (at the same time) C5 complement inhibitor therapy (such as Soliris, Ultomiris)

RENEWAL CRITERIA

Our guideline named **PEGCETACOPLAN (Empaveli)** requires the following rule(s) be met for renewal:

A. You have paroxysmal nocturnal hemoglobinuria (PNH: a rare disorder that causes red blood cells break)
B. You have had clinical benefit (such as reduction in number of blood transfusions [adding blood to your body], improvement/stabilization of lactate dehydrogenase [LDH: type of enzyme] and hemoglobin levels [type of protein in red blood cells]) compared to baseline during treatment with Soliris or Ultomiris

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PEGCETACOPLAN

RATIONALE
To ensure appropriate use of Empaveli based on FDA approved indication and prescribing information.

FDA APPROVED INDICATIONS
Empaveli is a complement inhibitor indicated for the treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH).

DOSING AND ADMINISTRATION
The recommended dosage of Empaveli is 1,080 mg by subcutaneous infusion twice weekly via a commercially available pump.

REFERENCES

- Empaveli [Prescribing Information]. Waltham, MA: Apellis Pharmaceuticals, Inc., May 2021.

Created: 10/21
Effective: 12/20/21 Client Approval: 11/19/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

PEGVALIASE

Generic	Brand	HICL	GCN	Exception/Other
PEGVALIASE-PQPZ	PALYNZIQ	44944		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **PEGVALIASE (Palynziq)** requires the following rules be met for approval:

A. You have phenylketonuria (PKU) (a type of birth defect that causes buildup of a chemical called phenylalanine)
B. You are 18 years of age or older
C. You have uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management, as confirmed by a measurement in the last 30 days
D. You have previously tried Kuvan (sapropterin)
E. You are NOT receiving Kuvan (sapropterin) at the same time as Palynziq (pegvaliase)

RENEWAL CRITERIA

Our guideline named **PEGVALIASE (Palynziq)** requires the following rules be met for renewal:

A. You have a diagnosis of phenylketonuria (PKU: type of birth defect that causes buildup of a chemical called phenylalanine)
B. Your phenylalanine levels have dropped by at least 20% from baseline or to a level under 600 micromol/L

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PEGVALIASE

RATIONALE
To ensure appropriate use of Palynziq (pegvaliase) consistent with FDA-approved indications and dosing.

FDA-APPROVED INDICATION
Palynziq is a phenylalanine-metabolizing enzyme indicated to reduce blood phenylalanine concentrations in adult patients with phenylketonuria who have uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management.

DOSAGE AND ADMINISTRATION
Treatment with Palynziq should be managed by a healthcare provider experienced in the management of phenylketonuria. Before initiating treatment, baseline blood phenylalanine concentrations should be obtained. After initiating treatment with Palynziq, blood phenylalanine concentrations should be obtained every 4 weeks until a maintenance dosage is established. After a maintenance dosage is established, periodic blood phenylalanine monitoring is recommended to assess blood phenylalanine control.

For hypersensitivity reactions, premedication may be considered with an H_1-receptor antagonist, H_2-receptor antagonist, and/or antipyretic prior to Palynziq administration based upon individual patient tolerability.

Induction:
The recommended initial induction dosage for Palynziq is 2.5 mg subcutaneously once weekly for 4 weeks. The initial dose should be administered under the supervision of a healthcare provider.

Titration:
Palynziq doses should be titrated in a stepwise manner based on tolerability, over at least 5 weeks, to achieve a dosage of 20 mg subcutaneously once daily.

Maintenance:
Therapeutic response may not be achieved until the patient is titrated to an effective maintenance dosage. The lowest effective and tolerated dosage of Palynziq should be used. Palynziq should be maintained at a dosage of 20 mg subcutaneously once daily for at least 24 weeks. Consider increasing the Palynziq dosage to a maximum of 60 mg once daily in patients who have been on 40 mg once daily continuously for at least 16 weeks without achieving blood phenylalanine control.

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PEGVALIASE

FDA-APPROVED INDICATION (CONTINUED)

Discontinuation:
Palynziq should be discontinued in patients who have not achieved a response (at least a 20% reduction in blood phenylalanine concentrations from pre-treatment baseline levels or blood phenylalanine concentrations ≤ 600 micromol/L) after 16 weeks of continuous treatment with the maximum dosage of 60 mg once daily.

Phase of Treatment	Palynziq Dosing Regimen	Duration[a]
Induction	2.5 mg SC once weekly	4 weeks
Titration	2.5 mg SC twice weekly	1 week
	10 mg SC once weekly	1 week
	10 mg SC twice weekly	1 week
	10 mg SC four times per week	1 week
	10 mg SC once daily	1 week
Maintenance[b]	20 mg SC once daily	24 weeks
	40 mg SC once daily	16 weeks
Maximum	60 mg SC once daily	16 weeks

[a]Additional time may be required prior to each dosage escalation based on patient tolerability.
[b]Treatment should be individualized to the lowest effective and tolerated dosage. Consider increasing to 40 mg once daily in patients who have not achieved a response with 20 mg once daily continuous treatment for at least 24 weeks. Consider increasing to a maximum of 60 mg once daily in patients who have not achieved a response with 40 mg once daily continuous treatment for at least 16 weeks.

REFERENCES

- Palynziq [prescribing information]. Novato, CA. BioMarin Pharmaceutical, Inc. November 2020.

Created: 06/18
Effective: 10/01/21 Client Approval: 08/26/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

PEGVISOMANT

Generic	Brand	HICL	GCN	Exception/Other
PEGVISOMANT	SOMAVERT	25062		

GUIDELINES FOR USE

Approval for Somavert requires a diagnosis of acromegaly with the failure to be treated with one of the following or the inability to be treated with any of the following: surgical resection, pituitary irradiation, or a dopamine agonist (e.g. cabergoline or bromocriptine) at maximally tolerated doses.

RATIONALE

To ensure appropriate use of Somavert based on FDA approved indication and dosing.

FDA APPROVED INDICATION

Somavert is a growth hormone receptor antagonist indicated for the treatment of acromegaly in patients who have had an inadequate response to surgery or radiation therapy, or for whom these therapies are not appropriate. The goal of treatment is to normalize serum insulin-like growth factor-I (IGF-I) levels.

DOSING AND ADMINISTRATION

The recommended loading dose of Somavert is 40 mg given subcutaneously, under healthcare provider supervision. Provide proper training in subcutaneous injection technique to patients or their caregivers so they can receive once daily subcutaneous injections. On the next day following the loading dose, instruct patients or their caregivers to begin daily subcutaneous injections of 10 mg of Somavert.

Titrate the dosage to normalize serum IGF-I concentrations (serum IGF-I concentrations should be measured every four to six weeks). The dosage should not be based on growth hormone (GH) concentrations or signs and symptoms of acromegaly. It is unknown whether patients who remain symptomatic while achieving normalized IGF-I concentrations would benefit from increased SOMAVERT dosage.

- Increase the dosage by 5 mg increments every 4 to 6 weeks if IGF-I concentrations are elevated.
- Decrease the dosage by 5 mg decrements every 4 to 6 weeks if IGF-I concentrations are below the normal range.
- IGF-I levels should also be monitored when a Somavert dose given in multiple injections is converted to a single daily injection.

REFERENCES

- Katznelson L, Atkinson J, Cook D, et al. American Association of Clinical Endocrinologists. Medical guidelines for clinical practice for the diagnosis and treatment of acromegaly – 2011 update. https://www.aace.com/files/acromegaly-guidelines.pdf. Published August 2011. Accessed October 11, 2017.
- Somavert [Prescribing Information]. New York, NY: Pfizer, Inc. April 2016.

Created: 02/18
Effective: 07/01/18 Client Approval: 05/21/18 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

PEMIGATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEMIGATINIB	PEMAZYRE	46462			

GUIDELINES FOR USE

Our guideline named **PEMIGATINIB (Pemazyre)** requires the following rule(s) be met for approval:

A. You have unresectable locally advanced or metastatic cholangiocarcinoma (bile duct cancer that has grown outside the organ but has not yet spread to other parts of the body and cannot be removed by surgery, or bile duct cancer that has spread to other parts of the body)
B. You are 18 years of age or older
C. You have previously been treated
D. You have a fibroblast growth factor receptor 2 (FGFR2: type of protein) fusion or other rearrangement as detected by an Food and Drug Administration (FDA)-approved test

RATIONALE

To ensure appropriate diagnostic, utilization, and safety criteria are used for the management of requests for pemigatinib.

INDICATIONS

Pemazyre is a kinase inhibitor indicated for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test.

DOSAGE

The recommended dose is 13.5 mg orally once daily for 14 consecutive days followed by 7 days off therapy in 21-day cycles. Continue treatment until disease progression or unacceptable toxicity occurs.

REFERENCES

- Pemazyre [Prescribing Information]. Wilmington, DE: Incyte Corporation; April 2020.

Created: 06/20
Effective: 07/01/20 Client Aproval: 06/05/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

PENICILLAMINE

Generic	Brand	HICL	GCN	Exception/Other
PENICILLAMINE	CUPRIMINE		7091	
PENICILLAMINE	DEPEN		7100	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named **PENICILLAMINE (Cuprimine, Depen)** will allow for approval for patients with a known family history of Wilson's disease or physical examination consistent with Wilson's disease, cystinuria, or active rheumatoid arthritis. The following criteria must also be met:

For patients with Wilson's disease, approval requires ONE of the following:

- Plasma copper-protein ceruloplasmin less than 20mg/dL
- Liver biopsy positive for an abnormally high concentration of copper (greater than 250mcg/g dry weight) **OR** the presence of Kayser-Fleischer rings
- The diagnosis has been confirmed by genetic testing for ATP7B mutations
- In addition, the following criteria must also be met:
  - The patient has maintained a reduced copper dietary intake (less than 2mg copper per day)
  - The medication is prescribed by or given in consultation with a hepatologist
  - For Cuprimine requests, the patient had a previous trial of or contraindication to Depen (penicillamine)

For patients with cystinuria, approval requires:

- Presence of nephrolithiasis and at least **ONE** of the following:
  - Stone analysis positive for cystine
  - Urinalysis positive for pathognomonic hexagonal cystine crystals
  - Family history of cystinuria with a positive cyanide-nitroprusside screen
- Daily cystine output greater than 300mg per 24 hours following urine cystine excretion testing
- Patient has failed to respond to an adequate trial of conventional therapy which includes **ALL** of the following (unless contraindicated):
  - Increased fluid intake
  - Modest reductions in sodium and protein intake
  - Urinary alkalinization
- The medication is prescribed by or given in consultation with a nephrologist
- For Cuprimine requests, the patient had a previous trial of or contraindication to Depen (penicillamine) **AND** Thiola (tiopronin)

For patients with active rheumatoid arthritis, approval requires:

- The medication is prescribed by or given in consultation with a rheumatologist
- The patient does not have a history of or other evidence of renal insufficiency
- The patient has failed to respond to ONE of the following DMARDs (disease-modifying antirheumatic drugs): methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- For Cuprimine requests, the patient had a previous trial of or contraindication to Depen (penicillamine)

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

PENICILLAMINE

RENEWAL CRITERIA

The guideline named **PENICILLAMINE (Cuprimine, Depen)** requires a diagnosis of Wilson's disease, cystinuria, or active rheumatoid arthritis. In addition, the following criteria must be met:

For patients with Wilson's disease, approval requires:

- The patient has achieved free serum copper of less than 10 mcg/dL

For patients with cystinuria, approval requires:

- The patient has achieved cystine excretion of less than 200 mg/day

For patients with active rheumatoid arthritis, approval requires:

- The patient does not have a history of or other evidence of renal insufficiency
- The patient has experienced or maintained improvement in tender joint count or swollen joint count while on therapy compared to baseline

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RATIONALE

Promote appropriate utilization of **PENICILLAMINE** based on FDA approved indication and to ensure appropriate diagnostic, utilization and safety criteria are used for the management of requests for penicillamine.

FDA APPROVED INDICATIONS

Wilson's disease, cystinuria, and in patients with severe, active rheumatoid arthritis who have failed to respond to an adequate trial of conventional therapy.

DOSAGE

Wilson's disease - Optimal dosage can be determined by measurement of urinary copper excretion and the determination of free copper in the serum. The urine must be collected in copper-free glassware, and should be quantitatively analyzed for copper before and soon after initiation of therapy with CUPRIMINE.

Determination of 24-hour urinary copper excretion is of greatest value in the first week of therapy with penicillamine. In the absence of any drug reaction, a dose between 0.75 and 1.5 g that results in an initial 24-hour cupriuresis of over 2 mg should be continued for about three months, by which time the most reliable method of monitoring maintenance treatment is the determination of free copper in the serum. This equals the difference between quantitatively determined total copper and ceruloplasmin-copper. Adequately treated patients will usually have less than 10 mcg free copper/dL of serum. It is seldom necessary to exceed a dosage of 2 g/day. If the patient is intolerant to therapy with CUPRIMINE, alternative treatment is trientine hydrochloride.
In patients who cannot tolerate as much as 1 g/day initially, initiating dosage with 250 mg/day, and increasing gradually to the requisite amount, gives closer control of the effects of the drug and may help to reduce the incidence of adverse reactions.

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PENICILLAMINE

RATIONALE (CONTINUED)

Cystinuria - The usual dosage of CUPRIMINE in the treatment of cystinuria is 2 g/day for adults, with a range of 1 to 4 g/day. For pediatric patients, dosage can be based on 30 mg/kg/day. The total daily amount should be divided into four doses. If four equal doses are not feasible, give the larger portion at bedtime. If adverse reactions necessitate a reduction in dosage, it is important to retain the bedtime dose.

Rheumatoid Arthritis - The currently recommended dosage regimen in rheumatoid arthritis begins with a single daily dose of 125 mg or 250 mg, which is thereafter increased at one to three month intervals, by 125 mg or 250 mg/day, as patient response and tolerance indicate. If a satisfactory remission of symptoms is achieved, the dose associated with the remission should be continued. If there is no improvement and there are no signs of potentially serious toxicity after two to three months of treatment with doses of 500-750 mg/day, increases of 250 mg/day at two to three month intervals may be continued until a satisfactory remission occurs or signs of toxicity develop. If there is no discernible improvement after three to four months of treatment with 1000 to 1500 mg of penicillamine/day, it may be assumed the patient will not respond and CUPRIMINE should be discontinued.

REFERENCES

- Cuprimine [Prescribing Information]. Bridgewater, NJ. Aton Pharma, a Division of Valeant Pharmaceuticals March 2018.
- Thiola [Prescribing Information]. San Antonio, TX: Mission Pharmacal. June 2019.
- Depen [Prescribing Information]. Somerset, NJ. Meda Pharmaceuticals. January 2019.

Created: 10/16
Effective: 03/09/20 Client Approval: 02/19/20 P&T Approval: N/A

PEXIDARTINIB

Generic	Brand	HICL	GCN	Exception/Other
PEXIDARTINIB	TURALIO	45912		

GUIDELINES FOR USE

The guideline for **PEXIDARTINIB (Turalio)** requires a diagnosis of symptomatic tenosynovial giant cell tumor (TGCT). In addition, the following criteria must be met:

- TGCT is associated with severe morbidity or functional limitations
- TGCT is NOT amenable to improvement with surgery
- The patient is 18 years of age or older

RATIONALE
Promote appropriate utilization and dosing of Turalio for its FDA approved indication.

FDA APPROVED INDICATIONS
Turalio is a kinase inhibitor indicated for the treatment of adult patients with symptomatic tenosynovial giant cell tumor associated with severe morbidity or functional limitations and not amenable to improvement with surgery.

DOSAGE AND ADMINISTRATION
Recommended starting dosage is 400 mg orally twice daily

AVAILABLE STRENGTHS
200 mg capsules

REFERENCES
Turalio [Prescribing Information]. Basking Ridge, NJ: Daiichi Sankyo, Inc.; August 2019.

Created: 10/19
Effective: 10/21/19 Client Approval: 10/07/19 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

PHENOXYBENZAMINE

Generic	Brand	HICL	GCN	Exception/Other
PHENOXYBENZAMINE	DIBENZYLINE	02098		ROUTE = ORAL

This drug requires a written request for prior authorization

GUIDELINES FOR USE

The guideline for **PHENOXYBENZAMINE (DIBENZYLINE)** requires a diagnosis of pheochromocytoma. In addition, the following criteria must also be met:

- The requested medication is used for the treatment of pheochromocytoma prior to pheochromocytoma resection/removal
- Therapy is prescribed by or in consultation with an endocrinologist, an endocrine surgeon, or a hematologist-oncologist
- The patient had a previous trial of or contraindication to an alpha-1 selective adrenergic receptor blockers (e.g. doxazosin, terazosin, or prazosin)

RATIONALE

Ensure appropriate utilization for phenoxybenzamine based on FDA approved indication and dosing.

FDA APPROVED INDICATIONS

Phenoxybenzamine is indicated for the treatment of pheochromocytoma, to control episodes of hypertension and sweating. If tachycardia is excessive, it may be necessary to use a beta-blocking agent concomitantly.

DOSAGE AND ADMINISTRATION

Initial dose for phenoxybenzamine is 10 mg orally twice a day. Dosage should be increased every other day, usually to 20 to 40 mg 2 or 3 times a day, until an optimal dosage is obtained, as judged by blood pressure control.

Dosage should be adjusted to fit the needs of each patient. Small initial doses should be slowly increased until the desired effect is obtained or the side effects from blockade become troublesome. After each increase, the patient should be observed on that level before instituting another increase. The dosage should be carried to a point where symptomatic relief and/or objective improvement are obtained, but not so high that the side effects from blockade become troublesome. Long-term use of phenoxybenzamine is not recommended.

REFERENCES

- Phenoxybenzamine [Prescribing Information]. West-Ward Pharmaceuticals Corp. Eatontown, NJ. May 2016.
- Lenders JWM, Duh QY, Eisenhofer G, et al. Pheochromocytoma and Paraganglioma: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. June 2014; 99 (6):1915-1942.
- UpToDate, Inc. Treatment of pheochromocytoma in adults. UpToDate [database online]. Last updated Oct 20, 2017.

Created: 03/19
Effective: 07/01/19 Client Approval: 05/13/19 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

PIMAVANSERIN

Generic	Brand	HICL	GCN	Exception/Other
PIMAVANSERIN	NUPLAZID	43373		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

Our guideline for **PIMAVANSERIN** requires a diagnosis of Parkinson's disease.

RATIONALE
To ensure the appropriate use of Nuplazid.

DOSAGE
The recommended dosage of Nuplazid is 34mg orally once daily, without titration, taken with or without food. Reduce dose to 10mg once daily when administering with a strong CYP3A4 inhibitor.

FDA APPROVED INDICATIONS
PIMAVANSERIN is an atypical antipsychotic indicated for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis.

AVAILABLE STRENGTHS
- 10 mg tablets
- 17 mg tablets
- 34 mg capsules

REFERNCES

- Nuplazid [Prescribing Information]. San Diego, CA: ACADIA Pharmaceuticals Inc; June 2018.
- Seppi K, Weintraub D, Coelho M, et al. The Movement Disorder Society Evidence-Based Medicine Review Update: Treatments for the Non-Motor Symptoms of Parkinson's Disease. *Mov Disord* 2011;26:20-25.

Created: 08/18
Effective: 09/10/18 Client Approval: 08/28/18 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

PIRFENIDONE

Generic	Brand	HICL	GCN	Exception/Other
PIRFENIDONE	ESBRIET	40237		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **PIRFENIDONE (Esbriet)** requires the following rule(s) be met for approval:
A. You have idiopathic pulmonary fibrosis (IPF: a type of lung condition)
B. You are 18 years of age or older
C. You do NOT have other known causes of interstitial lung disease. Other causes may include connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis (type of lung infection), systemic sclerosis (chronic hardening and tightening of the skin and connective tissues), rheumatoid arthritis (a type of joint condition), radiation, sarcoidosis (a type of inflammatory disorder), bronchiolitis obliterans organizing pneumonia (infection affecting the small airways of the lung), human immunodeficiency virus infection (HIV: a type of immune disorder), viral hepatitis (a type of liver inflammation), or cancer
D. You have a usual interstitial pneumonia (type of lung infection) pattern as evidenced by high-resolution computed tomography (HRCT: type of imaging test) alone or via a combination of surgical lung biopsy (removal of cells or tissue from the body for examination) and HRCT
E. You have a predicted forced vital capacity (FVC: amount of air exhaled from lungs) of at least 50% at baseline
F. You do NOT currently smoke cigarettes

RENEWAL CRITERIA

Our guideline named **PIRFENIDONE (Esbriet)** requires the following rule(s) be met for renewal:
A. You have idiopathic pulmonary fibrosis (IPF: a type of lung condition)
B. You have experienced a clinically meaningful improvement or maintenance in annual rate of decline.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

PIRFENIDONE

RATIONALE
Promote appropriate utilization of Esbriet based on FDA approved indication and dosage.

FDA APPROVED INDICATION
Esbriet is a pyridine indicated for the treatment of idiopathic pulmonary fibrosis (IPF).

DOSAGE
The recommended daily maintenance dose of Esbriet is 801 mg (or three 267 mg capsules or tablets) three times a day with food for a total of 2,403 mg/day.

Upon initiation of treatment, titrate to the full dosage of 2,403 mg per day over a 14-day period as follows:

TREATMENT DAYS	DOSAGE
Days 1 through 7	1 capsule three times a day with food
Days 8 through 14	2 capsules three times a day with food
Days 15 onward	3 capsules three times a day with food

Patients who miss 14 or more days of Esbriet should re-initiate treatment by undergoing the initial 2-week titration regimen up to the full maintenance dosage.

REFERENCES
Esbriet [Prescribing Information]. South San Francisco, CA: Genentech USA, Inc.; February 2022.

Created: 06/15
Effective: 09/12/22 Client Approval: 08/29/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

PITOLISANT

Generic	Brand	HICL	GCN	Exception/Other
PITOLISANT	WAKIX	45575		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named **PITOLISANT (Wakix)** requires that the patient is greater than or equal to 18 years of age and has a diagnosis of narcolepsy.

RENEWAL CRITERIA

Our guideline for **PITOLISANT (Wakix)** renewal requires that the patient has a previous authorization on file for the requested medication **AND** there is history of paid claims for 90 of the past 120 days.

RATIONALE
Promote prudent prescribing of agents for the treatment of narcolepsy.

INDICATIONS
Wakix is indicated for the treatment of excessive daytime sleepiness (EDS) in adult patients with narcolepsy.

DOSING
The recommended dosage range for Wakix is 17.8 mg to 35.6 mg administered orally once daily in the morning upon wakening. Titrate dosage as follows:

- Week 1: Initiate with a dosage of 8.9 mg (two 4.45 mg tablets) once daily
- Week 2: Increase dosage to 17.8 mg (one 17.8 mg tablet) once daily
- Week 3: May increase to the maximum recommended dosage of 35.6 mg (two 17.8 mg tablets) once daily

REFERENCES
Wakix [Prescribing Information]. Plymouth Meeting, PA: Harmony Biosciences, LLC; November 2019.

Created: 03/20
Effective: 05/01/20 Client Approval: 03/13/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

POMALIDOMIDE

Generic	Brand	HICL	GCN	Exception/Other
POMALIDOMIDE	POMALYST	39996		

GUIDELINES FOR USE

Our guideline named **POMALIDOMIDE (Pomalyst)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Multiple myeloma (MM: cancer that forms in your white blood cells)
   2. Kaposi sarcoma (KS: cancer that forms from the cells in your lymph or blood vessels)

B. **If you have multiple myeloma, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication is used in combination with dexamethasone
   3. You have tried at least two drugs including Revlimid (lenalidomide) and a proteasome inhibitor (type of cancer drug such as Velcade [bortezomib], Kyprolis [carfilzomib], or Ninlaro [ixazomib])

C. **If you have Kaposi sarcoma, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. You have acquired immunodeficiency syndrome (AIDS)-related Kaposi sarcoma after failing highly active antiretroviral therapy (HAART: medications used to treat human immunodeficiency virus [HIV])
      b. You are human immunodeficiency virus (HIV)-negative

RATIONALE

To ensure appropriate use of pomalidomide aligned with FDA approved indication.

FDA APPROVED INDICATIONS

Pomalyst (pomalidomide) is a thalidomide analogue indicated, for the treatment of adult patients:

- in combination with dexamethasone, for patients with multiple myeloma (MM) who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy
- with AIDS-related Kaposi sarcoma (KS) after failure of highly active antiretroviral therapy (HAART) or in patients with KS who are HIV-negative.

DOSAGE AND ADMINISTRATION

Multiple myeloma: 4 mg per day taken orally on Days 1 through 21 of repeated 28-day cycles until disease progression.

Kaposi sarcoma: 5 mg per day taken orally on Days 1 through 21 of repeated 28-day cycles until disease progression or unacceptable toxicity.

REFERENCES

- Pomalyst [Prescribing Information]. Summit, NJ: Celgene Corporation; December 2020.

Created: 06/15
Effective: 12/01/21 Client Approval: 11/01/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

PONATINIB

Generic	Brand	HICL	GCN	Exception/Other
PONATINIB HCL	ICLUSIG	39859		

GUIDELINES FOR USE

Our guideline for the drug named **PONATINIB (Iclusig)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Chronic Phase (CP) Chronic Myeloid Leukemia (CML: type of blood-cell cancer that begins in the bone marrow)
   2. Accelerated phase (AP) or blast phase (BP) chronic myeloid leukemia (CML: type of blood-cell cancer that begins in the bone marrow), OR Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) (type of white blood cell cancer)
   3. T315I-positive (a genetic mutation) chronic myeloid leukemia (CML: type of blood-cell cancer that begins in the bone marrow) OR T315I-positive (a genetic mutation) Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) (type of white blood cell cancer)

B. **If you have Chronic Phase (CP) Chronic Myeloid Leukemia (CML), approval also requires:**
   1. You are 18 years of older
   2. You are resistant to or not able to safely use at least two prior kinase inhibitor treatments such as Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imantinib)

C. **If you have Accelerated phase (AP) or blast phase (BP) chronic myeloid leukemia (CML), OR Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), approval also requires:**
   1. You are 18 years of older
   2. No other kinase inhibitors treatment, such as Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imantinib), can be used for your disease

D. **If you have T315I-positive chronic myeloid leukemia (CML), OR T315I-positive Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), approval also requires:**
   1. You are 18 years of older

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

PONATINIB

RATIONALE
Ensure appropriate utilization of ponatinib based on FDA approved indication and dosage.

FDA APPROVED INDICATIONS
Iclusig (ponatinib) is a kinase inhibitor indicated for the treatment of adult patients with:
- Chronic phase (CP) chronic myeloid leukemia (CML) with resistance or intolerance to at least two prior kinase inhibitors.
- Accelerated phase (AP) or blast phase (BP) CML or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) for whom no other kinase inhibitors are indicated.
- T315I-positive CML (chronic phase, accelerated phase, or blast phase) or T315I-positive Ph+ ALL.

DOSAGE AND ADMINISTRATION
- Recommended Dosage in CP-CML: Starting dose is 45 mg orally once daily with a reduction to 15 mg once daily upon achievement of ≤1% BCR-ABL1^{IS}.
- Recommended Dosage in AP-CML, BP-CML, and Ph+ ALL: Starting dose is 45 mg orally once daily.

REFERENCES

- Iclusig [Prescribing Information]. Cambridge, MA: ARIAD Pharmaceuticals, Inc.; December 2020.

Created: 06/15
Effective: 08/23/21 Client Approval: 07/30/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

PONESIMOD

Generic	Brand	HICL	GCN	Exception/Other
PONESIMOD	PONVORY	47221		

GUIDELINES FOR USE

Our guideline named **PONESIMOD (Ponvory)** requires the following rule(s) be met for approval:

A. You have a relapsing form of multiple sclerosis (type of disease where body attacks its own nerves and symptoms return after treatment) to include clinically isolated syndrome (occurs once), relapsing-remitting disease (periods of symptoms and no symptoms), and active secondary progressive disease (advanced disease)
B. You are 18 years of age or older
C. You had a trial of one agent indicated for the treatment of multiple sclerosis (e.g., Avonex, Rebif, Copaxone, Tecfidera, Gilenya, Aubagio)

RATIONALE

To ensure appropriate use of Ponvory consistent with FDA approved indication.

FDA APPROVED INDICATIONS

Ponvory is a sphingosine 1-phosphate receptor modulator indicated for the treatment of patients with the relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

PONESIMOD

FDA APPROVED INDICATIONS (CONTINUED)

DOSING

Treatment Initiation

A starter pack must be used for patients initiating treatment with Ponvory. Initiate Ponvory treatment with a 14-day titration; start with one 2 mg tablet orally once daily and progress with the titration schedule as shown in Table 1.

Table 1: Dose Titration Regimen

Titration Day	Daily Dose
Days 1 and 2	2 mg
Days 3 and 4	3 mg
Days 5 and 6	4 mg
Day 7	5 mg
Day 8	6 mg
Day 9	7 mg
Day 10	8 mg
Day 11	9 mg
Days 12, 13, and 14	10 mg
Day 15 and thereafter	20 mg

Maintenance Dosage

After dose titration is complete, the recommended maintenance dosage of Ponvory is 20 mg taken orally once daily starting on Day 15.

REFERENCES

Ponvory [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; March 2021.

Created: 04/21
Effective: 04/11/22 Client Approval: 03/09/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

PRALSETINIB

Generic	Brand	HICL	GCN	Exception/Other
PRALSETINIB	GAVRETO	46818		

GUIDELINES FOR USE

Our guideline named **PRALSETINIB (Gavreto)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
   2. Advanced or metastatic medullary thyroid cancer (MTC: thyroid cancer that started in the center of the thyroid and has spread to other parts of the body)
   3. Advanced or metastatic thyroid cancer (thyroid cancer that has spread to other parts of the body)

B. **If you have metastatic non-small cell lung cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You have a rearranged during transfection (*RET:* type of gene) fusion-positive tumor that has been detected by an Food and Drug Administration (FDA)-approved test

C. **If you have advanced or metastatic medullary thyroid cancer, approval also requires:**
   1. You are 12 years of age or older
   2. You have a rearranged during transfection (*RET:* type of gene) mutant tumor
   3. You need systemic therapy (medicine that goes into the entire body)

D. **If you have advanced or metastatic thyroid cancer, approval also requires:**
   1. You are 12 years of age or older
   2. You have a rearranged during transfection (*RET:* type of gene) fusion-positive tumor
   3. You need systemic therapy (medicine that goes into the entire body)
   4. You have received treatment with radioactive iodine, and it did not work or is no longer working (if radioactive iodine is appropriate)

RATIONALE

Ensure appropriate diagnostic, utilization and safety criteria are met for the management of requests for Gavreto.

FDA APPROVED INDICATIONS

Gavreto is a kinase inhibitor indicated for the treatment of adult patients with metastatic rearranged during transfection (RET) fusion-positive non-small cell lung cancer (NSCLC) as detected by an FDA approved test.

DOSING

The recommended dosage of Gavreto in adults is 400 mg orally once daily on an empty stomach.

REFERENCES

- Gavreto [Prescribing Information]. Cambridge, MA: Blueprint Medicines Corporation; December 2020.

Created: 09/20
Effective: 08/23/21 Client Approval: 08/11/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

PREGABALIN EXTENDED-RELEASE

Generic	Brand	HICL	GCN	Exception/Other
PREGABALIN	LYRICA CR		43986 43987 43988	

GUIDELINES FOR USE

The guideline named **PREGABALIN (LYRICA CR)** requires that the patient have a diagnosis of neuropathic pain associated with diabetic peripheral neuropathy or postherpetic neuralgia. A 30 day trial of immediate-release Lyrica (pregabalin) within the past 120 days is required unless the patient has been on Lyrica CR (at least 30 days Lyrica CR in the previous 60 days).

RATIONALE

Ensure appropriate utilization of Lyrica CR based on FDA approved indication and dosage.

FDA APPROVED INDICATIONS

Lyrica CR is indicated for the management of:

- Neuropathic pain associated with diabetic peripheral neuropathy (DPN)
- Postherpetic neuralgia (PHN)

Efficacy of Lyrica CR has not been established for the management of fibromyalgia or as adjunctive therapy for adult patients with partial onset seizures.

DOSAGE AND ADMINISTRATION

Indication	Dosing Regimen	Initial Dose	Maximum Dose
DPN Pain (2.2)	Single dose per day	165 mg/day	330 mg/day within 1 week.
PHN (2.3)	Single dose per day	165 mg/day	330 mg/day within 1 week. Maximum dose of 660 mg/day.

Conversion from Lyrica Capsules or Oral Solution to Lyrica CR

LYRICA Total Daily Dose (dosed 2 or 3 times daily)	LYRICA CR Dose (dosed once a day)
75 mg/daily	82.5 mg/day
150 mg/daily	165 mg/day
225 mg/daily	247.5 mg/day[a]
300 mg/daily	330 mg/day
450 mg/daily	495 mg/day[b]
600 mg/daily	660 mg/day[c]

a. 247.5 mg = 3 × 82.5 mg tablets taken once a day.
b. 495 mg = 3 × 165 mg tablets taken once a day.
c. 660 mg = 2 × 330 mg tablets taken once a day.

DOSAGE FORMS AND STRENGHTS

- Extended-release tablets: 82.5 mg, 165 mg, and 330 mg

REFERENCES

- Lyrica CR [Prescribing Information]. New York, NY: Pfizer; October 2017.

Created: 05/18
Effective: 07/01/18 Client Approval: 05/21/18 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

PREGABALIN IMMEDIATE-RELEASE

Generic	Brand	HICL	GCN	Exception/Other
PREGABALIN	LYRICA		23039, 23046, 23047, 23048, 23049, 23051, 23052, 25019, 32359	

GUIDELINES FOR USE

The guideline for **PREGABALIN IMMEDIATE-RELEASE (Lyrica)** requires that Lyrica (pregabalin) is prescribed for the treatment of generalized anxiety disorder (GAD), neuropathic pain associated with diabetic peripheral neuropathy (DPN), postherpetic neuralgia (PHN), partial onset seizures, fibromyalgia, or neuropathic pain associated with spinal cord injury.

Approval of the liquid formulation requires that the patient is unable to swallow regular capsules or has difficulty swallowing that requires use of a liquid formulation.

For patients new to therapy, the following criteria must also be met:

If you have neuropathic pain associated with diabetic peripheral neuropathy (DPN), our guideline requires that you have tried **ONE** of the following medications within the past 120 days:

- Serotonin-norepinephrine reuptake inhibitor (SNRI) (e.g., desvenlafaxine (Pristiq), venlafaxine (Effexor), duloxetine (Cymbalta), Fetzima, Savella)
- Tricyclic antidepressant (e.g., amitriptyline, desipramine, nortriptyline, doxepin, clomipramine, imipramine)
- Gabapentin

If you have postherpetic neuralgia (PHN), our guideline requires that you have tried **ONE** of the following medications within the past 120 days:

- Lidocaine patch
- Tricyclic antidepressant (e.g., amitriptyline, desipramine, nortriptyline, doxepin, clomipramine, imipramine)
- Gabapentin

If you have partial onset seizures, our guideline requires that **ALL** of the following criteria are met:

- You are one month of age or older
- You are using Lyrica as adjunctive therapy
- You have tried **TWO** of the following anticonvulsants within the past 365 days: carbamazepine, gabapentin, lamotrigine, levetiracetam IR or ER, oxcarbazepine, valproic acid or divalproex, topiramate, or zonisamide

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

PREGABALIN IMMEDIATE-RELEASE

If you have fibromyalgia, our guideline requires that you have tried **TWO** of the following medications within the past 365 days:

- Tricyclic antidepressant (e.g., amitriptyline, desipramine, nortriptyline, doxepin, clomipramine, imipramine)
- Gabapentin
- Cyclobenzaprine
- Selective serotonin reuptake inhibitor (SSRI) (e.g., fluoxetine, citalopram, escitalopram, sertraline, paroxetine)
- Duloxetine HCl
- Savella (milnacipran HCl)

If you have neuropathic pain from spinal cord injury, our guideline requires that you have tried **ONE** of the following medications within the past 120 days:

- Tricyclic antidepressant (e.g., amitriptyline, desipramine, nortriptyline, doxepin, clomipramine, imipramine)
- Gabapentin

RATIONALE
Ensure appropriate utilization of Lyrica based on indication and dosage.

The American Academy of Neurology guidelines suggest that pregabalin should be offered for diabetic peripheral neuropathy if clinically appropriate (evidence level A), and that gabapentin and amitriptyline should also be considered for the treatment of diabetic peripheral neuropathy (level B). The evidence level A for pregabalin does not indicate that the medication is better tolerated or more effective than other neuropathy medications, only that the number and quality of clinical studies for pregabalin use are higher.

The Expert Panel on Diabetic Neuropathy (international) recommends current first line agents for diabetic peripheral neuropathy: tricyclic antidepressants, duloxetine, pregabalin, and gabapentin. The Neuropathic Pain Special Interest Group of the International Association for the Study of Pain and the European Federation of Neurological Societies Task Force recommend the following first-line agents for neuropathic pain: tricyclic antidepressants, dual reuptake inhibitors of serotonin/norepinephrine, calcium channel alpha-2 delta ligands (gabapentin and pregabalin), and topical lidocaine.

FDA APPROVED INDICATIONS
Lyrica is indicated for:

- Management of neuropathic pain associated with diabetic peripheral neuropathy (DPN)
- Management of postherpetic neuralgia (PHN)
- Adjunctive therapy for the treatment of partial onset seizures in patients one month of age and older
- Management of fibromyalgia
- Management of neuropathic pain associated with spinal cord injury

OFF-LABEL INDICATION

- Generalized anxiety disorder (GAD)

DOSAGE AND ADMINISTRATION

Neuropathic Pain associated with Diabetic Peripheral Neuropathy:
The maximum recommended dose of LYRICA is 100 mg three times a day (300 mg/day) in patients with creatinine clearance of at least 60 mL/min. Begin dosing at 50 mg three times a day (150 mg/day). The dose may be increased to 300 mg/day within 1 week based on efficacy and tolerability. Although LYRICA was also studied at 600 mg/day, there is no evidence that this dose confers additional significant benefit and this dose was less well tolerated. In view of the dose-dependent adverse reactions, treatment with doses above 300 mg/day is not recommended.

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RATIONALE (CONTINUED)

Postherpetic Neuralgia:
The recommended dose of LYRICA is 75 to 150 mg two times a day, or 50 to 100 mg three times a day (150 to 300 mg/day) in patients with creatinine clearance of at least 60 mL/min. Begin dosing at 75 mg two times a day, or 50 mg three times a day (150 mg/day). The dose may be increased to 300 mg/day within 1 week based on efficacy and tolerability. Patients who do not experience sufficient pain relief following 2 to 4 weeks of treatment with 300 mg/day, and who are able to tolerate LYRICA, may be treated with up to 300 mg two times a day, or 200 mg three times a day (600 mg/day). In view of the dose-dependent adverse reactions and the higher rate of treatment discontinuation due to adverse reactions, reserve dosing above 300 mg/day for those patients who have on-going pain and are tolerating 300 mg daily.

Adjunctive Therapy for Partial Onset Seizures in Patients 4 Years of Age and Older:
The recommended dosage for adults and pediatric patients 4 years of age and older is included in Table 1. Administer the total daily dosage orally in two or three divided doses. In pediatric patients 4 years of age and older, the recommended dosing regimen is dependent upon body weight. Based on clinical response and tolerability, dosage may be increased, approximately weekly.

Table 1: Recommended Dosage for Adults and Pediatric Patients 4 Years and Older

Age and Body Weight	Recommended Initial Dosage (administer in two or three divided doses)	Recommended Maximum Dosage (administer in two or three divided doses)
Adults (17 years and older)	150 mg/day	600 mg/day
Pediatric patients weighing 30 kg or more	2.5 mg/kg/day	10 mg/kg/day (not to exceed 600 mg/day)
Pediatric patients weighing less than 30 kg	3.5 mg/kg/day	14 mg/kg/day

Management of Fibromyalgia:
The recommended dose of LYRICA for fibromyalgia is 300 to 450 mg/day. Begin dosing at 75 mg two times a day (150 mg/day). The dose may be increased to 150 mg two times a day (300 mg/day) within 1 week based on efficacy and tolerability. Patients who do not experience sufficient benefit with 300 mg/day may be further increased to 225 mg two times a day (450 mg/day). Although LYRICA was also studied at 600 mg/day, there is no evidence that this dose confers additional benefit and this dose was less well tolerated. In view of the dose-dependent adverse reactions, treatment with doses above 450 mg/day is not recommended.

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RATIONALE (CONTINUED)

Neuropathic Pain Associated with Spinal Cord Injury:
The recommended dose range of LYRICA for the treatment of neuropathic pain associated with spinal cord injury is 150 to 600 mg/day. The recommended starting dose is 75 mg two times a day (150 mg/day). The dose may be increased to 150 mg two times a day (300 mg/day) within 1 week based on efficacy and tolerability. Patients who do not experience sufficient pain relief after 2 to 3 weeks of treatment with 150 mg two times a day and who tolerate LYRICA may be treated with up to 300 mg two times a day.

DOSAGE FORMS AND STRENGTHS

- Capsules: 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg, and 300 mg
- Oral Solution: 20 mg/mL

REFERENCES

- Lyrica [Prescribing Information]. New York, NY: Pfizer; June 2020.
- Attal N, Cruccu G, Baron R, et al. EFNS Guidelines on the pharmacological treatment of neuropathic pain: 2010 revision. Eur J Neurology 2010; 17 (9): 1113-1188.
- Bril V, England J and Franklin G et al. Evidenced based guideline: treatment of painful diabetic neuropathy (American Academy of Neurology). Neurology 2011; 76: 1758-1765. Available online at: http://www.neurology.org/content/76/20/1758.full?sid=279eae73-9b0a-4b39-b138-88a6ca81ead3 [Accessed May 14, 2018].
- Dworkin R, O'Connor A, et al. Recommendations for the pharmacological management of neuropathic pain: an overview and literature update. Mayo Clin Proc, 2010 Mar; 85(Supp 3): S3-S14.
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- Tesfaye S, Vileikyte L, Rayman G, et al. Painful Diabetic Peripheral Neuropathy: Consensus Recommendations on Diagnosis, Assessment, and Management. Diabetic Metab Res Rev. June 2011 (epub ahead of print).
- Wiffen PJ, Collins S, et al. Anticonvulsant drugs for acute and chronic pain. Cochrane Database Syst Rev. 2005 Jul 20 ;(3):CD001133.

Created: 05/18
Effective: 08/08/22 Client Approval: 07/13/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

PROTON PUMP INHIBITORS

Generic	Brand	HICL	GCN	Exception/Other
DEXLANSOPRAZOLE	DEXILANT	36085		
ESOMEPRAZOLE MAGNESIUM	NEXIUM	21607		
ESOMEPRAZOLE STRONTIUM	ESOMEPRAZOLE STRONTIUM	40532		
LANSOPRAZOLE	PREVACID	08993		
OMEPRAZOLE	PRILOSEC	04673		
OMEPRAZOLE MAGNESIUM	PRILOSEC OTC	11115		
OMEPRAZOLE/SODIUM BICARBONATE	OMEPPI ZEGERID	33512		
PANTOPRAZOLE SODIUM	PROTONIX	11590		
RABEPRAZOLE SODIUM	ACIPHEX ACIPHEX SPRINKLE	18847		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline for non-preffered **PROTON PUMP INHIBITORS** requires that the patient has had a trial of **TWO** of the following in the previous 365 days:

- Omeprazole tablets/capsules
- Pantoprazole tablets
- Lansoprazole capsules

Our guideline for **PROTON PUMP INHIBITORS** for patients with claims suggesting therapeutic duplication requires that the medication in history is being discontinued.

Our guideline named **PROTON PUMP INHIBITORS** does not allow the use of the requested medication at the requested dose/regimen. Please consider an alternate dose or dosing schedule. Exceptions may be made for twice daily dosing of **PROTON PUMP INHIBITORS** if the patient has a diagnosis of eosinophilic esophagitis (EoE), Helicobacter pylori infection, duodenal ulcer, or gastric ulcer.

RENEWAL CRITERIA

Our guideline for **PROTON PUMP INHIBITORS** renewal requires that there is history of paid claims for the requested medication for 90 of the past 120 days and that the patient has a previous authorization on file for the requested medication.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

PROTON PUMP INHIBITORS

RATIONALE

To promote prudent prescribing of proton pump inhibitors (PPIs).

A look back period of 60 days will be utilized to identify potential therapeutic duplication.

REFERENCES

- Dellon, Evan S MD, MPH; et al. ACG Clinical Guideline: Evidenced Based Approach to the Diagnosis and Management of Esophageal Eosinophilia and Eosinophilic Esophagitis (EoE), American Journal of Gastroenterology: May 2013 - Volume 108 - Issue 5 - p 679-692. doi: 10.1038/ajg.2013.71

Created: 09/20
Effective: 07/01/21 Client Approval: 05/24/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

RANOLAZINE

Generic	Brand	HICL	GCN	Exception/Other
RANOLAZINE	ASPRUZYO SPRINKLE		52005, 52006	

GUIDELINES FOR USE

Our guideline named **RANOLAZINE (Aspruzyo Sprinkle)** requires the following rule(s) be met for approval:

A. You have chronic angina (a type of heart condition)
B. You had a trial of or contraindication (harmful for) to ranolazine ER (extended-release) tablets
C. You are unable to swallow the tablets

RATIONALE

Promote appropriate utilization of Aspruzyo Sprinkle based on FDA approved indication and dosing.

FDA APPROVED INDICATIONS

Aspruzyo Sprinkle is an antianginal indicated for the treatment of chronic angina.

DOSAGE

Initiate Aspruzyo Sprinkle dosing at 500 mg orally twice daily and increase to 1000 mg orally twice daily, as needed, based on clinical symptoms. The maximum recommended daily dose of Aspruzyo Sprinkle is 1,000 mg twice daily.

REFERENCES

Aspruzyo Sprinkle [Prescribing Information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; March 2022.

Created: 08/22
Effective: 09/19/22 Client Approval: 08/19/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

REGORAFENIB

Generic	Brand	HICL	GCN	Exception/Other
REGORAFENIB	STIVARGA		33363	

GUIDELINES FOR USE

Our guideline for **REGORAFENIB** requires a diagnosis of metastatic colorectal cancer; locally advanced, unresectable, or metastatic gastrointestinal stromal tumor (GIST); or hepatocellular carcinoma. Additional guideline requirements apply.

For the diagnosis of metastatic colorectal cancer, approval requires a trial of the following preferred therapies:

- An anti-VEGF therapy (such as Avastin or Zaltrap) **AND**
- A fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (such as FOLFOX, FOLFIRI, FOLFOXIRI, CapeOx, or infusional 5-FU/LV or capecitabine)

For patients with wild type KRAS metastatic colorectal cancer, a trial of an anti-EGFR therapy (such as Erbitux or Vectibix) is required.

For the diagnosis of locally advanced, unresectable, or metastatic gastrointestinal stromal tumor (GIST), approval requires a trial of Gleevec and Sutent.

For the diagnosis of hepatocellular carcinoma, approval requires a trial of Nexavar.
These prior therapies may be covered under the medical benefit and/or may require prior authorization.

RATIONALE
To ensure appropriate use of Stivarga consistent with FDA approved indication.

The recommended dose of Stivarga is 160 mg orally (four 40mg tablets), once daily for the first 21 days of each 28-day cycle with a low-fat breakfast. Do not take two doses of Stivarga on the same day to make up for a missed dose from the previous day. Treatment should be interrupted and dose reduction to 120mg and then 80mg daily should be considered in the presence of certain grade 2-4 adverse reactions.

Stivarga is a once daily oral medication for treatment-resistant metastatic colorectal cancer, treatment-resistant metastatic and / or unresectable gastrointestinal stromal tumors (GIST), and hepatocellular carcinoma. It is an inhibitor of multiple kinases involved in normal cellular functions and in pathologic processes such as oncogenesis, tumor angiogenesis, and maintenance of the tumor microenvironment. Stivarga is structurally similar to sorafenib, leading to its moniker of “son of Nexavar”.

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RATIONALE (CONTINUED)

Colorectal cancer originates in either the colon or rectum typically as a polyp that slowly develops over many years. About 50% to 60% of patients diagnosed with colorectal cancer will eventually develop metastases. The American Cancer Society estimates that there will be 103,170 new cases of colon cancer and 40,290 new cases of rectal cancer in 2012.

According to the National Comprehensive Cancer Network (NCCN) colon and rectal cancer guidelines, options for treatment of metastatic disease consist of 5-fluorouracil with leucovorin (5-FU/LV), irinotecan, capecitabine, oxaliplatin, bevacizumab, cetuximab, and panitumumab. Five chemotherapy regimens are recommended as initial treatment of metastatic disease: FOLFOX, FOLFIRI, CapeOx, infusional 5-FU/LV or capecitabine, or FOLFOXIRI.

Vascular endothelial growth factor (VEGF) inhibitor Avastin (bevacizumab), and the epidermal growth factor receptor (EGFR) antagonists Erbitux (cetuximab) and Vectibix (panitumumab) are newer biologic therapies that may also be used as part of initial therapy. KRAS gene mutation status is predictive of poor response to Erbitux and Vectibix. Stivarga is not yet included in the current version of the NCCN guidelines. Zaltrap (ziv-aflibercept), a novel VEGF inhibitor, was also recently approved for the treatment of metastatic colorectal cancer in patients who have been previously treated with other therapies.

Stivarga was evaluated in a trial that randomized 760 patients with previously treated metastatic colorectal cancer to receive 160 mg of regorafenib orally once daily (n=505) plus Best Supportive Care (BSC) or placebo (n=255) plus BSC for the first 21 days of each 28-day cycle. Stivarga was administered with a low-fat breakfast that contained less than 30% fat. Treatment continued until disease progression or unacceptable toxicity. The major efficacy outcome measure was overall survival (OS); supportive efficacy outcome measures included progression-free survival (PFS); and objective tumor response rate.

History of KRAS evaluation was reported for 729 (96%) patients; 430 (59%) of these patients were reported to have KRAS mutation. All patients received prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, and with bevacizumab. Patients received a median of three prior lines of therapy for metastatic disease.

The median OS for Stivarga with BSC was 6.4 months compared to 5.0 months for placebo with BSC. Stivarga also improved PFS (2.0 vs. 1.7 months) and overall response rate (1% vs. 0.4%) as compared to placebo.

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REGORAFENIB

RATIONALE (CONTINUED)

The safety data described below are derived from a randomized (2:1), double-blind, placebo-controlled trial (RESORCE) in which patients with previously-treated HCC received either STIVARGA (n=374) 160 mg orally on days 1 21 of each 4 week treatment cycle or placebo (n=193). The median age was 63 years, 88% were men, 98% had Child-Pugh A cirrhosis, 66% had an ECOG performance status (PS) of 0 and 34% had PS of 1. The median duration of therapy was 3.5 months (range 1 day to 29.4 months) for patients receiving STIVARGA. Of the patients receiving STIVARGA, 33% were exposed to STIVARGA for greater than or equal to 6 months and 14% were exposed to STIVARGA for greater than or equal to 12 months. Dose interruptions for adverse events were required in 58.3% of patients receiving STIVARGA and 48% of patients had their dose reduced. The most common adverse reactions requiring dose modification (interruption or dose reduction) were HFSR/PPES (20.6%), blood bilirubin increase (5.9%), fatigue (5.1%) and diarrhea (5.3%). Adverse reactions that resulted in treatment discontinuation were reported in 10.4% of STIVARGA-treated patients compared to 3.6% of patients who received placebo; the most common adverse reactions requiring discontinuation of STIVARGA were HFSR/PPES (1.9%) and AST increased (1.6%).

Warnings and precautions include hepatotoxicity, hemorrhage, dermatological toxicity, hypertension, cardiac ischemia and infarction, reversible posterior leukoencephalopathy syndrome, gastrointestinal perforation or fistulae, and wound healing complications. The Stivarga label contains a Boxed Warning alerting patients and health care professionals that severe and fatal liver toxicity occurred in patients treated with Stivarga during clinical studies.

The most common side effects of Stivarga are asthenia/fatigue, decreased appetite and food intake, hand-foot skin reaction (HFSR) [palmar-plantar erythrodysesthesia (PPE)], diarrhea, mucositis, weight loss, infection, hypertension, and dysphonia. Stivarga is Pregnancy Category D and can cause fetal harm when administered to a pregnant woman. Avoid concomitant use of strong CYP3A4 inducers (e.g. rifampin, phenytoin, carbamazepine, phenobarbital, and St. John's Wort) and strong CYP3A4 inhibitors (e.g. clarithromycin, grapefruit juice, itraconazole, ketoconazole, posaconazole, telithromycin, and voriconazole).

Stivarga is a kinase inhibitor indicated for the treatment of patients with:

- Metastatic colorectal cancer (CRC) who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if KRAS wild type, an anti-EGFR therapy.
- Locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) who have been previously treated with imatinib mesylate and sunitinib malate.
- Hepatocellular carcinoma who have been previously treated with sorafenib.

Anti-VEGF therapies approved for the treatment of colorectal cancer include Avastin and Zaltrap. Anti-EGFR therapies approved for the treatment of colorectal cancer include Erbitux and Vectibix.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

REGORAFENIB

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- Stivarga [Prescribing Information]. Wayne, NJ: Bayer HealthCare Pharmaceuticals Inc, April 2017.
- National Comprehensive Cancer Network. Colon Cancer Guideline Version 3.2012. Available at: http://www.nccn.org/professionals/physician_gls/pdf/colon.pdf [Accessed October 1, 2012].
- National Comprehensive Cancer Network. Rectal Cancer Guideline Version 3.2012. Available at: http://www.nccn.org/professionals/physician_gls/pdf/rectal.pdf [Accessed October 1, 2012].
- American Cancer Society. Colorectal Cancer Overview. Available at: http://www.cancer.org/Cancer/ColonandRectumCancer/OverviewGuide/colorectal-cancer-overview-what-is-colorectal-cancer. [Accessed October 1, 2012].
- ClinicalTrials.gov. Study of Regorafenib as a 3rd-line or Greater Treatment for Gastrointestinal Stromal Tumors (GIST) (GRID). Available at: http://clinicaltrials.gov/ct2/show/NCT01271712?term=regorafenib&rank=19 [Accessed October 1, 2012].

Created: 06/15
Effective: 09/18/17 Client Approval: 08/29/17 P&T Approval: 11/13

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

RELUGOLIX/ ESTRADIOL/ NORETHINDRONE

Generic	Brand	HICL	GCN	Exception/Other
RELUGOLIX/ ESTRADIOL/ NORETHINDRONE ACETATE	MYFEMBREE	47392		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **RELUGOLIX/ ESTRADIOL/ NORETHINDRONE (Myfembree)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. Management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids: non-cancerous growths in the uterus)
   2. Management of moderate to severe pain associated with endometriosis (condition affecting the uterus)

B. If the request is for management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids), approval also requires:
   1. You are 18 years of age or older
   2. You are a premenopausal (before menopause) woman
   3. You have tried hormonal contraceptives/therapy [e.g., oral tablets, vaginal ring, patch, intrauterine contraception (IUD)]
   4. You have not received a total of 24 months cumulative (total) treatment with Myfembree

C. If the request is for management of moderate to severe pain associated with endometriosis, approval also requires:
   1. You are 18 years of age or older
   2. You are a premenopausal (before menopause) woman
   3. ONE of the following:
      a. You have tried hormonal contraceptives/therapy [oral tablets, vaginal ring, patch, intrauterine contraception (IUD)] AND non-steroidal anti-inflammatory drug (NSAID) therapy
      b. The prescriber has submitted valid medical rationale against the use of both hormonal contraceptives/therapy AND non-steroidal anti-inflammatory drug (NSAID) therapy
   4. You have not received a total of 24 months cumulative (total) treatment with Myfembree

RENEWAL CRITERIA

Our guideline named **RELUGOLIX/ ESTRADIOL/ NORETHINDRONE (Myfembree)** requires the following rule(s) be met for renewal:

A. You have history of paid claim(s) for the requested medication in the past 90 day
B. You have a previous authorization on file for the requested medication
C. You will not exceed 24 total months of therapy with Myfembree

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

RELUGOLIX/ ESTRADIOL/ NORETHINDRONE

RATIONALE
Ensure appropriate diagnostic, utilization and safety criteria are used for the management of requests for Myfembree.

FDA APPROVED INDICATIONS
Myfembree is a combination of relugolix, a gonadotropin-releasing hormone (GnRH) receptor antagonist, estradiol, an estrogen, and norethindrone acetate, a progestin, indicated in premenopausal women for the:

- management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids)
- management of moderate to severe pain associated with endometriosis

Limitations of Use:
Use of Myfembree should be limited to 24 months due to the risk of continued bone loss which may not be reversible.

DOSING
The recommended dose of Myfembree is one tablet daily.

REFERENCES
Myfembree [Prescribing Information]. Brisbane, CA: Myovant Sciences, Inc., September 2022.

Created: 07/21
Effective: 01/30/23 Client Approval: 01/04/23 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

RESLIZUMAB

Generic	Brand	HICL	GCN	Exception/Other
RESLIZUMAB	CINQAIR	43211		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **RESLIZUMAB (Cinqair)** requires the following rule(s) be met for approval:

A. You have severe asthma with an eosinophilic phenotype (inflammatory type of asthma where there is a high number of a type of white blood cell)
B. You are 18 years of age or older
C. You are currently receiving therapy with **ONE** of the following:
    1. High-dose inhaled corticosteroid (ICS) AND a long-acting beta2 agonist (LABA)
    2. High-dose ICS/LABA combination product
D. Cinqair will be used as add-on maintenance treatment to one of the above inhaled asthma regimens
E. You have experienced at least ONE asthma exacerbation within the past 12 months (exacerbation is defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days)

RENEWAL CRITERIA

Our guideline named **RESLIZUMAB (Cinqair)** requires the following rule(s) be met for renewal:

A. You have severe asthma with an eosinophilic phenotype (inflammatory type of asthma where there is a high number of a type of white blood cell)
B. You will continue to use inhaled corticosteroid (ICS) or ICS-containing combination inhalers
C. You have shown a clinical response as evidenced by ONE of the following:
    1. Reduction in asthma exacerbation (worsening of symptoms) from baseline
    2. Decreased use of rescue medications
    3. Increase in percent predicted FEV1 (type of lung test) from pretreatment baseline
    4. Reduction in severity or frequency of asthma-related symptoms such as wheezing, shortness of breath, coughing, etc.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

RESLIZUMAB

RATIONALE
Promote appropriate utilization of **RESLIZUMAB** based on FDA approved indication.

FDA APPROVED INDICATION
Cinqair (reslizumab) is indicated as an add-on maintenance treatment of patients with severe asthma who are 18 years of age and older with an eosinophilic phenotype.

Limitations of Use:
Cinqair is not indicated for
- Treatment of other eosinophilic conditions
- Relief of acute bronchospasm or status asthmaticus

DOSAGE
The recommended dosage of Cinqair (reslizumab) is 3mg/kg administered by intravenous infusion once every four weeks by a healthcare provider.

REFERENCES

- Cinqair [Prescribing Information]. Frazer, PA. Teva Pharmaceutical Industries Ltd. February 2020.
- Chung KF, Wenzel SE, Brozek JL, et al. International ERS/ATS guidelines on definition, evaluation, and treatment of severe asthma. Eur Respir J. 2014;43(2):343-73.

Created: 12/17
Effective: 04/18/22 Client Approval: 03/15/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

RIBOCICLIB

Generic	Brand	HICL	GCN	Exception/Other
RIBOCICLIB	KISQALI	44151		
RIBOCICLIB LETROZOLE	KISQALI FEMARA CO-PACK	44246		

GUIDELINES FOR USE

The guideline named **RIBOCICLIB (Kisqali, Kisqali/Femara co-pack)** requires a diagnosis of advanced or metastatic breast cancer that is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative. In addition, the following criteria must be met:

For Kisqali-Femara Co-Pack request, approval requires:

- The patient is female and pre/perimenopausal **OR** post-menopausal
- The patient has not received prior endocrine-based therapy for metastatic breast cancer (e.g., letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
- The patient has **NOT** experienced disease progression following prior CDK inhibitor therapy

For Kisqali request, approval requires ONE of the following:

- **Kisqali will be used in combination with an aromatase inhibitor and meet all of the following:**
  - The patient is female and pre/perimenopausal **OR** post-menopausal
  - The patient has **NOT** received prior endocrine-based therapy for metastatic breast cancer (e.g., letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
  - The patient has **NOT** experienced disease progression following prior CDK inhibitor therapy
- **Kisqali will be used in combination with Faslodex (fulvestrant) and meet all of the following:**
  - The patient is female and post-menopausal
  - The patient has not received prior endocrine-based therapy for metastatic breast cancer (e.g., letrozole, anastrozole, tamoxifen, fulvestrant, exemestane) **OR** patient has experienced disease progression on endocrine therapy
  - The patient has **NOT** experienced disease progression following prior CDK inhibitor therapy

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RATIONALE

Promote appropriate utilization of **RIBOCICLIB** (Kisqali) based on FDA approved indication and dosing. The Kisqali/Femara co-pack indications have been updated based on the most current Prescribing Information for Kisqali.

FDA APPROVED INDICATION
KISQALI/FEMARA CO-PACK:

- Kisqali/Femara co-pack, a co-packaged product containing ribociclib, a kinase inhibitor, and letrozole, an aromatase inhibitor, is indicated as initial endocrine-based therapy for the treatment of postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer.

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RIBOCICLIB

FDA APPROVED INDICATION (CONTINUED)

KISQALI, a kinase inhibitor indicated in combination with:

- An aromatase inhibitor for the treatment of pre/perimenopausal or postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer as initial endocrine-based therapy, OR
- Fulvestrant for the treatment of postmenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer, either as initial endocrine therapy or following disease progression on endocrine therapy

DOSAGE AND ADMINISTRATION

KISQALI/FEMARA CO-PACK:

- The Kisqali/Femara co-pack, is comprised of ribociclib tablets copackaged with letrozole tablets, to provide a 28-day treatment regimen.
- The Kisqali/Femara co-pack, should be coadministered, with or without food
- The recommended starting dose is KISQALI 600 mg (three 200 mg tablets) taken orally, once daily for 21 consecutive days followed by 7 days off KISQALI treatment resulting in a complete cycle of 28 days, and Femara 2.5 mg (one tablet) taken once daily throughout the 28-day cycle.

KISQALI:

- The recommended starting dose is 600 mg orally (three 200 mg tablets) taken once daily with or without food for 21 consecutive days followed by 7 days off treatment (for complete 28 day cycle).
- Pre/perimenopausal women treated with the combination KISQALI plus an aromatase inhibitor or fulvestrant should be treated with a luteinizing hormone-releasing hormone (LHRH) agonist according to current clinical practice standards.

Patients should take Kisqali, Kisqali/Femara co-pack, and the aromatase inhibitor at approximately the same time each day, preferably in the morning.

If the patient vomits after taking the dose, or misses a dose, no additional dose should be taken that day. The next prescribed dose should be taken at the usual time. Kisqali tablets should be swallowed whole (tablets should not be chewed, crushed or split prior to swallowing). No tablet should be ingested if it is broken, cracked, or otherwise not intact.

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RIBOCICLIB

DOSAGE AND ADMINISTRATION (CONTINUED)

Dose interruption, reduction, and/or discontinuation may be required based on individual safety and tolerability.

Dose Level	Kisqali Dose
Recommended starting dose	600 mg/day
First dose reduction	400 mg/day
Second dose reduction	200 mg/day*

*If further dose reduction below 200 mg/day is required, discontinue the treatment.

Avoid concomitant use of strong CYP3A inhibitors; if must be co-administered with strong CYP3A inhibitor reduce Kisqali dose to 400 mg once daily.

REFERENCES

- Kisqali [Prescribing Information]. East Hanover, NJ. Novartis; July 2018.
- Kisqali/Femara Co-Pack [Prescribing Information]. East Hanover, NJ. Novartis; May 2018.

Created: 04/17
Effective: 03/18/19 Client Approval: 02/26/19 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

RIFAXIMIN

Generic	Brand	HICL	GCN	Exception/Other
RIFAXIMIN	XIFAXAN		28530, 93749	

**** Please use the criteria for the specific drug requested ****

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

XIFAXAN 550MG TABLETS

Our guideline named **RIFAXIMIN (Xifaxan 550 mg tablets)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses: reduction of risk of overt hepatic encephalopathy recurrence (loss of brain function when your liver cannot remove toxins from the blood) or irritable bowel syndrome with diarrhea (a condition of stomach pain with many periods of diarrhea)
B. **For reduction in risk of overt hepatic encephalopathy recurrence, approval also requires:**
   1. You are 18 years of age or older
   2. You have previously tried lactulose or you are currently taking lactulose monotherapy (drug used alone for treatment)
C. **If you have irritable bowel syndrome with diarrhea, approval also requires:**
   1. You are 18 years of age or older
   2. You have tried tricyclic anti-depressants (such as amitriptyline, nortriptyline, etc.) and dicyclomine, unless there is a medical reason why you cannot (contraindication)

XIFAXAN 200MG TABLETS

Our guideline named **RIFAXIMIN (Xifaxan 200 mg tablets)** requires the following rule(s) be met for approval:

A. You have **ONE** of the following diagnoses: travelers' diarrhea, *Clostridium difficile* infection (a type of bacterial infection) or for the treatment of overt hepatic encephalopathy (loss of brain function when your liver cannot remove toxins from the blood)
B. **If you have traveler's diarrhea, approval also requires:**
   1. You are 12 years of age or older
   2. You have previously tried oral azithromycin, ciprofloxacin, ofloxacin, or levofloxacin, unless there is a medical reason why you cannot (contraindication)
C. **For the treatment of overt hepatic encephalopathy, approval also requires:**
   1. The requested medication will be used in combination with lactulose
D. **If you have *Clostridium difficile* infection, approval also requires:**
   1. You had at least one previous occurrence of *Clostridium difficile* infection
   2. The requested medication will be used in combination with vancomycin

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RIFAXIMIN

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **RIFAXIMIN (Xifaxan 550 mg tablets)** requires the following rule(s) be met for renewal:

A. You have **ONE** of the following diagnoses: Reduction of risk of overt hepatic encephalopathy recurrence (loss of brain function when your liver cannot remove toxins from the blood) or irritable bowel syndrome with diarrhea (a condition of stomach pain with many periods of diarrhea)

B. **If you have irritable bowel syndrome with diarrhea, renewal also requires:**
   1. At least 10 weeks have passed since your last treatment course of rifaximin
   2. You have experienced at least 30% decrease in abdominal pain (on a 0-10 point pain scale)
   3. You have experienced at least 50% reduction in the number of days per week with a stool consistency of mushy stool (Bristol Stool scale type 6) or entirely liquid stool (Bristol Stool scale type 7)

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

RIFAXIMIN

RATIONALE
To ensure appropriate utilization of Xifaxan.

FDA APPROVED INDICATIONS
Xifaxan is a rifamycin antibacterial indicated for:
- Treatment of traveler's diarrhea (TD) caused by noninvasive strains of Escherichia coli in adult and pediatric patients 12 years of age and older
- Reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults
- Treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults

Limitations of Use
TD: Do not use in patients with diarrhea complicated by fever or blood in the stool or diarrhea due to pathogens other than Escherichia coli.

DOSING

Condition	Recommended Dosage Regimen
TD	One 200 mg tablet 3 times a day for 3 days
HE	One 550 mg tablet 2 times a day
IBS-D	One 550 mg tablet 3 times a day for 14 days. Patients who experience recurrence can be retreated up to two times with the same regimen.

REFERENCES

- Salix Pharmaceuticals, Inc. Xifaxan package insert. Raleigh, NC. October 2020.
- Task Force on the Management of Functional Bowel Disorders. American College of Gastroenterology Monograph on the Management of Irritable Bowel syndrome and Chronic Idiopathic Constipation. Am J Gastroenterol 2014; 109:S2-S26.

Created: 01/16
Effective: 03/14/22 Client Approval: 02/04/22 P&T Approval: N/A

RILONACEPT

Generic	Brand	HICL	GCN	Exception/Other
RILONACEPT	ARCALYST	35438		

GUIDELINES FOR USE

Our guideline named **RILONACEPT (Arcalyst)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Cryopyrin-Associated Periodic Syndromes (CAPS) such as Familial Cold Autoinflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS)
   2. Deficiency of interleukin-1 receptor antagonist (DIRA)
   3. Recurrent pericarditis (RP)

B. **If you have Cryopyrin-Associated Periodic Syndromes (CAPS) such as Familial Cold Autoinflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS), approval also requires:**
   1. You are 12 years of age or older

C. **If you have recurrent pericarditis (RP), approval also requires:**
   1. You are 12 years of age or older

RATIONALE

Ensure appropriate use of rilonacept.

FDA APPROVED INDICATIONS

Arcalyst is an interleukin-1β blocker indicated for:

- The treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), in adults and children 12 years of age and older including: Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS)
- The maintenance of remission of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) in adults and pediatric patients weighing at least 10 kg
- The treatment of recurrent pericarditis (RP) and reduction in risk of recurrence in adults and pediatric patients 12 years and older

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RILONACEPT

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

Cryopyrin-Associated Periodic Syndromes, Familial Cold Auto-Inflammatory Syndrome, Muckle-Wells Syndrome and Recurrent Pericarditis

Adults: Initiate treatment with a loading dose of 320 mg delivered as two, 2-mL, subcutaneous injections of 160 mg each, administered on the same day at two different injection sites. Continue dosing with a once-weekly injection of 160 mg administered as a single, 2-mL, subcutaneous injection.

Pediatric patients 12 years to 17 years: Initiate treatment with a loading dose of 4.4 mg/kg, up to a maximum dose of 320 mg, administered as one or two subcutaneous injections, not to exceed single-injection volume of 2 mL per injection site. If the initial dose is given as two injections, administer on the same day at two different sites. Continue dosing with a once-weekly injection of 2.2 mg/kg, up to a maximum of 160 mg, administered as a single subcutaneous injection, up to 2 mL.

Deficiency of IL-1 Receptor Antagonist

Adults: The recommended dose of Arcalyst is 320 mg, once weekly, administered as two subcutaneous injections on the same day at two different sites with a maximum single-injection volume of 2 mL. Arcalyst should not be given more often than once weekly.

Pediatric patients weighing 10 kg or more: The recommended dose of Arcalyst is 4.4 mg/kg (up to a maximum of 320 mg), once weekly, administered as one or two subcutaneous injections with a maximum single-injection volume of 2 mL. If the dose is given as two injections, administer both on the same day, each one at a different site.

REFERENCES

Arcalyst [prescribing information]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc. March 2021.

Created: 02/18
Effective: 04/11/22 Client Approval: 03/10/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

RILUZOLE

Generic	Brand	HICL	GCN	Exception/Other
RILUZOLE	EXSERVAN, TIGLUTIK		47362, 44091	

GUIDELINES FOR USE

The guideline named **RILUZOLE (Exservan, Tiglutik)** requires the following rule(s) be met for approval:

A. You have amyotrophic lateral sclerosis (ALS: nervous system disease that weakens muscles and affects physical function)
B. You are 18 years of age or older
C. You have tried riluzole tablets
D. You are unable to take riluzole tablet formulation

RATIONALE

Promote appropriate utilization of **RILUZOLE** based on FDA approved indication and dosing.

FDA APPROVED INDICATION

Riluzole is indicated for the treatment of amyotrophic lateral sclerosis (ALS).

DOSAGE

Exservan: The recommended dosage of Exservan is one 50 mg film twice daily, taken at least 1 hour before or 2 hours after a meal.

Tiglutik: The recommended dosage of Tiglutik is 50 mg (10 mL), twice daily, taken orally, every 12 hours.

REFERENCES

- Exservan. [Prescribing Information]. Warren, NJ: Aquestive Therapeutics; April 2020.
- Tiglutik. [Prescribing Information]. Berwyn, PA: ITF Pharma, Inc.; September 2018.

Created: 12/18
Effective: 07/19/21 Client Approval: 06/18/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

RIMEGEPANT

Generic	Brand	HICL	GCN	Exception/Other
RIMEGEPANT	NURTEC	46383		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **RIMEGEPANT (Nurtec)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. Treatment of acute (quick onset) migraine
   2. Preventive treatment of episodic migraines

B. You are 18 years of age or older

C. If the request is for the treatment of acute migraine, approval also requires:
   1. You have tried TWO triptans (such as sumatriptan, rizatriptan), unless there is a medical reason why you cannot (contraindication)

D. If the request is for the preventive treatment of episodic migraines, approval also requires:
   1. You have tried any **THREE** of the following preventative migraine treatments (chart notes required in the absence of electronic prescription claims history):
      a. beta-blocker (such as propranolol, timolol, or nadolol)
      b. candesartan
      c. cyproheptadine
      d. lisinopril
      e. tricyclic antidepressant (such as amitriptyline, nortriptyline, or doxepin)
      f. topiramate
      g. valproic acid/ divalproex sodium
      h. venlafaxine/ desvenlafaxine
      i. verapamil
   2. ONE of the following:
      a. You have tried TWO injectable calcitonin gene-related peptide (CGRP) antagonists (e.g., Ajovy, Aimovig, Emgality)
      b. You have needle phobia, dexterity issue, or other medical reason you cannot use an injectable CGRP inhibitor

RENEWAL CRITERIA

Our guideline named **RIMEGEPANT (Nurtec)** requires the following rule(s) be met for renewal:

A. The request is for ONE of the following:
   1. Treatment of acute (quick onset) migraine
   2. Preventive treatment of episodic migraines

B. You have history of paid claim(s) for the requested medication in the past 90 days

C. You have a previous authorization on file for the requested medication

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RIMEGEPANT

RATIONALE
To ensure appropriate diagnostic, utilization and safety criteria are used for the management of requests for rimegepant.

FDA APPROVED INDICATIONS
Nurtec is a calcitonin gene-related peptide receptor antagonist indicated for the:
- Acute treatment of migraine with or without aura in adults
- Preventive treatment of episodic migraine in adults

DOSING
- Recommended dosage for acute treatment of migraine: 75 mg taken orally, as needed. The maximum dose in a 24-hour period is 75 mg.
- Recommended dosage for preventive treatment of episodic migraine: 75 mg taken orally every other day.
- The safety of using more than 18 doses in a 30-day period has not been established.

REFERENCES
- Nurtec [Prescribing Information]. New Haven, CT: Biohaven Pharmaceuticals Inc; May 2021.

Created: 04/20
Effective: 12/15/21 Client Approval: 10/21/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

RIOCIGUAT

Generic	Brand	HICL	GCN	Exception/Other
RIOCIGUAT	ADEMPAS	40644		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline for **RIOCIGUAT (Adempas)** requires the following rule(s) be met for approval:

A. You have a diagnosis of a persistent/recurrent chronic thromboembolic pulmonary hypertension World Health Organization Group 4 (CTEPH: form of high blood pressure affecting the lungs caused by blood clots) or a diagnosis of pulmonary arterial hypertension World Health Organization Group 1 (PAH: type of high blood pressure affecting lungs and arteries)
B. The requested medication is prescribed by or given in consultation with a cardiologist (heart doctor) or pulmonologist (lung/ breathing doctor)
C. You are not concurrently taking nitrates or nitric oxide donors (such as amyl nitrate), phosphodiesterase inhibitors (such as sildenafil, tadalafil, or vardenafil), or non-specific phosphodiesterase inhibitors (such as dipyridamole, theophylline)

RENEWAL CRITERIA

Our guideline named **RIOCIGUAT (Adempas)** requires the following rule(s) be met for renewal:

A. You have history of paid claim(s) for the requested medication in the past 90 days
B. You have a previous authorization on file for the requested medication
C. You are not concurrently taking nitrates or nitric oxide donors (e.g., amyl nitrate), phosphodiesterase inhibitors (e.g., sildenafil, tadalafil, or vardenafil), or non-specific phosphodiesterase inhibitors (e.g., dipyridamole, theophylline)

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

RIOCIGUAT

RATIONALE
Ensure appropriate utilization of Adempas based on FDA approved indications.

FDA APPROVED INDICATIONS
Indicated for the treatment of adults with:
- Persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) (WHO (World Health Organization) Group 4) after surgical treatment or inoperable CTEPH to improve exercise capacity and WHO functional class.
- Pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise capacity, improve WHO functional class and to delay clinical worsening.

World Health Organization Classification of Pulmonary Hypertension Group 1:
- Idiopathic (familial)
- Congenital systemic-to-pulmonary shunts
- HIV infection
- Collagen vascular disease
- Portal Hypertension
- Drugs and toxins

World Health Organization Classification of Pulmonary Hypertension Group 4:
- Secondary to chronic thromboembolic disease

DOSAGE
The dose is 1mg three times daily to start, or 0.5mg three times daily for patients unlikely to tolerate the hypotensive effect of Adempas. After two weeks the dose may be increased by 0.5mg at two week intervals to a maximum daily dosage of 2.5mg three times daily.

For patients receiving strong CYP and P-gp/BCRP inhibitors, consider a starting dose of 0.5 mg three times a day. Monitor for hypotension. Separate administration of antacids by at least 1 hour.

Among smokers, Adempas may require dosages higher than 2.5 mg three times a day if tolerated. Dose decrease may be required in patients who stop smoking.

REFERENCES

- Adempas [Prescribing Information]. Wayne, NJ: Bayer HealthCare Pharmaceuticals Inc.; September 2021.

Created: 06/15
Effective: 12/15/21 Client Approval: 10/21/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

RIPRETINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RIPRETINIB	QINLOCK	46544		GPI-10 (2153407700)	

GUIDELINES FOR USE

Our guideline named **RIPRETINIB (Qinlock)** requires **ALL** of the following rule(s) be met for approval:

D. You have advanced gastrointestinal stromal tumor (GIST: a type of cancer in your digestive tract)
E. You are 18 years of age or older
F. You have received prior treatment with 3 or more kinase inhibitors (class of drugs), including imatinib

RATIONALE
Ensure appropriate diagnostic, utilization and safety criteria are used for the management of requests for ripretinib.

FDA APPROVED INDICATIONS
Qinlock is indicated for the treatment of adult patients with advanced gastrointestinal stromal tumor (GIST) who have received prior treatment with 3 or more kinase inhibitors, including imatinib.

DOSING
The recommended dosage of Qinlock is 150 mg orally once daily with or without food until disease progression or unacceptable toxicity.

REFERENCES
Qinlock [Prescribing Information]. Waltham, MA: Deciphera Pharmaceuticals, May 2020.

Created: 07/20
Effective: 08/03/20 Client Approval: 07/07/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

RISANKIZUMAB-RZAA

Generic	Brand	HICL	GCN	Exception/Other
RISANKIZUMAB-RZAA	SKYRIZI	45699		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **RISANKIZUMAB-RZAA (Skyrizi)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe Crohn's disease (CD: a type of bowel disorder)

B. **If you have moderate to severe plaque psoriasis, approval also requires:**
   1. You are 18 years of age or older
   2. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
   3. You have previously tried at least ONE form of the following standard therapies: PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
   4. You have previously tried **TWO** of the following: Cosentyx, Enbrel, or Humira

C. **If you have psoriatic arthritis, approval also requires:**
   1. You are 18 years of age or older
   2. You have previously tried at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs): methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   3. You have previously tried **TWO** of the following: Cosentyx, Enbrel, or Humira

D. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. You are 18 years of age or older
   2. You have had a trial of ONE or more of the following conventional agents: corticosteroids (e.g., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

RENEWAL CRITERIA

Our guideline named **RISANKIZUMAB-RZAA (Skyrizi)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe Crohn's disease (CD: a type of bowel disorder)

B. **If you have moderate to severe plaque psoriasis or psoriatic arthritis, renewal also requires:**
   1. You have experienced or maintained symptomatic improvement while on therapy.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

RISANKIZUMAB-RZAA

RATIONALE
Ensure appropriate diagnostic, utilization and safety criteria are used for the management of requests for risankizumab.

INDICATIONS
Skyrizi is indicated for the treatment of:
- moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.
- active psoriatic arthritis in adults.
- moderately to severely active Crohn's disease in adults

DOSING
Plaque Psoriasis: The recommended dosage is 150 mg administered by subcutaneous injection at Week 0, Week 4, and every 12 weeks thereafter.

Psoriatic Arthritis: The recommended dose is 150 mg administered by subcutaneous injection at Week 0, Week 4, and every 12 weeks thereafter. Skyrizi may be administered alone or in combination with non-biologic disease-modifying antirheumatic drugs (DMARDs).

Crohn's Disease:
- Induction: The recommended induction dosage of Skyrizi is 600 mg administered by intravenous infusion over a period of at least one hour at Week 0, Week 4, and Week 8.
- Maintenance: The recommended maintenance dosage of Skyrizi is 360 mg administered by subcutaneous injection at Week 12, and every 8 weeks thereafter.

DOSAGE FORMS AND STRENGTHS
- 75 mg/0.83 mL in each single-dose prefilled syringe
- 150 mg/mL single-dose prefilled syringe
- 150 mg/mL single-dose pen
- 180 mg/1.2 mL (150 mg/mL) single-dose prefilled cartridge with on-body injector
- 360 mg/2.4 mL (150 mg/mL) single-dose prefilled cartridge with on-body injector
- 600 mg/10 mL (60 mg/mL) single-dose vial

REFERENCES

- Skyrizi [Prescribing Information]. North Chicago, IL: AbbVie, Inc.; June 2022.
- Menter A, Strober BE, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.
- Singh JA, Guyatt G, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Care & Research. Vol. 71, No. 1, January 2019, pp 2–29. DOI 10.1002/acr.2378.
- Lichtenstein G, Loftus EV, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. American Journal of Gastroenterology: April 2018, Volume 113, Issue 4, pp 481-517. doi: 10.1038/ajg.2018.27

Created: 06/19
Effective: 01/16/23 Client Approval: 01/03/23 P&T Approval: N/A

ROFLUMILAST

Generic	Brand	HICL	GCN	Exception/Other
ROFLUMILAST	ZORYVE		52657	ROUTE = TOPICAL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ROFLUMILAST (Zoryve)** requires the following rule(s) be met for approval:
A. You have plaque psoriasis (a type of skin condition)
B. You are 12 years of age or older
C. You have psoriasis covering 2% to 20% of body surface area (BSA) (excluding scalp, palms, fingernails, toenails, and soles)
D. You are NOT concurrently (at the same time) using other systemic immunomodulating agents (such as Stelara, Otezla), topical corticosteroids (such as betamethasone dipropionate, clobetasol propionate), or topical non-steroidals (such as calcitriol, tazarotene)
E. You had a trial of or contraindication (harmful for) to TWO of the following (from different categories):
    1. High or super-high potency topical corticosteroid (such as triamcinolone acetonide, fluocinonide, clobetasol propionate, halobetasol propionate)
    2. Topical vitamin D analog (such as calcipotriene cream, calcitriol ointment)
    3. Topical calcineurin inhibitor (such as tacrolimus, pimecrolimus)
    4. Topical retinoid (such as tazarotene cream/gel)
    5. Anthralin

RENEWAL CRITERIA

Our guideline named **ROFLUMILAST (Zoryve)** requires the following rule(s) be met for renewal:
A. You have plaque psoriasis (a type of skin condition)
B. You have experienced or maintained symptomatic improvement while on therapy
C. You are NOT concurrently (at the same time) using other systemic immunomodulating agents (such as Stelara, Otezla), topical corticosteroids (such as betamethasone dipropionate, clobetasol propionate), or topical non-steroidals (such as calcitriol, tazarotene)

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ROFLUMILAST

RATIONALE
To promote appropriate utilization of roflumilast based on labeled indication.

FDA APPROVED INDICATIONS
Roflumilast is a phosphodiesterase 4 inhibitor indicated for topical treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older.

DOSAGE AND ADMINISTRATION
Roflumilast should be applied once daily to affected areas.

REFERENCES
Zoryve [Prescribing Information]. Westlake Village, CA: Arcutis Biotherapeutics, Inc.; July 2022.

Created: 09/22
Effective: 10/17/22 Client Approval: 09/16/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ROMIPLOSTIM

Generic	Brand	HICL	GCN	Exception/Other
ROMIPLOSTIM	NPLATE	35798		

GUIDELINES FOR USE
INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named **ROMIPLOSTIM (Nplate)** requires a diagnosis of chronic immune thrombocytopenia (ITP) and the patient is 1 years of age or older. In addition, the following criteria must be met.

- The patient had a trial of or contraindication to corticosteroids or immunoglobulins, or had an insufficient response to splenectomy

For patients between 1 and 17 years old, approval requires the patient has had ITP for at least 6 months

RENEWAL CRITERIA

The guideline named **ROMIPLOSTIM (Nplate)** requires a diagnosis of chronic immune thrombocytopenia (ITP) and **ONE** of the following criteria must be met:

- The patient had a clinical response, as defined by an increase in platelet count to at least 50 X 10(9)/L
- The patient received the maximum dose of 10mcg/kg for 4 consecutive weeks with a clinical response

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RATIONALE
Promote appropriate utilization and dosing of Nplate for its FDA approved indication.

FDA APPROVED INDICATIONS
Nplate is a thrombopoietin receptor agonist indicated for the treatment of thrombocytopenia in:

- Adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.
- Pediatric patients 1 year of age and older with ITP for at least 6 months who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.

DOSAGE AND ADMINISTRATION
The recommended initial dose is 1 mcg/kg once weekly as a subcutaneous injection.

AVAILABLE STRENGTHS
For injection: 125 mcg, 250 mcg, or 500 mcg of deliverable romiplostim as a lyophilized powder in single-dose vials.

REFERENCES

- Nplate [Prescribing Information] Thousand Oaks, CA: Amgen Inc.; December 2018.

Created: 09/19
Effective: 01/01/20 Client Approval: 10/14/19 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ROMOSOZUMAB

Generic	Brand	HICL	GCN	Exception/Other
ROMOSOZUMAB-AQQG	EVENITY	45681		

GUIDELINES FOR USE

The guideline named **ROMOSOZUMAB (Evenity)** requires a diagnosis of postmenopausal osteoporosis and the patient has not received a total of 12 months or more of Evenity therapy. In addition, **ONE** of the following criteria must be met:

- The patient is at high risk for fractures defined as **ONE** of the following:
  - History of osteoporotic (i.e., fragility, low trauma) fracture(s)
  - 2 or more risk factors for fracture (e.g., history of multiple recent low trauma fractures, BMD T-score less than or equal to -2.5, corticosteroid use, or use of gonadotropin-releasing hormone [GnRH] analogs such as nafarelin, etc.)
  - No prior treatment for osteoporosis **AND** FRAX score greater than or equal to 20% for any major fracture **OR** greater than or equal to 3% for hip fracture
- The patient is unable to use oral therapy (i.e., upper gastrointestinal [GI] problems - unable to tolerate oral medication, lower GI problems - unable to absorb oral medications, trouble remembering to take oral medications or coordinating an oral bisphosphonate with other oral medications or their daily routine)
- The patient has had a previous trial of or a contraindication to a bisphosphonate (e.g., Fosamax, Actonel, Reclast, or Boniva)

RATIONALE

To ensure appropriate use of Evenity based on FDA and compendia approved indications and dosing.

FDA APPROVED INDICATIONS

Evenity is a sclerostin inhibitor indicated for the treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.

DOSAGE AND ADMINISTRATION

The recommended dose of Evenity is 210 mg administered subcutaneously in the abdomen, thigh or upper arm. Administer Evenity once every month. The anabolic effect of Evenity wanes after 12 monthly doses of therapy. Therefore, the duration of Evenity use should be limited to 12 monthly doses. If osteoporosis therapy remains warranted, continued therapy with an anti-resorptive agent should be considered

REFERENCES

Evenity [Prescribing Information]. Thousand Oaks, CA: Amgen, Inc; December 2019.

Created: 01/20
Effective: 04/01/20 Client Approval: 02/24/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

RUCAPARIB

Generic	Brand	HICL	GCN	Exception/Other
RUCAPARIB CAMSYLATE	RUBRACA	44002		

GUIDELINES FOR USE

The guideline named **RUCAPARIB (Rubraca)** requires a diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer OR recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer. In addition, the following criteria must be met:

For diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval requires:

- The patient is 18 years of age or older
- The requested medication will be used as monotherapy
- The patient has a deleterious BRCA mutation (germline and/or somatic) as confirmed by an FDA-approved test for Rubraca
- The patient has been treated with two or more chemotherapies (e.g., paclitaxel, docetaxel, cisplatin, carboplatin)

For diagnosis of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval requires:

- The patient is 18 years of age or older
- The patient is in complete or partial response to platinum-based chemotherapy
- The requested medication will be used for maintenance treatment

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

RUCAPARIB

RATIONALE
Promote appropriate utilization of **RUCAPARIB** based on FDA approved indication and dosage.

FDA APPROVED INDICATIONS
RUBRACA is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated:

- For the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.
- For the treatment of adult patients with deleterious *BRCA* mutation (germline and/or somatic)-associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more chemotherapies. Select patients for therapy based on an FDA-approved companion diagnostic for RUBRACA.

DOSAGE AND ADMINISTRATION
The recommended dose of Rubraca is 600 mg (two 300 mg tablets) taken orally twice daily with or without food. Continue treatment until disease progression or unacceptable toxicity. If a patient misses a dose of Rubraca, instruct the patient to take the next dose at its scheduled time. Vomited doses should not be replaced.

To manage adverse reactions, consider interruption of treatment or dose reduction. Recommended dose reductions are indicated in Table 1.

Table 1. Recommended Dose Adjustments

Dose Reduction	Dose
Starting Dose	600 mg twice daily (two 300 mg tablets)
First Dose Reduction	500 mg twice daily (one 300 mg tablet and one 200 mg tablet)
Second Dose Reduction	400 mg twice daily (two 200 mg tablets)
Third Dose Reduction	300 mg twice daily (one 300 mg tablet)

REFERENCES

- Rubraca [Prescribing Information]. Boulder, CO: Clovis Oncology, Inc. April 2018.

Created: 07/17
Effective: 10/01/19 Client Approval: 09/04/19 P&T Approval: N/A

RUXOLITINIB

Generic	Brand	HICL	GCN	Exception/Other
RUXOLITINIB PHOSPHATE	JAKAFI	38202		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **RUXOLITINIB (Jakafi)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Intermediate or high-risk myelofibrosis, (type of bone marrow cancer such as primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis)
   2. Polycythemia vera
   3. Steroid-refractory acute graft-versus-host disease
   4. Chronic graft-versus-host disease (GVHD: a condition in which the donor bone marrow or stem cells attack the receiving person)

B. **If you have intermediate or high-risk myelofibrosis, such as primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis, approval also requires:**
   1. You are 18 years of age or older

C. **If you have polycythemia vera, approval also requires:**
   1. You are 18 years of age or older
   2. You had a trial of hydroxyurea, unless there is a medical reason why you cannot (contraindication)

D. **If you have steroid -refractory acute graft-versus-host disease, approval also requires:**
   1. You are 12 years of age or older

E. **If you have chronic graft-versus-host disease, approval also requires:**
   1. You are 12 years of age or older
   2. You had failure of at least TWO prior systemic therapies (treatment that spreads throughout the body) (e.g., corticosteroids, immunosuppressants)

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

RUXOLITINIB

RENEWAL CRITERIA

Our guideline named **RUXOLITINIB (Jakafi)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Intermediate or high-risk myelofibrosis, (type of bone marrow cancer such as primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis)
   2. Polycythemia vera
   3. Chronic graft-versus-host disease (GVHD: a condition in which the donor bone marrow or stem cells attack the receiving person)

B. **If you have a diagnosis of intermediate or high-risk myelofibrosis,** renewal also requires you have experienced or maintained symptom improvement [such as a 50% or greater reduction in total symptom score on the modified Myelofibrosis Symptom Assessment Form (MFSAF), 50% or greater reduction in palpable spleen length, or spleen reduction of 35% or greater from baseline spleen volume after 6 months of therapy]

C. **If you have a diagnosis of polycythemia vera or chronic graft-versus-host disease, renewal requires BOTH of the following:**
   1. You have history of paid claim(s) for the requested medication in the past 90 days
   2. You have previous authorization on file for the requested medication

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RATIONALE

Promote appropriate utilization and dosing of Jakafi for its FDA approved indication.

FDA APPROVED INDICATIONS

Jakafi is a kinase inhibitor indicated for treatment of:

- Intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis in adults.
- Polycythemia vera in adults who have had an inadequate response to or are intolerant of hydroxyurea.
- Steroid-refractory acute graft-versus-host disease in adult and pediatric patients 12 years and older.
- Chronic graft-versus-host disease after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older.

DOSAGE

Doses should be individualized based on safety and efficacy. Starting doses per indication are noted below.

Myelofibrosis

The starting dose of Jakafi is based on patient's baseline platelet count:

- Greater than 200 X 10^9/L: 20 mg given orally twice daily
- 100 X 10^9/L to 200 X 10^9/L: 15 mg given orally twice daily
- 50 X 10^9/L to less than 100 X 10^9/L: 5 mg given orally twice daily

Monitor complete blood counts every 2 to 4 weeks until doses are stabilized, and then as clinically indicated. Modify or interrupt dosing for thrombocytopenia.

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RUXOLITINIB

Polycythemia Vera and Chronic Graft-Versus-Host Disease
The starting dose of Jakafi is 10 mg given orally twice daily.

Steroid-Refractory Acute Graft-Versus-Host Disease
The starting dose of Jakafi is 5 mg given orally twice daily.

REFERENCES

- Incyte Corporation. Jakafi package insert. Wilmington, DE. September 2021.

Created: 06/15
Effective: 11/01/21 Client Approval: 10/15/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

SACROSIDASE

Generic	Brand	HICL	GCN	Exception/Other
SACROSIDASE	SUCRAID	18554		

GUIDELINES FOR USE

Our guideline named **SACROSIDASE (Sucraid)** requires the following rule(s) be met for approval:
A. You have genetically determined sucrose deficiency or congenital sucrase-isomaltase deficiency (CSID)

RATIONALE
To ensure use of Sucraid based on its FDA approved indication and dosing.

FDA APPROVED INDICATIONS
Sucraid oral solution is indicated as oral replacement therapy of the genetically determined sucrose deficiency, which is part of congenital sucrase-isomaltase deficiency (CSID).

REFERENCES
QOL Medical, LLC. Sucraid package insert. Vero Beach, FL. June 2011.

Created: 06/15
Effective: 08/08/22 Client Approval: 07/13/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

SAPROPTERIN DIHYDROCHLORIDE

Generic	Brand	HICL	GCN	Exception/Other
SAPROPTERIN DIHYDROCHLORIDE	KUVAN	35266		ROUTE = ORAL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline for **SAPROPTERIN DIHYDROCHLORIDE** requires a diagnosis of hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU) and that the patient follows a phenylalanine-restricted diet.

RENEWAL CRITERIA

Our guideline for **SAPROPTERIN DIHYDROCHLORIDE** renewal requires a diagnosis of hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU), in addition to the patient experiencing a greater than or equal to 30% decrease in blood phenylalanine from baseline after taking Kuvan (sapropterin dihydrochloride) and continuing to follow a phenylalanine-restricted diet.

RATIONALE

Promote appropriate utilization of **SAPROPTERIN DIHYDROCHLORIDE** based on FDA approved indication and dosing.

Phenylketonuria (PKU), in most cases, is caused by deficiency of phenylalanine hydroxylase (PAH). PAH is a hepatic enzyme that catalyzes the conversion of the essential amino acid phenylalanine to tyrosine. Tetrahydrobiopterin (BH4) is a cofactor required for PAH activity. PKU results in elevated blood and urine concentrations of phenylalanine and its metabolites, phenylacetate and phenyllactate. Tyrosine concentration is normal or low normal. Occasionally tyrosine concentrations are low.

Complete enzyme deficiency results in classic PKU, in which serum phenylalanine concentration exceeds 20 mg/dL (1200 micromol/L). Residual enzyme activity causes mild PKU (phenylalanine concentration 10 to 20 mg/dL, 600 to 1200 micromol/L) and hyperphenylalaninemia (HPA, phenylalanine concentration 2.5 to 10 mg/dL, 150 to 600 micromol/L).

Kuvan is a synthetic form of the cofactor BH4 (tetrahydrobiopterin) for the enzyme phenylalanine hydroxylase (PAH). BH4 activates residual PAH enzyme, improving normal phenylalanine metabolism and decreasing phenylalanine levels in Kuvan responders. Response to Kuvan treatment was defined in clinical trials as a ≥ 30% decrease in blood Phe from baseline. Approximately 25% to 50% of patients with PAH deficiency are responsive to sapropterin. The prevalence of responsiveness was 79 to 83% in patients with mild HPA, 49 to 60% in patients with mild PKU, and 7 to 10% in patients with classic PKU. Before routine treatment with Kuvan is initiated, a test should be conducted to determine if the patient is responsive.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

SAPROPTERIN DIHYDROCHLORIDE

DOSAGE

Patients 1 month to 6 years

- The recommended starting dose of Kuvan is 10 mg/kg taken once daily.

Patients 7 years and older

- The recommended starting dose of Kuvan is 10 to 20 mg/kg taken once daily.

Blood Phe levels should be checked after 1 week of Kuvan treatment and periodically for up to a month. If blood Phe does not decrease from baseline at 10 mg/kg per day, the dose may be increased to 20 mg/kg per day. Patients whose blood Phe does not decrease after 1 month of treatment at 20 mg/kg per day are nonresponders and treatment with Kuvan should be discontinued in these patients.

Once responsiveness to Kuvan has been established, the dosage may be adjusted within the range of 5 to 20 mg/kg per day according to response to therapy. Periodic blood Phe monitoring is recommended to assess blood Phe control.

FDA APPROVED INDICATIONS

Kuvan is a phenylalanine hydroxylase activator indicated to reduce blood phenylalanine (Phe) levels in patients with hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU). Kuvan is to be used in conjunction with a Phe restricted diet.

REFERENCES

- Kuvan [Prescribing Information]. BioMarin Pharmaceutical Inc. Novato, CA. May 2015.
- UpToDate, Inc. Overview of phenylketonuria. UpToDate [database online]. Waltham, MA. Available at: http://www.uptodate.com/home/index.html. Updated March 20, 2015.
- Kuvan. [Online Drug Database]. Available at: www.factsandcomparisons.com. Updated January 2015.

Created: 01/16
Effective: 03/01/16 Client Approval: 01/14/16 P&T Approval: 01/16

SARGRAMOSTIM

Generic	Brand	HICL	GCN	Exception/Other
SARGRAMOSTIM	LEUKINE	06074		

GUIDELINES FOR USE

This medication is not approved for the requested indication unless prescribed by a hematologist or oncologist.

RATIONALE

Ensure appropriate diagnostic usage criteria for sargramostim.

FDA APPROVED INDICATIONS

It is indicated for acute myelogenous leukemia following induction chemotherapy in older adult patients, bone marrow transplant engraftment delay or failure, mobilization of peripheral blood hematopoietic progenitor cells, myeloid reconstitution after autologous or allogenic bone marrow transplant, and neutropenia associated with chemotherapy, acute myelogenous leukemia, PBPC transplant, or peripheral blood stem cell transplantation.

REFERENCES

- Bayer Healthcare Pharmaceuticals, LLC. Leukine package insert. Seattle, WA. July 2009.
- Micromedex Healthcare Series [database online]. Greenwood Village, CO: Thomson Healthcare. Available at: http://www.thomsonhc.com/hcs/librarian/PFDefaultACtionId/pf.LoginAction. [Accessed: June 14, 2010].

Created: 06/15
Effective: 07/22/15 Client Approval: 06/15 P&T Approval: 08/10

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

SARILUMAB

Generic	Brand	HICL	GCN	Exception/Other
SARILUMAB	KEVZARA	44183		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SARILUMAB (Kevzara)** requires the following rule(s) be met for approval:

A. You have moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
B. You are 18 years of age or older
C. You have previously tried at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs): methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
D. You have previously tried **ONE** of the following: Enbrel or Humira

RENEWAL CRITERIA

Our guideline named **SARILUMAB (Kevzara)** requires the following rule(s) be met for renewal:

A. You have moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
B. You have experienced or maintained symptomatic improvement while on therapy.

RATIONALE
Ensure appropriate diagnostic, utilization and safety criteria are used for the management of requests for sarilumab.

FDA APPROVED INDICATION
Kevzara is an interleukin-6 (IL-6) receptor antagonist indicated for treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more disease-modifying antirheumatic drugs (DMARDs).

DOSING
Kevzara may be used as monotherapy or in combination with methotrexate (MTX) or other conventional DMARDs. The recommended dosage of Kevzara is 200 mg once every two weeks given as a subcutaneous injection. Reduce dose to 150 mg once every two weeks for management of neutropenia, thrombocytopenia and elevated liver enzymes.

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SARILUMAB

FDA APPROVED INDICATION (CONTINUED)

DOSAGE FORMS AND STRENGTHS
Single-dose prefilled syringes and pens are available for subcutaneous administration:
- 150 mg per 1.14 mL
- 200 mg per 1.14 mL

REFERENCES
- Kevzara [Prescribing Information]. Bridgewater, NJ: Sanofi-Aventis US LLC; April 2018
- Singh JA, Saag KG, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. 2016;68(1):1-25. DOI 10.1002/acr.22783

Created: 07/17
Effective: 04/11/22 Client Approval: 03/10/22 P&T Approval: N/A

SATRALIZUMAB-MWGE

Generic	Brand	HICL	GCN	Exception/Other
SATRALIZUMAB-MWGE	ENSPRYNG	46781		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SATRALIZUMAB-MWGE (ENSPRYNG)** requires the following rule(s) be met for approval:

A. You have neuromyelitis optica spectrum disorder (NMOSD: a rare immune system disease that affects the central nervous system and causes inflammation in the optic nerve and spinal cord)
B. You are 18 years of age or older
C. Your diagnosis is confirmed by a positive serologic (blood) test for anti-aquaporin-4 (AQP4: type of protein) antibodies
D. You have at least ONE of the following core clinical characteristics:
    1. Optic neuritis (inflammation that damages an eye nerve)
    2. Acute myelitis (sudden and severe inflammation of the spinal cord)
    3. Area postrema syndrome (attacks of uncontrollable nausea, vomiting, or hiccups)
    4. Acute brainstem syndrome (problems with vision, hearing, swallowing and muscle weakness in the head)
    5. Symptomatic narcolepsy (sudden attacks of sleep) or acute diencephalic clinical syndrome (rare disorder caused by a tumor above the brainstem) with NMOSD-typical diencephalic MRI lesions
    6. Symptomatic cerebral syndrome with NMOSD-typical brain lesions
E. You will NOT use rituximab, inebilizumab, or eculizumab together with Enspryng

RENEWAL CRITERIA

Our guideline named **SATRALIZUMAB-MWGE (ENSPRYNG)** requires the following rule(s) be met for renewal:

A. You have neuromyelitis optica spectrum disorder (NMOSD: a rare disorder that affects the central nervous system and causes inflammation in the optic nerve and spinal cord)
B. You had a reduction in relapse frequency from baseline

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SATRALIZUMAB-MWGE

RATIONALE
Ensure appropriate diagnostic, utilization and safety criteria are used for the management of requests for satralizumab-mwge.

FDA APPROVED INDICATIONS
Enspryng is an interleukin-6 (IL-6) receptor antagonist indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

DOSING
The recommended loading dosage of Enspryng for the first three administrations is 120 mg by subcutaneous injection at Weeks 0, 2, and 4, followed by a maintenance dosage of 120 mg every 4 weeks.

REFERENCES
Enspryng [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; August 2020.

Created: 08/21
Effective: 04/11/22 Client Approval: 03/10/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

SECUKINUMAB

Generic	Brand	HICL	GCN	Exception/Other
SECUKINUMAB	COSENTYX	41715		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SECUKINUMAB (Cosentyx)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
   5. Enthesitis-related arthritis (ERA: a type of joint condition)

B. **If you have moderate to severe plaque psoriasis (PsO), approval also requires:**
   1. You have previously tried at least **ONE** of the following preferred therapies: PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

RENEWAL CRITERIA

Our guideline named **SECUKINUMAB (Cosentyx)** requires the following rule(s) be met for renewal:

A. You have history of paid claim(s) for the requested medication in the past 90 days
B. You have a previous authorization on file for the requested medication

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

SECUKINUMAB

RATIONALE

Ensure appropriate diagnostic, utilization and safety criteria are used for the management of requests for Cosentyx.

FDA APPROVED INDICATIONS

Cosentyx is a human interleukin-17A antagonist indicated for the treatment of:

- Moderate to severe plaque psoriasis in patients 6 years and older who are candidates for systemic therapy or phototherapy
- Patients 2 years and older with active psoriatic arthritis
- Adults with active ankylosing spondylitis
- Adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation
- Patients 4 years and older with enthesitis-related arthritis (ERA)

DOSAGE

Plaque Psoriasis

Adults: The recommended dose is 300 mg subcutaneous injection at Weeks 0, 1, 2, 3, and 4 followed by 300mg every 4 weeks; For some patients, a dose of 150mg may be acceptable.

Pediatric Patients 6 Years and Older: The recommended dosage is based on body weight and administered by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter.

- Less than 50kg: 75mg
- Greater than or equal to 50kg: 150mg

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SECUKINUMAB

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE

Psoriatic Arthritis

For psoriatic arthritis patients with coexistent moderate to severe plaque psoriasis, use the dosing and administration recommendations for plaque psoriasis.

For other psoriatic arthritis patients, administer Cosentyx with or without a loading dose by subcutaneous injection. The recommended dosage:

- With a loading dose is 150 mg at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter.
- Without a loading dose is 150 mg every 4 weeks.
- If the patient continues to have active psoriatic arthritis, consider a dosage of 300 mg every 4 weeks.

Ankylosing Spondylitis

Administer Cosentyx with or without a loading dose by subcutaneous injection. The recommended dosage:

- With a loading dose is 150 mg at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter.
- Without a loading dose is 150 mg every 4 weeks.
- If the patient continues to have ankylosing spondylitis, consider a dosage of 300 mg every 4 weeks.

Non-radiographic Axial Spondyloarthritis

Administer Cosentyx with or without a loading dose by subcutaneous injection. The recommended dosage:

- With a loading dose is 150 mg at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter.
- Without a loading dose is 150 mg every 4 weeks

Enthesitis-related arthritis (ERA)

Pediatric Patients 4 Years and Older: The recommended dosage is based on body weight and administered by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter.

- Less than 50kg: 75mg
- Greater than or equal to 50kg: 150mg

DOSAGE FORMS AND STRENGTHS

Cosentyx Sensoready pen:

- NDC 0078-0639-41: Carton of two 150mg/ml (300mg) Sensoready pens (injection)
- NDC 0078-0639-68: Carton of one 150mg/ml (300mg) Sensoready pen (injection)

Cosentyx prefilled syringe:

- NDC 0078-0639-98: Carton of two 150mg/ml (300mg) single-use prefilled syringes (injection)
- NDC 0078-0639-97: Carton of one 150mg/ml (300mg) single-use prefilled syringe (injection)
- NDC 0078-1056-97: Carton of one 75 mg/0.5 mL single-dose prefilled syringe (injection)

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SECUKINUMAB

REFERENCES

- Cosentyx [Prescribing Information]. Novartis Pharmaceuticals Corporation. East Hanover, NJ: January 2022.
- Braun J, Davis J, et al. First update of the international ASAS consensus statement for the use of anti-TNF agents in patients with Ankylosing Spondylitis. Ann Rheum Dis. 2006; 65(3):316-20.
- Menter A, Strober BE, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019; 80:1029-72.
- Singh JA, Guyatt G, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Care & Research. Vol. 71, No. 1, January 2019, pp 2–29DOI 10.1002/acr.2378.

Created: 06/15
Effective: 03/28/22 Client Approval: 02/22/22 P&T Approval: N/A

SEDATIVE HYPNOTICS/ BENZODIAZEPINES/ DORA AGENTS

Generic	Brand	HICL	GCN	Exception/Other
ALPRAZOLAM	XANAX, XANAX XR	01617		
BUTABARBITAL SODIUM	BUTISOL SODIUM	01566		
CHLORDIAZEPOXIDE HCL	CHLORDIAZEPOXIDE HCL	01610		
CHLORDIAZEPOXIDE HCL/AMITRIPTYLINE	CHLORDIAZEPOXIDE HCL/AMITRIPTYLINE	01656		
CLONAZEPAM	KLONOPIN	01894		
CLORAZEPATE DIPOTASSIUM	TRANXENE-T	01612		
DARIDOREXANT	QUVIVIQ	47751		
DIAZEPAM	VALIUM		45500 14222 14220 14221 14200 31551 45560 14210	
ESTAZOLAM	ESTAZOLAM	06036		
ESZOPICLONE	LUNESTA	26791		
FLURAZEPAM	FLURAZEPAM	01593		
LEMBOREXANT	DAYVIGO	46275		
LORAZEPAM	ATIVAN, LOREEV XR	04846		
MEPROBAMATE	MEPROBAMATE	01605		
MIDAZOLAM HCL	MIDAZOLAM HCL		29134 40852	
OXAZEPAM	OXAZEPAM	01616		
QUAZEPAM	DORAL	01595		
SECOBARBITAL SODIUM	SECONAL SODIUM	01570		
SUVOREXANT	BELSOMRA	41333		
TEMAZEPAM	RESTORIL	01592		
TRIAZOLAM	HALCION	01594		
ZALEPLON	SONATA	20347		
ZOLPIDEM TARTRATE	AMBIEN, AMBIEN CR, EDLUAR, INTERMEZZO, ZOLPIMIST	07842		

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

SEDATIVE HYPNOTICS/ BENZODIAZEPINES/ DORA AGENTS

GUIDELINES FOR USE

INITIAL CRITERIA

Our guideline for **SEDATIVE HYPNOTICS/ BENZODIAZEPINES/ DORA AGENTS** for patients with claims suggesting therapeutic duplication (many drugs are used for the same indication) requires that the medications are being cross-tapered (dose of one medication is being decreased while the other is being increased at the same time) or that the medication in history is being discontinued. Please note that additional criteria apply for the benzodiazepine day supply limits. Your benzodiazepine prescription claim must not be greater than a 15-day supply of medication. You cannot receive more than 30 days' supply of benzodiazepine medication in the past 90 days. The current request for medication is also counted as a part of the 30 days' supply in the past 90 days.

Our guideline for **BENZODIAZEPINES** does not allow use of carisoprodol-containing products at the same time with the requested medication.

Our guideline for **LOREEV XR** requires **BOTH** of the following:

A. You have history of an oral lorazepam IR formulation (i.e., concentrated solution or tablets) for at least 90 of the past 180 days
B. You have history of a claim for at least 30 days' supply of an oral lorazepam IR formulation (i.e., concentrated solution or tablets) at a consistent scheduled dose of at least three times daily within the previous 35 days

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

SEDATIVE HYPNOTICS/ BENZODIAZEPINES/ DORA AGENTS

GUIDELINES FOR USE

Our guideline for **BENZODIAZEPINES** for patients with claims in history for opioid analgesics requires that your prescriber submit the required fax form documenting **ALL** of the following:

- The diagnosis contributing to the need for benzodiazepine therapy and previous therapy attempted, including dates and doses of prior therapies
  - For generalized anxiety disorder, a trial of one of the following is required: Selective serotonin reuptake inhibitor (SSRI), serotonin-noradrenaline reuptake inhibitor (SNRI), or pregabalin
  - For panic disorder, a trial of one of the following is required: SSRI or tricyclic antidepressant (TCA)
  - For social anxiety disorder (SAD), a trial of an SSRI is required
  - For obsessive compulsive disorder (OCD), a trial of an SSRI is required
  - For post-traumatic stress disorder (PTSD), a trial of one of the following is required: mirtazapine, paroxetine, amitriptyline, or phenelzine
  - For insomnia, a trial of one of the following is required: ramelteon or a sedating antidepressant (i.e., trazodone, amitriptyline, doxepin, mirtazapine)
- The diagnosis contributing to the need for opioid analgesic therapy and previous therapy attempted, including dates and doses of prior therapies
  - No additional criteria apply for patients with cancer-related pain, pain related to sickle cell disease, significant pain related to other terminal diagnosis, or pain in patients receiving palliative care
  - For short-acting opioid therapy requested for post-surgical pain or pain related to an acute injury, the date of surgery or injury is required **AND** your prescriber must provide documentation of a clear plan for opioid dose tapering and discontinuation
  - For short-acting opioid therapy requested for chronic moderate to severe pain, a trial of one non-drug treatment for pain (e.g., thermotherapy, cryotherapy, massage therapy, transcutaneous electrical nerve stimulation (TENS), spinal cord stimulation (SCS), physical therapy) for 6 weeks duration within the previous 2 years unless contraindicated **AND** two non-opioid drug treatments prescribed for pain from different drug classes (e.g., non-steroidal anti-inflammatory drugs, acetaminophen, anticonvulsants, antidepressants) for at least 4 weeks (7 days for muscle relaxants) at maximum therapeutic doses within the previous 365 days is required. Chart notes indicating doses and dates of therapy are required in the absence of electronic prescription claims history
  - For long-acting opioid therapy requested for chronic moderate to severe pain, **ALL** of the following are required:
    - You meet the definition of opioid tolerance (defined as those who are taking, for one week or longer, at least 60mg oral morphine/day, 40mg oral oxycodone/day, 15mg oral hydromorphone/day, 60mg oral hydrocodone/day, 400mg oral codeine/day, or an equianalgesic dose of another opioid)
    - For any long-acting opioid other than MS Contin or tramadol ER, a trial of at least 30 days generic MS Contin in the previous 120 days is required

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SEDATIVE HYPNOTICS/ BENZODIAZEPINES/ DORA AGENTS

GUIDELINES FOR USE (CONTINUED)

- Your prescriber's signed attestation as to **ALL** of the following:
  - Your prescriber will regularly review your controlled substance utilization contained within INSPECT
  - You have been educated about the risks of using benzodiazepines and opioid analgesics together at the same time
  - Both your prescriber and you accept the risk of using benzodiazepines and opioid analgesics together at the same time

Please note that additional criteria apply for the benzodiazepine day supply limits. Your benzodiazepine prescription claim must not be greater than a 15-day supply of medication. You cannot receive more than 30 days' supply of benzodiazepine medication in the past 90 days. The current request for medication is also counted as a part of the 30 days' supply in the past 90 days.

Our guideline named **BENZODIAZPINES** allows for up to 15 days' supply of medication per fill and no more than 30 days' supply of benzodiazepine medication in the past 90 days, including the current request for medication.
Exceptions may be granted for any ONE of the following:

A. You have a diagnosis of cancer
B. You have a terminal illness
C. You are taking the requested benzodiazepine for seizure disorder
D. You are taking the requested benzodiazepine for catatonia
E. You are taking the requested benzodiazepine for intractable (hard to control) Meniere's disease (an ear problem that causes dizziness or hearing loss)
F. You are taking the requested benzodiazepine for akathisia **AND** you have tried propranolol
G. You are taking the requested benzodiazepine for spasticity associated with a central neurological disorder (e.g., cerebral palsy, dystonia, paraplegia) **AND** you have tried **TWO** non-benzodiazepine muscle relaxants
H. You have prescription claims history of benzodiazepine use for at least 90 of the past 180 days

RENEWAL CRITERIA

Our guideline for **SEDATIVE HYPNOTICS/ BENZODIAZEPINES/ DORA AGENTS** therapeutic duplication renewal requires that there is history of paid claims for BOTH of the requested sedative hypnotic/ benzodiazepine/ DORA agents involved in the therapeutic duplication for 90 of the past 120 days and that the patient has a previous authorization on file for BOTH of the requested sedative hypnotic/ benzodiazepine/ DORA agents involved in the therapeutic duplication.

Our guideline for **SEDATIVE HYPNOTICS/ BENZODIAZEPINES/ DORA AGENTS** renewal requires that there is history of paid claims for the requested sedative hypnotic/ benzodiazepine/ DORA agent for 90 of the past 120 days and that the patient has a previous authorization on file for the requested sedative hypnotic/ benzodiazepine/ DORA agent.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

SEDATIVE HYPNOTICS/ BENZODIAZEPINES/ DORA AGENTS

RATIONALE

To promote prudent prescribing of sedative-hypnotics, benzodiazepines, and dual orexin receptor antagonist (DORA) agents and to promote patient safety when benzodiazepines are used in combination with other agents.

A look back period of 60 days will be utilized to identify potential therapeutic duplication of sedative hypnotics/ benzodiazepines, DORA agents.

Prior authorization is not required for rectal benzodiazepine preparations.

Long-Term Benzodiazepine Utilization and Guideline Recommendations

According to the National Institute for Health and Clinical Excellence (NICE) and the World Federation of Societies of Biological Psychiatry (WFSBP) treatment guidelines, benzodiazepines are not recommended, or are recommended in short-term situations or treatment-refractory patients only for the following disease states: generalized anxiety disorder (GAD), panic disorder, social anxiety disorder (SAD), obsessive compulsive disorder (OCD), and post-traumatic stress disorder (PTSD). The American Academy of Sleep Medicine does not recommend long-term hypnotic (including benzodiazepine) use, except for those patients with severe, refractory insomnia. Because of the high risk of side effects and accidental death associated with benzodiazepine use, practice guidelines are decreasingly utilizing benzodiazepines as appropriate options for treatment of mental health disorders. Per the Centers of Disease Control and Prevention, overdose deaths had increased by 23% between 2010 and 2014. Two of the top 10 drugs involved in these overdoses were alprazolam and diazepam, often in combination with other substances. Benzodiazepine agents were involved in around 30% of prescription-drug overdose deaths in 2013; the death rate related to benzodiazepine overdose quadrupled between 1999 and 2013.

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RATIONALE (CONTINUED)

Benzodiazepine use has both long-term and short-term consequences. Short-term effects include sleepiness, risk of motor vehicle accidents, risk of falls (and potentially consequential fractures), and propensity for abuse or misuse. Long-term consequences include tolerance and physical dependence, as well as cognitive and memory impairment. Treatment discontinuation after long-term use can precipitate withdrawal symptoms, including anxiety, depression, hypersensitivity to sensory stimuli, perceptual distortions, and depersonalizations. In addition, psychiatric symptoms may return in greater severity than pre-treatment levels and may persist for extended periods. Because of the many risks associated with discontinuation of long-term treatment, it is important to have a discontinuation protocol to minimize adverse events of withdrawal. Discontinuation protocols should include a plan for stepwise reduction in benzodiazepine use and methods for managing withdrawal symptoms during tapering.

When discontinuing benzodiazepine therapy, gradual dose tapering with the support of psychotherapy, follow-up visits, and written instructions to manage withdrawal symptoms is an effective discontinuation intervention. Discussing the risk of long-term benzodiazepine use as well as the advantages to discontinuation has been shown to be more effective in achieving benzodiazepine discontinuation when used concurrently with gradual dose tapering. Gradual dose tapering is patient-specific: evaluating current therapies, type of benzodiazepine, current dosing, and other patient factors when designing the taper.

When beginning a gradual taper, many guidelines recommend converting the total daily dose to a diazepam-equivalent dosing and slowly converting the benzodiazepine to a diazepam dose three times a day. Converting to diazepam may prevent sharp plasma fluctuations due to its long half-life, and it is available in multiple strengths that aid in dose reduction. Other studies state that converting to a long-acting benzodiazepine for tapering has not shown additional benefit in preventing withdrawal symptoms. However, if choosing to convert to diazepam, it is recommended to change the evening dose to diazepam first to help limit daytime sleepiness. The conversion table below reflects the approximate equivalent doses and half-life for available benzodiazepines.

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RATIONALE (CONTINUED)

Benzodiazepine	Half-life (hours) [active metabolite]	Approximately Equivalent Oral Dosages (mg)
alprazolam (Xanax)	6-12	0.5
chlordiazepoxide (Librium)	5-30 [36-200]	25
clobazam (Onfi)	12-60	20
clonazepam (Klonopin)	18-50	0.5
clorazepate (Tranxene)	[36-200]	15
diazepam (Valium)	20-100 [36-200]	10
estazolam	10-24	1-2
flurazepam	[40-250]	15-30
lorazepam (Ativan)	10-20	1
oxazepam	4-15	20
quazepam (Doral)	25-100	20
temazepam (Restoril)	8-22	20
triazolam (Halcion)	2	0.5
Non-Benzodiazepine with Similar Effects	**Half-life (hours) [active metabolite]**	**Approximately Equivalent Oral Dosages (mg)**
zaleplon (Sonata)	2	20
zolpidem (Ambien)	2	20
zopiclone	5-6	15
eszopiclone (Lunesta)	6 (9 in elderly)	3

When beginning the discontinuation phase, it is recommended that the dose be tapered with a 5-10% reduction every 1-2 weeks, with a slower dose reduction when achieving lower doses. Gradual benzodiazepine tapers can often take from 3-4 months to a year (or longer). Benzodiazepine tapers are patient-specific and should be tailored based upon patient factors and responses to the taper. An example dose reduction from diazepam 40mg per day is as follows:

- decrease the dose by 2-4mg every 1-2 weeks until reaching 20mg per day, then
- decrease by 1-2mg every 1-2 weeks until reaching 10mg per day, then
- decrease by 1mg every 1-2 weeks until reaching 5mg per day, then
- decrease dose by 0.5-1mg every 1-2 weeks until complete.

For additional examples on benzodiazepine tapers and information on when and how to convert benzodiazepine dosing to diazepam, please access the Ashton Guidelines at https://benzo.org.uk/manual/bzsched.htm.

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RATIONALE (CONTINUED)
In addition to planning a discontinuation protocol, it is important to engage a member in their discontinuation or dose reduction of benzodiazepine use. Empowering patients and providing educational interventions can catalyze a shared decision-making relationship, which can improve concordance and clinical outcomes when de-prescribing benzodiazepines. Education can include information regarding risks of benzodiazepine use, evidence for benzodiazepine-induced harms, drug interaction potential, and suggestions for equally or more effective therapeutic substitutes. Conversations regarding benzodiazepine discontinuation can be prescribed in both prescriber office and pharmacy settings.

Guideline-centered treatment should be considered as a substitute for short- and long-term benzodiazepine use. The NICE guidelines provide a stepped approach for the disease states below:

- Generalized Anxiety Disorder (GAD) - Those that have found no improvement with low-intensity psychological interventions (individual non-facilitated self-help, individual guided self-help, or psychoeducational group therapy) should be considered for individual high-intensity psychological intervention (cognitive behavioral therapy (CBT) or applied relaxation) and/or drug treatment. Selective serotonin reuptake inhibitors (SSRIs) should be offered as first-line drug therapy. Serotonin-noradrenaline reuptake inhibitors and pregabalin can be considered upon failure of or intolerance to a SSRI. Benzodiazepines are not recommended for the treatment of GAD in primary or secondary care except as a short-term measure during a crisis. Antipsychotics are also discouraged for the treatment of GAD.
- Panic Disorder - For patients with mild to moderate panic disorder, low-intensity interventions may be sufficient. Those with moderate to severe panic disorder should be considered for CBT or pharmacologic intervention. The evidence base suggests SSRI or tricyclic antidepressant (TCA) therapy for longer-term management of panic disorder. Benzodiazepines are associated with a less positive outcome with long-term use and should not be prescribed for the treatment of panic disorder. NICE guidelines also discourage the use of sedating antihistamines or antipsychotics for treatment.
- Social Anxiety Disorder (SAD) - CBT is recommended as the initial treatment option for adults with SAD. For those wishing to consider pharmacological intervention, SSRIs are the recommended therapeutic choice. Anticonvulsants, TCAs, benzodiazepines, and antipsychotics should not be routinely offered for the treatment of SAD.
- Obsessive Compulsive Disorder (OCD) - Initial approach should be low-intensity or high-intensity psychological intervention, depending on severity of the OCD. A SSRI should also be considered for those with moderate to severe functional impairment in coordination with psychological intervention. Benzodiazepine use for the treatment of OCD is not recommended within this guideline.
- Post-Traumatic Stress Disorder (PTSD) - All PTSD sufferers should be offered a course of trauma-focused psychological treatment. For those requiring pharmacological intervention, mirtazapine, paroxetine, amitriptyline, and phenelzine have evidence of clinically or statistically significant benefits. For those with sleep interruption due to PTSD, sedative-hypnotics may be appropriate for short-term use only. Benzodiazepine use for the treatment of PTSD is not recommended within this guideline.

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RATIONALE (CONTINUED)

- Insomnia - Initial approaches to treatment include behavioral interventions and sleep hygiene education. If pharmacological treatment is warranted, the American Academy of Sleep Medicine recommends short-term use of one of the following: sedative-hypnotics (zolpidem, eszopiclone, zaleplon, temazepam), ramelteon, or sedating antidepressants (trazodone, amitriptyline, doxepin, mirtazapine). Use of anti-epilepsy medications (gabapentin, tiagabine) or atypical antipsychotics (quetiapine, olanzapine) should only be considered when comorbidities may benefit from the primary action of the medications. Over-the-counter sleep remedies, barbiturates, and chloral hydrate are not recommended for the treatment of insomnia. Pharmacological therapy should be prescribed initially for 2 to 4 weeks only, followed by re-evaluation of the continued need for treatment. Chronic use of hypnotic medications may be indicated for those with severe or refractory insomnia or chronic comorbid illnesses.

For all of the above disease states, comorbidities (depression, substance abuse, etc.) should be considered and addressed for best clinical outcomes.

APPENDIX 1: Sedative Hypnotics/ Benzodiazepines/ DORA Agents Standard Quantity Limits

GPID	***Generic Drug Name***	***Product Name***	***Dosage Form***	***Route***	***Strength***	***Utilization Edit***
14260	ALPRAZOLAM	XANAX	TABS	OR	0.25 MG	4/DAY
14261	ALPRAZOLAM	XANAX	TABS	OR	0.5 MG	4/DAY
14262	ALPRAZOLAM	XANAX	TABS	OR	1 MG	4/DAY
14263	ALPRAZOLAM	XANAX	TABS	OR	2 MG	4/DAY
14264	ALPRAZOLAM	ALPRAZOLAM INTENSOL	CONC	OR	1 MG/ ML	4 ML/DAY
24368	ALPRAZOLAM	ALPRAZOLAM ODT	TBDP	OR	0.25 MG	4/DAY
24369	ALPRAZOLAM	ALPRAZOLAM ODT	TBDP	OR	0.5 MG	4/DAY
24373	ALPRAZOLAM	ALPRAZOLAM ODT	TBDP	OR	1 MG	4/DAY
24374	ALPRAZOLAM	ALPRAZOLAM ODT	TBDP	OR	2 MG	4/DAY
17423	ALPRAZOLAM	XANAX XR	TB24	OR	0.5 MG	1/DAY
17424	ALPRAZOLAM	XANAX XR	TB24	OR	1 MG	1/DAY
17425	ALPRAZOLAM	XANAX XR	TB24	OR	2 MG	1/DAY
19681	ALPRAZOLAM	XANAX XR	TB24	OR	3 MG	1/DAY
14033	CHLORDIAZEPOXIDE HCL	CHLORDIAZEPOXIDE HCL	CAPS	OR	5 MG	4/DAY
14031	CHLORDIAZEPOXIDE HCL	CHLORDIAZEPOXIDE HCL	CAPS	OR	10 MG	4/DAY
14032	CHLORDIAZEPOXIDE HCL	CHLORDIAZEPOXIDE HCL	CAPS	OR	25 MG	4/DAY
14092	CLORAZEPATE DIPOTASSIUM	TRANXENE T	TABS	OR	3.75 MG	4/DAY
14093	CLORAZEPATE DIPOTASSIUM	TRANXENE T	TABS	OR	7.5 MG	4/DAY
14090	CLORAZEPATE	CLORAZEPATE	TABS	OR	15 MG	4/DAY

	DIPOTASSIUM	DIPOTASSIUM				
82964	DARIDOREXANT	QUVIVIQ	TABS	OR	25 MG	1/DAY; Age 18 years and older
82965	DARIDOREXANT	QUVIVIQ	TABS	OR	50 MG	1/DAY; Age 18 years and older
14221	DIAZEPAM	VALIUM	TABS	OR	2 MG	4/DAY
14222	DIAZEPAM	VALIUM	TABS	OR	5 MG	4/DAY
14220	DIAZEPAM	VALIUM	TABS	OR	10 MG	4/DAY
45500	DIAZEPAM	DIAZEPAM INTENSOL	CONC	OR	5 MG/ ML	8 ML/DAY
47479	LEMBOREXANT	DAYVIGO	TABS	OR	5 MG	1/DAY; Age 18 years and older
47484	LEMBOREXANT	DAYVIGO	TABS	OR	10 MG	1/DAY; Age 18 years and older
14160	LORAZEPAM	ATIVAN	TABS	OR	0.5 MG	4/DAY
14161	LORAZEPAM	ATIVAN	TABS	OR	1 MG	4/DAY
14162	LORAZEPAM	ATIVAN	TABS	OR	2 MG	4/DAY
50771	LORAZEPAM	LOREEV XR	CAPS	OR	1 MG	1/DAY; Age 18 years and older
52048	LORAZEPAM	LOREEV XR	CAPS	OR	1.5 MG	1/DAY; Age 18 years and older
50801	LORAZEPAM	LOREEV XR	CAPS	OR	2 MG	2/DAY; Age 18 years and older
50781	LORAZEPAM	LOREEV XR	CAPS	OR	3 MG	3/DAY; Age 18 years and older
14230	OXAZEPAM	OXAZEPAM	CAPS	OR	10 MG	4/DAY
14231	OXAZEPAM	OXAZEPAM	CAPS	OR	15 MG	4/DAY
14232	OXAZEPAM	OXAZEPAM	CAPS	OR	30 MG	4/DAY
13801	MEPROBAMATE	MEPROBAMATE	TABS	OR	200 MG	4/DAY
13802	MEPROBAMATE	MEPROBAMATE	TABS	OR	400 MG	4/DAY
17470	CLONAZEPAM	KLONOPIN	TABS	OR	0.5 MG	3/DAY
17471	CLONAZEPAM	KLONOPIN	TABS	OR	1 MG	3/DAY
17472	CLONAZEPAM	KLONOPIN	TABS	OR	2 MG	3/DAY
19467	CLONAZEPAM	CLONAZEPAM ODT	TBDP	OR	0.125 MG	3/DAY
19468	CLONAZEPAM	CLONAZEPAM ODT	TBDP	OR	0.25 MG	3/DAY
19469	CLONAZEPAM	CLONAZEPAM ODT	TBDP	OR	0.5 MG	3/DAY
19470	CLONAZEPAM	CLONAZEPAM ODT	TBDP	OR	1 MG	3/DAY
19472	CLONAZEPAM	CLONAZEPAM ODT	TBDP	OR	2 MG	3/DAY

13102	BUTABARBITAL SODIUM	BUTISOL SODIUM	TABS	OR	30 MG	3/DAY
19181	ESTAZOLAM	ESTAZOLAM	TABS	OR	1 MG	1/DAY
19182	ESTAZOLAM	ESTAZOLAM	TABS	OR	2 MG	1/DAY
14250	FLURAZEPAM HCL	FLURAZEPAM HCL	CAPS	OR	15 MG	1/DAY
14251	FLURAZEPAM HCL	FLURAZEPAM HCL	CAPS	OR	30 MG	1/DAY
40870	QUAZEPAM	DORAL	TABS	OR	15 MG	1/DAY
36967	SUVOREXANT	BELSOMRA	TABS	OR	5 MG	1/DAY; Age 18 years and older
36968	SUVOREXANT	BELSOMRA	TABS	OR	10 MG	1/DAY; Age 18 years and older
36969	SUVOREXANT	BELSOMRA	TABS	OR	15 MG	1/DAY; Age 18 years and older
36971	SUVOREXANT	BELSOMRA	TABS	OR	20 MG	1/DAY; Age 18 years and older
13845	TEMAZEPAM	RESTORIL	CAPS	OR	7.5 MG	1/DAY
13840	TEMAZEPAM	RESTORIL	CAPS	OR	15 MG	1/DAY
24036	TEMAZEPAM	RESTORIL	CAPS	OR	22.5 MG	1/DAY
13841	TEMAZEPAM	RESTORIL	CAPS	OR	30 MG	1/DAY
14282	TRIAZOLAM	TRIAZOLAM	TABS	OR	0.125 MG	1/DAY
14280	TRIAZOLAM	HALCION	TABS	OR	0.25 MG	1/DAY
23927	ESZOPICLONE	LUNESTA	TABS	OR	1 MG	1/DAY
23926	ESZOPICLONE	LUNESTA	TABS	OR	2 MG	1/DAY
23925	ESZOPICLONE	LUNESTA	TABS	OR	3 MG	1/DAY
92713	ZALEPLON	SONATA	CAPS	OR	5 MG	2/DAY
92723	ZALEPLON	SONATA	CAPS	OR	10 MG	2/DAY
00870	ZOLPIDEM TARTRATE	AMBIEN	TABS	OR	5 MG	1/DAY
00871	ZOLPIDEM TARTRATE	AMBIEN	TABS	OR	10 MG	1/DAY
25456	ZOLPIDEM TARTRATE	AMBIEN CR	TBCR	OR	6.25 MG	1/DAY
25457	ZOLPIDEM TARTRATE	AMBIEN CR	TBCR	OR	12.5 MG	1/DAY
31562	ZOLPIDEM TARTRATE	INTERMEZZO	SUBL	SL	1.75 MG	1/DAY
31563	ZOLPIDEM TARTRATE	INTERMEZZO	SUBL	SL	3.5 MG	1/DAY
26183	ZOLPIDEM TARTRATE	EDLUAR	SUBL	SL	5 MG	1/DAY
26182	ZOLPIDEM TARTRATE	EDLUAR	SUBL	SL	10 MG	1/DAY
29375	ZOLPIDEM TARTRATE	ZOLPIMIST	SOLN	OR	5 MG/ACT	2 SPRAYS (0.25 ML) /DAY

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PRIOR AUTHORIZATION GUIDELINES

APPENDIX 2: BENZODIAZEPINE/OPIOID CONCURRENT USE FAX FORM

INDIANA HEALTH COVERAGE PROGRAMS (IHCP) PHARMACY BENEFIT
BENZODIAZEPINE AND OPIOID CONCURRENT THERAPY
PRIOR AUTHORIZATION REQUEST FORM

MDwise
Fax to: (858) 790-7100
c/o MedImpact Healthcare Systems, Inc.
Attn: Prior Authorization Department
10181 Scripps Gateway Court, San Diego, CA 92131
Phone: 1-800-788-2949

MDwise
A McLaren Company

Today's Date
☐☐ / ☐☐ / ☐☐☐☐

Note: This form must be completed by the prescribing provider.
****All sections must be completed or the request will be denied.****

Patient's Medicaid # ☐☐☐☐☐☐☐☐☐☐☐☐	**Date of Birth** ☐☐ / ☐☐ / ☐☐☐☐
Patient's Name	**Prescriber's Name**
Prescriber's IN License # ☐☐☐☐☐☐☐☐	**Specialty**
Prescriber's NPI # ☐☐☐☐☐☐☐☐☐☐	**Prescriber's Signature: **Required below within attestation section.****
Return Fax # ☐☐☐ - ☐☐☐ - ☐☐☐☐	**Return Phone #** ☐☐☐ - ☐☐☐ - ☐☐☐☐

PA is required for the following:

- **Claim(s) for new opioid(s) to be used concurrently with benzodiazepines and exceeding 7 days within a 180-day period.**
- **Claim(s) for new benzodiazepine(s) to be used concurrently with opioids and exceeding 7 days of therapy within a 180-day period and/or exceeding established benzodiazepine/opioid concurrent therapy quantity limits (see Sedative Hypnotics/Benzodiazepine PA criteria).**

Benzodiazepine Agents(s)	Prescriber Name*	Quantity	Dosage Regimen/Duration

Opioid Agents(s)	Prescriber Name*	Quantity	Dosage Regimen/Duration

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PRIOR AUTHORIZATION GUIDELINES

***NOTE: If prescribers of the opioid(s) and benzodiazepine(s) are not the same, please answer the following questions:**

- **Are you requesting PA for: Benzodiazepine Agent(s) ☐ Opioid Agent(s) ☐ Both ☐**
- **Is/are the other prescriber(s) aware of the request for concurrent therapy? □ Yes □ No**
- **Has/have the other prescriber(s) been consulted about the risks associated with concurrent therapy, and do all prescribers involved believe continuing with concurrent therapy is warranted, given the risks associated with concurrent use? □ Yes □ No**

PA Requirements:

Patient diagnosis/diagnoses for use of benzodiazepine therapy:

Prior therapies attempted for the above diagnosis/diagnoses (submission of chart notes required in absence of claims history):

Drug Therapy	Dosage Regimen	Dates of Utilization

Do you plan to continue benzodiazepine therapy for this patient? □ Yes □ No
If no, please provide withdrawal plan:

Patient diagnosis/diagnoses for use of opioid therapy:

Prior therapies (both drug and non-drug) attempted for the above diagnosis/diagnoses (submission of chart notes required in absence of claims history):

Drug/Non-Drug Therapy	Dosage Regimen	Dates of Utilization	Reason for Discontinuation or Failure

Do you plan to continue opioid therapy for this patient? □ Yes □ No
If no, please provide withdrawal plan:

Attestation:

I, _____, hereby attest to the following:
(Prescriber Name)

- **The patient's INSPECT report has been evaluated and continues to be evaluated on a regular basis (Per IC 35-48-7-11.1, DO NOT attach a copy of the INSPECT report to this PA request).**

- **I have educated the patient in regards to the risks of concurrent utilization of benzodiazepine and opioid therapy, and the patient accepts these risks.**
- **If applicable, I have consulted other prescriber(s) involved in concurrent therapy and all prescribers involved agree to pursue concurrent opioid and benzodiazepine therapy for this patient.**
- **I acknowledge, as the prescriber initiating or maintaining concurrent benzodiazepine and opioid therapy, the risk of adverse event(s), including respiratory depression, coma, and death, associated with concurrent utilization.**

Prescriber Signature:_____

****Prescriber signature is required for consideration. Electronic or stamped signature will not be accepted.****

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

SEDATIVE HYPNOTICS/ BENZODIAZEPINES

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Created: 02/19
Effective: 12/19/22 Client Approval: 12/05/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

SELEXIPAG

Generic	Brand	HICL	GCN	Exception/Other
SELEXIPAG	UPTRAVI	42922		ROUTE = ORAL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SELEXIPAG (Uptravi)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: type of high blood pressure that affects the lungs)
B. Therapy is prescribed by or given in consultation with a cardiologist (heart doctor) or pulmonologist (lung/breathing doctor)

RENEWAL CRITERIA

Our guideline named **SELEXIPAG (Uptravi)** requires the following rule(s) be met for renewal:

A. You have history of paid claim(s) for the requested medication in the past 90 days
B. You have a previous authorization on file for the requested medication

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

SELEXIPAG

RATIONALE
Promote appropriate utilization of **SELEXIPAG** based on FDA approved indication.

FDA APPROVED INDICATIONS
Uptravi is a prostacyclin receptor agonist indicated for the treatment of pulmonary arterial hypertension (PAH, WHO Group I) to delay disease progression and reduce the risk of hospitalization for PAH.

DOSAGE
The starting dose of Uptravi is 200mcg by mouth twice daily and increased in increments of 200 mcg twice daily, usually at weekly intervals, to the highest tolerated dose up to 1600mcg twice daily. The target dose will be individualized based on patient tolerability and tolerability may be improved with food. In addition, a dose reduction should be made in patients that reach a dose that can't be tolerated.

For patients with moderate hepatic impairment (Child-Pugh class B), the starting dose of Uptravi is 200 mcg once daily. Increase in increments of 200 mcg once daily at weekly intervals, as tolerated.

AVAILABLE STRENGTHS
- 200 microgram tablet
- 400 microgram tablet
- 600 microgram tablet
- 800 microgram tablet
- 1000 microgram tablet
- 1200 microgram tablet
- 1400 microgram tablet
- 1600 microgram tablet
- Titration pack: 140 count bottle of 200 microgram tablets and a 60 count bottle of 800 microgram tablets

REFERENCES

- Uptravi [Prescribing Information]; San Francisco, CA: Actelion Pharmaceuticals US, Inc.; July 2021.
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Created: 01/16
Effective: 12/15/21 Client Approval: 10/21/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

SELINEXOR

Generic	Brand	HICL	GCN	Exception/Other
SELINEXOR	XPOVIO	45854		

GUIDELINES FOR USE

Our guideline named **SELINEXOR (Xpovio)** requires the following rule(s) be met for approval:

G. You have ONE of the following diagnoses:
   1. Multiple myeloma (MM: cancer of a type of white blood cells called plasma cells)
   2. Relapsed or refractory multiple myeloma (RRMM: cancer of a type of white blood cells called plasma cells, that has return or did not respond to treatment)
   3. Relapsed or refractory diffuse large B-cell lymphoma (DLBCL: type of cancer that starts in the immune system), including DLBCL arising from follicular lymphoma

H. You are 18 years of age or older

If you have multiple myeloma, approval also requires:

1. The requested medication will be used in combination with Velcade (bortezomib) and dexamethasone
2. You have received at least one therapy before Xpovio

If you have relapsed or refractory multiple myeloma, approval also requires:

1. The requested medication will be used in combination with dexamethasone
2. You have received at least four prior therapies for the treatment of RRMM
3. Your RRMM is refractory (non-responsive) to **ALL** of the following:
   a. Two proteasome inhibitors (such as bortezomib, carfilzomib)
   b. Two immunomodulatory agents (such as lenalidomide, pomalidomide)
   c. One anti-CD38 monoclonal antibody (such as daratumumab)

If you have relapsed or refractory diffuse large B-cell lymphoma (DLBCL), approval also requires:

1. You have received at least two lines of systemic therapy (treatment that spreads throughout the body)

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

SELINEXOR

RATIONALE
Promote appropriate utilization and dosing of Xpovio for its FDA approved indications.

FDA APPROVED INDICATIONS
Xpovio is a nuclear export inhibitor indicated:
- In combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy
- In combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, two immunomodulatory agents, and an anti-CD38 monoclonal antibody.
- For the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma, after at least 2 lines of systemic therapy.

DOSAGE AND ADMINISTRATION
- Multiple myeloma in combination with dexamethasone (Sd): Recommended dosage of Xpovio is 100 mg taken orally once weekly in combination with dexamethasone.
- Multiple myeloma in combination with bortezomib and dexamethasone (SVd): Recommended dosage of Xpovio is 80 mg taken orally on Days 1 and 3 of each week in combination with bortezomib and dexamethasone.
- DLBCL: Recommended dosage of Xpovio is 60 mg taken orally on Days 1 and 3 of each week.

AVAILABLE STRENGTHS
20mg, 40mg, 50mg, and 60mg tablets

REFERENCES
Xpovio [Prescribing Information]. Newton, MA: Karyopharm Therapeutics Inc.; April 2021.

Created: 03/19
Effective: 06/21/21 Client Approval: 05/21/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

SELPERCATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SELPERCATINIB	RETEVMO	46525			

GUIDELINES FOR USE

Our guideline named **SELPERCATINIB (Retevmo)** requires the following rule(s) be met for approval:

A. You have one of the following diagnoses:
   1. Metastatic (disease has spread to other parts of the body) *RET* (type of gene) fusion-positive non-small cell lung cancer (NSCLC: type of lung cancer)
   2. Advanced or metastatic *RET*-mutant medullary thyroid cancer (MTC: type of thyroid cancer)
   3. Advanced or metastatic *RET* fusion-positive thyroid cancer

B. **If you have metastatic *RET* fusion-positive non-small cell lung cancer (NSCLC), approval also requires:**
   1. You are 18 years of age or older

C. **If you have advanced or metastatic *RET*-mutant medullary thyroid cancer (MTC), approval also requires:**
   1. You are 12 years of age or older
   2. You require systemic therapy (treatment that travels through the bloodstream to all areas of the body)

D. **If you have advanced or metastatic *RET* fusion-positive thyroid cancer, approval also requires:**
   1. You are 12 years of age or older
   2. You require systemic therapy
   3. You are radioactive iodine-refractory (your tumor is resistant to treatment with radioactive iodine), if radioactive iodine is appropriate

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RATIONALE

To ensure appropriate diagnostic, utilization, and safety criteria are used for the management of requests for selpercatinib.

INDICATIONS

Retevmo is a kinase inhibitor indicated for the treatment of:

- Adult patients with metastatic RET fusion-positive non-small cell lung cancer (NSCLC)
- Adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy
- Adult and pediatric patients 12 years of age and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate)

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SELPERCATINIB

INDICATION (CONTINUED)

DOSAGE
The recommended dosage in adults and pediatric patients 12 years of age or older is based on weight:
- Less than 50 kg: 120 mg orally twice daily
- 50 kg or greater: 160 mg orally twice daily

REFERENCES
- Retevmo [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC; May 2020.

Created: 06/20
Effective: 07/01/20 Client Aproval: 06/05/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

SELUMETINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SELUMETINIB	KOSELUGO	46451			

GUIDELINES FOR USE

Our guideline named **SELUMETINIB (Koselugo)** requires the following rule(s) be met for approval:

A. You have neurofibromatosis type 1 (NF1: a genetic disorder that causes light brown skin spots and non-cancerous tumors to form on nerve tissue)
B. You are 2 years of age or older
C. You have symptomatic, inoperable (not treatable by surgery) plexiform neurofibromas (PN: tumors that grow from nerves anywhere in the body)

RATIONALE

To ensure appropriate diagnostic, utilization, and safety criteria are used for the management of requests for selumetinib.

INDICATIONS

Koselugo is a kinase inhibitor indicated for the treatment of pediatric patients 2 years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic inoperable plexiform neurofibromas (PN).

DOSAGE

The recommended dosage is 20mg/m^2 taken orally twice daily.

REFERENCES

- Koselugo [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; April 2020.

Created: 06/20
Effective: 07/01/20 Client Aproval: 06/05/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

SHORT-ACTING OPIOID ANALGESICS

Generic	Brand	HICL	GCN	Exception/Other
BENZHYDROCODONE/ APAP	APADAZ	44795	44508 45986 45987	
BUTORPHANOL TARTRATE	BUTORPHANOL TARTRATE	01777	20351	
CODEINE/ ACETAMINOPHEN	TYLENOL-CODEINE NO.3, TYLENOL-CODEINE NO.4, ACETAMINOPHEN-CODEINE, CAPITAL W-CODEINE	01717	33589 55402 70110 33604 33606 70131 70134 70136	
CODEINE PHOS /CARISOPRODOL/ASA	CARISOPRODOL COMPOUND-CODEINE	01720	13995	
CODEINE SULFATE	CODEINE SULFATE	01722	16240 16241 16242	
DHCODEINE BT/ ACETAMINOPHN/CAFF	DVORAH, TREZIX	01739	37532 43264	
DIHYDROCODEINE/ ASPIRIN/CAFFEINE	SYNALGOS-DC	01734 34574	52190	
HYDROCODONE BIT/ ACETAMINOPHEN	VICODIN, VICODIN ES, VICODIN HP, ZAMICET, HYCET, LORTAB, NORCO, XODOL, VERDROCET, LORCET PLUS, LORCET HD	01730	29246 99967 22929 70330 35153 70361 70337 12486 35154 26470 26709 16227 21146 31419 12488	
HYDROCODONE/ IBUPROFEN	IBUDONE, XYLON 10, VICOPROFEN, REPREXAIN	14296	99371 16279 22678 63101	
HYDROMORPHONE HCL	DILAUDID	01695	20251 16141 16130 16143 16144	

LEVORPHANOL TARTRATE	LEVORPHANOL TARTRATE	01743	16350 45941	
MEPERIDINE HCL,	DEMEROL	01687	15980 15990 15991	
MORPHINE SULFATE	MSIR	01694	16051 16060 16063 35166 16070 16052 16062 32719 16054 16071 16053 45662	
OPIUM/ BELLADONNA ALKALOIDS	BELLADONNA-OPIUM	01758	70741 70742	
OXYCODONE HCL	OXAYDO, ROXICODONE, ROXYBOND, OXECTA	01742	16291 20091 21194 16281 20092 16285 16290 32047 16280 31256 41853 44877 44878	
OXYCODONE HCL/ ACETAMINOPHEN	PRIMLEV, PERCOCET, ENDOCET, NALOCET, ROXICET, PROLATE	01741	70470 70491 14965 14966 70492 26953 26954 26955 26956 49308	
OXYCODONE HCL/ ASPIRIN	ENDODAN	04576	70481	
OXYCODONE HCL/ IBUPROFEN	OXYCODONE HCL/ IBUPROFEN	26757	23827	
OXYMORPHONE HCL	OPANA	01696	27243 27244	

PENTAZOCINE HCL/ NALOXONE HCL	PENTAZOCINE-NALOXONE HCL	01781	71060	
TAPENTADOL HCL	NUCYNTA	36411	26163 26164 26165	
TRAMADOL HCL	ULTRAM, QDOLO	08317	7221 92069 48598	
TRAMADOL HCL/ ACETAMINOPHEN	ULTRACET	22880	13909	
TRAMADOL HCL/ CELECOXIB	SEGLENTIS	47670	51517	

GUIDELINES FOR USE

RENEWAL CRITERIA will apply in the following scenarios only:
- For patients active with MDwise for 90 days or longer AND previous prior authorization approval for the same medication with the same strength AND recent paid pharmacy claims for the requested medication. Chart notes and/or cash pay for opioid use is not accepted.
- For patients new to MDwise within the past 90 days AND chart notes are provided that document the patient is stable on the requested medication.

All other requests will be reviewed against the INITIAL CRITERIA.

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

Our guideline for **SHORT-ACTING OPIOID ANALGESICS** for patients with past use of opioid dependency agents (such as, buprenorphine/naloxone SL tablets/films or buprenorphine SL tablets) requires the buprenorphine/naloxone or buprenorphine prescribing physician be notified about prescribed opiate therapy and must approve the use before the opioid analgesic will be authorized.

Our guideline for **SHORT-ACTING OPIOID ANALGESICS** does not permit concurrent use with carisoprodol-containing products. Please work with your doctor to use a different medication.

Our guideline for **SHORT-ACTING OPIOID ANALGESICS**, reviewed for Demerol (meperidine), requires you to meet **ALL** of the following criteria:
- Demerol (meperidine) is prescribed for one of the following indications:
  - Cancer
  - Sickle cell disease
  - Palliative care
  - Other terminal diagnosis associated with significant pain
- You have tried and failed **TWO** oral short-acting opioid analgesics (e.g., codeine/APAP, hydrocodone/APAP, hydromorphone, morphine sulfate IR, oxycodone/APAP, oxycodone IR)

Please note that additional criteria apply for concurrent use of opioid analgesics and benzodiazepines, including submission of signed prescriber attestation on a state-mandated fax form.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

SHORT-ACTING OPIOID ANALGESICS

Our guideline for **SHORT-ACTING OPIOID ANALGESICS**, reviewed for Prolate (oxycodone/APAP) oral solution, requires you to meet **ALL** of the following criteria:

- Prolate (oxycodone/APAP) oral solution, is prescribed for one of the following indications:
  - Cancer
  - Sickle cell disease
  - Palliative care
  - Other terminal diagnosis associated with significant pain
- You have tried and failed **TWO** oral short-acting opioid analgesics (e.g., codeine/APAP, hydrocodone/APAP, hydromorphone, morphine sulfate IR, oxycodone IR)
- You are unable to swallow tablets
- You have tried crushed Prolate (oxycodone/acetaminophen) tablets

Please note that additional criteria apply for concurrent use of opioid analgesics and benzodiazepines, including submission of signed prescriber attestation on a state-mandated fax form.

Our guideline for **SHORT-ACTING OPIOID ANALGESICS,** reviewed for QDOLO (tramadol oral solution), requires you to meet **ALL** of the following criteria:

- Qdolo (tramadol oral solution) is prescribed for one of the following indications:
  - Cancer
  - Sickle cell disease
  - Palliative care
  - Other terminal diagnosis associated with significant pain
- You are 12 years of age or older
- You are unable to swallow tablets
- You have tried crushed tramadol tablets

Please note that additional criteria apply for concurrent use of opioid analgesics and benzodiazepines, including submission of signed prescriber attestation on a state-mandated fax form.

Our guideline for **SHORT-ACTING OPIOID ANALGESICS**, reviewed for Demerol (meperidine), requires **ALL** of the following criteria to be met:

- You have a diagnosis of chronic moderate to severe pain
- Documentation of one non-pharmacological ancillary treatment for pain [such as thermotherapy, cryotherapy, massage therapy, transcutaneous electrical nerve stimulation (TENS), spinal cord stimulation (SCS), physical therapy] of 6 weeks duration within the past 2 years unless contraindicated. Documentation must include dates of therapy
- You have tried and failed **TWO** non-opioid pharmacological ancillary treatments prescribed for pain from different drug classes (e.g., NSAIDs, acetaminophen, anticonvulsants, antidepressants) for at least 4 weeks (7 days for muscle relaxants) at maximum therapeutic doses within the past 365 days. Submission of chart notes documenting trial dates and dosage is required in the absence of electronic prescription claims history
- You have tried and failed **TWO** oral short-acting opioid analgesics (e.g., codeine/APAP, hydrocodone/APAP, hydromorphone, morphine sulfate IR, oxycodone/APAP, oxycodone IR)

Please note that additional criteria apply for concurrent use of opioid analgesics and benzodiazepines, including submission of signed prescriber attestation on a state-mandated fax form.

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SHORT-ACTING OPIOID ANALGESICS

INITIAL CRITERIA (CONTINUED)

Our guideline for **SHORT-ACTING OPIOID ANALGESICS**, reviewed for Prolate (oxycodone/APAP) oral solution, requires **ALL** of the following criteria to be met:

- You have a diagnosis of chronic moderate to severe pain
- Documentation of one non-pharmacological ancillary treatment for pain [such as thermotherapy, cryotherapy, massage therapy, transcutaneous electrical nerve stimulation (TENS), spinal cord stimulation (SCS), physical therapy] of 6 weeks duration within the past 2 years unless contraindicated. Documentation must include dates of therapy
- You have tried and failed **TWO** non-opioid pharmacological ancillary treatments prescribed for pain from different drug classes (e.g., NSAIDs, acetaminophen, anticonvulsants, antidepressants) for at least 4 weeks (7 days for muscle relaxants) at maximum therapeutic doses within the past 365 days. Submission of chart notes documenting trial dates and dosage is required in the absence of electronic prescription claims history
- You have tried and failed **TWO** oral short-acting opioid analgesics (e.g., codeine/APAP, hydrocodone/APAP, hydromorphone, morphine sulfate IR, oxycodone/APAP, oxycodone IR)
- You are unable to swallow tablets
- You have tried crushed Prolate (oxycodone/acetaminophen) tablets

Please note that additional criteria apply for concurrent use of opioid analgesics and benzodiazepines, including submission of signed prescriber attestation on a state-mandated fax form.

Our guideline for **SHORT-ACTING OPIOID ANALGESICS**, reviewed for QDOLO (tramadol oral solution), requires **ALL** of the following criteria to be met:

- You have a diagnosis of chronic moderate to severe pain
- Documentation of one non-pharmacological ancillary treatment for pain [such as thermotherapy, cryotherapy, massage therapy, transcutaneous electrical nerve stimulation (TENS), spinal cord stimulation (SCS), physical therapy] of 6 weeks duration within the past 2 years unless contraindicated. Documentation must include dates of therapy.
- You have tried and failed **TWO** non-opioid pharmacological ancillary treatments prescribed for pain from different drug classes (e.g., NSAIDs, acetaminophen, anticonvulsants, antidepressants) for at least 4 weeks (7 days for muscle relaxants) at maximum therapeutic doses within the past 365 days. Submission of chart notes documenting trial dates and dosage is required in the absence of electronic prescription claims history.
- You are 12 years of age or older
- You are unable to swallow tablets
- You have tried crushed tramadol tablets

Please note that additional criteria apply for concurrent use of opioid analgesics and benzodiazepines, including submission of signed prescriber attestation on a state-mandated fax form.

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SHORT-ACTING OPIOID ANALGESICS

INITIAL CRITERIA (CONTINUED)

Our guideline for **SHORT-ACTING OPIOID ANALGESICS** for patients with post-surgical pain (pain after surgery) or pain related to an acute (sudden and severe) injury requires your prescriber has provided **BOTH** of the following:

- The date of surgery/injury
- Documentation of a clear plan for opioid dose tapering (slow decrease in dose) and discontinuation

Please note that additional criteria apply for concurrent use of opioid analgesics and benzodiazepines, including submission of signed prescriber attestation on a state-mandated fax form.

Our guideline for **SHORT-ACTING OPIOID ANALGESICS** for patients with moderate to severe chronic pain requires that **BOTH** of the following rules are met:

- Your provider documented the trial of one non-drug treatment (for example, thermotherapy, cryotherapy, massage therapy, transcutaneous electrical nerve stimulation (TENS), spinal cord stimulation (SCS), physical therapy) of 6 weeks duration within the past 2 years unless contraindicated. Documentation must include dates of therapy.
- You have tried **TWO** non-opioid drug treatments prescribed for pain from different drug classes (for example, non-steroidal anti-inflammatory drugs, acetaminophen, anticonvulsants, antidepressants) for at least 4 weeks (7 days for muscle relaxants) at maximum therapeutic doses within the past 365 days. Chart notes indicating dates of trial and dosage is required in the absence of electronic prescription claims history

Exceptions may be granted for patients with cancer, sickle cell disease, other terminal diagnosis associated with significant pain, or those receiving opioids as part of a palliative care (medical care for symptoms related to diagnosis) plan.

Please note that additional criteria apply for concurrent use of opioid analgesics and benzodiazepines, including submission of signed prescriber attestation on a state-mandated fax form.

Our guideline named **SHORT-ACTING OPIOID ANALGESICS** for concurrent use of more than one short-acting opioid requires that you meet **ALL** of the following criteria:

- You have a diagnosis of moderate to severe pain
- You have a pain that is not responding to treatment despite concurrent (used at the same time) therapy with one short-acting opioid and one long-acting opioid
- Your prescriber has consulted with you regarding the risks of opioid therapy and developed a pain management plan with clear treatment goals

Exceptions may be granted for patients with cancer, sickle cell disease, other terminal diagnosis associated with significant pain, or those receiving opioids as part of a palliative care (medical care for symptoms related to diagnosis) plan.

Please note that additional criteria apply for concurrent use of opioid analgesics and benzodiazepines, including submission of signed prescriber attestation on a state-mandated fax form.

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SHORT-ACTING OPIOID ANALGESICS

INITIAL CRITERIA (CONTINUED)

Our guideline for **SHORT-ACTING OPIOID ANALGESICS** for patients with claims in history for benzodiazepines requires that your doctor submit the required fax form documenting **ALL** of the following:

- The diagnosis contributing to the need for benzodiazepine therapy and previous therapy attempted, including dates and doses of prior therapies, documented in chart notes
  - For generalized anxiety disorder, one of the following is required: Selective serotonin reuptake inhibitor (SSRI, such as sertraline or citalopram), serotonin-noradrenaline reuptake inhibitor (SNRI, such as duloxetine or venlafaxine), or pregabalin (generic for Lyrica)
  - For panic disorder, one of the following is required: SSRI or tricyclic antidepressant (TCA, such as amitriptyline or nortriptyline)
  - For social anxiety disorder (SAD), a trial of an SSRI is required
  - For obsessive compulsive disorder (OCD), a trial of an SSRI is required
  - For post-traumatic stress disorder (PTSD), one of the following is required: mirtazapine, paroxetine, amitriptyline, or phenelzine
  - For insomnia, one of the following is required: ramelteon or a sedating antidepressant (for example, trazodone, amitriptyline, doxepin, mirtazapine)
- The diagnosis contributing to the need for opioid analgesic therapy and previous therapy attempted, including dates and doses of prior therapies
  - For short term opioid therapy (up to 30 days) requested for post-surgical pain (pain after surgery) or pain related to an acute (sudden and severe) injury, the date of surgery or injury is required AND your provider must provide documentation of a clear plan for opioid dose tapering (slowly lowering the dosage) and discontinuation
  - For chronic opioid therapy (greater than 30 days), a trial of one non-drug treatment (for example, thermotherapy, cryotherapy, massage therapy, transcutaneous electrical nerve stimulation (TENS), spinal cord stimulation (SCS), physical therapy) for 6 weeks duration within the past 2 years unless there is a medical reason why you cannot (contraindication) AND **TWO** non-opioid drug treatments prescribed for pain from different drug classes (for example, non-steroidal anti-inflammatory drugs, acetaminophen, anticonvulsants, antidepressants) for at least 4 weeks (7 days for muscle relaxants) at maximum therapeutic doses within the past 365 days is required. Chart notes indicating doses and dates of therapy are required in the absence of electronic prescription claims history
  - For a diagnosis of moderate to severe cancer-related pain, pain related to sickle cell disease, or pain in patients receiving palliative care, no additional criteria applies

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SHORT-ACTING OPIOID ANALGESICS

INITIAL CRITERIA (CONTINUED)

- Your prescriber has signed an attestation as to **ALL** of the following:
  - Your provider will regularly review your controlled substance utilization contained within INSPECT
  - You have been educated about the risks of using benzodiazepines and opioid analgesics together at the same time
  - Both you and your provider accept the of using benzodiazepines and opioid analgesics together at the same time

Please note that additional criteria apply for the benzodiazepine day supply limits. Your benzodiazepine prescription claim must not be greater than a 15-day supply of medication. You cannot receive more than 30 days' supply of benzodiazepine medication in the past 90 days. The current request for medication is also counted as a part of the 30 days' supply in the past 90 days.

Our guideline named **SHORT-ACTING OPIOID ANALGESICS** for patients with claims in history for Lybalvi (olanzapine/samidorphan) requires that you have not taken Lybalvi (olanzapine/samidorphan) less than or equal to 5 days prior to initiating opioid therapy.

RENEWAL CRITERIA

Our guideline for **SHORT-ACTING OPIOID ANALGESICS** does not permit concurrent use with carisoprodol-containing products.

Our guideline named **SHORT-ACTING OPIOID ANALGESICS** for renewal of opioid analgesic therapy requires that you meet **ALL** of the following rules:

- Opioid therapy has resulted in a meaningful improvement in your pain and/or function
- Your doctor has developed an updated pain management plan with clear treatment goals
- A risk assessment has been performed including review of the state prescription drug monitoring program (PDMP) data (for example, INSPECT)
- Adherence to the prescribed opioid regimen has been periodically assessed (for example, urine drug screen, pill counts)

In addition, requests for renewal of concurrent use (used at the same time with) of more than one short-acting opioid requires you to meet **ALL** of the following rules:

- You have a diagnosis of moderate to severe pain
- You have a pain that is not responding to treatment despite concurrent (used at the same time) therapy with one short-acting opioid and one long-acting opioid (such as, generic MS Contin)
- Your prescriber has consulted with you regarding the risks of opioid therapy and developed a pain management plan with clear treatment goals

Please note that additional criteria apply for concurrent use of opioid analgesics and benzodiazepines, including submission of signed prescriber attestation on a state-mandated fax form.

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RENEWAL CRITERIA (CONTINUED)

Our renewal guideline for **SHORT-ACTING OPIOID ANALGESICS** requires your provider to verify that you meet **ALL** of the following criteria:

- Opioid therapy has resulted in a meaningful improvement in your pain and/or function
- Your prescriber has developed an updated pain management plan with clear treatment goals
- Risk assessment has been performed including review of the state prescription drug monitoring program (PDMP) data (such as, INSPECT)
- Adherence to prescribed opioid regimen has been periodically assessed (for example, urine drug screen, pill counts)

Please note that additional criteria apply for concurrent use of opioid analgesics and benzodiazepines, including submission of signed prescriber attestation on a state-mandated fax form.

Our renewal guideline for **SHORT-ACTING OPIOID ANALGESICS** for patients with claims in history for benzodiazepines requires that the prescriber submit the required fax form documenting **ALL** of the following:

- The diagnosis contributing to the need for benzodiazepine therapy and previous therapy attempted, including dates and doses of prior therapies
  - For generalized anxiety disorder, one of the following is required: Selective serotonin reuptake inhibitor (SSRI, such as sertraline or citalopram), serotonin-noradrenaline reuptake inhibitor (SNRI, such as duloxetine or venlafaxine), or pregabalin (generic for Lyrica)
  - For panic disorder, one of the following is required: SSRI or tricyclic antidepressant (TCA, such as amitriptyline or nortriptyline)
  - For social anxiety disorder (SAD), a trial of an SSRI is required
  - For obsessive compulsive disorder (OCD), a trial of an SSRI is required
  - For post-traumatic stress disorder (PTSD), one of the following is required: mirtazapine, paroxetine, amitriptyline, or phenelzine
  - For insomnia, one of the following is required: ramelteon or a sedating antidepressant (for example, trazodone, amitriptyline, doxepin, mirtazapine)
- The diagnosis contributing to the need for renewal of the requested opioid analgesic therapy
- Your prescriber has signed an attestation as to **ALL** of the following:
  - Your provider will regularly review your controlled substance utilization contained within INSPECT
  - You have been educated about the risks of using benzodiazepines and opioid analgesics together at the same time
  - Both you and your provider accept the of using benzodiazepines and opioid analgesics together at the same time

Please note that additional criteria apply for the benzodiazepine day supply limits. Your benzodiazepine prescription claim must not be greater than a 15-day supply of medication. You cannot receive more than 30 days' supply of benzodiazepine medication in the past 90 days. The current request for medication is also counted as a part of the 30 days' supply in the past 90 days.

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SHORT-ACTING OPIOID ANALGESICS

RENEWAL CRITERIA (CONTINUED)

Our guideline named **SHORT-ACTING OPIOID ANALGESICS** for patients with claims in history for Lybalvi (olanzapine/samidorphan) requires that you have not taken Lybalvi (olanzapine/samidorphan) less than or equal to 5 days prior to initiating opioid therapy.

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SHORT-ACTING OPIOID ANALGESICS

RATIONALE

To ensure opioid analgesics are used according to FDA approved indications with patient safety in mind, and to encourage the use of more cost-effective analgesics.

From 2000-2014, almost half a million people died due to drug overdose, with 2014 being the highest year for deaths on record. In that time, the number of opioids prescribed, as well as the number of opioid overdoses, has risen exponentially. At least half of all opioid overdose deaths involve a prescription opioid. Indiana was among the states that had a statistically significant increase of overdose deaths from 2013-2014.

According to recent research, the opioid epidemic has a disproportionate impact on Medicaid beneficiaries. Medicaid patients are prescribed opioids at double the rate of non-Medicaid patients, and are subsequently at much higher risk of prescription opioid overdose.
Improving the way that opioids are prescribed can ensure safer and more effective pain treatment, and reduce the addiction, misuse, abuse, and overdose of these drugs. These guidelines are to ensure that the use of opioids is consistent with their FDA approved indications, and to initiate action combating the current opioid epidemic.

Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 morphine milligram equivalents (MME)/day such as 60mg oral morphine/day, 25mcg transdermal fentanyl/hour, 40mg oral oxycodone/day, 15mg oral hydromorphone/day, 60mg oral hydrocodone/day, 400mg oral codeine/day, or an equianalgesic dose of another opioid for a week or longer.

Buprenorphine Conversion Table

Buprenorphine Product	Oral MME Conversion Factor
Belbuca buccal film (mcg/hr)	0.03
buprenorphine, tablet or film for opioid use disorder	30
Butrans transdermal patch (mcg/hr)	12.6

Example: 900 mcg buprenorphine buccal film x (60 films/30 days) x 0.03=54 MME/day
Example: 5 mcg buprenorphine patch x (4 patches/28 days) x 12.6= 9 MME/day

Fentanyl Conversion Table

Fentanyl Product	Oral MME Conversion Factor
fentanyl buccal or SL tablets, or lozenge/troche (mcg)	0.13
fentanyl film or oral spray (mcg)	0.18
fentanyl nasal spray (mcg)	0.16
fentanyl patch (mcg)	7.2

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RATIONALED (CONTINUED)

Opioid Conversion Table

Drug	Oral MME Conversion Factor (1mg of drug to mg morphine)	60mg Morphine Equivalent Dose
benzhydrocodone	1.22	50mg
butorphanol	7	8.5mg
codeine	0.15	400mg
dihydrocodeine	0.25	240mg
hydrocodone	1	60mg
hydromorphone HCl	4	15mg
levorphanol tartrate	11	5.5mg
meperidine HCl	0.1	600mg
morphine	1	60mg
oxycodone HCl	1.5	40mg
oxymorphone HCl	3	20mg
pentazocine HCl	0.37	162mg
tapentadol HCl	0.4	150mg
tramadol HCl	0.1	600mg

Methadone Conversion Table

Methadone daily dose (mg/day)	Oral MME Conversion Factor (1mg of drug to mg morphine)	60mg Morphine Equivalent Dose
>0, <= 20	4	20mg
>20, <=40	8	7.5mg
>40, <=60	10	6mg
>60	12	5mg

Opioid Usage in Chronic Pain Management
Per systematic review in the CDC Guideline for Prescribing Opioids for Chronic Pain, long-term (≥ 1 year) efficacy of opioids in management of chronic pain, function, or quality of life is not established. Most randomized controlled trials present effectiveness within 6 weeks or less. Conversely, significant risks of adverse events are present with chronic opioid therapy, including opioid abuse and dependence, social role withdrawal, and increased risk of CNS depression, and withdrawal emergencies.

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RATIONALED (CONTINUED)

The CDC also recommends re-evaluating and re-establishing treatment goals, including realistic expectation for pain and function, as well as discontinuation strategies when benefits do not outweigh risks. The guideline provides the following recommendations for opioid selection, dosage, duration, follow-up and discontinuation:

- Immediate-release (IR) opioids are preferred over extended-release (ER) forms.
- The lowest effective dosage is preferred with initial opioid use. Caution is warranted at any dose and reassessing benefits and risks is recommended for 50 morphine milligram equivalents (MME) daily or more. 90 MME daily or more should be avoided if possible.
- Within 1 to 4 weeks of therapy, clinicians should evaluate benefits and harms of using opioids to treat chronic pain. Therapy continuation should be evaluated every 3 months or sooner. If benefits do not outweigh harms to continue opioid therapy, other therapies should be optimized and opioid tapering/discontinuation should be considered and encouraged.

Assessing Risk and Addressing Harms of Opioid Use

- Prior to and throughout opioid therapy, adverse events should be evaluated periodically. Factors that increase risk for opioid overdose include history of overdose or substance use disorder, 50 MME daily or more, and concurrent benzodiazepine use.
- Prescription drug monitoring program (PDMP) data (e.g., RXINSPECT) are useful to monitor total opioid dosage. PDMP data is helpful for initial and periodic opioid usage evaluations.
- Prescribing opioids and benzodiazepines concurrently should be avoided.
- For patients with substance use disorder, evidence-based treatment (medication-assisted and behavioral therapy) is recommended.

Analysis performed by the US Department of Health and Human Services Center for Disease Control and Prevention (CDC) determined the risk of harm to individuals increases as their opioid dose increases and as their length of opioid therapy increases. For example:

- Individuals taking opioid doses > 50 morphine milligram equivalents (MMEs) per day had twice the risk of death from an overdose than those taking < 20 MMEs per day.
- Individuals taking opioid doses > 90 (MMEs) per day had 10 times the risk of death from an overdose than those taking < 20 MMEs per day.
- Individuals taking an opioid for > 3 months (even at low doses) had 15 times the risk of addiction to those taking opioids for < 3 months.

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SHORT-ACTING OPIOID ANALGESICS

APPENDIX 1: BENZODIAZEPINE/OPIOID CONCURRENT USE FAX FORM
INDIANA HEALTH COVERAGE PROGRAMS (IHCP) PHARMACY BENEFIT
BENZODIAZEPINE AND OPIOID CONCURRENT THERAPY
PRIOR AUTHORIZATION REQUEST FORM

MDwise
Fax to: (858) 790-7100
c/o MedImpact Healthcare Systems, Inc.
Attn: Prior Authorization Department
10181 Scripps Gateway Court, San Diego, CA 92131
Phone: 1-800-788-2949

Today's Date
☐☐ / ☐☐ / ☐☐☐☐

Note: This form must be completed by the prescribing provider.
****All sections must be completed or the request will be denied.****

Patient's Medicaid # ☐☐☐☐☐☐☐☐☐☐☐☐	**Date of Birth** ☐☐ / ☐☐ / ☐☐☐☐
Patient's Name	**Prescriber's Name**
Prescriber's IN License # ☐☐☐☐☐☐☐☐	**Specialty**
Prescriber's NPI # ☐☐☐☐☐☐☐☐☐☐	**Prescriber's Signature: **Required below within attestation section.****
Return Fax # ☐☐☐ - ☐☐☐ - ☐☐☐☐	**Return Phone #** ☐☐☐ - ☐☐☐ - ☐☐☐☐

PA is required for the following:

- **Claim(s) for new opioid(s) to be used concurrently with benzodiazepines and exceeding 7 days within a 180-day period.**
- **Claim(s) for new benzodiazepine(s) to be used concurrently with opioids and exceeding 7 days of therapy within a 180-day period and/or exceeding established benzodiazepine/opioid concurrent therapy quantity limits (see Sedative Hypnotics/Benzodiazepine PA criteria).**

Benzodiazepine Agent(s)	Prescriber Name*	Quantity	Dosage Regimen/Duration

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Opioid Agent(s)	Prescriber Name*	Quantity	Dosage Regimen/Duration

***NOTE: If prescribers of the opioid(s) and benzodiazepine(s) are not the same, please answer the following questions:**

- **Are you requesting PA for: Benzodiazepine Agent(s) ☐ Opioid Agent(s) ☐ Both ☐**
- **Is/are the other prescriber(s) aware of the request for concurrent therapy? □ Yes □ No**
- **Has/have the other prescriber(s) been consulted about the risks associated with concurrent therapy, and do all prescribers involved believe continuing with concurrent therapy is warranted, given the risks associated with concurrent use? □ Yes □ No**

PA Requirements:

Patient diagnosis/diagnoses for use of benzodiazepine therapy:

Prior therapies attempted for the above diagnosis/diagnoses (submission of chart notes required in absence of claims history):

Drug Therapy	Dosage Regimen	Dates of Utilization

Do you plan to continue benzodiazepine therapy for this patient? □ Yes □ No
If no, please provide withdrawal plan:

Patient diagnosis/diagnoses for use of opioid therapy:

Prior therapies (both drug and non-drug) attempted for the above diagnosis/diagnoses (submission of chart notes required in absence of claims history):

Drug/Non-Drug Therapy	Dosage Regimen	Dates of Utilization	Reason for Discontinuation or Failure

Do you plan to continue opioid therapy for this patient? □ Yes □ No
If no, please provide withdrawal plan:

Attestation:

I, _____, hereby attest to the following:
(Prescriber Name)

- **The patient's INSPECT report has been evaluated and continues to be evaluated on a regular basis (Per IC 35-48-7-11.1, DO NOT attach a copy of the INSPECT report to this PA request).**
- **I have educated the patient in regards to the risks of concurrent utilization of benzodiazepine and opioid therapy, and the patient accepts these risks.**
- **If applicable, I have consulted other prescriber(s) involved in concurrent therapy and all prescribers involved agree to pursue concurrent opioid and benzodiazepine therapy for this patient.**
- **I acknowledge, as the prescriber initiating or maintaining concurrent benzodiazepine and opioid therapy, the risk of adverse event(s), including respiratory depression, coma, and death, associated with concurrent utilization.**

Prescriber Signature:_____

****Prescriber signature is required for consideration. Electronic or stamped signature will not be accepted.****

CONFIDENTIAL INFORMATION
This facsimile transmission (and attachments) may contain protected health information from the Indiana Health Coverage Programs (IHCP), which is intended only for the use of the individual or entity named in this transmission sheet. Any unintended recipient is hereby notified that the information is privileged and confidential, and any use, disclosure, or reproduction of this information is prohibited.

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Created: 09/19
Effective: 06/13/2022 Client Approval: 05/26/22 P&T Approval: N/A

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PRIOR AUTHORIZATION GUIDELINES

SILTUXIMAB

Generic	Brand	HICL	GCN	Exception/Other
SILTUXIMAB	SYLVANT	41101		

GUIDELINES FOR USE

Our guideline for **SILTUXIMAB** requires a diagnosis of multicentric Castleman's disease (MCD) and that the patient is negative for both human immunodeficiency virus (HIV) and human herpesvirus-8 (HHV-8).

RATIONALE

Promote appropriate utilization of Sylvant based on FDA approved indication.

Castleman's disease (CD), also known as angiofollicular lymph node hyperplasia, is comprised of two distinct diseases: unicentric and multicentric. Unicentric CD usually affects a single group of lymph nodes and removal of the mass cures 90-95% of cases. Multicentric CD (MCD) involves more than a single group of lymph nodes and can affect other organs containing lymphoid tissue. Patients with MCD often have serious infections, severe fatigue, night sweats, recurrent fever, and weight loss. Patients may also experience peripheral edema, anemia, hypoalbuminemia, peripheral neuropathy and hepatosplenomegaly. CD is not officially a cancer, but the multicentric disease form is more aggressive than unicentric CD and roughly 20% of patients with MCD develop lymphoma.

Because MCD is a rare disease and most cases are seen in patients who are HIV/HHV-8 positive, the utilization of Sylvant is expected to be relatively minimal given its specific FDA indication for HIV/HHV-8 negative MCD patients.

DOSAGE

Sylvant 11 mg/kg is given over 1 hour as an intravenous infusion administered every 3 weeks until treatment failure (defined as disease progression based on increase in symptoms, radiologic progression or deterioration in performance status) or unacceptable toxicity.

FDA APPROVED INDICATIONS

Sylvant is indicated for the treatment of patients with Multicentric Castleman's disease (MCD) who are human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative.

Limitation of Use: Sylvant was not studied in patients with MCD who are HIV positive or HHV-8 positive because Sylvant did not bind to virally produced IL-6 in a nonclinical study.

REFERENCES

- Sylvant [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc; May 2014

Created: 10/15
Effective: 11/12/15 Client Approval: 10/19/15 P&T Approval: 10/15

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

SIMVASTATIN 80MG

Generic	Brand	HICL	GCN	Exception/Other
EZETIMIBE/SIMVASTATIN	VYTORIN		23126	
SIMVASTATIN	ZOCOR, SIMVASTATIN		26535	

GUIDELINES FOR USE

Our guideline named **SIMVASTATIN 80MG (VYTORIN, ZOCOR)** requires the following rule(s) be met for approval:
A. You have been taking the medication for at least 12 months

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RATIONALE
To ensure safe and appropriate use of simvastatin per approved indication and dosing.

FDA APPROVED INDICATIONS
Simvastatin is an HMG-CoA reductase inhibitor indicated:
- To reduce the risk of total mortality by reducing risk of coronary heart disease death, non-fatal myocardial infarction and stroke, and the need for coronary and non-coronary revascularization procedures in adults with established coronary heart disease, cerebrovascular disease, peripheral vascular disease, and/or diabetes, who are at high risk of coronary heart disease events.
- As an adjunct to diet to reduce low-density lipoprotein cholesterol (LDL-C):
  - In adults with primary hyperlipidemia.
  - In adults and pediatric patients aged 10 years and older with heterozygous familial hypercholesterolemia (HeFH).
- As an adjunct to other LDL-C-lowering therapies to reduce LDL-C in adults with homozygous familial hypercholesterolemia (HoFH).
- As an adjunct to diet for the treatment of adults with:
  - Primary dysbetalipoproteinemia.
- Hypertriglyceridemia.

DOSAGE AND ADMINISTRATION
The maximum recommended dosage of simvastatin is 40 mg once daily. Due to the increased risk of myopathy including rhabdomyolysis, the simvastatin 80 mg daily dosage is restricted to patients who have been taking simvastatin 80 mg daily chronically (e.g., for 12 months or more) without evidence of muscle toxicity.
- Adults: Recommended dosage is 20 mg to 40 mg once daily.
- Pediatric Patients Aged 10 Years and Older with HeFH: Recommended dosage is 10 mg to 40 mg once daily.

REFERENCES

- Vytorin [Prescribing Information]. Whitehouse Station, NJ: Merck & Co., Inc.; June 2021.
- Zocor [Prescribing Information]. Whitehouse Station, NJ: Merck & Co., Inc.; May 2022.

Created: 12/22
Effective: 12/19/22 Client Approval: 12/05/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

SIPONIMOD

Generic	Brand	HICL	GCN	Exception/Other
SIPONIMOD	MAYZENT	45670		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named **SIPONIMOD (Mayzent)** requires the following rule(s) be met for approval:

A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), to include clinically isolated syndrome (symptoms occur once), relapsing-remitting disease (symptoms go return and go away), or active secondary progressive disease (advanced disease)
B. You are 18 years of age or older
C. You have CYP2C9 (type of enzyme) 1/1, 1/2, 2/2, 1/3, or 2/3 genotype

RENEWAL CRITERIA

Our guideline named **SIPONIMOD (Mayzent)** requires the following rule(s) be met for renewal:

A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), to include clinically isolated syndrome (symptoms occur once), relapsing-remitting disease (symptoms return and go away), or active secondary progressive disease (advanced disease)
B. You have demonstrated a clinical benefit compared to pre-treatment baseline
C. You do not have lymphopenia (low levels of a type of white blood cell)
D. You have CYP2C9 (type of enzyme) 1/1, 1/2, 2/2, 1/3, or 2/3 genotype

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

SIPONIMOD

RATIONALE
To ensure safe and appropriate use of siponimod per approved indication and dosing.

FDA APPROVED INDICATIONS
Mayzent (siponimod) is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

DOSAGE AND ADMINISTRATION
Recommended Dosage in Patients With CYP2C9 Genotypes *1/*1, *1/*2, or *2/*2
Initiate Mayzent with a 5-day titration, as shown in Table 1. After treatment titration, the recommended maintenance dosage of Mayzent is 2 mg taken orally once daily starting on Day 6.

Table 1: Dose Titration Regimen to Reach Mayzent 2 mg Maintenance Dosage

Day	Titration Dose	Titration Regimen
Day 1	0.25 mg	1 x 0.25 mg
Day 2	0.25 mg	1 x 0.25 mg
Day 3	0.50 mg	2 x 0.25 mg
Day 4	0.75 mg	3 x 0.25 mg
Day 5	1.25 mg	5 x 0.25 mg

Recommended Dosage in Patients With CYP2C9 Genotypes *1/*3 or *2/*3
Initiate Mayzent with a 4-day titration, as shown in Table 2. After treatment titration, the recommended maintenance dosage of Mayzent is 1 mg taken orally once daily starting on Day 5.

Table 2: Dose Titration Regimen to Reach Mayzent 1 mg Maintenance Dosage

Day	Titration Dose	Titration Regimen
Day 1	0.25 mg	1 x 0.25 mg
Day 2	0.25 mg	1 x 0.25 mg
Day 3	0.50 mg	2 x 0.25 mg
Day 4	0.75 mg	3 x 0.25 mg

REFERENCES
Mayzent [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2022.

Created: 06/19
Effective: 05/09/22 Client Approval: 04/21/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

SODIUM/ CALCIUM/ MAG/ POT OXYBATE

Generic	Brand	HICL	GCN	Exception/Other
SODIUM, CALCIUM, MAG, POT OXYBATE	XYWAV	46743		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SODIUM/ CALCIUM/ MAG/ POT OXYBATE (Xywav)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Idiopathic hypersomnia (IH: a type of sleep disorder)
   2. Narcolepsy with cataplexy (sudden and uncontrollable muscle weakness or paralysis associated with a sleep disorder) and/or excessive daytime sleepiness in narcolepsy (sleep disorder)

B. **If you have idiopathic hypersomnia, approval also requires:**
   1. You are 18 years of age or older

C. **If you have narcolepsy with cataplexy and/or excessive daytime sleepiness, approval also requires:**
   1. You are 7 years of age or older

RENEWAL CRITERIA

Our guideline named **SODIUM/ CALCIUM/ MAG/ POT OXYBATE (Xywav)** requires the following rule(s) be met for renewal:

A. You have history of paid claim(s) for the requested medication in the past 90 days
B. You have a previous authorization on file for the requested medication
C. Your prescriber has submitted documentation of an attempt to decrease dose OR that you have tried and failed an alternative therapy within the past year
D. Your prescriber has submitted documentation indicating you continue to benefit from the medication (reduction in frequency of cataplexy, reduction in symptoms of excessive daytime sleepiness, etc.) without significant adverse events

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

SODIUM/CALCIUM/MAG/POT OXYBATE

RATIONALE
Promote prudent prescribing of agents for the treatment of narcolepsy.

INDICATIONS
Xywav is a central nervous system depressant indicated for the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy and for idiopathic hypersomnia (IH) in adults.

DOSING
The recommended dosage for Xywav is as follows:

- Adults: The recommended starting dosage is 4.5 grams (g) per night administered orally, divided into two doses: 2.25 g at bedtime and 2.25 g taken 2.5 to 4 hours later. Increase the dosage by 1.5 g per night at weekly intervals (additional 0.75 g at bedtime and 0.75 g taken 2.5 to 4 hours later) to the effective dosage range of 6 g to 9 g per night orally. Doses higher than 9 g per night have not been studied and should not ordinarily be administered.
- Children: Xywav is administered orally twice nightly. The recommended starting pediatric dosage, titration regimen, and maximum total nightly dosage are based on patient weight, as specified in the Table below. The dosage may be gradually titrated based on efficacy and tolerability.

Patient Weight	**Initial Dosage**		**Maximum Weekly Dosage**		**Maximum Recommended Dosage**	
	Take at Bedtime	**Take 2.5 to 4 Hours Later**	**Take at Bedtime**	**Take 2.5 to 4 Hours Later**	**Take at Bedtime**	**Take 2.5 to 4 Hours Later**
<20 kg	There is insufficient information to provide specific dosing recommendations for patients who weigh less than 20 kg.					
20 kg to <30 kg	≤1 g	≤1 g	0.5 g	0.5 g	3 g	3 g
30 kg to <45 kg	≤1.5 g	≤1.5 g	0.5 g	0.5 g	3.75 g	3.75 g
≥45 kg	≤2.25 g	≤2.25 g	0.75 g	0.75 g	4.5 g	4.5 g

REFERENCES
- Xywav [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; August 2021.

Created: 10/20
Effective: 12/01/21 Client Approval: 11/01/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

SODIUM OXYBATE

Generic	Brand	HICL	GCN	Exception/Other
SODIUM OXYBATE	XYREM	12346		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SODIUM OXYBATE (Xyrem)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Narcolepsy (sleep disorder) with cataplexy (sudden and uncontrollable muscle weakness or paralysis associated with a sleep disorder) and/or excessive daytime sleepiness
   2. Fibromyalgia

B. You are 7 years of age or older

C. **If you have fibromyalgia, approval also requires:**
   1. You have tried or have a contraindication (medical reason why you cannot use) **ALL** of the following:
      a. Amitriptyline
      b. Serotonin-norepinephrine reuptake inhibitor (SNRI) (e.g., duloxetine, venlafaxine)
      c. Selective serotonin reuptake inhibitor (SSRI) (e.g., fluoxetine)
      d. Gabapentin or pregabalin
      e. NSAIDs and acetaminophen

RENEWAL CRITERIA

Our guideline for **SODIUM OXYBATE (Xyrem)** requires both of the following for renewal:

A. You have a previous authorization on file for the requested medication
B. You have history of paid claims for 90 of the past 120 days for the requested medication

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SODIUM OXYBATE

RATIONALE
Promote prudent prescribing of agents for the treatment of narcolepsy.

INDICATIONS
Xyrem is a central nervous system depressant indicated for the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy

DOSING
The recommended dosage for Xyrem is as follows:

- Adults: The recommended starting dosage is 4.5 grams (g) per night administered orally, divided into two doses: 2.25 g at bedtime and 2.25 g taken 2.5 to 4 hours later. Increase the dosage by 1.5 g per night at weekly intervals (additional 0.75 g at bedtime and 0.75 g taken 2.5 to 4 hours later) to the effective dosage range of 6 g to 9 g per night orally. Doses higher than 9 g per night have not been studied and should not ordinarily be administered.
- Children: Xyrem is administered orally twice nightly. The recommended starting pediatric dosage, titration regimen, and maximum total nightly dosage are based on patient weight, as specified in the Table below. The dosage may be gradually titrated based on efficacy and tolerability.

Patient Weight	**Initial Dosage**		**Maximum Weekly Dosage**		**Maximum Recommended Dosage**	
	Take at Bedtime	**Take 2.5 to 4 Hours Later**	**Take at Bedtime**	**Take 2.5 to 4 Hours Later**	**Take at Bedtime**	**Take 2.5 to 4 Hours Later**
<20 kg	There is insufficient information to provide specific dosing recommendations for patients who weigh less than 20 kg.					
20 kg to <30 kg	≤1 g	≤1 g	0.5 g	0.5 g	3 g	3 g
30 kg to <45 kg	≤1.5 g	≤1.5 g	0.5 g	0.5 g	3.75 g	3.75 g
≥45 kg	≤2.25 g	≤2.25 g	0.75 g	0.75 g	4.5 g	4.5 g

REFERENCES
- Xyrem [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; September 2020.

Created: 03/20
Effective: 11/16/20 Client Approval: 10/27/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

SODIUM PHENYLBUTYRATE ORAL PELLETS

Generic	Brand	HICL	GCN	Exception/Other
SODIUM PHENYLBUTYRATE	PHEBURANE		36733	

GUIDELINES FOR USE

Our guideline named **SODIUM PHENYLBUTYRATE ORAL PELLETS (Pheburane)** requires the following rule(s) be met for approval:

A. You have urea cycle disorder (a genetic disorder that causes high ammonia levels in the blood)
B. The requested medication will be used as adjunctive (add-on) therapy
C. You are unable to swallow the tablet formulation
D. You had a trial and failure of (drug did not work) or contraindication to (harmful for) generic sodium phenylbutyrate oral powder

RATIONALE

Ensure appropriate criteria are used for the management of requests for Pheburane according to approved indication, dosing, and national guidelines.

FDA APPROVED INDICATIONS

Pheburane is indicated as adjunctive therapy to standard of care, which includes dietary management, for the chronic management of adult and pediatric patients with urea cycle disorders (UCDs), involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC) or argininosuccinic acid synthetase (AS).

DOSAGE & ADMINISTRATION

The recommended dosage of Pheburane (measured as sodium phenylbutyrate) for patients with urea cycle disorders is:

- Patients weighing less than 20 kg: 450 to 600 mg/kg/day of sodium phenylbutyrate orally. Divide the calculated total daily dose into three to six doses. Administer as three to six divided doses and take with food.
- Patients weighing greater than or equal to 20 kg: 9.9 to13 g/m^2/day of sodium phenylbutyrate orally. Divide the calculated total daily dose into three to six doses. Administer as three to six divided doses and take with food.

The maximum dosage is 20 grams per day. Combine Pheburane with dietary protein restriction and, in some cases, amino acid supplementation (e.g., essential amino acids, arginine, citrulline, and protein-free calorie supplements).

REFERENCES

Pheburane [Prescribing Information]. Bryn Mawr, PA: Medunik USA, Inc.; June 2022.

Created: 10/22
Effective: 11/21/22 Client Approval: 10/21/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

SOLRIAMFETOL

Generic	Brand	HICL	GCN	Exception/Other
SOLRIAMFETOL	SUNOSI	45666		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named **SOLRIAMFETOL (Sunosi)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
1. Narcolepsy
2. Obstructive sleep apnea

B. **If you have narcolepsy, approval also requires** that you are greater than or equal to 18 years of age

C. **If you have obstructive sleep apnea, approval also requires:**
1. You are greater than or equal to 18 years of age
2. You have had a trial of modafinil or armodafinil in the previous 365 days, unless contraindicated

RENEWAL CRITERIA

Our guideline for **SOLRIAMFETOL (Sunosi)** renewal requires that the patient has a previous authorization on file for the requested medication **AND** there is history of paid claims for 90 of the past 120 days.

RATIONALE
Promote prudent prescribing of agents for the treatment of narcolepsy.

INDICATIONS
Sunosi is a dopamine and norepinephrine reuptake inhibitor (DNRI) indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA).

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SOLRIAMFETOL

INIDICATIONS (CONTINUED)

DOSING

- Narcolepsy: Initiate Sunosi at 75 mg once daily in adults with narcolepsy. The recommended dose range for Sunosi is 75 mg to 150 mg once daily. Based on efficacy and tolerability, the dosage of Sunosi may be doubled at intervals of at least 3 days. The maximum recommended dose is 150 mg once daily. Dosages above 150 mg daily do not confer increased effectiveness sufficient to outweigh dose-related adverse reactions.

- OSA: Initiate Sunosi at 37.5 mg once daily in adults with OSA. The recommended dosage range for Sunosi is 37.5 mg to 150 mg once daily. Based on efficacy and tolerability, the dosage of Sunosi may be doubled at intervals of at least 3 days. The maximum recommended dosage is 150 mg once daily. Dosages above 150 mg daily do not confer increased effectiveness sufficient to outweigh dose-related adverse reactions.

REFERENCES

- Sunosi [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; June 2019.

Created: 03/20
Effective: 07/27/20 Client Approval: 07/16/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN

Generic	Brand	HICL	GCN	Exception/Other
SOMATROPIN	GENOTROPIN, HUMATROPE, NORDITROPIN FLEXPRO, NUTROPIN AQ, NUTROPIN AQ NUSPIN, OMNITROPE, SAIZEN, SEROSTIM, ZOMACTON ZORBTIVE	02824		

****Please use the criteria for the specific drug requested.****

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

SEROSTIM

Our guideline for **SOMATROPIN (Serostim)** requires the following rule(s) be met for approval:

A. You have a diagnosis of HIV (human immunodeficiency virus) wasting/cachexia (extreme weight loss and muscle loss)
B. You are on HIV (human immunodeficiency virus) anti-retroviral therapy
C. You have an inadequate response to ONE of the following: Marinol (dronabinol), Megace (megestrol acetate), or anabolic steroids
D. You meet **ONE** of the following criteria for weight loss:
    1. Unintentional/involuntary weight loss of greater than 10% of baseline total body weight
    2. Body cell mass (BCM) of less than 30%

ZORBTIVE

Our guideline for **Somatropin (Zorbtive)** requires the following rule(s) be met for approval:

A. You have a diagnosis of short bowel syndrome
B. You are currently on specialized nutritional support such as high carbohydrate, low-fat diet, adjusted for individual requirements and preferences

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN

INITIAL CRITERIA (CONTINUED)

GENOTROPIN

Our guideline for **SOMATROPIN (Genotropin)** requires the following rule(s) be met for approval:

A. You have tried Norditropin Flexpro, unless there is a medical reason why you cannot
B. **If you are less than 18 years of age, approval also requires ONE of the following:**
   1. ALL of the following:
      a. You have ONE of the following diagnoses:
         Pediatric growth hormone deficiency (GHD)
         Short stature associated with Turner Syndrome (type of genetic disorder where you are missing a X chromosome)
         Growth failure due to Prader-Willi Syndrome (PWS: genetic disorder that causes obesity, intellectual disability, and short height)
         Growth failure in children born small for gestational age (SGA)
      b. If you are 10 to 17 years of age, your epiphyses are NOT closed (as confirmed by radiograph or written documentation)
      c. Your bone age is 15 years or less if you are female OR 17 years or less if you are male (as confirmed by radiograph or written documentation)
   2. BOTH of the following:
      a. Your baseline height measurement is more than 2.0 standard deviations below population mean for given age (growth chart)
      b. Your baseline growth rate is 5 cm/year or less
C. **If you are 18 years of age or older, approval also requires ONE of the following:**
   1. BOTH of the following:
      a. You have a diagnosis of adult growth hormone deficiency
      b. Your doctor has submitted biochemical evidence/testing confirming the diagnosis
   2. ALL of the following:
      a. You previously received growth hormone therapy as a pediatric patient
      b. You have reached adult height
      c. You stopped growth hormone therapy for at least 1-month before re-evaluation of the need for continued therapy
      d. Your doctor has determined that you will experience growth hormone deficiency into adulthood and would receive clinical benefit from continued growth hormone therapy

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN

INITIAL CRITERIA(CONTINUED)

HUMATROPE

Our guideline for **SOMATROPIN (Humatrope)** requires the following rule(s) be met for approval:

A. You have tried Norditropin Flexpro, unless there is a medical reason why you cannot
B. **If you are less than 18 years of age, approval also requires ONE of the following:**
    1. ALL of the following:
        a. You have ONE of the following diagnoses:
            1) Pediatric growth hormone deficiency (GHD)
            2) Short stature associated with Turner Syndrome (type of genetic disorder where you are missing a X chromosome)
            3) Growth failure due to Prader-Willi Syndrome (PWS: genetic disorder that causes obesity, intellectual disability, and short height)
            4) Growth failure in children born small for gestational age (SGA)
            5) Growth failure in children with SHOX deficiency
        b. If you are 10 to 17 years of age, your epiphyses are NOT closed (as confirmed by radiograph or written documentation)
        c. Your bone age is 15 years or less if you are female OR 17 years or less if you are male (as confirmed by radiograph or written documentation)
    2. BOTH of the following:
        a. Your baseline height measurement is more than 2.0 standard deviations below population mean for given age (growth chart)
        b. Your baseline growth rate is 5 cm/year or less
C. **If you are 18 years of age or older, approval also requires ONE of the following:**
    1. BOTH of the following:
        a. You have a diagnosis of adult growth hormone deficiency
        b. Your doctor has submitted biochemical evidence/testing confirming the diagnosis
    2. ALL of the following:
        a. You previously received growth hormone therapy as a pediatric patient
        b. You have reached adult height
        c. You stopped growth hormone therapy for at least 1-month before re-evaluation of the need for continued therapy
        d. Your doctor has determined that you will experience growth hormone deficiency into adulthood and would receive clinical benefit from continued growth hormone therapy

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN

INITIAL CRITERIA (CONTINUED)

NORDITROPIN FLEXPRO

Our guideline for **SOMATROPIN (Norditropin Flexpro)** requires the following rule(s) be met for approval:

A. **If you are less than 18 years of age, approval also requires ONE of the following:**
   1. ALL of the following:
      a. You have ONE of the following diagnoses:
         1) Pediatric growth hormone deficiency (GHD)
         2) Short stature associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
         3) Growth failure due to Prader-Willi syndrome (PWS: genetic disorder that causes obesity, intellectual disability, and short height)
         4) Growth failure in children born small for gestational age (SGA)
         5) Growth failure in children with Noonan syndrome
      b. If you are 10 to 17 years of age, your epiphyses are NOT closed (as confirmed by radiograph or written documentation)
      c. Your bone age is 15 years or less if you are female OR 17 years or less if you are male (as confirmed by radiograph or written documentation)
   2. BOTH of the following:
      a. Your baseline height measurement is more than 2.0 standard deviations below population mean for given age (growth chart)
      b. Your baseline growth rate is 5 cm/year or less

B. **If you are 18 years of age or older, approval also requires ONE of the following:**
   1. BOTH of the following:
      a. You have a diagnosis of adult growth hormone deficiency
      b. Your doctor has submitted biochemical evidence/testing confirming the diagnosis
   2. ALL of the following:
      a. You previously received growth hormone therapy as a pediatric patient
      b. You have reached adult height
      c. You stopped growth hormone therapy for at least 1-month before re-evaluation of the need for continued therapy
      d. Your doctor has determined that you will experience growth hormone deficiency into adulthood and would receive clinical benefit from continued growth hormone therapy

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN

INITIAL CRITERIA (CONTINUED)

NUTROPIN AQ/ NUTROPIN AQ NUSPIN

Our guideline for **SOMATROPIN (Nutropin AQ/ Nutropin AQ Nuspin)** requires the following rule(s) be met for approval:

A. **You have tried Norditropin Flexpro, unless there is a medical reason why you cannot**
B. **If you are less than 18 years of age, approval also requires ONE of the following:**
    1. ALL of the following:
        a. You have ONE of the following diagnoses:
            1) Pediatric growth hormone deficiency (GHD)
            2) Short stature associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
            3) Growth failure due to Prader-Willi syndrome (PWS: genetic disorder that causes obesity, intellectual disability, and short height)
            4) Growth failure in children born small for gestational age (SGA)
            5) Growth failure in children with chronic renal insufficiency
        b. If you are 10 to 17 years of age, your epiphyses are NOT closed (as confirmed by radiograph or written documentation)
        c. Your bone age is 15 years or less if you are female OR 17 years or less if you are male (as confirmed by radiograph or written documentation)
    2. BOTH of the following:
        a. Your baseline height measurement is more than 2.0 standard deviations below population mean for given age (growth chart)
        b. Your baseline growth rate is 5 cm/year or less
C. **If you are 18 years of age or older, approval also requires ONE of the following:**
    1. BOTH of the following:
        a. You have a diagnosis of adult growth hormone deficiency
        b. Your doctor has submitted biochemical evidence/testing confirming the diagnosis
    2. ALL of the following:
        a. You previously received growth hormone therapy as a pediatric patient
        b. You have reached adult height
        c. You stopped growth hormone therapy for at least 1-month before re-evaluation of the need for continued therapy
        d. Your doctor has determined that you will experience growth hormone deficiency into adulthood and would receive clinical benefit from continued growth hormone therapy

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN

INITIAL CRITERIA (CONTINUED)

OMNITROPE

Our guideline for **SOMATROPIN (Omnitrope)** requires the following rule(s) be met for approval:

A. You have tried Norditropin Flexpro, unless there is a medical reason why you cannot
B. **If you are less than 18 years of age, approval also requires ONE of the following:**
    1. ALL of the following:
        a. You have ONE of the following diagnoses:
            1) Pediatric growth hormone deficiency (GHD)
            2) Short stature associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
            3) Growth failure due to Prader-Willi syndrome (PWS: genetic disorder that causes obesity, intellectual disability, and short height)
            4) Growth failure in children born small for gestational age (SGA)
        b. If you are 10 to 17 years of age, your epiphyses are NOT closed (as confirmed by radiograph or written documentation)
        c. Your bone age is 15 years or less if you are female OR 17 years or less if you are male (as confirmed by radiograph or written documentation)
    2. BOTH of the following:
        a. Your baseline height measurement is more than 2.0 standard deviations below population mean for given age (growth chart)
        b. Your baseline growth rate is 5 cm/year or less
C. **If you are 18 years of age or older, approval also requires ONE of the following:**
    1. BOTH of the following:
        a. You have a diagnosis of adult growth hormone deficiency
        b. Your doctor has submitted biochemical evidence/testing confirming the diagnosis
    2. ALL of the following:
        a. You previously received growth hormone therapy as a pediatric patient
        b. You have reached adult height
        c. You stopped growth hormone therapy for at least 1-month before re-evaluation of the need for continued therapy
        d. Your doctor has determined that you will experience growth hormone deficiency into adulthood and would receive clinical benefit from continued growth hormone therapy

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN

INITIAL CRITERIA (CONTINUED)

SAIZEN

Our guideline for **SOMATROPIN (Saizen)** requires the following rule(s) be met for approval:

A. You have tried Norditropin Flexpro, unless there is a medical reason why you cannot
B. **If you are less than 18 years of age, approval also requires ONE of the following:**
    1. ALL of the following:
        a. You have a diagnosis of pediatric growth hormone deficiency (GHD)
        b. If you are 10 to 17 years of age, your epiphyses are NOT closed (as confirmed by radiograph or written documentation)
        c. Your bone age is 15 years or less if you are female OR 17 years or less if you are male (as confirmed by radiograph or written documentation)
    2. BOTH of the following:
        a. Your baseline height measurement is more than 2.0 standard deviations below population mean for given age (growth chart)
        b. Your baseline growth rate is 5 cm/year or less
C. **If you are 18 years of age or older, approval also requires ONE of the following:**
    1. BOTH of the following:
        a. You have a diagnosis of adult growth hormone deficiency
        b. Your doctor has submitted biochemical evidence/testing confirming the diagnosis
    2. ALL of the following:
        a. You previously received growth hormone therapy as a pediatric patient
        b. You have reached adult height
        c. You stopped growth hormone therapy for at least 1-month before re-evaluation of the need for continued therapy
        d. Your doctor has determined that you will experience growth hormone deficiency into adulthood and would receive clinical benefit from continued growth hormone therapy

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SOMATROPIN

INITIAL CRITERIA (CONTINUED)

ZOMACTON

Our guideline named **SOMATROPIN (Zomacton)** requires the following rule(s) be met for approval:

A. You have tried Norditropin Flexpro, unless there is a medical reason why you cannot
B. **If you are less than 18 years of age, approval also requires ONE of the following:**
   1. ALL of the following:
      a. You have ONE of the following diagnoses:
         1) Pediatric growth hormone deficiency (GHD)
         2) Short stature associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
         3) Growth failure due to Prader-Willi syndrome (PWS: genetic disorder that causes obesity, intellectual disability, and short height)
         4) Growth failure in children born small for gestational age (SGA)
         5) Growth failure in children with SHOX deficiency
      b. If you are 10 to 17 years of age, your epiphyses are NOT closed (as confirmed by radiograph or written documentation)
      c. Your bone age is 15 years or less if you are female OR 17 years or less if you are male (as confirmed by radiograph or written documentation)
   2. BOTH of the following:
      a. Your baseline height measurement is more than 2.0 standard deviations below population mean for given age (growth chart)
      b. Your baseline growth rate is 5 cm/year or less
C. **If you are 18 years of age or older, approval also requires ONE of the following:**
   1. BOTH of the following:
      a. You have a diagnosis of adult growth hormone deficiency
      b. Your doctor has submitted biochemical evidence/testing confirming the diagnosis
   2. ALL of the following:
      a. You previously received growth hormone therapy as a pediatric patient
      b. You have reached adult height
      c. You stopped growth hormone therapy for at least 1-month before re-evaluation of the need for continued therapy
      d. Your doctor has determined that you will experience growth hormone deficiency into adulthood and would receive clinical benefit from continued growth hormone therapy

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SOMATROPIN

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

SEROSTIM

Our guideline for **SOMATROPIN (Serostim)** requires the following rule(s) be met for renewal:

A. You have a diagnosis of HIV (human immunodeficiency virus) wasting/cachexia (severe muscle and weight loss)
B. You must be on HIV anti-retroviral therapy
C. Your current total body weight or lean body mass has increased as compared to baseline

ZORBTIVE

Our guideline for **SOMATROPIN (Zorbtive)** requires the following rule(s) be met for renewal:

A. You have short bowel syndrome (a condition in which your body cannot absorb nutrients because part of the small intestine is missing or not working properly
B. You are currently on specialized nutritional support (such as high carbohydrate, low-fat diet, adjusted for individual requirements and preferences)

GENOTROPIN

Our guideline for **SOMATROPIN (Genotropin)** requires the following rule(s) be met for renewal:

A. **If you are less than 18 years of age, ONE of the following is required for renewal:**
    1. ALL of the following:
        a. You have ONE of the following diagnoses:
            1) Pediatric growth hormone deficiency (GHD)
            2) Short stature associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
            3) Growth failure due to Prader-Willi syndrome (PWS: genetic disorder that causes obesity, intellectual disability, and short height)
            4) Growth failure in children born small for gestational age (SGA)
        b. If 10 to 17 years of age, your epiphyses are NOT closed (as confirmed by radiograph or written documentation)
        c. Your bone age is 15 years or less if you are female OR 17 years or less if you are male (as confirmed by radiograph or written documentation)
    2. You have grown 2 cm/year or more since initiation of therapy
B. **If you are 18 years of age or older, BOTH of the following are required for renewal:**
    a. You have a diagnosis of adult growth hormone deficiency
    b. Your doctor has submitted biochemical evidence/testing confirming the diagnosis

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SOMATROPIN

RENEWAL CRITERIA (CONTINUED)

HUMATROPE

Our guideline for **SOMATROPIN (Humatrope)** requires the following rule(s) be met for renewal:

A. **If you are less than 18 years of age, ONE of the following is required for renewal:**
   1. ALL of the following:
      a. You have ONE of the following diagnoses:
         1) Pediatric growth hormone deficiency (GHD)
         2) Short stature associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
         3) Growth failure due to Prader-Willi syndrome (PWS: genetic disorder that causes obesity, intellectual disability, and short height)
         4) Growth failure in children born small for gestational age (SGA)
         5) Growth failure in children with SHOX deficiency
      b. If 10 to 17 years of age, your epiphyses are NOT closed (as confirmed by radiograph or written documentation)
      c. Your bone age is 15 years or less if you are female OR 17 years or less if you are male (as confirmed by radiograph or written documentation)
   2. You have grown 2 cm/year or more since initiation of therapy

B. **If you are 18 years of age or older, BOTH of the following are required for renewal:**
   1. You have a diagnosis of adult growth hormone deficiency
   2. Your doctor has submitted biochemical evidence/testing confirming the diagnosis

NORDITROPIN FLEXPRO

Our guideline for **SOMATROPIN (Norditropin)** requires the following rule(s) be met for renewal:

A. **If you are less than 18 years of age, ONE of the following is required for renewal:**
   1. ALL of the following:
      a. You have ONE of the following diagnoses:
         1) Pediatric growth hormone deficiency (GHD)
         2) Short stature associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
         3) Growth failure due to Prader-Willi syndrome (PWS: genetic disorder that causes obesity, intellectual disability, and short height)
         4) Growth failure in children born small for gestational age (SGA)
         5) Growth failure in children with Noonan syndrome
      b. If you are 10 to 17 years of age, your epiphyses are NOT closed (as confirmed by radiograph or written documentation)
      c. Your bone age is 15 years or less if you are female OR 17 years or less if you are male (as confirmed by radiograph or written documentation)
   2. You have grown 2 cm/year or more since initiation of therapy

B. **If you are 18 years of age or older, BOTH of the following are required for renewal:**
   1. You have a diagnosis of adult growth hormone deficiency
   2. Your doctor has submitted biochemical evidence/testing confirming the diagnosis

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RENEWAL CRITERIA (CONTINUED)

NUTROPIN AQ/ NUTROPIN AQ NUSPIN

Our guideline for **SOMATROPIN (Nutropin AQ, Nutropin AQ Nuspin)** requires the following rule(s) be met for renewal:

A. **If you are less than 18 years of age, ONE of the following is required for renewal:**
   1. ALL of the following:
      a. You have ONE of the following diagnoses:
         1) Pediatric growth hormone deficiency (GHD)
         2) Short stature associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
         3) Growth failure due to Prader-Willi syndrome (PWS: genetic disorder that causes obesity, intellectual disability, and short height)
         4) Growth failure in children born small for gestational age (SGA)
         5) Growth failure in children with chronic renal insufficiency
      b. If 10 to 17 years of age, your epiphyses are NOT closed (as confirmed by radiograph or written documentation)
      c. Your bone age is 15 years or less if you are female OR 17 years or less if you are male (as confirmed by radiograph or written documentation)
   2. You have grown 2 cm/year or more since initiation of therapy

B. **If you are 18 years of age or older, BOTH of the following are required for renewal:**
   1. You have a diagnosis of adult growth hormone deficiency
   2. Your doctor has submitted biochemical evidence/testing confirming the diagnosis

OMNITROPE

Our guideline for **SOMATROPIN (Omnitrope)** requires the following rule(s) be met for approval:

A. **If you are less than 18 years of age, ONE of the following is required for renewal:**
   1. ALL of the following:
      a. You have ONE of the following diagnoses:
         1) Pediatric growth hormone deficiency (GHD)
         2) Short stature associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
         3) Growth failure due to Prader-Willi syndrome (PWS: genetic disorder that causes obesity, intellectual disability, and short height)
         4) Growth failure in children born small for gestational age (SGA)
      b. If 10 to 17 years of age, your epiphyses are NOT closed (as confirmed by radiograph or written documentation)
      c. Your bone age is 15 years or less if you are female OR 17 years or less if you are male (as confirmed by radiograph or written documentation)
   2. You have grown 2 cm/year or more since initiation of therapy

B. **If you are 18 years of age or older, BOTH of the following are required for renewal:**
   1. You have a diagnosis of adult growth hormone deficiency
   2. Your doctor has submitted biochemical evidence/testing confirming the diagnosis

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SOMATROPIN

RENEWAL CRITERIA (CONTINUED)

SAIZEN

Our guideline for **SOMATROPIN (Saizen)** requires the following rule(s) be met for renewal:

A. **If you are less than 18 years of age, ONE of the following is required for renewal:**
   1. ALL of the following:
      a. You have a diagnosis of pediatric growth hormone deficiency (GHD)
      b. If 10 to 17 years of age, your epiphyses are NOT closed (as confirmed by radiograph or written documentation)
      c. Your bone age is 15 years or less if you are female OR 17 years or less if you are male (as confirmed by radiograph or written documentation)
   2. You have grown 2 cm/year or more since initiation of therapy
B. **If you are 18 years of age or older, BOTH of the following are required for renewal:**
   1. You have a diagnosis of adult growth hormone deficiency
   2. Your doctor has submitted biochemical evidence/testing confirming the diagnosis

ZOMACTON (formerly called TEV-TROPIN)

Our guideline for **SOMATROPIN (Zomacton)** requires the following rule(s) be met for approval:

A. **If you are less than 18 years of age, ONE of the following is required for renewal:**
   1. ALL of the following:
      a. You have ONE of the following diagnoses:
         1) Pediatric growth hormone deficiency (GHD)
         2) Short stature associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
         3) Growth failure due to Prader-Willi syndrome (PWS: genetic disorder that causes obesity, intellectual disability, and short height)
         4) Growth failure in children born small for gestational age (SGA)
         5) Growth failure in children with SHOX deficiency
      b. If 10 to 17 years of age, your epiphyses are NOT closed (as confirmed by radiograph or written documentation)
      c. Your bone age is 15 years or less if you are female OR 17 years or less if you are male (as confirmed by radiograph or written documentation)
   2. You have grown 2 cm/year or more since initiation of therapy
B. **If you are 18 years of age or older, BOTH of the following are required for renewal:**
   1. You have a diagnosis of adult growth hormone deficiency
   2. Your doctor has submitted biochemical evidence/testing confirming the diagnosis

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN

RATIONALE
Ensure appropriate use of growth hormone with respect to evidence-based guidelines.

FDA APPROVED INDICATIONS
Currently, there are nine rhGH products being marketed. With the exception of Serostim and Zorbtive, all of the products are indicated for the treatment of pediatric GH deficiency, and additional indications are product specific. Recombinant GH products are used off-label for anti-aging effects and enhancing athletic performance. Use of rhGH in patients with Idiopathic Short Stature (ISS) is controversial as these patients are not growth hormone deficient.

	PED GROWTH HORMONE DEFICIENCY	ADULT GROWTH HORMONE DEFICIENCY	SMALL FOR GESTATIONAL AGE	IDIOPATHIC SHORT STATURE	TURNER SYNDROME	PRADER WILLI SYNDROME	HIV-ASSOCIATED WASTING	SHORT BOWEL SYNDROME	NOONAN SYNDROME	SHORT STATURE HOMEOBOX-CONTAINING GENE (SHOX) DEFIECIENCY	CHRONIC KIDNEY DISEASE (CHRONIC RENAL INSUFFICIENCY)
ZORBTIVE								√			
SEROSTIM							√				
GENOTROPIN	√	√	√	√	√	√					
NORDITROPIN	√	√	√		√	√			√		
HUMATROPE	√	√	√	√	√					√	
NUTROPIN	√	√	√	√	√						√
OMNITROPE	√	√	√	√	√	√					
SAIZEN	√	√									
ZOMACTON	√										

DOSING
Dosing of rhGH products varies amongst the products and their indications. Treatment guidelines recommend that treatment be individualized. For pediatric patients, weight based-dosing is utilized whereas in adult patients, either weight based dosing or fixed-doses may be used.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN

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- Nutropin [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; December 2016.
- Omnitrope [Prescribing Information]. Princeton, NJ: Sandoz, Inc.; June 2019.
- Saizen [Prescribing Information]. Rockland, MA: EMD Serono, Inc.; February 2020.
- Serostim [Prescribing Information]. Rockland, MA: EMD Serono, Inc.; June 2019.
- Zorbtive [Prescribing Information]. Rockland, MA: EMD Serono, Inc.; May 2017.
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Created: 05/15
Effective: 12/15/21 Client Approval: 10/26/21 P&T Approval: N/A

SONIDEGIB

Generic	Brand	HICL	GCN	Exception/Other
SONIDEGIB	ODOMZO	42369		

GUIDELINES FOR USE

Our guideline for **SONIDEGIB** requires a diagnosis of locally advanced basal cell carcinoma (BCC) that has recurred following surgery or radiation therapy, or that the patient is not a candidate for surgery or radiation therapy. In addition, the patient must have obtained baseline serum creatine kinase (CK) and serum creatinine levels.

RATIONALE

Promote appropriate utilization of **SONIDEGIB** based on FDA approved indication.

Skin cancer is the most common cancer and basal cell carcinoma accounts for approximately 80 percent of non-melanoma skin cancers. The vast majority of patients can be successfully managed with a variety of simple procedures, such as cryotherapy, curettage and electrodesiccation, topical treatments (5-fluorouracil, imiquimod), or simple surgical excision. When lesions are more advanced, Mohs micrographic surgery, more extensive surgical resection, or radiation therapy generally are generally sufficient to control locoregional disease. The use of systemic therapy is limited to patients with distant metastases or locally advanced disease that cannot be adequately managed with surgical or radiotherapeutic techniques.

The Hedgehog (Hh) signaling pathway plays a key role in directing growth and patterning during embryonic development and is required in vertebrates for the normal development of many structures, including the skin. Signaling in this pathway is initiated by the cell surface receptor smoothened homolog (SMO). In adults, this pathway normally is inhibited by another cell surface receptor, the patched homolog 1 (PTCH1). In the pathogenesis of basal cell carcinoma, either SMO or PTCH1 could have a mutation resulting in aberrant cell proliferation.

Odomzo works by binding to and inhibiting SMO protein, thereby blocking activation of the Hh pathway and the proliferation of tumor cells. It offers an alternative to Erivedge (vismodegib) with a similar safety profile for patients who have a recurrence of BCC following surgery or radiation therapy, or for those patients who are not candidates for surgery or radiation.

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SONIDEGIB

RATIONALE (CONTINUED)

The safety and effectiveness of Odomzo was evaluated in a single clinical trial conducted in patients with locally advanced basal cell carcinoma (laBCC) or metastatic basal cell carcinoma who received Odomzo 200 mg orally, once daily, until disease progression or intolerable toxicity. A total of 66 patients randomized to Odomzo 200 mg daily had laBCC and were followed for at least 12 months unless discontinued earlier. Seventy-six percent of patients had prior therapy for treatment of BCC; this included surgery (73%), radiotherapy (18%), and topical/photodynamic therapies (21%). Approximately half of these patients (56%) had aggressive histology. The ORR was 58% (95% confidence interval: 45, 70), consisting of 3 (5%) complete responses and 35 (53%) partial responses. Among the 38 patients with an objective response, 7 (18%) patients experienced subsequent disease progression with 4 of these 7 patients having maintained a response of 6 months or longer. The remaining 31 patients (82%) have ongoing responses ranging from to 1.9+ to 18.6+ months and the median duration of response has not been reached.

The most common adverse effects seen while using Odomzo were muscle spasms, alopecia, dysgeusia, fatigue, nausea, musculoskeletal pain, diarrhea, decreased weight, decreased appetite, myalgia, abdominal pain, headache, pain, vomiting, and pruritus.

There is a **black box warning** for embryo-fetal death and severe birth defects. Pregnancy Category D.

DOSAGE
Odomzo is taken as a single 200 mg capsule, once daily, on an empty stomach, at least 1 hour before or 2 hours after a meal. Odomzo therapy should be continued until disease progression or unacceptable toxicity.

FDA APPROVED INDICATIONS
Treatment of adult patients with locally advanced basal cell carcinoma (BCC) that has recurred following surgery or radiation therapy, or those who are not candidates for surgery or radiation therapy.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

SONIDEGIB

REFERENCES

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- FDA [Online Press Release]. Available at: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm455862.htm Updated: July 24, 2015.
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Created: 10/15
Effective: 12/17/15 Client Approval: 10/28/15 P&T Approval: 11/15

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

SORAFENIB

Generic	Brand	HICL	GCN	Exception/Other
SORAFENIB TOSYLATE	NEXAVAR	33400		

GUIDELINES FOR USE

Approval requires a diagnosis of advanced renal cell carcinoma (RCC), unresectable hepatocellular carcinoma, or locally recurrent/metastatic, progressive, differentiated thyroid carcinoma (DTC) that is refractory to radioactive iodine treatment.

RATIONALE

Ensure appropriate utilization of sorafenib based on FDA approved indication and NCCN guidelines.

FDA APPROVED INDICATION

Sorafenib is indicated for the treatment of unresectable hepatocellular carcinoma, advanced renal cell carcinoma and locally recurrent or metastatic, progressive, differentiated thyroid carcinoma (DTC) that is refractory to radioactive iodine treatment.

REFERENCES

- Bayer HealthCare Pharmaceuticals Inc. Nexavar package insert. Wayne, NJ. November 2013.
- National Comprehensive Cancer Network, Inc. The NCCN Clinical Practice Guidelines in Oncology. Hepatobiliary Cancers. (Version 1.2011).
- National Comprehensive Cancer Network, Inc. The NCCN Clinical Practice Guidelines in Oncology. Kidney Cancer. (Version 2.2011).

Created: 06/15
Effective: 07/22/15 Client Approval: 06/15 P&T Approval: 02/14

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

SOTORASIB

Generic	Brand	HICL	GCN	Exception/Other
SOTORASIB	LUMAKRAS	47400		

GUIDELINES FOR USE

Our guideline named **SOTORASIB (Lumakras)** requires the following rule(s) be met for approval:

A. You have locally advanced or metastatic (cancer that has grown outside the organ it started in but has not spread to other parts of the body or cancer that has spread to other parts of the body) non-small cell lung cancer (NSCLC: a type of lung cancer)
B. You are 18 years of age or older
C. You have a KRAS G12C-mutation (type of gene mutation), as determined by a Food and Drug Administration (FDA)-approved test
D. You have received at least one prior systemic therapy (treatment that spreads throughout the body through the bloodstream)

RATIONALE

To ensure appropriate use of Lumakras consistent with FDA approved indication.

FDA APPROVED INDICATIONS

Lumakras is an inhibitor of the RAS GTPase family indicated for the treatment of adult patients with *KRAS G12C*-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA-approved test, who have received at least one prior systemic therapy.

DOSAGE AND ADMINISTRATION

Recommended dosage: 960 mg orally once daily.

REFERENCES

- Lumakras [Prescribing Information]. Thousand Oaks, CA: Amgen, Inc.; May 2021.

Created: 07/21
Effective: 09/20/21 Client Approval: 08/20/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

SSRI/ SNRI/ NRI AGENTS

Generic	Brand	HICL	GCN	Exception/Other
ATOMOXETINE HCL	STRATTERA	24703		
CITALOPRAM HYDROBROMIDE	CELEXA	10321		
DESVENLAFAXINE	KHEDEZLA	40202		
DESVENLAFAXINE SUCCINATE	PRISTIQ ER	35420		
DULOXETINE HCL	CYMBALTA, DRIZALMA	26521		
ESCITALOPRAM OXALATE	LEXAPRO	24022		
FLUOXETINE HCL	PROZAC, SARAFEM	01655		
FLUVOXAMINE MALEATE	LUVOX, LUVOX CR	06338		
LEVOMILNACIPRAN HCL	FETZIMA	40632		
MILNACIPRAN	SAVELLA	21229		
OLANZAPINE/FLUOXETINE HCL	SYMBYAX	25800		
PAROXETINE HCL	PAXIL, PAXIL CR	07344		
PAROXETINE MESYLATE	BRISDELLE, PEXEVA	25796		
SERTRALINE HCL	ZOLOFT	06324		
VENLAFAXINE BESYLATE	VENLAFAXINE BESYLATE	48091		
VENLAFAXINE HCL	EFFEXOR, EFFEXOR XR	08847		
VILAZODONE HCL	VIIBRYD	37597		
VILOXAZINE HCL	QELBREE	07345		
VORTIOXETINE HBR	TRINTELLIX	40637		

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

SSRI/ SNRI/ NRI AGENTS

NOTE: Please reference Rationale for a definition of each acronym (e.g., SSRI, SNRI, NRI) and an explanation of which concurrent uses will be allowed. See Appendix to determine which drugs are classified as SSRI, SNRI and NRI agents.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline for **SSRI/ SNRI/ NRI AGENTS** for patients with claims suggesting therapeutic duplication requires that the medications are being cross-tapered or that the historical medication is being discontinued.

Concurrent use of an SSRI with an NRI (atomoxetine or viloxazine) will be allowed as follows:
- SSRI product with an atomoxetine (Strattera) product
- SSRI product with a viloxazine (Qelbree) product

RENEWAL CRITERIA

Our guideline for **SSRI/ SNRI/ NRI AGENTS** renewal requires that there is history of paid claims for **BOTH** medications identified in the therapeutic duplication for 90 of the past 120 days.

Our guideline for **SSRI/ SNRI/ NRI AGENTS** renewal requires that there is history of paid claims for the requested SSRI/ SNRI/ NRI agent for 90 of the past 120 days and that the patient has a previous authorization on file for the requested SSRI/ SNRI/ NRI agent.

RATIONALE

To promote prudent prescribing of SSRI (selective serotonin reuptake inhibitor), SNRI (serotonin norepinephrine reuptake inhibitor), and NRI (norepinephrine reuptake inhibitor) agents.

A lookback period of 60 days will be utilized to identify potential therapeutic duplication.

Concurrent use of an SSRI with an NRI (atomoxetine or viloxazine) will be allowed as follows:
- SSRI product with an atomoxetine (Strattera) product (NRI)
- SSRI product with a viloxazine (Qelbree) product (NRI)

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RATIONALE (CONTINUED)

APPENDIX: SSRI/SNRI Age Edits and Quantity Limits

GPID	Generic Name	Product Name	Category	Dosage Form	Route	Strength	Utilization Edit
18776	ATOMOXETINE HCL	STRATTERA	NRI	CAPS	OR	10 MG	2/DAY
18777	ATOMOXETINE HCL	STRATTERA	NRI	CAPS	OR	18 MG	2/DAY
18778	ATOMOXETINE HCL	STRATTERA	NRI	CAPS	OR	25 MG	2/DAY
18779	ATOMOXETINE HCL	STRATTERA	NRI	CAPS	OR	40 MG	2/DAY
18781	ATOMOXETINE HCL	STRATTERA	NRI	CAPS	OR	60 MG	1/DAY
26538	ATOMOXETINE HCL	STRATTERA	NRI	CAPS	OR	80 MG	1/DAY
26539	ATOMOXETINE HCL	STRATTERA	NRI	CAPS	OR	100 MG	1/DAY
26198	BUPROPION HBR	APLENZIN	NDRI	TB24	OR	174 MG	1/DAY
16996	BUPROPION HBR	APLENZIN	NDRI	TB24	OR	348 MG	1/DAY
17050	BUPROPION HBR	APLENZIN	NDRI	TB24	OR	522 MG	1/DAY
16384	BUPROPION HCL	BUPROPION HCL	NDRI	TABS	OR	75 MG	4/DAY
16385	BUPROPION HCL	BUPROPION HCL	NDRI	TABS	OR	100 MG	4/DAY
16387	BUPROPION HCL	WELLBUTRIN SR	NDRI	TB12	OR	100 MG	2/DAY
16386	BUPROPION HCL	WELLBUTRIN SR	NDRI	TB12	OR	150 MG	2/DAY
27901	BUPROPION HCL	BUPROPION HCL	NDRI	TB12	OR	150 MG	2/DAY; Age 18 years and older
17573	BUPROPION HCL	WELLBUTRIN SR	NDRI	TB12	OR	200 MG	2/DAY
20317	BUPROPION HCL	WELLBUTRIN XL	NDRI	TB24	OR	150 MG	1/DAY
20318	BUPROPION HCL	WELLBUTRIN XL	NDRI	TB24	OR	300 MG	1/DAY
33081	BUPROPION HCL	FORFIVO XL	NDRI	TB24	OR	450 MG	1/DAY
51883	CITALOPRAM HYDROBROMIDE	CITALOPRAM HYDROBROMIDE	SSRI	CAPS	OR	30 MG	1/DAY
16345	CITALOPRAM HYDROBROMIDE	CELEXA	SSRI	TABS	OR	10 MG	1.5/DAY
16342	CITALOPRAM HYDROBROMIDE	CELEXA	SSRI	TABS	OR	20 MG	1.5/DAY
16343	CITALOPRAM HYDROBROMIDE	CELEXA	SSRI	TABS	OR	40 MG	1/DAY
16344	CITALOPRAM HYDROBROMIDE	CITALOPRAM HYDROBROMIDE	SSRI	SOLN	OR	10 MG/ 5 ML	20 ML/DAY
35582	DESVENLAFAXINE ER	KHEDEZLA	SNRI	TB24	OR	50 MG	1/DAY
35584	DESVENLAFAXINE ER	KHEDEZLA	SNRI	TB24	OR	100 MG	2/DAY
38222	DESVENLAFAXINE SUCCINATE	PRISTIQ	SNRI	TB24	OR	25 MG	1/DAY
99451	DESVENLAFAXINE SUCCINATE	PRISTIQ	SNRI	TB24	OR	50 MG	1/DAY
99452	DESVENLAFAXINE SUCCINATE	PRISTIQ	SNRI	TB24	OR	100 MG	2/DAY
23161	DULOXETINE HCL	CYMBALTA	SNRI	CPEP	OR	20 MG	2/DAY

23162	DULOXETINE HCL	CYMBALTA	SNRI	CPEP	OR	30 MG	2/DAY
38728	DULOXETINE HCL	DULOXETINE HCL	SNRI	CPEP	OR	40 MG	2/DAY
23164	DULOXETINE HCL	CYMBALTA	SNRI	CPEP	OR	60 MG	2/DAY
46703	DULOXETINE HCL	DRIZALMA	SNRI	CSDR	OR	20 MG	2/DAY
46713	DULOXETINE HCL	DRIZALMA	SNRI	CSDR	OR	30 MG	2/DAY
46714	DULOXETINE HCL	DRIZALMA	SNRI	CSDR	OR	40 MG	2/DAY
46715	DULOXETINE HCL	DRIZALMA	SNRI	CSDR	OR	60 MG	2/DAY
18975	ESCITALOPRAM OXALATE	LEXAPRO	SSRI	TABS	OR	5 MG	1/DAY
17851	ESCITALOPRAM OXALATE	LEXAPRO	SSRI	TABS	OR	10 MG	1.5/DAY
17987	ESCITALOPRAM OXALATE	LEXAPRO	SSRI	TABS	OR	20 MG	1.5/DAY
19035	ESCITALOPRAM OXALATE	LEXAPRO	SSRI	SOLN	OR	5 MG/ 5 ML	20 ML/DAY
16353	FLUOXETINE HCL	PROZAC	SSRI	CAPS	OR	10 MG	1/DAY
16354	FLUOXETINE HCL	PROZAC	SSRI	CAPS	OR	20 MG	4/DAY
16355	FLUOXETINE HCL	PROZAC	SSRI	CAPS	OR	40 MG	2/DAY
16356	FLUOXETINE HCL	FLUOXETINE HCL	SSRI	TABS	OR	10 MG	1.5/DAY
16359	FLUOXETINE HCL	FLUOXETINE HCL	SSRI	TABS	OR	20 MG	4/DAY
30817	FLUOXETINE HCL	FLUOXETINE HCL	SSRI	TABS	OR	60 MG	1/DAY
16357	FLUOXETINE HCL	FLUOXETINE HCL	SSRI	SOLN	OR	20 MG/ 5 ML	20 ML/DAY
12929	FLUOXETINE HCL	PROZAC WEEKLY	SSRI	CPDR	OR	90 MG	4/28 DAYS
16347	FLUVOXAMINE MALEATE	FLUVOXAMINE MALEATE	SSRI	TABS	OR	25 MG	1/DAY
16348	FLUVOXAMINE MALEATE	FLUVOXAMINE MALEATE	SSRI	TABS	OR	50 MG	1/DAY
16349	FLUVOXAMINE MALEATE	FLUVOXAMINE MALEATE	SSRI	TABS	OR	100 MG	3/DAY
99481	FLUVOXAMINE MALEATE	FLUVOXAMINE MALEATE CR	SSRI	CP24	OR	100 MG	2/DAY
99482	FLUVOXAMINE MALEATE	FLUVOXAMINE MALEATE CR	SSRI	CP24	OR	150 MG	2/DAY
35335	LEVOMILNACIPRAN HCL	FETZIMA SR TITRATION PACK	SNRI	CAPS	OR	20/40 MG	1/DAY
35327	LEVOMILNACIPRAN HCL	FETZIMA SR	SNRI	CAPS	OR	20 MG	1/DAY
35328	LEVOMILNACIPRAN HCL	FETZIMA SR	SNRI	CAPS	OR	40 MG	1/DAY
35329	LEVOMILNACIPRAN HCL	FETZIMA SR	SNRI	CAPS	OR	80 MG	1/DAY
35334	LEVOMILNACIPRAN HCL	FETZIMA SR	SNRI	CAPS	OR	120 MG	1/DAY
98648	OLANZAPINE/ FLUOXETINE HCL	SYMBYAX	SSRI	CAPS	OR	3 MG/ 25 MG	1/DAY; Age 10 years and older
20868	OLANZAPINE/ FLUOXETINE HCL	SYMBYAX	SSRI	CAPS	OR	6 MG/ 25 MG	1/DAY; Age 10 years and older
20869	OLANZAPINE/ FLUOXETINE HCL	SYMBYAX	SSRI	CAPS	OR	6 MG/ 50 MG	1/DAY; Age 10 years and older
20870	OLANZAPINE/ FLUOXETINE HCL	SYMBYAX	SSRI	CAPS	OR	12 MG/ 25 MG	1/DAY; Age 10 years and older

20872	OLANZAPINE/ FLUOXETINE HCL	SYMBYAX	SSRI	CAPS	OR	12 MG/ 50 MG	1/DAY; Age 10 years and older
16364	PAROXETINE HCL	PAXIL	SSRI	TABS	OR	10 MG	1.5/DAY; Age 18 years and older
16366	PAROXETINE HCL	PAXIL	SSRI	TABS	OR	20 MG	1/DAY; Age 18 years and older
16367	PAROXETINE HCL	PAXIL	SSRI	TABS	OR	30 MG	2/DAY; Age 18 years and older
16368	PAROXETINE HCL	PAXIL	SSRI	TABS	OR	40 MG	2/DAY; Age 18 years and older
16369	PAROXETINE HCL	PAXIL	SSRI	SUSP	OR	10 MG/ 5 ML	40 ML/DAY; Age 18 years and older
17078	PAROXETINE HCL	PAXIL CR	SSRI	TB24	OR	12.5 MG	1/DAY; Age 18 years and older
17077	PAROXETINE HCL	PAXIL CR	SSRI	TB24	OR	25 MG	1/DAY; Age 18 years and older
17079	PAROXETINE HCL	PAXIL CR	SSRI	TB24	OR	37.5 MG	2/DAY; Age 18 years and older
34876	PAROXETINE MESYLATE	BRISDELLE	SSRI	CAPS	OR	7.5 MG	1/DAY
20854	PAROXETINE MESYLATE	PEXEVA	SSRI	TABS	OR	10 MG	1/DAY; Age 18 years and older
20855	PAROXETINE MESYLATE	PEXEVA	SSRI	TABS	OR	20 MG	1/DAY; Age 18 years and older
20856	PAROXETINE MESYLATE	PEXEVA	SSRI	TABS	OR	30 MG	1/DAY; Age 18 years and older
20857	PAROXETINE MESYLATE	PEXEVA	SSRI	TABS	OR	40 MG	1/DAY; Age 18 years and older
16382	SERTRALINE HCL	SERTRALINE HCL	SSRI	CAPS	OR	150 MG	2/DAY
16383	SERTRALINE HCL	SERTRALINE HCL	SSRI	CAPS	OR	200 MG	1/DAY
16373	SERTRALINE HCL	ZOLOFT	SSRI	TABS	OR	25 MG	2/DAY
16374	SERTRALINE HCL	ZOLOFT	SSRI	TABS	OR	50 MG	2/DAY
16375	SERTRALINE HCL	ZOLOFT	SSRI	TABS	OR	100 MG	3/DAY
16376	SERTRALINE HCL	ZOLOFT	SSRI	CONC	OR	20 MG/ ML	10 ML/DAY
52506	VENLAFAXINE BESYLATE	VENLAFAXINE BESYLATE	SNRI	TABS	OR	112.5 MG	2/DAY
16811	VENLAFAXINE HCL	VENLAFAXINE HCL	SNRI	TABS	OR	25 MG	3/DAY
16812	VENLAFAXINE HCL	VENLAFAXINE HCL	SNRI	TABS	OR	37.5 MG	3/DAY
16813	VENLAFAXINE HCL	VENLAFAXINE HCL	SNRI	TABS	OR	50 MG	3/DAY
16814	VENLAFAXINE HCL	VENLAFAXINE HCL	SNRI	TABS	OR	75 MG	3/DAY
16815	VENLAFAXINE HCL	VENLAFAXINE HCL	SNRI	TABS	OR	100 MG	3/DAY
16816	VENLAFAXINE HCL	EFFEXOR XR	SNRI	CP24	OR	37.5 MG	1/DAY
16817	VENLAFAXINE HCL	EFFEXOR XR	SNRI	CP24	OR	75 MG	3/DAY
16818	VENLAFAXINE HCL	EFFEXOR XR	SNRI	CP24	OR	150 MG	2/DAY
14349	VENLAFAXINE HCL	VENLAFAXINE HCL ER	SNRI	TB24	OR	37.5 MG	1/DAY
14352	VENLAFAXINE HCL	VENLAFAXINE HCL ER	SNRI	TB24	OR	75 MG	3/DAY
14353	VENLAFAXINE HCL	VENLAFAXINE HCL ER	SNRI	TB24	OR	150 MG	2/DAY
14354	VENLAFAXINE HCL	VENLAFAXINE HCL	SNRI	TB24	OR	225 MG	1/DAY

		ER					
29916	VILAZODONE HCL	VIIBRYD	SSRI	TABS	OR	10 MG	1/DAY
29917	VILAZODONE HCL	VIIBRYD	SSRI	TABS	OR	20 MG	1/DAY
29918	VILAZODONE HCL	VIIBRYD	SSRI	TABS	OR	40 MG	1/DAY
49447	VILOXAZINE HCL ER	QELBREE	NRI	CAPS	OR	100 MG	1/DAY; Age 6 years and older
49449	VILOXAZINE HCL ER	QELBREE	NRI	CAPS	OR	150 MG	2/DAY; Age 6 years and older
49452	VILOXAZINE HCL ER	QELBREE	NRI	CAPS	OR	200 MG	3/DAY; Age 6 years and older
35346	VORTIOXETINE HBR	TRINTELLIX	SSRI	TABS	OR	5 MG	1/DAY
35347	VORTIOXETINE HBR	TRINTELLIX	SSRI	TABS	OR	10 MG	1/DAY
35349	VORTIOXETINE HBR	TRINTELLIX	SSRI	TABS	OR	20 MG	1/DAY

Created: 07/16
Effective: 01/23/23 Client Approval: 08/31/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

STANDARD STEP THERAPY

Generic	Brand	HICL	GCN	Exception/Other
N/A	N/A	N/A	N/A	N/A

GUIDELINES FOR USE

Our guideline named **STANDARD STEP THERAPY** requires that you have tried preferred options before receiving coverage for this drug. In order for your request to be approved, your provider needs to tell us that you have tried the step therapies listed below. Your provider may give a reason why you cannot take our suggested step therapies, including a statement that these therapies would not work as well or could cause side effects. In some cases, the requested medication or alternatives offered may have additional approval requirements.

Created: 05/21
Effective: 06/15/21 Client Approval: 06/24/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

STIRIPENTOL

Generic	Brand	HICL	GCN	Exception/Other
STIRIPENTOL	DIACOMIT	35461		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **STIRIPENTOL (Diacomit)** requires the following rule(s) be met for approval:
A. You have seizures associated with Dravet syndrome (a rare type of seizure)
B. You are 2 years of age or older
C. You are currently being treated with clobazam (a type of seizure drug)
D. You had a trial of or contraindication (harmful for) to TWO of the following: a valproic acid derivative, clobazam, or topiramate

RENEWAL CRITERIA

Our guideline named **STIRIPENTOL (Diacomit)** requires the following rule(s) be met for renewal:
A. You have seizures associated with Dravet syndrome (a rare type of seizure)
B. You are currently being treated with clobazam (type of seizure drug)

RATIONALE
To ensure appropriate use of Diacomit based on FDA approved indications and dosing.

INDICATION
Diacomit is indicated for the treatment of seizures associated with Dravet syndrome in patients 2 years of age and older taking clobazam. There are no clinical data to support the use of Diacomit as monotherapy in Dravet syndrome.

DOSING
The recommended oral dosage of Diacomit is 50 mg/kg/day, administered in 2 or 3 divided doses (i.e., 16.67 mg/kg three times daily or 25 mg/kg twice daily). If the exact dosage is not achievable given the available strengths, round to the nearest possible dosage, which is usually within 50 mg to 150 mg of the recommended 50 mg/kg/day. A combination of the two Diacomit strengths can be used to achieve this dosage. The maximum recommended total dosage is 3,000 mg/day.

REFERENCES
Diacomit [Prescribing Information]. Beauvais, France: Biocodex, May 2020.

Created: 08/22
Effective: 10/01/22 Client Approval: 08/19/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

SUNITINIB

Generic	Brand	HICL	GCN	Exception/Other
SUNITINIB MALATE	SUTENT	33445		

GUIDELINES FOR USE

Our guideline for **SUNITINIB** requires a diagnosis of advanced renal cell carcinoma (RCC), gastrointestinal stromal tumor (GIST), unresectable locally advanced or metastatic pancreatic neuroendocrine carcinoma (pNET), or for adjuvant treatment of renal cell carcinoma. In addition, the following must be met:

For diagnosis of gastrointestinal stromal tumor (GIST), approval requires:
- The patient has had a previous trial of or contraindication to imatinib mesylate (Gleevec)

For diagnosis of unresectable locally advanced or metastatic pancreatic neuroendocrine carcinoma (pNET), approval requires:
- The patient's tumor is progressive and well-differentiated

For adjuvant treatment of renal cell carcinoma, approval requires:
- Patient is at least 18 years old
- Patient is at high risk of recurrent renal cell carcinoma (RCC) following nephrectomy

RATIONALE

Ensure appropriate utilization of sunitinib based on FDA approved indication.

FDA APPROVED INDICATIONS

Sutent is a kinase inhibitor indicated for the treatment of:
- Gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib mesylate
- Advanced renal cell carcinoma (RCC)
- Progressive, well-differentiated pancreatic neuroendocrine tumors (pNET) in patients with unresectable locally advanced or metastatic disease
- Adjuvant treatment of adult patients at high risk of recurrent RCC following nephrectomy

DOSAGE AND ADMINISTRATION

GIST and Advanced RCC:
- 50 mg orally once daily, with or without food, 4 weeks on treatment followed by 2 weeks off.

Adjuvant RCC:
- 50 mg orally once daily, with or without food, 4 weeks on treatment followed by 2 weeks off for nine 6-week cycles

pNET:
- 37.5 mg orally once daily, with or without food, continuously without a scheduled off-treatment period.

REFERENCES

- Pfizer Labs. Sutent package insert. New York, NY. November 2017.

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

TADALAFIL

Generic	Brand	HICL	GCN	Exception/Other
TADALAFIL	CIALIS		20736 99409	

GUIDELINES FOR USE

Our guidelines for **TADALAFIL** requires a diagnosis of Benign Prostatic Hyperplasia (BPH) and a trial of a formulary alpha blocker (for example, doxazosin, terazosin, or tamsulosin) AND finasteride.

RATIONALE

To limit the coverage of Cialis to the Medicaid covered indication of benign prostatic hyperplasia (BPH) and exclude coverage for erectile dysfunction (ED). The recommended dose for the treatment of BPH is 5mg daily. A starting dose of 2.5mg daily is recommended for patients with a creatine clearance of 30 to 50mL/min.

FDA APPROVED INDICATIONS

Cialis is indicated for the treatment of ED, the signs and symptoms of BPH, and ED and the signs and symptoms of BPH. Cialis may be administered once daily or on an as needed basis for the treatment of ED. For the treatment of BPH, Cialis is recommended to be administered on a daily basis.

REFERENCES

- AUA practice guidelines Committee. AUA guideline on management of benign prostatic hyperplasia. Chapter 1: Guideline on the Management of Benign Prostatic Hyperplasia. 2010: American Urological Association Education and Research, Inc.
- Eli Lilly and Company. Cialis package insert. Indianapolis, IN. October 2011.
- MICROMEDEX® Healthcare Series [database online]. Greenwood Village, CO: Thomson Healthcare; Available at: https://www.thomsonhc.com/hcs/librarian/PFDefaultActionId/pf.LoginAction. [Accessed: October, 31, 2014].

Created: 06/15
Effective: 07/01/17 Client Approval: 05/01/17 P&T Approval: 11/14

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

TAFAMIDIS

Generic	Brand	HICL	GCN	Exception/Other
TAFAMIDIS MEGLUMINE	VYNDAQEL	41631		
TAFAMIDIS	VYNDAMAX	45729		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TAFAMIDIS (Vyndaqel, Vyndamax)** requires the following rule(s) be met for approval:

A. You have cardiomyopathy associated with wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM: heart disease caused by a build-up of a type of protein) which is confirmed by ONE of the following:
   1. Histological analysis
   2. Genetic testing
B. You are 18 years of age or older

RENEWAL CRITERIA

Our guideline named **TAFAMIDIS (Vyndaqel, Vyndamax)** requires the following rule(s) be met for renewal:

A. You have history of paid claim(s) for the requested medication in the past 90 days
B. You have previous authorization on file for the requested medication

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RATIONALE

To ensure safe and appropriate use of tafamidis per approved indication and dosing and national treatment guidelines.

FDA APPROVED INDICATIONS

Vyndaqel and Vyndamax are transthyretin stabilizers indicated for the treatment of the cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization.

DOSAGE AND ADMINISTRATION

The recommended dosage is either Vyndaqel 80 mg (four 20-mg tafamidis meglumine capsules) orally once daily or Vyndamax 61 mg (one 61-mg tafamidis capsule) orally once daily.

REFERENCES

- Vyndaqel [Prescribing Information]. New York, NY: Pfizer Inc.; June 2021.
- Vyndamax [Prescribing Information]. New York, NY: Pfizer Inc.; June 2021.

Created: 06/19
Effective: 03/14/22 Client Approval: 02/04/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

TALAZOPARIB TOSYLATE

Generic	Brand	HICL	GCN	Exception/Other
TALAZOPARIB TOSYLATE	TALZENNA	45368		

GUIDELINES FOR USE

Our guideline named **TALAZOPARIB (Talzenna)** requires the following rule(s) be met for approval:

A. You have human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer (breast cancer that does not have a type of protein and has spread from where it started to nearby tissue or lymph nodes or has spread to other parts of the body)
B. You are 18 years of age or older
C. You have a deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutation (*gBRCAm*: a type of gene mutation) as confirmed by a Food and Drug Administration-approved test
D. You have been treated with chemotherapy in the neoadjuvant (drugs used to treat cancer given before main treatment), adjuvant (add-on to main treatment), or metastatic setting (treating disease that has spread)
E. **If you have hormone receptor (HR)-positive breast cancer, approval also requires:**
    1. You have had additional prior treatment with endocrine (hormone) therapy or are considered inappropriate for endocrine therapy

RATIONALE

To ensure appropriate diagnostic, utilization and safety criteria are used for the management of requests for talazoparib tosylate.

FDA APPROVED INDICATIONS

Talzenna is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (*gBRCAm*) HER2-negative locally advanced or metastatic breast cancer. Select patients for therapy based on an FDA-approved companion diagnostic for Talzenna.

DOSING

The recommended dose of Talzenna is 1 mg taken orally once daily, with or without food. The 0.25 mg, 0.5 mg, and 0.75 mg capsules are available for dose reduction. Patients should be treated until disease progression or unacceptable toxicity occurs.

REFERENCES

- Talzenna [Prescribing Information]. New York, NY: Pfizer Labs; September 2021.

Created: 12/18
Effective: 03/28/22 Client Approval: 03/07/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

TAPINAROF

Generic	Brand	HICL	GCN	Exception/Other
TAPINAROF	VTAMA	48031		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TAPINAROF (Vtama)** requires the following rule(s) be met for approval:
A. You have plaque psoriasis (a type of skin condition)
B. You are 18 years of age or older
C. You have psoriasis covering 3% to 20% of body surface area (BSA) (excluding scalp, palms, fingernails, toenails, and soles)
D. You are NOT concurrently (at the same time) using other systemic immunomodulating agents (such as Stelara, Otezla), topical corticosteroids (such as betamethasone dipropionate, clobetasol propionate), or topical non-steroidals (such as calcitriol, tazarotene)
E. You had a trial of or contraindication (harmful for) to TWO of the following (from different categories):
    1. High or super-high potency topical corticosteroid (such as triamcinolone acetonide, fluocinonide, clobetasol propionate, halobetasol propionate)
    2. Topical vitamin D analog (such as calcipotriene cream, calcitriol ointment)
    3. Topical calcineurin inhibitor (such as tacrolimus, pimecrolimus)
    4. Topical retinoid (such as tazarotene cream/gel)
    5. Anthralin

RENEWAL CRITERIA

Our guideline named **TAPINAROF (Vtama)** requires the following rule(s) be met for renewal:
A. You have plaque psoriasis (a type of skin condition)
B. You have experienced or maintained symptomatic improvement while on therapy
C. You are NOT concurrently (at the same time) using other systemic immunomodulating agents (such as Stelara, Otezla), topical corticosteroids (such as betamethasone dipropionate, clobetasol propionate), or topical non-steroidals (such as calcitriol, tazarotene)

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

TAPINAROF

RATIONALE
To ensure appropriate diagnostic, utilization and safety criteria are used for the management of requests for tapinarof.

FDA APPROVED INDICATIONS
Vtama is an aryl hydrocarbon receptor agonist indicated for the topical treatment of plaque psoriasis in adults.

DOSAGE
Apply a thin layer of VTAMA cream to affected areas once daily

REFERENCES

- Vtama [Prescribing Information]. Long Beach, CA: Dermavant Sciences, Inc.; May 2022.
- Elmets CA, Korman NJ, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.

Created: 07/22
Effective: 08/15/22 Client Approval: 07/15/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

TASIMELTEON

Generic	Brand	HICL	GCN	Exception/Other
TASIMELTEON	HETLIOZ, HETLIOZ LQ	40927		

GUIDELINES FOR USE

The guideline for **TASIMELTEON (Hetlioz and Hetlioz HQ)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Non-24-Hour Sleep-Wake Disorder (Non-24)
   2. Nighttime sleep disturbances associated with Smith-Magenis syndrome

B. **If you have Non-24-Hour Sleep-Wake Disorder (Non-24), approval also requires:**
   1. You are 18 years of age or greater

C. **If you have nighttime sleep disturbances associated with Smith-Magenis syndrome, approval also requires:**
   1. You are 3 years of age or greater

D. **If you are greater than 17 years of age and the request is for Hetlioz HQ suspension, approval also requires:**
   1. You are unable to swallow Hetlioz capsules

RATIONALE
To ensure the appropriate use of Hetlioz.

FDA APPROVED INDICATIONS
Non-24-Hour Sleep-Wake Disorder (Non-24)
Hetlioz (tasimelteon) capsules are indicated for the treatment of Non-24 in adults.

Nighttime Sleep Disturbances in Smith-Magenis Syndrome (SMS)
Hetlioz (tasimelteon) capsules are indicated for the treatment of nighttime sleep disturbances in SMS in patients 16 years of age and older. Hetlioz LQ (tasimelteon) oral suspension is indicated for the treatment of nighttime sleep disturbances in SMS in pediatric patients 3 to 15 years of age.

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TASIMELTEON

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE
The recommended dosage of Hetlioz capsules for Non-24 in adults is 20 mg orally per day taken before bedtime, at the same time every night.

The recommended dosage of Hetlioz capsules for SMS in patients 16 years and older is 20 mg one hour before bedtime, at the same time every night.

The recommended dosage of Hetlioz LQ oral suspension in pediatric patients 3 years to 15 years of age is based on body weight (Table 1). Administer HETLIOZ one hour before bedtime, at the same time every night.

Table 1

Body Weight	Daily Dose (oral suspension)
≤28 kg	0.7 mg/kg one hour before bedtime
>28 kg	20 mg one hour before bedtime

Hetlioz capsules and Hetlioz LQ oral suspension are not substitutable

AVAILABLE STRENGTHS
- 20 mg capsules
- 4mg/mL oral suspension

REFERNCES
- Hetlioz [Prescribing Information]. Washington, D.C.: Vanda Pharmaceuticals, Inc.; December 2020.

Created: 03/19
Effective: 04/01/21 Client Approval: 03/26/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

TAVABOROLE

Generic	Brand	HICL	GCN	Exception/Other
TAVABOROLE	KERYDIN	41353		

GUIDELINES FOR USE

Our guideline for **TAVABOROLE** requires the following: a diagnosis of onychomycosis of the toenails; presence of complicating factors such as diabetes, peripheral vascular disease, a suppressed immune system, or pain surrounding the nail or soft tissue; and previous trial or contraindication to oral terbinafine or oral itraconazole and ciclopirox topical solution.

RATIONALE

to promote clinically appropriate utilization of Kerydin (tavaborole) based on its FDA approved indication and dosing.

Kerydin is an oxaborole antifungal. Onychomycosis refers to nail infections caused by any fungus, including yeasts and non-dermatophyte molds. Although onychomycosis is usually a cosmetic concern to patients, it also causes physical discomfort for some, particularly with more severe or advanced disease. Patients may experience chronic pain or acute pain exacerbated by nail cutting, footwear, or pressure from bedclothes. Additionally, in patients with diabetes or other immunocompromised states, onychomycosis may increase the risk of bacterial infections such as cellulitis.

Kerydin may not be as efficacious as oral antifungals (e.g. terbinafine and itraconazole) in the treatment of onychomycosis, but its safety profile is improved. The most common adverse reactions associated with Kerydin are ingrown toenails, application site reactions (i.e. dermatitis, exfoliation, erythema). Additionally, Kerydin neither interacts with cytochrome P450 enzymes nor is associated with hepatotoxicity, as seen with oral antifungals.

DOSAGE AND ADMINISTRATION

Apply enough medication to cover the entire toenail surface and under the tip of each affected toenail once daily for 48 weeks. Use the dropper tip to gently spread Kerydin to the entire toenail up to the edges of the toenail as well as under the tip of the toenail.

For topical use only and not for oral, ophthalmic, or intravaginal use.

FDA APPROVED INDICATIONS

For the topical treatment of onychomycosis of the toenails due to *Trichophyton rubrum* or *Trichophyton mentagrophytes*.

REFERENCES

- Kerydin [Prescribing Information]. Palo Alto, CA: Anacor Pharmaceuticals; July 2018.

Created: 06/15
Effective: 04/15/19 Client Approval: 03/28/19 P&T Approval: 11/14

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

TAZEMETOSTAT

Generic	Brand	HICL	GCN	Exception/Other
TAZEMETOSTAT	TAZVERIK	46312		

GUIDELINES FOR USE

Our guideline named **TAZEMETOSTAT (Tazverik)** requires the following rule(s) be met for approval:

- You have metastatic (cancer that has spread to other parts of the body) or locally advanced (cancer has grown outside the organ it started in, but has not yet spread to distant parts of the body) epithelioid sarcoma (rare type of soft tissue cancer)
- You are 16 years of age or older
- You are not eligible for complete resection (surgically removing all of a tissue/organ)

RATIONALE

To ensure appropriate diagnostic, utilization and safety criteria are used for the management of requests for tazemetostat.

FDA APPROVED INDICATIONS

Tazverik is a methyltransferase inhibitor indicated for the treatment of adults and pediatric patients aged 16 years and older with metastatic or locally advanced epithelioid sarcoma not eligible for complete resection.

DOSING

The recommended dose of Tazverik is 800 mg taken orally twice daily with or without food until disease progression or unacceptable toxicity.

REFERENCES

- Tazverik [Prescribing Information]. Cambridge, MA: Epizyme, Inc.; January 2020.

Created: 03/20
Effective: 03/30/20 Client Approval: 03/05/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

TEDUGLUTIDE

Generic	Brand	HICL	GCN	Exception/Other
TEDUGLUTIDE	GATTEX	39890		

GUIDELINES FOR USE

The guideline named **TEDUGLUTIDE (Gattex)** requires a diagnosis of short bowel syndrome (SBS). In addition, the following criteria must be met.

- The patient is at least 1 year of age
- The patient is dependent on intravenous parenteral nutrition, defined as requiring parenteral nutrition at least three times per week.

RATIONALE

To ensure appropriate use of Gattex based on FDA approved indication.

FDA APPROVED INDICATIONS

Gattex (teduglutide [rDNA origin]) is indicated for the treatment of patients 1 year of age and older with Short Bowel Syndrome (SBS) who are dependent on parenteral support.

DOSING

The recommended daily dose of Gattex is 0.05mg/kg body weight administered by subcutaneous injection once daily. Gattex should not be administered intravenously or intramuscularly. Patients should be advised to alternate sites of injection. Recommended sites of administration include: thighs, arms and quadrants of the abdomen. Missed doses should be taken as soon as possible that day but patients should not take 2 doses on the same day.

A 50% dose reduction is recommended in patient with moderate and severe renal impairment (creatine clearance < 50ml/min) and ESRD. There is potential for increased absorption of concomitant oral medications, which should be considered if these drugs require titration or have a narrow therapeutic index.

REFERENCES

- Gattex [Prescribing Information]. Bedminister, NJ: NPS Pharmaceutical; June 2019.

Created: 06/15
Effective: 03/09/20 Client Approval: 02/17/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

TELOTRISTAT ETIPRATE

Generic	Brand	HICL	GCN	Exception/Other
TELOTRISTAT ETIPRATEE	XERMELO	44132		

GUIDELINES FOR USE

Approval for **TELOTRISTAT (Xermelo)** requires a diagnosis of carcinoid tumors, trial and failure monotherapy with a somatostatin analog (e.g., lanreotide, octreotide acetate), and use of Xermelo in combination with a somatostatin analog (e.g., lanreotide, octreotide acetate).

RATIONALE

To ensure appropriate use of Xermelo based on FDA approved indication and dosing.

FDA APPROVED INDICATIONS

Xermelo is a tryptophan hydroxylase inhibitor indicated for the treatment of carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in adults inadequately controlled by SSA therapy.

Dosing:
The recommended dosage of Xermelo in adult patients is 250 mg three times daily for patients whose diarrhea is inadequately controlled by a SSA therapy.

REFERENCE

- Xermelo [package insert]. The Woodlands, TX: Lexicon Pharmaceuticals, Inc.; February 2017.

Created: 05/17
Effective: 07/22/17 Client Approval: 05/30/17 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

TEMOZOLOMIDE - PO

Generic	Brand	HICL	GCN	Exception/Other
TEMOZOLOMIDE - PO	TEMODAR - PO		92903, 92893, 92933, 92913, 98310, 98311	

GUIDELINES FOR USE

Our guideline named **TEMOZOLOMIDE (Temodar)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Anaplastic astrocytoma (type of brain tumor)
   2. Glioblastoma multiforme (type of tumor affecting brain or spine)
   3. Metastatic melanoma (type of skin cancer)
   4. Small cell lung cancer (SCLC: a type of lung cancer)

RATIONALE

Ensure appropriate use of TEMOZOLOMIDE based on FDA approved indications and NCCN guidance.

FDA APPROVED INDICATIONS

Temodar is an alkylating drug indicated for the treatment of adult patients with:

- Newly diagnosed glioblastoma multiforme (GBM) concomitantly with radiotherapy and then as maintenance treatment.
- Refractory anaplastic astrocytoma patients who have experienced disease progression on a drug regimen containing nitrosourea and procarbazine.

REFERENCES

Schering Corporation, a subsidiary of Merck & Co., Inc. Temodar package insert. Whitehouse Station, NJ. November 2022.

Created: 06/15
Effective: 01/30/23 Client Approval: 01/05/23 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

TERIFLUNOMIDE

Generic	Brand	HICL	GCN	Exception/Other
TERIFLUNOMIDE	AUBAGIO	39624		

GUIDELINES FOR USE

Our guideline for **TERIFLUNOMIDE (Aubagio)** requires you have a diagnosis of multiple sclerosis (immune system eats away at protective covering of nerves)

RATIONALE

To ensure appropriate use of Aubagio consistent with FDA approved indication.

FDA APPROVED INDICATIONS

Aubagio is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

DOSING

The recommended dose of Aubagio is 7 mg or 14 mg orally once daily, with or without food.

REFERENCES

- Aubagio [Prescribing Information]. Cambridge, MA: Genzyme Corporation; April 2021.

Created: 06/15
Effective: 08/16/21 Client Approval: 07/07/21 P&T Approval: N/A

TEPOTINIB

Generic	Brand	HICL	GCN	Exception/Other
TEPOTINIB HCL	TEPMETKO	47095		

GUIDELINES FOR USE

Our guideline named **TEPOTINIB (Tepmetko)** requires the following rule(s) be met for approval:
A. You have metastatic non-small cell lung cancer (NSCLC)
B. You are 18 years of age or older
C. Mesenchymal-epithelial transition (MET) exon 14 skipping alterations (abnormal change in a gene that makes MET protein) are present

RATIONALE
To ensure appropriate diagnostic, utilization, and safety criteria are used for the management of requests for tepotinib.

INDICATIONS
Tepmetko is a kinase inhibitor indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) harboring mesenchymal-epithelial transition (*MET*) exon 14 skipping alterations.

DOSING
The recommended dosage of Tepmetko is 450 mg orally once daily with food until disease progression or unacceptable toxicity.

REFERENCES

- Tepmetko [Prescribing Information]. Rockland, MA: EMD Serono, Inc.; February 2021.

Created: 03/21
Effective: 04/19/21 Client Approval: 03/22/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

TERIPARATIDE

Generic	Brand	HICL	GCN	Exception/Other
TERIPARATIDE	FORTEO	24700		

GUIDELINES FOR USE

The guideline named **TERIPARATIDE (Forteo)** requires that the patient has a diagnosis of postmenopausal osteoporosis, primary or hypogonadal osteoporosis in a male patient, or glucocorticoid-induced osteoporosis, **AND** the patient has not received a total of 24 months or more of parathyroid hormone therapy with Tymlos or Forteo. In addition, one of the following criteria must be met:

- The patient is at high risk for fractures defined as **ONE** of the following:
  - History of osteoporotic (e.g., fragility, low trauma) fracture(s)
  - 2 or more risk factors for fracture (e.g., history of multiple recent low trauma fractures, BMD T-score less than or equal to -2.5, corticosteroid use, or use of GnRH analogs such as nafarelin, etc.)
  - No prior treatment for osteoporosis **AND** FRAX score ≥ 20% for any major fracture **OR** ≥ 3% for hip fracture
- The patient is unable to use oral therapy (e.g., upper gastrointestinal [GI] problems - unable to tolerate oral medication, lower GI problems - unable to absorb oral medications, trouble remembering to take oral medications or coordinating an oral bisphosphonate with other oral medications or their daily routine)
- The patient has an adequate trial of, intolerance to, or a contraindication to bisphosphonates (e.g., alendronate, risedronate, ibandronate)

RATIONALE

To ensure safe use of teriparatide for the treatment of osteoporosis in patients who have failed or are intolerant to anti-resorptive agents.

FDA APPROVED INDICATIONS

- For the treatment of postmenopausal women with osteoporosis at high risk for fracture
- To increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture
- For the treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy (daily dosage equivalent to 5 mg or greater of prednisone) at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy

REFERENCE

- Eli Lilly and Company. Forteo package insert. Indianapolis, IN. October 2019.

Created: 08/17
Effective: 04/20/20 Client Approval: 03/25/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

TESAMORELIN

Generic	Brand	HICL	GCN	Exception/Other
TESAMORELIN	EGRIFTA	37268		

GUIDELINES FOR USE

Approval requires that the patient is infected with HIV (AIDS), and has excess abdominal fat with lipodystrophy.

RATIONALE

Ensure that tesamorelin is used solely for its FDA approved indication.

FDA APPROVED INDICATION

Tesamorelin is indicated for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.

REFERENCES

- EMD Serono, Inc. Egrifta package insert. Rockland, MA. November 2010.

Created: 06/15
Effective: 07/22/15 Client Approval: 06/15 P&T Approval: 02/11

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

TETRABENAZINE

Generic	Brand	HICL	GCN	Exception/Other
TETRABENAZINE	XENAZINE	07350		

GUIDELINES FOR USE

Our guideline for **TETRABENAZINE** requires a diagnosis of chorea (involuntary movements) associated with Huntington's disease and that the medication has been prescribed or recommended by a neurologist. Requests for a tetrabenzine dosage that exceeds 50mg requires that the patient has been genotyped for CYP2D6 and is identified as an extensive (EM) or intermediate metabolizer (IM) of CYP2D6.

RATIONALE

Ensure appropriate diagnostic, utilization and safety criteria are used for tetrabenazine management.

FDA APPROVED INDICATION

Xenazine is indicated for the treatment of chorea associated with Huntington's disease.

DOSAGE

The dose of Xenazine should be individualized.

Dosing Recommendations Up to 50 mg per day

The starting dose should be 12.5 mg per day given once in the morning. After one week, the dose should be increased to 25 mg per day given as 12.5 mg twice a day. Xenazine should be titrated up slowly at weekly intervals by 12.5 mg daily, to allow the identification of a tolerated dose that reduces chorea. If a dose of 37.5 to 50 mg per day is needed, it should be given in a three times a day regimen. The maximum recommended single dose is 25 mg. If adverse reactions such as akathisia, restlessness, parkinsonism, depression, insomnia, anxiety or sedation occur, titration should be stopped and the dose should be reduced. If the adverse reaction does not resolve, consideration should be given to withdrawing Xenazine treatment or initiating other specific treatment.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

TETRABENAZINE

Dosing Recommendations Above 50 mg per day

Patients who require doses of Xenazine greater than 50 mg per day should be first tested and genotyped to determine if they are poor metabolizers (PMs) or extensive metabolizers (EMs) by their ability to express the drug metabolizing enzyme, CYP2D6. The dose of Xenazine should then be individualized accordingly to their status as PMs or EMs.

- Extensive and Intermediate CYP2D6 Metabolizers
  Genotyped patients who are identified as extensive (EMs) or intermediate metabolizers (IMs) of CYP2D6, who need doses of Xenazine above 50 mg per day, should be titrated up slowly at weekly intervals by 12.5 mg daily, to allow the identification of a tolerated dose that reduces chorea. Doses above 50 mg per day should be given in a three times a day regimen. The maximum recommended daily dose is 100 mg and the maximum recommended single dose is 37.5 mg. If adverse reactions such as akathisia, parkinsonism, depression, insomnia, anxiety or sedation occur, titration should be stopped and the dose should be reduced. If the adverse reaction does not resolve, consideration should be given to withdrawing Xenazine treatment or initiating other specific treatment (e.g., antidepressants).
- Poor CYP2D6 Metabolizers
  In PMs, the initial dose and titration is similar to EMs except that the recommended maximum single dose is 25 mg, and the recommended daily dose should not exceed a maximum of 50 mg.

REFERENCES

- Lundbeck Pharmaceuticals, Inc. Xenazine package insert. Deerfield, IL. June, 2015.

Created: 02/16
Effective: 06/01/16 Client Approval: 04/18/16 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

THALIDOMIDE

Generic	Brand	HICL	GCN	Exception/Other
THALIDOMIDE	THALOMID	11465		

GUIDELINES FOR USE

Approval requires a diagnosis of multiple myeloma and that Thalomid is being used in combination with dexamethasone or prednisone; or a diagnosis of erythema nodosum leprosum (ENL); or a diagnosis of anemia due to myelodysplastic syndrome that has been previously treated; or a diagnosis of Waldenström's Macroglobulinemia.

RATIONALE

To ensure appropriate use aligned with FDA approved indications and NCCN guidelines.

The FDA approved dose for multiple myeloma is 200mg once daily along with dexamethasone 40mg daily on days 1-4, 9-12, and 17-20 every 28 days. For cutaneous erythema nodosum leprosum the dosage is 100 to 300mg daily and up to 400mg daily for severe cases.

NCCN multiple myeloma treatment guidelines consider primary induction therapy for stem cell transplant candidates with lenalidomide in combination with dexamethasone, and thalidomide in combination with bortezomib and dexamethasone to have the strongest evidence. Other combinations involving bortezomib, lenalidomide or thalidomide are also considered effective. For primary induction therapy for non-transplant candidates in patients with newly diagnosed multiple myeloma, NCCN considers thalidomide and melphalan in combination prednisone, melphalan in combination with prednisone and bortezomib, and lenalidomide in combination with low-dose dexamethasone to have the strongest evidence. Other combinations involving melphalan, lenalidomide or thalidomide are also considered effective. For maintenance therapy following disease response in patients with newly diagnosed multiple myeloma who undergo stem cell transplant, NCCN considers thalidomide monotherapy to have the strongest evidence. Lenalidomide monotherapy, thalidomide in combination with prednisone and interferon monotherapy are also considered effective. For salvage therapy in patients who did not respond to or were ineligible for stem cell transplant, re-induction with the same regimen can be considered if the relapse occurs at greater than 6 months after completion of the initial induction therapy. NCCN considers lenalidomide in combination with dexamethasone to have the best evidence. Other therapies involving lenalidomide, thalidomide or bortezomib may be considered.

The NCCN myelodysplastic syndrome guidelines recognize thalidomide as a non-chemotherapy, low-intensity agent that has demonstrated efficacy in a phase II trial.

NCCN guidelines for Waldenström's Macroglobulinemia state that primary treatment options include oral alkylators, nucleoside analogs, rituximab alone or in combination with cyclophosphamide, bortezomib, nucleoside analogues, thalidomide, or bendamustine.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

THALIDOMIDE

FDA APPROVED INDICATIONS

Thalomid in combination with dexamethasone is indicated for the treatment of patients with newly diagnosed multiple myelomas. Thalomid is indicated for the acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL). Thalomid is not indicated as monotherapy for such ENL treatment in the presence of moderate to severe neuritis. Thalomid is also indicated as maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence.

REFERENCES

- Celgene Corporation. Thalomid package insert. Summit, NJ. February 2012.
- National Comprehensive Cancer Network, Inc. The NCCN Clinical Practice Guidelines in Oncology. Multiple Myeloma. (Version 1.2012).
- National Comprehensive Cancer Network, Inc. The NCCN Clinical Practice Guidelines in Oncology. Myelodysplastic Syndromes. (Version 1.2012).
- National Comprehensive Cancer Network, Inc. The NCCN Clinical Practice Guidelines in Oncology. Waldenström's Macroglobulinemia / Lymphoplasmacytic Lymphoma. (Version 1.2012).

Created: 06/15
Effective: 07/22/15 Client Approval: 06/15 P&T Approval: 08/12

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

THYROTROPIN ALFA FOR INJECTION

Generic	Brand	HICL	GCN	Exception/Other
THYROTROPIN ALFA FOR INJECTION	THYROGEN	18855		

GUIDELINES FOR USE

The guideline requires that the requested product being used as adjunctive treatment for radioiodine ablation of thyroid tissue remnants for thyroid cancer without evidence of metastatic disease.

RATIONALE

To ensure appropriate use of Thyrogen based on FDA approved indication and dosage. Limit diagnostic use to the medical benefit.

Two-injection regimen of Thyrogen 0.9 mg IM, followed by a second 0.9 mg IM injection 24 hours later.

FDA APPROVED INDICATION

Thyrogen (thyrotropin alfa for injection) is indicated for use as an adjunctive diagnostic tool for serum thyroglobulin (Tg) testing with or without radioiodine imaging in the follow-up of patients with well-differentiated thyroid cancer.

Thyrogen (thyrotropin alfa for injection) is indicated for use as an adjunctive treatment for radioiodine ablation of thyroid tissue remnants in patients who have undergone a near-total or total thyroidectomy for well-differentiated thyroid cancer and who do not have evidence of metastatic thyroid cancer.

REFERENCES

- Thyrogen (thyrotropin alfa for injection) [Prescribing Information]. Cambridge, MA: Genzyme Corporation.; July 2012.

Created: 09/18
Effective: 04/01/19 Client Approval: 03/13/19 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

TILDRAKIZUMAB-ASMN

Generic	Brand	HICL	GCN	Exception/Other
TILDRAKIZUMAB-ASMN	ILUMYA	44823		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TILDRAKIZUMAB-ASMN (Ilumya)** requires the following rule(s) be met for approval:

A. You are 18 years of age or older
B. You have moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
C. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
D. You have previously tried ONE of the following conventional therapies: PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
E. You have previously tried TWO of the following: Cosentyx, Enbrel, or Humira

RENEWAL CRITERIA

Our guideline named **TILDRAKIZUMAB-ASMN (Ilumya)** requires the following rule(s) be met for renewal:

A. You have moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
B. You have experienced or maintained symptomatic improvement while on therapy

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RATIONALE
Ensure appropriate diagnostic, utilization and safety criteria are used for the management of requests for Ilumya.

FDA APPROVED INDICATIONS
Ilumya is an interleukin-23 antagonist indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

DOSAGE
Ilumya is administered by subcutaneous injection. Ilumya should only be administered by a healthcare provider. The recommended dose is 100 mg at Week 0, Week 4, and every 12 weeks thereafter.

DOSAGE FORMS AND STRENGTHS
Single-dose prefilled syringes are available for subcutaneous administration: 100 mg per mL.

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TILDRAKIZUMAB-ASMN

REFERENCES

- Ilumya [Prescribing Information]. Sharjah, U.A.E.: Sun Pharma Global FZE, Inc. July 2020.
- Menter A, Strober BE, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.

Created: 03/19
Effective: 04/11/22 Client Approval: 03/10/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

TIVOZANIB

Generic	Brand	HICL	GCN	Exception/Other
TIVOZANIB HCL	FOTIVDA	45740		

GUIDELINES FOR USE

Our guideline named **TIVOZANIB (Fotivda)** requires the following rule(s) be met for approval:

A. You have relapsed or refractory advanced renal cell carcinoma (type of kidney cancer that returns or has not responded to treatment)
B. You are 18 years of age or older
C. You previously had two or more systemic therapies for renal cell carcinoma

RATIONALE

To ensure appropriate use of Fotivda consistent with FDA approved indication.

FDA APPROVED INDICATIONS

Fotivda is a kinase inhibitor indicated for the treatment of adult patients with relapsed or refractory advanced renal cell carcinoma (RCC) following two or more prior systemic therapies.

DOSING

The recommended dosage of Fotivda is 1.34 mg taken orally once daily for 21 days on treatment followed by 7 days off treatment for a 28-day cycle.

REFERENCES

- Fotivda [Prescribing Information]. Boston, MA: AVEO Pharmaceuticals, Inc.; March 2021.

Created: 04/21
Effective: 06/21/21 Client Approval: 05/21/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

TOBRAMYCIN INHALED

Generic	Brand	HICL	GCN	Exception/Other
TOBRAMYCIN	BETHKIS		16122	
TOBRAMYCIN IN 0.225% NACL	TOBI		61551	
TOBRAMYCIN	TOBI PODHALER		30025, 34461	

GUIDELINES FOR USE

Our guideline named **TOBRAMYCIN INHALED (Bethkis, Tobi, Tobi Podhaler)** requires the following rule(s) be met for approval:

A. ONE of the following:
   1. You have cystic fibrosis (inherited life-threatening disorder that damages the lungs and digestive system)
   2. You have non-cystic fibrosis bronchiectasis
   3. You have chronic bronchial infection

B. You have a lung infection with *Pseudomonas aeruginosa*

RATIONALE

Promote appropriate utilization of inhaled tobramycin based on FDA approved indication.

FDA APPROVED INDICATIONS

Tobi is indicated for the management of cystic fibrosis patients with *P. aeruginosa*. Safety and efficacy have not been demonstrated in patients under the age of 6 years, patients with FEV_1 <25% or >75% predicted, or patients colonized with *Burkholderia cepacia.*

Tobi Podhaler is an antibacterial aminoglycoside indicated for the management of cystic fibrosis patients with *Pseudomonas aeruginosa*. Safety and efficacy have not been demonstrated in patients under the age of 6 years, patients with forced expiratory volume in 1 second (FEV_1) <25% or >80% or patients colonized with *Burkholderia cepacia*.

Bethkis is an inhaled aminoglycoside antibacterial indicated for the management of cystic fibrosis patients with Pseudomonas aeruginosa. Safety and efficacy have not been demonstrated in patients under the age of six years, patients with a forced expiratory volume in less than one second (FEV1) less than 40% or greater than 80% predicted, or patients colonized with Burkholderia cepacia.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

TOBRAMYCIN INHALED

DOSING

Tobi Dosage: One ampule (300mg/5mL) every 12 hours in repeated cycles of 28 days on drug followed by 28 days off drug.

Tobi Podhaler Dosage: Inhale the contents of four 28mg capsules twice daily for 28 days. After 28 days of therapy, patients should stop Tobi Podhaler therapy for the next 28 days, and then resume therapy for the next 28 day on and 28 day off cycle.

Bethkis Dosage: One ampule (300mg/4mL) twice daily by oral inhalation in repeated cycles of 28 days on drug, followed by 28 days off drug.

REFERENCES

- Novartis Pharmaceuticals Corporation. Tobi package insert. East Hanover, NJ. November 2009.
- Novartis Pharmaceuticals Corporation. Tobi Podhaler package insert. East Hanover, NJ. October 2015.
- Chiesi Pharma, Inc. Bethkis package insert. Woodstock, Illinois. December 2019.

Created: 03/15
Effective: 06/13/2022 Client Approval: 06/01/2022 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

TOCILIZUMAB - IV

Generic	Brand	HICL	GCN	Exception/Other
TOCILIZUMAB - IV	ACTEMRA - IV		27366 27367 27368	

NOTE: For requests for the SQ dosage form of Actemra, please see the TOCILIZUMAB SQ PA Guideline.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

Our guideline named **TOCILIZUMAB - IV (Actemra - IV)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in many joints in children)
   3. Systemic juvenile idiopathic arthritis (SJIA: swelling and stiffness in joints in children that can affect organs)
   4. Chimeric antigen receptor (CAR) T cell-induced severe or life-threatening Cytokine Release Syndrome (inflammatory response that can be triggered by a variety of factors such as infections and certain drugs)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. You have previously tried at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs): methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   3. You have previously tried **ONE** of the following: Enbrel or Humira

C. **If you have polyarticular juvenile idiopathic arthritis (PJIA), approval also requires:**
   1. You are 2 years of age or older
   2. You have previously tried at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs): methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   3. You have previously tried **ONE** of the following: Enbrel or Humira

D. **If you have systemic juvenile idiopathic arthritis (SJIA), approval also requires:**
   1. You are 2 years of age or older

E. **For the treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS), approval also requires:**
   1. You are 2 years of age or older

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TOCILIZUMAB - IV

RENEWAL CRITERIA (CONTINUED)

Our guideline named **TOCILIZUMAB - IV (Actemra - IV)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in many joints in children)
   3. Systemic juvenile idiopathic arthritis (SJIA: swelling and stiffness in joints in children that can affect organs)

B. You have experienced or maintained symptomatic improvement while on therapy.

RATIONALE

Ensure appropriate diagnostic, utilization, and safety criteria are used for the management of requests for tocilizumab.

FDA APPROVED INDICATIONS

Actemra - IV (tocilizumab - IV) is an interleukin-6 (IL-6) receptor antagonist indicated for:

- The treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to one or more Disease-Modifying Anti-Rheumatic Drugs (DMARDs).
- The treatment of active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older.
- The treatment of active systemic juvenile idiopathic arthritis in patients 2 years of age and older.
- The treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome in adults and pediatric patients 2 years of age and older.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

TOCILIZUMAB - IV

DOSING

Rheumatoid Arthritis	
Recommended Adult Intravenous (IV) Dosage	
When used in combination with DMARDs or as monotherapy the recommended starting dose is 4 mg per kg every 4 weeks followed by an increase to 8 mg per kg every 4 weeks based on clinical response. Doses exceeding 800 mg per infusion are not recommended in RA patients.	
Polyarticular Juvenile Idiopathic Arthritis (PJIA)	
Recommended Intravenous PJIA Dosage Every 4 Weeks	
Patients less than 30 kg weight	10 mg per kg
Patients at or above 30 kg weight	8 mg per kg
Systemic Juvenile Idiopathic Arthritis (SJIA)	
Recommended Intravenous SJIA Dosage Every 2 Weeks	
Patients less than 30 kg weight	12 mg per kg
Patients at or above 30 kg weight	8 mg per kg
Cytokine Release Syndrome (CRS)	
Recommended Intravenous CRS Dosage	
Patients less than 30 kg weight	12 mg per kg
Patients at or above 30 kg weight	8 mg per kg
Alone or in combination with corticosteroids.	
If no clinical improvement in the signs and symptoms of CRS occurs after the first dose, up to 3 additional doses of ACTEMRA may be administered. The interval between consecutive doses should be at least 8 hours. Doses exceeding 800 mg per infusion are not recommended in CRS patients.	

Use only the subcutaneous route for treatment of giant cell arteritis (GCA) and systemic sclerosis-associated interstitial lung disease (SSc-ILD). Intravenous administration is not approved for GCA or SSC-ILD.

DOSAGE FORMS AND STRENGTHS

Single-use vials of ACTEMRA (20 mg per mL) are available for intravenous administration:

- 80 mg per 4 mL
- 200 mg per 10 mL
- 400 mg per 20 mL

REFERENCES

- Actemra [Prescribing Information]. South San Francisco, CA: Genentech. June 2022.
- Onel KB, Horton DB, et al. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. Arthritis Care Res 2022 Apr;74(4):505-520.
- Singh JA, Saag KG, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. 2016;68(1):1-25. DOI 10.1002/acr.22783

Created: 02/18
Effective: 09/12/22 Client Approval: 08/30/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

TOCILIZUMAB - SQ

Generic	Brand	HICL	GCN	Exception/Other
TOCILIZUMAB - SQ	ACTEMRA - SQ		35486 45082	

PLEASE NOTE: For requests for the IV dosage form of Actemra, please see the Actemra IV PA Guideline.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TOCILIZUMAB - SQ (Actemra - SQ)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Giant cell arteritis (GCA: inflammatory disease affecting the large blood vessels of the scalp, neck and arms)
   3. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: disorder that causes hardening of lung tissue)
   4. Polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in many joints in children)
   5. Systemic juvenile idiopathic arthritis (SJIA: swelling and stiffness in joints in children that can affect organs)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. You have previously tried at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs): methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   3. You have previously tried **ONE** of the following: Enbrel or Humira

C. **If you have giant cell arteritis (GCA), approval also requires:**
   1. You are 18 years of age or older

D. **If you have polyarticular juvenile idiopathic arthritis (PJIA), approval also requires:**
   1. You are 2 years of age or older
   2. You have previously tried at least **ONE** of the following DMARDs (disease-modifying antirheumatic drugs): methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   3. You have previously tried **ONE** of the following: Enbrel or Humira

E. **If you have systemic juvenile idiopathic arthritis (SJIA), approval also requires:**
   1. You are 2 years of age or older

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

TOCILIZUMAB - SQ

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **TOCILIZUMAB - SQ (Actemra - SQ)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Giant cell arteritis (GCA: inflammatory disease affecting the large blood vessels of the scalp, neck and arms)
   3. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: disorder that causes hardening of lung tissue)
   4. Polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in many joints in children)
   5. Systemic juvenile idiopathic arthritis (SJIA: swelling and stiffness in joints in children that can affect organs)
B. You have experienced or maintained symptomatic improvement while on therapy

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RATIONALE
Ensure appropriate diagnostic, utilization, and safety criteria are used for the management of requests for tocilizumab.

FDA APPROVED INDICATIONS
Actemra - SQ (tocilizumab - SQ) is an interleukin-6 (IL-6) receptor antagonist indicated for:

- Treatment of moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to one or more Disease-Modifying Anti-Rheumatic Drugs (DMARDs) in adult patients.
- Treatment of giant cell arteritis (GCA) in adult patients.
- Slowing the rate of decline in pulmonary function in adult patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD).
- Treatment of active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older.
- Treatment of active systemic juvenile idiopathic arthritis in patients 2 years of age and older.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

TOCILIZUMAB - SQ

DOSING

Rheumatoid Arthritis	
Recommended Adult Subcutaneous (SQ) Dosage Every 4 Weeks	
Patients less than 100 kg weight	162 mg administered subcutaneously every other week, followed by an increase to every week based on clinical response
Patients at or above 100 kg weight	162 mg administered subcutaneously every week
Giant Cell Arteritis	
Recommended Adult Subcutaneous (SQ) Dosage Every 4 Weeks	
162 mg given once every week as a subcutaneous injection in combination with a tapering course of glucocorticoids.	
Systemic Sclerosis-Associated Interstitial Lung Disease	
Recommended Adult Subcutaneous (SQ) Dosage Every 4 Weeks	
162 mg given once every week as a subcutaneous injection	
Polyarticular Juvenile Idiopathic Arthritis (PJIA)	
Recommended Subcutaneous (SQ) Dosage	
Patients less than 30 kg weight	162 mg once every 3 weeks
Patients at or above 30 kg weight	162 mg once every 2 weeks
Systemic Juvenile Idiopathic Arthritis (SJIA)	
Recommended Subcutaneous (SQ) Dosage	
Patients less than 30 kg weight	162 mg once every 2 weeks
Patients at or above 30 kg weight	162 mg once every week

Use only the intravenous route for treatment of cytokine release syndrome (CRS). Subcutaneous administration is not approved for CRS.

DOSAGE FORMS AND STRENGTHS

Actemra (tocilizumab) injection is supplied as a preservative-free solution for subcutaneous administration. The following packaging configurations are available:

- Each single-dose prefilled syringe delivers 162 mg/0.9 mL (NDC 50242-138-01).
- Each single-dose autoinjector (ACTPen™) delivers 162 mg/0.9 mL (NDC 50242-143-01).

REFERENCES

- Actemra (tocilizumab) [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; June 2022.
- Onel KB, Horton DB, et al. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. Arthritis Care Res 2022 Apr;74(4):505-520.
- Singh JA, Saag KG, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. 2016;68(1):1-25. DOI 10.1002/acr.22783.

Created: 03/15
Effective: 09/12/22 Client Approval: 08/30/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

TOFACITINIB

Generic	Brand	HICL	GCN	Exception/Other
TOFACITINIB CITRATE	XELJANZ		33617, 44882, 48684	
TOFACITINIB CITRATE	XELJANZ XR		38086 47546	

GUIDELINES FOR USE
INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline for **TOFACITINIB** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   4. Active polyarticular course juvenile idiopathic arthritis (pcJIA: a type of joint condition)
   5. Ankylosing spondylitis (AS: a type of joint condition)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. You have previously tried ONE of the following DMARDs (disease-modifying antirheumatic drugs): methotrexate, leflunomide, hydroxychloroquine, sulfasalazine
   3. You have previously tried ONE of the following: Enbrel or Humira

C. If you have psoriatic arthritis (PsA), approval also requires:
   1. You are 18 years of age or older
   2. You have previously tried ONE of the following DMARDs (disease-modifying antirheumatic drugs): methotrexate, leflunomide, hydroxychloroquine, sulfasalazine
   3. You have previously tried TWO of the following: Cosentyx, Enbrel, or Humira

D. **If you have moderate to severe ulcerative colitis (UC), approval also requires:**
   1. You are 18 years of age or older
   2. You have previously tried ONE of the following conventional therapies: corticosteroids (e.g., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   3. You have previously tried Humira

E. **If you have active polyarticular course juvenile idiopathic arthritis (pcJIA), approval also requires:**
   1. You are 2 years of age or older
   2. You have previously tried ONE of the following DMARDs (disease-modifying antirheumatic drugs): methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   3. You have previously tried ONE of the following: Enbrel or Humira

F. **If you have ankylosing spondylitis (AS), our guideline also requires:**
   1. You are 18 years of age or older
   2. You have previously tried a non-steroidal anti-inflammatory agent (NSAID), unless there is a medical reason why you cannot
   3. You have previously tried TWO of the following: Cosentyx, Enbrel, or Humira

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TOFACITINIB

RENEWAL CRITERIA (CONTINUED)

Our guideline for **TOFACITINIB** requires the following rule(s) be met for renewal:

- You have ONE of the following diagnoses:
  - Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
  - Psoriatic arthritis (PsA: a type of skin and joint condition)
  - Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
  - Active polyarticular course juvenile idiopathic arthritis (pcJIA: a type of joint condition)
  - Ankylosing spondylitis (AS: a type of joint condition)
- You have experienced or maintained symptomatic improvement while on therapy

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RATIONALE

To ensure appropriate diagnostic, utilization, and safety criteria are used for the management of requests for tofacitinib.

FDA APPROVED INDICATIONS

Xeljanz/Xeljanz XR is indicated for:

- The treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to methotrexate.
- The treatment of adult patients with psoriatic arthritis who have had an inadequate response or intolerance to methotrexate or other disease-modifying antirheumatic drugs (DMARDs).
- The treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response or who are intolerant to TNF blockers.
- The treatment of active polyarticular course juvenile idiopathic arthritis (pcJIA) in patients 2 years of age and older.
- The treatment of adult patients with ankylosing spondylitis who have had an inadequate response or who are intolerant to TNF blockers.

Xeljanz/Xeljanz XR should not be used in combination with biologic DMARDs or potent immunosuppressants such as azathioprine and cyclosporine.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

TOFACITINIB

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE
Xeljanz/Xeljanz XR may be used as monotherapy or in combination with methotrexate or other non-biologic disease-modifying anti-rheumatic drugs (DMARDs).

The recommended dose of Xeljanz for rheumatoid arthritis, psoriatic arthritis, or ankylosing spondylitis is 5 mg orally twice daily, and the recommended dose of Xeljanz XR is 11 mg once daily.

The recommended dosage regimen of Xeljanz for ulcerative colitis is as follows:
- Induction: 10 mg twice daily for at least 8 weeks; evaluate patients and transition to maintenance therapy depending on therapeutic response. If needed continue 10 mg twice daily for a maximum of 16 weeks. Discontinue 10 mg twice daily after 16 weeks if adequate therapeutic response is not achieved.
- Maintenance: 5 mg twice daily. For patients with loss of response during maintenance treatment, a dosage of 10 mg twice daily may be considered and limited to the shortest duration, with careful consideration of the benefits and risks for the individual patient. Use the lowest effective dose needed to maintain response.

The recommended dosage regimen of Xeljanz XR for ulcerative colitis is as follows:
- Induction: 22 mg once daily for at least 8 weeks; evaluate patients and transition to maintenance therapy depending on therapeutic response. If needed continue 22 mg once daily for a maximum of 16 weeks. Discontinue 22 mg once daily after 16 weeks if adequate therapeutic response is not achieved.
- Maintenance: 11 mg once daily. For patients with loss of response during maintenance treatment, a dosage of 22 mg once daily may be considered and limited to the shortest duration, with careful consideration of the benefits and risks for the individual patient. Use the lowest effective dose needed to maintain response.

Switching from Xeljanz Tablets to Xeljanz XR Extended-Release Tablets
Patients treated with Xeljanz 5 mg twice daily may be switched to Xeljanz XR 11 mg once daily the day following the last dose of Xeljanz 5 mg. Patients treated with Xeljanz 10 mg tablets twice daily may be switched to Xeljanz XR extended-release tablets 22 mg once daily the day following the last dose of Xeljanz 10 mg.

The recommended dosage regimen of Xeljanz for active polyarticular course juvenile idiopathic arthritis (pcJIA) is as follows:
- 10 kg ≤ body weight <20 kg: 3.2 mg (3.2 mL oral solution) twice daily
- 20 kg ≤ body weight <40 kg: 4 mg (4 mL oral solution) twice daily
- Body weight ≥40 kg: 5 mg (one 5 mg tablet or 5 mL oral solution*) twice daily

AVAILABLE STRENGTHS
- 5 and 10 mg immediate-release
- 11 and 22 mg extended-release tablets
- 1 mg/mL oral solution

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TOFACITINIB

REFERENCES

- Xeljanz [Prescribing Information]. New York, NY: Pfizer; December 2021.
- Kornbluth A, Sachar DB. Ulcerative colitis practice guidelines in adults: American College of Gastroenterology, Practice Parameters Committee. *Am J Gastroenterol* 2010;105:501-523.
- Singh JA, Guyatt G, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Care & Research. Vol. 71, No. 1, January 2019, pp 2–29DOI 10.1002/acr.2378.
- Singh JA, Saag KG, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. 2016;68(1):1-25. DOI 10.1002/acr.22783.
- Beukelman T, Patkar NM, et al. 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: Initiation and safety monitoring of therapeutic agents for the treatment of arthritis and systemic features. Arthritis Care Res, 63: 465–482. doi: 10.1002/acr.20460.
- Braun J, Davis J, et al. First update of the international ASAS consensus statement for the use of anti-TNF agents in patients with Ankylosing Spondylitis. Ann Rheum Dis. 2006; 65(3):316-20.

Created: 03/15
Effective: 03/28/22 Client Approval: 02/22/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

TOLVAPTAN

Generic	Brand	HICL	GCN	Exception/Other
TOLVAPTAN	JYNARQUE		24294, 24302, 39956, 39957, 39958, 48066, 48068	BRAND NAME = JYNARQUE

GUIDELINES FOR USE

Our guideline named **TOLVAPTAN (Jynarque)** requires the following rule(s) be met for approval:

A. You are 18 years of age or older
B. You are at high risk of rapidly progressing autosomal dominant polycystic kidney disease

RATIONALE

To promote appropriate utilization of JYNARQUE based on FDA approved indication and dosing.

FDA APPROVED INDICATION

Jynarque is a selective vasopressin V2-receptor antagonist indicated to slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease.

DOSAGE & ADMINISTRATION

The initial dosage for Jynarque is 60 mg orally per day as 45 mg taken on waking and 15 mg taken 8 hours later. Titrate to 60 mg plus 30 mg then to 90 mg plus 30 mg per day if tolerated with at least weekly intervals between titrations. Patients may down-titrate based on tolerability.

Initial dosage		**Titration Step**		**Target Dosage**	
1st Dose	45 mg	1st Dose	60 mg	1st Dose	90 mg
2nd dose (8 hours later)	15 mg	2nd dose (8 hours later)	30 mg	2nd dose (8 hours later)	30 mg
Total Daily Dose	**60 mg**	**Total Daily Dose**	**90 mg**	**Total Daily Dose**	**120 mg**

REFERENCES

- Jynarque [Prescribing Information]. Rockville, MD: Otsuka America Pharmaceutical Inc. October 2020.

Created: 05/18
Effective: 10/18/21 Client Approval: 09/21/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

TOPICAL ACNE PRODUCTS

Generic	Brand	HICL	GCN	Exception/Other
ADAPALENE	DIFFERIN, PLIXDA	11233		
TAZAROTENE	ARAZLO, FABIOR, TAZORAC	13315		
TRETINOIN	ALTRENO, ATRALIN, AVITA, RETIN-A, TRETIN-X	02468, 33394		ROUTE ≠ ORAL **OR** MISCELL.
TRETINOIN MICROSPHERES	RETIN-A MICRO	32888		
TRETINOIN/BENZOYL PEROXIDE	TWYNEO	47506		
TRIFAROTENE	AKLIEF	46048		

GUIDELINES FOR USE

Our guideline named **TOPICAL ACNE PRODUCTS** requires that you have a non-cosmetic diagnosis.

Our guideline named **TOPICAL ACNE PRODUCTS** requires that you have tried preferred options. Your provider may give a reason why you cannot take our suggested step therapies, including a statement that these therapies would not work as well or could cause side effects (e.g., contraindication, allergy/hypersensitivity). In some cases, the requested medication or alternatives offered may have additional approval requirements.

RATIONALE
To prevent use of tazarotene, tretinoin, trifarotene, and adapalene products for the treatment of cosmetic conditions such as melasma, photoaging, or wrinkles.

FDA APPROVED INDICATION
Tazarotene, tretinoin, trifarotene, and adapalene are indicated for the topical treatment of acne vulgaris.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

TOPICAL ACNE PRODUCTS

REFERENCES

- Galderma Laboratories, L.P. Differin package insert. Fort Worth, TX. March 2014.
- Valeant Pharmaceuticals. Atralin package insert. Bridgewater, NJ. July 2016.
- Bausch Health Companies, Inc. Retin-A package insert. Bridgewater, NJ. September 2019.
- Bausch Health Companies, Inc. Altreno package insert. Bridgewater, NJ. April 2019.
- Galderma Laboratories, L.P. Aklief package insert. Fort Worth, TX, October 2019.
- Bausch Health Companies, Inc. Arazlo package insert. Bridgewater, NJ. December 2019.
- Mayne Pharma, LLC. Fabior package insert. Greenville, NC. June 2018.
- Allergan USA, Inc. Tazorac package insert. Madison, NJ. April 2018.
- Galderma Laboratories, L.P. Epiduo Forte package insert. Fort Worth, TX. July 2015.
- Mylan Pharmceuticals, Inc. Avita package insert. Morgantown, WV. August 2011.
- Sol-Gel Technologies, Inc. Twyneo package insert. Whippany, NJ. July 2021.

Created: 02/17
Effective: 04/18/22 Client Approval: 03/22/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

TOREMIFENE

Generic	Brand	HICL	GCN	Exception/Other
TOREMIFENE CITRATE	FARESTON	11632		

Approval requires the patient to be a female who is postmenopausal with a diagnosis of estrogen receptor-positive or unknown hormone receptor status metastatic breast cancer.

RATIONALE
Coverage of Fareston (toremifene) is based on FDA approved indication and NCCN recommendations.

Fareston is dosed 60mg daily.

NCCN guidelines recognize several hormonal therapies as appropriate options for the treatment of ER-positive metastatic breast cancer including: anastrozole, letrozole, exemestane, fulvestrant, tamoxifen, toremifene, megestrol acetate, fluoxymesterone, and ethinyl estradiol. Premenopausal patients with ER-positive disease should have ovarian ablation/suppression and follow postmenopausal guidelines.

FDA Approved Indication
Fareston is an estrogen agonist/antagonist indicated for the treatment of metastatic breast cancer in postmenopausal women with estrogen-receptor positive or unknown tumors.

REFERENCES

- ProStrakan Inc. Fareston package insert. Memphis, TN. March 2011.
- National Comprehensive Cancer Network, Inc. NCCN Clinical Practice Guidelines in Oncology. Breast Cancer. (Version 3.2013).

Created: 06/15
Effective: 07/22/15 Client Approval: 06/15 P&T Approval: 08/13

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

TRALOKINUMAB-LDRM

Generic	Brand	HICL	GCN	Exception/Other
TRALOKINUMAB-LDRM	ADBRY	47741		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **TRALOKINUMAB-LDRM (Adbry)** requires the following rule(s) be met for approval:

A. You have moderate to severe atopic dermatitis (a type of skin condition)
B. You are 18 years of age or older
C. You had a trial of a high or super-high potency topical corticosteroid (such as triamcinolone acetonide, fluocinonide, clobetasol propionate, halobetasol propionate) AND one non-steroidal topical immunomodulating agent (such as Eucrisa, Opzelura, pimecrolimus, tacrolimus)
D. You had a trial of or contraindication to Dupixent (dupilumab)

RENEWAL CRITERIA

Our guideline named **TRALOKINUMAB-LDRM (ADBRY)** requires the following rule(s) be met for renewal:

A. You have moderate to severe atopic dermatitis (a type of skin condition)
B. You have experienced or maintained improvement in at least TWO of the following:
    1. Intractable pruritus (a type of skin condition)
    2. Cracking and oozing/bleeding of affected skin
    3. Impaired activities of daily living

RATIONALE

Ensure appropriate diagnostic, utilization and safety criteria are met for the management of requests for tralokinumab-ldrm.

FDA APPROVED INDICATIONS

Adbry is an interleukin-13 antagonist indicated for the treatment of moderate-to-severe atopic dermatitis in adult patients whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Adbry can be used with or without topical corticosteroids.

DOSING

The recommended dosage of Adbry is an initial dose of 600 mg (four 150 mg injections), followed by 300 mg (two 150 mg injections) administered every other week. A dosage of 300 mg every 4 weeks may be considered for patients below 100 kg who achieve clear or almost clear skin after 16 weeks of treatment.

REFERENCES

Adbry [Prescribing Information]. Ballerup, Denmark: LEO Pharma A/X, December 2021.

Created: 02/22
Effective: 03/21/22 Client Approval: 02/18/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

TRAMETINIB

Generic	Brand	HICL	GCN	Exception/Other
TRAMETINIB DIMETHYL SULFOXIDE	MEKINIST	40361		

GUIDELINES FOR USE

Our guideline named **TRAMETINIB (Mekinist)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Unresectable or metastatic melanoma (a type of skin cancer that cannot be removed by surgery or it has spread to other parts of the body)
   2. Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other part of the body)
   3. Melanoma (a type of skin cancer)
   4. Locally advanced or metastatic anaplastic thyroid cancer (ATC: a type of thyroid cancer that has spread from where it started to nearby tissue or lymph nodes or it has spread to other parts of the body)
   5. Unresectable or metastatic solid tumors (tumors that cannot be removed by surgery or it has spread to other parts of the body)

B. **If you have unresectable or metastatic melanoma, approval also requires:**
   1. You have BRAF V600E or V600K mutations (types of genes) as detected by a Food and Drug Administration (FDA)-approved test
   2. The requested medication will be used in combination with Tafinlar (dabrafenib) OR as a single agent in a BRAF-inhibitor treatment-naïve patient (you have not been previously treated for this cancer)

C. **If you have metastatic non-small cell lung cancer (NSCLC), approval also requires:**
   1. You have BRAF V600E mutation (type of gene) as detected by a Food and Drug Administration -approved test
   2. The requested medication will be used in combination with Tafinlar (dabrafenib)

D. **If you have melanoma, approval also requires:**
   1. You have BRAF V600E or V600K mutations (types of genes) as detected by a Food and Drug Administration (FDA)-approved test
   2. The requested medication will be used as an adjuvant therapy in combination with Tafinlar (dabrafenib)
   3. There is involvement of lymph node(s), following complete resection (surgical removal)

E. **If you have locally advanced or metastatic anaplastic thyroid cancer (ATC), approval also requires:**
   1. You have BRAF V600E mutation (type of gene mutation) as detected by a Food and Drug Administration (FDA)-approved test
   2. The requested medication will be used in combination with Tafinlar (dabrafenib)
   3. You do not have any satisfactory locoregional treatment options available (treatments that are focused on the affected area)

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TRAMETINIB

GUIDELINES FOR USE (CONTINUED)

F. **If you have unresectable or metastatic solid tumors, approval also requires:**
   1. You are 6 years of age or older
   2. You have BRAF V600E mutation (type of gene mutation) as detected by a Food and Drug Administration (FDA)-approved test
   3. The requested medication will be used in combination with Tafinlar (dabrafenib)
   4. You have progressed following prior treatment and have no satisfactory alternative treatment options

RATIONALE

Ensure appropriate use of Mekinist based on FDA approved indications and dosing.

FDA APPROVED INDICATIONS

Mekinist is a kinase inhibitor indicated as a single agent for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test.

Mekinist is indicated, in combination with dabrafenib, for:

- The treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test
- The adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations, as detected by an FDA-approved test, and involvement of lymph node(s) following complete resection
- The treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA-approved test
- The treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options
- The treatment of adult and pediatric patients 6 years of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options

DOSAGE AND ADMINISTRATION

The recommended dosage for Mekinist in adult patients is 2 mg orally once daily.

The recommended dosage for Mekinist in pediatric patients who weigh at least 26 kg is based on body weight (Table 1). A recommended dose has not been established in patients who weigh less than 26 kg.

Table 1: Dosing in Pediatric Patients from 6 to 17 Years Old (Weight-Adjusted Dose)

Body Weight	Recommended Dose
26 to 37 kg	1 mg orally once daily
38 to 50 kg	1.5 mg orally once daily
51 kg or greater	2 mg orally once daily

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

TRAMETINIB

REFERENCES

Mekinist [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2022

Created: 06/15
Effective: 01/30/23 Client Approval: 01/05/23 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

TREPROSTINIL

Generic	Brand	HICL	GCN	Exception/Other
TREPROSTINIL SODIUM	REMODULIN	23650		
TREPROSTINIL	TYVASO	36537 36539 36541		
TREPROSTINIL DIOLAMINE	ORENITRAM	40827		

****Please use the criteria for the specific drug requested****

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

REMODULIN

Our guideline named **TREPROSTINIL (Remodulin)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: form of high blood pressure that affects blood vessels in lungs and heart) World Health Organization (WHO) Group I (type of classification of the disease)
B. Therapy is prescribed by or given in consultation with a cardiologist (heart doctor) or pulmonologist (lung/breathing doctor)

TYVASO

Our guideline named **TREPROSTINIL (Tyvaso, Tyvaso DPI)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
    1. Pulmonary arterial hypertension (PAH: form of high blood pressure that affects blood vessels in lungs and heart) World Health Organization (WHO) Group I (type of classification of the disease)
    2. Pulmonary hypertension associated with interstitial lung disease (PH-ILD: scarring and inflammation of the tissues in the lungs which makes it difficult to breathe) World Health Organization (WHO) Group 3 (type of classification of the disease)
B. Therapy is prescribed by or given in consultation with a cardiologist (heart doctor) or pulmonologist (lung/breathing doctor)

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TREPROSTINIL

INITIAL CRITERIA (CONTINUED)

ORENITRAM

Our guideline named **TREPROSTINIL (Orenitram**) requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: form of high blood pressure that affects blood vessels in lungs and heart) World Health Organization (WHO) Group I (type of classification of the disease)
B. Therapy is prescribed by or given in consultation with a cardiologist (heart doctor) or pulmonologist (lung/breathing doctor)

RENEWAL CRITERIA

REMODULIN, ORENITRAM. TYVASO, TYVASO DPI

Our guideline named **TREPROSTINIL (Remodulin, Orenitram. Tyvaso, Tyvaso DPI)** requires the following rule(s) be met for renewal:

A. You have history of paid claim(s) for the requested medication in the past 90 days
B. You have a previous authorization on file for the requested medication

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RATIONALE

Ensure appropriate use of Remodulin, Tyvaso and Orenitram.

FDA APPROVED INDICATION

Remodulin is indicated for:

- Treatment of pulmonary arterial hypertension (PAH; WHO Group 1) to diminish symptoms associated with exercise.
- Patients who require transition from epoprostenol, to reduce the rate of clinical deterioration.

Tyvaso is indicated for the treatment of:

- Pulmonary arterial hypertension (PAH; WHO Group 1) to improve exercise ability.
- Pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability.

Orenitram is indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to delay disease progression and improve exercise capacity.

REFERENCES

- United Therapeutics. Remodulin package insert. Research Triangle Park, NC. July 2021.
- United Therapeutics. Tyvaso package insert. Research Triangle Park, NC. March 2021.
- United Therapeutics. Orenitram Package Insert. Research Triangle Park, NC. May 2021.

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

TRIENTINE

Generic	Brand	HICL	GCN	Exception/Other
TRIENTINE	CLOVIQUE, SYPRINE	01109		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline for **TRIENTINE HCL (Clovique, Syprine)** will allow for approval for patients with known family history of Wilson's disease or physical examination consistent with Wilson's disease and who meets **ONE** of the following criteria:

- Plasma copper-protein ceruloplasmin less than 20mg/dL
- Liver biopsy positive for an abnormally high concentration of copper (greater than 250mcg/g dry weight) **OR** the presence of Kayser-Fleischer rings
- Diagnosis has been confirmed by genetic testing for ATP7B mutations

In addition, the following criteria must also be met:

- The patient has maintained a reduced copper dietary intake (less than 2mg copper per day)
- Medication is prescribed by or given in consultation with a hepatologist
- The patient has had a previous trial of or contraindication to Depen (penicillamine)

RENEWAL CRITERIA

The guideline named **TRIENTINE (Clovique, Syprine)** requires a diagnosis of Wilson's disease **AND** the patient has achieved a free serum copper of less than 10 mcg/dL.

RATIONALE
Promote appropriate utilization of **TRIENTENE HCL (Clovique, Syprine)** based on FDA approved indication and American Association for Study of Liver Diseases (AASLD) guideline recommendations.

FDA APPROVED INDICATION
Clovique and Syprine are indicated in the treatment of patients with Wilson's disease who are intolerant of penicillamine. Trientene and penicillamine cannot be considered interchangeable. Trientene should be used when continued treatment with penicillamine is no longer possible because of intolerable of life endangering side effects.

DOSAGE
Systemic evaluation of dose and/or interval between dose has not been done. However, on limited clinical experience, the recommended initial dose of trientene is 500-750 mg/day for pediatric patients and 750-1250 mg/day for adults given in divided doses two, three or four times daily. This may be increased to a maximum of 2000 mg/day for adults or 1500 mg/day for pediatric patients age 12 or under.

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TRIENTINE

DOSAGE (CONTINUED)

The daily dose of trientene should be increased only when the clinical response is not adequate or the concentration of free serum copper is persistently above 20 mcg/dL. Optimal long-term maintenance dosage should be determined at 6-12 month intervals.

REFERENCES

- Clovique [Prescribing Information]. Warrendale, PA: Kadmon Pharmaceuticals, LLC; September 2019.
- Syprine [Prescribing Information]. Bridgewater, NJ: Valeant Pharmaceuticals. December 2016.
- Roberts EA, Schilsky ML; American Association for Study of Liver Diseases (AASLD). Diagnosis and treatment of Wilson disease: an update. Hepatology 2008; 47:2089-111.

Created: 11/16
Effective: 07/01/20 Client Approval: 05/12/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

TRIFLURIDINE/TIPIRACIL

Generic	Brand	HICL	GCN	Exception/Other
TRIFLURIDINE/TIPIRACIL	LONSURF	42544		

GUIDELINES FOR USE

Our guideline for **TRIFLURIDINE/TIPIRACIL (Lonsurf)** requires a diagnosis of metastatic colorectal cancer, metastatic gastric or gastroesophageal junction adenocarcinoma. The following criteria must also be met:

For patients with a diagnosis of metastatic colorectal cancer, approval requires:

- The patient must have had previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, and an anti-VEGF biological therapy [e.g., Avastin (bevacizumab), Zaltrap (ziv-aflibercept), or Cyramza (ramucirumab)]
- For patients who are negative for the RAS mutation (e.g., patient is RAS wild-type), approval requires that the patient had a previous treatment with an anti-EGFR agent [e.g., Erbitux (cetuximab), Vectibix (panitumumab)]

For patients with a diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma, approval requires the patient has had previous treatment with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy

RATIONALE

To ensure appropriate use of Lonsurf consistent with FDA approved indication.

FDA APPROVED INDICATIONS

Lonsurf is a combination of trifluridine, a nucleoside metabolic inhibitor, and tipiracil, a thymidine phosphorylase inhibitor, indicated for the treatment of adult patients with:

- metastatic colorectal cancer who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy.
- metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy.

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TRIFLURIDINE/TIPIRACIL

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE

The recommended starting dose is 35mg/m^2/dose (up to a maximum of 80 mg per dose, which based on trifluridine component and rounded to the nearest 5mg increment) orally twice a day within one hour of consuming the morning and evening meals on Days 1 through 5 and on Days 8 through 12 of each 28-day cycle. Treatment should be continued until unacceptable toxicity or disease progression.

AVAILABLE STRENGTHS:

- 15 mg trifluridine/ 6.14mg tipiracil tablet
- 20 mg trifluridine/ 8.19mg tipiracil tablet

REFERENCE

- Lonsurf [Prescribing Information]; Princeton, NJ: Taiho Oncology, Inc; February 2019.

Created: 10/15
Effective: 02/03/20 Client Approval: 12/26/19 P&T Approval: 11/15

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

TUCATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TUCATINIB	TUKYSA	46459			

GUIDELINES FOR USE

Our guideline named **TUCATINIB (Tukysa)** requires the following rule(s) be met for approval:

A. You have advanced unresectable (cannot be removed with surgery) or metastatic (disease that has spread to other parts of the body) human epidermal growth factor receptor 2 (HER2: type of protein)-positive breast cancer
B. You are 18 years of age or older
C. You have previously received one or more anti-HER2-based treatment for metastatic disease
D. The requested medication will be used in combination with trastuzumab and capecitabine

RATIONALE

To ensure appropriate diagnostic, utilization, and safety criteria are used for the management of requests for tukatinib.

INDICATIONS

Tukysa is a kinase inhibitor indicated in combination with trastuzumab and capecitabine for treatment of adult patients with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting.

DOSAGE

The recommended dosage of Tukysa is 300 mg taken orally twice daily in combination with trastuzumab and capecitabine until disease progression or unacceptable toxicity.

REFERENCES

- Tukysa [Prescribing Information]. Bothell, WA: Seattle Genetics, Inc.; April 2020.

Created: 06/20
Effective: 07/01/20 Client Aproval: 06/05/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

UBROGEPANT

Generic	Brand	HICL	GCN	Exception/Other
UBROGEPANT	UBRELVY	46273		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **UBROGEPANT (Ubrelvy)** requires the following rule(s) be met for approval:

1. You are being treated for acute (quick onset) migraine
2. You are 18 years of age or older
3. You have tried **TWO** triptans (such as sumatriptan, rizatriptan), unless there is a medical reason why you cannot (contraindication)

RENEWAL CRITERIA

Our guideline named **UBROGEPANT (Ubrelvy)** requires the following rule(s) be met for renewal:

A. You are being treated for acute (quick onset) migraine
B. You have history of paid claim(s) for the requested medication in the past 90 days
C. You have a previous authorization on file for the requested medication

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RATIONALE

To ensure appropriate diagnostic, utilization and safety criteria are used for the management of requests for ubrogepant.

FDA APPROVED INDICATIONS

Ubrelvy is a calcitonin gene-related peptide receptor antagonist indicated for the acute treatment of migraine with or without aura in adults.

DOSING

The recommended dose is 50 mg or 100 mg taken orally, as needed; if needed, a second dose may be administered at least 2 hours after the initial dose. The maximum dose in a 24-hour period is 200 mg.

The recommended dose in patients with severe hepatic or severe renal impairment is 50 mg; if needed, a second 50 mg dose may be taken at least 2 hours after the initial dose.

REFERENCES

- Ubrelvy [Prescribing Information]. Madison, NJ: Allergan; March 2021.

Created: 02/20
Effective: 12/15/21 Client Approval: 10/21/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

UPADACITINIB

Generic	Brand	HICL	GCN	Exception/Other
UPADACITINIB	RINVOQ	45955		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **UPADACITINIB (Rinvoq)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe atopic dermatitis (a type of skin condition)
   4. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)
   5. Ankylosing spondylitis (inflammation and stiffness affecting spine and large joints)
   6. Non-radiographic axial spondyloarthritis (NR-axSpA: a type of joint condition)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. You have previously tried at least ONE of the following DMARDs (disease-modifying antirheumatic drugs): methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   3. You have previously tried ONE of the following: Enbrel or Humira

C. **If you have psoriatic arthritis (PsA), our guideline also requires:**
   1. You are 18 years of age or older
   2. You have previously tried at least ONE of the following DMARDs (disease-modifying antirheumatic drugs): methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   3. You have previously tried TWO of the following: Cosentyx, Enbrel, or Humira

D. **If you have moderate to severe atopic dermatitis, approval also requires:**
   1. You are 12 years of age or older
   2. You have had a trial of a high or super-high potency topical corticosteroid (e.g., triamcinolone acetonide, fluocinonide, clobetasol propionate, halobetasol propionate) **AND** one non-steroidal topical immunomodulating agent (e.g., Eucrisa, Opzelura, pimecrolimus, tacrolimus)

E. **If you have moderate to severe ulcerative colitis (UC), approval also requires:**
   1. You are 18 years of age or older
   2. You have previously tried ONE of the following conventional agents: corticosteroids (e.g., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   3. You have previously tried Humira

F. **If you have ankylosing spondylitis (AS), approval also requires:**
   1. You are 18 years of age or older
   2. You have previously tried a non-steroidal anti-inflammatory agent (NSAID, non-steroidal anti-inflammatory drug such as ibuprofen, naproxen, meloxicam**,** diclofenac), unless there is a medical reason why you cannot
   3. You have previously tried TWO of the following: Cosentyx, Enbrel, or Humira

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

UPADACITINIB

INITIAL CRITERIA (CONTINUED)

G. **If you have non-radiographic axial spondyloarthritis, approval also requires:**
   1. You are 18 years of age or older
   2. You have previously tried a non-steroidal anti-inflammatory agent (NSAID, non-steroidal anti-inflammatory drug such as ibuprofen, naproxen, meloxicam, diclofenac) unless there is a medical reason why you cannot
   3. You have previously tried Cosentyx
   4. You have ONE of the following signs of inflammation:
      a. C-reactive protein (CRP: a measure of how much inflammation you have) levels above the upper limit of normal
      b. Sacroiliitis (type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI: type of imaging lab)

RENEWAL CRITERIA

Our guideline named **UPADACITINIB (Rinvoq)** requires the following rule(s) be met for renewal:
A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe atopic dermatitis (a type of skin condition)
   4. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)
   5. Ankylosing spondylitis (inflammation and stiffness affecting spine and large joints)
   6. Non-radiographic axial spondyloarthritis (NR-axSpA: a type of joint condition)
B. **If you have moderate to severe rheumatoid arthritis, psoriatic arthritis, ulcerative colitis, ankylosing spondylitis, or non-radiographic axial spondyloarthritis, renewal also requires:**
   1. Documentation (i.e., chart notes) that you have experienced or maintained symptomatic improvement while on therapy
C. **If you have moderate to severe atopic dermatitis, renewal also requires:**
   1. You have documentation showing that you have experienced or maintained improvement in at least TWO of the following:
      a. Intractable pruritus (severe itching)
      b. Cracking and oozing/bleeding of affected skin
      c. Impaired activities of daily living

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

UPADACITINIB

RATIONALE
Ensure appropriate diagnostic, utilization and safety criteria are used for the management of requests for upadacitinib.

INDICATIONS
Rinvoq is indicated for the treatment of:
- adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers.
- adults with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers.
- adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable.
- adults with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more TNF blockers.
- adults with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers.
- adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation who have had an inadequate response or intolerance to TNF blocker therapy.

DOSING
- Rheumatoid arthritis: The recommended dose is 15 mg once daily.
- Psoriatic arthritis: The recommended dose is 15 mg once daily.
- Atopic dermatitis: The recommended dose is 15 mg once daily; may increase to 30 mg once daily if inadequate response.
- Ulcerative colitis: The recommended induction dose is 45 mg once daily for 8 weeks. The recommended dose of Rinvoq for maintenance treatment is 15 mg once daily. A dosage of 30 mg once daily may be considered for patients with refractory, severe or extensive disease.
- Ankylosing spondylitis: The recommended dose is 15 mg once daily.
- Non-radiographic axial spondyloarthritis: The recommended dose is 15 mg once daily.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

UPADACITINIB

REFERENCES

- Rinvoq [Prescribing Information]. North Chicago, IL: AbbVie Inc., October 2022.
- Singh JA, Saag KG, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. 2016;68(1):1-25. DOI 10.1002/acr.22783.
- Singh JA, Guyatt G, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Care & Research. Vol. 71, No. 1, January 2019, pp 2–29. DOI 10.1002/acr.2378.
- Sidbury R, et al. Guidelines of care for the management of atopic dermatitis: section 4. Prevention of disease flares and use of adjunctive therapies and approaches. J Am Acad Dermatol 2014;71:1218-1233.
- Wollenberg A, et al. ETFAD/EADV Eczema task force 2015 position paper on diagnosis and treatment of atopic dermatitis in adult and pediatric patients. JEADV 2016;30:729-747.
- Kornbluth A, Sachar DB. Ulcerative colitis practice guidelines in adults: American College of Gastroenterology, Practice Parameters Committee. *Am J Gastroenterol* 2010;105:501-523.
- Braun J, Davis J, et al. First update of the international ASAS consensus statement for the use of anti-TNF agents in patients with Ankylosing Spondylitis. Ann Rheum Dis. 2006; 65(3):316-20.

Created: 10/19
Effective: 12/19/22 Client Approval: 12/07/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

USTEKINUMAB

Generic	Brand	HICL	GCN	Exception/Other
USTEKINUMAB IV	STELARA IV		42351	
USTEKINUMAB SC	STELARA SC		19903 28158 28159	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **USTEKINUMAB (Stelara)** requires the following rules be met for approval:

A. You have ONE of the following:
   1. Psoriatic arthritis (PsA: a type of skin and joint condition)
   2. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   3. Moderate to severe Crohn's Disease (CD: a type of bowel disorder)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. **If you have psoriatic arthritis (PsA) without co-existent plaque psoriasis (PsO), approval also requires:**
   1. You are 6 years of age or older
   2. You have tried at least ONE of the following DMARDs (disease-modifying antirheumatic drugs): methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   3. ONE of the following:
      a. You are 6 to 17 years of age AND have tried or have a contraindication (harmful for) to the following preferred medication: Cosentyx
      b. You are 18 years of age or older AND have tried TWO of the following: Cosentyx, Enbrel, or Humira

C. **If you have moderate to severe plaque psoriasis (PsO) or moderate to severe plaque psoriasis (PsO) with co-existent psoriatic arthritis (PsA), approval also requires:**
   1. You are 6 years of age or older
   2. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
   3. You have tried ONE of the following preferred therapies: PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
   4. ONE of the following:
      a. You are 6 to 17 years of age AND have tried ONE of the following: Cosentyx or Enbrel
      b. You are 18 years of age or older AND have tried TWO of the following: Cosentyx, Enbrel, or Humira

D. **If you have moderate to severe Crohn's disease (CD), approval also requires:**
   1. You are 18 years of age of older
   2. You have previously tried ONE of the following conventional agents: corticosteroids (e.g., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   3. You have previously tried Humira
   4. Your current weight has been documented

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INITIAL CRITERIA (CONTINUED)

E. **If you have moderate to severe ulcerative colitis (UC), approval also requires:**
   1. You are 18 years of age or older
   2. You have previously tried ONE of the following conventional agents: corticosteroids (e.g., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   3. You have previously tried Humira
   4. Your current weight has been documented

RENEWAL CRITERIA

Our guideline named **USTEKINUMAB (Stelara)** requires the following rules be met for renewal:

A. You have ONE of the following diagnoses:
   1. Psoriatic arthritis (PsA: a type of skin and joint condition)
   2. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   3. Moderate to severe Crohn's Disease (CD: a type of bowel disorder)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. **If you have moderate to severe psoriatic arthritis (PsA), renewal also requires:**
   1. Documentation (i.e., chart notes) that you have experienced or maintained symptomatic improvement while on therapy

C. **If you have moderate to severe plaque psoriasis (PsO), renewal also requires:**
   1. **If you are requesting Stelara dosed every 84 days, renewal also requires BOTH of the following:**
      a. Your provider submitted documentation (i.e., chart notes) that you have experienced or maintained symptomatic improvement while on therapy
      b. Your provider submitted documentation of your current weight
   2. **If you are requesting Stelara dosed every 56 days, renewal also requires ALL of the following:**
      a. Documentation of your current weight
      b. ONE of the following:
         i. You have had a previous trial of at least a 6-month regimen of Stelara dosed every 84 days and have refractory symptoms
         ii. **ALL** of the following:
            1) You have history of paid claim(s) for Stelara dosed every 56 days in the past 90 days
            2) You have a previous authorization on file for Stelara dosed every 56 days
            3) Your provider submitted documentation (i.e., chart notes) that you have experienced or maintained symptomatic improvement while on therapy

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USTEKINUMAB

RENEWAL CRITERIA (CONTINUED)

D. **If you have moderate to severe Crohn's disease (CD) or ulcerative colitis (UC), renewal also requires:**
   1. **If you are requesting Stelara dosed every 56 days, renewal also requires the following:**
      a. Documentation (i.e., chart notes) that you have experienced or maintained symptomatic improvement while on therapy
   2. **If you are requesting Stelara dosed every 28 days, renewal also requires ONE of the following:**
      a. You have tried 6 months of Stelara dosed every 56 days and have refractory symptoms
      b. **ALL** of the following:
         i. You have history of paid claim(s) for Stelara dosed every 28 days in the past 90 days
         ii. You have a previous authorization on file for Stelara dosed every 28 days
         iii. Your provider submitted documentation (i.e., chart notes) that you have experienced or maintained symptomatic improvement while on therapy

USTEKINUMAB

RATIONALE
Ensure that appropriate diagnostic, utilization, and safety criteria are utilized for the management of Stelara.

FDA APPROVED INDICATIONS
Stelara is a human interleukin-12 and -23 antagonist indicated for the treatment of:
- Adult patients with:
  - Moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy
  - Active psoriatic arthritis (PsA), alone or in combination with methotrexate
  - Moderately to severely active Crohn's disease (CD)
  - Moderately to severely active ulcerative colitis
- Pediatric patients (6 years or older) with moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy

DOSAGE
Psoriatic Arthritis
- The recommended dose is 45mg initially and 4 weeks later, followed by 45mg every 12 weeks
- For patients with co-existent moderate-to-severe plaque psoriasis weighing >100kg (220lbs), the recommended dose is 90mg initially and 4 weeks later, followed by 90mg every 12 weeks

Psoriasis Adult Subcutaneous Recommended Dosage:
- For patients weighing <100 kg (220lbs), the recommended dose is 45mg initially and 4 weeks later, followed by 45mg every 12 weeks
- For patients weighing >100 kg (220lbs), the recommended dose is 90mg initially and 4 weeks later, followed by 90mg every 12 weeks

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

USTEKINUMAB

Psoriasis Adolescent (12 years and older) Subcutaneous Recommended Dosage:
Weight based dosing is recommended at the initial dose, 4 weeks later, then every 12 weeks thereafter.

- Less than 60 kg: 0.75 mg/kg
- 60 kg to 100 kg: 45 mg
- Greater than 100 kg: 90 mg

Crohn's Disease and Ulcerative Colitis:

- Intravenous Induction Adult Dosage Regimen: A single intravenous infusion dose using the weight-based dosage regimen specified in Table 1

Table 1. Initial Intravenous Dosage of Stelara

Body weight of patient at the time of dosing	Dose	Number of 130 mg/26 mL (5 mg/mL) vials
⩽ 55 kg	260 mg	2
> 55 - 85 kg	390 mg	3
> 85 kg	520 mg	4

- Subcutaneous Maintenance Adult Dosage Regimen: The recommended maintenance dosage is a subcutaneous 90 mg dose administered 8 weeks after the initial intravenous dose, then every 8 weeks thereafter.

REFERENCES

- Stelara prescribing information. Horsham, PA: Janssen Biotech, Inc. December 2020.
- Kornbluth A, Sachar DB. Ulcerative colitis practice guidelines in adults: American College of Gastroenterology, Practice Parameters Committee. *Am J Gastroenterol* 2010;105:501-523.
- Lichtenstein G, Loftus EV, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. American Journal of Gastroenterology: April 2018, Volume 113, Issue 4, pp 481-517. doi: 10.1038/ajg.2018.27
- Braun J, Davis J, et al. First update of the international ASAS consensus statement for the use of anti-TNF agents in patients with Ankylosing Spondylitis. Ann Rheum Dis. 2006; 65(3):316-20.
- Singh JA, Guyatt G, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Care & Research. Vol. 71, No. 1, January 2019, pp 2–29DOI 10.1002/acr.2378.

Created: 03/15
Effective: 04/11/22 Client Approval: 03/10/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

VALBENAZINE

Generic	Brand	HICL	GCN	Exception/Other
VALBENAZINE	INGREZZA	44202		

GUIDELINES FOR USE

INITIAL CRITERIA

Our guideline named **VALBENAZINE (Ingrezza)** requires the following rule(s) be met for approval:

A. You have moderate to severe tardive dyskinesia (involuntary movements, usually due to certain drugs) and it has been present for at least 4 weeks
B. You are 18 years of age or older
C. You have a history of using antipsychotic medications or dopamine receptor blocking drugs used in the treatment of nausea and gastroparesis (e.g., metoclopramide, prochlorperazine, promethazine) for at least 3 months (or at least 1 month if you are 60 years of age or older) as documented in the medical record or in your prescription claims history

RENEWAL CRITERIA

Our guideline named **VALBENAZINE (INGREZZA)** requires the following rule(s) be met for renewal:

A. You have moderate to severe tardive dyskinesia
B. You have experienced or maintained clinical improvement while on Ingrezza

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RATIONALE

Promote appropriate utilization of **VALBENAZINE** (Ingrezza) based on FDA approved indication and dosing.

FDA APPROVED INDICATION

Ingrezza is indicated for the treatment of adults with tardive dyskinesia.

DOSAGE

The initial dose for Ingrezza is 40 mg once daily. After one week, increase the dose to the recommended dose of 80 mg once daily. Continuation of 40 mg once daily may be considered for some patients. Administer Ingrezza orally with or without food.

REFERENCES

Ingrezza [Prescribing Information]. San Diego, CA. Neurocrine Biosciences, Inc; April 2021.

Created: 07/17
Effective: 04/11/22 Client Approval: 03/09/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

VEDOLIZUMAB

Generic	Brand	HICL	GCN	Exception/Other
VEDOLIZUMAB	ENTYVIO	41146		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **VEDOLIZUMAB (Entyvio)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe Crohn's Disease (CD: type of inflammatory disease that affects lining of digestive tract)
   2. Moderate to severe Ulcerative Colitis (UC: type of inflammatory disease that affects lining of digestive tract)

B. **If you have moderate to severe Crohn's Disease (CD), approval also requires:**
   1. You are 18 years of age or older
   2. You have previously tried ONE of the following conventional agents: corticosteroids (e.g., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   3. You have previously tried Humira

C. **If you have moderate to severe Ulcerative Colitis (UC), approval also requires:**
   1. You are 18 years of age or older
   2. You have previously tried ONE of the following conventional agents: corticosteroids (e.g., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   3. You have previously tried Humira

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VEDOLIZUMAB

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named **VEDOLIZUMAB (Entyvio)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   2. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)

B. **If you are requesting Entyvio 300mg dosed every 56 days, renewal also requires:**
   1. Documentation (i.e., chart notes) that you have experienced or maintained symptomatic improvement while on therapy

C. **If you are requesting Entyvio 300mg dosed every 28 days OR every 42 days, renewal also requires ONE of the following:**
   1. You have tried 6 months of Entyvio 300mg dosed every 56 days and have refractory symptoms
   2. ALL of the following:
      a. You have history of paid claim(s) for Entyvio dosed every 28 days or every 42 days in the past 90 days
      b. You have a previous authorization on file for Entyvio dosed every 28 days or every 42 days
      c. Your provider submitted documentation (i.e., chart notes) that you have experienced or maintained symptomatic improvement while on therapy

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

VEDOLIZUMAB

RATIONALE
Ensure appropriate diagnostic, utilization, and safety criteria are used for the management of requests for Entyvio (vedolizumab).

FDA APPROVED INDICATIONS
Adult Ulcerative Colitis (UC)

- Adult patients with moderately to severely active UC who have had an inadequate response with, lost response to, or were intolerant to a tumor necrosis factor (TNF) blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids:
  - Inducing and maintaining clinical response
  - Inducing and maintaining clinical remission
  - Improving endoscopic appearance of the mucosa
  - Achieving corticosteroid-free remission

Adult Crohn's Disease (CD)

- Adult patients with moderately to severely active CD who have had an inadequate response with, lost response to, or were intolerant to a TNF blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids:
  - Achieving clinical response
  - Achieving clinical remission
  - Achieving corticosteroid-free remission

DOSING
Ulcerative colitis: 300 mg IV infusion over 30 minutes at week 0, 2, and 6, then every 8 weeks
Crohn's disease: 300 mg IV infusion over 30 minutes at week 0, 2, and 6, then every 8 weeks

REFERENCES

- Entyvio [Prescribing Information]. Deerfield, IL: Takeda Pharmaceuticals America, Inc. March 2020.
- Kornbluth A, Sachar DB. Ulcerative colitis practice guidelines in adults: American College of Gastroenterology, Practice Parameters Committee. *Am J Gastroenterol* 2010;105:501-523.
- Lichtenstein G, Loftus EV, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. American Journal of Gastroenterology: April 2018, Volume 113, Issue 4, pp 481-517. doi: 10.1038/ajg.2018.27

Created: 02/18
Effective: 04/11/22 Client Approval: 03/10/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

VEMURAFENIB

Generic	Brand	HICL	GCN	Exception/Other
VEMURAFENIB	ZELBORAF	37837		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

The guideline named **VEMURAFENIB (ZELBORAF)** requires a diagnosis of unresectable or metastatic melanoma with a BRAFV600E mutation as detected by an FDA-approved test or Erdheim-Chester Disease with a BRAF V600 mutation.

RATIONALE
Ensure appropriate use of vemurafenib based on FDA approved indication.

FDA APPROVED INDICATIONS
Zelboraf is a kinase inhibitor indicated for the treatment of patients with

- Unresectable or metastatic melanoma with $BRAF^{V600E}$ mutation as detected by an FDA-approved test.
- Erdheim-Chester Disease with $BRAF^{V600}$ mutation.

Limitation of Use: Zelboraf is not recommended for use in patients with wild-type BRAF melanoma.

DOSAGE AND ADMINISTRATION
Confirm the presence of BRAF V600E mutation in tumor specimens prior to initiation of treatment with ZELBORAF.

Recommended dose: 960 mg orally twice daily taken approximately 12 hours apart with or without a meal.

REFERENCES

- Genentech, Inc. Zelboraf package insert. South San Francisco, CA. December 2017.

Created: 06/15
Effective: 11/01/18 Client Approval: 09/24/18 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

VENETOCLAX

Generic	Brand	HICL	GCN	Exception/Other
VENETOCLAX	VENCLEXTA	43284		

GUIDELINES FOR USE

The guideline named **VENETOCLAX (Venclexta)** requires a diagnosis of chronic lymphocytic leukemia, small lymphocytic lymphoma, or newly-diagnosed acute myeloid leukemia (AML). In addition, the following must be met:

For patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), approval requires:

- The patient is 18 years of age or older

For patients with newly-diagnosed acute myeloid leukemia (AML), approval requires:

- The patient is 75 years of age or older, OR the patient is 18 years of age or older with comorbidities that preclude the use of intensive induction chemotherapy
- The requested medication will be used in combination with azacitidine or decitabine or low-dose Cytarabine

RATIONALE

To ensure appropriate use of Venclexta consistent with FDA approved indication and dosing.

FDA APPROVED INDICATIONS

Venclexta is a BCL-2 inhibitor indicated

- For the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).
- In combination with azacitidine or decitabine or low-dose cytarabine for the treatment of newly-diagnosed acute myeloid leukemia (AML) in adults who are age 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy.

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VENETOCLAX

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE

All Venclexta dose regimens begin with a 5-week ramp-up. The ramp-up dosing schedule is designed to gradually reduce tumor burden (debulk) and decrease the risk of tumor lysis syndrome (TLS).

Venclexta is prescribed at a dose of 20 mg orally daily for 7 days and then titrated up on a weekly schedule (according the table below) to a daily dose of 400 mg.

Week	Venclexta Daily Dose
1	20 mg
2	50 mg
3	100 mg
4	200 mg
5 and beyond	400 mg

HOW SUPPLIED

The CLL/SLL Starting Pack provides the first 4 weeks of VENCLEXTA according to the ramp-up schedule. Venclexta is also available as 10mg 50mg, and 100mg tablets.

REFERENCES

- Venclexta [Prescribing Information]. Abbvie Inc.: North Chicago, IL; July 2019.

Created: 06/17
Effective: 04/20/20 Client Approval: 03/24/20 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

VERICIGUAT

Generic	Brand	HICL	GCN	Exception/Other
VERICIGUAT	VERQUVO	47075		

GUIDELINES FOR USE

INITIAL CRITERIA

Our guideline named **VERICIGUAT (Verquvo)** requires the following rule(s) be met for approval:

A. You have chronic heart failure
B. You have an ejection fraction (measurement of how well your heart pumps out blood with each heartbeat) of less than 45%
C. You are 18 years of age or older
D. You will not be taking Verquvo together with long-acting nitrates or nitric oxide donors (such as isosorbide dinitrate, isosorbide mononitrate, transdermal nitroglycerin), riociguat, or PDE-5 inhibitors (such as vardenafil, tadalafil)
E. You have previously tried ONE of the following sodium-glucose transporter-2 inhibitors (SGLT-2 inhibitors: class of drugs) unless there is a medical reason why you cannot (contraindication): Farxiga, Segluromet, Steglatro, or Xigduo XR
F. You have previously tried ONE agent from EACH of the following classes unless there is a medical reason why you cannot (contraindication):
    1. Angiotensin converting enzyme (ACE) inhibitors (such as enalapril, lisinopril), angiotensin II receptor blockers (ARB: such as valsartan, candesartan), or angiotensin receptor-neprilysin inhibitor (ARNI: such as sacubitril/valsartan)
    2. Beta-blocker (bisoprolol, carvedilol, metoprolol succinate)
    3. Aldosterone antagonists (spironolactone or eplerenone)

RENEWAL CRITERIA

Our guideline named **VERICIGUAT (Verquvo)** requires the following rule(s) be met for renewal:

A. You have chronic heart failure
B. You have an ejection fraction (measurement of how well your heart pumps out blood with each heartbeat) of less than 45%
C. You will not be taking Verquvo together with long-acting nitrates or nitric oxide donors (such as isosorbide dinitrate, isosorbide mononitrate, transdermal nitroglycerin), riociguat, or PDE-5 inhibitors (such as vardenafil, tadalafil)

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

VERICIGUAT

RATIONALE
Ensure appropriate utilization of Verquvo based on FDA approved indications.

FDA APPROVED INDICATIONS
Verquvo is a soluble guanylate cyclase (sGC) stimulator, indicated to reduce the risk of cardiovascular death and heart failure (HF) hospitalization following a hospitalization for heart failure or need for outpatient IV diuretics, in adults with symptomatic chronic HF and ejection fraction less than 45%.

DOSAGE
The recommended starting dose of Verquvo is 2.5 mg orally once daily with food. Double the dose of Verquvo approximately every 2 weeks to reach the target maintenance dose of 10 mg once daily, as tolerated by the patient.

REFERENCES

- Verquvo [Prescribing Information]. Whitehouse Station, NJ: Merck & Co., Inc.; January 2021.

Created: 04/21
Effective: 09/26/22 Client Approval: 09/12/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

V-GO INSULIN DEVICES

Generic	Brand	HICL	GCN	Exception/Other
SUB-Q INSULIN DEVICE, 20 UNIT	V-GO 20	38483		
SUB-Q INSULIN DEVICE, 30 UNIT	V-GO 30	38484		
SUB-Q INSULIN DEVICE, 40 UNIT	V-GO 40	38486		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **V-GO INSULIN DEVICES** requires the following rule(s) be met for approval:

A. You are 18 years of age or older
B. The requested insulin pump is prescribed by or given in consultation with an endocrinologist (hormone doctor)
C. You follow a maintenance program of at least 3 injections of insulin per day
D. You have worked with your doctor to adjust your insulin dose for the past 6 months and still have not met your glucose (blood sugar) goals
E. You do not require regular adjustments to your basal rate during a 24-hour time period
F. You require bolus insulin dosing in increments of 2 units per bolus
G. You do not require a total daily insulin dose of more than 76 units
H. You are on a multiple daily insulin injection regimen and meet ONE of the following criteria:
    1. You have a glycosylated hemoglobin level (HbA1c: measure of how well controlled your blood sugar has been over a period of about 3 months) greater than 7 percent
    2. You have a history of recurring hypoglycemia (low blood sugar)
    3. You have wide fluctuations in blood sugar before mealtime
    4. You experience the dawn phenomenon (abnormal early morning increase in blood sugar, usually between 2 a.m. and 8 a.m.) with fasting blood glucose levels frequently exceeding 200 mg/dL
    5. You have a history of severe glycemic excursions (sudden spikes in blood sugar levels)

RENEWAL CRITERIA

Our guideline named **V-GO INSULIN DEVICES** requires the following rule(s) be met for renewal:

A. You have shown a positive response to therapy AND are adherent to your doctor follow-up visits

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RATIONALE

To ensure appropriate use of V-Go insulin pumps and devices consistent with FDA approved indications, treatment guidelines, and current literature.

REFERENCES

V-Go. Zealand Pharma. Indications and Safety Information. Available at: https://www.go-vgo.com/hcp/important-safety-information/

Created: 02/22
Effective: 04/01/22 Client Approval: 02/21/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

VIGABATRIN

Generic	Brand	HICL	GCN	Exception/Other
VIGABATRIN	SABRIL, VIGABATRIN, VIGADRONE	07377		

GUIDELINES FOR USE

Our guideline named **VIGABATRIN (Sabril)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Refractory complex partial seizures (a type of seizure)
   2. Infantile spasms (a type of seizure disorder in infancy and childhood)

B. **If you have refractory complex partial seizures, approval also requires:**
   1. You are 2 years of age or older
   2. You had a trial of or contraindication (harmful for) to THREE antiepileptic medications, at least two of which must be generic (seizure drugs such as carbamazepine, divalproex/valproic acid, oxcarbazepine, levetiracetam immediate-release/extended-release, gabapentin, zonisamide, topiramate, lamotrigine)
   3. The benefits of treatment outweigh the risk for permanent vision loss

C. **If you have infantile spasms, approval also requires:**
   1. You are 1 month to 2 years of age
   2. The requested medication will be used as monotherapy (one drug for treatment)
   3. The benefits of treatment outweigh the risk for permanent vision loss

RATIONALE
To ensure appropriate use of Sabril based on FDA approved indications and dosing.

INDICATION
Sabril is indicated for the treatment of:

- Refractory Complex Partial Seizures as adjunctive therapy in patients 2 years of age and older who have responded inadequately to several alternative treatments; SABRIL is not indicated as a first line agent.
- Infantile Spasms - monotherapy in infants 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

VIGABATRIN

DOSING

Refractory Complex Partial Seizures

- Adult Patients (17 Years of Age and Older): Treatment should be initiated at 1000 mg/day (500 mg twice daily). Total daily dose may be increased in 500 mg increments at weekly intervals, depending on response. The recommended dose of Sabril in adults is 3000 mg/day (1500 mg twice daily). A 6000 mg/day dose has not been shown to confer additional benefit compared to the 3000 mg/day dose and is associated with an increased incidence of adverse events.
- Pediatric Patients (2 to 16 Years of Age): The recommended dosage is based on body weight and administered as two divided doses, as shown in Table 1. The dosage may be increased in weekly intervals to the total daily maintenance dosage, depending on response. Pediatric patients weighing more than 60 kg should be dosed according to adult recommendations.

Table 1: CPS Dosing Recommendations for Pediatric Patients Weighing 10 to 60 kg

Body Weight (kg)	Total Daily* Starting Dose (mg/day)	Total Daily* Maintenance Dose (mg/day)
10 to 15 kg	350 mg	1050 mg
Greater than 15 kg to 20 kg	450 mg	1300 mg
Greater than 20 kg to 25 kg	500 mg	1500 mg
Greater than 25 kg to 60 kg	500 mg	2000 kg

*Administered in two divided doses

Infantile Spasms

The initial daily dosing is 50 mg/kg/day given in two divided doses (25 mg/kg twice daily); subsequent dosing can be titrated by 25 mg/kg/day to 50 mg/kg/day increments every 3 days, up to a maximum of 150 mg/kg/day given in 2 divided doses (75 mg/kg twice daily).

REFERENCES

Sabril [Prescribing Information]. Deerfield, IL: Lundbeck, October 2021.

Created: 08/22
Effective: 10/01/22 Client Approval: 08/19/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

VISMODEGIB

Generic	Brand	HICL	GCN	Exception/Other
VISMODEGIB	ERIVEDGE	38455		

GUIDELINES FOR USE

Approval requires a diagnosis of metastatic basal cell carcinoma or locally advanced basal cell carcinoma that has recurred following surgery or the patient is not a candidate for surgery or radiation.

RATIONALE

To promote appropriate utilization of Erivedge based on its FDA approved indication.

Vismodegib is an inhibitor of the Hedgehog signaling pathway. This pathway is important in embryonic development and becomes reactivated in cancer. Because this pathway is not required in most adult tissues, inhibitors selectively attack tumor cells. Vismodegib is the first drug approved for advanced BCC. BCC is the most common type of skin cancer and is typically localized, slow-growing and painless. Localized disease is usually curable by surgery and radiation treatment. Advanced disease is more deadly and has no other FDA approved treatment options.

A single-arm, open-label trial was conducted in patients with either mBCC (n=33) or laBCC (n=71) who received 150mg vismodegib daily until disease progression or unacceptable toxicity. Objective response rates were 30.3% for mBCC and 42.9% for laBCC. No mBCC patients achieved complete response, while 20.6% of laBCC patients had a complete response. Median response duration was 7.6 months for both mBCC and laBCC.

The common adverse reactions are muscle spasms, alopecia, dysgeusia, weight loss, fatigue, nausea, diarrhea, decreased appetite, constipation, arthralgias, vomiting, and ageusia.

There is a **black box warning** for embryo-fetal death and severe birth defects. Pregnancy Category D.

Dosage: One 150mg capsule once daily with or without food.

FDA APPROVED INDICATION

Erivedge is indicated for the treatment of adults with metastatic basal cell carcinoma, or with locally advanced basal cell carcinoma that has recurred following surgery or who are not candidates for surgery, and who are not candidates for radiation.

REFERENCES

- Genentech, Inc. Erivedge package insert. South San Francisco, CA. January 2012.

Created: 06/15
Effective: 07/22/15 Client Approval: 06/15 P&T Approval: 11/13

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

VOCLOSPORIN

Generic	Brand	HICL	GCN	Exception/Other
VOCLOSPORIN	LUPKYNIS	47077		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **VOCLOSPORIN (Lupkynis)** requires the following rule(s) be met for approval:

A. You have active lupus nephritis (LN: inflammation of the kidneys caused by lupus when the immune system attacks its own tissues)
B. You are 18 years of age or older
C. The requested medication will be used in combination with a background immunosuppressive therapy regimen (such as mycophenolate mofetil, corticosteroids)

RENEWAL CRITERIA

Our guideline named **VOCLOSPORIN (Lupkynis)** requires the following rule(s) be met for renewal:

A. You have active lupus nephritis (LN: inflammation of the kidneys caused by lupus when the immune system attacks its own tissues)
B. You have improvement in renal response from baseline laboratory values (eGFR [measurement of kidney function] or proteinuria [level of protein in urine]) and/or clinical parameters (such as fluid retention, use of rescue drugs, glucocorticoid use)

RATIONALE

To ensure appropriate use of Lupkynis consistent with FDA approved indication.

FDA APPROVED INDICATIONS

Lupkynis is a calcineurin-inhibitor immunosuppressant indicated in combination with a background immunosuppressive therapy regimen for the treatment of adult patients with active lupus nephritis (LN).

DOSAGE AND ADMINISTRATION

The recommended starting dose of Lupkynis is 23.7 mg twice a day. Use Lupkynis in combination with mycophenolate mofetil (MMF) and corticosteroids. Because safety and efficacy of Lupkynis have not been established in combination with cyclophosphamide, use of Lupkynis is not recommended in this situation.

If the patient does not experience therapeutic benefit by 24 weeks, consider discontinuation of Lupkynis.

REFERENCES

Lupkynis [Prescribing Information]. Victoria, BC: Aurinia Pharmaceuticals Inc.; January 2021.

Created: 07/21
Effective: 03/28/22 Client Approval: 02/24/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

VONOPRAZAN

Generic	Brand	HICL	GCN	Exception/Other
VONOPRAZAN/ AMOXICILLIN	VOQUEZNA DUAL PAK	47981		
VONOPRAZAN/ AMOXICILLIN/CLARITH	VOQUEZNA TRIPLE PAK	47983		

GUIDELINES FOR USE

Our guideline named **VONOPRAZAN (Voquezna)** requires the following rule(s) be met for approval:
A. You are being treated for *Helicobacter pylori (H. pylori*: a type of bacteria*)* infection
B. You are 18 years of age or older
C. You have had a trial of or contraindication (harmful for) to a bismuth-based quadruple regimen (bismuth/tetracycline/metronidazole plus proton pump inhibitor [PPI, such as omeprazole, lansoprazole])

RATIONALE

Ensure appropriate diagnostic, utilization and safety criteria are used for the management of requests for Voquezna.

FDA APPROVED INDICATIONS

Voquezna Triple Pak is a co-packaged product containing vonoprazan, a potassium-competitive acid blocker (PCAB), amoxicillin, a penicillin class antibacterial, and clarithromycin, a macrolide antimicrobial, indicated for the treatment of Helicobacter pylori (H. pylori) infection in adults.
Voquezna Dual Pak is a co-packaged product containing vonoprazan, a PCAB, and amoxicillin, a penicillin class antibacterial, indicated for the treatment of H. pylori infection in adults.

DOSING

Voquezna Triple Pak: The recommended dosage regimen is vonoprazan 20 mg plus amoxicillin 1,000 mg plus clarithromycin 500 mg, each given twice daily (morning and evening, 12 hours apart), with or without food, for 14 days.

Voquezna Dual Pak: The recommended dosage regimen is vonoprazan 20 mg twice daily (morning and evening) plus amoxicillin 1,000 mg, three times a day (morning, mid-day, and evening), with or without food, for 14 days.

REFERENCES

Voquezna [Prescribing Information]. Buffalo Grove, IL: Phathom Pharmaceuticals, Inc.; May 2022.

Created: 07/22
Effective: 08/15/22 Client Approval: 07/15/22 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ZANUBRUTINIB

Generic	Brand	HICL	GCN	Exception/Other
ZANUBRUTINIB	BRUKINSA	46212		

GUIDELINES FOR USE

Our guideline named **ZANUBRUTINIB (BRUKINSA)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Mantle cell lymphoma (type of white blood cell cancer)
   2. Waldenström's macroglobulinemia
   3. Relapsed or refractory marginal zone lymphoma (MZL: a type of blood cancer)

B. You are 18 years of age or older

C. **If you have a diagnosis of mantle cell lymphoma, approval also requires:**
   1. You have previously received at least ONE prior therapy for mantle cell lymphoma

D. **If you have a diagnosis of relapsed or refractory marginal zone lymphoma (MZL), approval also requires:**
   1. You have received at least ONE anti-CD20-based regimen (a type of blood cancer treatment plan)

RATIONALE

To promote appropriate utilization of Brukinsa based on FDA approved indication and dosage.

FDA Approved Indication

Brukinsa is a kinase inhibitor indicated for the treatment of adult patients with:

- Mantle cell lymphoma (MCL) who have received at least one prior therapy
- Waldenström's macroglobulinemia
- Relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen

DOSAGE AND ADMINISTRATION

The recommended dose of Brukinsa is 160 mg taken orally twice daily or 320 mg taken orally once daily until disease progression or unacceptable toxicity.

REFERENCES

- Brukinsa [Prescribing Information]. San Mateo, CA: BeiGene USA, Inc.; September 2021.

Created: 01/20
Effective: 01/01/22 Client Approval: 11/30/21 P&T Approval: N/A

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ZOLEDRONIC ACID (RECLAST)

Generic	Brand	HICL	GCN	Exception/Other
ZOLEDRONIC ACID	RECLAST		25026	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline for **ZOLEDRONIC ACID (Reclast)** requires that the patient has a diagnosis of postmenopausal osteoporosis, glucocorticoid-induced osteoporosis, male osteoporosis, or Paget's disease. For all diagnoses, a trial of or contraindication to an oral bisphosphonate is required. Reclast will not be approved for the prevention or treatment of osteoporosis in men. The following criteria must also be met:

- **For the prevention and treatment of glucocorticoid-induced osteoporosis**, patients must be taking a systemic glucocorticoid daily dose equivalent of 7.5mg or more of prednisone and expected to remain on glucocorticoids for at least 12 months.

RENEWAL CRITERIA

Our guideline for renewal of **ZOLEDRONIC ACID (Reclast)** requires that the patient have a diagnosis of postmenopausal osteoporosis, male osteoporosis, glucocorticoid-induced osteoporosis, or Paget's disease. The following criteria must also be met:

- **For the prevention and treatment of glucocorticoid-induced osteoporosis,** patients must be taking a systemic glucocorticoid daily dose equivalent of 7.5mg or more of prednisone and expected to remain on glucocorticoids for at least 12 months.

RATIONALE
To ensure appropriate use of RECLAST based on FDA approved indications and dosing.

RECLAST Dosing:

- Treatment of Osteoporosis in Postmenopausal Women: Administer 5mg IV infusion over no less than 15 minutes once a year.
- Prevention of Osteoporosis in Postmenopausal Women: Administer 5mg IV infusion over no less than 15 minutes every 2 years.
- Treatment of Osteoporosis in Men: Administer 5mg IV infusion over no less than 15 minutes once a year.
- Treatment and Prevention of Glucocorticoid-Induced Osteoporosis: Administer 5mg IV infusion over no less than 15 minutes once a year.
- Treatment of Paget's Disease: Administer 5mg IV infusion over no less than 15 minutes as a single dose. Patients should receive 1500 mg elemental calcium and 800 international units vitamin D daily. The Endocrine Society guidelines suggest re-treatment is seldom required within 5 years.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ZOLEDRONIC ACID (RECLAST)

FDA APPROVED INDICATIONS

RECLAST is an infused bisphosphonate indicated for:

- Treatment and Prevention of Osteoporosis in Postmenopausal Women
- Treatment of Osteoporosis in Men
- Treatment and Prevention of Glucocorticoid-Induced Osteoporosis.
- Treatment of Paget's Disease

Limitations of use: Patients at low-risk for fracture should be considered for drug discontinuation after 3 to 5 years of use.

REFERENCES

- Reclast (zoledronic acid) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2017.
- American Association of Clinical Endocrinologists (AACE) medical guidelines for clinical practice for the diagnosis and treatment of postmenopausal osteoporosis. Accessed online July 12, 2018 at: www.aace.com.
- Endocrine Society Clinical Guidelines: Osteoporosis in Men. Accessed online July 12, 2018 at: www.endocrine.org.

Created: 09/18
Effective: 10/01/18 Client Approval: 08/22/18 P&T Approval: 3QTR

MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ZOLEDRONIC ACID (ZOMETA)

Generic	Brand	HICL	GCN	Exception/Other
ZOLEDRONIC ACID	ZOMETA		34227 34228 30489 19476	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

Our guideline for **ZOLEDRONIC ACID (Zometa)** requires that the patient have a diagnosis of: (1) hypercalcemia of malignancy; (2) multiple myeloma; (3) documented bone metastases from solid tumors; or (4) prostate cancer that has progressed after treatment with at least one hormonal therapy. Zometa will not be approved for use in hyperparathyroidism or non-tumor-related hypercalcemia.

RATIONALE
To ensure appropriate use of ZOMETA based on FDA approved indications and dosing.

ZOMETA Dosing:
- Hypercalcemia of malignancy: Administer 4mg as a single-use IV infusion over no less than 15 minutes. Patients may receive 4mg as retreatment after a minimum of 7 days if needed.
- Multiple myeloma and bone metastasis from solid tumors: Administer 4mg as a single-use IV infusion over no less than 15 minutes every 3-4 weeks for patients with creatinine clearance of greater than 60mL/min.
  - CrCl >60 mL/minute: 4 mg (no dosage adjustment is necessary)
  - CrCl 50 to 60 mL/minute: Reduce dose to 3.5 mg
  - CrCl 40 to 49 mL/minute: Reduce dose to 3.3 mg
  - CrCl 30 to 39 mL/minute: Reduce dose to 3 mg
  - CrCl <30 mL/minute: Use is not recommended.
- Coadminister oral calcium supplements of 500 mg and a multiple vitamin containing 400 international units of vitamin D daily.

FDA APPROVED INDICATIONS
- Hypercalcemia of malignancy
- Multiple myeloma and bone metastasis from solid tumors, in conjunction with standard antineoplastic therapy. Prostate cancer should have progressed after treatment with at least one hormonal therapy.

Limitation of use: The safety and efficacy of Zometa has not been established for use in hyperparathyroidism or nontumor-related hypercalcemia.

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MDwise MANAGED MEDICAID
PRIOR AUTHORIZATION GUIDELINES

ZOLEDRONIC ACID (ZOMETA)

REFERENCES

- Zometa (zoledronic acid) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2016.
- National Comprehensive Cancer Network. Prostate Cancer. Version 1.2015. Accessed online July 12, 2018 at: http://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf.
- National Comprehensive Cancer Network. Breast Cancer. Version 3.2015. Accessed online July 12, 2018 at: http://www.nccn.org/professionals/physician_gls/pdf/breast.pdf.

Created: 09/18
Effective: 10/01/18 Client Approval: 08/22/18 P&T Approval: 3QTR

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