Adbry, Dupixent, Ebglyss, Nemluvio
Prior Authorization Guidelines

Affected Medication(s)

- Dupixent (dupilimab) subcutaneous solution
- Adbry (tralokinumab) subcutaneous solution
- Ebglyss (lebrikizumab-lbkz) subcutaneous solution
- Nemluvio (nemolizmuab-ilto) injection

FDA Approved Indication(s)

- Dupixent:
  - Treatment of patients ages 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
  - As an add-on maintenance treatment in patient with moderate-to-severe asthma ages 6 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma
  - As an add-on maintenance treatment in adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP)
  - Treatment of adult and pediatric patients 1 years and older weighing at least 15 kg with eosinophilic esophagitis (EoE)
  - Treatment of adult patients with prurigo nodularis
  - As an add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype
  - Treatment of adult and pediatric patients with chronic spontaneous urticaria (CSU) who remain symptomatic despite H1 antihistamine treatment
  - Treatment of adult patients with bullous pemphigoid
- Adbry:
  - Treatment of moderate-to-severe atopic dermatitis in adult and pediatric patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable
- Ebglyss:
  - Treatment of adults and pediatric patients 12 years of age and older who weigh at least 40 kg with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable
- Nemluvio:
  - Treatment of adults and pediatric patients 12 years of age and older with moderate-to-severe atopic dermatitis in combination with topical corticosteroids and/or calcineurin inhibitors when the disease is not adequately controlled with topical prescription therapies
  - Treatment of adults with prurigo nodularis

Dosing

- Refer to respective package insert for dosing information

Initial Authorization Criteria

1. Is the request for continuation of the same therapy for the same condition?
   a. If yes, continue to Reauthorization

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b. If no, continue to #2

2. Is the request for use to treat an FDA-approved indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Will the requested drug be used concurrently with other biologic therapy? (Examples: Actemra, Enbrel, Cimzia, Humira, Otezla, Cosentyx, etc.)
    a. If yes, clinical review required
    b. If no continue to #4
4. What is the diagnosis that the drug is being requested for?
    a. Atopic dermatitis, continue to corresponding criteria
    b. Moderate to severe asthma, continue to corresponding criteria
    c. Chronic rhinosinusitis, continue to corresponding criteria
    d. Eosinophilic esophagitis, continue to corresponding criteria
    e. Prurigo nodularis, continue to corresponding criteria
    f. Chronic obstructive pulmonary disease, continue to corresponding criteria
    g. Chronic spontaneous urticaria, continue to corresponding criteria
    h. Bullous pemphigoid, continue to corresponding criteria
    i. Other indication, clinical review required

<u>Atopic Dermatitis</u>

1. Does the member have at least 10% body surface area involvement? (Provide documentation of body surface area affected)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for Dupixent (dupilimub)?
    a. If yes, continue to #4
    b. If no, continue to #3
3. Does the member have a documented trial with insufficient response, intolerance or contraindication to Dupixent (dupilimab)? (Provide documentation to support insufficient response, intolerance, and/or contraindication)
    a. If yes, continue to #4
    b. If no, continue to #5
4. Does the member have a documented trial with insufficient response, or intolerance, or contraindication to TWO of the following therapies: topical agent (high-potency steroid/calcineurin inhibitor), immunomodulatory agent (azathioprine, cyclosporine, methotrexate, mycophenolate), or phototherapy? (Provide supporting documentation of all therapies tried)
    a. If yes, continue to #8
    b. If no, clinical review required
5. Does the member have a documented trial with insufficient response, or intolerance, or contraindication to both a high-potency topical steroid (i.e. clobetasol 0.05%, fluocinonide 0.1%, halobetasol 0.05%, or

betamethasone dipropionate 0.05%) and a topical calcineurin inhibitor (i.e. tacrolimus or pimecrolimus)? (Provide supporting documentation of all therapies tried)

   a. If yes, continue to #6
   b. If no, clinical review required

6. Does the member have a documented trial with insufficient response or intolerance or contraindication to at least one systemic immunomodulatory agent (i.e. azathioprine, cyclosporine, methotrexate, or mycophenolate)? (Provide supporting documentation of all therapies tried)

   a. If yes, continue to #7
   b. If no, clinical review required

7. Does the member have a documented trial with insufficient response, intolerance, or contraindication to phototherapy? (Provide documentation to support insufficient response, intolerance, and/or contraindication)

   a. If yes, continue to #8
   b. If no, clinical review required

8. Is the requested drug being prescribed by or in consultation with a dermatologist, allergist, or immunologist?

   a. If yes, approve for 6 months unless otherwise specified
   b. If no, clinical review required

Moderate to severe asthma

1. Does the member have a baseline forced expiratory volume in 1 second (FEV1) less than 80% of predicted normal for adults or FEV1 of less than 90% in adolescents despite adherence to asthma maintenance regimen? (Provide baseline FEV1)

   a. If yes, continue to #2
   b. If no, clinical review required

2. Has the member experienced at least one severe exacerbation within the last 12 months that requires an urgent care visit, or hospitalization OR at least two exacerbations requiring oral corticosteroids despite adherence to asthma maintenance regimen? (Provide supporting documentation of past medical history)

   a. If yes, continue to #3
   b. If no, clinical review required

3. Does the member have a baseline eosinophil count greater than 150 cells/mcL or is the member dependent on daily maintenance oral corticosteroids for the treatment of asthma for at least 6 months?

   a. If yes, continue to #4
   b. If no, clinical review required

4. Is the member currently on a high-dose inhaled corticosteroids (ICS)?

   a. If yes, continue to #5
   b. If no, clinical review required

5. Is the member currently on a long-acting beta agonist (LABA)? (Provide documentation of medication history)

   a. If yes, continue to #7
   b. If no, continue to #6

6. Does the member have a history of intolerance or contraindication to LABA and is on a leukotriene modifier (LTRA)? (Provide supporting documentation)

a. If yes, continue to #7
b. If no, clinical review required

7. Is the requested treatment dose appropriate?
    a. If yes, continue to #8
    b. If no, clinical review required
8. Is Dupixent (dupilumab) being prescribed by or in consultation with an allergist or pulmonologist?
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Chronic rhinosinusitis with nasal polyposis

1. Does the member bilateral nasal polyposis and chronic symptoms of sinusitis?
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member had history of sinus surgery but developed recurrent refractory disease?
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member have documented treatment failure with systemic corticosteroids after the sinus surgery?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the requested treatment dose appropriate?
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is Dupixent (dupilumab) being prescribed by or in consultation with an otolaryngologist?
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Eosinophilic Esophagitis (EoE)

1. Is the member 1 year of age or older?
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member have a diagnosis of eosinophilic esophagitis (confirmed by endoscopic biopsy) defined as greater than or equal to 15 intraepithelial eosinophils per high-power field (eos/hpf)? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member currently have on-going symptoms of dysphagia (pain when swallowing, drooling, sensation of food getting stuck in the throat, chest pain) despite dietary modifications? (Provide documentation of symptoms)
    a. If yes, continue to #4
    b. If no, clinical review required

4. Does the patient weigh greater than or equal to 15 kg? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have a documented trial with an insufficient response, intolerance or contraindication to a minimum 8-week trial of at least one proton pump inhibitor (omeprazole, lansoprazole, pantoprazole, etc.)? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Does the member have a documented trial with insufficient response, intolerance or contraindication to at least one topical (budesonide, fluticasone) or oral glucocorticoid therapy? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Is Dupixent (dupilumab) being prescribed or in consultation with a gastroenterologist or other appropriate specialist?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Prurigo Nodularis

1. Is the member 18 years of age or older?
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member have at least 10% body surface area involvement? (Provide documentation of body surface area affected)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member have a documented trial with insufficient response, or intolerance, or contraindication to TWO of the following therapies: topical agent (high-potency steroid/calcineurin inhibitor), immunomodulatory agent (cyclosporine, methotrexate), or phototherapy? (Provide supporting documentation of all therapies tried)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the request for Dupixent (dupilumab)?
    a. If yes, continue to #6
    b. If no, continue to #5
5. Does the member have a documented trial with an insufficient response, intolerance or contraindication to a minimum 12-week trial of Dupixent (dupilumab)?
    a. If yes, continue to #6
    b. If no, clinical review required
6. Is the requested drug being prescribed by or in consultation with a dermatologist, allergist, or immunologist?
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Chronic Obstructive Pulmonary Disease

1. Does the member have documentation of moderate, severe, or very severe COPD (i.e. FEV1 of < 80% predicted)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member have a history of COPD exacerbations (i.e. one or more hospitalizations for an exacerbation within the past 12 months)? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member have a previous trial of at least 8-weeks with inadequate response, intolerance, or contraindication to ALL of the following?
        - Long-acting bronchodilator (LABA)
        - Long-acting muscarinic antagonist (LAMA)
        - Inhaled corticosteroid (ICS)

    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have a baseline eosinophil count of 300 cells/mcL or above? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is the medication being prescribed by, or in consultation with, a pulmonologist or other respiratory specialist?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Chronic Spontaneous Urticaria

1. Did the member have an insufficient response to TWO high dose antihistamines with a duration of at least 2 weeks each? (Provide documentation of past medications used along with response to therapy)
    a. If yes, continue to #4
    b. If no, continue to #2
2. Does the member have a contraindication to antihistamines?
    a. If yes, continue to #3
    b. If no, clinical review required
3. Did the member have an insufficient response or contraindication to leukotriene modifiers (LTRA)? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Did the member have an insufficient response to combination therapy with high dose second-generation antihistamines with at least one of the following for a minimum of 4 weeks trial? (Provide documentation of past medications used along with response to therapy)
        - A H2-antagonist

- A 1st generation antihistamine at bedtime
- A leukotriene modifier (LTRA

a. If yes, continue to #5
b. If no, clinical review required

5. Does the member have an insufficient response, intolerance, or contraindication to hydroxyzine or doxepin? (Provide documentation of response to therapy)

   a. If yes, continue to #6
   b. If no, clinical review required

6. Is the medication being prescribed by, or in consultation with, an allergist or dermatologist?

   a. If yes, approve for 6 months
   b. If no, clinical review required

<u>Bullous Pemphigoid</u>

1. Does the member have a Bullous Pemphigoid Disease Area Index (BPDAI) activity score of at least 24 on a scale of 0-360? (Provide supporting documentation)

   a. If yes, continue to #2
   b. If no, clinical review required

2. Does the member have a documented trial with insufficient response, or intolerance, or contraindication to a high-potency topical steroid (i.e. clobetasol 0.05%, fluocinonide 0.1%, halobetasol 0.05%, or betamethasone dipropionate 0.05%)? (Provide supporting documentation of all therapies tried)

   a. If yes, continue to #3
   b. If no, clinical review required

3. Does the member have a previous trial with inadequate response, intolerance, or contraindication to oral corticosteroids?

   a. If yes, continue to #4
   b. If no, clinical review required

4. Does the member have a documented trial with insufficient response to at least one systemic immunomodulatory agent (i.e. azathioprine, methotrexate, or mycophenolate) OR an antibiotic (i.e. doxycycline or dapsone)? (Provide supporting documentation of all therapies tried)

   a. If yes, continue to #7
   b. If no, continue to #5

5. Does the member have an intolerance or contraindication to systemic immunomodulatory agents (i.e. azathioprine, methotrexate, or mycophenolate) AND antibiotics (i.e. doxycycline and dapsone)? (Provide supporting documentation)

   a. If yes, continue to #6
   b. If no, clinical review required

6. Is the medication being prescribed by, or in consultation with, a dermatologist or immunologist?

   a. If yes, approve for 6 months
   b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA-approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Will the requested medication be used with other biologic therapy? (Examples: Enbrel, Actemra, Cimzia, Simponi, Orencia, Taltz, Cosentyx, Otezla, etc)
    a. If yes, clinical review required
    b. If no, continue to #3
3. Were updated chart notes (dated within 1 year) provided with documentation of significant clinical response to therapy? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the requested drug being prescribed by or in consultation with a dermatologist, allergist, immunologist, or other appropriate specialist?
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

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References:

1. Dupixent (dupilumab) [Prescribing Information]. Tarrytown, NY: Sanofi-aventis U.S. LLC. June 2025.
2. Dupixent. Micromedex. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed September 14, 2018.
3. Adbry (tralokinumab-ldrm) [Prescribing Information]. Ballerup, Denmark: LEO Pharma A/S. May 2024.
4. Nemluvio (nemolizumab-ilto) subcutaneous injection, [Prescribing Information]. Dallas, TX: Galderma Laboratories, L.P..; June 2025.
5. Ebglyss (lebrikizumab-lbkz) subcutaneous injection, [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; May 2025.
6. Halilos MD, Holbrook MD. Chronic rhinosinusitis: Management. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed October 29, 2024.
7. Cloutier MM, et al. 2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group. J Allergy Clin Immunol. 2020 Dec;146(6):1217-1270. doi: 10.1016/j.jaci.2020.10.003. Erratum in: J Allergy Clin Immunol. 2021 Apr;147(4):1528-1530. PMID: 33280709; PMCID: PMC7924476.
8. Hirano, Ikuo, et al. "AGA institute and the joint task force on allergy-immunology practice parameters clinical guidelines for the management of eosinophilic esophagitis." Gastroenterology 158.6 (2020): 1776-1786.

Last Reviewed: 9/19/2018, 11/20/19, 1/21/20, 7/21/21, 1/19/22, 7/20/22, 9/21/22, 9/15/23, 9/20/24, 11/15/24, 3/21/25, 9/19/25
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9. Watsky, K. Prurigo Nodularis. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed August 29, 2023.
10. Davis DMR, Drucker AM, Alikhan A, et al. Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic therapies. J Am Acad Dermatol. 2024;90(2):e43-e56. Academy of Dermatology and Venereology 32.6 (2018): 850-878.
11. Bernstein JA, Lang DM, Khan DA, et al. The diagnosis and management of acute and chronic urticaria: 2014 update. J Allergy Clin Immunol 2014; 133:1270.
12. Borradori L, Van Beek N, Feliciani C, et al: Updated S2 K guidelines for the management of bullous pemphigoid initiated by the European Academy of Dermatology and Venereology (EADV). J Eur Acad Dermatol Venereol 2022; 36(10):1689-1704.

Allergen Extracts
Prior Authorization Guidelines

Affected Medication(s)

- Grastek sublingual tablet
- Odactra sublingual tablet
- Oralair sublingual tablet
- Ragwitek sublingual tablet

FDA Approved Indication(s)

- **Grastek:** As an immunotherapy 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 for patients between 5 and 65 years of age
- **Odactra:** As an 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 for patients between 5 and 65 years of age
- **Oralair:** As an immunotherapy 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 this product for patients between 5 and 65 years of age
- **Ragwitek:** As an immunotherapy for the treatment of short ragweed pollen-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive skin test or *in vitro* testing for pollen-specific IgE antibodies for short ragweed pollen for patients between 5 and 65 years of age

Dosing

- Refer to corresponding package insert for specific dosing recommendations

Authorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member remain symptomatic despite treatment with a nasal steroid AND oral antihistamine at the maximum indicated doses? (Provide supporting documentation of relevant past/current medication history and symptom history)
    a. If yes, continue to #3
    b. If no, clinical review required
3. For Grastek, Oralair, and Ragwitek: Will the treatment begin prior to the start of allergy season and continue throughout the allergy season? (12 weeks prior for Grastek or Ragwitek, 16 weeks prior for Oralair)
    a. If yes, continue to #4
    b. If no, clinical review required
    c. If not applicable, continue to #4
4. Does the member have a positive skin test or *in vitro* testing for pollen specific IgE antibodies to the corresponding allergen listed below? (Provide relevant test results for review)

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- Grastek: Timothy grass or cross-reactive grass
- Odactra: *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites
- Oralair: Sweet vernal, Orchard, perennial Rye, Timothy, or Kentucky blue grass
- Ragwitek: Short Ragweed

a. If yes, continue to #5
b. If no, clinical review required

5. Does the member have any of the following contraindications to the requested treatment?

- Severe, unstable, or uncontrolled asthma
- History of any severe systemic allergic reaction or severe local reaction after taking any sublingual allergen immunotherapy
- History of eosinophilic esophagitis
- Hypersensitivity to any of the inactive ingredients

a. If yes, clinical review required
b. If no, continue to #6

6. Is the requested drug Grastek?

a. If yes, go to #7
b. If no, continue to #8

7. Has the member completed 3 consecutive years of therapy (including intervals between grass pollen seasons)?

a. If yes, clinical review required
b. If no, continue to #8

8. Is the treatment being prescribed by, or in consult with an allergist, immunologist, or otolaryngologist?

a. If yes, approve for 12 months unless otherwise specified
b. If no, clinical review required

Note:

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References:

1. Odactra (dermatophagoides pteronyssinus and dermatophagoides farinae) [Prescribing Information]. Horsholm, Denmark: ALK-Abello A/S. February 2025.
2. Oralair (anthoxanthum odoratum pollen, dactylis glomerata pollen, lolium perenne pollen, phleum pratense pollen, and poa pratensis) [Prescribing Information]. Antony, France: Stallergenes. June 2025.
3. Ragwitek (ambrosia artemisiifolia pollen) [Prescribing Information]. Horsholm, Denmark: ALK-Abello A/S. September 2022.
4. Grastek (timothy grass pollen allergen extract) [Prescribing Information]. Horsholm, Denmark: ALK-Abello A/S. September 2022.

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Effective Date: 1/1/19, 1/1/20, 9/1/21, 10/15/24, 10/31/25

5. Greenhawt, M, Oppenheimer J, Nelson M, et al. Sublingual immunotherapy: a focused allergen immunotherapy practice parameter update. Annals of Allergy, Asthma & Immunology 118(2017) 276-282. https://doi.org/10.1016/j.anai.2016.12.009. Accessed October 2018.

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Amyotrophic Lateral Sclerosis (ALS) Agents
Prior Authorization Guidelines

Affected Medication(s)

- Radicava ORS (edavarone) oral suspension

FDA Approved Indication(s)

- Treatment of amyotrophic lateral sclerosis (ALS) in adults

Dosing

- Radicava: 105 mg orally once daily for 14 days, followed by 14-day drug-free period, then 105 mg once daily for 10 days within a 14-day period, followed by a 14-day drug-free period

Initial Authorization Criteria

1. Is the request for continuation of Radicava ORS (edavarone) therapy?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member at least 18 years of age?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the treatment prescribed by or in consultation with a neurologist?
    a. If yes, continue to #5
    b. If no, clinical review required
5. Has the member been diagnosed with ALS defined by the revised El Escorial criteria, Awaji criteria, or Gold Coast criteria? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Is the patient currently on riluzole therapy or have a documented contraindication or intolerance to riluzole? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Does the member have a disease duration of less than or equal to 2 years? (Provide supporting documentation)
    a. If yes, continue to #8

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b. If no, clinical review required

8. Does the member have a forced vital capacity (%FVC) of greater than or equal to 80% of predicted? (Provide supporting documentation)
    a. If yes, continue to #9
    b. If no, clinical review required
9. Does the member have a baseline documentation of the revised ALS Functional Rating Scale (ALSFRS-R) score with greater than 2 points in each of the 12 items? (Provide supporting documentation)
    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication Food and Drug Administration (FDA) approved or supported by major compendia? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Has the member experienced a documented positive response to therapy? (ex. no tracheostomy or assisted ventilation required) (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the treatment being prescribed by, or in consultation with, a neurologist?
    a. If yes, approve for 12 months reauthorization
    b. If no, clinical review required

Note:

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References:

1. Miller, Robert G., et al. "Practice parameter update: the care of the patient with amyotrophic lateral sclerosis: drug, nutritional, and respiratory therapies (an evidence-based review): report of the Quality Standards Subcommittee of the American Academy of Neurology." Neurology 73.15 (2009): 1218-1226.
2. EFNS Task Force on Diagnosis and Management of Amyotrophic Lateral Sclerosis, et al. "EFNS guidelines on the clinical management of amyotrophic lateral sclerosis (MALS)–revised report of an EFNS task force." European journal of neurology 19.3 (2012): 360-375.
3. Radicava ORS (edaravone) oral suspension [package insert]. Jersey City, NJ: Mitsubishi Tanabe Pharma Corporation; 2023

Last Reviewed: 11/16/22, 5/19/23, 5/17/24, 5/16/25
Effective Date:1/1/23, 7/15/23, 8/1/24

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5. Writing Group; Edaravone (MCI-186) ALS 19 Study Group. Safety and efficacy of edaravone in well defined patients with amyotrophic lateral sclerosis: a randomised, double-blind, placebo-controlled trial. Lancet Neurol. 2017;16(7):505-512.

Aminocaproic Acid
Prior Authorization Guidelines

Affected Medication(s)

- Amicar oral solution
- Amicar oral tablet
- Aminocaproic acid oral solution
- Aminocaproic acid oral tablet

FDA Approved Indication(s)

- Enhancing hemostasis when fibrinolysis contributes to bleeding
- Hemorrhage secondary to various disorders including aplastic anemia, abruption placentae, hepatic cirrhosis, and neoplastic diseases

Dosing

- 4 to 5 g administered during the first hour of treatment, followed by a continuing rate of 1 to 1.25 g per hour, continued for about 8 hours or until the bleeding situation has been controlled (Maximum daily dose: 30g)

Authorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member have a trial with inadequate response, intolerance, or contraindication to tranexamic acid? (Provide documentation of trial with inadequate response, intolerance, or contraindication)
    a. If yes, approve for 1 month unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Amicar. Micromedex. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed October 14, 2023.
2. Amicar (aminocaproic acid) [Prescribing Information]. Lake Forest, IL: Clover Pharmaceuticals, Corp. June 2022.

Last Reviewed: 11/21/18, 11/20/19, 7/21/21, 11/16/22, 11/17/23, 9/20/24, 9/19/25
Effective Date: 1/1/19, 1/1/20, 9/1/21, 12/20/23, 10/15/24

Anti-Asthmatic Agent Policy
Prior Authorization Guidelines

Affected Medication(s)

- Fasenra (benralizumab) subcutaneous solution
- Nucala (mepolizumab) auto-injector solution
- Nucala (mepolizumab) syringe
- Tezspire (tezepelumab) auto-injector solution
- Tezspire (tezepelumab) syringe
- Xolair (omalizumab) subcutaneous solution

FDA Approved Indication(s)

Fasenra

- As add-on maintenance treatment of adult and pediatric patients 6 years of age and older with severe asthmaand with an eosinophilic phenotype
- For the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA)

Nucala

- As an add-on maintenance therapy for adult and pediatric patients 6 years of age and older with severe asthma and with an eosinophilic phenotype
- As add-on maintenance treatment of nasal polyps in adult patients 18 years of age and older with inadequate response to nasal corticosteroids
- As add-on maintenance for the treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype
- For the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA)
- For the treatment of adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome (HES) for ≥6 months without an identifiable non-hematologic secondary cause

Tezspire

- As add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma

Xolair

- For patients 6 years of age and older with moderate to severe persistent asthma who have a positive skin test or *in vitro* reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids
- As add-on maintenance for the treatment of nasal polyps in adult patients 18 years of age and older with inadequate response to nasal corticosteroids
- For the treatment of adults and adolescents 12 years of age and older with chronic idiopathic urticaria who remain symptomatic despite H1 antihistamine treatment
- For IgE-mediated food allergy in adult and pediatric patients aged 1 year and older for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods, to be used in conjunction with food allergen avoidance

Dosing

- Reference dosing recommendations in package insert

Last Reviewed: 11/7/18, 3/18/20, 5/19/21, 7/20/22, 5/19/23, 3/15/24, 11/15/24, 11/21/25
Effective Date: 1/1/19, 5/1/20, 6/15/21, 9/1/22, 7/15/23, 5/1/24, 1/1/25, 1/1/26

Initial Authorization Criteria

1. Is the request for continuation of injectable anti-asthmatic therapy for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication and age? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Which diagnosis the injectable anti-asthmatic being requested for?
    a. Moderate to severe persistent asthma, continue to corresponding criteria
    b. Chronic Idiopathic Urticaria (CIU), continue to corresponding criteria
    c. Eosinophilic granulomatosis with polyangiitis (EGPA), continue to corresponding criteria
    d. Hypereosinophilic syndrome (HES), continue to the corresponding criteria
    e. Nasal polyps, continue to corresponding criteria
    f. IgE-mediated food allergy, continue to corresponding criteria
    g. Chronic obstructive pulmonary disease (COPD), continue to corresponding criteria

<u>Moderate to severe persistent asthma</u>

1. Does the member have a reduced lung function at baseline defined as pre-bronchodilator FEV1 less than 80%? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the member currently on a high-dose inhaled corticosteroid (ICS)? (Provide documentation of medication history)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member on a long acting beta agonist (LABA)? (Provide documentation of medication history)
    a. If yes, continue to #5
    b. If no, continue to #4
4. Does the member have a history of intolerance or contraindication to LABA and is on a leukotriene modifier (LTRA)? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Has the member experienced 2 or more exacerbations within the last 12 months that required systemic steroid treatment, an urgent care visit, or hospitalization despite adherence to asthma maintenance therapy? (Provide documentation of exacerbation history)
    a. If yes, continue to #6
    b. If no, clinical review required

6. Does the member have eosinophilic phenotype asthma defined as baseline eosinophil count greater than equal to 150 cells/ul within 12 months? (Provide supporting documentation)
    a. If yes, continue to #11
    b. If no, continue to #7
7. Does the member have a baseline immunogloblin E (IgE) level between 30 and 700 IU/mL? (Provide baseline IgE lab results)
    a. If yes, continue to #8
    b. If no, continue to #10
8. Does the member have body weight less than 150 kg?
    a. If yes, continue to #9
    b. If no, continue to #10
9. Does the member have a positive skin test or *in vitro* reactivity to a perennial aeroallergen? (Provide allergen test results)
    a. If yes, continue to #11
    b. If no, continue to #10
10. Is the request for Tezspire?
    a. If yes, continue to #11
    b. If no, clinical review required
11. Is the requested injectable anti-asthmatic to be used in combination with current asthma treatment regimen? (Provide documentation of planned treatment regimen)
    a. If yes, continue to #12
    b. If no, clinical review required
12. Is the injectable anti-asthmatic prescribed by, or in consult with, an allergist or pulmonologist?
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

<u>Chronic Idiopathic Urticaria (CIU)</u>

1. Is the member 12 years of age or older?
    a. If yes, continue to #2
    b. If no, clinical review required
2. Did the member have an insufficient response to TWO high dose antihistamines with a duration of at least 2 weeks each? (Provide documentation of past medications used along with response to therapy)
    a. If yes, continue to #5
    b. If no, continue to #3
3. Does the member have a contraindication to antihistamines? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required

4. Did the member have an insufficient response or contraindication to leukotriene modifiers (LTRA)? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required

5. Did the member have an insufficient response to combination therapy with high dose second-generation antihistamines with at least one of the following for a minimum of 4 weeks trial? (Provide documentation of past medications used along with response to therapy)
    - A H2-antagonist
    - A 1st generation antihistamine at bedtime
    - A leukotriene modifier (LTRA)

    a. If yes, continue to #6
    b. If no, clinical review required

6. Does the member have an insufficient response, intolerance, or contraindication to hydroxyzine or doxepin? (Provide documentation of response to therapy)
    a. If yes, continue to #7
    b. If no, clinical review required

7. Is Xolair (omalizumab) prescribed by, or in consult with, an allergist or dermatologist?
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

<u>Eosinophilic granulomatosis with polyangiitis (EGPA)</u>

1. Does the member have relapsing or refractory eosinophilic granulomatosis with polyangiitis with at least one of the following characteristics?
    - Asthma
    - Sinusitis
    - Pulmonary infiltrates
    - Neuropathy
    - Eosinophilic vasculitis of one or more end-organs

    a. If yes, continue to #2
    b. If no, clinical review required

2. Does the member have relapsing or refractory disease despite treatment with TWO separate trials of the following therapies in combination glucocorticoid: azathioprine, methotrexate, leflunomide?
    a. If yes, continue to #3
    b. If no, clinical review required

3. Has the member been established on stable dose of oral steroid therapy for 4 weeks or more?
    a. If yes, continue to #4
    b. If no, clinical review required

4. Does the member have a baseline blood eosinophil level of 10% and higher OR an absolute eosinophil count of 1000 cells/ul or higher? (Provide supporting lab for review)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is the requested medication being prescribed by or in consult with a specialist who is experienced in treating EGPA?
    a. If yes, approve for 6 months, unless otherwise specified
    b. If no, clinical review required

Hypereosinophilic Syndrome (HES)

1. Does the member have documentation of primary HES without non-hematologic secondary causes? (i.e. drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member have a blood eosinophil count of 1,000 cells/mcL or higher?
    a. If yes, continue to #3
    b. If no, clinical review required
3. Has the member trialed HES therapy consisting of chronic/episodic oral corticosteroids, immunosuppressive, or cytotoxic therapy?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Has the member experienced at least 2 HES flares within the past 12 months? (defined as HES-related worsening of clinical symptoms or blood eosinophil counts requiring an escalation in therapy)
    a. If yes, continue to #3
    b. If no, clinical review required
5. Is the requested medication being prescribed by, or in consult with, a specialist who is experienced in treating HES?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Nasal Polyps

1. Does the member have documentation of bilateral nasal polyps confirmed by endoscopy with a total nasal polyp score (NPS) of 5 or greater and NPS score of 2 or greater per nostril? (NPS range 0-4 per nostril, 0-8 total)
    - 0= no polyps
    - 1=small polyps in the middle meatus not reaching below the inferior border of the middle turbinate
    - 2=polyps reaching below the lower border of the middle turbinate
    - 3=large polyps reaching the lower border of the inferior turbinate or polyps medial to the middle turbinate

- 4=large polyps causing complete obstruction of the inferior nasal cavity)

a. If yes, continue to #2
b. If no, clinical review required

2. Does the member have documented moderate to severe nasal congestion?

a. If yes, continue to #3
b. If no, clinical review required

3. Has the member previously trialed nasal corticosteroids at the maximum recommended dose?

a. If yes, continue to #4
b. If no, clinical review required

4. Is the requested medication being prescribed by, or in consultation with, an ENT specialist?

a. If yes, approve for 6 months
b. If no, clinical review required

IgE-Mediated Food Allergy

1. Does the member have documentation of IgE-mediated food allergy confirmed by allergen skin testing completed within 12 months? (Provide relevant test results for review)

a. If yes, continue to #2
b. If no, clinical review required

2. Does the member have a history of a previous systemic allergic reaction to food requiring the use of epinephrine or resulting in ER visit/hospitalization?

a. If yes, continue to #3
b. If no, clinical review required

3. Is medical rationale provided for why adhering to a food allergen avoidant diet alone is not sufficient therapy?

a. If yes, continue to #4
b. If no, clinical review required

4. Will the medication be used in combination with food allergen avoidance?

a. If yes, continue to #5
b. If no, clinical review required

5. Is the requested medication being prescribed by, or in consult with, an allergist or immunologist?

a. If yes, approve for 6 months
b. If no, clinical review required

Chronic obstructive pulmonary disease (COPD)

1. Does the member have documentation of moderate, severe, or very severe COPD (i.e. FEV1 of < 80% predicted)

a. If yes, continue to #2
b. If no, clinical review required

2. Does the member have a history of COPD exacerbations (i.e. one or more hospitalizations for an exacerbation within the past 12 months)? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member have a previous trial of at least 8-weeks with inadequate response, intolerance, or contraindication to ALL of the following?
    - Long-acting bronchodilator (LABA)
    - Long-acting muscarinic antagonist (LAMA)
    - Inhaled corticosteroid (ICS)

    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have a previous trial of at least 8 weeks with inadequate response, intolerance, or contraindication to Dupixent?
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have a baseline eosinophil count of 300 cells/mcL or above? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Is the medication being prescribed by, or in consultation with, a pulmonologist or other respiratory specialist?
    a. If yes, approve for 6 months
    b. <u>If no, clinical review required</u>

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Which diagnosis is the requested medicaiton being used for?
    a. Moderate to severe persistent asthma, please see corresponding criteria
    b. Chronic Idiopathic Urticaria (CIU), please see corresponding criteria
    c. Eosinophilic granulomatosis with polyangiitis (EGPA), continue to corresponding criteria
    d. Hyperesosinophilic Syndrome, continue to corresponding criteria
    e. Nasal polyps, continue to corresponding criteria
    f. IgE-mediated food allergy, continue to corresponding criteria
    g. Chronic obstructive pulmonary disease (COPD), continue to corresponding criteria

<u>Moderate to severe persistent asthma</u>

1. Is the member adherent to asthma maintenance therapy defined as a high-dose ICS plus a LABA or LTRA?
    a. If yes, continue to # 2

b. If no, clinical review required

2. Is the member responding positively to therapy defined as reduction in exacerbations, reductions in corticosteroid dose, or improvement in FEV1 compared to baseline? (Provide supporting documentation)

    a. If yes, continue to #3
    b. If no, clinical review required

3. Is the requested medication being prescribed by, or in consult with an allergist or pulmonologist?

    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Chronic Idiopathic Urticaria (CIU)

1. Is the member responding positively to therapy defined as reduction in symptoms compared to baseline? (Provide supporting documentation)

    a. If yes, continue to #2
    b. If no, clinical review required

2. Is Xolair (omalizumab) prescribed by, or in consult with, an allergist or dermatologist?

    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Eosinophilic granulomatosis with polyangiitis (EGPA)

1. Is the member responding positively to therapy defined as reduction in relapse and or ability to taper down on glucocorticoid use? (Provide supporting documentation)

    a. If yes, continue to #2
    b. If no, clinical review required

2. Is Nucala (omalizumab) prescribed by, or in consult with, an allergist or dermatologist?

    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Hyperesosinophilic Syndrome

1. Is the member responding positively to therapy defined by an improvement in symptoms and/or a reduction in the frequency of exacerbation? (Provide supporting documentation)

    a. If yes, continue to #2
    b. If no, clinical review required

2. Is the medication being prescribed by, or in consultation with, a specialist who is experienced in treating HES?

    a. If yes, approve for 12 months
    b. If no, clinical review required

Nasal Polyps

1. Is the member responding positively to therapy defined as an improvement in Nasal Polyps Score (NPS) and a decrease in the severity of nasal congestion?

    a. If yes, continue to #2
    b. If no, clinical review required

2. Is the medication being prescribed by, or in consultation with, an ENT specialist?
    a. If yes, approve for 12 months
    b. If no, clinical review required

IgE-Mediated Food Allergy

1. Is the member responding positively to therapy defined by a reduction in the frequency of anaphylactic events? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the medication being prescribed by, or in consultation with, an allergist or immunologist?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Chronic obstructive pulmonary disease (COPD)

1. Is the member responding positively to therapy defined as reduction in exacerbations or improvement in FEV1 compared to baseline? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the requested medication being prescribed by, or in consult with an allergist or pulmonologist?
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Xolair Prescribing Information. Irvine, CA: Genentech, Inc.; November 2024.
2. Nucala Prescribing Information. Philadelphia, PA: GlaxoSmithKline LLC; August 2025.
3. Fasenra Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceutical, LP; September 2024.
4. TEZSPIRE® (tezepelumab-ekko) injection [package insert]. Sodertalje, Sweden: AstraZeneca AB; May 2023.
5. National Asthma Education and Prevention Program: Expert panel report III: Guidelines for the diagnosis and management of asthma. Bethesda, MD: National Heart, Lung, and Blood Institute, 2007. (NIH publication no. 08-4051). Available at http://www.nhlbi.nih.gov/health-pro/guidelines/current/asthma-guidelines.
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7. Zuberbier T, Aberer W, Asero R, Bindslev-Jensen C, Brzoza Z, Canonica GW, et al. The EAACI/GA(2) LEN/EDF/WAO Guideline for the definition, classification, diagnosis, and management of urticaria: the 2013 revision and update. Allergy 2014;69:868-87.

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Effective Date: 1/1/19, 5/1/20, 6/15/21, 9/1/22, 7/15/23, 5/1/24, 1/1/25, 1/1/26

8. Fine LM, Bernstein JA. Guideline of Chronic Urticaria Beyond. Allergy Asthma Immunol Res. 2016 September; 8(5): 396-403.
9. MICROMEDEX® Healthcare Series [Internet database]. Greenwood Village, CO: Thomson Healthcare. Updated periodically.
10. Wechsler ME, Akuthotha P, Jayne D, ed al. Mepolizumab or placebo for eosinophilic granulomatosis with Polyangiitis. N Engl J Med. 2017; 376(20); 1921-1932. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5548295/
11. Global Initiative for Asthma (GINA). Global strategy for asthma management and prevention. https://ginasthma.org/gina-reports/. Updated 2022. [Accessed 23 October 2023.]
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Apokyn® (apomorphine), Inbrija® (levodopa)
Prior Authorization Guidelines

Affected Medication(s)

- Apokyn subcutaneous solution
- Apomorphine subcutaneous solution
- Inbrija inhalation powder

FDA Approved Indication(s)

- For the acute, intermittent treatment of hypomobility, "off" episodes ("end-of-dose wearing off" and unpredictable "on/off" episodes) in patients with advanced Parkinson's disease

Dosing

- Apokyn: Initially 0.2 mL (2 mg) titrated up to a maximum of 0.6 mL (6 mg)
- Inbrija:
  - 84mg (contents of two capsules) inhaled, as needed, for OFF symptoms up to five times a day
  - The maximum dose per OFF period is 84mg, and the maximum recommended daily dosage of Inbrija is 420mg

Initial Authorization Criteria

1. Is the request for continuation of Apokyn (apomorphine hydrochloride) or Inbrija (levodopa) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2
2. Is the medication being requested for an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
   a. If yes, continue to #3
   b. If no, clinical review required
3. Does the member have a diagnosis of advanced Parkinson's disease? (Provide supporting documentation)
   a. If yes, continue to #4
   b. If no, clinical review required
4. Is the member 18 years of age or older?
   a. If yes, continue to #5
   b. If no, clinical review required
5. Does the member have significant hypomobility or "off" episodes that last at least 2 hours? (Provide supporting documentation)
   a. If yes, continue to #6
   b. If no, clinical review required
6. Is the member on a maximally tolerated dose of levodopa AND one additional agent from one of the following classes? (Provide relevant medication history)
   - Dopamine agonist (Examples include: ropinirole, rotigotine)
   - Catechol-O-methyl transferase (COMT) inhibitor (Examples include: entacapone, tolcapone)

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- Monoamine oxidase type B inhibitor (MAO-B) (Examples include: rasagiline, safinamide, selegiline)

a. If yes, continue to #7
b. If no, clinical review required

7. Is the request for Apokyn or apomorphine?

a. If yes, continue to #8
b. If no, continue to #9

8. Does the member have a trial with inadequate response to, intolerance, or contraindication to Inbrija? (Provide supporting documentation)

a. If yes, continue to #9
b. If no, clinical review required

9. Is the treatment being prescribed by, or in consultation with, a neurologist?

a. If yes, approve for 12 months unless otherwise specified
b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)

a. If yes, continue to #2
b. If no, clinical review required

2. Is the member demonstrating positive clinical response to therapy defined by a decrease in frequency of hypomobility or "off" episodes? (Provide supporting documentation)

a. If yes, continue to #3
b. If no, clinical review required

3. Is the treatment being prescribed by, or in consultation with, a neurologist?

a. If yes, approve for 12 months reauthorization unless otherwise specified
b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Apokyn [package insert]. Rockville, MD: MDD US Operations, LLC. October 2024.
2. Pahwa R, Factor SA, Lyons KE, et al. Practice Parameter: Treatment of Parkinson disease with motor fluctuations and dyskinesia (an evidence-based review). Report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology*. 2006; 66:983-995.
3. DRUGDEX® System [Internet database]. Greenwood Village, CO:Thomson Healthcare. Updated periodically.

Last Reviewed: 10/17/18, 1/21/20, 11/18/20, 11/17/21, 1/20/23, 11/17/23, 9/20/24, 9/19/25

Effective Date: 1/1/19, 2/15/20, 12/15/20, 1/1/22, 3/15/23, 12/20/23, 10/15/24

4. INBRIJA (levodopa inhalation powder) inhalation powder [package insert]. Pearl River, NY: Merz Pharmaceuticals, LLC; December 2024.
5. Tsao-Wei L, Tarsy, D. Medical management of motor fluctuations and dyskinesia in Parkinson disease. Hurtig HI, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed October 2021.

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Arcalyst® (rilonacept)
Prior Authorization Guidelines

Affected Medication(s)

- Arcalyst powder for reconstitution for subcutaneous solution

FDA Approved Indication(s)

- For treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older
- Maintenance of remission of deficiency of interleukin-1 receptor antagonist in adults and pediatric patients weighing ≥10 kg
- Treatment of recurrent pericarditis and reduction in risk of recurrence in adults and pediatric patients 12 years of age and older

Dosing

- Refer to corresponding package insert for information

Initial Authorization Criteria

1. Is the request for continuation of Arcalyst (rilonacept) therapy?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Will Arcalyst (rilonacept) be used with other biologic agent(s)? (Examples: Kineret, Ilaris, Actemra)
    a. If yes, clinical review required
    b. If no, continue to #4
4. What is the diagnosis that the medication is being requested for?
    a. Cryopyrin-Associated Periodic Syndromes (CAPS), continue to corresponding criteria
    b. Deficiency of Interleukin-1 Receptor Antagonist (DIRA), continue to corresponding criteria
    c. Pericarditis, continue to corresponding criteria
    d. Other indication, continue to corresponding criteria

Cryopyrin-Associated Periodic Syndromes (CAPS)

1. Is the genetic testing result confirming diagnosis of CAPS received? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the member 12 years of age or older?
    a. If yes, continue to #3
    b. If no, clinical review required

Last Reviewed: 10/17/18, 5/20/20, 7/21/21, 11/16/22, 11/17/23, 9/20/24, 9/19/25
Effective Date: 1/1/19, 7/1/20, 9/1/21, 12/20/23

3. Is the treatment being prescribed by or in consultation with a rheumatologist?
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

1. Does the member weigh at least 10kg?
    a. If yes, continue to #2
    b. If no, clinical review required

2. Has the diagnosis been confirmed by a mutation in the *IL1RN* gene?
    a. If yes, continue to #3
    b. If no, clinical review required

3. Has the member demonstrated prior clinical benefit with Kineret (anakinra)? (Examples of clinical benefit include: normalized acute phase reactants, resolution of fever, skin rash and bone pain or reduced dosage of corticosteroids)
    a. If yes, continue to #4
    b. If no, clinical review required

4. Is the treatment being prescribed by or in consultation with a rheumatologist, dermatologist or a physician specializing in the treatment of autoinflammatory disorders?
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Recurrent Pericarditis

1. Does the member have recurrent pericarditis as defined as at least three (3) episodes within the past year?
    a. If yes, continue to #2
    b. If no, clinical review required

2. Is the member receiving standard treatment for pericarditis (i.e. NSAIDs, colchicine, and/or systemic corticosteroids) and still symptomatic?
    a. If yes, continue to #4
    b. If no, continue to #3

3. Does the member have a documented inadequate response, intolerance, or contraindication to standard treatment options? (Provide documentation of inadequate responses, contraindications, and/or intolerances)
    a. If yes, continue to #4
    b. If no, clinical review required

4. Is the treatment being prescribed by or in consultation with a rheumatologist or cardiologist?
    a. If yes, approve for 3 months unless otherwise specified
    b. If no, clinical review required

Other Indications

1. Has the member tried and had an inadequate response OR dose the member have a contradiction to ALL standard treatment options for the requested indication (Provide all prior treatment history, contraindication if appropriate, and treatment plan)?

    a. If yes, approve for 3 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)

    a. If yes, continue to #2
    b. If no, clinical review required

2. Is the member responding positively to therapy as defined by the following: (Provide supporting documentation)

    - Cryopyrin-Associated Periodic Syndromes (CAPS): decrease in symptoms from baseline and/or improvement in serum levels of inflammatory proteins (i.e. CRP)
    - Deficiency of Interleukin-1 Receptor Antagonist (DIRA): sustained clinical remission, resolution of fever, skin rash, and bone pain or normalized acute phase reactants
    - Recurrent Pericarditis: absence of chest pain with normalization of inflammatory biomarkers such as erythrocyte sedimentation rate and/or C-reactive protein, continued resolution of fever and bone pain
    - Other Indication: Clinical documentation confirming disease responsiveness to therapy provided

    a. If yes, continue to #3
    b. If no, clinical review required

3. Is the treatment being prescribed by or in consultation with the appropriate specialist?

    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Arcalyst Prescribing Information. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; March 2025.
2. Hoffman HM, Throne ML, Amar NJ, et al. Efficacy and safety of rilonacept (interleukin-1 trap) in patients with cryopyrin-associated periodic syndromes. Arthritis and Rheum. 2008;58(8): 2443-2452.
3. Nigrovic, P. Cryoprin-associated periodic syndromes and related disorders. Orange S, Kaplan S, eds. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed May, 2020.
4. Garg M, de Jesus AA, Chapelle D, et al. Rilonacept maintains long-term inflammatory remission in patients with deficiency of the IL-1 receptor antagonist. JCI Insight. 2017 Aug 17;2(16):e94838. doi: 10.1172/jci.insight.94838.

Last Reviewed: 10/17/18, 5/20/20, 7/21/21, 11/16/22, 11/17/23, 9/20/24, 9/19/25
Effective Date: 1/1/19, 7/1/20, 9/1/21, 12/20/23

5. Klein AL, Imazio M, Cremer P, et al. Phase 3 trial of interleukin-1 trap rilonacept in recurrent pericarditis. N Engl J Med. 2021;384(1):31-41.

Arikayce® (amikacin)
Prior Authorization Guidelines

Affected Medication(s)

- Arikayce oral suspension for inhalation

FDA Approved Indication(s)

- In adults who have limited or no alternative treatment options, for the treatment of *Mycobacterium avium* complex (MAC) lung disease as part of a combination antibacterial drug regimen in patients who do not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy

Dosing

- Once daily inhalation of the contents of one 590 mg/8.4 mL ARIKAYCE vial (590 mg of amikacin) using the Lamira Nebulizer System

Initial Authorization Criteria

1. Is the request for continuation of Arikayce (amikacin) therapy?

    a. If yes, continue to Reauthorization
    b. If no, continue to #2

2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)

    a. If yes, continue to #3
    b. If no, clinical review required

3. Does the member have *Mycobacterium avium* complex (MAC) lung disease as confirmed by positive sputum culture? (Provide positive sputum culture for review)

    a. If yes, continue to #4
    b. If no, clinical review required

4. Is the member 18 years of age or older?

    a. If yes, continue to #5
    b. If no, clinical review required

5. Has the member trialed a minimum of 6-months of a multidrug background regimen (listed below) with failure confirmed by sputum culture? (Note: Failure defined as continued positive sputum culture) (Provide supporting documentation)

    - Clarithromycin/azithromycin + ethambutol + rifampin/rifabutin
    - Clarithromycin/azithromycin + ethambutol + rifampin/rifabutin + parenteral streptomycin/amikacin

    a. If yes, continue to #6
    b. If no, clinical review required

Last Reviewed: 9/18/19, 11/18/20, 9/15/21, 11/16/22, 11/17/23, 9/20/24, 9/19/25
Effective Date: 10/15/19, 12/15/20, 10/15/24

6. Is the treatment being prescribed by or in consultation with an ID specialist or pulmonologist?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication Food and Drug Administration (FDA) approved or supported by major compendia?
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (within the past 6 months) with documentation of negative sputum cultures received? (Note: Treatment should be continued until sputum cultures are consecutively negative for at least 12 months) (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the treatment being prescribed by or in consultation with an ID specialist or pulmonologist?
    a. If yes, approve for 12 months reauthorization
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. ARIKAYCE (amikacin liposome inhalation suspension) for oral inhalation [package insert]. Bridgewater, NJ: Insmed Incorporated; March 2025.
2. Drugs@FDA: FDA Approved Drug Products. 2018. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed Nov 5. 2018].
3. Griffith, David E., et al. "An official ATS/IDSA statement: diagnosis, treatment, and prevention of nontuberculous mycobacterial diseases." American journal of respiratory and critical care medicine 175.4 (2007): 367-416.
4. Daley, Charles L., et al. "Treatment of nontuberculous mycobacterial pulmonary disease: an official ATS/ERS/ESCMID/IDSA clinical practice guideline: executive summary." Clinical Infectious Diseases 71.4 (2020): e1-e36.

Last Reviewed: 9/18/19, 11/18/20, 9/15/21, 11/16/22, 11/17/23, 9/20/24, 9/19/25
Effective Date: 10/15/19, 12/15/20, 10/15/24

Augtyro (repotrectinib)
Prior Authorization Guidelines

Affected Medication(s)

- Augtyro (repotrectinib) capsule

Indication(s)

- Refer to major compendia for supported use

Dosing

- Refer to indication specific compendia supported dosing

Initial Authorization Criteria

1. Is the request for continuation of therapy with the same medication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the medication being requested to be used for an FDA approved indication? (Provide documentation of diagnosis)
    a. If yes, continue to #4
    b. If no, continue to #3
3. Is the medication being requested being used for an indication supported by the National Comprehensive Cancer Network (NCCN) with an evidence level of 2A or higher? (Provide disease staging, all prior treatment history, pathology report, and anticipated treatment plan for review)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the medication being prescribed by or in consultation with an oncologist?
    a. If yes, approve for 4 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication approved by the FDA or supported by the NCCN recommendation with an evidence level of 2A or higher? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is there clinical documentation confirming disease responsiveness to therapy provided? (Examples include reduction in tumor size, objective response, delay in progression, partial response, etc.) (Provide supporting documentation)
    a. If yes, continue to #2

Last Reviewed: 9/19/25
Effective Date: 10/31/25

b. If no, clinical review required

3. Is the medication being prescribed by or in consultation with an oncologist?

   a. If yes, approve for 12 months unless otherwise specified
   b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Augtyro [package insert]. Bristol-Myers Squibb Company: Princeton, NJ; June 2024.
2. National Comprehensive Cancer Network. NCCN – NCCN Guidelines. Available at: https://www.nccn.org.

Last Reviewed: 9/19/25
Effective Date:10/31/25

Benlysta® (belimumab)
Prior Authorization Guidelines

Affected Medication(s)

- Benlysta subcutaneous solution

FDA Approved Indication(s)

- Treatment of patients 5 years of age and older with active, autoantibody-positive, systemic lupus erythematosus (SLE) who are receiving standard therapy
- Treatment of patients 5 years of age and older with active lupus nephritis who are receiving standard therapy

Dosing

- Refer to package insert for pediatric dosing
- Systemic lupus erythematosus: 200 mg subcutaneously once weekly
- Lupus nephritis: 400 mg subcutaneously once weekly for 4 doses, then 200 mg once weekly thereafter

Initial Authorization Criteria

1. Is the request for continuation of Benlysta (belimumab) therapy?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member 5 years of age or older with a positive autoantibody test? (Antinuclear antibody (ANA) titer ≥1:80 OR Anti-dsDNA autoantibodies ≥30 IU/mL) (Provide test result for review)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have an active infection?
    a. If yes, clinical review required
    b. If no, continue to #5
5. Does the member have any of the following exclusion criteria?
    - Severe active central nervous system lupus
    - Use of other biologics or IV cyclophosphamide
    - Received a live vaccine within 30 days before starting or concurrently with Benlysta

    a. If yes, clinical review required
    b. If no, continue to #6
6. What is the indication that the medication is being requested for?
    a. Systemic lupus erythematosus (SLE), see corresponding criteria

Last Reviewed: 9/19/2018, 5/20/20, 11/17/21, 3/17/23, 1/19/24, 1/17/25, 11/21/25
Effective Date: 1/1/2019, 7/1/20, 1/1/22, 3/1/24, 1/1/26

b. Lupus nephritis, see corresponding criteria

Systemic lupus erythematosus (SLE)

1. Has the member failed to respond adequately to at least TWO (2) standard therapies (anti-malarials, corticosteroids, non-steroidal anti-inflammatory drugs, immunosuppressives (excluding intravenous cyclophosphamide))? (Provide documentation of treatment history)

    a. If yes, continue to #2
    b. If no, clinical review required

2. Does the member have one of the following? (Provide assessment score for review)

    - Safety of Estrogens in Lupus Erythematosus National Assessment – Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score of ≥6
    - Two or more British Isles Lupus Assessment Group (BILAG) B organ domain scores

    a. If yes, continue to #3
    b. If no, clinical review required

3. Is Benlysta (belimumab) being prescribed by or in consultation with a rheumatologist or specialist experienced in treatment of SLE?

    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Lupus Nephritis

1. Does the member have active lupus nephritis Class III, IV, or V as confirmed by a kidney biopsy?

    a. If yes, continue to #2
    b. If no, clinical review required

2. Has the member had an inadequate response, intolerance or contraindication to standard therapies including corticosteroids AND either cyclophosphamide or mycophenolate mofetil?

    a. If yes, continue to #3
    b. If no, clinical review required

3. Have baseline measurements for one or more of the following been provided: urine protein:creatinine ratio (uPCR), estimated glomerular filtration rate (eGFR), or urine protein? (Document baseline measurements)

    a. If yes, continue to #4
    b. If no, clinical review required

4. Is Benlysta (belimumab) being prescribed by or in consultation with a rheumatologist or specialist experienced in treatment of SLE?

    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Does member continue to meet initial authorization criteria as outlined above?
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is there documentation of an absence of unacceptable toxicity from the medication? (Examples of unacceptable toxicity include the following: depression, suicidal thoughts, serious infections, signs or symptoms of progressive multifocal leukoencephalopathy (PML), malignancy, severe hypersensitivity reaction, etc.)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is Benlysta (belimumab) being prescribed by or in consultation with a rheumatologist or specialist experienced in treatment of SLE?
    a. If yes, continue to #4
    b. If no, clinical review required
4. What is the indication that the medication is being requested for?
    a. Systemic lupus erythematosus (SLE), see corresponding criteria
    b. Lupus nephritis, see corresponding criteria

Systemic lupus erythematosus (SLE)

1. Were updated chart notes (within 1 year) provided with documentation of disease stability and/or improvement as indicated by one or more of the following when compared to pre-treatment baseline? (Provide updated assessment score for review)
    - Improvement in the SELENA-SLEDAI score of ≥4 points; OR
    - No new BILAG-A organ domain score or 2 new BILAG-B organ domain scores; OR
    - No worsening (<0.30-point increase) in Physician's Global Assessment (PGA) score; OR
    - Seroconverted (negative) or had a 20% reduction in autoantibody level;

    a. If yes, approve for 12 months reauthorization unless otherwise specified
    b. If no, clinical review required

Lupus nephritis

1. Has documentation of disease stability and/or improvement (from pre-treatment baseline) for one or more of the following measurements been provided: urine protein:creatinine ratio (uPCR), estimated glomerular filtration rate (eGFR), or urine protein? (Document updated measurements)

    a. If yes, approve for 12 months reauthorization unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as

medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Benlysta [package insert]. Rockville, MD; Human Genome Sciences/GlaxoSmithKline; June 2025. Accessed May 2020.
2. Boyce EG, Fusco BE. Belimumab: review of use in systemic lupus erythematosus. Clin Ther. 2012 May;34(5):1006-22. doi: 10.1016/j.clinthera.2012.02.028. Epub 2012 Mar 30.
3. Navarra SV, Guzmán RM, Gallacher AE, et al. Efficacy and safety of belimumab in patients with active systemic lupus erythematosus: a randomised, placebo-controlled, phase 3 trial. Lancet. 2011 Feb;377(9767):721-31. doi: 10.1016/SO140-6736(10)61354-2. Epub 2011 Feb 4.
4. Furie R, Petri M, Zamani O, et al. A phase III, randomized, placebo-controlled study of belimumab, a monoclonal antibody that inhibits B lymphocyte stimulator, in patients with systemic lupus erythematosus. Arthritis Rheum. 2011 Dec;63(12):3918-30. doi: 10.1002/art.30613.
5. Petri M, Orbai AM, Alarcón GS, et al. Derivation and validation of the Systemic Lupus International Collaborating Clinics classification criteria for systemic lupus erythematosus. Arthritis Rheum. 2012 Aug;64(8):2677-86. doi: 10.1002/art.34473.
6. Furie R, Stohl W, Ginzler EM, et al. Biologic activity and safety of belimumab, a neutralizing anti-B-lymphocyte stimulator (BLyS) monoclonal antibody: a phase I trial in patients with systemic lupus erythematosus. Arthritis Res Ther. 2008;10(5):R109. doi: 10.1186/ar2506. Epub 2008 Sep 11.
7. Kim SS, Kirou KA, Erkan D. Belimumab in systemic lupus erythematosus: an update for clinicians. Ther Adv Chronic Dis. 2012 Jan;3(1):11-23. doi: 10.1177/2040622311424806.
8. Calvo-Alén J1, Silva-Fernández L, Úcar-Angulo E, et al. SER consensus statement on the use of biologic therapy for systemic lupus erythematosus. Reumatol Clin. 2013 Sep-Oct;9(5):281-96.
9. Gordon C, Amissah-Arthur MB, Gayed M, et al. The British Society for Rheumatology guideline for the management of systemic lupus erythematosus in adults. Rheumatol 2017 Oct 6. doi: 10.1093/rheumatology/kex286.
10. NICE. Belimumab for treating active autoantibody-positive systemic lupus erythematosus: Technology Appraisal Guidance [TAG397]. https://www.nice.org.uk/guidance/ta397/ Accessed November 2017.
11. Wisconsin Physician Service Insurance Corp. Local Coverage Determination (LCD): Drugs and Biologics (Non-chemotherapy) (L34741). Centers for Medicare & Medicare Services. Updated on 10/17/2017 with effective dates 11/1/2017. Accessed November 2017.
12. Stohl W, Schwarting A, Okada M, et al. Efficacy and Safety of Subcutaneous Belimumab in Systemic Lupus Erythematosus: A Fifty-Two-Week Randomized, Double-Blind, Placebo-Controlled Study. *Arthritis Rheumatol*. 2017;69(5):1016–1027. doi:10.1002/art.40049

Last Reviewed: 9/19/2018, 5/20/20, 11/17/21, 3/17/23, 1/19/24, 1/17/25, 11/21/25
Effective Date: 1/1/2019, 7/1/20, 1/1/22, 3/1/24, 1/1/26

Besremi® (ropeginterferon alfa-2b-njft)
Prior Authorization Guidelines

Affected Medication(s)

- Besremi (ropeginterferon alfa-2b-njft) subcutaneous solution

FDA Approved Indication(s)

- Treatment of adults with polycythemia vera

Dosing

- Patients not already on hydroxyurea: Starting dose of 100 mcg subcutaneous injection every two weeks, increasing dose by 50mcg every two weeks (up to a maximum of 500 mcg), until hematological parameters are stabilized
- Patients transitioning from hydroxyurea: Starting dose of 50 mcg subcutaneous injection every two weeks in combination with hydroxyurea. Gradually taper off the hydroxyurea (see package insert for taper). Increase Besremi dose by 50 mcg every two weeks (up to a maximum of 500 mcg), until hematological parameters are stabilized
- If hematological stability achieved for at least 1 year, the dosing interval may be expanded to every 4 weeks

Initial Authorization Criteria

1. Is the request for continuation of a previously approved Besremi (ropeginterferon alfa-2b-njft) prior authorization with the same indication as the previous approval?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)
    a. If yes, continue to #4
    b. If no, continue to #3
3. Is the medication being requested for an indication supported by the National Comprehensive Cancer Network (NCCN) recommendation with an evidence level of 2A or higher? (Provide disease staging, all prior treatment history, pathology report, and anticipated treatment plan for review)
    a. If yes, continue to #4
    b. If not, clinical review required
4. Is the treatment being prescribed by, or in consultation with, an oncologist or hematologist?
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have Karnofsky Performance Status greater or equal to 50% OR Eastern Cooperative Oncology Group (ECOG) performance status of 0-2? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required

Last Reviewed: 3/16/22, 3/17/23, 1/19/24, 1/17/25, 11/21/25
Effective Date: 4/15/22

6. Has the member previously trialed hydroxyurea with inadequate response, OR has a previous intolerance, contraindication, or medical rationale to avoid therapy with hydroxyurea been noted? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Has the member previously trialed Pegasys with inadequate response or has a documented intolerance or contraindication to treatment with Pegasys been provided? (Provide supporting documentation)
    a. If yes, approve for 4 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved indication or supported by NCCN recommendation with an evidence level of 2A or higher? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the treatment being prescribed by, or in consultation with, an oncologist or hematologist?
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is there clinical documentation confirming disease responsiveness to therapy provided? (Examples include reduction in hematocrit <45% without phlebotomy, platelets ≤400 × 10^9/L and leukocytes ≤10 × 10^9/L, normal spleen size, etc.) (Provide supporting documentation)
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. BESREMi (ropeginterferon alfa-2b-njft) injection, [package insert]. Burlington, MA: PharmaEssentia Corp; 2024.
2. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 01 Feb. 2022].
3. Clinical Practice Guidelines in Oncology (NCCN Guidelines): Myeloproliferative Neoplasms. Version 2.2025 National Comprehensive Cancer Network website. Available from https://www.nccn.org/professionals/physician_gls/pdf/mpn.pdf. Accessed December 30, 2024.
4. Gisslinger, Heinz, et al. "Ropeginterferon alfa-2b versus standard therapy for polycythaemia vera (PROUD-PV and CONTINUATION-PV): a randomised, non-inferiority, phase 3 trial and its extension study." The Lancet Haematology 7.3 (2020): e196-e208.

Last Reviewed: 3/16/22, 3/17/23, 1/19/24, 1/17/25, 11/21/25
Effective Date: 4/15/22

5. Gisslinger, Heinz, et al. "Ropeginterferon alfa-2b, a novel IFNα-2b, induces high response rates with low toxicity in patients with polycythemia vera." Blood, The Journal of the American Society of Hematology 126.15 (2015): 1762-1769.

Bylvay® (odevixibat) & Livmarli (maralixibat)
Prior Authorization Guidelines

Affected Medication(s)

- Bylvay capsule/pellet
- Livmarli oral solution
- Livmarli oral tablet

FDA Approved Indication(s)

Bylvay:

- Treatment of pruritus in patients ≥3 months of age with progressive familial intrahepatic cholestasis (PFIC) (NOTE: May not be effective in PFIC type 2 patients with ABCB11 variants resulting in non-functional or complete absence of bile salt export pump protein (BSEP-3))
- Treatment of cholestatic pruritis in patients 12 months of age and older with Alagille Syndrome (ALGS)

Livmarli:

- Treatment of pruritus in patients 5 years of age and older with progressive familial intrahepatic cholestasis (PFIC) (NOTE: Livmarli is not recommended in a subgroup of PFIC type 2 patients with specific ABCB11 variants resulting in non-functional or complete absence of bile salt export pump (BSEP) protein)
- Treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) 3 months of age and older

Dosing

- Refer to package insert for specific dosing recommendations

Initial Authorization Criteria

1. Has the requested medication previously been approved by OHSU for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. What diagnosis is the medication being requested for?
    a. Progressive Familial intrahepatic cholestasis (PFIC), continue to corresponding criteria.
    b. Alagille syndrome, continue to corresponding criteria
    c. Other indication, clinical review required

Progressive Familial Intrahepatic Cholestasis

1. Does the member have a diagnosis of familial intrahepatic cholestasis (PFIC) Type I or II confirmed by presence of a mutation in the *ATP8B1 (FIC$_1$)* or *ABCB11* gene, liver biopsy or ultrasound or biliary lipid analysis? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required

Last Reviewed: 9/15/21, 3/17/23, 9/15/23, 9/20/24, 7/18/25
Effective Date: 11/1/21, 11/20/23, 10/15/24, 8/1/25

2. Is the requested medication FDA approved for the member's age?
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member have a clinical history of cholestasis and have the other main causes of cholestasis been ruled out (e.g. biliary atresia, Alagille syndrome, alpha1antitrypsine deficiency, cystic fibrosis, sclerosing cholangitis and extrahepatic bile duct obstruction)? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have documentation of an inadequate response, intolerance, or contraindication to at least TWO of the following: ursodiol, cholestyramine, or rifampin? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is the request for Livmarli (maralixibat)
    a. If yes, continue to #6
    b. If no, continue to #7
6. Has the member previously trialed a maximum tolerated dose of Bylvay (odevixibat) for at least 4 weeks with treatment failure, or is there a documented intolerance or contraindication to Bylvay (odevixibat) (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Has the member previously undergone partial or total biliary diversion surgery that has been ineffective in relieving pruritus OR is medical rationale provided why the member cannot undergo surgery? (Provide supporting documentation)
    a. If yes, continue to #8
    b. If no, clinical review required
8. Is the medication prescribed by, or in consultation with, a hepatologist or an appropriate biliary specialist?
    a. If yes, approve for 6 months
    b. If no, clinical review required

<u>Alagille Syndrome</u>

1. Is the requested medication FDA approved for the member's age?
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member have documentation of Alagille syndrome confirmed by genetic testing or liver biopsy? (genetic testing with JAG1 or NOTCH2 mutation present) (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required

3. Has the member previously trialed a maximum tolerated dose of all of the following for at least 4 weeks with treatment failure, or is there a documented intolerance/contraindication to all of the following: rifampin, ursodiol, and cholestyramine/colesevelam? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the request for Bylvay (odevixibat)?
    a. If yes, continue to #5
    b. If no, continue to #6
5. Has the member previously trialed a maximum tolerated dose of Livmarli (maralixibat) for at least 4 weeks with treatment failure, or is there a documented intolerance/contraindication to Livmarli (maraliximab)? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Is there documentation member is experiencing moderate to severe pruritus despite current therapy? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Is the requested drug being prescribed by, or in consultation with, a gastroenterologist or specialist experienced in treating Alagille syndrome?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication Food and Drug Administration (FDA) approved or supported by major compendia?
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (within 1 year) with documentation of improvement in pruritis symptoms from baseline received? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the treatment being prescribed by, or in consultation with, a hepatologist or an appropriate biliary specialist?
    a. If yes, approve for 12 months reauthorization
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

Last Reviewed: 9/15/21, 3/17/23, 9/15/23, 9/20/24, 7/18/25
Effective Date: 11/1/21, 11/20/23, 10/15/24, 8/1/25

References:

1. BYLVAY (odevixibat) capsule/pellets [package insert]. Boston, MA: Albireo Pharma, Inc.; March 2025.
2. LIVMARLI™ (maralixibat) oral solution, [package insert]. Foster City, CA: Mirum Pharmaceuticals, Inc; April 2025.
3. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 23 Nov. 2021].
4. Roy-Chowdhury J, Roy-Chowdhury N. Inherited disorders associated with conjugated hyperbilirubinemia. In: UpToDate, K. Lindor, S. Grover (Eds), UpToDate, Waltham, MA. (Accessed on August 27, 2021.)
5. Davit-Spraul, Anne, et al. "Progressive familial intrahepatic cholestasis." Orphanet journal of rare diseases 4.1 (2009): 1-12.
6. Gunaydin, Mithat, and Asudan Tugce Bozkurter Cil. “Progressive familial intrahepatic cholestasis: diagnosis, management, and treatment.” Hepatic medicine: evidence and research vol. 10 95-104. 10 Sep. 2018, doi:10.2147/HMER.S137209
7. Gonzales, Emmanuel, et al. "Efficacy and safety of maralixibat treatment in patients with Alagille syndrome and cholestatic pruritus (ICONIC): a randomized phase 2 study." The Lancet 398.10311 (2021): 1581-1592.
8. Poupon R, Chopra S. Pruritus associated with cholestasis. In: UpToDate, K. Lindor, S. Grover (Eds), UpToDate, Waltham, MA. (Accessed on April 14, 2022.)

Last Reviewed: 9/15/21, 3/17/23, 9/15/23, 9/20/24, 7/18/25
Effective Date: 11/1/21, 11/20/23, 10/15/24, 8/1/25

Cablivi® (caplacizumab-yhdp)
Prior Authorization Guidelines

Affected Medication(s)

- Cablivi (caplacizumab-yhdp) subcutaneous solution

FDA Approved Indication(s)

- Treatment of adult patients with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange and immunosuppressive therapy

Dosing

Should be administered upon initiation of plasma exchange therapy:

- First day of treatment: 11 mg bolus intravenous (IV) injection at least 15 minutes prior to plasma exchange followed by an 11 mg subcutaneous (SC) injection after completion of plasma exchange on day 1
- Subsequent days of treatment during daily plasma exchange: 11 mg SC injection once daily following plasma exchange
- Treatment after plasma exchange period: 11 mg SC injection once daily continuing for 30 days following the last daily plasma exchange. Treatment may be extended for a maximum of 28 days if patient have signs of persistent underlying disease such as suppressed ADAMTS13 activity levels remain present after initial treatment course.

Authorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the member 18 years of age or older?
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member have a diagnosis of acquired TTP confirmed by severe ADAMTS13 deficiency with ADAMTS13 activity levels of less than 10% and thrombocytopenia and/or microangiopathic hemolytic anemia OR a PLASMIC scored of 6-7? (Provide ADAMTS13 activity level or PLASMIC score for review)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Was the therapy started upon initiation of plasma exchange therapy in combination with corticosteroids?
    a. If yes, continue to #5
    b. If no, clinical review required
5. Has the member received, or planning to receive, the IV bolus dose?
    a. If yes, continue to #6
    b. If no, clinical review required

Last Reviewed: 5/20/20, 3/10/21, 3/16/22, 5/19/23, 5/17/24, 5/16/25
Effective Date: 7/1/20, 5/1/21, 4/15/22, 6/15/24

6. Is this medication being prescribed by, or in consultation with, a hematologist?
    a. If yes, approve up to 30 days following the last day of plasma exchange therapy
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Caplacizumab-yhdp (Cablivi) [package insert]. Cambridge, MA: Genzyme Corporation; November 2024.
2. Cully M, Hunt BJ, Benjamin S, et al. Guidelines on the diagnosis and management of thrombotic thrombocytopenic purpura and other thrombotic microangiopathies. Br J Haematol. 2012;158(3):323-35.
3. Schwartz J, Padmanabhan A, Aqui N, et al. Guidelines on the use of therapeutic apheresis in clinical practice-evidence-based approach from the writing committee of the American society for apheresis: The Seventh special issue. J Clin Pher. 2016 Jun;31(3):149-62.
4. Bendapudi PK, Hurwitz S, Fry A, et al. Derivation and external validation of the PLASMIC score for rapid assessment of adults with thrombotic microangiopathies: a cohort study. Lancet Haematology. 2017;4(4):e157
5. Zheng ZL, Vesely SK, Cataland SR, et al. ISTH guidelines for treatment of thrombotic thrombocytopenic purpura. J Thromb Haemost. 2020;18(10):2496-2502.

Last Reviewed: 5/20/20, 3/10/21, 3/16/22, 5/19/23, 5/17/24, 5/16/25
Effective Date: 7/1/20, 5/1/21, 4/15/22, 6/15/24

Camzyos® (mavacamten)
Prior Authorization Guidelines

Affected Medication(s)

- Camzyos (mavacamten) oral capsule

FDA Approved Indication(s)

- Treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms

Dosing

- Recommended starting dose: 5 mg once daily
- Allowable subsequent doses with titration are 2.5, 5, 10, or 15 mg once daily

Initial Authorization Criteria

1. Is the request for continuation of Camzyos (mavacamten) therapy?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA-approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member aged 18 years of age or older?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have documentation of NYHA class II to III obstructive hypertrophic cardiomyopathy (HCM) and is experiencing symptoms? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have documentation of a left ventricular ejection fraction (LVEF) of 55% or greater? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Does the member have documentation of a LVOT peak gradient of 50 mmHg or greater at rest or with provocation? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Has the member previous trialed all of the following classes of medications at maximally indicated doses unless intolerance or contraindication is present? (Provide supporting documentation)
    - Non-vasodilating beta-blocker (i.e. atenolol, bisoprolol, metoprolol, propranolol)

Last Reviewed: 7/20/22, 7/21/23, 7/19/24, 7/18/25
Effective Date: 9/1/22, 8/15/24

- Non-dihydropyridine calcium channel blocker (i.e. verapamil, diltiazem)
- Disopyramide

a. If yes, continue to #8
b. If no, clinical review is required

8. Is Camzyos® (mavacamten) being prescribed by, or in consult with, a cardiologist?

a. If yes, approve for 6 months
b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA-approved or major compendia supported indication? (Provide documentation of diagnosis)

a. If yes, continue to #2
b. If no, clinical review required

2. Is the treatment being prescribed by or in consultation with a cardiologist?

a. If yes, continue to #3
b. If no, clinical review required

3. Were updated chart notes (within the past year) provided with documentation of significant clinical response to prior therapy received? (i.e. improvement NYHA Class II-III symptoms) (Provide supporting documentation)

a. If yes, continue to #4
b. If no, clinical review required

4. Does the member have an updated echocardiogram (within that past year and since starting therapy) showing LVEF of at least 50%?

a. If yes, approve for 12 months
b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. CAMZYOS (mavacamten) capsules, [package insert]. Brisbane, CA: MyoKardia, Inc.; April 2025.
2. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 11 May. 2024].
3. Olivotto, Iacopo, et al. "Mavacamten for treatment of symptomatic obstructive hypertrophic cardiomyopathy (EXPLORER-HCM): a randomised, double-blind, placebo-controlled, phase 3 trial." The Lancet 396.10253 (2020): 759-769.
4. Ommen SR, Ho CY, Asif IM, et al. 2024 AHA/ACC/AMSSM/HRS/PACES/SCMR Guideline for the Management of Hypertrophic Cardiomyopathy: A Report of the American Heart Association/American College of Cardiology Joint

Last Reviewed: 7/20/22, 7/21/23, 7/19/24, 7/18/25
Effective Date: 9/1/22, 8/15/24

Committee on Clinical Practice Guidelines [published correction appears in Circulation. 2024 Aug 20;150(8):e198. doi: 10.1161/CIR.0000000000001277.]..

Carglumic Acid
Prior Authorization Guidelines

Affected Medication(s)

- Carbaglu oral tablet
- Carglumic acid oral tablet

FDA Approved Indication(s)

- Adjunctive therapy in pediatric and adult patients for treatment of acute hyperammonemia due to deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS)
- Maintenance therapy in pediatric and adult patients for treatment of chronic hyperammonemia due to deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS)
- Adjunctive treatment in adult and pediatric patients for the treatment of acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA)

Dosing

NAGS Deficiency:

- Acute: 100 to 250 mg/kg/day divided into 2 to 4 doses (rounded to the nearest 100 mg)
- Maintenance: 10 to 100 mg/kg/day divided into 2 to 4 doses (rounded to the nearest 100 mg)

Acute Hyperammonemia due to PA or MMA:

- Patients ≤15 kg: 150 mg/kg/day in two equal doses administered 12 hours apart (rounded to the nearest 50 mg)
- Patients >15 kg: 3.3 g/m^2/day in two equal doses administered 12 hours apart (rounded to the nearest 50 mg)

Initial Authorization Criteria

1. Is the request for continuation of carglumic acid therapy for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the diagnosis of NAGS deficiency, MMA, or PA confirmed by plasma amino acid/urine orotic acid or enzyme analysis? (Provide lab report confirming diagnosis)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is baseline plasma ammonia level provided? (Provide lab for review)
    a. If yes, continue to #5
    b. If no, clinical review required

Last Reviewed: 11/21/18, 11/18/20, 11/17/21, 3/17/23, 1/19/24, 1/17/25, 11/21/25
Effective Date: 1/1/19, 1/1/22, 6/1/23, 3/1/24, 2/1/25, 1/1/26

5. Will carglumic acid be used with other methods to lower plasma ammonia level? (i.e. hemodialysis, sodium phenylacetate and sodium benzoate)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Is the member adherent to a protein restrictive diet? (Provide documentation of restrictive diet)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Is the treatment being initiated by a provider that specializes in the treatment of inherited metabolic disorders? (Examples include a medical geneticist or an endocrinologist)
    a. If yes, approve for 3 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member show a positive clinical response to therapy as defined as a decrease in plasma ammonia levels from baseline? (Provide documentation of current and baseline plasma ammonia levels for review)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the treatment being initiated by a provider that specializes in the treatment of inherited metabolic disorders? (Examples include a medical geneticist or an endocrinologist)
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Carbaglu [prescribing information]. Puteaux, France: Recordati Rare Diseases Inc; January 2024.
2. Lee, B. Urea cycle disorder: clinical features and diagnosis. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed January 2025.
3. Lee, B. Urea cycle disorder: management. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed January 2025.

Last Reviewed: 11/21/18, 11/18/20, 11/17/21, 3/17/23, 1/19/24, 1/17/25, 11/21/25
Effective Date: 1/1/19, 1/1/22, 6/1/23, 3/1/24, 2/1/25, 1/1/26

Cayston® (aztreonam)
Prior Authorization Guidelines

Affected Medication(s)

- Cayston powder for inhalation solution

FDA Approved Indication(s)

- To improve respiratory symptoms in cystic fibrosis (CF) patients with *Pseudomonas aeruginosa*

Dosing

- For adults and children 7 years of age and older:
  - One vial (75mg) reconstituted with 1 mL of sterile diluent administered 3 times a day for a 28 day course

Initial Authorization Criteria

1. Is the request for continuation of Cayston (aztreonam) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
   a. If yes, continue to #3
   b. If no, clinical review required
3. Does the member have cystic fibrosis and a lung infection with a positive culture demonstrating *Pseudomonas aeruginosa* infection? (Provide supporting documentation of cystic fibrosis diagnosis and positive culture for *Pseudomonas aeruginosa*)
   a. If yes, continue to #4
   b. If no, clinical review required
4. Does the member have baseline FEV1 greater than 25%? (Provide FEV1 for review)
   a. If yes, continue to #5
   b. If no, clinical review required
5. Does the member have a previous trial with inadequate response, contraindication, or intolerance to tobramycin inhaled solution? (Provide supporting documentation for review)
   a. If yes, approve for 1 month unless otherwise specified
   b. If no, continue to # 6
6. Does the member have a culture showing resistance to tobramycin? (Provide culture results for review)
   a. If yes, approve for 1 month unless otherwise specified
   b. If no, clinical review required

Last Reviewed: 11/21/18, 11/18/20, 11/17/21, 3/17/23, 1/19/24, 1/17/25, 11/21/25
Effective Date: 1/1/19, 3/1/24

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is documentation confirming improvement in respiratory symptoms provided? (Provide supporting documentation for review)
    a. If yes approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Cayston (aztreonam) [Prescribing Information]. Foster City, CA: Gilead Sciences, Inc. December 2021.
2. Oermann, CM, Retsch-Bogart, GZ, Ouittner, AL, et al. An 18-month Study of the Safety and Efficacy of Repeated Course of Inhaled Aztreonam Lysine in Cystic Fibrosis. Pediatric Pulmonology. 2010 November; 45(11): doi:10.1002/ppul.21301.
3. Wainwright, CE, Quittner AL, Geller, DE, et al. Aztreonam for inhalation (AZLI) in patients with cystic fibrosis, mild lung impairment, and *P.aeruginosa*. Journal of Cystic Fibrosis 10(2011) 234-242.
4. Mogayzel Jr, Peter J., et al. "Cystic Fibrosis Foundation pulmonary guideline. Pharmacologic approaches to prevention and eradication of initial Pseudomonas aeruginosa infection." Annals of the American Thoracic Society 11.10 (2014): 1640-1650.
5. Langton Hewer SC, Smith S, Rowbotham NJ, Yule A, Smyth AR. Antibiotic strategies for eradicating Pseudomonas aeruginosa in people with cystic fibrosis. *Cochrane Database Syst Rev*. 2023;6(6):CD004197. Published 2023 Jun 2.

Last Reviewed: 11/21/18, 11/18/20, 11/17/21, 3/17/23, 1/19/24, 1/17/25, 11/21/25
Effective Date: 1/1/19, 3/1/24

Chenodal®, Ctexli (chenodiol)
Prior Authorization Guidelines

Affected Medication(s)

- Chenodal oral tablet
- Ctexli oral tablet

FDA Approved Indication(s)

- Chenodal: 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
- Ctexli: Treatment of cerebrotendinous xanthomatosis (CTX) in adults

Dosing

- Chenodal: Initially: 250mg twice daily for 2 weeks, then, increase by 250 mg/day each week until recommended or maximum tolerated dose is reached
- Ctexli: 250 mg orally three times daily

Initial Authorization Criteria

1. Is the request for continuation of the same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. What diagnosis is the medication being requested for?
    a. Gallstone dissolution, continue to corresponding criteria
    b. Cerebrotendinous xanthomatosis, continue to corresponding criteria

Gallstone Dissolution

1. Is there documentation that the member is not a candidate for surgery? (Provide rationale stating why member is not a candidate for surgery)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member have documentation of a previous inadequate response, contraindication or intolerance to ursodiol? (Provide history of ursodiol use or contraindication to therapy)
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Cerebrotendinous xanthomatosis (CTX)

Last Reviewed: 10/3/18, 11/18/20, 11/17/21, 3/17/23, 1/19/24, 1/17/25, 5/16/25
Effective Date: 1/1/19, 3/1/24, 6/1/25

1. Does the member have a diagnosis of cerebrotendinous xanthomatosis confirmed by genetic testing and elevated cholestanol? (Provide supporting documentation and test results)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the treatment being prescribed by, or in consultation with, a geneticist, neurologist, ophthalmologist, or metabolic specialist?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Has the member had a positive clinical response to therapy?
    a. If yes, approve for up to 12 months unless otherwise specified (Not to exceed 24 months of treatment for Chenodiol)
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Chenodal tablets [prescribing information]. San Diego, CA: Retrophin; November 2021.
2. Ctexli tablets [prescribing information]. Foster City, CA: Mirum Pharmaceuticals, Inc.; February 2025.
3. Chenodal. Micromedex. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed September 21, 2021.
4. Zakko MD. Nonsurgical treatment of gallstones. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed September 19, 2018.

Last Reviewed: 10/3/18, 11/18/20, 11/17/21, 3/17/23, 1/19/24, 1/17/25, 5/16/25
Effective Date: 1/1/19, 3/1/24, 6/1/25

Cholbam® (cholic acid)
Prior Authorization Guidelines

Affected Medication(s)

- Cholbam oral capsule

FDA Approved Indication(s)

- 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

Dosing

- Refer to package insert for specific dosing recommendations

Initial Authorization Criteria

1. Is the request for continuation of Cholbam (cholic acid) therapy?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member have a diagnosis of peroxisomal disorder? (Provide documentation to support confirmation of diagnosis)
    a. If yes, continue to #4
    b. If no, continue to #7
4. Does the member have manifestations of at least one of the following? (Provide supporting documentation)
        - Liver disease (ex. jaundice or elevated liver enzymes)
        - Steatorrhea
        - Complications from decreased fat-soluble vitamin absorption
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is the treatment intended for extrahepatic signs and/or symptoms of peroxisomal disorders? (Examples include psychomotor retardation, neurologic dysfunctions, hearing loss, visual abnormalities, and/or osteoporosis)
    a. If yes, clinical review required
    b. If no, continue to #6

Last Reviewed: 10/17/18, 1/20/21, 3/16/22, 3/17/23, 3/15/24, 3/21/25
Effective Date: 1/1/19, 6/1/23

6. Was a baseline liver function test and INR received? (Provide lab results)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Is the treatment being prescribed by, or in consult with, a medical geneticist, a pediatric gastroenterologist, a hepatologist, or a specialist experienced in treating inborn errors of metabolism?
    a. If yes, approve for 4 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Has the member demonstrated a positive clinical response to therapy defined as decreased signs and/or symptoms from baseline? (Provide supporting documentation and updated liver function tests)
    a. If yes, continue to #3
    b. If no, clinical response required
3. Is the treatment being prescribed by, or in consult with, a medical geneticist, a pediatric gastroenterologist, a hepatologist, or a specialist experienced in treating inborn errors of metabolism?
    a. If yes, approve for 1 year unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Cholbam [Prescribing Information]. Baltimore, MD: Manchester Pharmaceuticals LLC; March 2023.
2. Wanders, R. Peroxisomal disorders. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed January 20, 2025..

Last Reviewed: 10/17/18, 1/20/21, 3/16/22, 3/17/23, 3/15/24
Effective Date: 1/1/19, 6/1/23

Compounded Medications
Prior Authorization Guidelines

Affected Medication(s)

- All compounded medications that are not commercially available

FDA Approved Indication(s)

- Refer to indications associated with active ingredient(s)

Dosing

- Refer to dosing associated with active ingredient(s)

Initial & Reauthorization Authorization Criteria

1. Are all active ingredients in the compounded medication FDA-approved?
    a. If yes, continue to #2
    b. If no, clinical review required
2. Are all active ingredients being used for an FDA approved or major compendia supported indication? (Provide documentation of diagnosis and treatment plan)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is there an FDA-approved commercially available medication on the market for treatment of the requested condition?
    a. If yes, continue to #4
    b. If no, approve for 3 months unless otherwise specified
4. Is there documentation to support medical necessity over commercially available products? (Provide documentation supporting use over commercially available product)
    a. If yes, approve for 3 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

Last Reviewed: 9/19/2018, 11/18/20, 11/17/21, 3/17/23, 3/15/24, 3/21/25
Effective Date: 1/1/2019

Crenessity (crinercerfont)
Prior Authorization Guidelines

Affected Medication(s)

- Crenessity (crinercerfont) oral capsule
- Crenessity (crinercerfont) oral solution

FDA Approved Indication(s)

- As adjunctive treatment to glucocorticoid replacement to control androgens in adults and pediatric patients 4 years of age and older with classic congenital adrenal hyperplasia (CAH)

Dosing

- 10 to less than 20 kg: 25 mg orally twice daily
- 20 to less than 55 kg: 50 mg orally twice daily
- Greater than 55 kg: 100 mg orally twice daily

Initial Authorization Criteria

1. Is the request for continuation of therapy with the same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member have documentation of medically classic congenital adrenal hyperplasia due to 21-hydroxylase deficiency confirmed by ONE of the following? (Provide supporting documentation)
    - Elevated 17-hydroxyprogesterone (17-OHP) level
    - Confirmed cytochrome CYP21A2 genotype
    - Positive newborn screening with confirmatory second-tier testing
    - Diagnostic results after cosyntropin stimulation

    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the member on a supraphysiologic dose of glucocorticoids of at least 12 mg/m^2/day for those less than 18 years of age or at least 14 mg/m^2/day for 18 years and older in hydrocortisone dose equivalents? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Will the member continue to take glucocorticoids concurrently with Crenessity (crinercerfont)? (Provide treatment plan)
    a. If yes, continue to #6
    b. If no, clinical review required

Last Reviewed: 3/21/25
Effective Date: 4/1/25

6. Is Crenessity (crinercerfont) being prescribed by, or in consultation with, an endocrinologist or other specialist with experience treating congenital adrenal hyperplasia?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (within past year) provided with documentation of significant clinical response to therapy received? (i.e. decrease in glucocorticoid dose)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is Crenessity (crinercerfont) being used concurrently with glucocorticoids?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is Crenessity (crinercerfont) being prescribed by, or in consultation with, an endocrinologist or other specialist with experience treating congenital adrenal hyperplasia?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. CRENESSITY (crinercerfont) oral capsules, [package insert]. San Diego, CA: Neurocrine Biosciences, Inc.; 2024.
2. Drugs@FDA: FDA Approved Drug Products. 2025. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 19 Jan 2025]
3. Speiser PW, Arlt W, Auchus RJ, et al. Congenital Adrenal Hyperplasia Due to Steroid 21-Hydroxylase Deficiency: An Endocrine Society Clinical Practice Guideline [published correction appears in J Clin Endocrinol Metab. 2019 Jan 1;104(1):39-40.]. J Clin Endocrinol Metab. 2018;103(11):4043-4088.
4. Auchus RJ, Hamidi O, Pivonello R, et al. Phase 3 Trial of Crinecerfont in Adult Congenital Adrenal Hyperplasia. N Engl J Med. 2024;391(6):504-514.
5. Sarafoglou K, Kim MS, Lodish M, et al. Phase 3 Trial of Crinecerfont in Pediatric Congenital Adrenal Hyperplasia. N Engl J Med. 2024;391(6):493-503.

Last Reviewed: 3/21/25

Effective Date: 4/1/25

Cresemba® (isavuconazonium)
Prior Authorization Guidelines

Affected Medication(s)

- Cresemba oral capsule

FDA Approved Indication(s)

- For patients 6 years of age and older who weigh 16 kilograms and greater for the treatment of invasive aspergillosis
- For patients 6 years of age and older who weigh 16 kilograms and greater for the treatment of invasive mucormycosis

Dosing

- Adults:
  - Loading dose: Two 186 mg-capsules (372 mg) orally every 8 hours for 48 hours
  - Maintenance dose: Two 186 mg-capsules (372 mg) orally once daily
- Pediatrics:
  - See package insert for specific pediatric weight based dosing

Authorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required
2. Is the member 6 years of age or older?
   a. If yes, continue to #3
   b. If no, clinical review required
3. What is the requested diagnosis?
   a. Invasive aspergillosis, continue to #4
   b. Invasive mucormycosis, continue to #6
4. Is documentation of rationale for avoidance or contraindication to both voriconazole and posaconazole received? (Provide supporting documentation)
   a. If yes, continue to #9
   b. If no, continue to #5
5. Did the member initiate Cresemba (isavuconazonium) therapy during the inpatient stay?
   a. If yes, continue to #9
   b. If no, clinical review required
6. Did the member have a trial with response to amphotericin B or documentation of intolerance or contraindication? (Provide supporting documentation)
   a. If yes, continue to #7
   b. If no, continue to #8

Last Reviewed: 10/17/18, 1/20/21, 3/16/22, 5/19/23, 5/17/24, 5/16/25
Effective Date: 1/1/19, 4/15/22, 6/15/24

7. Is documentation of rationale for avoidance or contraindication to posaconazole received? (Provide supporting documentation)
    a. If yes, continue to #9
    b. If no, continue to #8

8. Did the member initiate Cresemba (isavuconazonium) therapy during the inpatient stay?
    a. If yes, continue to #9
    b. If no, clinical review required

9. Is the treatment being initiated by an infectious disease specialist?
    a. If yes, approve for 3 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Cresemba Prescribing Information. Northbrook, IL: Astellas, Inc.; March 2025.
2. Patterson TF, Thompson GR, Denning DW et al. Practice Guidelines for the Diagnosis and Management of Aspergillosis: 2016 Update by the Infectious Diseases Society of America. Clin Infect Dis. 2016 Aug 15;63(4):e1-e60. doi: 10.1093/cid/ciw326.
3. Tissot F, Agrawal S, Pagano L, et al. ECIL-6 guidelines for the treatment of invasive candidiasis, aspergillosis and mucormycosis in leukemia and hematopoietic stem cell transplant patients. Haematologica. Mar 2017, 102(3) 433-444.
4. Centers for Disease Control and Prevention. Fungal Diseases: Treatment of Mucormycosis. Last updated December 30, 2015. Available at: https://www.cdc.gov/fungal/diseases/mucormycosis/treatment.html.
5. Kauffman, CA. Treatment and prevention of invasive aspergillosis. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed September 2018.
6. Cox, GM. Mucormycosis (zygomycosis). Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed September 2018.

Last Reviewed: 10/17/18, 1/20/21, 3/16/22, 5/19/23, 5/17/24, 5/16/25
Effective Date: 1/1/19, 4/15/22, 6/15/24

Cystagon®, Procysbi® (cysteamine)
Prior Authorization Guidelines

Affected Medication(s)

- Cystagon oral capsule
- Procysbi oral capsule delayed release
- Procysbi DR granule packet

FDA Approved Indication(s)

- Cystagon: Management of nephropathic cystinosis in children and adults
- Procysbi: Treatment of nephropathic cystinosis in adults and pediatric patients 1 year of age and older

Dosing

- Cystagon:
  - Initially: Start at 1/4 to 1/6 of the maintenance dose and increase over 4-6 weeks
  - Maintenance dose: 1.30 grams/m^2/day divided into four doses/daily
  - Use chart in package insert for weight-based dosing
- Procysbi:
  - Initially: Start at 1/4 to 1/6 of the maintenance dose and increase over 4-6 weeks
  - Maintenance dose: 1.30 grams/m^2/day divided into two doses/daily
  - Use chart in package insert for weight-based dosing

Initial Authorization Criteria

1. Is the request for continuation of Cystagon (cysteamine) or Procysbi (cysteamine) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
   a. If yes, continue to #3
   b. If no, clinical review required
3. Does the member have confirmation of nephropathic cystinosis defined by elevated leukocyte cysteine levels (LCL) or presence of the CTNS gene mutation? (Provide documentation of elevated LCL or CTNS gene mutation)
   a. If yes, continue to #4
   b. If no, clinical review required
4. Is the request for Procysbi (cysteamine)?
   a. If yes, continue to #5
   b. If no, continue to #7
5. Is clinical rationale for avoiding Cystagon (cysteamine) provided? (Provide supporting documentation with inadequate response or intolerance)
   a. If yes, continue to #6

Last Reviewed: 11/21/18, 3/18/20, 7/21/21, 3/17/23, 3/15/24, 3/21/25
Effective Date: 1/1/19, 5/1/20

b. If no, clinical review required

6. Is the member at least one year of age or older?
    a. If yes, continue to #7
    b. If no, clinical review required
7. Is the treatment being initiated by a specialist experienced in the management of nephropathic cystinosis? (Examples include endocrinologist, nephrologist, or urologist)
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member have documentation of a positive clinical response to therapy as evidenced by a reduction in WBC cysteine levels compared to pre-treatment? (Provide supporting documentation for review)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the treatment being initiated by a specialist experienced in the management of nephropathic cystinosis? (examples include endocrinologist, nephrologist, or urologist)
    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Procysbi [package insert]. Deerfield, IL: Horizon Therapeutics USA, Inc.; February 2022.
2. Cystagon [package insert]. Morgantown, WV: Mylan Pharmaceuticals, Inc.; August 2021.
3. Langman CB, Greenbaum LA, Sarwal M, et al. A randomized controlled crossover trial with delayed-release cysteamine bitartrate in nephropathic cystinosis: effectiveness on white blood cell cysteine levels and comparison of safety. Clin J Am Soc Nephrol 2012;7:1112-1120.
4. Niaudet P. Cystinosis. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed January 2025.

Last Reviewed: 11/21/18, 3/18/20, 7/21/21, 3/17/23, 3/15/24, 3/21/25
Effective Date: 1/1/19, 5/1/20

Cystaran®, Cystadrops® (cysteamine hydrochloride) Prior Authorization Guidelines

Affected Medication(s)

- Cystaran 0.44% ophthalmic solution
- Cystadrops 0.37% ophthalmic solution

FDA Approved Indication(s)

- Treatment of corneal cystine crystal accumulation in patients with cystinosis

Dosing

- Cystaran:
  - One drop in each eye, every waking hour
- Cystadrops
  - One drop in each eye 4 times daily during waking hours

Initial Authorization Criteria

1. Is the request for continuation of Cystaran (cysteamine hydrochloride) or Cystadrops (cysteamine hydrochloride) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
   a. If yes, continue to #3
   b. If no, clinical review required
3. Does the member have a presence of corneal cysteine accumulation? (Provide supporting documentation)
   a. If yes, continue to #4
   b. If no, clinical review required
4. Is the request for use of Cystadrops?
   a. If yes, continue to #5
   b. If no, continue to #6
5. Has the member had a previous trial with inadequate response or intolerance to treatment with Cystaran?
   a. If yes, continue to #6
   b. If no, clinical review required
6. Is the treatment being prescribed by, or in consultation with an ophthalmologist?
   a. If yes, approve for 6 months unless otherwise specified
   b. If no, clinical review required

Reauthorization Criteria

Last Reviewed: 10/17/18, 11/18/20, 1/20/21,3/16/22, 5/19/23, 5/17/24, 5/16/25
Effective Date: 1/1/19, 12/15/20, 3/1/21, 4/15/22, 6/15/24

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member currently have a presence of corneal cysteine accumulation OR did the member previously have corneal cysteine accumulation prior to the start of Cystaran or Cystadrops therapy? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Has the member demonstrated a positive clinical response to therapy? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the treatment being prescribed by, or in consultation with an ophthalmologist?
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Cystaran Prescribing Information. Amityville, NY: Hi-Tech Pharmacal Co., Inc., October 2012. Available at http://www.cystaran.com/. Accessed October 23, 2020.
2. Cystadrops Prescribing Information. Lebanon, NJ: Recordati Rare Diseases Inc., September 2020. Accessed January 15, 2021.
3. Cystinosis. National Organization for Rare Disorders website. https://rarediseases.org/rare-diseases/cystinosis/. Published 1986. Updated 2017. Accessed September 2018.

Last Reviewed: 10/17/18, 11/18/20, 1/20/21, 3/16/22, 5/19/23, 5/17/24, 5/16/25
Effective Date: 1/1/19, 12/15/20, 3/1/21, 4/15/22, 6/15/24

Cystic Fibrosis Modulators
Prior Authorization Guidelines

Affected Medication(s)

- Alyftrek (vanzacaftor/tezacaftor/deutivacaftor) oral tablet
- Kalydeco (ivacaftor) oral tablet
- Kalydeco (ivacaftor) oral granule packet
- Orkambi (lumacaftor/ivacaftor) oral tablet
- Orkambi (lumacaftor/ivacaftor) oral granule packet
- Symdeko (tezacaftor/ivacaftor) oral tablet
- Trikafta (elexcaftor/tezacaftor/ivacaftor) oral tablet
- Trikafta (elexcaftor/tezacaftor/ivacaftor) oral granule packet

FDA Approved Indication(s)

- Alyftrek
  - Treatment of cystic fibrosis (CF) in patients 6 years of age and older who have at least one F508del mutation or another responsive mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene
- Kalydeco
  - Treatment of cystic fibrosis (CF) in patients aged 1 month and older who have at least one mutation in the CFTR gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data
- Orkambi
  - Treatment of cystic fibrosis (CF) in patients aged 1 year and older who are homozygous for the F508del mutation in the CFTR gene
- Symdeko
  - Treatment of cystic fibrosis (CF) in patients aged 6 years and older who are homozygous for the F508del mutation or who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor based on in vitro data and/or clinical evidence
- Trifkafta
  - Treatment of cystic fibrosis (CF) in patients aged 2 years and older who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene or a mutation in the CFTR gene that is responsive based on clinical and/or in vitro data

Dosing

- Refer to package insert for specific dosing recommendations

Initial Authorization Criteria

1. Is the request for continuation of therapy with the same medication for the same indication?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
   a. If yes, continue to #3
   b. If no, clinical review required

Last Reviewed: 3/21/25
Effective Date: 4/1/25

3. Is the request for an FDA-approved age and CFTR gene mutation? (Provide supporting documentation) (Refer to package insert for FDA-approved indication and list of responsive gene mutations)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the patient have documentation of baseline FEV1, ALT, AST, and bilirubin? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is the request for Alyftrek?
    a. If yes, continue to #6
    b. If no, continue to #7
6. Does the member have documentation of trial with insufficient response, intolerance, or contraindication to Trikafta? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Is the requested medication being prescribed by, or in consult with, a pulmonologist or a specialist experienced in treating cystic fibrosis patient?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (within past year) provided with documentation of significant clinical response to prior therapy received? (i.e. improvement of FEV1 from baseline, reduction in exacerbations, improvement in BMI) (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Were updated chart notes (within past year) provided with documentation of follow up liver function tests? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the medication being prescribed by, or in consult with, a pulmonologist or a specialist experienced in treating cystic fibrosis patient?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

Last Reviewed: 3/21/25

Effective Date: 4/1/25

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Alyftrek (vanzacaftor, tezacaftor, and deutivacaftor) oral tablets, [Prescribing Information]. Boston, MA: Vertex Pharmaceuticals, Inc.; January 2025.
2. Trikafta™ (elexacaftor/tezacaftor, and ivacaftor) [Prescribing Information]. Boston, MA: Vertex Pharmaceuticals Inc. February 2025.
3. Orkambi® (lumacaftor/ivacaftor) [Prescribing Information]. Boston, MA: Vertex Pharmaceuticals Inc. December 2024.
4. Symdeko (tezacaftor/ivacaftor) [Prescribing Information]. Boston, MA: Vertex Pharmaceuticals Inc. February 2024.
5. Kalydeco® (ivacaftor) [Prescribing Information]. Boston, MA: Vertex Pharmaceuticals Inc. June 2024.
6. Southern KW, Castellani C, Lammertyn E, et al. Standards of care for CFTR variant-specific therapy (including modulators) for people with cystic fibrosis. J Cyst Fibros. 2023;22(1):17-30.
7. Simon, MD. Cystic fibrosis: Overview of the treatment of lung disease. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com.

Daybue® (trofinetide)
Prior Authorization Guidelines

Affected Medication(s)

- Daybue (trofinetide) oral tablet

FDA Approved Indication(s)

- Treatment of Rett syndrome in adults and pediatric patients 2 years of age and older

Dosing

- Refer to package insert for dosing recommendations

Initial Authorization Criteria

1. Is the request for continuation of therapy with the same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is Daybue® (trofinetide) being requested for an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member 2 years of age or older?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have documentation of typical Rett syndrome according to the Rett Syndrome Diagnostic Criteria with a disease-causing mutation in the MECP2 gene as confirmed by genetic testing? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have a current clinically significant cardiovascular, endocrine (such as hypo- or hyperthyroidism, Type 1 diabetes mellitus, or uncontrolled Type 2 diabetes mellitus), renal, hepatic, respiratory or gastrointestinal disease (such as celiac disease or inflammatory bowel disease)? (Provide supporting documentation)
    a. If yes, clinical review required
    b. If no, continue to #6
6. Does the member have a history of or current cerebrovascular disease or brain trauma? (Provide supporting documentation)
    a. If yes, clinical review required
    b. If no, continue to #7
7. Does the member have significant, uncorrected visual or hearing impairment? (Provide supporting documentation)
    a. If yes, clinical review required

Last Reviewed: 5/19/23, 7/19/24, 7/18/25
Effective Date: 7/15/23, 8/15/24

b. If no, continue to #8

8. Is the treatment being prescribed by, or in consultation with, a clinical geneticist or neurologist?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (within past year) provided with documentation of clinical response to prior therapy received?
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the treatment being prescribed by, or in consultation with, a clinical geneticist or neurologist?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. DAYBUE (trofinetide) oral solution, [package insert]. San Diego, CA: Acadia Pharmaceuticals Inc.; 2024.
2. Drugs@FDA: FDA Approved Drug Products. 2023. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 27 Mar. 2023].
3. Neul, J. L., Percy, A. K., Benke, T. A., Berry-Kravis, E. M., Glaze, D. G., Peters, S. U., Jones, N. E., & Youakim, J. M. (2022). Design and outcome measures of LAVENDER, a phase 3 study of trofinetide for Rett syndrome. Contemporary clinical trials, 114, 106704.
4. Fu, C., Armstrong, D., Marsh, E., Lieberman, D., Motil, K., Witt, R., Standridge, S., Nues, P., Lane, J., Dinkel, T., Coenraads, M., von Hehn, J., Jones, M., Hale, K., Suter, B., Glaze, D., Neul, J., Percy, A., & Benke, T. (2020). Consensus guidelines on managing Rett syndrome across the lifespan. BMJ paediatrics open, 4(1), e000717.
5. Jeffrey L. Neul, , Kaufmann, W.E., Glaze, D.G., Christodoulou, J., Clarke, A.J., Bahi-Buisson, N., Leonard, H., Bailey, M.E.S., Schanen, N.C., Zappella, M., Renieri, A., Huppke, P., Percy, A.K. and (2010), Rett syndrome: Revised diagnostic criteria and nomenclature. Ann Neurol., 68: 944-950.

Last Reviewed: 5/19/23, 7/19/24, 7/18/25

Effective Date: 7/15/23, 8/15/24

Deferasirox
Prior Authorization Guidelines

Affected Medication(s)

- Exjade oral tablet for suspension
- deferasirox oral tablet for suspension
- Jadenu oral tablet/sprinkle granules
- deferasirox oral tablet/sprinkle granules

FDA Approved Indication(s)

- Treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis) in patients 2 years of age and older
- 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 concentration (LIC) of at least 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw) and a serum ferritin greater than 300 mcg/L

Dosing

- Refer to package insert for dosing recommendations

Initial Authorization Criteria

1. Is the request for continuation of deferasirox therapy for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the treatment being prescribed by, or in consult with, a hematologist?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the member concurrently using other iron chelators (Examples include: Ferriprox, Desferal, Depen, and Cuprimine)?
    a. If yes, clinical review required
    b. If no, continue to #5
5. What is the indication that the medication is being requested for?
    a. Chronic iron overload due to blood transfusions, see corresponding criteria
    b. Chronic iron overload due to non-transfusion-dependent thalassemia (NTDT), see corresponding criteria

Chronic iron overload due to blood transfusions

1. Is the member 2 years of age or older?
    a. If yes, continue to #2

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b. If no, clinical review required

2. Does the member have a history of transfusion with at least 100 mL/kg of packed red blood cells? (Provide supporting documentation for review)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is serum ferritin consistently greater than 1000 mcg/L? (Provide supporting labs for review)
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Chronic iron overload due to non-transfusion-dependent thalassemia (NTDT)

1. Is the member 10 years of age or older?
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member have a serum ferritin level of > 300 mcg/L and a liver iron concentration of ≥ 5 mg Fe/g of liver dry weight? (Provide documentation of lab result)
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the treatment being prescribed by, or in consult with a hematologist?
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member concurrently using other iron chelators?
    a. If yes, clinical review required
    b. If no, continue to #4
4. What is the indication that the medication is being requested for?
    a. Chronic iron overload due to blood transfusions, see corresponding criteria
    b. Chronic iron overload due to non-transfusion-dependent thalassemia (NTDT), see corresponding criteria

Chronic iron overload due to blood transfusions

1. Does the member have a serum ferritin level ≥ 500 mcg/L? (Provide documentation of serum ferritin level within the past 30 days)
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Last Reviewed: 10/17/18, 1/21/20, 9/15/21, 3/17/23, 3/15/24, 3/21/25
Effective Date: 1/1/19, 4/15/24, 4/1/25

Chronic iron overload due to non-transfusion-dependent thalassemia (NTDT)

1. Does the member have a liver iron concentration of ≥ 3 mg Fe/g of liver dry weight? (Provide documentation of lab result within the past 90 days)
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Exjade Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2024.
2. Jadenu Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2024.
3. Oken M, Creech R, Tormey D, et al. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982;5:649-655. http://ecog-acrin.org/resources/ecog-performance-status.
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5. Hoffbrand AV, Taher A, Cappellini MD. How I treat tranfusional iron overload. Blood. November 1, 2012; 120(18): 3657-3669.
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Last Reviewed: 10/17/18, 1/21/20, 9/15/21, 3/17/23, 3/15/24, 3/21/25
Effective Date: 1/1/19, 4/15/24, 4/1/25

Deferiprone
Prior Authorization Guidelines

Affected Medication(s)

- Deferiprone oral tablet
- Ferriprox oral solution
- Ferriprox oral tablet
- Ferriprox Twice-A-Day tablet

FDA Approved Indication(s)

- Treatment of transfusional iron overload in adults and pediatric patients ≥8 years of age (tablets) or adults and pediatric patients ≥3 years of age (solution) with thalassemia syndromes, sickle cell disease, or other anemias

Dosing

- Refer to package insert for dosing recommendations

Initial Authorization Criteria

1. Is the request for continuation of deferiprone therapy?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member have an ANC greater than 1.5 x 10^9/L and a baseline serum ferritin level greater than 1,000 mcg/L? (Provide ANC and serum ferritin level for review)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have a trial with inadequate response, intolerance, or contraindication to an iron chelator? (Examples include Desferal, Exjade, or Jadenu) (Inadequate response defined as serum ferritin > 2,500 mcg/L) (Provide documentation of trial and response, intolerance, or contraindication)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is the treatment being prescribed by, or in consultation with, a hematologist?
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

Last Reviewed: 11/21/18, 11/18/20, 3/16/22, 5/19/23, 5/17/24, 5/16/25
Effective Date: 1/1/19, 12/15/20, 4/15/22, 7/1/23, 6/15/24

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Has the member had a positive clinical response to therapy as defined by a ≥20% decline in serum ferritin within one year of starting therapy and is ANC being monitored weekly while on therapy? (Provide supporting documentation for review)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the treatment being prescribed by, or in consultation with, a hematologist?
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Ferriprox [prescribing information]. Toronto, Ontario: ApoPharma USA, Inc.; April 2021.
2. Galanello R. Deferiprone in the treatment of transfusion-dependent thalassemia: a review and perspective. Therapeutics and Clinical Risk Management 2007;3(5):795- 805
3. Porter JB, Shah FT. Iron overload in thalassemia and related conditions: therapeutic goals and assessment of response to chelation therapies. Hematol Oncol Clin N Am 2010; 24;1109-1130
4. Cappellini MD, Cohen A, Porter, J, et al. A short guide for the management of transfusion dependent thalassaemia. 3rd Edition. Available at: Short-GUIDE-low-res.pdf (thalassaemia.org.cy). Accessed on March, 2022.

Last Reviewed: 11/21/18, 11/18/20, 3/16/22, 5/19/23, 5/17/24, 5/16/25
Effective Date: 1/1/19, 12/15/20, 4/15/22, 7/1/23, 6/15/24

Denosumab (Prolia)
Prior Authorization Guidelines

Affected Medication(s)

- Bildyos (denosumab-nxxp) subcutaneous solution
- Conexxence (denosumab-bnht) subcutaneous solution
- Jubbonti (denosumab-bbdz) subcutaneous solution
- Ospomyv (denosumab-dssb) subcutaneous solution
- Prolia (denosumab) subcutaneous solution
- Stoboclo (denosumab-bmwo) subcutaneous solution

FDA Approved Indication(s)

- Treatment of postmenopausal women with osteoporosis 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.
- Treatment to increase bone mass in men with osteoporosis 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
- Treatment of glucocorticoid-induced osteoporosis in men and women at high risk of fracture who are either initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone and expected to remain on glucocorticoids for at least 6 months. High risk of fracture is 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
- Treatment to increase bone mass in men at high risk for 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

Dosing

- 60 mg subcutaneously once every 6 months

Initial Authorization Criteria

1. Is the request for continuation of denosumab for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member have a documented diagnosis of osteoporosis as indicated by one or more of the following? (Provide supporting documentation including DXA report within 2 years)
    - Hip DXA (femoral neck or total hip) or lumbar spine T-score less than or equal to -2.5 and/or forearm DXA 33% (one-third) radius

Last Reviewed: 11/7/18, 5/19/21, 7/20/22, 7/21/23, 7/19/24, 9/19/25, 11/21/25
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- T-score less than or equal to -1 or low bone mass AND a history of fragility fracture to the hip or spine
- T-score between -1 and -2.5 with a FRAX 10-year probability for major fracture ≥20% or hip fracture ≥3%

a. If yes, continue to #6
b. If no, continue to #4

4. Does the member have non-metastatic prostate cancer and is currently receiving androgen deprivation therapy with confirmed osteopenia? (Provide supporting documentation)

   a. If yes, continue to #13
   b. If no, continue to #5

5. Does the member have breast cancer and is receiving adjuvant aromatase inhibitor with confirmed osteopenia?

   a. If yes, continue to #13
   b. If no, clinical review required

6. Is the member currently on systemic glucocorticoid therapy with a daily dosage equivalent of prednisone 7.5 mg or greater?

   a. If yes, continue to #7
   b. If no, continue to #8

7. Will the member continue with systemic glucocorticoid therapy at a daily dosage equivalent to 7.5 mg or greater of prednisone for at least 6 months?

   a. If yes, continue to #11
   b. If no, continue to #8

8. Is member at high risk for fracture as defined by one or more of the following? (Provide supporting documentation)

   - History of an osteoporotic fracture as an adult
   - Parental history of hip fracture
   - Low BMI
   - Rheumatoid arthritis
   - Alcohol intake of 3 or more drinks per day
   - Current smoking
   - History of oral glucocorticoids ≥ 5 mg/day of prednisone (or equivalent) for > 3 months in lifetime
   - Early menopause

   a. If yes, continue to #9
   b. If no, clinical review required

9. Does the member have five years of continuous treatment with bisphosphonates? (Provide all prior therapy history)

   a. If yes, continue to #13
   b. If no, continue to #10

10. Does the member have a trial with insufficient response to at least 12 months of bisphosphonate therapy (oral or IV) as defined by a decrease in T-score from baseline or member had a fracture while on bisphosphonate therapy? (Provide past relevant medication list with documentation of response to therapy)
    a. If yes, continue to #13
    b. If no, continue to #11
11. Does the member have a contraindication or intolerance to oral bisphosphonates? (Provide supporting documentation)
    a. If yes, continue to #12
    b. If no, clinical review required
12. Does the member with a contraindication or intolerance to IV bisphosphonates? (Provide supporting documentation)
    a. If yes, continue to #13
    b. If no, clinical review required
13. Is the request for Jubbonti (denosumab-bbdz)?
    a. If yes, continue to #15
    b. If no, continue to #14
14. Does the member have a documented clinical rationale for avoiding Jubbonti (denosumab-bbdz)? (Provide supporting documentation)
    a. If yes, continue to #15
    b. If no, clinical review required
15. Is the member currently supplementing with at least 1,000 mg of calcium and 400 IU of vitamin D daily that will be continued throughout therapy? (Provide list of current relevant medications)
    a. If yes, continue to #16
    b. If no, clinical review required
16. Does member have any of the following contraindications to treatment with denosumab? (Provide serum calcium level for review)
    - Hypersensitivity to any component of the product
    - Hypocalcemia
    - Pregnancy

    a. If yes, clinical review required
    b. If no, continue to #17
17. Will denosumab be used concurrently with bisphosphonates or a PTH analog?
    a. If yes, clinical review required
    b. If no, continue to #18
18. Is the treatment being prescribed by or in consultation with an endocrinologist, a rheumatologist, or oncologist? (oncologist consultation if the patient has prostate or breast cancer)
    a. If yes, approve for up to 2 years unless otherwise specified

b. If no, clinical review required

Reauthorization Criteria

1. Does the member continue to meet initial authorization criteria? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member demonstrate positive clinical response to therapy as defined by absence of fractures and/or an increase in bone mineral density from pretreatment baseline? (Provide updated DXA report and other supporting documentation)
    a. If yes, approve for up to 2 years unless otherwise specified
    b. If no, clinical review required

Note:

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References:

1. Prolia [package insert]. Thousand Oaks, CA; Amgen, Inc.; May 2025.
2. Camacho PM, Petak SM, Binkley N, et al. AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS AND AMERICAN COLLEGE OF ENDOCRINOLOGY CLINICAL PRACTICE GUIDELINES FOR THE DIAGNOSIS AND TREATMENT OF POSTMENOPAUSAL OSTEOPOROSIS - 2016. Endocr Pract. 2016 Sep 2; 22(Suppl 4):1-42.
3. Gnant M, Pfeiler G, Dubsky PC,et al. Adjuvant denosumab in breast cancer (ABCSG-18): a multicentre, randomised, double-blind, placebo-controlled trial. Lancet. 2015 Aug 1;386(9992):433-43.
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5. Jeremiah MP, Unwin BK, Greenawald MH, et al. Diagnosis and Management of Osteoporosis. Am Fam Physician. 2015 Aug 15;92(4):261-8.
6. Camacho, Pauline M., et al. "American Association of Clinical Endocrinologists/American College of Endocrinology clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis 2020 update." Endocrine Practice 26 (2020): 1-46.
7. Humphrey MB, Russell L, Danila MI, et al. 2022 American College of Rheumatology Guideline for the Prevention and Treatment of Glucocorticoid-Induced Osteoporosis. *Arthritis Rheumatol*. 2023;75(12):2088-2102.

Last Reviewed: 11/7/18, 5/19/21, 7/20/22, 7/21/23, 7/19/24, 9/19/25, 11/21/25
Effective Date: 1/1/19, 8/15/24, 10/31/25, 1/1/26

Diacomit® (stiripentol)
Prior Authorization Guidelines

Affected Medication(s)

- Diacomit oral capsule
- Diacomit oral powder for suspension

FDA Approved Indication(s)

- Treatment of seizures associated with Dravet syndrome (DS) in patients 6 months of age and older and weighing 7 kg or more taking clobazam

Note: There is no clinical data to support use of Diacomit as monotherapy in Dravet syndrome

Dosing

- 50 mg/kg/day administered in 2 or 3 divided doses

Initial Authorization Criteria

1. Is the request for continuation of Diacomit (stiripentol) therapy?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member currently have a diagnosis of Dravet syndrome?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Has the patient previously trialed valproate, topiramate, and clobazam, unless intolerance or contraindication, and continued to have 4 or more generalized tonic-clonic seizures per month despite optimized therapy?
    a. If yes, continue to #5
    b. If no, clinical review required
5. Will Diacomit (stiripentol) be used in conjunction with clobazam?
    a. If yes, continue to #6
    b. If no, clinical review required
6. Is the treatment being prescribed by, or in consultation with, a neurologist?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Last Reviewed: 9/18/19, 11/20/19, 7/21/21, 11/16/22, 9/15/23, 9/20/24, 9/19/25
Effective Date: 10/15/19, 1/1/23, 11/30/23, 10/15/24

Reauthorization Criteria

1. Is the documented indication Food and Drug Administration (FDA) approved or supported by major compendia?
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (within the past 6 months) with documentation of at least a 50% decrease in the frequency of generalized clonic and tonic-clonic seizures?
    a. If yes, continue to #3
    b. If no, clinical review required
3. Will Diacomit (stiripentol) be used in combination with clobazam?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the treatment being prescribed by or in consultation with a neurologist?
    a. If yes, approve for 12 months reauthorization
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Lexicomp [internet database]. Hudson, OH: Wolters Kluwer. Updated periodically. Accessed August 13, 2019.
2. Stiripentol (Diacomit) Capsule and powder for suspension [package insert]. Redwood City, USA: Bicodex Inc; June 2024.
3. Drugs@FDA: FDA Approved Drug Products. 2019. accessdatafda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 13 Aug. 2019].
4. National Institute for Health and Care Excellence; Epilepsies: Diagnosis and Management Clinical Guidelines. *NICE Guideline*. May 2021. Available at: https://www.nice.org.uk/guidance/cg137
5. Wilmhurst JM, Gaillard WD, Vinayan KP, et al. Summary of recommendations for the management of infantile seizures: Task force report for the ILAE commission of pediatrics. Epilepsia. 2015; 56(8):1185-1197

Last Reviewed: 9/18/19, 11/20/19. 7/21/21, 11/16/22, 9/15/23, 9/20/24, 9/19/25
Effective Date: 10/15/19, 1/1/23, 11/20/23, 10/15/24

Dichlorphenamide
Prior Authorization Guidelines

Affected Medication(s)

- dichlorphenamide oral tablet
- Keveyis oral tablet
- Ormalvi oral tablet

FDA Approved Indication(s)

- Treatment of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, and related variants

Dosing

- Initially: 50 mg once or twice daily
- Titrate as needed based on response with maximum dose of 200 mg per day

Initial Authorization Criteria

1. Is the request for continuation of dichlorphenamide therapy for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Are both baseline serum potassium and bicarbonate levels received? (Provide supporting labs for review)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have a previous trial with inadequate response, intolerance, or contraindication to treatment with acetazolamide? (Provide documentation of trial with inadequate response, intolerance, or contraindication)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is the treatment being prescribed by, or in consultation with, a neurologist?
    a. If yes, continue to #6
    b. If no, clinical review required
6. What diagnosis is the medication being requested for?
    a. Hypokalemic periodic paralysis, continue to corresponding criteria
    b. Hyperkalemic periodic paralysis, continue to corresponding criteria

Hypokalemic periodic paralysis

Last Reviewed: 11/21/18, 3/17/21, 5/18/22, 5/19/23, 5/17/24, 5/16/25
Effective Date: 1/1/19, 6/15/24, 6/1/25

1. Does the member have a history of two or more attacks of muscle weakness with documented serum potassium <3.5 mEq/L? (Provide supporting documentation of attacks with muscle weakness and serum potassium levels for review)
    a. If yes, continue to #4
    b. If no, continue to #2
2. Does the member have a history of one attack of muscle weakness and one attack of weakness in one family relative with documented serum potassium <3.5 mEq/L? (Provide supporting documentation of members' and their family relatives' attack with muscle weakness and serum potassium levels for review)
    a. If yes, continue to #4
    b. If no, continue to #3
3. Does the member have three or more of the following six clinical/laboratory features?
    - Onset in the first or second decade of life (childhood or teenage years)
    - Duration of attack (muscle weakness involving ≥1 limbs) longer than two hours
    - The presence of triggers (previous carbohydrate rich meal, symptom onset during rest after exercise, stress)
    - Improvement in symptoms with potassium intake
    - A family history of the condition or genetically confirmed skeletal calcium or sodium channel mutation
    - Positive long exercise test

    a. If yes, continue to #4
    b. If no, clinical review required
4. Have other causes of hypokalemia been ruled out? (i.e. renal, adrenal, thyroid dysfunction; renal tubular acidosis; diuretic and laxative abuse)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Have dietary interventions been trialed with inadequate response? (Provide documentation of high potassium intake and low sodium intake)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Has the member been taking and will continue to take a potassium supplement throughout therapy? (Provide supporting documentation)
    a. If yes, approve for 6 months, unless otherwise specified
    b. If no, clinical review required

<u>Hyperkalemic periodic paralysis</u>

1. Has the member's diagnosis been confirmed by electromyography, genetic testing, or provocative testing? (Provide supporting documentation of testing done to confirm diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Has the member had an ECG performed to exclude prolonged QT and/or ventricular arrhythmias? (Provide supporting documentation)

a. If yes, continue to #3
b. If no, clinical review required

3. Have other causes of hyperkalemia been ruled out? (i.e. Andersen-Tawil syndrome, adrenal insufficiency, renal dysfunction, or drug abuse)

    a. If yes, continue to #4
    b. If no, clinical review required

4. Have dietary and exercise restrictions been trialed with inadequate response? (Provide documentation of low potassium intake and exercise restrictions)

    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)

    a. If yes, continue to #2
    b. If no, clinical review required

2. Has the member had a positive clinical response to therapy as defined by a decrease in the frequency in paralytic attacks? (Provide supporting documentation for review)

    a. If yes, continue to #3
    b. If no, clinical review required

3. Is the treatment being prescribed by, or in consultation with, a neurologist?

    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Keveyis [prescribing information]. Taro Pharmaceuticals U.S.A., Inc. Hawthorne, NY. December 2021.
2. Vicart S, Sternberg D, Arzel-Hézode M, et al. Hypokalemic Periodic Paralysis. 2002 Apr 30 [Updated 2014 Jul 31]. In: Pagon RA, Adam MP, Ardinger HH, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2015. Available from: http://www.ncbi.nlm.nih.gov/books/NBK1338/?report=classic
3. Jurkat-Rott K, Lehmann-Horn F. Hyperkalemic Periodic Paralysis Type 1. 2003 Jul 18 [Updated 2011 May 31]. In: Pagon RA, Adam MP, Ardinger HH, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2015. Available from: http://www.ncbi.nlm.nih.gov/books/NBK1496/

Last Reviewed: 11/21/18, 3/17/21, 5/18/22, 5/19/23, 5/17/24, 5/16/25
Effective Date: 1/1/19, 6/15/24, 6/1/25

Doptelet® (avatrombopag maleate) & Mulpleta® (lusutrombopag) Prior Authorization Guidelines

Affected Medication(s)

- Doptelet (avatrombopag) oral tablet
- Doptelet (avatrombopag) sprinkle capsule
- Mulpleta (lusutrombopag) oral tablet

FDA Approved Indication(s)

- Doptelet:
  - Treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure
  - Treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia who have had an insufficient response to a previous treatment
  - Treatment of thrombocytopenia in pediatric patients 1 year and older with persistent or chronic immune thrombocytopenia who have had an insufficient response to a previous treatment
- Mulpleta:
  - Treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure

Dosing

- Doptelet:
  - Chronic liver disease:
    - Platelet count <40: 60 mg for 5 days
    - Platelet count 40-50: 40 mg for 5 days
  - Chronic ITP in adults
    - Starting dose 20 mg once daily, refer to package insert for dose adjustments based on platelet counts
  - Persistent or chronic ITP in pediatric patients
    - Starting dose 10 mg once daily, refer to package insert for dose adjustments based on platelet counts
- Mulpleta
  - 3 mg for 7 days 8 to 14 days prior to a scheduled procedure

Authorization Criteria

1. Is the request for continuation of Doptelet for the treatment of chronic immune thrombocytopenia?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
   a. If yes, continue to #3
   b. If no, clinical review required

Last Reviewed: 11/21/18, 5/19/21, 11/16/22, 11/17/23, 9/20/24, 7/18/25, 11/21/25
Effective Date: 1/1/19, 6/15/21, 1/1/23, 10/15/24, 8/1/25, 1/1/26

3. Is the member 18 years of age or older?
    a. If yes, continue to #4
    b. If no, clinical review required
4. What indication is the medication being requested for?
    a. Thrombocytopenia in adults with chronic liver disease, continue to corresponding criteria
    b. Thrombocytopenia in adults with chronic immune thrombocytopenia or pediatric patients with persistent or chronic ITP, continue to corresponding criteria (Doptelet only)

<u>Thrombocytopenia in adults with chronic liver disease</u>

1. Does the member have a platelet count of less than 50 x 10^9/L (50,000 mcL)? (Provide documentation of platelet count)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member have a planned medical or dental procedure with intermediate-to-high bleeding risk within the next 30 days? (Provide date and type of scheduled procedure for review)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the treatment being prescribed by, or in consultation with, a hematologist, hepatologist, or gastroenterologist?
    a. If yes, continue to #4
    b. If no, clinical review required
4. What is the requested medication?
    a. Doptelet (avatrombopag maleate), continue to #5
    b. Mulpleta (lusutrombopag), continue to #6
5. Is the treatment plan to begin therapy 10-13 days prior to the scheduled procedure and undergo the procedure within 5 to 8 days after the last dose? (Provide documentation of treatment plan and date of scheduled procedure)
    a. If yes, approve for 5 days
    b. If no, clinical review required
6. Does the member have a previous trial with inadequate response, intolerance, or contraindication to Doptelet? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Is the treatment plan to begin therapy 8-14 days prior to the scheduled procedure and undergo the procedure 2-8 days after the last dose? (Provide documentation of treatment plan and date of scheduled procedure)
    a. If yes, approve for 7 days
    b. If no, clinical review required

<u>Thrombocytopenia in adults with chronic immune thrombocytopenia (ITP) or pediatric patients with persistent or chronic ITP</u>

1. Does the member have a platelet count less than 30 x 10^9/L (30,000/mcL) that was taken within the last 30 days? (Provide platelet count for review)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Has the member had an inadequate response, intolerance, or contraindication to glucocorticoids AND splenectomy or rituximab or immunoglobulins for ITP (Inadequate response defined as platelet count fails to each greater than or equal to 50 x 10^9/L (50,000/mcL)? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member have a previous trial with inadequate response, intolerance, or contraindication to eltrombopag? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the medication being prescribed by, or in consultation with, a hematologist?
    a. If yes, approve for 3 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (within previous 6 months) provided with documentation of significant clinical response to prior therapy received (i.e. platelet count greater than or equal to 50 x 10^9/L (50,000/mcL))? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the treatment being prescribed by, or in consultation with, a hematologist?
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Doptelet Prescribing Information. Morrisville, NC: AkaRx, Inc.; August 2025.

Last Reviewed: 11/21/18, 5/19/21, 11/16/22, 11/17/23, 9/20/24, 7/18/25, 11/21/25
Effective Date: 1/1/19, 6/15/21, 1/1/23, 10/15/24, 8/1/25, 1/1/26

2. Mulpleta Prescribing Information. Florham Park, NJ: Shionogi Inc.; October 2020.
3. Hayashi H, Beppu T, Shirabe K, Maehara Y, and Baba H. Management of thrombocytopenia due to liver cirrhosis: a review. World J Gastroenterol. 2014; 20(10): 2595-2605.
4. George, PhD, Arnold, MD. Immune thrombocytopenia (ITP) in adults: Second-line and subsequent therapies. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed September 28, 2022.
5. Ghanima W, Cuker A, Michel M. Insights on treatment of adult ITP: algorithm for management and role of multimodal therapy. Hematology Am Soc Hematol Educ Program. 2024;2024(1):678-684. doi:10.1182/hematology.2024000594

Last Reviewed: 11/21/18, 5/19/21, 11/16/22, 11/17/23, 9/20/24, 7/18/25, 11/21/25
Effective Date: 1/1/19, 6/15/21, 1/1/23, 10/15/24, 8/1/25, 1/1/26

Droxidopa
Prior Authorization Guidelines

Affected Medication(s)

- Northera oral capsule
- droxidopa oral capsule

FDA Approved Indication(s)

- 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

Dosing

- Starting dose: 100 mg, taken orally three times daily
- Titrate to symptomatic response, in increments of 100 mg three times daily every 24 to 48 hours up to a maximum dose of 600 mg three times daily

Initial Authorization Criteria

1. Is the request for continuation of droxidopa therapy for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member have documentation of primary autonomic failure (by Parkinson's disease [PD], multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the member 18 years of age or older?
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is there documentation that the member has tried at least TWO non-pharmacological interventions to treat the conditions as outlined below? (Provide supporting documentation of non-pharmacological interventions tried)
        i. Elevation of the bed by 5-20 degrees
        ii. Use of compression stockings
        iii. Increased salt and water intake

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iv. Avoidance of precipitating factors including arising too quickly, alcohol consumption, hot baths, or hot environments

v. Discontinuation of drugs which can cause orthostatic hypotension (i.e. diuretics, antihypertensive medications, nitrates, alpha-adrenergic antagonists, etc.)

a. If yes, continue to #6
b. If no, clinical review required

6. Does the member have a sufficient trial with inadequate response, intolerance, or contraindication to both midodrine AND fludrocortisone? (Provide supporting documentation)

a. If yes, continue to #7
b. If no, clinical review required

7. Is the treatment being prescribed by, or in consultation with, a neurologist, cardiologist, or nephrologist?

a. If yes, approve for 2 weeks
b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)

a. If yes, continue to #2
b. If no, clinical review required

2. Did the member have a positive clinical response to therapy as defined as less frequent episodes of orthostatic dizziness, lightheadedness, or the "feeling that you are about to black out"? (Provide supporting documentation of less frequent symptomatic episodes)

a. If yes, continue to #3
b. If no, clinical review required

3. Is the treatment being prescribed by, or in consultation with, a neurologist, cardiologist, or nephrologist?

a. If yes, continue to #4
b. If no, clinical review required

4. Is clinical rationale provided for continued use beyond 2 weeks? (Provide supporting documentation)

a. If yes, approve for 6 months unless otherwise specified
b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Northera [prescribing information]. Deerfield, IL: Lundbeck. July 2019.

Last Reviewed: 11/21/18, 11/18/20, 3/17/21, 5/18/22, 7/21/23, 7/19/24, 7/18/25
Effective Date: 1/1/19, 12/15/20, 5/1/21, 7/15/22, 8/15/24, 8/1/25

2. Kaufman H, Freeman R, Biagginoi I, et. al. Droxidopa for Neurogenic Orthostatic Hypotension. A Randomized, Placebo-Controlled, Phase 3Trial. Neurology. 2014;83:1-8.
3. Kaufmann H, Malamut R, Norcliffe-Kaufmann L, Rosa K, Freeman R. The Orthostatic Hypotension Questionnaire (OHQ): validation of a novel symptom assessment scale. Clin Auton Res. 2012;22(2):79-80.
4. Freeman R. Clinical Practice. Neurogenic orthostatic hypotension. N Engl J Med. 2008;358(6);615-624.

Last Reviewed: 11/21/18, 11/18/20, 3/17/21, 5/18/22, 7/21/23, 7/19/24, 7/18/25
Effective Date: 1/1/19, 12/15/20, 5/1/21, 7/15/22, 8/15/24, 8/1/25

Duvyzat (givinostat)
Prior Authorization Guidelines

Affected Medication(s)

- Duvyzat (givinostat) oral suspension

FDA Approved Indication(s)

- Treatment of Duchenne muscular dystrophy (DMD) in patients 6 years of age and older

Dosing

- 10 to less than 20 kg: 22.2 mg twice daily
- 20 kg to less than 40 kg: 31 mg twice daily
- 40 kg to less than 60 kg: 44.3 mg twice daily
- 60 kg or more: 53.2 mg twice daily

Initial Authorization Criteria

1. Is the request for continuation of therapy with the same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member 6 years of age or older?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have a documented diagnosis of Duchenne muscular dystrophy (DMD) as confirmed by genetic testing? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is the member currently receiving corticosteroids for treatment of DMD at a stable dose for at least six months and will continue with corticosteroid therapy? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Is the member ambulatory? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Is the medication being prescribed by, or in consultation with, a provider who specializes in the management of Duchenne muscular dystrophy?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Last Reviewed: 9/20/24, 9/19/25
Effective Date: 10/15/24

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (within past year) provided with documentation of clinical response to prior therapy received?
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the medication being prescribed by, or in consultation with, a provider who specializes in the management of Duchenne muscular dystrophy?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. DUVYZAT (givinostat hydrochloride) oral suspension [prescribing information]. Madrid, Spain: Italfarmaco S.A.; 2024.
2. Drugs@FDA: FDA Approved Drug Products. 2022. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 17 Jan. 2024].
3. Gloss D, Moxley RT 3rd, Ashwal S, Oskoui M. Practice guideline update summary: Corticosteroid treatment of Duchenne muscular dystrophy: Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2016;86(5):465-472.
4. Guglieri M, Clemens PR, Perlman SJ, et al. Efficacy and Safety of Vamorolone vs Placebo and Prednisone Among Boys With Duchenne Muscular Dystrophy: A Randomized Clinical Trial. JAMA Neurol. 2022;79(10):1005-1014.

Last Reviewed: 9/20/24, 9/19/25

Effective Date: 10/15/24

Egrifta (tesamorelin)
Prior Authorization Guidelines

Affected Medication(s)

- Egrifta SV subcutaneous injection
- Egrifta WR subcutaneous injection

FDA Approved Indication(s)

- Reduction of excess abdominal fat in HIV-infected adult patients with lipodystrophy

Dosing

- Egrifta SV: 1.4 mg subcutaneously once daily
- Egrifta WR: 1.28 mg subcutaneously once daily

Initial Authorization Criteria

1. Is the request for continuation of Egrifta (tesamorelin) therapy?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA-approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member currently 18 years of age or older?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have a confirmed diagnosis of HIV-associated lipodystrophy?
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member meet one of the following? (Provide supporting documentation)
    - Male: waist circumference is ≥ 95 cm (37.4 in) and waist-to-hip ratio is ≥ 0.94
    - Female: waist circumference is ≥ 94 cm (37 in) and waist-to-hip ratio is ≥ 0.88

    a. If yes, continue to #6
    b. If no, clinical review required
6. Is the member established on an antiretroviral regimen for at least 8 weeks? (Provide documentation of regimen)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Is the treatment being prescribed by, or in consultation with, an endocrinologist or a physician specializing in the treatment of HIV infection?
    a. If yes, approve for 6 months unless otherwise specified

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b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA-approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (within 1 year) provided with documentation of significant clinical response to therapy such as reduction in visceral adipose tissue measured by waist circumference or computed tomography (CT) scan? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the treatment being prescribed by, or in consultation with, an endocrinologist or a physician specializing in the treatment of HIV infection?
    a. If yes, approve for 12 months reauthorization unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Egrifta SV® injection [prescribing information]. Montreal, Quebec, Canada: Theratechnologies Inc.; December 2024.
2. Egrifta WR® injection [prescribing information]. Montreal, Quebec, Canada: Theratechnologies, Inc.; March 2025.
3. HIV and Lipodystrophy. US Department of Health and Human Services. Available at: https://aidsinfo.nih.gov/understanding-hiv-aids/fact-sheets/22/61/hiv-and-lipodystrophy. Accessed October 18, 2022.
4. Falutz J, Potvin D, Mamputu JC, et al. Effects of tesamorelin, a growth hormone-releasing factor, in HIV infected patients with abdominal fat accumulation: a randomized placebo-controlled trial with a safety extension. J Acquir Immune Defic Syndr. 2010;53(3):311-322.
5. Stanley T, Falutz J, Marsolais C, et al. Reduction in visceral adiposity is associated with an improved metabolic profile in HIV-infected patients receiving tesamorelin.
6. Clin Infect Dis. 2012 Jun;54(11):1642-51.Makimura H, Feldpausch MN, Rope AM, et al. Metabolic effects of a growth hormone-releasing factor in obese subjects with reduced growth hormone secretion: a randomized controlled trial. J Clin Endocrinol
Metab. 2012;97(12):4769-4779.

Last Reviewed: 11/16/22, 11/17/23, 9/20/24, 9/19/25
Effective Date: 1/1/23, 10/15/24, 10/31/25

Eltrombopag
Prior Authorization Guidelines

Affected Medication(s)

- Alvaiz (eltrombopag choline) oral tablet
- Eltrombopag olamine oral tablet
- Eltrombopag olamine oral suspension packet
- Promacta (eltrombopag olamine) oral tablet
- Promacta (eltrombopag olamine) oral suspension packet

FDA Approved Indication(s)

- Alvaiz
  - For the treatment of thrombocytopenia in adult and pediatric patients 6 years and older with persistent or chronic immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy
  - For the treatment of thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy
  - For the treatment of adult patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy
- Promacta, eltrombopag olamine:
  - For the treatment of thrombocytopenia in adult and pediatric patients 1 years and older with persistent or chronic immune (idiopathic) thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy
  - For the treatment of thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy
  - For the treatment of patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy
  - For first-line treatment of severe aplastic anemia, in combination with standard immunosuppressive therapy, in pediatric patients 2 years and older

Dosing

- Refer to respective package insert for dosing information

Initial Authorization Criteria

1. Is the request for continuation of the same therapy for the same indication?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2
2. Is the medication being requested for an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
   a. If yes, continue to #3
   b. If no, clinical review required
3. What is the diagnosis that the drug is being requested for?
   a. Persistent or chronic idiopathic thrombocytopenic purpura (ITP), continue to corresponding criteria
   b. Severe aplastic anemia, continue to corresponding criteria

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c. Chronic hepatitis C-associated thrombocytopenia, continue to corresponding criteria
d. Other indication, clinical review required

Persistent or Chronic Idiopathic Thrombocytopenic Purpura

1. Is the member's platelet count less than 30 x 10^9/L (30,000/mm)? (Provide platelet count for review)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Has the member had an inadequate response, intolerance, or contraindication to glucocorticoids AND splenectomy or rituximab or immunoglobulins for ITP (Inadequate response defined as platelet count fails to reach greater than or equal to 50 x 10^9/L (50,000/mm))? (Provide supporting documentation for prior treatment history)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the medication being prescribed by or in consultation with a hematologist?
    a. If yes, approve for 3 months unless otherwise specified
    b. If no, clinical review required

Severe Aplastic Anemia

1. Is the member's platelet count less than 30 x 10^9/L (30,000/mm)? (Provide CBC with differential and platelet count for review)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Has the member had a trial with an inadequate response, an intolerance, or contraindication to at least one prior immunosuppressive therapy (Example: cyclosporine)? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the medication being prescribed by or in consultation with a hematologist?
    a. If yes, approve for 4 months unless otherwise specified
    b. If no, clinical review required

Chronic Hepatitis C-associated Thrombocytopenia

1. Is the patient's platelet count less than 75 x 109/L (75,000/mm)? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is there documentation of compensated liver disease (Defined as Child-Pugh Class A)? (Provide supported lab for review)
    a. If yes, continue to #3
    b. If no, clinical review required

3. Is the medication being prescribed by or in consultation with a hepatologist or ID specialist?
    a. If yes, approve for 2 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (within previous 6 months) and supporting labs received with documentation meeting one of the following? (Provide supporting documentation including lab results for review)
    - Confirmed diagnosis of idiopathic thrombocytopenic purpura with platelet count greater than or equal to 50 x 10^9/L (50,000/mm)
    - Confirmed diagnosis of severe aplastic anemia with platelet count increases to 20 x 10^9/L above baseline OR stable platelet counts without transfusion for 8 or more weeks or hemoglobin increases by > 1.5 g/dL OR ANC increases 100% or ANC increase > 0.5 x10^9/L
    - Confirmed diagnosis of chronic hepatitis C-associated thrombocytopenia with platelet count increase to greater than or equal to 90 x 10^9/L (90,000/mm))

    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the medication being prescribed by or in consultation with an appropriate specialist for the indicated diagnosis?
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Promacta® (eltrombopag) [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. June 2025.
2. Alvaiz™ (eltrombopag) [Prescribing Information]. Parsippany, NJ: Teva Pharmaceuticals. July 2024.
3. Arnold, DM, Cuker A. Immune thrombocytopenia (ITP) in adults: Second-line and subsequent therapies. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed February 3, 2025.
4. Afdhal NH, Dusheiko GM, Giannini EG, et al. Eltrombopag increases platelet numbers in thrombocytopenic patients with HCV infection and cirrhosis, allowing for effective antiviral therapy. Gastroenterology. 2014 Feb;146(2):442-52.e1.
5. Kulasekararaj A, Cavenagh J, Dokal I, et al. Guidelines for the diagnosis and management of adult aplastic anaemia: A British Society for Haematology Guideline. *Br J Haematol*. 2024;204(3):784-804.

Last Reviewed: 11/7/18, 5/20/20, 5/18/22, 7/21/23, 3/15/24, 3/21/25, 7/18/25
Effective Date: 1/1/19, 7/1/20, 7/15/22, 4/15/24, 8/1/25

Enspryng® (satralizumab-mwge)
Prior Authorization Guidelines

Affected Medication(s)

- Enspryng subcutaneous injection solution

FDA Approved Indication(s)

- Treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive

Dosing

- Recommended loading dose for first three administrations is 120mg by subcutaneous injection at weeks 0, 2, and 4, followed by maintenance dosage of 120mg every four weeks

Initial Authorization Criteria

1. Is the request for continuation of a previously approved Enspryng (satralizumab-mwge) prior authorization with the same indication as the previous approval?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the treatment being prescribed by, or in consultation with, a neurologist?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member currently have documented diagnosis of neuromyelitis optica spectrum disorder (NMOSD) and are they anti-aquaporin-4 (AQP4) antibody positive? (Provide supporting documentation of diagnosis and AQP4 status)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is the member 18 years of age or older?
    a. If yes, continue to #6
    b. If no, clinical review required
6. Has the member previously trialed rituximab with inadequate response, intolerance, or contraindication? (Provide supporting documentation)
    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

Last Reviewed: 1/20/21, 1/19/22, 3/16/22, 3/17/23, 1/19/24, 1/17/25
Effective Date: 3/1/21, 4/15/22, 3/1/24, 2/1/25

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the treatment being prescribed by, or in consultation with, a neurologist?
    a. If yes, continue to #3
    b. If no, clinical review required
3. Were updated chart notes (within the past 6 months) provided with documentation of significant clinical response? (Provide supporting documentation)
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. ENSPRYNG™ (satralizumab-mwge) injection,solution, [package insert]. San Francisco, CA: Genentech, Inc.; 2023.
2. Kümpfel T, Giglhuber K, Aktas O, et al. Update on the diagnosis and treatment of neuromyelitis optica spectrum disorders (NMOSD) - revised recommendations of the Neuromyelitis Optica Study Group (NEMOS). Part II: Attack therapy and long-term management [published correction appears in J Neurol. 2024 Jun;271(6):3702-3707. doi: 10.1007/s00415-024-12288-2]. J Neurol. 2024;271(1):141-176.
3. Sellner, Johann, et al. "EFNS guidelines on diagnosis and management of neuromyelitis optica." European journal of neurology 17.8 (2010): 1019-1032.
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Last Reviewed: 1/20/21, 1/19/22, 3/16/22, 3/17/23, 1/19/24, 1/17/25
Effective Date: 3/1/21, 4/15/22, 3/1/24, 2/1/25

Epidiolex® (cannabidiol)
Prior Authorization Guidelines

Affected Medication(s)

- Epidiolex (cannabidiol) solution

FDA Approved Indication(s)

- Treatment of seizures associated with Lennox-Gastaut syndrome (LGS), Dravet syndrome (DS), or tuberous sclerosis complex (TSC) in patients 1 year of age and older

Dosing

- Starting dose: 2.5mg/kg taken twice daily for one week
- Maintenance dose:
  - LGS or DS: 5mg/kg twice daily up to maximum dose 10mg/kg twice daily
  - TSC:12.5 mg/kg twice daily

Initial Authorization Criteria

1. Is the request for continuation of Epidiolex (cannabidiol) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
   a. If yes, continue to #3
   b. If no, clinical review required
3. Is the member 1 year of age or older?
   a. If yes, continue to #4
   b. If no, clinical review required
4. Is the member currently taking at least one other antiepileptic drug with inadequate response? (Provide documentation of antiepileptic therapy and seizure frequency)
   a. If yes, continue to #5
   b. If no, clinical review required
5. Is Epidiolex being requested for management of Lennox-Gastaut syndrome (LGS)?
   a. If yes, continue to #6
   b. If no, continue to #7
6. Has the member had a previous trial with inadequate response, intolerance, or contraindication to clobazam? (Provide documentation of trial with inadequate response)
   a. If yes, continue to #7
   b. If no, clinical review required
7. Will the member continue therapy with at least one other antiepileptic drug in combination with Epidiolex (cannabidiol)?

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a. If yes, continue to #8
b. If no, clinical review required

8. Is the medication prescribed by, or in consultation with, a neurologist?

    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)

    a. If yes, continue to #2
    b. If no, clinical review required

2. Were updated chart notes (within 1 year) with documentation of significant clinical response to prior therapy received? (Significant clinical response is defined by a decrease in seizure frequency compared to pre- treatment baseline)

    a. If yes, continue to #3
    b. If no, clinical review required

3. Is the treatment being prescribed by, or in consultation with, a neurologist?

    a. If yes, approve for 12 months reauthorization
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. EPIDIOLEX (cannabidiol) oral solution [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; July 2025.
2. National Institute of Neurological Disorders and Stroke. Dravet Syndrome Information Page. Available at: https://www.ninds.nih.gov/Disorders/All-Disorders/Dravet-Syndrome-Information-Page.
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Last Reviewed: 1/16/19, 5/19/21, 11/16/22, 9/15/23, 9/20/24, 9/19/25
Effective Date: 2/1/19, 6/15/21, 1/1/23, 10/15/24

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Erythropoiesis Stimulation Agents
Prior Authorization Guidelines

Affected Medication(s)

- Aranesp (darbepoetin alfa) injection solution
- Epogen (epoetin alfa) injection solution
- Procrit (epoetin alfa) injection solution
- Retacrit (epoetin alfa-epbx) injection solution
- Mircera (methoxy polyethylene glycol-epoetin beta) injection solution
- Jesduvroq (daprodustat) oral tablet
- Vafseo (vadadustat) oral tablet

FDA Approved Indication(s)

Epogen, Procrit, Retacrit:

- Treatment of anemia due to chronic kidney disease (CKD), including patients on dialysis and not on dialysis to decrease the need for red blood cell (RBC) transfusion
- Treatment of anemia due to zidovudine administered at ≤ 4200 mg/week in patients with HIV-infection with endogenous serum erythropoietin levels of ≤ 500 mUnits/mL
- Treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy
- To reduce the need for allogeneic red blood cell (RBC) transfusions among patients with perioperative hemoglobin > 10 to ≤ 13 g/dL who are at high risk for perioperative blood loss from elective, non-cardiac, nonvascular surgery. Epoetin alfa is not indicated for patients who are willing to donate autologous blood pre-operatively

Aranesp:

- Treatment of anemia due to chronic kidney disease (CKD), including patients on dialysis and patients not on dialysis
- Treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy

Mircera:

- Treatment of anemia associated with chronic kidney disease (CKD) in adult patient on dialysis and not on dialysis and pediatric patients 3 months to 17 years of age on dialysis or not on dialysis or are converting from another ESA after their hemoglobin level was stabilized with an ESA

Jesduvroq

- Treatment of anemia due to chronic kidney disease (CKD) in adults who have been receiving dialysis for at least four months

Vafseo

- Treatment of anemia due to chronic kidney disease (CKD) in adults who have been receiving dialysis for at least three months

Dosing

- Refer to package insert for specific dosing recommendations

Initial Authorization Criteria

Last Reviewed: 10/17/18, 7/21/21, 3/17/23, 3/15/24, 1/17/25
Effective Date: 1/1/19, 9/1/21, 4/15/24, 2/1/25

1. Is the request for continuation of therapy with the same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the medication being requested for an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Have serum ferritin, transferrin saturation, hemoglobin (Hb), and hematocrit (Hct) labs been completed within 30 days of planned administration? (Provide labs for review)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have a serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20%? (Provide labs for review)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have a hemoglobin (Hb) < 10 g/dL and/or Hematocrit (Hct) < 30%?
    a. If yes, continue to #7
    b. If no, continue to #6
6. Is the medication being requested to reduce allogeneic blood transfusions in elective, non-cardiac, non-vascular surgery?
    a. If yes, continue to #7
    b. If no, clinical review required
7. Have other causes of anemia (e.g. hemolysis, bleeding, vitamin deficiency, etc.) been ruled out?
    a. If yes, continue to #8
    b. If no, clinical review required
8. Is Retacrit (epoetin alfa-apbx) being requested?
    a. If yes, continue to #10
    b. If no, continue to #9
9. Does the member have a contraindication or history of intolerance to a trial of Retacrit (epoetin alfa-apbx)? (Provide supporting documentation of contraindication and/or intolerance)
    a. If yes, continue to #10
    b. If no, clinical review required
10. Which indication is epoetin alfa being requested for? (Record submitted diagnosis and review all criteria based on the submitted diagnosis)
    a. Anemia secondary to myelodysplastic syndrome (MDS), continue to corresponding criteria
    b. Anemia secondary to Myeloproliferative Neoplasms (MPN) – Myelofibrosis, continue to corresponding criteria
    c. Anemia secondary to chemotherapy treatment, continue to corresponding criteria
    d. Anemia secondary to chronic kidney disease, approve for 3 months unless otherwise specified
    e. Anemia secondary to zidovudine treated, HIV-infected patients, continue to corresponding criteria

f. Reduction of allogeneic blood transfusions in elective, non-cardiac, non-vascular surgery, continue to corresponding criteria
g. Other Indication, continue to corresponding criteria

Anemia secondary to myelodysplastic syndrome (MDS)

1. Does the member have symptomatic anemia? (Examples include: exertional dyspnea, dyspnea at rest, fatigue, lethargy, confusion, etc.) (Provide supporting documentation of symptoms)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the member's endogenous serum erythropoietin level ≤ 500 mUnits/mL? (Provide serum erythropoietin level for review)
    a. If yes, approve for 45 days unless otherwise specified
    b. If no, clinical review required

Anemia secondary to Myeloproliferative Neoplasms (MPN) – Myelofibrosis

1. Is the members endogenous serum erythropoietin level < 500 mUnits/mL? (Provide serum erythropoietin level for review)
    a. If yes, approve for 45 days unless otherwise specified
    b. If no, clinical review required

Anemia secondary to chemotherapy treatment

1. Is the member receiving concurrent myelosuppressive chemotherapy for non-myeloid malignancies?
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the therapy intention of the chemotherapy curative?
    a. If yes, clinical review required
    b. If no, continue to #3
3. Are there two or more additional months of planned chemotherapy remaining? (Provide documentation of treatment plan)
    a. If yes, approve for 6 months or until completion of chemotherapy course, whichever is less
    b. If no, clinical review required

Anemia secondary to zidovudine treated, HIV-infected patients

1. Does the member have an endogenous serum erythropoietin level ≤ 500 mUnits/mL AND is the member currently receiving zidovudine administered at ≤ 4200 mg/week? (Provide serum erythropoietin level or current zidovudine dose for review)
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Reduction of allogeneic blood transfusions in elective, non-cardiac, non-vascular surgery

1. Does the member have a hemoglobin (Hb) level between 10 g/dL and 13 g/dL and/or is the hematocrit (Hct) between 30% and 39%? (Provide supporting documentation with Hb and Hct lab values for review)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the surgery high-risk for perioperative blood loss? (i.e. expected to lose >2 units of blood)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is patient unwilling to donate autologous blood pre-operatively?
    a. If yes, approve for 45 days unless otherwise specified
    b. If no, clinical review required

Other Indications

1. Is the requested use supported by major compendia? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Has the member tried and had an inadequate response OR dose the member have a contradiction to ALL standard treatment options for the requested indication? (Provide all prior treatment history, contraindication if appropriate, and treatment plan)
    a. If yes, approve for 45 days unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Was the last dose of the requested drug less than 60 days ago? (Provide date of last dose)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Were updated chart notes (within 1 year) provided with documentation of significant clinical response to therapy? (Provide documentation of clinical response)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is there documentation of an absence of unacceptable toxicity from the drug? (Examples include severe cardiovascular events (stroke, myocardial infarction, thromboembolism, uncontrolled hypertension), tumor progression or recurrence in members with cancer, seizures, pure red cell aplasia, severe cutaneous reactions (erythema multiforme, Stevens-Johnson syndrome/toxic epidermal necrolysis), “gasping syndrome” (central nervous system depression, metabolic acidosis, gasping respirations) due to benzyl alcohol preservative, etc.)
    a. If yes, continue to #5
    b. If no, clinical review required

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5. Were lab values obtained within 30 days of the date of administration (unless otherwise indicated)? (Provide updated lab result for review)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Does the member have adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% measured within the previous 3 months? (Provide lab result for review)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Have other causes of anemia (e.g. hemolysis, bleeding, vitamin deficiency, etc.) been ruled out?
    a. If yes, continue to #8
    b. If no, clinical review required
8. Does the member meet the clinical requirements for their corresponding diagnosis as defined below? (Provide supporting documentation)
    - Anemia secondary to myelodysplastic syndrome (MDS) with Hemoglobin (Hb) < 12 g/dL and/or Hematocrit (Hct) < 36%
    - Anemia secondary to myeloproliferative neoplasms (MF, post-PV myelofibrosis, post-ET myelofibrosis) with Hemoglobin (Hb) < 10 g/dL and/or Hematocrit (Hct) < 30%
    - Reduction of allogeneic blood transfusions in elective, non-cardiac, non-vascular surgery with Hemoglobin (Hb) between 10 g/dL and 13 g/dL and/or Hematocrit (Hct) between 30% and 39%
    - Anemia secondary to palliative myelosuppressive chemotherapy for non-myeloid malignancies with Hemoglobin (Hb) <10 g/dL and/or Hematocrit (Hct) < 30% and requesting epoetin alfa to be used concurrently with chemotherapy with minimum two additional months of therapy remaining
    - Anemia secondary to zidovudine treated, HIV-infected patients with Hemoglobin (Hb) < 12 g/dL and/or Hematocrit (Hct) < 36% AND receiving zidovudine administered at ≤ 4200 mg/week
    - Anemia secondary to chronic kidney disease with hemoglobin (Hb) <12 g/dL and/or hematocrit (Hct) <36% in pediatric patients OR hemoglobin (Hb) <11 g/dL and/or hematocrit (Hct) <33% in adult patients
    - Hemoglobin (Hb) < 11 g/dL and/or Hematocrit (Hct) < 33% for all other indications
    - Use supported my major compendia

    a. If yes, approve for 1 year unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Procrit [package insert]. Horsham, PA; Janssen Products, LP; September 2017.
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Last Reviewed: 10/17/18, 7/21/21, 3/17/23, 3/15/24, 1/17/25
Effective Date: 1/1/19, 9/1/21, 4/15/24, 2/1/25

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18. Reiter PD, Rosenberg AA, Valuck RJ. Factors associated with successful epoetin alfa therapy in premature infants. Ann Pharmacother 2000; 34:433-439.

Evenity® (romosozumab-aqqg)
Prior Authorization Guidelines

Affected Medication(s)

- Evenity subcutaneous solution

FDA Approved Indication(s)

- 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.

Dosing

- 210 mg subcutaneously every month (limited to 12 months cumulative use per lifetime)

Initial Authorization Criteria

1. Is the request for continuation of Evenity therapy?
    a. If yes, clinical review required
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member 18 years of age or older?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the member a postmenopausal female? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have osteoporosis defined as one of the following? (Provide supporting documentation including DXA report within the last 2 years)
    - Hip DXA (femoral neck or total hip) or lumbar spine T-score less than or equal to -2.5 and/or forearm DXA 33% (one-third) radius
    - T-score less than or equal to -1 or low bone mass AND a history of fragility fracture to the hip or spine
    - T-score between -1 and -2.5 with a FRAX 10-year probability for major fracture ≥20% or hip fracture ≥3%

    a. If yes, continue to #6
    b. If no, clinical review required
6. Does the member have a high risk for fracture as defined by one or more of the following? (Provide supporting documentation)

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- History of an osteoporotic fracture as an adult
- Parental history of hip fracture
- Low BMI
- Rheumatoid arthritis
- Alcohol intake of 3 or more drinks per day
- Current smoking
- History of oral glucocorticoids ≥ 5 mg/day of prednisone (or equivalent) for > 3 months in lifetime
- Early Menopause

a. If yes, continue to #7
b. If no, clinical review required

7. Does the member have five years of cumulative treatment with bisphosphonates? (Provide all prior therapy history)

    a. If yes, continue to #11
    b. If no, continue to #8

8. Does the member have a trial with insufficient response to at least 12 months of bisphosphonate therapy (oral or IV) as defined by a decrease in T-score from baseline or member had a fracture while on bisphosphonate therapy? (Provide past relevant medication list with documentation of response to therapy)

    a. If yes, continue to #11
    b. If no, continue to #9

9. Does the member have a contraindication or intolerance to oral bisphosphonates? (Provide supporting documentation)

    a. If yes, continue to #10
    b. If no, clinical review required

10. Does the member have a contraindication or intolerance to IV bisphosphonates? (Provide supporting documentation)

    a. If yes, continue to #11
    b. If no, clinical review required

11. Does the member have a previous trial with insufficient response to at least 12 months of a preferred denosumab agent as defined by a decrease in T-score from baseline or member had a fracture while on denosumab OR an intolerance or contraindication to denosumab? (Provide past relevant medication list with documentation of response to therapy)

    a. If yes, continue to #12
    b. If no, clinical review required

12. Is the member currently supplementing with at least 1,000 mg of calcium and 400 IU of vitamin D daily that will be continued throughout therapy? (Provide list of current relevant medications)

    a. If yes, continue to #13
    b. If no, clinical review required

13. Is the requested medication being prescribed by, or in consultation with, an endocrinologist, rheumatologist, or specialist experienced in treatment of osteoporosis?

    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm
2. EVENITY (romosozumab-aqqg) Injectable solution [package insert]. Thousand Oaks, CA: Amgen Inc.; April 2025.
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Last Reviewed: 11/20/19, 5/19/21, 5/18/22, 5/19/23, 5/17/24, 5/16/25, 9/19/25
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Evrysdi® (risdiplam)
Prior Authorization Guidelines

Affected Medication(s)

- Evrysdi (risdiplam) oral powder for solution
- Evrysdi (risdiplam) oral tablet

FDA Approved Indication(s)

- Treatment of spinal muscular atrophy (SMA) in pediatric and adult patients

Dosing

- Less than 2 months of age: 0.15 mg/kg/day
- 2 months to less than 2 years of age: 0.2 mg/kg/day
- 2 years of age and older, weighing less than 20kg: 0.25 mg/kg/day
- 2 years of age and older, weight 20kg or more: 5 mg/day

Initial Authorization Criteria

1. Is the request for renewal of a previously approved Evrysdi (risdiplam) prior authorization with the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA-approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member have a confirmed diagnosis of SMA type 1, 2, or 3, with four or fewer copies of SMN2? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have advanced SMA disease defined as ventilator dependence >16 hours/day or tracheostomy? (Provide supporting documentation)
    a. If yes, clinical review required
    b. If no, continue to #5
5. Was baseline motor function assessed by one of the following? (Provide supporting documentation)
    - Hammersmith Infant Neurological Examination (HINE-2)
    - Motor Function Measure 32 (MFM32)
    - Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
    - Upper Limb Module (ULM)
    - Revised Upper Limb Module (RULM)
    - Hammersmith Functional Motor Scale (HFMS)
    - Bayley Scales of Infant and Toddler Development – Third Edition (BSID-III)

    a. If yes, continue to #6

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b. If no, clinical review required

6. Does the member have a history of prior treatment with Zolgensma or will this medication be used in combination with Spinraza?
    a. If yes, clinical review required
    b. If no, continue to #7
7. Is the requested medication being prescribed by, or in consultation with, a neurologist?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is Evrysdi (risdiplam) being requested for an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (within 1 month of reauthorization request date) with documentation of significant clinical response to therapy defined as improvement from baseline in one of the following received? (Provide supporting documentation)
    - Hammersmith Infant Neurological Examination (HINE-2)
    - Motor Function Measure 32 (MFM32)
    - Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
    - Upper Limb Module (ULM)
    - Revised Upper Limb Module (RULM)
    - Hammersmith Functional Motor Scale (HFMS)
    - Bayley Scales of Infant and Toddler Development – Third Edition (BSID-III)

    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the requested medication being prescribed by, or in consultation with, a neurologist?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Drugs@FDA: FDA Approved Drug Products. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 22 Mar 2023].
2. EVRYSDI™ (risdiplam)oral solution [package insert]. San Francisco, CA: Genentech, Inc 2022.

Last Reviewed: 3/17/21, 5/18/22, 5/19/23, 5/17/24, 3/21/25
Effective Date: 5/1/21, 7/15/22, 7/1/23, 6/15/24, 4/1/25

3. Glascock, Jacqueline, et al. "Treatment algorithm for infants diagnosed with spinal muscular atrophy through newborn screening." Journal of neuromuscular diseases 5.2 (2018): 145-158.
4. Glascock, Jacqueline, et al. "Revised recommendations for the treatment of infants diagnosed with spinal muscular atrophy via newborn screening who have 4 copies of SMN2." Journal of neuromuscular diseases 7.2 (2020): 97.
5. Michelson, David, et al. "Evidence in focus: Nusinersen use in spinal muscular atrophy: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology." Neurology 91.20 (2018): 923-933.

Last Reviewed: 3/17/21, 5/18/22, 5/19/23, 5/17/24, 3/21/25
Effective Date: 5/1/21, 7/15/22, 7/1/23, 6/15/24, 4/1/25

Fertility Agents
Prior Authorization Guidelines

Affected Medication(s)

- Cetrotide (cetrorelix acetate) subcutaneous powder for solution
- cetrorelix acetate subcutaneous powder for solution
- chorionic gonadotropin intramuscular powder for solution
- clomiphene oral tablet
- Crinone 8% (progesterone) vaginal gel
- Endometrin (progesterone) vaginal tablet
- Follistim AQ (follitropin beta) subcutaneous solution
- Fyremadel (ganirelix acetate) subcutaneous solution
- ganirelix acetate subcutaneous solution
- Gonal-F (follitropin alfa) subcutaneous powder for solution
- Menopur (menotropins) subcutaneous powder for solution
- Milophene (clomiphene) tablet
- Novarel (chorionic gonadotropin) intramuscular powder for solution
- Ovidrel (chorionic gonadotropin alfa, recombinant) subcutaneous solution
- Pregnyl (chorionic gonadotropin) intramuscular powder for solution
- Progesterone micronized vaginal insert

FDA Approved Indication(s)

- Refer to package insert for specific indications for each medication

Dosing

- Refer to corresponding package insert for specific dosing recommendations

Fertility Benefit Note

- Services for removal and preservation of oocytes and sperm prior to gonadotoxic treatment are not subject to the lifetime infertility maximum. The Plan covers these services at the applicable Member Cost Share when Prior Authorization is obtained by the Plan

Authorization Criteria

1. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)

    a. If yes, continue to #2
    b. If no, clinical review required

2. Does the member meet one or more of the following conditions? (**Please note:** Per plan provisions, coverage of medications under the fertility benefit is limited to services rendered by OHSU Fertility Clinic)

    Female or assigned female at birth:
    - 35 years of age or younger with failure to conceive after regular unprotected sexual intercourse for 1 year or more

Last Reviewed: 12/19/18, 4/2/19, 5/19/21, 1/1/22, 1/20/23, 1/19/24, 7/19/24, 7/18/25, 11/21/25
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- 35 years of age or older with failure to conceive after regular unprotected sexual intercourse for 6 months or more
- Requiring medical assistance to conceive (e.g. oligoovulation due to PCOS) including same-sex couples and single persons using partner or donor gametes
- Prior diagnosis of infertility
- Recurrent pregnancy loss defined as two or more pregnancy losses (miscarriages) prior to 20 weeks gestation
- Prior cycle of in vitro fertilization or intracytoplasmic sperm injection with failure
- Premature ovarian insufficiency or decreased ovarian reserve due to gonadotoxic therapy
- History of bilateral oophorectomy
- Carrier of a genetic disease (or affected by a genetic disease) and/or has a partner who is a carrier of a genetic disease (or affected by a genetic disease) and at risk of having a child with a genetic disease

Male partner or assigned male at birth:

- Infertility due to gonadotoxic therapy (e.g., orchiectomy, chemotherapy, or lupus therapy)
- Non-obstructive azoospermia or severe oligospermia
- Paraplegia and sperm retrieval required to achieve pregnancy
- Carrier of a genetic disease (or affected by a genetic disease) and/or has a partner who is a carrier of a genetic disease (or affected by a genetic disease) and at risk of having a child with a genetic disease

a. If yes, approve for 12 months or up to duration of benefit
b. If no, continue to #3

3. Is the male partner (or assigned male at birth) HIV positive and meet BOTH the following requirements?

- Adherent with antiretroviral therapy regimen
- Washed sperm needed for insemination to prevent HIV transmission to female partner

a. If yes, approve for 12 months or up to duration of benefit
b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Cetrotide (cetrorelix acetate) [Prescribing Information]. Rockland, MA: EMD Serono, Inc. June 2024.
2. Chorionic gonadotropin [Prescribing Information]. Lake Zurich, IL: Fresenius Kabi USA, LLC. July 2017.
3. Clomiphene [Prescribing Information]. Chestnut Ridge, NY: Par Pharmaceuticals, Inc. October 2017.
4. Crinone (progesterone) [Prescribing Information]. North Chicago, IL: Abbvie. May 2024.
5. Endometrin (progesterone) [Prescribing Information]. Parsippany, NJ: Ferring Pharmaceuticals Inc. March 2025.

Last Reviewed: 12/19/18, 4/2/19, 5/19/21, 1/1/22, 1/20/23, 1/19/24, 7/19/24, 7/18/25, 11/21/25
Effective Date: 1/1/19, 4/2/19, 7/1/21, 1/1/22, 3/15/23, 3/1/24, 8/15/24, 1/1/26

6. Follistim AQ (follitropin beta) [Prescribing Information]. Jersey City, NJ: Organon USA Inc. February 2025.
7. Ganirelix acetate [Prescribing Information]. Whitehouse Station, NJ: Organon USA Inc. May 2018.
8. Gonal-F (follitropin alfa) [Prescribing Information]. Rockland, MA: EMD Serono, Inc. July 2024.
9. Menopur (menotropins) [Prescribing Information]. Parsippany, NJ: Ferring Pharmaceuticals Inc. November 2024.
10. Novarel (chorionic gonadotropin) [Prescribing Information]. Parsippany, NJ: Ferring Pharmaceuticals Inc. November 2024.
11. Ovidrel (chorionic gonadotropin alfa, recombinant) [Prescribing Information]. Rockland, MA: EMD Serono, Inc. December 2023.
12. Pregnyl (chorionic gonadotropin) [Prescribing Information]. Jersey City, NJ: Organon USA Inc. March 2025.

Last Reviewed: 12/19/18, 4/2/19, 5/19/21, 1/1/22, 1/20/23, 1/19/24, 7/19/24, 7/18/25, 11/21/25
Effective Date: 1/1/19, 4/2/19, 7/1/21, 1/1/22, 3/15/23, 3/1/24, 8/15/24, 1/1/26

Filspari (sparsentan), Vanrafia (atrasentan)
Prior Authorization Guidelines

Affected Medication(s)

- Filspari (sparsentan) oral tablet
- Vanrafia (atrasentan) oral tablet

FDA Approved Indication(s)

- To reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression

Dosing

- Filspari: 200 mg once daily for 14 days, then increase to the recommended dose of 400 mg daily if tolerated
- Vanrafia: 0.75 mg orally once daily

Initial Authorization Criteria

1. Is the request for continuation of the same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA-approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member 18 years of age or older?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have documentation of primary immunoglobulin A nephropathy as proven by biopsy? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have documentation of estimated glomerular filtration rate (eGFR) of 30 mL/min/1.73m^2 or greater? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Does the member have documentation of a total urine protein greater than or equal to 1 gram/day? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, clinical review required

Last Reviewed: 5/19/23, 5/17/24, 5/16/25
Effective Date: 7/15/23, 6/15/24, 6/1/25

7. Did the member have an inadequate response to a 12 week trial of the following classes of medications at maximally indicated doses unless intolerance or contraindication is present to all three classes? (Provide supporting documentation)

    - Angiotensin-converting enzyme inhibitor (i.e. lisinopril, benazepril, enalapril); OR
    - Angiotensin receptor blocker (i.e. irbesartan, losartan); AND
    - Sodium-glucose Cotransporter-2 inhibitor (i.e. Farxiga)

    a. If yes, continue to #8
    b. If no, clinical review is required

8. Is the requested medication being prescribed by, or in consult with, a nephrologist?

    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA-approved or major compendia supported indication? (Provide documentation of diagnosis)

    a. If yes, continue to #2
    b. If no, clinical review required

2. Were updated chart notes (within past year) provided with documentation of significant clinical response to prior therapy received? (i.e. reduction in UPCR or UACR, increased or stable eGFR)

    a. If yes, continue to #3
    b. If no, clinical review required

3. Is the requested medication being prescribed by, or in consult with, a nephrologist?

    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Filspari (sparsentan) tablets, [package insert]. San Diego, CA: Travere Therapeutics, Inc; April 2025.
2. VANRAFIA™ (atrasentan)oral tablet [package insert]. East H anover, NJ: Novartis Pharmaceuticals; 2025.
3. Drugs@FDA: FDA Approved Drug Products. 2023. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 22 Mar. 2023].
4. KDIGO Glomerular Diseases Work Group. 2021. KDIGO 2021 Clinical Practice Guideline for the Management of Glomerular Diseases. Kidney International Supplements. 2021;11(2):1-221.
5. Wheeler, D. C., Toto, R. D., Stefansson, B. V., Jongs, N., Chertow, G. M., Greene, T., & Committees, D. C. T. (2021). A pre-specified analysis of the DAPA-CKD trial demonstrates the effects of dapagliflozin on major adverse kidney events in patients with IgA nephropathy. Kidney International, 100(1), 215-224.

Last Reviewed: 5/19/23, 5/17/24, 5/16/25
Effective Date: 7/15/23, 6/15/24, 6/1/25

Filsuvez (birch triterpenes)
Prior Authorization Guidelines

Affected Medication(s)

- Filsuvez (birch triterpenes) topical gel

FDA Approved Indication(s)

- Treatment of wounds associated with dystrophic and junctional epidermolysis bullosa (EB) in adult and pediatric patients 6 months of age and older

Dosing

- Apply 1 mm layer to the affected wound surface at dressing changes. Discard tube after use.

Initial Authorization Criteria

1. Is the request for continuation of therapy with the same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member 6 months of age or older?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have a diagnosis of dystrophic OR junctional epidermolysis bullosa as confirmed by genetic testing? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have partial-thickness wounds that have been present for longer than 21 days and less than 9 months and do not show signs of infection? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Is the treatment being prescribed by, or in consultation with, a dermatologist?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #2

Last Reviewed: 7/19/24, 7/18/25
Effective Date: 8/15/24

b. If no, clinical review required

2. Were updated chart notes (within past year) provided with documentation of significant clinical response to therapy received? (i.e. decrease in wound size, decrease in wound pain or itching)

   a. If yes, continue to #3
   b. If no, clinical review required

3. Is the treatment being prescribed by, or in consultation with, a clinical geneticist or neurologist?

   a. If yes, approve for 12 months
   b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. FILSUVEZ (birch triterpenes) topical gel [package insert]. Wahlstedt, Germany: Lichtenheldt GmbH Pharmazeutische Fabrik; February 2024.
2. Drugs@FDA: FDA Approved Drug Products. 2024. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 6 Feb. 2024].
3. Has C, El Hachem M, Bučková H, et al. Practical management of epidermolysis bullosa: consensus clinical position statement from the European Reference Network for Rare Skin Diseases. J Eur Acad Dermatol Venereol. 2021;35(12):2349-2360.
4. Kern JS, Schwieger-Briel A, Löwe S, Sumeray M, Davis C, Martinez AE. Oleogel-S10 Phase 3 study "EASE" for epidermolysis bullosa: study design and rationale. Trials. 2019;20(1):350. Published 2019 Jun 11.

Fintepla® (fenfluramine)
Prior Authorization Guidelines

Affected Medication(s)

- Fintepla oral solution

FDA Approved Indication(s)

- Treatment of seizures associated with Dravet syndrome and Lennox-Gastaut syndrome in patients 2 years of age and older

Dosing

- Initial starting dose: 0.1 mg/kg twice daily, which can be increased weekly based on efficacy and tolerability
- Patients not on concomitant Diacomit (stiripentol): The maximum daily maintenance dosage of Fintepla is 0.35 mg/kg twice daily (maximum daily dosage of 26 mg)
- Patients taking concomitant Diacomit (stiripentol) plus clobazam: The maximum daily maintenance dosage of Fintepla for patients taking these medications is 0.2 mg/kg twice daily (maximum daily dosage of 17 mg)

Initial Authorization Criteria

1. Is the request for continuation of a previously approved Fintepla (fenfluramine) prior authorization and indication is for the same as previous approval?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member age 2 years or older?
    a. If yes, continue #4
    b. If no, clinical review required
4. Will the member continue therapy with at least one other antiepileptic drug or antiepileptic treatment (i.e. vagal nerve stimulation or ketogenic diet) in combination with Fintepla? (Provide treatment regimen)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is the treatment being prescribed by, or in consultation with, a neurologist?
    a. If yes, continue to #6
    b. If no, clinical review required
6. What is the indication Fintepla is being requested for?
    a. Dravet syndrome, continue to corresponding criteria
    b. Lennox-Gastaut syndrome, continue to corresponding criteria

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Effective Date: 11/15/20, 11/1/21, 3/15/23, 3/1/24

Dravet Syndrome

1. Has the member previously trialed valproate, topiramate, and clobazam (unless intolerance or contraindication provided) and continued to have 4 or more convulsive seizures per month despite optimized therapy? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Has the member previously had an inadequate response, intolerance or contraindication to Diacomit in combination with clobazam? (Provide supporting documentation)
    a. If yes, approve for 6 months
    b. If no, clinical review required

Lennox-Gastaut Syndrome

1. Has the member previously had an inadequate response, intolerance or contraindication to at least two other antiseizure medications (i.e. felbamate, clobazam, lamotrigine, topiramate, valproic acid, levetiracetam, zonisamide, etc.)? (Provide supporting documentation)
    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (within the past 12 months) with documentation of at least a 50% decrease in the frequency of convulsive seizures compared to pre-therapy baseline? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Has the member continued therapy with at least one other antiepileptic drug or antiepileptic treatment (i.e. vagal nerve stimulation or ketogenic diet) in combination with Fintepla? (Provide treatment regimen)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the treatment being prescribed by or in consultation with a neurologist?
    a. If yes, approve for 12 months reauthorization
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

Last Reviewed: 9/16/20, 9/15/21, 1/20/23, 1/19/24, 1/17/25
Effective Date: 11/15/20, 11/1/21, 3/15/23, 3/1/24

References:

1. FINTEPLA® (fenfluramine) oral solution [package insert]. Emeryville, CA: Zogenix, Inc; September 2023.
2. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 26 November. 2023].
3. Lagae, Lieven, et al. "Fenfluramine hydrochloride for the treatment of seizures in Dravet syndrome: a randomised, double-blind, placebo-controlled trial." The Lancet 394.10216 (2019): 2243-2254.
4. Nabbout, Rima, et al. "Fenfluramine for treatment-resistant seizures in patients with Dravet syndrome receiving stiripentol-inclusive regimens: a randomized clinical trial." JAMA neurology 77.3 (2020): 300-308.
5. National Institute for Health and Care Excellence; Epilepsies: Diagnosis and Management Clinical Guidelines. NICE Guideline. May 2021. Available at: https://www.nice.org.uk/guidance/cg137
6. Wilmhurst JM, Gaillard WD, Vinayan KP, et al. Summary of recommendations for the management of infantile seizures: Task force report for the ILAE commission of pediatrics. Epilepsia. 2015; 56(8):1185-1197
7. Wirrell, Elaine C., et al. "Optimizing the diagnosis and management of Dravet syndrome: recommendations from a North American consensus panel." Pediatric neurology 68 (2017): 18-34.
8. Asadi-Pooya AA. Lennox-Gastaut syndrome: a comprehensive review. Neurol Sci. 2018 Mar;39(3):403-414. doi: 10.1007/s10072-017-3188-y. Epub 2017 Nov 9. https://www.ncbi.nlm.nih.gov/pubmed/29124439
9. National Institute of Neurological Disorders and Stroke. Lennox-Gastaut Syndrome Information Page. Available at: https://www.ninds.nih.gov/Disorders/All-Disorders/Lennox-Gastaut-Syndrome-Information-Page.
10. Hancock EC, Cross JH. Treatment of Lennox-Gastaut syndrome. Cochrane Database of Systematic Reviews 2013, Issue 2. Art. No.: CD003277.

Last Reviewed: 9/16/20, 9/15/21, 1/20/23, 1/19/24, 1/17/25
Effective Date: 11/15/20, 11/1/21, 3/15/23, 3/1/24

Fuzeon® (enfuvirtide), Rukobia® (fostemsavir tromethamine) Prior Authorization Guidelines

Affected Medication(s)

- Fuzeon (enfuvirtide) subcutaneous solution
- Rukobia (fostemsavir tromethamine) oral tablet

FDA Approved Indication(s)

- **Fuzeon:** Treatment of HIV-1 infection, in combination with other antiretroviral agents, in treatment-experienced patients with evidence of HIV-1 replication despite ongoing antiretroviral therapy
- **Rukobia:** Treatment of HIV-1 infection, in combination with other antiretroviral agents, in heavily treatment-experienced adults with multidrug-resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations

Dosing

- Refer to corresponding package insert for specific dosing recommendations

Initial Authorization Criteria

1. Is the request for continuation of the same antiretroviral agent for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for an FDA approved or major compendia supported indication?
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member currently have documented resistance or contraindications to 3 or more different classes of antiretrovirals? (examples include: NRTIs, INSTIs, PIs, NNRTIs, CCR5 antagonist) (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Will the requested medication be taken in combination with an optimized antiviral background regimen including one or more other antiretroviral medications? (Provide treatment regimen)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is the treatment being prescribed by, or in consultation with, an infectious disease specialist or provider experienced in the treatment of HIV?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the requested indication Food and Drug Administration (FDA) approved or supported by major compendia?

Last Reviewed: 9/16/20, 9/15/21, 3/17/23, 3/15/24, 3/21/25
Effective Date: 11/15/20, 11/1/21, 6/1/23, 4/15/24, 4/1/25

a. If yes, continue to #2
b. If no, clinical review required

2. Were updated chart notes (within the past 6 months) provided with documentation of decreased viral load compared to pre-therapy baseline? (Provide supporting documentation)

    a. If yes, continue to #3
    b. If no, clinical review required

3. Will the requested medication continue to be taken in combination with an optimized antiviral background regimen including one or more other antiretroviral medications? (Provide treatment regimen)

    a. If yes, continue to #4
    b. If no, clinical review required

4. Is the treatment being prescribed by or in consultation with an infectious disease specialist or provider experienced in the treatment of HIV?

    a. If yes, approve for 12 months reauthorization
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. RUKOBIA (fostemsavir) oral extended-release tablet [package insert]. Triangle Park, NC: Viiv Healthcare; January 2022.
2. FUZEON (enfuvirtide) kit [package insert] South San Francisco, CA: Genentech, Inc; December 2016.
3. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 27 July. 2020].
4. HIV Clinical Guidelines for Adult and Adolescent ARV. Clinicalinfo.HIV.gov. Published September 12, 2024. Accessed January 30, 2025. https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/
5. World Health Organization. "Guidelines for managing advanced HIV disease and rapid initiation of antiretroviral therapy, July 2017." (2017).
6. Kozal M, Aberg J, Pialoux G, et al. Fostemsavir in Adults with Multidrug-Resistant HIV-1 Infection. N Engl J Med. 2020;382(13):1232-1243. doi:10.1056/NEJMoa1902493
7. Lagishetty C, Moore K, Ackerman P, Llamoso C, Magee M. Effects of Temsavir, Active Moiety of Antiretroviral Agent Fostemsavir, on QT Interval: Results from a Phase I Study and an Exposure-Response Analysis. Clin Transl Sci. 2020;13(4):769-776. doi:10.1111/cts.12763

Last Reviewed: 9/16/20, 9/15/21, 3/17/23, 3/15/24, 3/21/25
Effective Date: 11/15/20, 11/1/21, 6/1/23, 4/15/24, 4/1/25

Galafold® (migalastat hydrochloride)
Prior Authorization Guidelines

Affected Medication(s)

- Galafold oral capsule

FDA Approved Indication(s)

- Treatment of adults with a confirmed diagnosis of Fabry disease and an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data

Dosing

- 123 mg orally once every other day

Initial Authorization Criteria

1. Is the request for continuation of Galafold (migalastat hydrochloride) therapy?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member 18 years of age or older?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have a diagnosis of Fabry disease that is confirmed by biochemical and/or molecular genetic testing? (Provide genetic testing results for review)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Were baseline plasma or urinary globotriaosylceramide (Gb3/GL-3), globotriaosylsphingosine (lyso-Gb3), or kidney interstitial capillary cell globotriaosylceramide (KIC GL-3) labs provided?
    a. If yes, continue to #6
    b. If no, clinical review required
6. Does the member have a GLA variant based on in vitro assay that is considered amenable? (Provide documentation of amenable GLA variant)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Is the member female?
    a. If yes, continue to #8
    b. If no, continue to #9

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Effective Date: 1/1/19, 6/15/24

8. Does the member have documented clinical manifestations of Fabry disease? (Provide documentation of disease manifestations e.g. cardiac, renal, neurologic)
    a. If yes, continue to #9
    b. If no, clinical review required
9. Will Galafold (migalastat hydrochloride) be used in combination with other enzyme replacement therapy for treatment of Fabry disease?
    a. If yes, clinical review required
    b. If no, continue to #10
10. Is the treatment being prescribed by, or in consultation with, a clinical geneticist?
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member have a positive clinical response to therapy as defined as reduction in levels of plasma or urinary globotriaosylceramide (Gb3/GL-3), globotriaosylsphingosine (lyso-Gb3), or kidney interstitial capillary cell globotriaosylceramide (KIC GL-3) and/or an improvement or stabilization of clinical signs and symptoms (e.g., dermatologic, gastrointestinal, pulmonary, vascular, renal, cardiac, neurologic manifestations)? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the patient have documentation of estimated glomerular filtration rate (eGFR) of 30 mL/min/1.73m2 or greater? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the treatment being prescribed by, or in consultation with, a clinical geneticist?
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

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References:

1. Galafold [Product Information], Amicus Therapeutics U.S., Inc. Philadelphia, PA. March 2025.

Last Reviewed: 12/19/18, 11/18/20, 9/15/21, 11/16/22, 9/15/23, 5/17/24, 5/16/25
Effective Date: 1/1/19, 6/15/24

2. Germain DP, Hughes DA, Nicholls K, et al.: Treatment of Fabry's Disease with the Pharmacologic Chaperone Migalastat. NEJM 2016; 375:545-555.
3. Desnick RJ, Brady R, Barranger J, et al. Fabry disease, an Under-Recognized Multisystemic Disorder: Expert Recommendations for Diagnosis, Management, and Enzyme Replacement Therapy. Ann Intern Med. 2003; 138(4):338-46.
4. Ortiz, Alberto, et al. "Fabry disease revisited: management and treatment recommendations for adult patients." Molecular genetics and metabolism 123.4 (2018): 416-427.
5. Müntze J, Gensler D, Maniuc O, et al. Oral Chaperone Therapy Migalastat for Treating Fabry Disease: Enzymatic Response and Serum Biomarker Changes After 1 Year. Clin Pharmacol Ther. 2019;105(5):1224-1233.

Last Reviewed: 12/19/18, 11/18/20, 9/15/21, 11/16/22, 9/15/23, 5/17/24, 5/16/25
Effective Date: 1/1/19, 6/15/24

Gattex® (teduglutide)
Prior Authorization Guidelines

Affected Medication(s)

- Gattex kit for subcutaneous administration

FDA Approved Indication(s)

- Treatment of adult and pediatric patients 1 year of age or older with Short Bowel Syndrome (SBS) who are dependent on parenteral support

Dosing

- 0.05 mg/kg body weight administered by subcutaneous injection once daily

Initial Authorization Criteria

1. Is the request for continuation of Gattex (teduglutide) therapy?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member at least 1 year of age?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Has the member been dependent on parenteral nutrition support at least 3 times a week for at least 12 consecutive months prior to planned date of Gattex (teduglutide) initiation? (Provide documentation of parenteral nutritional support history and frequency)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is the treatment being prescribed by, or in consultation with, a gastroenterologist?
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required

Last Reviewed: 11/21/18, 11/18/20, 11/17/21, 3/17/23, 3/15/24, 3/21/25
Effective Date: 1/1/19, 12/15/20, 4/15/23

2. Has the member's requirement for parenteral nutritional support decreased at least 1 day per week from pre-treatment baseline? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the treatment being prescribed by, or in consultation with, a gastroenterologist?
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Gattex [package insert]. Cambridge, MA: Takeda Pharmaceuticals America, Inc.; September 2024.
2. Jeppesen P, Pertkiewicz M, Messing B, et al. Teduglutide reduces need for parenteral support among patients with short bowel syndrome with intestinal failure. Gastroenterology. 2012;143:1473-1481.
3. Parrish, Carol Rees, and John K. DiBaise. "Managing the adult patient with short bowel syndrome." Gastroenterology & hepatology 13.10 (2017): 600.

Last Reviewed: 11/21/18, 11/18/20, 11/17/21, 3/17/23, 3/15/24, 3/21/25
Effective Date: 1/1/19, 12/15/20, 4/15/23

Glucagon-Like Peptide-1 (GLP-1) Receptor Agonist Agents
Prior Authorization Guidelines

Affected Medication(s)

- Bydureon BCise (exenatide microspheres) subcutaneous auto injector
- Byetta (exenatide) subcutaneous pen injector
- Liraglutide subcutaneous pen injector
- Mounjaro (tirzepatide) subcutaneous pen
- Ozempic (semaglutide) subcutaneous pen injector
- Rybelsus (semaglutide) oral tablet
- Trulicity (dulaglutide) subcutaneous pen injector
- Victoza 2-Pak (liraglutide) subcutaneous pen injector
- Victoza 3-Pak (liraglutide) subcutaneous pen injector

FDA Approved Indication(s)

Bydureon/Byetta:

- As an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years of age and older with type 2 diabetes mellitus

Victoza/liraglutide:

- As an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years of age and older with type 2 diabetes mellitus
- To reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease

Mounjaro:

- As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus

Ozempic:

- As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
- To reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease
- To reduce the risk of sustained eGFR decline, end-stage kidney disease, and cardiovascular death in adults with type 2 diabetes mellitus and chronic kidney disease

Rybelsus:

- As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus

Trulicity:

- As an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years of age and older with type 2 diabetes mellitus
- To reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus who have established cardiovascular disease or multiple cardiovascular risk factors

Dosing

Last Reviewed: 11/15/24, 3/21/25, 5/16/25, 7/18/25
Effective Date: 3/1/25, 4/1/25, 6/1/25, 8/1/25

- Refer to corresponding package insert for specific dosing recommendations

Initial Authorization Criteria

1. Is the request for continuation of the same therapy for the same condition that was previously approved through plan?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Was a baseline lab confirming diagnosis of type 2 diabetes based on the following provided? (Provide supporting results obtained through certified lab facility)
    - HbA1c ≥ 6.5%*
    - Fasting plasma glucose (FPG) ≥ 126 mg/dL (≥7.0 mmol/L) during*
    - 2-h oral glucose tolerance test (OGTT) performed as described by WHO with 2-h plasma glucose (PG) ≥ 200 mg/dL (≥ 11.1 mmol/L)*
    - Random plasma glucose ≥ 200mg/dL (≥11.1 mmol/L) in patient with class symptoms of hyperglycemia or hyperglycemic crisis

    *Two abnormal results from different tests obtained the same time or the same test from two different time periods are needed.

    a. If yes, continue to #4
    b. If no, clinical review required
4. Is documentation showing member's condition remains uncontrolled (i.e. HbA1c >7%)? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have blood glucose levels ≥ 300 mg/dL or HbA1c >10%? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, continue to #7
6. Is the member currently on insulin therapy? (Provides supporting documentation)
    a. If yes, continue to #7
    b. If no, clinical review required
7. What is the diagnosis that the medication being requested for?
    a. As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus OR to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease, continue to #8

b. To reduce the risk of sustained eGFR decline, end-stage kidney disease, and cardiovascular death in adults with type 2 diabetes mellitus and chronic kidney disease, continue to #11

8. Did the member have an inadequate response to metformin? (Provides supporting documentation)
    a. If yes, continue to #10
    b. If no, continue to #9
9. Did the member have an intolerance to metformin despite prior dose titration OR a contraindication to metformin? (Provide documentation of intolerance and/or contraindication. Note: Metformin ER must be tried if intolerance due to GI side effects)
    a. If yes, continue to #10
    b. If no, clinical review required
10. Did the member have an inadequate response or contraindication to one of the following Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors – Steglatro, dapagliflozin (Farxiga), or Jardiance? (Provide supporting documentation)
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required
11. Does the member have an eGFR of at least 30 mL/min/1.73 m2?
    a. If yes, continue to #12
    b. If no, continue to #13
12. Did the member have an inadequate response or intolerance to metformin despite prior dose titration OR a contraindication to metformin? (Provide documentation of intolerance and/or contraindication. Note: Metformin ER must be tried if intolerance due to GI side effects)
    a. If yes, continue to #13
    b. If no, clinical review required
13. Is the member receiving a maximally tolerated dose of a renin-angiotensin-aldosterone system (RAAS) blocking agent including an angiotensin converting enzyme (ACE) inhibitor or an angiotensin II receptor blocker (ARB) unless contraindicated? (Provide supporting documentation)
    a. If yes, continue to #14
    b. If no, clinical review required
14. Did the member have an inadequate response or contraindication to one of the following Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors – dapagliflozin, Farxiga, or Jardiance? (Provide supporting documentation)
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required

2. Were baseline labs confirming a diagnosis of type 2 diabetes using ADA guidelines received? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Were updated HbA1c and chart notes (within 1 year) provided with documentation of significant clinical response?
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Bydureon BCise (exenatide microspheres) [Prescribing Information]. AstraZeneca Pharmaceuticals LP. May 2025.
2. Byetta (exenatide) [Prescribing Information]. AstraZeneca Pharmaceuticals LP. May 2025.
3. Mounjaro (tirzepatide) [Prescribing Information]. Eli Lilly and Company. June 2025.
4. Ozempic (semaglutide) [Prescribing Information]. Novo Nordisk Inc. January 2025.
5. Rybelsus (semaglutide) [Prescribing Information]. Novo Nordisk Inc. December 2024.
6. Trulicity (dulaglutide) [Prescribing Information]. Eli Lily and Company. June 2025.
7. Victoza (liraglutide) [Prescribing Information]. Novo Nordisk Inc. May 2025.
8. American Diabetes Association Professional Practice Committee. Standards of Care in Diabetes-2025. Diabetes Care. 2025;48(1 Suppl 1).
9. Kidney Disease: Improving Global Outcomes (KDIGO) CKD Work Group. KDIGO 2024 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease. *Kidney Int*. 2024;105(4S):S117-S314.

Last Reviewed: 11/15/24, 3/21/25, 5/16/25, 7/18/25
Effective Date: 3/1/25, 4/1/25, 6/1/25, 8/1/25

Glucosylceramide Synthase Inhibitors
Prior Authorization Guidelines

Affected Medication(s)

- Cerdelga (eliglustat) oral capsule
- miglustat oral capsule
- Opfolda (miglustat) oral capsule
- Yargesa (miglustat) oral capsule
- Zavesca (miglustat) oral capsule

FDA Approved Indication(s)

- Cerdelga: Long-term treatment of adult patients with Gaucher disease type 1 (GD1) who are CYP2D6 extensive metabolizers (EMs), intermediate metabolizers (IMs), or poor metabolizers (PMs) as detected by an FDA-cleared test
- Opfolda: Treatment, in combination with cipaglucosidase alfa, of adult patients with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) weighing ≥40 kg and who are not improving on their current enzyme replacement therapy (ERT)
- Yargesa, Zavesca: Monotherapy for the treatment of adult patients with mild to moderate type 1 Gaucher disease for whom enzyme replacement therapy (examples include: imiglucerase, velaglucerase alfa, or taliglucerase alpha) is not a therapeutic option (e.g. due to allergy, hypersensitivity, or poor venous access)

Dosing

- Refer to corresponding package insert for specific dosing recommendations

Initial Authorization Criteria

1. Is the request for continuation of the same glucosylceramide synthase inhibitor for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA-approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the treatment being initiated by a provider that specializes in the treatment of inherited metabolic disorders? (Examples include a medical geneticist or an endocrinologist)
    a. If yes, continue to #4
    b. If no, clinical review required
4. What is the indication that the medication is being requested for? (Provide genetic testing result for review)
    a. Type 1 Gaucher disease, continue to corresponding criteria
    b. Pompe disease (lysosomal acid alpha-glucosidase deficiency), continue to corresponding criteria
    c. Niemann-Pick disease Type C, continue to corresponding criteria
    d. Other Indication, clinical review required

Last Reviewed: 10/3/18, 11/18/20, 1/19/22, 3/17/23, 3/15/24, 1/17/25
Effective Date: 1/1/19, 3/1/22, 4/15/24, 2/1/25

Type 1 Gaucher Disease

1. Has the member had a previous inadequate response, intolerance, or contraindication (i.e. due to allergy, hypersensitivity, or poor venous access) to enzyme replacement therapy (i.e. velaglucerase alfa, imiglucerase, or taliglucerase alpha)? (Provide history of enzyme replacement therapy or contraindication to use)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for Cerdelga (eliglustat)?
    a. If yes, continue to #3
    b. If no, approve for 3 months unless otherwise specified
3. For approval of Cerdelga (eliglustat): Is the member a CYP2D6 poor metabolizer, extensive metabolizer, or intermediate metabolizer as confirmed using an FDA-cleared test?
    a. If yes, approve for 3 months unless otherwise specified
    b. If no, clinical review required

Pompe Disease

1. Has the member had a previous inadequate response, intolerance, or contraindication (i.e. due to allergy, hypersensitivity, or poor venous access) to enzyme replacement therapy (i.e.alglucosidase alfa)? (Provide history of enzyme replacement therapy or contraindication to use)
    a. If yes, approve for 3 months
    b. If no, clinical review required

Niemann-Pick disease Type C

1. Does the member have at least one neurological symptom? (Examples: hearing loss, vertical supranuclear gaze palsy, ataxia, dementia, dystonia, seizures, dysarthria, or dysphagia)
    a. If yes, approve for 3 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA-approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the treatment being prescribed by or in consultation with a provider who specializes in the treatment of inherited metabolic disorders? (Examples include a medical geneticist or an endocrinologist)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is there documentation that the member has a clinical response to therapy defined by an improvement in symptoms and quality of life?
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Last Reviewed: 10/3/18, 11/18/20, 1/19/22, 3/17/23, 3/15/24, 1/17/25
Effective Date: 1/1/19, 3/1/22, 4/15/24, 2/1/25

Note:

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References:

1. Cerdelga. Micromedex. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed October 23, 2020
2. Zavesca. Micromedex. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed October 23, 2020
3. Cerdelga (eligustat) [Prescribing Information]. Waterford, Ireland: Genzyme Corporation. December 2019.
4. Zavesca (miglustat) [Prescribing Information]. South San Francisco, CA: Actelion Pharmaceuticals US, Inc. June 2020.
5. Hughes MD. Gaucher disease: Treatment. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed December 9, 2022.
6. Geberhiwot T, Moro A, Dardis A, et al. Consensus clinical management guidelines for Niemann-Pick disease type C. Orphanet J Rare Dis. 2018;13(1):50. Published 2018 Apr 6.

Last Reviewed: 10/3/18, 11/18/20, 1/19/22, 3/17/23, 3/15/24, 1/17/25
Effective Date: 1/1/19, 3/1/22, 4/15/24, 2/1/25

GnRH Agonists
Prior Authorization Guidelines

Affected Medication(s)

- Eligard (leuprolide acetate) subcutaneous powder for suspension
- Fensolvi (leuprolide acetate) subcutaneous powder for suspension
- Leuprolide acetate solution for subcutaneous injection
- Lupron (leuprolide acetate) subcutaneous powder for suspension
- Lupron Depot (leuprolide acetate) for intramuscular injection
- Lupron Depot- Ped (leuprolide acetate) for intramuscular injection
- Synarel (nafarelin acetate) nasal spray
- Trelstar (triptorelin pamoate) intramuscular powder for suspension
- Triptodur (triptorelin) intramuscular powder for suspension

FDA Approved Indication(s)

- **Eligard**: For the palliative treatment of advanced prostate cancer
- **Fensolvi**: For the treatment of pediatric patients 2 years of age and older with central precocious puberty (CPP)
- **Leuprolide acetate**: For the palliative treatment of advanced prostate cancer
- **Lupron**: For the palliative treatment of advanced prostatic cancer
- **Lupron Depot**: (endometriosis, duration is 6 months, preop, duration is 1 dose)
    - For management of endometriosis, including pain relief and reduction of endometriotic lesions
    - For initial management of the painful symptoms of endometriosis and for management of recurrence of symptoms when use in combination with norethindrone acetate
    - For the preoperative hematologic improvement of patients with anemia caused by uterine leiomyomata when used concomitantly with iron therapy
- **Lupron Depot-Ped**: For the treatment of children with central precocious puberty (CPP)
- **Synarel**:
    - For the treatment of central precocious puberty (gonadotropin-dependent precocious puberty) in children of both sexes
    - For management of endometriosis, including pain relief and reduction of endometriotic lesions in adult patient
- **Trelstar**: For the palliative treatment of advanced prostate cancer
- **Triptodur**: For the treatment of pediatric patients 2 years of age and older with central precocious puberty

Dosing

- Refer to corresponding package insert for specific dosing recommendations

Initial Authorization Criteria

1. Is the request for continuation of the same GnRH agonist therapy for the same indication?

    a. If yes, continue to Reauthorization
    b. If no, continue to #2

2. Is the request for use to treat an FDA approved indication or major compendia supported indication? (Provide documentation of diagnosis)

Last Reviewed: 12/19/18, 7/15/20, 7/20/22, 11/17/23, 9/20/24, 9/19/25
Effective Date: 1/1/19, 8/15/20, 9/1/22, 12/20/23, 10/15/24

a. If yes, continue to #3
b. If no, clinical review required

3. What indication is the medication being requested for?

    a. Anemia associated with uterine leiomyomata (fibroids), continue to corresponding criteria
    b. Endometriosis, continue to corresponding criteria
    c. Central precocious puberty, continue to corresponding criteria
    d. Gender affirming treatment, continue to corresponding criteria
    e. Oncology indication, continue to corresponding criteria
    f. Other indication, continue to corresponding criteria

<u>Anemia Associated with Uterine Leiomyomata (fibroids)</u>

1. Is the member's hematocrit (Hct) ≤30% and/or hemoglobin (Hb) ≤ 10.2g/dL?

    a. If yes, continue to #2
    b. If no, clinical review required

2. Is the member currently taking adequate iron supplementation with insufficient response? (Provide documentation trial with inadequate response)

    a. If yes, continue to #3
    b. If no, clinical review required

3. Will the member continue to take iron supplementation throughout therapy? (Provide documentation of complete treatment regimen)

    a. If yes, continue to #4
    b. If no, clinical review required

4. Is the member scheduled to have surgical removal of fibroids within the next 6 months? (Provide documentation of surgical date for review)

    a. If yes, continue to #5
    b. If no, clinical review required

5. Is the medication being prescribed by, or in consultation with, a gynecologist?

    a. If yes, approve for up to 6 months unless otherwise specified
    b. If no, clinical review required

<u>Endometriosis</u>

1. Does the member have a previous trial with inadequate response, intolerance or contraindication to continuous contraception? (Provide supporting documentation)

    a. If yes, continue to #2
    b. If no, clinical review required

2. Is the medication being prescribed by, or in consultation with, a gynecologist?

    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

<u>Central Precocious Puberty</u>

1. Is the member less than 8 years old if female or less than 9 years old if male?
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member have confirmation of diagnosis by measurement of serum luteinizing hormone (LH), follicle-stimulating hormone (FSH), and estradiol and/or testosterone? (Provide documentation of LH, FSH, and estradiol and/or testosterone levels)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the request for Triptodur, or Synarel?
    a. If yes, continue to #4
    b. If no, continue to #5
4. Does the member have a previous trial with inadequate response, intolerance, or contraindication to treatment with Lupron?
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is the medication prescribed by, or in consultation with, a pediatric endocrinologist?
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Gender Affirming Treatment

1. Does the member have a diagnosis of gender dysphoria by a qualified mental health professional? (Provide supporting documentation)
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Oncology Indication

1. Is the medication being requested for an indication supported by the National Comprehensive Cancer Network (NCCN) with an evidence level of 2A or higher? (Provide disease staging, all prior treatment history, pathology report, and anticipated treatment plan for review)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member have Karnofsky Performance Status greater or equal to 50% OR Eastern Cooperative Oncology Group (ECOG) performance status of 0-2? (Provide performance status for review)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the medication being prescribed by or in consultation with an oncologist?
    a. If yes, approve for 4 months unless otherwise specified
    b. If no, clinical review required

Other Indications

1. Is the request supported by current medical guidelines?
    a. If yes, continue to #2
    b. If no, clinical review required
2. Has the member tried and had an inadequate response or have a contraindication to all preferred treatment options for the treatment of the requested condition?
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the medication being prescribed by or in consultation with an appropriate specialist experienced in treating the requested condition?
    a. If yes, approve for standard treatment duration OR up to 12 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for reauthorization of Synarel?
    a. If yes, clinical review required
    b. If no, continue to #3
3. What indication is the medication being requested for?
    a. Anemia associated with uterine leiomyomata (fibroids), clinical review required
    b. Endometriosis, clinical review required
    c. Central precocious puberty, continue to corresponding criteria
    d. Gender affirming treatment, approve x 1 year
    e. Oncology indication, continue to corresponding criteria
    f. Other indication, continue to corresponding criteria

<u>Central Precocious Puberty</u>

1. Does the member show a positive clinical response to therapy? (Examples include: adequate hormone suppression, cessation of menses in girls, normalization and stabilization of linear growth and bone age advancement, and stabilization in the clinical signs/symptoms of puberty) (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the medication being prescribed by, or in consultation with, a pediatric endocrinologist?
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

<u>Oncology Indication</u>

1. Does the member show a positive clinical response to therapy defined by documentation of disease responsiveness? (Examples include reduction in PSA to normal values, serum testosterone level ≤50 ng/dL, etc.) (Provide supporting documentation of disease response)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the medication being prescribed by, or in consultation with, an oncologist?
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Other Indications

1. Were updated chart notes (dated within 1 year) provided with documentation of significant clinical response to therapy? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the medication being prescribed by or in consultation with an appropriate specialist experienced in treating the requested condition?
    a. If yes, approve for standard treatment duration OR up to 12 months
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

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Growth Hormone
Prior Authorization Guidelines

Affected Medication(s)

- Genotropin (somatropin)
- Humatrope (somatropin)
- Ngenla (somatrogon)
- Norditropin (somatropin)
- Nutropin (somatropin)
- Omnitrope (somatropin)
- Serostim (somatropin)
- Skytrofa (lonapegsomatropin)
- Sogroya (somapacitan)
- Zomacton (somatropin)

Indication(s)

- For the treatment of children with growth failure due to growth hormone deficiency (GHD), Prader-Willi syndrome (PWS), Small for Gestational Age (SGA), Turner syndrome (TS), and Idiopathic Short Stature (ISS)
  - Genotropin, Omnitrope
- For the treatment of children with short stature or growth failure associated with GHD, TS, ISS, short stature homeobox-containing gene (SHOX) deficiency, and short stature born SGA with no catch-up growth by 2 years to 4 years
  - Humatrope, Zomacton
- For the treatment of pediatric members with growth failure due to inadequate secretion of endogenous growth hormone (GH), short stature associated with Noonan syndrome (NS), short stature associated with TS, SGA with no catch-up growth by age 2 to 4 years, ISS, and growth failure due to PWS
  - Norditropin
- For the treatment of children with growth failure due to GHD, ISS, TS, and chronic kidney disease (CKD) up to the time of renal transplantation
  - Nutropin AQ
- For the treatment of children with growth failure due to GHD
  - Ngenla, Skytrofa, Sogroya
- For the treatment of adults with either adult onset or childhood onset GHD
  - Genotropin, Nutropin AQ, Omnitrope
- For replacement of endogenous GH in adults with GH deficiency
  - Humatrope, Norditropin, Sogroya, Zomacton
- For the treatment of HIV patients with wasting or cachexia to increase lean body mass and body weight and improve physical endurance. Concomitant antiretroviral therapy is necessary
  - Serostim

Dosing

- Refer to corresponding package insert for dosing recommendations

Initial Authorization Criteria

1. Is the request for renewal of a previously approved prior authorization for the same medication with the same indication?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2
2. Is the treatment being prescribed by, or in consultation with, an appropriate specialist (e.g. endocrinologist, HIV specialist, gastroenterologist, etc.)?
   a. If yes, continue to #3

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b. If no, clinical review required

3. Is the requested medication Norditropin?

   a. If yes, continue to #5
   b. If no, continue to #4

4. Does the member have a trial with insufficient response, an intolerance, or contraindication to Norditropin OR use is inappropriate for FDA approved indication? (Provide supporting documentation)

   a. If yes, continue to #5
   b. If no, clinical review required

5. Is the request for one of the below indications AND matches the medication's FDA approved indication for use? (Provide documentation of diagnosis, patient weight, and requested dosing/dosing frequency)

   - Growth failure due to growth hormone deficiency (GHD) in pediatrics
   - Growth failure due to Prader-Willi Syndrome (PWS) in pediatrics
   - Short stature born small for gestational age (SGA) with no catch-up growth by age 2 to 4 years in pediatrics
   - Short stature associated with Turner's Syndrome (TS) in pediatrics
   - Idiopathic short stature (ISS)
   - Short stature homeobox-containing gene (SHOX) deficiency in pediatrics
   - Short stature associated with Noonan Syndrome (NS) in pediatrics
   - Chronic renal insufficiency in pediatrics
   - Adult acquired GHD
   - GHD in adults who had childhood onset GHD
   - Acquired immunodeficiency syndrome (AIDS) wasting or cachexia

   a. If yes, continue to corresponding criteria
   b. If no, clinical review required

<u>Growth hormone deficiency (GHD) in pediatrics</u>

1. Does the member meet at least ONE of the following criteria for short stature? (Provide supporting documentation)

   - Height is greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
   - Height velocity is less than the 25th percentile for member's age
   - Documentation of low peak growth hormone (less than 10 ng/mL) on two growth hormone stimulation tests OR insulin-like growth factor 1 (IGF-1) is greater than or equal to 2 standard deviations below the mean for member's age and gender

   a. If yes, continue to #2
   b. If no, clinical review required

2. Is there documentation of open epiphyses? (Provide supporting documentation)

   a. If yes, approve for 6 months unless otherwise specified
   b. If no, clinical review required

<u>Prader-Willi Syndrome (PWS) in pediatrics</u>

1. Does the member have a diagnosis of PWS confirmed by genetic testing? (Provide supporting documentation)
    a. If yes, approve for 6 months
    b. If no, clinical review required

Small for gestational age (SGA) in pediatrics

1. Is the member's height greater than or equal to 2 standard deviations below the mean height for normal children of the same age and gender? (Provide documentation of birth weight and length)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Did the member fail to achieve postnatal catch-up growth by 2 years of age? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is there documentation of open epiphyses? (Provide supporting documentation)
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Turner's Syndrome (TS)in pediatrics

1. Does the member have a diagnosis of TS confirmed by karyotype analysis? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the member's height greater than or equal to 2 standard deviations below the mean height for normal children of the same age and gender? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
3. Is there documentation of open epiphyses? (Provide supporting documentation)
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Idiopathic short stature (ISS) in pediatrics

1. Does the member have ISS as defined as height greater than or equal to 2.25 standard deviations below mean height for age in the absence of any endocrinal, metabolic, or other cause that explains short stature? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the member's predicted adult height below the normal range (less than 63 inches for males or less than 59 inches for females)? (Provide documentation of predicted adult height)
    a. If yes, continue to #3

b. If no, clinical review required

3. Has the provider thoroughly informed the member/member's family of the risks versus benefits and limitations of growth hormone therapy? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is there documentation of open epiphyses? (Provide supporting documentation)
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

<u>SHOX deficiency in pediatrics</u>

1. Does the member have SHOX deficiency as diagnosed by DNA analysis? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the member's height greater than or equal to 2 standard deviations below the mean height for normal children of the same age and gender? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is there documentation of open epiphyses? (Provide supporting documentation)
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

<u>Noonan Syndrome in pediatrics</u>

1. Does the member have Noonan syndrome confirmed by genetic testing? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the member's height greater than or equal to 2 standard deviations below the mean height for normal children of the same age and gender? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is there documentation of open epiphyses? (Provide supporting documentation)
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

<u>Chronic renal insufficiency in pediatrics</u>

1. Does the member have chronic renal insufficiency with an estimated GFR <75 mL/min per 1.73 m^2? (Provide documentation of GFR)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the member's height greater than or equal to 2 standard deviations below the mean height for normal children of the same age and gender? (Provide supporting documentation)

a. If yes, continue to #2
b. If no, clinical review required

3. Is the member pre-kidney transplantation? (Provide supporting documentation)

    a. If yes, approve for 3 months unless otherwise specified
    b. If no, clinical review required

Adult GHD

1. Was the diagnosis of growth hormone deficiency confirmed by ONE of the following? (Provide supporting documentation)

    - Growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism)
    - Result of pituitary diseases (disease of a major hormone producing gland)
    - Hypothalamic disease (disease of a small area of the brain important for hormone production and body processes), surgery, radiation therapy, or trauma
    - Continuation of therapy from childhood onset growth hormone deficiency

    a. If yes, continue to #2
    b. If no, clinical review required

2. Will the requested medication be used for anti-aging therapy, to enhance athletic ability, or for body building purposes? (Provide supporting documentation)

    a. If yes, clinical review required
    b. If no, approve for 6 months unless otherwise specified

HIV-associated wasting or cachexia

1. Does the member have HIV and one the following? (Provide supporting documentation)

    - Unintentional weight loss of ≥10% over 12 months
    - Weight < 90% of the lower limit of ideal body weight
    - BMI <20 kg/m^2

    a. If yes, continue to #2
    b. If no, clinical review required

2. Have other possible illnesses aside from HIV/AIDS been ruled out as the cause of weight loss?

    a. If yes, continue to #3
    b. If no, clinical review required

3. Will the member receive antiretroviral therapy for HIV/AIDS concomitantly with the requested medication? (Provide supporting documentation of treatment plan)

    a. If yes, continue to #4
    b. If no, clinical review required

4. Does the member have a documented trial with insufficient response, an intolerance, or contraindication to at least one appetite stimulants and/or anabolic agents? (Provide supporting documentation)

a. If yes, continue to #5
b. If no, clinical review required

5. Is the member less than 18 years of age?

a. If yes, clinical review required
b. If no, approve for 3 months unless otherwise specified

Reauthorization Criteria

1. Is the request for one of the below indications AND matches the medication's FDA-labeled indications for use? (Provide documentation of diagnosis, patient weight, and requested dosing/dosing frequency)

a. GHD in pediatrics, continue to corresponding criteria
b. PWS, continue to corresponding criteria
c. SGA, ISS, TS, SHOX, NS in pediatrics, continue to the corresponding criteria
d. CKD in pediatrics, continue to corresponding criteria
e. Adults with GHD, continue to corresponding criteria
f. Acquired immunodeficiency syndrome (AIDS) wasting or cachexia, continue to corresponding criteria

<u>GHD in pediatrics</u>

1. Does the member meet ONE of the following:

- Annual growth velocity is 2 cm or more compared with what was observed from the previous year
- Annual growth velocity is 1 cm or more compared with what was observed from the previous year if the member is near the terminal (end) phase of puberty

a. If yes, continue to #2
b. If no, clinical review required

2. Is there documentation of open epiphyses? (Provide supporting documentation)

a. If yes, approve for 12 months
b. If no, clinical review required

<u>Prader-Willi Syndrome</u>

1. Has the member had a positive response to therapy defined as an improvement in body composition?

a. If yes, approve for 12 months
b. If no, clinical review required

<u>SGA, ISS, TS, SHOX, NS in pediatrics</u>

1. Does the member have a positive response to therapy defined as ONE of the following? (Provide supporting documentation)

- Growth velocity is 2 cm or more compared with what was observed from the previous year
- Not reached 50th percentile of predicted adult height

a. If yes, continue to #2
b. If no, clinical review required

2. Is there documentation of open epiphyses? (Provide supporting documentation)
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

CKD in pediatrics

1. Is the member pre-renal transplantation? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member have a positive response to therapy defined as ONE of the following? (Provide supporting documentation)
    - Growth velocity is 2 cm or more compared with what was observed from the previous year
    - Not reached 50th percentile of predicted adult height

    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Adults with GHD (childhood or adult onset)

1. Is the member's IGF-1 concentration within the age-specific range of normal? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is there documentation the member is benefiting from GH therapy (e.g. increase quality of life, improvements in body composition, cardiovascular risk markers, etc)? (Provide supporting documentation)
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

HIV-associated wasting or cachexia

1. Is there documentation of positive response from therapy (i.e. increase in body weight or BCM)? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member continue to have evidence of wasting? (Provide supporting documentation)
    a. If yes, approve for 12 weeks unless otherwise specified (maximum total duration 48 weeks)
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

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Harliku (nitisinone)
Prior Authorization Guidelines

Affected Medication(s)

- Harliku oral tablet

Indication(s)

- For the reduction of urine homogentisic acid (HGA) in adult patients with alkaptonuria (AKU)

Dosing:

- 2 mg orally twice daily

Initial Authorization Criteria

1. Is the request for continuation of therapy for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is Harliku being requested for an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is documentation confirming diagnosis of alkaptonuria based upon urinary homogentisic acid (HGA) excretion greater than 0.4 g/24h? (Provide documentation of biochemical testing, clinical presentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have evidence of hip or joint involvement such as pain or decreased range of motion? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is the treatment being prescribed by, or in consultation with, a provider that is specialized in treatment of alkptonuria or related disorders?
    a. If yes, approve for 4 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is Harliku being requested for an FDA approved or major compendia supported indication?
    a. If yes, continue to #2
    b. If no, clinical review required
2. Has documentation of significant clinical response to therapy been provided? (Provide supporting documentation of decreased urine homogentisic acid confirmed by lab result)

Last Reviewed: 9/19/25
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a. If yes, continue to #3
b. If no, clinical review required

3. Is the treatment being prescribed by or in consultation with a provider that is specialized in treatment of alkaptonuria or related disorders?

    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Harliku (nitisinone) oral tablet [package insert]. Cambridge, UK: Cycle Pharmaceuticals Ltd: June 2025.
2. Introne WJ, Perry MB, Troendle J, Tsilou E, Kayser MA, Suwannarat P, O'Brien KE, Bryant J, Sachdev V, Reynolds JC, Moylan E, Bernardini I, Gahl WA. A 3-year randomized therapeutic trial of nitisinone in alkaptonuria. Mol Genet Metab. 2011 Aug;103(4):307-14.

Hepatitis C Direct Acting Antivirals
Prior Authorization Guidelines

Affected Medication(s)

- Epclusa (sofosbuvir/velpatasvir) oral tablet / pellets
- Sofosbuvir/velpatasvir oral tablet
- Mavyret (glecaprevir/pibrentasvir) oral tablet / pellets
- Vosevi (sofosbuvir/velpatasvir/voxilaprevir) oral tablet

FDA Approved Indication(s)

- **Epclusa**: Treatment of chronic hepatitis C (HCV) genotype 1, 2, 3, 4, 5, or 6 infection in adults and pediatric patients ≥3 years of age without cirrhosis or with compensated cirrhosis or in combination with ribavirin in patients with decompensated cirrhosis
- **Mavyret**: Treatment of acute or chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection in adults and pediatric patients ≥3 years of age without cirrhosis or with compensated cirrhosis (Child-Pugh A); HCV genotype 1 infection in adults and pediatric patients ≥3 years of age previously treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both
- **Vosevi**: Treatment of adults with chronic HCV infection without cirrhosis or with compensated cirrhosis (Child-Pugh A) who have genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor or who have genotype 1a or 3 infection and have previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor

Dosing

- Refer to indication specific compendia supported dosing

Initial Authorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for continuation of a hepatitis C regimen?
    a. If yes, clinical review required
    b. If no, continue to #3
3. Have all of the following pre-treatment test results been submitted for regimen appropriateness review? (Provide documentation of all requested test results)
        - HCV genotype for members with cirrhosis
        - Fibrosis staging if appropriate
        - Quantifiable baseline HCV RNA (within the last 12 months or rationale indicating why HCV RNA labs were completed >12 months prior)
        - HBV serology
        - Treatment history and outcome
    a. If yes, continue to #4
    b. If no, clinical review required

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4. If positive HBsAg or positive anti-HBc with negative HBsAb: Is there a documented monitoring plan? (Provide documentation of monitoring plan)
    a. If yes, continue to #5
    b. If no, clinical review required
    c. N/A, continue to #5
5. Is the requested treatment being prescribed by a provider who meets one of the following criteria:
    - No specialist required: Fibrosis score F0-F2, treatment naive with no prior Hepatitis B exposure
    - ECHO participant: Fibrosis score F3-F4 or prior Hepatitis B exposure
    - Specialist (i.e. gastroenterologist, hepatologist, ID): Decompensated cirrhosis or multiple DAA-failures

    a. If yes, continue to #6
    b. If no, clinical review required
6. Is this medication appropriate considering comorbid conditions or contraindications for use (e.g. pregnancy, malignancy outside of the liver not meeting oncologic criteria for cure, etc.)? (Provide documentation of comorbid conditions)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Does the requested regimen match one of the approved regimens below or is it supported by current AASLD-IDSA guidelines with an evidence rating of Class I, Level B and higher? (Provide documentation of treatment regimen)
    a. If yes, approve for appropriate duration
    b. If no, clinical review required

REGIMENS

Table 1: Recommended Treatment Regimens for Adults, and Adolescents 12 years of age and older with Hepatitis C virus

Treatment History	Cirrhosis Status	Recommended Regimen
Treatment Naïve (Genotype 1-6)		
Treatment naïve or confirmed reinfection	Non-Cirrhotic or Compensated Cirrhosis	• G/P x 8 weeks • SOF/VEL x 12 weeks (Baseline resistance testing recommended for GT3 patien with compensated cirrhosis)
	Decompensated Cirrhosis	• SOF/VEL + RBV x 12 weeks • SOF/VEL x 24 weeks if ribavirin ineligible
Treatment Experienced		
Sofosbuvir based regimen treatment failures, including:	Non-cirrhotic or compensated cirrhosis	• SOF/VEL/VOX x 12 weeks • G/P x 16 weeks (except GT3

Sofosbuvir + ribavirin Ledipasvir/sofosbuvir Velpatasvir/sofosbuvir	Decompensated cirrhosis	• SOF/VEL + RBV x 24 weeks
Elbasvir/grazoprevir treatment failures	Non-cirrhotic or compensated cirrhosis	• SOF/VEL/VOX x 12 weeks
Glecaprevir/pibrentasvir treatment failures	Non-cirrhotic or compensated cirrhosis	• G/P + SOF + RBV x 16 weeks • SOF/VEL/VOX x 12 weeks (plus RBV if compensated cirrhosis)
Multiple DAA Treatment Failures, including: sofosbuvir/velpatasvir/voxilaprevir glecaprevir/pibrentasvir + sofosbuvir	Non-cirrhotic or compensated cirrhosis	• G/P + SOF + RBV x 16-24 weeks • SOF/VEL/VOX + RBV x 24 weeks

Abbreviations: DAA = direct acting antiviral; G/P = glecaprevir and pibrentasvir; PEG= pegylated interferon; RBV = ribavirin; SOF = sofosbuvir; SOF/VEL = sofosbuvir/velpatasvir; SOF/VEL/VOX = sofosbuvir/velpatasvir/voxilaprevir

Ribavirin ineligible/intolerance may include: 1) neutrophils < 750 mm3, 2) hemoglobin < 10 g/dl, 3) platelets <50,000 cells/mm3, autoimmune hepatitis or other autoimmune condition, hypersensitivity or allergy to ribavirin

Rarely, genotyping assays may indicate the presence of a mixed infection (e.g., genotypes 1a and 2). Treatment data for mixed genotypes with direct-acting antivirals are limited. However, in these cases, a pangenotypic regimen is appropriate.

Ribavirin-containing regimens are absolutely contraindicated in pregnant women and in the male partners of women who are pregnant. Documented use of two forms of birth control in patients and sex partners for whom a ribavirin containing regimen is chosen is required.

All regimens containing a protease inhibitor (elbasvir, glecaprevir, simeprevir, paritaprevir, voxilaprevir) should not be used in patients with moderate to severe hepatic impairment (CTP B and C).

Table 2: Recommended Treatment Regimens for children ages 3 - 12 years of age with Hepatitis C virus

Treatment History	Cirrhosis Status	Recommended Regimen
Treatment Naïve Genotype 1-6		
Treatment naïve, confirmed reinfection or prior treatment with PEG/RBV	Non-cirrhotic or compensated cirrhosis	• SOF/VEL x 12 weeks • G/P x 8 weeks
	Decompensated Cirrhosis	• SOF/VEL + RBV x 12 weeks
Treatment Experienced with DAA regimen		
Note: Efficacy and safety data extremely limited in treatment experienced to other DAAs in this population. Can consider recommended treatment regimens in adults if FDA approved for pediatric use. Recommend consulting with hepatologist.		

Abbreviations: DAA = direct acting antiviral; G/P = glecaprevir and pibrentasvir; RBV = ribavirin; SOF/VEL = sofosbuvir/velpatasvir

- All regimens containing a protease inhibitor (elbasvir, glecaprevir, simeprevir, paritaprevir, voxilaprevir) should not be used in patients with moderate to severe hepatic impairment (CTP B and C)

Table 3: Recommended dosage of sofosbuvir/velpatasvir in pediatric patients 3 years of age and older:

Body Weight	Dosing of sofosbuvir/velpatasvir
Less than 17 kg	One 150 mg/37.5 mg pellet packet once daily
17 kg to less than 30 kg	One 200 mg/50 mg pellet packet OR tablet once daily
At least 30 kg	Two 200 mg/50 mg pellet packets once daily OR one 400 mg/100 mg tablet once daily

Table 4: Recommended dosage of glecaprevir/pibrentasvir in pediatric patients 3 years of age and older:

Body Weight	Dosing of sofosbuvir/velpatasvir
Less than 20 kg	Three 50mg/20 mg pellet packets once daily
20 kg to less than 30 kg	Four 50 mg/20 mg pellet packets once daily
30 kg to less than 45 kg	Five 50 mg/20 mg pellet packets once daily
45 kg and greater OR 12 years of age and older	Three 100mg/40 mg tablets once daily

Table 5: Unique Populations

Characteristics	Cirrhosis Status	Recommended Regimen
POST LIVER TRANSPLANT: GENOTYPE 1-6 in the allograft		
Treatment-naïve or -experienced	Non-cirrhotic or compensated cirrhosis	• SOF/VEL x 12 weeks • G/P x 12 weeks
	Decompensated cirrhosis	• SOF/VEL + RBV x 12 weeks (naïve) • SOF/VEL + RBV x 24 weeks (experienced)
Treatment experienced with direct acting antiviral (DAA) regimen	Non-cirrhotic or compensated cirrhosis	• SOF/VEL/VOX x 12 weeks
POST KIDNEY TRANSPLANT: GENOTYPE 1-6		
Treatment-naive or non-DAA experienced	Non-cirrhotic or compensated cirrhosis	• SOF/VEL x 12 week • G/P x 12 weeks
Treatment experienced with direct acting antiviral (DAA) regimen	Non-cirrhotic or compensated cirrhosis	• SOF/VEL/VOX +/- RBV x 12 weeks
HIV/HCV - COINFECTION		
HIV/HCV-coinfected persons should be treated and retreated the same as persons without HIV infection, after recognizing and managing interactions with antiretroviral medications		

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as

medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:.

1. American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA). Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. Updated December 19, 2023. Accessed August 8, 2025.
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3. Epclusa (sofosbuvir/velpatasvir/voxilaprevir) [prescribing information]. Foster City, CA: Gilead Sciences, Inc. June 2024.
4. Vosevi (sofosbuvir/velpatasvir) [prescribing information]. Foster City, CA: Gilead Sciences, Inc. July 2025.
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Last Reviewed: 9/19/2018, 5/15/2019, 7/17/19, 11/17/21, 11/16/22, 11/17/23, 9/20/24, 9/19/25
Effective Date: 1/1/2019, 7/1/2019, 9/1/19, 1/1/22, 12/20/23, 10/31/25

Hereditary Angioedema Agents Policy
Prior Authorization Guidelines

Affected Medication(s)

- Andembry (garadacimab-gxii) subcutaneous solution
- Berinert (human c1-esterase inhibitor) intravenous solution
- Cinryze (human c1-esterase inhibitor) intravenous solution
- Dawnzera (donidalorsen) subcutaneous solution
- Ekterly (sebetralstat) oral tablet
- Firazyr (icatibant acetate) subcutaneous solution
- Icatibant acetate subcutaneous solution
- Haegarda (human c1-esterase inhibitor) subcutaneous solution
- Kalbitor (ecallantide) subcutaneous solution
- Orladeyo (berotralstat) oral capsule
- Ruconest (c1-esterase inhibitor recombinant) intravenous solution
- Sajazir (icatibant acetate) subcutaneous solution
- Takhzyro (lanadelumab-flyo) subcutaneous solution

Indication(s)

- **Andembry:** Prophylaxis to prevent attacks of hereditary angioedema (HAE) in adult and pediatric patients ages 12 years and older
- **Berinert**: Treatment of acute abdominal, facial, or laryngeal hereditary angioedema (HAE) attacks in adult and pediatric patients 6 years of age and older
- **Cinryze**: Routine prophylaxis against angioedema attacks in adults, adolescents and pediatric patients (6 years old and above) with Hereditary Angioedema (HAE)
- **Dawnzera:** Prophylaxis to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years and older
- **Ekterly:** Treatment of acute attacks of hereditary angioedema (HAE) in adult and pediatric patients ages 12 years and older
- **Firazyr (icatibant, Sajazir)**: Treatment of acute attacks of hereditary angioedema (HAE) in adults 18 years of age and older
- **Haegarda**: Routine prophylaxis to prevent Hereditary Angioedema (HAE) attacks in adolescent and adult patients 6 years of age and older
- **Kalbitor:** Treatment of acute attacks of hereditary angioedema (HAE) in patients 12 years and older
- **Orladeyo:** Prophylaxis to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years and older
- **Ruconest**: Treatment of acute attacks in adult and adolescent patients with hereditary angioedema (HAE) 13 years of age and older
- **Takhzyro**: Prophylaxis to prevent attacks of hereditary angioedema (HAE) in patients 2 years and older

Dosing

- Refer to package insert for recommended dosing

Last Reviewed: 1/16/19, 3/17/21, 9/15/21, 5/18/22, 7/21/23, 7/19/24, 7/18/25, 9/19/25, 11/21/25
Effective Date: 2/1/19, 5/1/21, 11/1/21, 7/15/22, 9/15/23, 8/15/24, 10/31/25, 1/1/26

Initial Authorization Criteria

1. Is the request for continuation of the same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the medication being requested for an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member avoiding possible triggers for HAE attacks? Possible triggers include:
    - Helicobacter pylori infections (confirmed by lab test)
    - Systemic estrogen products
    - Antihypertensive agents containing ACE inhibitors
    - Dipeptidyl peptidase IV (DPP-IV) inhibitors (e.g., sitagliptin)
    - Neprilysin inhibitors (e.g., sacubitril)

    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have at least 2 HAE attacks per month at baseline? (Provide supporting documentation for review)
    a. If yes, continue to #6
    b. If no, continue to #5
5. Does the member have a history of moderate to severe cutaneous or abdominal attacks OR mild to severe airway swelling attacks of HAE? (i.e. debilitating cutaneous/gastrointestinal symptoms OR laryngeal/pharyngeal/tongue swelling) (Provide supporting documentation for review)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Does the member have one of the following clinical presentations consistent with HAE subtype? (Provide supporting documentation)
    - For HAE I (C1-inhibitor deficiency):
        - Low C1 inhibitor (C1-INH) antigenic level (C1-INH antigenic level below the lower limit of normal as defined by the laboratory performing the test); AND
        - Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test); AND
        - Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test); AND
            - Patient has a family history of HAE OR
            - Normal C1q level
    - For HAE II (C1-inhibitor dysfunction):
        - Normal to elevated C1-INH antigenic level; AND

- Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test); AND
- Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test)

a. If yes, continue to #7
b. If no, clinical review required

7. Is the request for either Andembry, Dawnzera, Takhzyro, Cinryze, or Orladeyo?

a. If yes, continue to #8
b. If no, continue to #9

8. Has the member had a previous trial with inadequate response, intolerance, or contraindication to therapy with Haegarda? (Provide supporting documentation) (NOTE: Takhzyro can be used if member is <6 years old)

a. If yes, continue to #11
b. If no, clinical review required

9. Is the request for Berinert, Ekterly, Sajazir, Firazyr, Kalbitor, or Ruconest?

a. If yes, continue to #10
b. If no, continue to #11

10. Has the member had a previous trial with inadequate response, intolerance, or contraindication to therapy with generic icatibant? (Provide supporting documentation)

a. If yes, continue to #11
b. If no, clinical review required

11. Is the medication being prescribed by or in consultation with a specialist in allergy, immunology, hematology, pulmonology, or medical genetics?

a. If yes, approve for 3 months unless otherwise specified
b. If no, clinical review required

Reauthorization Criteria

1. Does the member continue to meet initial criteria?

a. If yes, continue to #2
b. If no, clinical review required

2. Has the member demonstrated significant improvement in severity and duration of attacks that has been achieved and sustained? (Provide supporting documentation of improvement in severity or duration of attacks)

a. If yes, continue to #3
b. If no, clinical review required

3. Is there documentation that there has been an absence of unacceptable toxicity from the drug? (Examples of unacceptable toxicity include the following: hypersensitivity reactions, serious thrombotic events, laryngeal attacks, etc.) (Provide supporting documentation)

a. If yes, continue to #4
b. If no, clinical review required

4. Is the medication being prescribed by or in consultation with a specialist in allergy, immunology, hematology, pulmonology, or medical genetics?

a. If yes, approve for 12 months unless otherwise specified
b. If no, clinical review required

Note:

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References:

1. Ruconest [package insert]. Warren, NJ: Pharming Healthcare. April 2020. .
2. Firazyr [package insert]. Lexington, MA; Takeda Pharmaceutical Company Ltd. January 2024..
3. Berinert [package insert]. Marburg, Germany. CSL Behring GmbH. September 2021.
4. Cinryze [package insert]. Cambridge, MA.: Takeda Pharmaceuticals America. December 2024.
5. Haegarda [package insert]. Kankakee, IL; CSL Behring GmbH. February 2022.
6. ORLADEYO™ (berotralstat) capsules, [package insert]. Durham, NC: Biocyst Pharmaceuticals, Inc.; October 2024.
7. TAKHZYRO (lanadelumab-flyo) SC injection [package insert]. Cambridge, MA: Takeda Pharmaceuticals; February 2025.
8. Kalbitor (ecallantide) [Prescribing Information]. Lexington, MA. Takeda Pharmaceutical Company Ltd. December 2023.
9. ANDEMBRY (garadacimab-gxii) injection, [package insert]. King of Prussia, PA: CSL Behring LLC.; June 2025.
10. EKTERLY (sebetralstat) tablets [package insert]. Cambridge, MA: KalVista Pharmaceuticals, Inc.; 2025.
11. DAWNZERA (donidalorsen) subcutaneous injection, [package insert]. Carlsbad, CA: Ionis Pharmaceuticals, Inc.; 2025.
12. Bygum A, Andersen KE, Mikkelsen CS. Self-administration of intravenous C1-inhibitor therapy for hereditary angioedema and associated quality of life benefits. Eur J Dermatol. Mar-Apr 2009;19(2):147-151.
13. Bowen T, Cicardi M, Farkas H, et al. 2010 International consensus algorithm for the diagnosis, therapy and management of hereditary angioedema. Allergy Asthma Clin Immunol. 2010;6(1):24.
14. Craig T, Aygören-Pürsün E, Bork K, et al. WAO Guideline for the Management of Hereditary Angioedema. World Allergy Organ J. 2012 Dec;5(12):182-99.
15. Gompels MM, Lock RJ, Abinun M, et al. C1 inhibitor deficiency: consensus document. Clin Exp Immunol. 2005;139(3):379.
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18. Zuraw BL, Bernstein JA, Lang DM, et al. A focused parameter update: hereditary angioedema, acquired C1 inhibitor deficiency, and angiotensin-converting enzyme inhibitor-associated angioedema. J Allergy Clin Immunol. 2013 Jun;131(6):1491-3. doi: 10.1016/j.jaci.2013.03.034.

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20. Frank MM, Zuraw B, Banerji A, et al. Management of children with Hereditary Angioedema due to C1 Inhibitor deficiency. Pediatrics. 2016 Nov. 135(5)
21. Maurer M, Mager M, Ansotegui I, et al. The international WAO/EAACI guideline for the management of hereditary angioedema-The 2017 revision and update. Allergy. 2018 Jan 10. doi: 10.1111/all.13384.Busse PJ, Christiansen SC, Riedl MA, et al. US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema. J Allergy Clin Immunol Pract. 2021;9(1):132-150.e3.

Hetlioz® (tasimelteon)
Prior Authorization Guidelines

Affected Medication(s)

- Hetlioz oral capsule
- Hetlioz LQ oral suspension
- Tasimelteon capsule

FDA Approved Indication(s)

- Hetlioz capsules:
  - For the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) in adults
  - For the treatment of nighttime sleep disturbances in SMS in patients 16 years of age and older.
- Hetlioz LQ:
  - For the treatment of nighttime sleep disturbances in SMS in pediatric patients 3 to 15 years of age

Dosing

- 20 mg by mouth taken before bedtime at the same time every night

Initial Authorization Criteria

1. Is the request for continuation of Hetlioz (tasimelteon) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
   a. If yes, continue to #3
   b. If no, clinical review required
3. Does the member have documentation of a minimum trial of 12 weeks of melatonin with insufficient response, intolerance, or contraindication to therapy? (Provide relevant current/past medication history)
   a. If yes, continue to #4
   b. If no, clinical review required
4. Is Hetlioz (tasimelteon) being requested for nighttime sleep disturbances related to Smith-Magenis syndrome (SMS)?
   a. If yes, continue to #6
   b. If no, continue to #5
5. Is the member completely blind with no light perception? (Provide supporting documentation)
   a. If yes, continue to #6
   b. If no, clinical review required
6. Is the treatment being prescribed by or in consult with a specialist specialized in sleep disorders?
   a. If yes, approve for 6 months unless otherwise specified
   b. If no, clinical review required

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Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Has the member had a positive clinical response to therapy as defined as decreased symptoms? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the treatment being prescribed by or in consult with a specialist in sleep disorders?
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Hetlioz Prescribing Information. Washington, D.C.: Vanda Pharmaceuticals Inc.; December 2022.
2. Auger RR, Burgess HJ, Emens JS, Deriy LV, Thomas SM, and Sharkey KM. Clinical practice guideline for the treatment of intrinsic circadian rhythm sleep-wake disorders: advanced sleep-wake phase disorder (ASWPD), delayed sleep-wake phase disorder (DSWPD), non-24-hour sleep-wake rhythm disorder (N24SWD), and irregular sleep-wake rhythm disorder (ISWRD) - an update for 2015. J Clin Sleep Med. 2015; 11(10): 1199-1236.
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Last Reviewed: 10/17/18, 7/21/21, 7/20/22, 3/17/23, 3/15/24, 3/21/25
Effective Date: 1/1/19, 9/1/21, 9/1/22, 6/1/23, 4/15/24

Impavido® (miltefosine)
Prior Authorization Guidelines

Affected Medication(s)

- Impavido oral capsule

FDA Approved Indication(s)

- In adults and adolescents 12 years of age or older and weighing greater or equal to 30kg for treatment of:
  - Visceral leishmaniasis caused by *Leishmania donovani*
  - Cutaneous leishmaniasis caused by *Leishmania braziliensis*, *Leishmania guyanensis*, and *Leishmania panamensis*
  - Mucosal leishmaniasis caused by *Leishmania braziliensis*

Dosing

- Patients weighing 30 to 44 kg: 50 mg twice daily with food for 28 days
- Patients weighing 45 kg or greater: 50 mg three times daily with food for 28 days

Authorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
   a. If yes, continue to #3
   b. If no, continue to #2
2. Does the member currently have a free-living ameba infection? (Examples include: primary amebic meningoencephalitis (PAM) due to *Naegleria fowleri*, granulomatous amebic encephalitis (GAE) due to *Balamuthia mandrillaris,* or keratitis due to *Acanthamoeba spp.*)? (Provide documentation of diagnosis)
   a. If yes, continue to #3
   b. If no, clinical review required
3. Is the member at least 12 years of age and weighs at least 30 kg? (Provide member weight for review)
   a. If yes, continue to #4
   b. If no, clinical review required
4. Is the requested dosing appropriate for the member's weight?
   a. If yes, continue to #5
   b. If no, clinical review required
5. Is the treatment being prescribed by, or in consultation with, an infectious disease specialist?
   a. If yes, approve for 1 month
   b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as

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Effective Date: 1/1/19, 3/1/24

medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Impavido (prescribing information). Profounda Inc, Orlando, FL. December 2024.
2. CDC Guidelines. Acanthamoeba Infections. https://www.cdc.gov/acanthamoeba/about/index.html. Accessed December 31, 2024.
3. Centers for Disease Control and Prevention: Leishmaniasis – Resources for Health Professionals. Available at: https://www.cdc.gov/leishmaniasis/hcp/clinical-care/index.html. Last updated: March 2024. Accessed on Decembeer 31, 2024.

Last Reviewed: 11/21/18, 1/20/21, 1/19/22, 1/20/23, 1/19/24, 1/17/25
Effective Date: 1/1/19, 3/1/24

Increlex® (mecasermin)
Prior Authorization Guidelines

Affected Medication(s)

- Increlex subcutaneous solution

FDA Approved Indication(s)

Children ≥ 2 years old and adolescents:

- Treatment of growth failure with severe primary IGF-1 deficiency
- Treatment of growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH

Dosing

- Recommended starting dose: 0.04 to 0.08 mg/kg twice daily
- Maximum dose: 0.12 mg/kg twice daily

Initial Authorization Criteria

1. Is the request for continuation of Increlex (mecasermin) therapy?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member have documentation of open epiphyses demonstrated on bone radiograph? (Provide documentation of open epiphyses)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have any of the following secondary forms of IGF-1 deficiency?
    - Growth Hormone deficiency (GHD)
    - Malnutrition
    - Hypothyroidism
    - Chronic treatment with pharmacologic doses of steroidal anti-inflammatories

    a. If yes, clinical review required
    b. If no, continue to #5
5. Is the medication being prescribed by, or in consultation with, a pediatric endocrinologist?
    a. If yes, continue to #6
    b. If no, clinical review required
6. What diagnosis is Increlex being requested for?
    a. Severe IGF-1 deficiency, continue to corresponding criteria

Last Reviewed: 12/19/18, 7/21/21, 7/20/22, 7/21/23, 7/19/24, 7/18/25
Effective Date: 1/1/19, 8/15/24

b. Growth hormone (GH) gene deletion, continue to corresponding criteria

Severe IGF-1 Deficiency

1. Does the member have a height standard deviation score of less than or equal to -3.0? (Provide documentation of height standard deviation score for review)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member have a basal IGF-1 standard deviation score of less than or equal to -3.0? (Provide documentation of basal IGF-1 standard deviation score for review)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member have normal or elevated growth hormone levels? (Provide documentation of growth hormone level for review)
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Growth hormone (GH) Gene Deletion

1. Does the member have a basal IGF-1 level below normal range? (Provide documentation of basal IGF-1 level for review)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member have a presence of neutralizing antibodies to GH as confirmed by serum testing or genetic testing? (Provide supporting documentation of neutralizing antibodies)
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member have a positive clinical response to therapy as defined by a height velocity of at least 2cm per year? (Provide documentation of height velocity for review)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Has the member met their expected adult height goal? (Provide documentation of expected adult height and current height for review)
    a. If yes, clinical review required

Last Reviewed: 12/19/18, 7/21/21, 7/20/22, 7/21/23, 7/19/24, 7/18/25
Effective Date: 1/1/19, 8/15/24

b. If no, approve for 12 months unless otherwise specified

Note:

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References:

1. Increlex (mecasermin [rDNA origin] injection) [Product Information], Eton Pharmaceuticals. Deer Park, IL. May 2025.
2. Grimberg A, DiVall SA, Polychronakos C, et al. Guidelines for Growth Hormone and Insulin-Like Growth Factor-I Treatment in Children and Adolescents: Growth Hormone Deficiency, Idiopathic Short Stature, and Primary Insulin-Like Growth Factor-I Deficiency. Horm Res Paediatr. 2016;86(6):361-397.

Last Reviewed: 12/19/18, 7/21/21, 7/20/22, 7/21/23, 7/19/24, 7/18/25
Effective Date: 1/1/19, 8/15/24

Injectable CGRP Antagonists
Prior Authorization Guidelines

Affected Medication(s)

- Aimovig (erenumab-aooe) subcutaneous solution
- Ajovy (fremanezumab-vfrm) subcutaneous solution
- Emgality (galcanezumab-gnlm) subcutaneous solution

FDA Approved Indication(s)

- Aimovig/Emgality: As the preventive therapy of migraine in adults
- Ajovy: Preventive treatment of migraine in adults and preventive treatment of episodic migraine in pediatric patients 6 to 17 years of age and weighing 45 kg or greater
- Emgality: For treatment of episodic cluster headache in adults

Dosing

- Aimovig: 70 mg to140 mg subcutaneously once monthly
- Ajovy: 225 mg subcutaneously once monthly or 675 mg subcutaneously every 3 months
- Emgality:
  - Migraine: 240 mg subcutaneously once as loading dose, then 120 mg subcutaneously once monthly
  - Cluster headache: 300 mg at the onset of the cluster period and then monthly until the end of the cluster period

Initial Authorization Criteria

1. Has the requested medication previously been approved by OHSU?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
   a. If yes, continue to #3
   b. If no, clinical review required
3. What is the requested drug being used for?
   a. Migraine, continue to #4
   b. Cluster Headache, continue to #7
   c. Other indication, clinical review required
4. Has the member experienced 4 or more migraine headache days per month?
   a. If yes, continue to #5
   b. If no, clinical review required
5. Has the member had a two-month trial and failure or intolerance to (2) of the following age-appropriate alternative agents with differing mechanisms of action for migraine prophylaxis: topiramate, divalproex, metoprolol, propranolol, timolol, atenolol, nadolol, amitriptyline, nortriptyline, venlafaxine, duloxetine?
   a. If yes, continue to #10

Last Reviewed: 12/19/18, 7/17/19, 5/1/20, 9/16/20, 11/18/20, 11/17/21, 11/16/22, 11/17/23, 9/20/24, 1/17/25, 11/21/25
Effective Date: 1/1/19, 9/1/19, 7/1/20, 11/15/20, 12/15/20, 1/1/22, 1/1/23, 12/20/23, 10/15/24, 2/1/25, 1/1/26

b. If no, continue to #6

6. Does the member have contraindications to all of the following age-appropriate alternative agents used for migraine prophylaxis: topiramate, divalproex, metoprolol, propranolol, timolol, atenolol, nadolol, amitriptyline, nortriptyline, venlafaxine, duloxetine?

    a. If yes, continue to #10
    b. If no, clinical review required

7. Does this member have at least two cluster periods lasting at least seven days to one year with at least five attacks?

    a. If yes, continue to #8
    b. If no, clinical review required

8. Are the member's cluster periods separated by at least three (3) months of pain-free remission?

    a. If yes, continue to #9
    b. If no, clinical review required

9. Has the member had a trial and failure or intolerance to a two-month trial of verapamil?

    a. If yes, continue to #10
    b. If no, clinical review required

10. Will CGRP antagonist to be used in combination with Botox?

    a. If yes, clinical review required
    b. If no, continue to #11

11. Will the injectable CGRP antagonist be used in combination with another CGRP antagonist for prophylactic use? (including oral CGRP antagonists)

    a. If yes, clinical review required
    b. If no, approve for 6 months unless otherwise specified

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)

    a. If yes, continue to #2
    b. If no, clinical review required

2. Does the member have a positive clinical response to therapy as defined by a reduction in the frequency of migraine days per month or 50% or more reduction in weekly cluster headache attack frequency from pre-treatment baseline?

    a. If yes, continue to #3
    b. If no, clinical review required

3. Will the injectable CGRP antagonist be used in combination with another CGRP antagonist for prophylactic use? (including oral CGRP antagonists)

    a. If yes, clinical review required

Last Reviewed: 12/19/18, 7/17/19, 5/20/20, 9/16/20, 11/18/20, 11/17/21, 11/16/22, 11/17/23, 9/20/24, 1/17/25, 11/21/25
Effective Date: 1/1/19, 9/1/19, 7/1/20, 11/15/20, 12/15/20, 1/1/22, 1/1/23, 12/20/23, 10/15/24, 2/1/25, 1/1/26

b. If no, approve for 12 months unless otherwise specified

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Aimovig [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; June 2025.
2. Ajovy [Prescribing Information]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; August 2025.
3. Emgality [Prescribing Information]. Indianaplois, IN: Eli Lilly and Company: May 2025.
4. Silberstein SD, Holland S, Freitag F, et al. American Academy of Neurology: Evidence-based guideline update: Pharmacologic treatment for episodic migraine prevention in adults. Neurology 2012; 78: 1337-45.
5. Institute for clinical and economic review (ICER). Calcitonin Gene-Related Peptide (CGRP) inhibitors as preventive treatments for patients with episodic or chronic migraine: effectiveness and value. May 2018. Accessed October 11, 2018.
6. Robbins MS, Starling AJ, Pringsheim TM, et al. Treatment of Cluster Headache: The American Headache Society Evidence-Based Guidelines. Headache. 2016;56:1096-1106. Available at: https://headachejournal.onlinelibrary.wiley.com/doi/epdf/10.1111/head.12866.
7. The American Headache Society Position Statement on Integrating New Migraine Treatments Into Clinical Practice. Headache. 2019;59:1-18. Available at: https://headachejournal.onlinelibrary.wiley.com/doi/epdf/10.1111/head.13456.
8. Headache Classification Committee of the International Headache Society (IHS) The International Classification of Headache Disorders, 3rd edition. Cephalagia. 2018;38(1);1-211. Available at: https://journals.sagepub.com/doi/pdf/10.1177/0333102417738202.
9. Charles AC, Digre KB, Goadsby PJ, Robbins MS, Hershey A; American Headache Society. Calcitonin gene-related peptide-targeting therapies are a first-line option for the prevention of migraine: An American Headache Society position statement update. Headache. 2024;64(4):333-341.
10. Oskoui, Maryam, et al. "Practice guideline update summary: Pharmacologic treatment for pediatric migraine prevention: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology and the American Headache Society." Neurology 93.11 (2019): 500-509.

Last Reviewed: 12/19/18, 7/17/19, 5/20/20, 9/16/20, 11/18/20, 11/17/21, 11/16/22, 11/17/23, 9/20/24, 1/17/25, 11/21/25
Effective Date: 1/1/19, 9/1/19, 7/1/20, 11/15/20, 12/15/20, 1/1/22, 1/1/23, 12/20/23, 10/15/24, 2/1/25, 1/1/26

Inqovi® (decitabine and cedazuridine), Onureg® (azacitidine) Prior Authorization Guidelines

Affected Medication(s)

- Inqovi oral tablet
- Onureg oral tablet

FDA Approved Indication(s)

- Inqovi:
  - 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.
- Onureg:
  - Continued treatment of adult patients with acute myeloid leukemia (AML) 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

- Inqovi:
  - One tablet (35mg decitabine and 100mg cedazuridine) by mouth one time daily on Days 1 through 5 of each 28-day cycle
- Onureg:
  - 300mg orally once time daily on days 1 through 14 of each 28-day cycle

Initial Authorization Criteria

1. Is the request for continuation of a previously approved Inqovi or Onureg prior authorization with the same indication as the previous approval?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2
2. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)
   a. If yes, continue to #4
   b. If no, continue to #3
3. Is the medication being requested for an indication supported by the National Comprehensive Cancer Network (NCCN) recommendation with an evidence level of 2A or higher? (Provide disease staging, all prior treatment history, pathology report, and anticipated treatment plan for review)
   a. If yes, continue to #4
   b. If not, clinical review required
4. Is the treatment being prescribed by, or in consultation with, an oncologist?
   a. If yes, continue to #5
   b. If no, clinical review required

Last Reviewed: 1/20/21, 3/16/22, 5/19/23, 5/17/24, 5/16/25
Effective Date: 3/1/21

5. Does the member have Karnofsky Performance Status greater or equal to 50% OR Eastern Cooperative Oncology Group (ECOG) performance status of 0-2? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Is there medical rationale why the member cannot use generic IV formulation? (Provide supporting documentation)
    a. If yes, approve for 4 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved indication or supported by NCCN recommendation with an evidence level of 2A or higher? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the treatment being prescribed by, or in consultation with, an oncologist?
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is there clinical documentation confirming disease responsiveness to therapy provided? (Example include reduction in tumor size, objective response, delay in progression, partial response, etc.) (Provide supporting documentation)
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 05 Oct. 2020].
2. INQOVI® (decitabine and cedazuridine) tablets, [package insert]. Princeton, NJ: Taiho Oncology, Inc; 2024.
3. ONUREG (azacitidine) tablets, [package insert]. Summit, NJ: Celegene Corp.; 2022.
4. Clinical Practice Guidelines in Oncology (NCCN Guidelines): Myelodysplastic Syndromes. Version 2.2025 National Comprehensive Cancer Network website. Available from https://www.nccn.org/professionals/physician_gls/default.aspx. Accessed April 17, 2025.
5. Garcia-Manero, Guillermo, et al. "Oral cedazuridine/decitabine: a phase 2, pharmacokinetic/pharmacodynamic, randomized, crossover study in MDS and CMML." Blood (2020).
6. Wei, Andrew H., et al. "The QUAZAR AML-001 Maintenance Trial: results of a phase III international, randomized, double-blind, placebo-controlled study of CC-486 (oral formulation of azacitidine) in patients with acute myeloid leukemia (AML) in first remission." (2019): LBA-3.

Last Reviewed: 1/20/21, 3/16/22, 5/19/23, 5/17/24, 5/16/25
Effective Date: 3/1/21

7. Clinical Practice Guidelines in Oncology (NCCN Guidelines): Acute Myeloid Leukemia. Version 2.2025 National Comprehensive Cancer Network website. Available from https://www.nccn.org/professionals/physician_gls/default.aspx. Accessed April 17, 2025.

Idiopathic Pulmonary Fibrosis (IPF) agents
Prior Authorization Guidelines

Affected Medication(s)

- Esbriet (pirfenidone) oral capsule/tablet
- Ofev (nintedanib) oral capsule
- pirfenidone oral capsule/tablet

FDA Approved Indication(s)

- Esbriet: For the treatment of idiopathic pulmonary fibrosis (IPF)
- Ofev:
  - For the treatment of adult with idiopathic pulmonary fibrosis (IPF)
  - For the treatment of adult with chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype
  - To slow the rate of decline in pulmonary function in adult patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD).

Dosing

- Esbriet: 801 mg three times daily (refer to package insert for titration recommendations)
- Ofev: 150 mg twice daily

Initial Authorization Criteria

1. Is the request for continuation of Esbriet (pirfenidone) or Ofev (nintedanib) therapy for the same indication?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
   a. If yes, continue to #3
   b. If no, clinical review required
3. Is the treatment being prescribed by or in consultation with a pulmonologist?
   a. If yes, continue to #4
   b. If no, clinical review required
4. Is the member 18 years of age or older?
   a. If yes, continue to #5
   b. If no, clinical review required
5. What is the requested indication?
   a. Idiopathic pulmonary fibrosis, continue to corresponding criteria
   b. Chronic fibrosing interstitial lung disease with progressive phenotype (Ofev only), continue to corresponding criteria
   c. To slow the rate of decline in pulmonary function in patients with systemic sclerosis-associated interstitial lung disease (SSC-ILD) (Ofev only), continue to corresponding criteria

Last Reviewed: 10/17/18, 1/20/21, 3/16/22, 5/18/22, 5/19/23, 5/17/24, 5/16/25
Effective Date: 1/1/19, 3/1/21, 4/15/22, 7/15/22, 6/15/24

d. Other indication, clinical review required

Idiopathic pulmonary fibrosis

1. Is documentation confirming diagnosis of idiopathic pulmonary fibrosis (IPF) including presence of usual interstitial pneumonia (UIP), high resolution computed tomography (HRCT) result, or surgical lung biopsy result provided? (Provide supporting documentation for review)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Have known causes of interstitial lung disease been ruled out? (i.e. rheumatic disease, drug induced UIP, occupational exposures)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the requested medication Ofev (nintedanib) capsules?
    a. If yes, continue to #4
    b. If no, approve for 6 months
4. Has the member had a trial with insufficient response, intolerance, or contraindication to pirfenidone (Esbriet) tablets or capsules? (Provide supporting documentation)
    a. If yes, approve for 6 months
    b. If no, clinical review required

Chronic fibrosing interstitial lung disease with progressive phenotype (Ofev only)

1. Does the member have pulmonary fibrosis that is confirmed by high resolution computed tomography (HRCT)?
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member have any of the following clinical signs of progression?
    - FVC decline ≥10%
    - FVC decline ≥5% and <10% with worsening respiratory symptoms or imaging
    - Worsening respiratory symptoms and worsening imaging

    a. If yes, approve for 6 months
    b. If no, clinical review required

Systemic sclerosis-associated interstitial lung disease (Ofev only)

1. Does the member have pulmonary fibrosis that is confirmed by high resolution computed tomography (HRCT)?
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member have signs of systemic sclerosis? [Signs include: skin thickening of the fingers, fingertip lesions, telangiectasia, abnormal nailfold capillaries, pulmonary arterial hypertension, Raynaud's phenomenon, SSc-related antibodies (anticentromere, anti-topoisomerase I, anti-RNA polymerase III)]
    a. If yes, approve for 6 months

Last Reviewed: 10/17/18, 1/20/21, 3/16/22, 5/18/22, 5/19/23, 5/17/24, 5/16/25
Effective Date: 1/1/19, 3/1/21, 4/15/22, 7/15/22, 6/15/24

b. If no, clinical review required

Reauthorization Criteria

1. Is the request to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member demonstrate a positive clinical response to therapy as defined by no disease progression, a slowed rate of progression, or improved respiratory symptoms? (Provide FVC test result and supportive documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the treatment being prescribed by or in consultation with a pulmonologist?
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Esbriet Prescribing Information. South San Francisco, CA: Genentech USA, Inc.; November 2024.
2. Raghu G, Remy-Jardin M, Richeldi L, et al. Idiopathic Pulmonary Fibrosis (an Update) and Progressive Pulmonary Fibrosis in Adults: An Official ATS/ERS/JRS/ALAT Clinical Practice Guideline. *Am J Respir Crit Care Med*. 2022;205(9):e18-e47.
3. Ofev Prescribing Information. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; October 2024.
4. Van Den Hoogen, Frank, et al. "2013 classification criteria for systemic sclerosis: an American College of Rheumatology/European League against Rheumatism collaborative initiative." Arthritis & Rheumatism 65.11 (2013): 2737-2747.
5.

Last Reviewed: 10/17/18, 1/20/21, 3/16/22, 5/18/22, 5/19/23, 5/17/24, 5/16/25
Effective Date: 1/1/19, 3/1/21, 4/15/22, 7/15/22, 6/15/24

Isturisa® (osilodrostat)
Prior Authorization Guidelines

Affected Medication(s)

- Isturisa (osilodrostat) oral tablet

FDA Approved Indication(s)

- Treatment of adult patients with Cushing's Disease for whom pituitary surgery is not an option or has not been curative

Dosing

- Initiate dosage at 2 mg orally twice daily. Titrate dosage by 1 to 2 mg twice daily no more frequently than every 2 weeks based on rate of cortisol changes, individual tolerability and improvement in signs and symptoms. Maximum recommended dosage is 30 mg twice daily

Initial Authorization Criteria

1. Is the request for continuation of Isturisa (osilodrostat) therapy?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the treatment prescribed by or in consultation with an endocrinologist?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Has the member been diagnosed with endogenous Cushing's Disease and has either failed pituitary surgery or is not a candidate for surgery? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have a 24-hour mean urinary free cortisol level greater than 1.5 times the upper limit of normal? (Above 67 µg/24 hours) (Provide supporting lab values)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Does the member have a previous trial with inadequate response, intolerance, or contraindication to ketoconazole? (Provide supporting documentation)
    a. If yes, approve for 6 months
    b. If no, clinical review required

Last Reviewed: 11/18/20, 11/17/21, 3/17/23, 3/15/24, 3/21/25
Effective Date: 12/15/20, 4/15/24

Reauthorization Criteria

1. Is the documented indication Food and Drug Administration (FDA) approved or supported by major compendia?

    a. If yes, continue to #2
    b. If no, clinical review required

2. Is the treatment prescribed by or in consultation with an endocrinologist?

    a. If yes, continue to #3
    b. If no, clinical review required

3. Has the member been diagnosed with endogenous Cushing's Disease and has either failed pituitary surgery or is not a candidate for surgery? (Provide supporting documentation)

    a. If yes, continue to #4
    b. If no, clinical review required

4. Has the member experienced a documented positive response to therapy defined by a reduction in 24-hour urinary free cortisol levels to normal levels and/or improvement in signs or symptoms? (Provide supporting documentation) Note: For subsequent renewals documented maintenance of initial response is required.

    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

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References:

1. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 27 July. 2020].
2. ISTURISA (osilodrostat) oral tablet [package insert]. Lebanon, NJ: Recordati Rare Disease, Inc; November 2023.
3. Pivonello, Rosario, et al. "Efficacy and safety of osilodrostat in patients with Cushing's disease (LINC 3): a multicentre phase III study with a double-blind, randomised withdrawal phase." The Lancet Diabetes & Endocrinology 8.9 (2020): 748-761.
4. Lynnette K. Nieman, Beverly M. K. Biller, James W. Findling, M. Hassan Murad, John Newell-Price, Martin O. Savage, Antoine Tabarin, Treatment of Cushing's Syndrome: An Endocrine Society Clinical Practice Guideline, The Journal of Clinical Endocrinology & Metabolism, Volume 100, Issue 8, 1 August 2015, Pages 2807–2831, https://doi.org/10.1210/jc.2015-1818

Last Reviewed: 11/18/20, 11/17/21, 3/17/23, 3/15/24, 3/21/25
Effective Date: 12/15/20, 4/15/24

Ivabradine
Prior Authorization Guidelines

Affected Medication(s)

- Corlanor oral tablet
- Corlanor oral solution
- Ivabradine oral tablet

FDA Approved Indication(s)

- To reduce the risk of hospitalization for worsening heart failure in patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction ≤ 35%, who are in sinus rhythm with resting heart rate ≥ 70 beats per minute and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use
- Treatment of stable symptomatic heart failure due to dilated cardiomyopathy (DCM) in pediatric patients aged 6 months and older, who are in sinus rhythm with an elevated heart rate

Dosing

- Adults:
  - Initial: 5 mg twice daily with meals
  - After 2 weeks, adjust dose to achieve a resting heart rate between 50-60 beats per minute (reference dosage adjustments in package insert)
- Pediatrics:
  - Please see package insert for specific pediatric weight-based dosing

Initial Authorization Criteria

1. Is the request for continuation of ivabradine therapy for the same indication?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2
2. Is the request for use to treat an FDA-approved or major compendia supported indication? (Provide documentation of diagnosis)
   a. If yes, continue to #3
   b. If no, clinical review required
3. Is the member aged 6 months or older?
   a. If yes, continue to #4
   b. If no, clinical review required
4. What is the indication the medication is being requested for?
   a. Chronic heart failure, continue to question #5
   b. Inappropriate sinus tachycardia, continue to #8
   c. Other indication, clinical review required
5. Does the member have a left ventricular ejection fraction of 35% or less for adults or 45% or less for pediatrics? (Provide documentation for review)
   a. If yes, continue to #6

Last Reviewed: 10/3/18, 11/18/20, 5/18/22, 5/19/23, 5/17/24, 9/20/24, 9/19/25
Effective Date: 1/1/19, 12/15/20, 7/15/22, 6/15/24, 10/15/24

b. If no, clinical review required

6. Is the member currently in sinus rhythm with a resting heart rate meeting one of the below? (Provide heart rate for review)
    - ≥ 70 bpm for ages 5 years and older
    - ≥75 bpm for ages 3-5 years
    - ≥95 bpm for ages 1-3 years
    - ≥105 bpm for ages 6-12 months

    a. If yes, continue to # 7
    b. If no, clinical review required
7. Is the member on a maximally tolerated dose of a beta-blocker (i.e. metoprolol succinate, carvedilol, or bisoprolol) or have contraindication to their use? (Provide history of beta-blocker use or contraindication to therapy)

    a. If yes, continue to #10
    b. If no, clinical review required
8. Does the member have confirmation of inappropriate sinus tachycardia defined as a sinus heart rate greater than 100 bpm at rest (with a mean 24-hour heart rate >90 bpm not due to primary causes) AND is associated with distressing symptoms of palpitations (i.e. presyncope, headache, dyspnea, etc.)? (Provide supporting documentation)

    a. If yes, continue to #9
    b. If no, clinical review required
9. Have all other causes of sinus tachycardia have been ruled out (examples include thyroid disease or drug induced)?

    a. If yes, continue to #10
    b. If no, clinical review required
10. Is the treatment being prescribed by or in consult with a cardiologist or other appropriate specialist?

    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA-approved or major compendia supported indication? (Provide documentation of diagnosis)

    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the treatment being prescribed by or in consultation with a cardiologist or other appropriate specialist?

    a. If yes, continue to #3
    b. If no, clinical review required
3. Were updated chart notes provided with documentation of significant clinical response to therapy? (Provide updated clinical information for review such as heart rate stabilization, improvement in HF symptoms, etc.)

    a. If yes, approve for 12 months unless otherwise specified

Last Reviewed: 10/3/18, 11/18/20, 5/18/22, 5/19/23, 5/17/24, 9/20/24, 9/19/25
Effective Date: 1/1/19, 12/15/20, 7/15/222, 6/15/24, 10/15/24

b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Corlanor. Micromedex. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed October 23, 2020
2. Corlanor (ivabradine) [Prescribing Information]. Thousand Oaks, CA: Amgen. February 2022.
3. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2022;145(18):e895-e1032.
4. Sheldon, Robert S., et al. "2015 heart rhythm society expert consensus statement on the diagnosis and treatment of postural tachycardia syndrome, inappropriate sinus tachycardia, and vasovagal syncope." Heart rhythm 12.6 (2015): e41-e63.

Last Reviewed: 10/3/18, 11/18/20, 5/18/22, 5/19/23, 5/17/24, 9/20/24, 9/19/25
Effective Date: 1/1/19, 12/15/20, 7/15/222, 6/15/24, 10/15/24

Iwilfin (eflornithine)
Prior Authorization Guidelines

Affected Medication(s)

- Iwilfin (eflornithine) oral tablet

FDA Approved Indication(s)

- To reduce the risk of relapse in adult and pediatric patients with high-risk neuroblastoma (HRNB) who have demonstrated at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy

Dosing

- 0.25 to <0.5 m2: 192 mg by mouth twice daily
- 0.5 to <0.75 m2: 384 mg by mouth twice daily
- 0.75 to 1.5 m2: 576 mg by mouth twice daily
- Greater than 1.5 m2: 768 mg by mouth twice daily

Initial Authorization Criteria

1. Is the request for continuation of therapy with the same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the medication being requested for an indication supported by the National Comprehensive Cancer Network (NCCN) recommendation with an evidence level of 2A or higher? (Provide disease staging, all prior treatment history, pathology report, and anticipated treatment plan for review)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have Karnofsky Performance Status greater or equal to 50% OR Eastern Cooperative Oncology Group (ECOG) performance status of 0-2? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is the medication being prescribed by, or in consultation with, an oncologist?
    a. If yes, approve for 4 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #2

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b. If no, clinical review required

2. Is there clinical documentation confirming disease responsiveness to therapy provided? (Example include reduction in tumor size, objective response, delay in progression, partial response, etc.) (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the medication being prescribed by or in consultation with an oncologist?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. IWILFIN™ (eflornithine) tablets [package insert]. Louisville, KY: USWM, LLC 2024.
2. Clinical Practice Guidelines in Oncology (NCCN Guidelines): Neuroblastoma. Version 2.2024 National Comprehensive Cancer Network website. Available from https://www.nccn.org/professionals/physician_gls/pdf/neuroblastoma.pdf. [Accessed February 3, 2025.]
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Last Reviewed: 3/15/24, 3/21/25
Effective Date: 4/15/24, 4/1/25

Janus Kinase Inhibitor
Prior Authorization Guidelines

Affected Medication(s)

- Cibinqo™ (abrocitinib) oral tablet
- Olumiant® (baricitinib) oral tablet
- Rinvoq® (upadacitinib) oral tablet/solution
- Xeljanz® (tofacitinib citrate) oral tablet/solution
- Xeljanz® XR oral tablet

FDA Approved Indication(s)

- Drug Compendia supported indications may be covered

Drug Name	RA	JIA	PsA	AS	UC	CD	AD	Other
Cibinqo							X	
Rinvoq	X	X	X	X	X	X	X	X
Rinvoq LQ		X	X					
Xeljanz	X	X	X	X	X			
Xeljanz Solution		X						
Xeljanz XR	X		X	X	X			
Olumiant	X							X

Dosing

- Refer to corresponding package insert for information

Initial Authorization Criteria

1. Is the request for continuation of therapy?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA-approved indication or a major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Will the requested medication be used concurrently with any other biologic therapy? (Examples: Enbrel, Actemra, Cimzia, Simponi, Orencia, Taltz, Cosentyx, Otezla, etc)
    a. If yes, clinical review required
    b. If no, continue to #4
4. What is the diagnosis that the medication is being requested for?
    a. Rheumatoid arthritis, continue to corresponding criteria
    b. Juvenile idiopathic arthritis, continue to corresponding criteria
    c. Psoriatic arthritis, continue to corresponding criteria
    d. Ankylosing spondylitis, continue to corresponding criteria

Last Reviewed: 11/16/22, 7/21/23, 3/15/24, 7/19/24, 5/16/25
Effective Date: 1/1/23, 9/15/23, 4/15/24, 8/15/24, 6/1/25

e. Ulcerative colitis, continue to corresponding criteria
f. Crohn's disease, continue to corresponding criteria
g. Atopic Dermatitis, continue to corresponding criteria
h. Other indication, continue to corresponding criteria

Rheumatoid Arthritis (RA)

1. Is the diagnosis of rheumatoid arthritis (RA) confirmed by ACR/EULAR classification criteria AND has the diagnosis been documented for greater for 6 months? (Provide supporting documentation)

    a. If yes, continue to #2
    b. If no, clinical review required

2. Does the member have moderate to severe active RA confirmed by one of the tests below and despite the current RA management regimen? (Provide current RA management regimen and test result for review)

    - Patient Activity Scale (PAS) or PASII of 3.7 or higher
    - Routine Assessment of Patient Index Data 3 (RAPID3) of 2.0 or higher
    - Clinical Disease Activity Index (CDAI) of 10 or higher
    - Disease Activity Score (DAS) 28 erythrocyte sedimentation rate (ESR) of 3.2 or higher
    - Simplified Disease Activity Index (SDAI) of 11 or higher

    a. If yes, continue to #3
    b. If no, clinical review required.

3. Did the member have an inadequate response to a 12 week trial of methotrexate? (Provide documentation of inadequate response to methotrexate)

    a. If yes, continue to #6
    b. If no, continue to #4

4. Does the member have a contraindication or history of intolerance to methotrexate? (Provide documentation of contraindication and/or intolerance. Note: 1. Alcohol consumption is not considered a contraindication 2. Nausea to oral formulation is not considered an intolerance)

    a. If yes, continue to #5
    b. If no, clinical review required

5. Does the member have a contraindication to all of the following OR an inadequate response to one 12 week trial with the following disease-modifying antirheumatic drugs: leflunomide, sulfasalazine, or hydroxychloroquine? (Provide documentation of contraindication or inadequate response to therapy)

    a. If yes, continue to #6
    b. If no, clinical review required

6. Is the request for Olumiant (baricitinib)?

    a. If yes, continue to #7
    b. If no, continue to #9

7. Does the member have a documented inadequate response, contraindication, or intolerance to TWO of the following agents: preferred adalimumab biosimilar, Cimzia (certolizumab pegol), Rinvoq (upadacitinib), Simponi (golimumab), or Xeljanz/Xeljanz XR (tofacitinib citrate)? (Provide documentation of inadequate responses, contraindications, and/or intolerances)

    a. If yes, continue to #8

b. If no, clinical review required

8. Does the member have a documented inadequate response, contraindication, or intolerance to Kevzara (sarilumab)? (Provide documentation of inadequate responses, contraindications, and/or intolerances)
    a. If yes, continue to #9
    b. If no, clinical review required
9. Is the medication being prescribed by or in consultation with a rheumatologist?
    a. If yes, approve 6 months unless otherwise specified
    b. If no, clinical review required

Juvenile Idiopathic Arthritis (JIA/PJIA)

1. Does the member have moderate to severe active polyarticular JIA defined as greater or equal to 5 swollen joints and at least 3 joints with limitation in motion? (Provide documentation of affected joints and current treatment regimen)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Did the member have an inadequate response to a 12 week trial of methotrexate? (Provide documentation of trial with inadequate response)
    a. If yes, continue to #5
    b. If no, continue to #3
3. Does the member have a contraindication or history of intolerance to methotrexate? (Provide documentation of contraindication and/or intolerance. Note: 1. Alcohol consumption is not considered a contraindication 2. Nausea to oral formulation is not considered an intolerance)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Did the member have a contraindication or history of intolerance to leflunomide? (Provide documentation of contraindication and/or intolerance)
    a. If yes, continue to #5
    b. If no, deny. Clinical criteria not met
5. Does the member have documentation of an inadequate response, intolerance, or contraindication to a preferred adalimumab biosimilar? (Provide documentation of inadequate response, contraindication, and/or intolerance)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Is the request for Xeljanz oral tablet or Xeljanz oral solution? (Note: Xeljanz XR tablet is not FDA approved for treatment of PJIA)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Is the medication being prescribed by or in consultation with a rheumatologist?
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Psoriatic Arthritis (PsA)

1. Does the member currently have active psoriatic arthritis defined as greater or equal to 3 swollen joints AND greater or equal to 3 tender or painful joints despite the current treatment regimen? (Provide documentation of affected joints and current treatment regimen)

    a. If yes, continue to #2
    b. If no, clinical review required

2. Does the member have a contraindication or an inadequate response to a 12 week trial with one of the following: methotrexate, leflunomide, cyclosporine, sulfasalazine? (Provide documentation of trial with inadequate response or contraindication)

    a. If yes, continue to #3
    b. If no, clinical review required

3. Does the member have a documented inadequate response, contraindication, or intolerance to TWO of the following agents: preferred adalimumab biosimilar, Cimzia (certolizumab pegol), Simponi (golimumab), Skyrizi (risankizumab), Selarsdi (ustekinumab-aekn),Stelara (ustekinumab), or Yesintek (ustekinumab-kfce)? (Provide documentation of inadequate responses, contraindications, and/or intolerances)

    a. If yes, continue to #6
    b. If no, continue to # 4

4. Is the request for Xeljanz (tofacitinib)?

    a. If yes, continue to #5
    b. If no, continue to #6

5. Does the member have documented needle phobia to the degree that the member has previously refused any injectable therapy or medical procedure? (refer to DSM-V-TR F40.2 for specific phobia diagnostic criteria)

    a. If yes, continue to #7
    b. If no, clinical review required

6. Does the member have a documented inadequate response, contraindication, or intolerance to BOTH of the following agents: Taltz (ixekizumab) and Xeljanz (tofacitinib)? (Provide documentation of inadequate responses, contraindication, and/or intolerance) [n/a if requested drug is Xeljanz]

    a. If n/a, continue to #7
    b. If yes, continue to # 7
    c. If no, clinical review required

7. Is the medication being prescribed by or in consultation with a rheumatologist or dermatologist?

    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

<u>Ankylosing Spondylitis (AS)</u>

1. Does the member currently have active AS despite a current treatment regimen as defined by the below? (Provide supporting documentation)

    - Bath ankylosing spondylitis disease activity index (BASDAI) greater or equal to 4 <u>OR</u>
    - Ankylosing Spondylitis Disease Activity Score (ASDAS) greater or equal to 2.1 <u>AND</u>
    - Elevated CRP, positive MRI, or Radiographic sacroiliitis

    a. If yes, continue to #2
    b. If no, clinical review required

Last Reviewed: 11/16/22, 7/21/23, 3/15/24, 7/19/24, 5/16/25
Effective Date: 1/1/23, 9/15/23, 4/15/24, 8/15/24, 6/1/25

2. Did the member have an inadequate response or intolerance to TWO separate 4 week trials of prescription strength oral nonsteroidal anti-inflammatory drugs (NSAIDs)? (Provide documentation of NSAIDs tried, examples: ibuprofen, naproxen, diclofenac, meloxicam, etc.)
    a. If yes, continue to #4
    b. If no, continue to #3
3. Does the member have a contraindication to oral NSAIDs? (Provide documentation of contraindication)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have isolated sacroilitis, or enthesitis disease? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, continue to #7
5. Did the member have an inadequate response to a parenteral glucocorticoid injection? (Provide documentation of trial with inadequate response)
    a. If yes, continue to #9
    b. If no, continue to #6
6. Does the member have a contraindication to a parenteral glucocorticoid injection? (Provide documentation of contraindication)
    a. If yes, continue to #9
    b. If no, clinical review required
7. Does the member have predominantly active axial or peripheral disease? (Provide supporting documentation)
    a. If axial, continue to #10
    b. If peripheral, continue to #8
8. Did the member have an inadequate response to a 12 week trial with sulfasalazine? (Provide documentation of trial with inadequate response)
    a. If yes, continue to #10
    b. If no, continue to #9
9. Does the member have a contraindication or history of intolerance to sulfasalazine? (Provide documentation of contraindication and/or intolerance)
    a. If yes, continue to #10
    b. If no, clinical review required
10. Does the member have a documented inadequate response, intolerance, or contraindication to TWO of the following agents: preferred adalimumab biosimilar, Cimzia (certolizumab pegol), or Simponi (golimumab)? (Provide documentation of inadequate responses, contraindications, and/or intolerances)
    a. If yes, continue to #11
    b. If no, clinical review required
11. Is Rinvoq (upadacitinib) the requested medication?
    a. If yes, continue to #12
    b. If no, continue to #13

12. Does the member have a documented inadequate response, intolerance, or contraindication to Taltz (ixekizumab) or Xeljanz (tofacitinib)? (Provide documentation of inadequate response, contraindication, and/or intolerance)

    a. If yes, continue to #13
    b. If no, clinical review required

13. Is the medication being prescribed by or in consultation with a rheumatologist?

    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Ulcerative Colitis (UC)

1. Does the member currently have active Ulcerative Colitis? (Provide documentation of diagnosis confirmed by endoscopy, colonoscopy, or sigmoidoscopy with Mayo score of greater than 2)

    a. If yes, continue to #2
    b. If no, clinical review required

2. Does the member have a documented inadequate response, intolerance, or contraindication to TWO of the following: preferred adalimumab biosimilar, Simponi (golimumab), Skyrizi (risankizumab), Selarsdi (ustekinumab-aekn), Stelara (ustekinumab), or Yesintek (Ustekinumab-kfce)? (Provide documentation of inadequate responses, contraindications, and/or intolerances)

    a. If yes, continue to #5
    b. If no, continue to #3

3. What is the requested medication?

    a. Xeljanz (tofacitinib), continue to #4
    b. Rinvoq (upadacitinib), clinical review required

4. Does the member with needle phobia to the degree that the member has previously refused any injectable therapy or medical procedure? (refer to DSM-V-TR F40.2 for specific phobia diagnostic criteria)

    a. If yes, continue to #6
    b. If no, clinical review required

5. Does the member have a documented inadequate response, intolerance, or contraindication to Xeljanz (tofacitinib)? (Provide documentation of inadequate response, contraindications, and/or intolerances)

    a. If yes, continue to #6
    b. If n/a, continue to #6
    c. If not, clinical review required

6. Is the medication being prescribed by, or in consultation with, a gastroenterologist?

    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Crohn's Disease (CD)

1. Does the member currently have active CD defined as a Crohn's Disease Activity Index (CDAI) greater than 220 despite the current treatment regimen? (Provide documentation of CDAI and current treatment regimen)

    a. If yes, continue to #2
    b. If no, clinical review required

2. Did the member have an inadequate response to TWO of the following oral agents for a minimum trial of 12 weeks each: 6-mercaptopurine, azathioprine, corticosteroid, methotrexate, mesalamine, or sulfasalazine? (Provide documentation of 12-week trials with inadequate responses)
    a. If yes, continue to #4
    b. If no, continue to #3
3. Does the member have a contraindication or history of intolerance to at least TWO of the following oral agents: 6-mercaptopurine, azathioprine, corticosteroids, methotrexate, mesalamine, or sulfasalazine? (Provide documentation of contraindications and/or intolerances)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have a documented inadequate response, contraindication, or intolerance to TWO of the following agents: preferred adalimumab biosimilar, Cimzia (certolizumab pegol), Skyrizi (risankizumab), Selarsdi (ustekinumab-aekn) Stelara (ustekinumab), or Yesintek(ustekinumab-kfce)?? (Provide documentation of inadequate responses, contraindications, and/or intolerances)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is the medication being prescribed by, or in consultation with, a gastroenterologist?
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Atopic Dermatitis

1. Does the member have at least 10% body surface area involvement? (Provide documentation of body surface area affected)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member have a documented trial with insufficient response, intolerance, or contraindication to Dupixent (dupilimab)? (Provide documentation to support insufficient response, intolerance, and/or contraindication)
    a. If yes, continue to #3
    b. If no, continue to #4
3. Does the member have a documented trial with insufficient response, or intolerance, or contraindication to TWO of the following therapies: topical agent (high-potency steroid/calcineurin inhibitor), immunomodulatory agent (azathioprine, cyclosporine, methotrexate, mycophenolate), or phototherapy? (Provide supporting documentation of all therapies tried)
    a. If yes, continue to #7
    b. If no, clinical review required
4. Does the member have a documented trial with insufficient response, or intolerance, or contraindication to both a high-potency topical steroid (i.e. clobetasol 0.05%, fluocinonide 0.1%, halobetasol 0.05%, or betamethasone dipropionate 0.05%) and a topical calcineurin inhibitor (i.e. tacrolimus or pimecrolimus)? (Provide supporting documentation of all therapies tried)
    a. If yes, continue to #5
    b. If no, clinical review required

5. Does the member have a documented trial with insufficient response or intolerance or contraindication to at least one systemic immunomodulatory agent (i.e. azathioprine, cyclosporine, methotrexate, or mycophenolate)? (Provide supporting documentation of all therapies tried)

    a. If yes, continue to #6
    b. If no, clinical review required

6. Does the member have a documented trial with insufficient response, intolerance, or contraindication to phototherapy? (Provide documentation to support insufficient response, intolerance, and/or contraindication)

    a. If yes, continue to #7
    b. If no, clinical review required

7. Is the requested drug being prescribed by or in consultation with a dermatologist, allergist, or immunologist?

    a. If yes, approve for 6 months unless otherwise
    b. If no, clinical review required

Other Indications

1. Is the request for a FDA approved indication?

    a. If yes, continue to #4
    b. If no, continue to #2

2. Is the requested use supported by major compendia not otherwise excluded by plan design?

    a. If yes, continue to #3
    b. If no, clinical review required

3. Has the member tried and had an inadequate response OR does the member have a contraindication to ALL standard treatment options for the requested indication? (Provide documentation of inadequate responses, contraindications, and/or intolerances)

    a. If yes, continue to #4
    b. If no, clinical review required

4. Is the treatment being prescribed by or in consultation with an appropriate specialist?

    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication FDA-approved or supported by major compendia? (Provide documentation of diagnosis)

    a. If yes, continue to #2
    b. If no, clinical review required

2. Were updated chart notes (dated within 1 year) provided with documentation of significant clinical response to therapy? (Provide supporting documentation)

    a. If yes, continue to #3
    b. If no, clinical review required

3. Will the requested medication be used with other biologic therapy? (Examples: Enbrel, Actemra, Cimzia, Simponi, Orencia, Taltz, Cosentyx, Otezla, etc)

a. If yes, clinical review required
b. If no, continue to #4

4. Is the treatment being prescribed by or in consultation with an appropriate specialist?

    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:
Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Cibinqo [prescribing information]. New York, NY: Pfizer Inc., February 2022.
2. Rinvoq [prescribing information]. North Chicago, IL: AbbVie Inc., April 2024.
3. Olumiant [prescribing information]. Indianapolis, IN: Eli Lilly and Company., June 2022.
4. Xeljanz [prescribing information]. New York, NY: Pfizer Inc., December 2022.
5. Aletaha D, Neogi T, Silman AJ, et al. 2010 Rheumatoid Arthritis Classification Criteria. Arthritis & Rheumatism. 2010;62(9):2569-2581. Available at: https://www.rheumatology.org/Portals/0/Files/2010_revised_criteria_classification_ra.pdf.
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Joenja® (leniolisib)
Prior Authorization Guidelines

Affected Medication(s)

- Joenja (leniolisib) oral tablet

FDA Approved Indication(s)

- Treatment of activated phosphoinositide 3-kinase delta (PI3Kδ) syndrome in adult and pediatric patients 12 years of age and older

Dosing

- 70 mg orally twice daily

Initial Authorization Criteria

1. Is the request for continuation of therapy with the same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is Joenja® (leniolisib) being requested for an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member 12 years of age or older?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have confirmed APDS-associated PI3Kδ mutation with a documented variant in PIK3CD or PIK3R1? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have nodal and/or extranodal lymphoproliferation with measurable index lesions? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Does the member have clinical findings and manifestations compatible with APDS such as recurrent sinopulmonary infections, intermittent herpesvirus viremia, and/or organ dysfunction? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Will Joenja be used in combination with immunosuppressive medications, PI3Kδ inhibitors, or B-cell depleters such as rituximab? (Provide supporting documentation)
    a. If yes, clinical review required
    b. If no, continue to #8

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Effective Date: 7/15/23, 8/15/24

8. Is the treatment being prescribed by, or in consultation with, an immunologist?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (within past year) provided with documentation of clinical response to prior therapy received (ex. decrease in size of index lesions, decrease in infections)?
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the treatment being prescribed by, or in consultation with, an immunologist?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Joenja (leniolisib) tablets, [package insert]. Saint Quentin Fallavier, France: Skypharma Production SAS for Pharming Technologies B.V.; 2023
2. Drugs@FDA: FDA Approved Drug Products. 2023. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 17 Apr. 2023]
3. Rao VK, Webster S, Šedivá A, et al. A randomized, placebo-controlled phase 3 trial of the PI3Kδ inhibitor leniolisib for activated PI3Kδ syndrome. Blood. 2023;141(9):971-983.
4. Coulter TI, Cant AJ. The Treatment of Activated PI3Kδ Syndrome. Front Immunol. 2018 Sep 7;9:2043.

Last Reviewed: 5/19/23, 7/19/24, 7/18/25

Effective Date: 7/15/23, 8/15/24

Juxtapid® (lomitapide mesylate)
Prior Authorization Guidelines

Affected Medication(s)

- Juxtapid oral capsule

FDA Approved Indication(s)

- 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 (apo B), and non-high-density lipoprotein cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH)

Dosing

- Initially 5mg orally once daily
- Refer to package insert for dose titration chart

Initial Authorization Criteria

1. Is the request for continuation of the same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the medication being prescribed by or in consultation with cardiologist, endocrinologist, or lipid specialist?
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have a diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) as supported by one of the following? (Provide supporting documentation)
    - Genetic mutation testing (mutations in LDL receptor gene, proprotein convertase subtilisin kexin9 [PCSK9] gene, apo B gene, LDL receptor adaptor protein 1 [LDLRAP1] gene)
    - Treated LDL-C ≥ 300 mg/dL or untreated LDL-C ≥ 500 mg/dL AND one of the following (i or ii):
        i. Tendon or cutaneous xanthoma prior to age 10 years
        ii. Evidence of HeFH in both parents (e.g., documented history of elevated LDL-C ≥ 190 mg/dL prior to lipid-lowering therapy)

    a. If yes, continue to #5
    b. If no, clinical review required
5. Is all of the following documentation received? (Provide supporting documentation)
    - Complete lipid panel performed within the last 3 months

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- Baseline LDL-C
- Documentation of dietary measures being undertaken to lower cholesterol

a. If yes, continue to #6
b. If no, clinical review required

6. Has the member been on high-intensity statin therapy for the last 3 consecutive months and will continue with high-intensity statin therapy? (High-intensity statin therapy includes: atorvastatin 40-80 mg or rosuvastatin 20-40 mg) (Document current statin regimen with initiation date and verify adherence)

    a. If yes, continue to #11
    b. If no, continue to #7

7. What is the rationale provided for avoiding high-intensity statin therapy? (Provide supporting documentation for review)

    a. Statin intolerance due to myalgia or myopathy, continue to #8
    b. History of rhabdomyolysis with creatinine kinase (CK) levels greater than 10-times upper limit of normal (document date occurred) OR labeled contraindication to all statin therapy, continue to #11
    c. All other rationale, clinical review required

8. Is the member currently receiving a maximally tolerated dose of a statin AND ezetimibe and will continue statin and ezetimibe with the requested medication?

    a. If yes, continue to #11
    b. If no, continue to #9

9. Is documentation of persistent myalgia or myopathy on two separate 8-week trials with pravastatin, rosuvastatin, or fluvastatin provided?

    a. If yes, continue to #10
    b. If no, clinical review required

10. Has the member been on ezetimibe for 3 consecutive months and will continue with the requested medication?

    a. If yes, continue to #11
    b. If no, clinical review required

11. Does the member have a documented trial with insufficient response, intolerance, or contraindication to a PCSK9 inhibitor (Examples: Repatha or Praluent)? (Provide supporting documentation)

    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is the medication being prescribed by or in consultation with cardiologist, endocrinologist, or lipid specialist?

    a. If yes, continue to #2
    b. If no, clinical review required

2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)

Last Reviewed: 11/7/18, 9/16/20, 9/15/21, 1/20/23, 1/19/24, 1/17/25
Effective Date: 1/1/19, 11/15/20, 3/15/23, 3/1/24, 2/1/25

a. If yes, continue to #3
b. If no, clinical review required

3. Does the member have a diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) as supported by one of the following? (Provide supporting documentation)

    - Genetic mutation testing (mutations in LDL receptor gene, proprotein convertase subtilisin kexin9 [PCSK9] gene, apo B gene, LDL receptor adaptor protein 1 [LDLRAP1] gene)
    - Treated LDL-C ≥ 300 mg/dL or untreated LDL-C ≥ 500 mg/dL AND one of the following (i or ii):
        i. Tendon or cutaneous xanthoma prior to age 10 years
        ii. Evidence of HeFH in both parents (e.g., documented history of elevated LDL-C ≥ 190 mg/dL prior to lipid-lowering therapy)

    a. If yes, continue to #4
    b. If no, clinical review required

4. Has the member demonstrated a positive clinical response to therapy? (Provide documentation of an LDL-C reduction since the initiation of therapy)

    a. If yes, continue to #5
    b. If no, clinical review required

5. Is an updated lipid panel result received? (Provide lipid panel results for review)

    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Juxtapid Prescribing Information. Dublin, Ireland: Amryt Pharmaceuticals; April 2022. Available at http://www.juxtapidpro.com/prescribing-information.
2. Stone NJ, Robinson JG, Lichtenstein AH, et al. 2013 ACC/AHA guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation. 2014 June 24; 129[suppl 2]: S1-S45.
3. Jacobson TA, et al. National Lipid Association recommendations for patient-centered management of dyslipidemia: part 1 – full report. Journal of Clinical Lipidology. March-April 2015; 9(2): 129-169. http://dx.doi.org/10.1016/j.jacl.2015.02.003
4. Familial hypercholesterolemia: screening, diagnosis and management of pediatric and adult patients: clinical guidance from the National Lipid Association Expert Panel on Familial Hypercholesterolemia. Journal of Clinical Lipidology. June 2011; 5(3S): 1-15
5. Fitchett DH, Hegele RA, Verma S. Statin intolerance. Circulation. 2015;131:e389-391. https://doi.org/10.1161/CIRCULATIONAHA.114.013189.

Last Reviewed: 11/7/18, 9/16/20, 9/15/21, 1/20/23, 1/19/24, 1/17/25
Effective Date: 1/1/19, 11/15/20, 3/15/23, 3/1/24, 2/1/25

6. Jellinger PS, Handelsman Y, Rosenblit PD, et al. American association of clinical endocrinologists and American college of endocrinology guidelines for management of dyslipidemia and prevention of cardiovascular disease. Endocrine Practice April 2017; 23(4): 479-497. Available at: https://doi.org/10.4158/EP171764.GL
7. Grundy SM, Stone NJ, et al. 2018 ACC/AHA guideline on the management of blood cholesterol: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Journal of the American College of Cardiology. 2019;73(24):e285-e350. Available at: https://www.onlinejacc.org/content/73/24/e285.
8. Cuchel, Marina, et al. "Homozygous familial hypercholesterolaemia: new insights and guidance for clinicians to improve detection and clinical management. A position paper from the Consensus Panel on Familial Hypercholesterolaemia of the European Atherosclerosis Society." European heart journal 35.32 (2014): 2146-2157.

Korlym® (mifepristone)
Prior Authorization Guidelines

Affected Medication(s)

- Korlym oral tablet
- mifepristone 300 mg oral tablet

FDA Approved Indication(s)

- 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

Dosing

- 300 mg orally once daily

Initial Authorization Criteria

1. Is the request for continuation of mifepristone therapy for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member 18 years of age or older?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the member a female of reproductive age?
    a. If yes, continue to #5
    b. If no, continue to #6
5. Has pregnancy been excluded by a negative pregnancy test and will the member use contraception while on therapy? (Provide documentation of negative pregnancy test and contraception use)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Does the member have endogenous hypercortisolism? (i.e. not hypercortisolism due to chronic high dose glucocorticoids) (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Does the member have type 2 diabetes or glucose intolerance secondary to hypercortisolism confirmed by HbA1c? (Provide supporting documentation including current HbA1c)

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Effective Date: 1/1/19, 4/15/24, 4/1/25

a. If yes, continue to #8
b. If no, clinical review required

8. Has the member failed surgery or is the member not a surgical candidate? (Trans-sphenoidal surgery for pituitary dependent Cushing's or surgical removal of an adrenocortical tumor in malignant Cushing's) (Provide supporting documentation of surgery or rationale for avoiding surgery)

    a. If yes, continue to #9
    b. If no, clinical review required

9. Has the member had a trial with inadequate response or an intolerance to a steroidogenesis inhibitor? (i.e. ketoconazole, metyrapone)

    a. If yes, continue to #10
    b. If no, clinical review required

10. Does the member have a trial with inadequate response, an intolerance, or contraindication to treatment with maximum dose of metformin? Note: If patient has GI discomfort, metformin ER (Glucophage XR) should be trialed (Provide documentation of trial, intolerance, or contraindication)

    a. If yes, continue to #11
    b. If no, clinical review required

11. Is the treatment being prescribed by, or in consultation with, an endocrinologist?

    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)

    a. If yes, continue to #2
    b. If no, clinical review required

2. Is the member a female of reproductive age?

    a. If yes, continue to #3
    b. If no, continue to #6

3. Have more than 14 days passed between the last dose and the next scheduled dose? (Provide documentation of date of last dose and date of next scheduled dose)

    a. If yes, continue to #4
    b. If no, continue to #5

4. Has pregnancy been excluded by a negative pregnancy test? (Provide documentation of date of last dose and negative pregnancy test if indicated)

    a. If yes, continue to #5
    b. If no, clinical review required

5. Does the member use contraception while on therapy? (Provide documentation of contraception use)

    a. If yes, continue to #6

Last Reviewed: 11/21/18, 5/19/21, 7/20/22, 3/17/23, 3/15/24, 3/21/25
Effective Date: 1/1/19, 4/15/24, 4/1/25

b. If no, clinical review required

6. Has the member had a positive clinical response to therapy as defined by improved glucose control? (Provide supporting documentation including an updated HbA1c)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Is the treatment being prescribed by, or in consultation with, an endocrinologist?
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Korlym [package insert]. Corcept Therapeutics Inc., Menlo Park, CA, April 2024.
2. Johanssen S, Allolio B. Mifeprisone (RU 486) in Cushing's syndrome. European Journal of Endocrinology/European Federation of Endocrine Societies 2007; 157: 561-569.
3. Barbot M, Ceccato F, Scaroni C. Diabetes Mellitus Secondary to Cushing's Disease. Front Endocrinol (Lausanne). 2018;9:284. Published 2018 Jun 5. doi:10.3389/fendo.2018.00284
4. Nieman LK, Biller BM, Findling JW. Treatment of Cushing's Syndrome: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2015;100(8):2807-2831.

Last Reviewed: 11/21/18, 5/19/21, 7/20/22, 3/17/23, 3/15/24, 3/21/25
Effective Date: 1/1/19, 4/15/24, 4/1/25

Leqembi® Iqlik (lecanemab-irmb)
Prior Authorization Guidelines

Affected Medication(s)

- Leqembi® Iqlik (lecanemab-irmb) subcutaneous injection

FDA Approved Indication(s)

- Treatment of Alzheimer's disease (AD)

Note: Treatment with LEQEMBI should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials

Dosing

- 360 mg subcutaneously once weekly

Initial Authorization Criteria

1. Is the request for continuation of therapy with the same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is Leqembi Iqlik (lecanemab-irmb) being requested for an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member have a diagnosis of mild cognitive impairment (MCI) due to Alzheimer's Disease or mild Alzheimer's dementia?
    a. If yes, clinical review required
    b. If no, continue to #4
4. Does the member have a Positron Emission Tomography (PET) scan positive for amyloid beta plaque or CSF assessment positive for hybrid ratios of Aβ 42/40, CSF p-tau 181/Aβ 42, or CSF t-tau/Aβ 42?
    a. If yes, continue to #5
    b. If no, clinical review required
5. Has baseline disease severity been assessed utilizing at least ONE of the following measures or tools? (Provide supporting documentation)
    - Mini-Mental Status Exam [MMSE]
    - Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-Cog-13/14]
    - Alzheimer's Disease Cooperative Study-Activities of Daily Living
    - Inventory-Mild Cognitive Impairment version [ADCS-ADL-MCI]
    - Clinical Dementia Rating-Sum of Boxes [CDR-SB]
    - Montreal Cognitive Assessment (MoCA)

    a. If yes, continue to #6
    b. If no, clinical review required
6. Does the member meet at least one of the following criteria? (Provide supporting documentation)

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- Clinical Dementia Rating (CDR)-Global Score of 0.5-1.0 with Memory Box Score of 0.5 or greater
- MMSE score between 20-28
- Montreal Cognitive Assessment (MoCA) score 18-25

a. If yes continue to #7
b. If no, clinical review required

7. Does the member have any of the following risk factors for intracerebral hemorrhage: findings suggestive of cerebral amyloid angiopathy (prior cerebral hemorrhage greater than 1 cm in greatest diameter, greater than 4 microhemorrhages, superficial siderosis, vasogenic edema) or other lesions (aneurysm, vascular malformation) that could potentially increase the risk of intracerebral hemorrhage? (Provide supporting documentation)

    a. If yes, clinical review required
    b. If no, continue to #8

8. Is the member receiving antithrombotic medication such as aspirin, other antiplatelets, or anticoagulants? (Provide supporting documentation)

    a. If yes, clinical review required
    b. If no, continue to #9

9. Did the member receive a baseline brain magnetic resonance imaging (MRI) prior to initiating treatment and periodic MRIs as indicated in package insert? (Provide supporting documentation)

    a. If yes, continue to #10
    b. If no, clinical review required

10. Does the member have severe, unstable, or symptomatic amyloid-related imaging abnormalities (ARIA) seen on MRI of the brain? (Provide supporting documentation)

    a. If yes, clinical review required
    b. If no, continue to #11

11. Has the member had a stroke or transient ischemic attack (TIA) or seizures in the past 12 months? (Provide supporting documentation)

    a. If yes, clinical review required
    b. If no, continue to #12

12. Is the member receiving any other anti-amyloid immunotherapies (i.e., donanemab, aducanumab, etc.)?

    a. If yes, clinical review required
    b. If no, continue to #13

13. Have other conditions mimicking, but of non-Alzheimer's Dementia etiology, have been ruled out (e.g., vascular dementia, dementia with Lewy bodies [DLB], frontotemporal dementia [FTD], normal pressure hydrocephalus, etc.)? (Provide supporting documentation)

    a. If yes, continue to #14
    b. If no, clinical review required

14. Has the member received at least 18 months of Leqembi intravenous infusions and has transitioned to maintenance dosing?

    a. If yes, continue to #15
    b. If no, clinical review required

15. Is the treatment being prescribed by, or in consultation with, a neurologist, gerontologist, or specialist with experience treating Alzheimer's disease?

    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide supporting documentation)

    a. If yes, continue to #2
    b. If no, clinical review required

2. Were updated chart notes (within past year) provided with documentation of clinical response such as slowing or stopping of cognitive decline received as assessed by a standardized tool (ADAS-Cog 13/14; ADCS-ADL-MCI; MMSE; CDR-SB, MoCA)? (Provide supporting documentation)

    a. If yes, continue to #3
    b. If no, clinical review required

3. Has the member experienced unacceptable toxicity from the requested drug such as intracerebral hemorrhage or severe hypersensitivity reactions? (Provide supporting documentation)

    a. If yes, clinical review required
    b. If no, continue to #4

4. Does the member have severe, unstable, or symptomatic amyloid-related imaging abnormalities (ARIA) seen on MRI of the brain? (Provide supporting documentation)

    a. If yes, clinical review required
    b. If no, continue to #5

5. Is the treatment being prescribed by, or in consultation with, a neurologist, gerontologist, or specialist with experience treating Alzheimer's disease?

    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Leqembi [package insert]. Nutley, NJ; Esai, Inc.; January 2025.
2. Drugs@FDA: FDA Approved Drug Products. 2023. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 6 November 2025].
3. Cummings J, Apostolova L, Rabinovici GD, Atri A, Aisen P, Greenberg S, Hendrix S, Selkoe D, Weiner M, Petersen RC, Salloway S. Lecanemab: Appropriate Use Recommendations. J Prev Alzheimers Dis. 2023;10(3):362-377.
4. van Dyck CH, Swanson CJ, Aisen P, et al. Lecanemab in Early Alzheimer's Disease. *N Engl J Med*. 2023;388(1):9-21.

Last Reviewed: 11/21/25

Effective Date: 1/1/26

Leukine® (sargramostim)
Prior Authorization Guidelines

Affected Medication(s)

- Leukine for subcutaneous injection

FDA Approved Indication(s)

- In adult patients with cancer undergoing autologous hematopoietic stem cell transplantation for the mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis
- To increase survival in adult and pediatric patients from birth to 17 years of age acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS])
- To shorten time to neutrophil recovery and to reduce the incidence of severe, life-threatening, or fatal infections following induction chemotherapy in adult patients 55 years and older with acute myeloid leukemia (AML)
- For the acceleration of myeloid reconstitution following autologous peripheral blood progenitor cell (PBPC) or bone marrow transplantation in adult and pediatric patients 2 years of age and older with non-Hodgkin's lymphoma (NHL), acute lymphoblastic leukemia (ALL) and Hodgkin's lymphoma (HL)
- For the acceleration of myeloid reconstitution in adult and pediatric patients 2 years of age and older undergoing allogeneic bone marrow transplantation from HLA-matched related donors
- For the treatment of adult and pediatric patients 2 years and older who have undergone allogeneic or autologous bone marrow transplantation in whom neutrophil recovery is delayed or failed

Dosing

- Refer to package insert for specific dosing recommendations

Authorization Criteria

1. Is the medication being requested for an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)

    a. If yes, continue to #2
    b. If no, clinical review required

2. Is Leukine (sargramostim) being requested for one of the following FDA approved indications? (For intravenous administration request, contact medical benefit administer for coverage)

    - Peripheral Blood Progenitor Cell (PBPC) mobilization, collection, or transplantation
    - Patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome [H-ARS])

    a. If yes, continue to #3
    b. If no, clinical review required

3. Does the member have a documented trial with insufficient response, intolerance, or contraindication to myeloid growth factors (Examples: Zarxio, Neupogen, etc)? (Provide supporting documentation)

    a. If yes, continue to #4
    b. If no, clinical review required

Last Reviewed: 11/7/18, 3/17/21, 5/18/22, 5/19/23, 5/17/24, 5/16/25
Effective Date: 1/1/19, 6/15/24

4. Is the treatment being prescribed by or in consultation with an oncologist, hematologist, or a transplant specialist?

    a. If yes, approve for 3 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Leukine [package insert]. Lexington, MA: Partner Therapeutics, Inc; December 2024.
2. Clinical Practice Guidelines in Oncology (NCCN Guidelines): Hematopoietic Growth Factors. Version 1.2025 National Comprehensive Cancer Network website. Available from https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf. Accessed April 17, 2025.
3. Clinical Practice Guidelines in Oncology (NCCN Guidelines): Neuroblastoma. Version 1.2025 National Comprehensive Cancer Network website. Available from https://www.nccn.org/professionals/physician_gls/pdf/neuroblastoma.pdf. Accessed April 17, 2025.
4. Wisconsin Physicians Service Insurance Corporation. Local Coverage Determination (LCD): Human Granulocyte/Macrophage Colony Stimulating Factors (L34699). Centers for Medicare & Medicaid Services, Inc. Updated on 1/23/2018 with effective date 02/1/2018. Accessed March 2018.
5. Palmetto GBA. Local Coverage Determination (LCD): White Cell Colony Stimulating Factors (L37176). Centers for Medicare & Medicaid Services, Inc. Updated on 12/7/2017 with effective date 2/26/2018. Accessed March 2018.

Last Reviewed: 11/7/18, 3/17/21, 5/18/22, 5/19/23, 5/17/24, 5/16/25
Effective Date: 1/1/19, 615/24

Lupkynis® (voclosporin)
Prior Authorization Guidelines

Affected Medication(s)

- Lupkynis (voclosporin) oral capsule

FDA Approved Indication(s)

- In combination with a background immunosuppressive therapy regimen for treatment of adult patients with active lupus nephritis

Dosing

- 23.7 mg twice daily

Initial Authorization Criteria

1. Is the request for renewal of a previously approved Lupkynis (voclosporin) prior authorization with the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member have a confirmed diagnosis of active lupus nephritis? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the member 18 years of age or older?
    a. If yes, continue to #5
    b. If no, clinical review required
5. Has the member trialed at least 2 of the following medications with an inadequate response: cyclosporine, tacrolimus, mycophenolate mofetil, azathioprine? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, continue to #6
6. Does the member have documentation of intolerance and/or contraindication to all of the following: cyclosporine, tacrolimus, mycophenolate mofetil, azathioprine? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Does the member have a previous trial with inadequate response, intolerance, or contraindication to Benlysta (belimumab)? (Provide documentation of trial, intolerance, or contraindication)
    a. If yes, continue to #7
    b. If no, clinical review required
8. Will the member be using Lupkynis in combination with mycophenolate and corticosteroids? (Provide treatment plan)

Last Reviewed: 3/17/21, 5/18/22, 5/19/23, 5/17/24, 5/16/25
Effective Date: 5/1/21, 7/15/22, 7/1/23, 6/15/24

a. If yes, continue to #8
b. If no, clinical review required

9. Is the requested medication being prescribed by, or in consultation with, a rheumatologist or a specialist experienced in treatment of SLE?

    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is Lupkynis (voclosporin) being requested for an FDA approved or major compendia supported indication? (Provide supporting documentation)

    a. If yes, continue to #2
    b. If no, clinical review required

2. Were updated chart notes (within 1 year) with documentation of significant clinical response to therapy defined as one of the following received? (Provide supporting documentation)

    - A decrease in urine protein-to-creatinine ratio to ≤0.5 mg/mg plus a eGFR >60mL/min/1.73m^2
    - No decrease of 20% or more from baseline eGFR

    a. If yes, continue to #3
    b. If no, clinical review required

3. Is the requested medication being prescribed by, or in consultation with, a rheumatologist or specialist experienced in treatment of SLE?

    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. LUPKYNIS (voclosporin) capsules, [package insert]. Rockville, MD: Aurinia Pharmaceuticals, Inc.; 2021.
2. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 12 Jan. 2021].
3. Rovin, Brad H., et al. "A randomized, controlled double-blind study comparing the efficacy and safety of dose-ranging voclosporin with placebo in achieving remission in patients with active lupus nephritis." Kidney international 95.1 (2019): 219-231.
4. Mok, Chi Chiu. "Calcineurin inhibitors in systemic lupus erythematosus." Best Practice & Research Clinical Rheumatology 31.3 (2017): 429-438.
5. Kidney Disease: Improving Global Outcomes (KDIGO) Lupus Nephritis Work Group. KDIGO 2024 Clinical Practice Guideline for the management of LUPUS NEPHRITIS. *Kidney Int*. 2024;105(1S):S1-S69.

Last Reviewed: 3/17/21, 5/18/22, 5/19/23, 5/17/24, 5/16/25
Effective Date: 5/1/21, 7/15/22, 4/1/23, 6/15/24

Medical Necessity
Prior Authorization Guidelines

Affected Medication(s)

- Abilify Mycite Kit
- Absorica LD
- Absorica 25mg capsule
- Apap-caffeine-dihydrocodeine 325
- Acthar gel selfject
- Acular LS
- Adlarity patch
- Admelog
- Adzenys XR-ODT
- Aemcolo
- Afrezza
- Agamree suspension
- Airsupra
- Alkindi
- Akynzeo
- Ala-scalp lotion
- Alrex
- Altoprev
- Amcinonide cream and ointment
- Amlodipine-atorvastatin tablet
- Amphetamine sulfate
- Amphetamine ER suspension
- Amphetamine ER-ODT
- Amzeeq
- Anzemet
- Anzupgo
- Apadaz
- Apexicon E cream
- Apidra
- Aplenzin
- Aptensio XR
- Aripiprazole ODT tablet
- Aspruzyo sprinkle ER
- Atorvaliq
- Auvelity
- auranofin
- Auvi-Q 0.15 mg
- Azstarys
- Baclofen suspension
- Dipentum
- Dolobid
- Doral
- Doxycycline mono 75mg and 150mg capsule
- Drizalma
- Duobrii lotion
- Durlaza ER
- Dyanavel XR
- Dyrenium
- Ecoza
- Econazole 1% foam
- Elepsia XR
- Elyxyb solution
- Emflaza
- Emsam patch
- Enbumyst
- Enstilar 0.005%-0.064% foam
- Entadfi capsule
- Eohilia
- Equetro capsule
- Ergomar
- Ertaczo 2% cream
- Escitalopram capsule
- Eulexin
- Evamist spray
- Evekeo
- Exelderm 1% solution & cream
- Exservan
- Extina
- Exxua
- Eysuvis
- Ezetimibe-atorvastatin
- Fenofibrate 50mg, 90mg, 150mg capsule
- Fenofibrate 40mg, 120mg tablet
- Fenofibric acid 105mg tablet
- Fenoglide (fenofibrate)
- Fenoprofen
- Likmez suspension
- Lipofen (fenofibrate)
- Liqrev oral suspension
- Livtencity
- Lodoco
- Lofena
- Loreev XR
- Lorzone 375/750mg tablets
- Loteprednol 0.2% eye drop
- Lurbiro
- Lyumjev
- Lyvispah packet
- Meloxicam capsule
- Memantine-donepezil ER cap
- Meperidine tablet/solution
- Metaxalone 400 & 640 mg tab
- Metformin 625 mg & 750 mg tab
- Metformin ER OSM/gastr
- Methamphetamine tablet
- Methocarbamol 1000mg
- Methoxsalen 10 mg cap
- Methsuximide
- Methylphenidate ER 10mg, 15mg, 20mg, 30mg, 40mg, 50mg, 60mg capsules (Aptensio)
- Methylphenidate ER 45mg, 63mg, and 72 mg tablet (Relexxi)
- Methylphenidate patch
- Metoclopramide ODT
- Metronidazole 125mg tablet
- Metronidazole 375mg capsule
- Pyridostigmine ER 105 mg
- Pyrimethamine
- Qbrexza
- Qdolo
- Qelbree
- Qnasl/Qnasl Children
- Quazepam
- Qudexy XR
- Quillichew ER
- Quillivant XR
- Quviviq
- Raldesy solution
- Rasuvo
- Rayaldee ER
- Rayos DR
- Reltone capsule
- Relexxii ER
- Restasis MultiDose
- Reyvow
- Ribavirin
- Ridaura
- Rocklatan
- Roxybond
- Sancuso
- Scalacort lotion
- Seglentis
- Sernivo spray
- Sertraline capsule
- Seysara
- Siklos
- Sivextro
- Sofdra
- Soliqua 100-33
- Solosec granule packet
- Soltamox
- Sorilux 0.005% foam
- Sovaldi tablet/ pellet
- Sovuna
- Spritam
- Strensiq
- Sular ER tablet

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Medical Necessity
Prior Authorization Guidelines

- Baxdela
- Belbuca Film
- Belsomra
- Benzhydroco-apap
- Bismuth-metronidazole-tetracycline capsule
- Bisopropolol-Hctz tablet
- Blujepa
- Bonjesta
- Brekiya
- Brexafemme
- Breztri Aerosphere
- Bromfenac sod 0.09% eye drop
- Bryhali lotion
- Bucapsol
- Bupap 50-300
- Butalbital-acetaminophen 50-300
- Butalb-apap-caffeine w/ codeine 50-300-40-30 capsule
- Butorphanol Spray
- Cabtreo gel
- Caduet tablet
- Calcipotriene 0.005% foam
- Calcipotriene-betamethasone DP oint/susp
- Calcitonin-Salmon
- Cambia packet
- Carisoprodol-aspirin-codeine tablet
- Celontin
- Cequa
- Chlorzoxazone 250/375/750mg tablets
- Citalopram capsule
- Clobetasol 0.03% cream
- clobetasol 0.05% eye drop
- Clocortolone 0.1% cream pump
- Clonidine ER 0.17 mg
- Fenopron
- Fibricor (fenofibrate)
- finasteride-tadalafil cap
- Fioricet w/ Codeine
- Firdapse
- Flagyl 375mg capsule
- Flector patch
- Fleqsuvy
- FloLipid
- Fluoxetine DR 90 mg capsule
- Flurandrenolide cream
- Flurbiprofen
- Furoscix
- Fycompa
- Gabapentin ER tablet
- Gabarone
- Glimepiride 3 mg tablet
- Gimoti
- Glumetza ER
- Glycate
- Glycopyrrolate 1.5mg tablet
- Gocovri
- Gralise
- Granisetron tablet
- H.P. Acthar
- Halobetasol foam
- Halocinonide cream
- Halog cream, ointment, and solution
- Harvoni tablet/ pellet
- Hemady
- Hemlibra
- Horizant
- Humalog Mix
- Humalog U-100/200/JR
- Humalog Tempo Pen
- Humulin 70/30
- Humulin N, Humulin R
- Hydrocodone ER
- Hydrocortisone 2.5% solution
- Hysingla ER
- Miacalcin
- Miconazole-zinc-petro 0.25-15%
- Micort-HC
- Migergot suppository
- Mirapex ER
- Mondoxyne 75mg cap
- Motofen
- Motpoly XR capsule
- Mydayis ER
- Nalfon
- Nalocet
- Namzaric
- Naprelan
- Naproxen CR
- Naproxen-esomeprazole
- Nascobal spray
- Natesto
- Neffy
- Nexiclon XR
- Nexletol
- Nexlizet
- Niacor
- Nisoldipine ER
- Nitro-DUR patch 0.3mg/hr & 0.8 mg/hr
- Nitrofurantoin 50 mg/5mL suspension
- Nocdurna
- Norgesic tablet
- Norgesic Forte
- Noritate
- Noxafil 300 mg powdermix susp
- Nucynta
- Nuzyra
- Olanzapine-fluoxetine capsule
- Omnaris
- Omeclamox-pak combo pack
- Omeprazole-bicarb packet
- Sulconazole nitrate 1% soln & cream
- Sumatriptan-naproxen
- Suprax chewable tablet
- Symax duotab
- Symbravo
- Sympazan Film
- Syprine
- Taclonex 0.005%-0.064% suspension
- Tadliq suspension
- Talicia DR
- Tanlor
- Tasmar
- Tavaborole 5% solution
- Tarpeyo (budesonide)
- Teglutik suspension
- Terbutaline
- Tetracycline tablet
- Texacort solution
- Thalitone 15mg tablet
- Tiagabine
- Tlando
- Tolcapone
- Tolmetin
- Tolsura
- Tolectin
- Tonmya
- Topiramate 50 mg sprinkle cap
- Topiramate ER
- Tramadol ER TBMP
- Tramadol 25 mg & 75 mg tablet
- Tramadol solution
- Treximet tablet
- Triamterene
- Trientine hclcapsule
- Trokendi XR
- Trudhesa
- Tryptyr
- Tryvio
- Ultravate lotion
- Ursodiol 200/400 cap

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Medical Necessity
Prior Authorization Guidelines

- Cobenfy
- Condylox 0.5% gel
- Conjupri
- Cordran cream, ointment, and tape
- Cortisone tablet
- Cortrophin Gel
- Cotempla XR-ODT
- Coxanto capsule
- Cuvrior
- Cyanocobalamin spray
- Cycloset
- Cystadane
- Dapsone 7.5% gel
- Daraprim
- Dartisla ODT
- Daytrana (methylphenidate)
- Deflazacort
- Desonide gel
- Desoxyn (methamphetamine)
- Dextroamphetamine oral tablet (2.5mg, 7.5mg, 15mg, 20mg, 30mg)
- Dextroamphatemine-amphetamine ER capsules (Mydayis)
- Diclofenac patch
- Diclofenac 25mg, 35mg cap
- Diclofenac pot 25mg tablet
- Diclofenac powd pk
- Diclofenac 2% pump
- Diclofenac-misoprostol tablet
- Dicyclomine 40 mg tablet
- Diflorasone cream and ointment
- Digoxin 62.5 mcg tablet
- Dihydroergotamine ampule
- Ibsrela
- Igalmi film
- Impoyz cream
- Inderal XL
- Indocin suspension
- Indocin suppository
- Indomethacin suppository
- Indomethacin suspension
- Intrarosa
- Innopran XL
- Insulin lispro Pen/Vial
- Isordil 40mg tablet
- Isosorbide dinitrate 40mg tablet
- Isotretinoin 25mg & 35 mg capsules (Absorica)
- Iyuzeh drops
- Jalyn (dutasteride-tamsulosin)
- Jaythari
- Jornay PM
- Journavx
- Jublia
- Kapvay
- Kerendia
- Ketoconazole 2% foam
- Ketodan
- Ketorolac 0.4% opth sol
- Konvomep
- Labetalol 400 mg tablet
- Lactulose packets
- Lamictal ODT
- Lamotrigine ODT
- Lampit
- Lanoxin 62.5 mcg tablet
- Lanso-amox-clarithro
- Ledipasvir-sofosbuvir oral tablet
- Levamlodipine
- Levorphanol
- Lexette foam
- Licart 1.3% Patch
- Ondansetron ODT 16mg
- Onyda XR
- Opipza
- Opzelura
- Orapred ODT
- Oravig
- Orlynvah
- Orphenadrine-asa-caf
- Orphengesic forte
- Osmolex
- Osphena
- Otrexup
- Oxaprozin capsule
- Oxbryta
- Oxcarbazepine ER
- Oxiconazole 1% cream
- Oxistat 1% cream/lotion
- Oxybutynin 2.5 mg tab
- Oxycodone (Roxybond)
- Oxycodone-apap 2.5/300, 5/300, 7.5/300 10/300, 5/325/5ml soln
- Oxtellar XR
- Pandel cream
- Pennsaid pump
- Pegasys
- Pentazocine-naloxone
- Perampanel
- Phospholine iodide 0.125% drop
- Phyrago
- Pioglitazone-glimepiride
- Podofilox 0.5% gel
- Pokonza packet
- Pramipexole ER tablet
- Prednisolone tab/ODT
- ProAir Respiclick/Digihaler
- Proctofoam-HC 1%-1%
- Prolate tablet/solution
- Pylera
- Pyquvi
- Valtoco
- Varubi
- Verkazia
- Venlafaxine besylate ER
- Veozah
- Verapamil PM
- Verdeso foam
- Verelan PM
- Vevye
- Viberzi
- Voquezna
- Vtama
- Vuity
- Vusion ointment
- Vyscoxa
- Wynzora
- Xaciato vaginal gel
- Xdemvy
- Xelstrym
- Xenleta
- Xerese cream
- Xhance spray
- Ximino
- Xphozah
- Xromi
- Xultophy 100-3.6
- Xuriden
- Zanaflex 8 mg
- Zcort
- Zegerid packet
- Zembrace Symtouch
- Zelnorm
- Zelsuvmi
- Zenzedi except 5 and 10 mg
- Zepatier
- Zetonna
- Zileuton ER tablet
- Zipsor
- Zirgan
- Zoryve cream and foam
- Ztlido
- Zunveyl
- Zyflo Filmtab

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Medical Necessity
Prior Authorization Guidelines

Authorization Criteria

1. Is the requested medication being used for an FDA approved or major compendia supported indication? (Verify regimen and dosing)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request supported by current medical guidelines?
    a. If yes, continue to #3
    b. If no, clinical review required
3. Did the member exhaust all formulary alternative products for treatment of the requested condition? (Provide supporting documentation)
    a. If yes, approve for lesser of 12 months OR standard treatment duration
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

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Mesna
Prior Authorization Guidelines

Affected Medication(s)

- Mesna oral tablet
- Mesnex oral tablet

FDA Approved Indication(s)

- Prophylactic agent to reduce the incidence of ifosfamide-induced hemorrhagic cystitis

Dosing

- Two oral doses after bolus IV injection
- Oral doses of 40% of the ifosfamide dose at 2 and 6 hours after ifosfamide administration
- Repeat on each day ifosfamide is administered

Authorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the member currently receiving or planning to receive ifosfamide containing chemotherapy regimen? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member's body surface area and treatment plan provided for review of appropriate dosing? (Provide BSA and treatment plan for review)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the treatment being prescribed by, or in consultation with, an oncologist?
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Mesnex (mesna) [Prescribing Information]. Deerfield, IL: Baxter Healthcare Corporation. December 2021.

Last Reviewed: 11/21/18, 7/21/21, 3/17/23, 1/19/24, 1/17/25, 3/21/25
Effective Date: 1/1/19, 3/1/24, 4/1/25

Methyltestosterone Products
Prior Authorization Guidelines

Affected Medication(s)

- Methyltestosterone oral capsule
- Methitest oral tablet

FDA Approved Indication(s)

- In males:
  - Primary hypogonadism (congenital or acquired)
  - Hypogonadotropic hypogonadism (congenital or acquired)
  - To stimulate puberty in carefully selected males with clearly delayed puberty
- In females:
  - May be used secondarily in women with advancing inoperable metastatic (skeletal) mammary cancer who are 1 to 5 years postmenopausal
  - Premenopausal women with breast cancer who have benefitted from oophorectomy and are considered to have a hormone-responsive tumor

Dosing

- In males: initial dosage of 10-50 mg daily
- In females: 50-200 mg daily

Initial Authorization Criteria

1. Is the request for continuation of therapy with the same methyltestosterone product for the same indication?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
   a. If yes, continue to #3
   b. If no, clinical review required
3. What is the indication that the methyltestosterone product is being requested for?
   a. Male member with delayed puberty, continue to corresponding criteria
   b. Male member with hypogonadism, continue to corresponding criteria
   c. Female member with breast cancer, continue to corresponding criteria
   d. Gender affirming treatment, continue to corresponding criteria

Assigned male at birth member with delayed puberty

1. Is the member 14 years of age or older?
   a. If yes, continue to #2
   b. If no, clinical review required
2. Does the member have Tanner Staging of III or below?

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a. If yes, approve for 6 months unless otherwise specified
b. If no, clinical review required

Assigned male at birth member with hypogonadism

1. Does the member have documentation of TWO baseline total testosterone levels < 300 ng/dL that were taken in the morning on different days? (Provide documentation of total testosterone levels)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member have at least TWO signs/symptoms of hypogonadism? (e.g. sleep disturbances, gynecomastia, decreased lean body mass, visceral obesity, hot flashes, changes in mood) (Provide supporting documentation of signs/symptoms)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is there medical rationale why the member cannot use a generic injectable AND topical testosterone product? (Provide supporting documentation)
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Assigned female at birth member with Breast Cancer

1. Is the medication being prescribed by or in consultation with an oncologist?
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Gender Affirming Treatment

1. Does the member have a diagnosis of gender dysphoria by a qualified mental health professional? (Provide supporting documentation)
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member have documentation of a positive clinical response to therapy defined by one of the following? (Provide supporting documentation)
    - For members with delayed puberty, documentation of progression into puberty AND with Tanner Staging of IV or less
    - For members with hypogonadism, documentation of normal testosterone levels
    - For members seeking gender affirming treatment, approve for 12 months

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a. If yes, approve for 12 months unless otherwise specified
b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Methitest Prescribing Information. Global Pharmaceuticals, Division of Impax Laboratories Inc. May 2019.
2. Hembree WC, Cohen-Kettenis P, Delemarre-van de Waal HA, et al. Endocrine Society. Endocrine treatment of transsexual persons: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2009 Sep;94(9):3132-3154.
3. Biro FM, Chan YM. Normal puberty. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com.
4. Olson-Kennedy J, Rosenthal SM, Hastings J, et al. UCSF Transgender Care & Treatment Guidelines: Health consideration for gender non-forming children and transgender adolescents. 2016 Jun. Available at: https://transcare.ucsf.edu/guidelines/youth

Last Reviewed: 12/19/18, 7/21/21, 7/20/22, 7/21/23, 11/17/23, 9/20/24, 9/19/25
Effective Date: 1/1/19, 9/1/21, 9/1/22, 12/20/23, 10/15/24

Multiple Sclerosis Agents
Prior Authorization Guidelines

Affected Medication(s)

- Aubagio (teriflunomide)
- Avonex (interferon beta-1a)
- Bafiertam (monoethyl fumarate)
- Betaseron (interferon beta-1b)
- Copaxone (glatiramer acetate)
- Dimethyl fumarate
- Fingolimod
- Gilenya (fingolimod)
- Glatiramer
- Glatopa (glatiramer)
- Kesimpta (ofatumumab)
- Mavenclad (cladribine)
- Mayzent (siponimod)
- Plegridy (interferon beta-1a)
- Ponvory (ponesimod)
- Rebif (interferon beta-1a)
- Tascenso ODT (fingolimod)
- Tecfidera (dimethyl fumarate)
- Teriflunomide
- Vumerity (diroximel fumarate)

FDA Approved Indication(s)

- For treatment of adult patients with relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease:
  - Avonex, Aubagio, Bafiertam, Betaseron, Copaxone, Extavia, Kesimpta, Mayzent, Plegridy, Ponvory, Rebif, Tecfidera, Vumerity
- For treatment of patients 10 years of age and older with relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease:
  - Gilenya, Tascenso ODT
- For the treatment of adult patients relapsing forms of multiple sclerosis, to include relapsing-remitting disease and active secondary progressive disease
  - Mavenclad

Dosing

- **Avonex**: 30 mcg IM injection once a week
- **Aubagio**: 7 mg or 14 mg orally once daily
- **Bafiertam**: 190 mg orally twice daily
- **Betaseron**: 0.25 mg SC injection every other day
- **Extavia**: 0.25 mg SC injection every other day
- **Gilenya, Tascenso ODT**: 0.25 mg to 0.5 mg orally once daily
- **Kesimpta**: 20 mg SC injection once monthly
- **Copaxone**: 20 mg SC injection daily OR 40 mg SC injection three times weekly
- **Mavenclad**: Cumulative dosage of 3.5mg/kg orally and divided into 2 yearly treatment courses (1.75mg/kg per treatment course)

Last Reviewed: 10/3/18, 5/15/19, 11/20/19, 5/20/20, 9/16/20, 11/18/20, 1/19/22, 11/16/22, 5/19/23, 7/21/23, 5/17/24, 5/16/25
Effective Date: 1/1/19, 7/1/19, 1/1/20, 7/1/20, 11/15/20, 12/15/20, 3/1/22, 1/1/23, 7/15/23, 9/15/23, 6/15/24, 6/1/25

- **Mayzent**: 1mg to 2mg once daily (reference PI for specific dosing based on CYP2C9 genotype)
- **Plegridy**: 125 mcg subcutaneous injection every 14 days
- **Ponvory:** 20 mg orally once daily (refer to package insert for titration schedule)
- **Rebif**: 22 mcg or 44 mcg SC injection three times per week
- **Tecfidera**: 240 mg orally twice daily
- **Vumerity**: 462 mg orally twice daily

Initial Authorization Criteria

1. Is the request for continuation of a multiple sclerosis agent therapy?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is an MRI result consistent with multiple sclerosis received? (Provide MRI for review)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the member 18 years of age or older? (Note: Gilenya/Tascenso ODT are the only drugs approved for use in adolescents)
    a. If yes, continue to #5
    b. If no, continue to #7
5. Is the requested medication dimethyl fumarate, teriflunomide, fingolimod, or glatiramer acetate?
    a. If yes, continue to #7
    b. If no, continue to #6
6. Does the member have a history of inadequate response, intolerance or contraindication to at least one drug from each of the following groups? (Provide supporting documentation)
        - Glatiramer acetate
        - Dimethyl fumarate or Teriflunomide
        - Fingolimod
    a. If yes, continue to #7
    b. If no, clinical review required
7. Will the requested medication be used with other disease-modifying therapy for multiple sclerosis?
    a. If yes, clinical review required
    b. If no, continue to #8
8. Is the requested multiple sclerosis agent being prescribed by or in consultation with a neurologist?
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Last Reviewed: 10/3/18, 5/15/19, 11/20/19, 5/20/20, 9/16/20, 11/18/20, 1/19/22, 11/16/22, 5/19/23, 7/21/23, 5/17/24, 5/16/25
Effective Date: 1/1/19, 7/1/19, 1/1/20, 7/1/20, 11/15/20, 12/15/20, 3/1/22, 1/1/23, 7/15/23, 9/15/23, 6/15/24, 6/1/25

Reauthorization Criteria

1. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Will the requested medication be used with other disease-modifying therapy for multiple sclerosis?
    a. If yes, clinical review required
    b. If no, continue to #3
3. Is clinical documentation confirming responsiveness to therapy provided? (Provide documentation of disease stability)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the requested multiple sclerosis agent being prescribed by or in consultation with a neurologist?
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Avonex (interferon beta-1a) [Prescribing Information]. Cambridge, MA: Biogen, Inc. July 2019.
2. Aubagio (teriflunomide) [Prescribing Information]. Cambridge, MA: Genzyme Corporation, A Sanofi Company. September 2019
3. Bafiertam (monoethyl fumarate) [Prescribing Information]. High Point NC, NJ: Banner Life Sciences LLC. April 2020.
4. Betaseron (interferon beta-1b) [Prescribing Information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc. August 2019.
5. Extavia (interferon beta-1b) [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. October 2019.
6. Gilenya (fingolimod) [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. August 2019.
7. Kesimpta (ofatumumab) [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. August 2020.
8. Copaxone (glatiramer acetate) [Prescribing Information]. North Wales, PA: Teva Pharmaceuticals USA, Inc. July 2019.
9. Mavenclad (cladribine) [Prescribing Information]. Rockland, MA: EMD Serono, Inc. April 2019.
10. Mayzent (siponimod) tablets [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corp.; March 2019

Last Reviewed: 10/3/18, 5/15/19, 11/20/19, 5/20/20, 9/16/20, 11/18/20, 1/19/22, 11/16/22, 5/19/23, 7/21/23, 5/17/24, 5/16/25
Effective Date: 1/1/19, 7/1/19, 1/1/20, 7/1/20, 11/15/20, 12/15/20, 3/1/22, 1/1/23, 7/15/23, 9/15/23, 6/15/24, 6/1/25

11. Plegridy (peginterferon beta-1a) [Prescribing Information]. Cambridge, MA: Biogen, Inc. July 2019.
12. Ponvory (ponesimod) tablet [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals. August 2023.
13. Rebif (interferon beta-1a) [Prescribing Information]. Rockland, MA: EMD Serono, Inc. October 2019.
14. Tascenso ODT (fingolimod) [Prescribing Information]. Cambridge, United Kingdom: Cycle Pharmaceuticals Ltd. December 2022.
15. Tecfidera (dimethyl fumarate) [Prescribing Information]. Cambridge, MA: Biogen, Inc. July 2019.
16. Vumerity (diroximel fumarate) delayed-release capsules, [package insert]. Cambridge, MA: Biogen, Inc.; 2019.
17. Rae-Grand A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis. Neurology. 2018;90(17):777-788. Available at: http://n.neurology.org/content/neurology/90/17/777.full.pdf.

Myalept® (metreleptin)
Prior Authorization Guidelines

Affected Medication(s)

- Myalept powder for subcutaneous injection

FDA Approved Indication(s)

- As an adjunct to diet as replacement therapy to treat the complications of leptin deficiency in patients with congenital or acquired generalized lipodystrophy

Dosing

- Refer to package insert for recommended doses based on gender and weight

Initial Authorization Criteria

1. Is the request for continuation of Myalept (metreleptin) therapy?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member have at least one of the following complications associated with leptin deficiency in patients with congenital or acquired generalized lipodystrophy? (Provide supporting documentation)
    - Diabetes mellitus
    - Hypertriglyceridemia
    - Increased fasting insulin levels

    a. If yes, continue to #4
    b. If no, clinical review required
4. Have baseline HbA1c, fasting glucose, and fasting triglycerides levels been received? (Provide labs for review)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have documentation of a trial with insufficient response to the following conventional therapies to treat each metabolic complication present?
    - Diabetes mellitus or insulin resistance
        - Diet modification
        - Optimized insulin therapy at maximally tolerated doses
    - Hypertriglyceridemia
        - Diet modification
        - Optimized therapy with at least two triglyceride lowering agents from different classes (i.e. fibrates, statins) at maximally tolerated doses

Last Reviewed: 11/7/18, 1/20/21, 7/20/22, 7/21/23, 7/19/24, 7/18/25
Effective Date: 1/1/19, 9/1/22, 8/15/24

a. If yes, continue to #6
b. If no, clinical review required

6. Is the requested medication being used for any of the following conditions? (Provide clinical documentation for review)

    - Partial lipodystrophy
    - Nonalcoholic steatohepatitis (NASH)
    - HIV-related lipodystrophy
    - Metabolic disease without concurrent evidence of congenital or acquired generalized lipodystrophy

    a. If yes, clinical review required
    b. If no, continue to #7

7. Is the treatment being prescribed by, or in consultation with an endocrinologist?

    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)

    a. If yes, continue to #2
    b. If no, clinical review required

2. Has the member demonstrated a positive clinical response to therapy as defined by improvement in at least one metabolic parameter? (Provide documentation and updated HbA1c, fasting glucose, or fasting triglycerides level for review)

    a. If yes, continue to #3
    b. If no, clinical review required

3. Is the treatment being prescribed by, or in consultation with an endocrinologist?

    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Myalept. Micromedex. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed September 27, 2018.
2. Myalept (metreleptin) [Prescribing Information]. Cary, NC: Chiesi USA Inc. March 2024.

Last Reviewed: 11/7/18, 1/20/21, 7/20/22, 7/21/23, 7/19/24, 7/18/25
Effective Date: 1/1/19, 9/1/22, 8/15/24

3. Mantzoros, C. Lipodystrophic syndromes. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed October 2018.

Myeloid Growth Factors
Prior Authorization Guidelines

Affected Medication(s)

- Fulphila (pegfilgrastim-jmdb) subcutaneous solution
- Fylnetra (pegfilgrastim-pbbk) subcutaneous solution
- Granix (tbo-filgrastim) injection solution
- Neulasta (pegfilgrastim) subcutaneous solution
- Neupogen (filgrastim) injection solution
- Nivestym (filgrastim-aafi) injection solution
- Nypozi (filgrastim-txid) injection solution
- Nyvepria (pegfilgrastim-apgf) subcutaneous solution
- Rolvedon (eflapegrastim-xnst) subcutaneous solution
- Releuko (filgrastim-ayow) injection solution
- Stimufend (pegfilgrastim-fbgk) subcutaneous solution
- Udenyca (pegfilgrastim-cbqv) subcutaneous solution
- Zarxio (filgrastim-sndz) injection solution
- Ziextenzo (pegfilgrastim-bmez) subcutaneous solution

FDA Approved Indication(s)

- To reduce the duration of severe neutropenia in adult and pediatric patients 1 month and older with non-myeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia
  - Granix
- To decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia
  - Fulphila, Fylnetra, Neulasta, Neupogen, Nivestym, Nypozi, Nyvepria, Releuko, Rolvedon, Stimufend, Udenyca, Ziextenzo, Zarxio
- For reducing the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML)
  - Neupogen, Nivestym, Releuko, Zarxio
- To reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with non-myeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation
  - Neupogen, Nivestym, Releuko, Zarxio
- For the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
  - Neupogen, Nivestym, Zarxio
- For chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia
  - Neupogen, Nivestym, Releuko, Zarxio
- To increase survival in patients acutely exposed to myelosuppressive doses of radiation
  - Neulasta, Neupogen, Stimufend, Udenyca

Dosing

Last Reviewed: 11/7/18, 7/17/19, 3/17/21, 1/20/23, 1/19/24, 1/17/25
Effective Date: 1/1/19, 9/1/19, 5/1/21, 3/1/24, 3/1/25

- Refer to package insert for recommended dosing for corresponding diagnosis

Authorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the medication being prescribed by or in consultation with an oncologist, hematologist, or an appropriate specialist?
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the submitted diagnosis for hematopoietic radiation injury syndrome?
    a. If yes, continue to #4
    b. If no, continue to #6
4. Is Neupogen, Stimufend, or Udenyca being requested?
    a. If yes, approve for 4 months unless otherwise specified
    b. If no, continue to #5
5. Does the member have a documented clinical rationale for avoiding Neupogen (filgrastim), Stimufend (pegfilgrastim-fbgk), AND Udenyca (pegfilgrastim-cbqv)? (Provide supporting documentation)
    a. If yes, approve for 4 months unless otherwise specified
    b. If no, clinical review required
6. Is the request for Nivestym (filgrastim-aafi) or Fulphila (pegfilgrastim-jmdb)?
    a. If yes, continue to #8
    b. If no, continue to #7
7. Does the member have a documented clinical rationale for avoiding Nivestym (filgrastim-aafi) AND Fulphila (pegfilgrastim-jmdb)? (Provide supporting documentation)
    a. If yes, continue to #8
    b. If no, clinical review required
8. What is the medication being requested for? (Provide clinical documentation to support diagnosis)
    a. Bone Marrow Transplantation, approve for 4 months unless otherwise specified
    b. Peripheral Blood Progenitor cell (PBPC) mobilization, approve for 4 months unless otherwise specified
    c. Acute myeloid leukemia (AML) patient undergoing induction or consolidation chemotherapy, approve for 4 months unless otherwise specified
    d. Prophylaxis of febrile neutropenia in patients with non-myeloid malignancy, continue to corresponding criteria
    e. Treatment of chemotherapy-induced febrile neutropenia, continue to corresponding criteria
    f. Severe Chronic Neutropenia, continue to corresponding criteria
    g. Other indication, continue to corresponding criteria

<u>Prophylaxis of febrile neutropenia in patients with non-myeloid malignancy</u>

Last Reviewed: 11/7/18, 7/17/19, 3/17/21, 1/20/23, 1/19/24, 1/17/25
Effective Date: 1/1/19, 9/1/19, 5/1/21, 3/1/24, 3/1/25

1. Does the planned chemotherapy regimen have a high risk (greater than 20% risk) of febrile neutropenia?
    a. If yes, continue to #2
    b. If no, continue to #4
2. Is the planned chemotherapy regimen for curative treatment intent?
    a. If, yes approve for 4 months unless otherwise specified
    b. If no, continue to #3
3. Is clinical rationale provided to support the use of a high-risk regimen in the palliative setting? (Provide supporting documentation)
    a. If yes, approve for 4 months unless otherwise specified
    b. If no, clinical review required
4. Does the member have at least one of the following risk factors for febrile neutropenia? (Provide supporting documentation)
    - 65 years or older and receiving full chemotherapy dose intensity
    - Prior chemotherapy or radiotherapy
    - Persistent neutropenia
    - Tumor involvement in the bone marrow
    - Recent surgery and/or open wounds
    - Renal dysfunction (creatinine clearance <50)
    - Liver dysfunction (bilirubin >2.0)

    a. If yes, continue to #5
    b. If no, continue to #6
5. Does the planned chemotherapy regimen have an intermediate risk (10 to 20% risk) of febrile neutropenia?
    a. If yes, continue to #7
    b. If no, clinical review required
6. Is the member continuing the same chemotherapy regimen which induced a dose-limiting neutropenic event on a previous cycle? (Provide supporting clinical documentation)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Is the planned chemotherapy regimen for curative treatment intent?
    a. If yes, approve for 4 months unless otherwise specified
    b. If no, clinical review required

<u>Treatment of chemotherapy-induced febrile neutropenia</u>

1. Has the member received a prophylaxis regimen for febrile neutropenia with a granulocyte colony stimulating factor on the current chemotherapy cycle?
    a. If yes, clinical review required
    b. If no, continue to #2

2. Does the member have an absolute neutrophil count (ANC) <500/mm^3? (Provide documentation of ANC lab value)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member have one or more of the following risk factors for developing infection-related complications? (Provide supporting documentation)
    - Sepsis Syndrome
    - Age >65
    - Absolute neutrophil count [ANC] <100/mcL
    - Duration of neutropenia expected to be greater than 10 days
    - Pneumonia or other clinically documented infections
    - Invasive fungal infection
    - Hospitalization at the time of fever
    - Prior episode of febrile neutropenia

    a. If yes, approve for 1 month unless otherwise specified
    b. If no, clinical review required

<u>Severe chronic neutropenia</u>

1. Does the member have an absolute neutrophil count (ANC) <500/mm^3? (Provide CBC with differential for review)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member have a diagnosis of one of the following? (Provide documentation of diagnosis)
    - Congenital neutropenia
    - Cyclic neutropenia
    - Idiopathic neutropenia

    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member have neutropenia symptoms (i.e. fever, infections, etc.)? (Provide documentation of symptoms)
    a. If yes, approve for 4 months unless otherwise specified
    b. If no, clinical review required

<u>Other Indication</u>

1. Is the requested use supported by major compendia? (Examples: Micromedex, Clinical Pharmacology, NCCN, etc.) (Provide supporting documentation confirming diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required

2. Has the member tried and had an inadequate response OR does the member have a contraindication to ALL standard treatment options for the requested indication (Provide all prior treatment history, contraindication if appropriate, and treatment plan)
    a. If yes, approve for 4 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Central Nervous System Cancers. Version 1.2025. Available at https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf. Accessed January 9, 2025.
2. Smith TJ, Bohlke K, Lyman GH, Carson KR, Crawford J, Cross SJ, Goldberg JM, Khatcheressian JL, Leighl NB, Perkins CL, Somlo G, Wade JL, Wozniak AJ, Armitage JO. Recommendations for the use of WBC growth factors: American Society of Clinical Oncology Clinical Practice Guideline Update. J Clin Oncol. 2015 Jul 13. pii: JCO.2015.62.3488. [Epub ahead of print]

Last Reviewed: 11/7/18, 7/17/19, 3/17/21, 1/20/23, 1/19/24, 1/17/25
Effective Date: 1/1/19, 9/1/19, 5/1/21, 3/1/24, 3/1/25

Mytesi® (crofelemer)
Prior Authorization Guidelines

Affected Medication(s)

- Mytesi delayed-release oral tablet

FDA Approved Indication(s)

- For symptomatic relief of non-infectious diarrhea in adult patients with HIV/AIDS on anti-retroviral therapy

Dosing

- 125 mg taken orally twice daily

Initial Authorization Criteria

1. Is the request for continuation of Mytesi (crofelemer) therapy?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member 18 years of age or older?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the member currently on anti-retroviral therapy and has had non-infectious diarrhea for longer than one month? (Provide list of relevant current medications and supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have a trial with insufficient response, intolerance, or contraindication to one of the following alternative anti-diarrheal medications: loperamide, bismuth subsalicylate, or diphenoxylate/atropine? (Provide relevant past medication history and/or intolerance/contraindication)
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required

Last Reviewed: 11/7/18, 11/18/20, 1/19/22, 1/20/23, 1/19/24, 1/17/25
Effective Date: 1/1/19, 3/1/24

2. Does the member demonstrate a positive clinical response to therapy as defined as a decrease in the frequency and/or severity of diarrhea? (Provide supporting documentation)
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Mytesi Prescribing Information. San Francisco, CA: Napo Pharmaceuticals, Inc. February 2024. Available at: www.mytesi.com.
2. Mangel AW, Chaturvedi P. Evaluation of crofelemer in the treatment of diarrhea-predominant irritable bowel syndrome patients. Digestion. 2008; 78(4): 180-186.
3. MacArthur, Rodger D., et al. "Efficacy and safety of crofelemer for noninfectious diarrhea in HIV-seropositive individuals (ADVENT trial): a randomized, double-blind, placebo-controlled, two-stage study." HIV clinical trials 14.6 (2013): 261-273.
4. Mytesi. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically.

Last Reviewed: 11/7/18, 11/18/20, 1/19/22, 1/20/23, 1/19/24, 1/17/25
Effective Date: 1/1/19, 3/1/24

Niemann-Pick disease Type C Agents
Prior Authorization Guidelines

Affected Medication(s)

- Aqneursa (levacetylleucine) powder packet
- Miplyffa (arimoclomol) oral capsule

FDA Approved Indication(s)

- Aqneursa: Treatment of neurological manifestations of Niemann-Pick type C (NPC) in adults and pediatric patients weighing greater than or equal to 15 kg
- Miplyffa: Treatment of neurological manifestations of Niemann-Pick disease type C (NPC) in adult and pediatric 2 years of age and older, in combination with miglustat

Dosing

- Refer to package insert for dosing recommendations

Initial Authorization Criteria

1. Is the request for continuation of therapy with the same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member have Niemann-Pick disease type C as confirmed by genetic testing? (Provide genetic testing result for review)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have at least one neurological symptom? (Examples: hearing loss, vertical supranuclear gaze palsy, ataxia, dementia, dystonia, seizures, dysarthria, or dysphagia)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is the treatment being initiated by a provider that specializes in the treatment of inherited metabolic disorders? (Examples include a medical geneticist or an endocrinologist)
    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #2

Last Reviewed: 1/17/25
Effective Date: 2/1/25

b. If no, clinical review required

2. Were updated chart notes (within past year) provided with documentation of clinical response to therapy defined by an improvement in symptoms and quality of life?
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the treatment being prescribed by or in consultation with a provider who specializes in the treatment of inherited metabolic disorders? (Examples include a medical geneticist or an endocrinologist)
    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. AQNEURSA™ (levacetylleucine) for oral suspension [package insert]. Austin, TX: IntraBio, Inc; 2024.
2. MIPLYFFA (arimoclomol) capsules, [package insert]. Celebration, FL: Zevra Therapeutics, Inc, 2024.
3. Drugs@FDA: FDA Approved Drug Products. 2022. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 10 Oct. 2024].
4. Geberhiwot T, Moro A, Dardis A, et al. Consensus clinical management guidelines for Niemann-Pick disease type C. Orphanet J Rare Dis. 2018;13(1):50. Published 2018 Apr 6.
5. Schiffmann R, Nordli DR Jr, Dashe JF. Overview of acid sphingomyelinase deficiency and Niemann-Pick disease type C. UpToDate. https://www.uptodate.com/contents/overview-of-acid-sphingomyelinase-deficiency-and-niemann-pick-disease-type-c Updated November 20, 2024. Accessed December 30, 2024.

Nourianz® (istradefylline)
Prior Authorization Guidelines

Affected Medication(s)

- Nourianz oral tablet

FDA Approved Indication(s)

- For the intermittent treatment of "OFF" episodes in patients with Parkinson's disease treated with carbidopa/levodopa

Dosing

- 20 mg once daily
- Maximum dose is 40mg once daily

Initial Authorization Criteria

1. Is the request for continuation of Nourianz (istradefylline) therapy?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member have a diagnosis of advanced Parkinson's disease? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the member 18 years of age or older?
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member experience "OFF" episodes despite adjustment in carbidopa/levodopa dosing? (Examples include increasing levodopa dose or decreasing dose and increasing frequency) (Provide supporting documentation of dose adjustments trialed and response)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Does the member have a previous trial with inadequate response or intolerance to at least 2 different classes of medications to help reduce "OFF" time as listed below OR a contraindication to all 3 classes? (Provide supporting documentation of agents trialed with inadequate response, intolerance, or contraindication)
    - Dopamine agonist (Examples include: ropinirole, rotigotine)
    - Catechol-O-methyl transferase (COMT) inhibitor (Examples include: entacapone, tolcapone)

Last Reviewed: 9/18/19, 5/1/20, 11/17/21, 3/17/23, 3/15/24, 3/21/25
Effective Date: 10/15/19, 7/1/20, 1/1/22, 4/15/24

- Monoamine oxidase type B inhibitor (MAO-B) (Examples include: rasagiline, safinamide, selegiline)

a. If yes, continue to #7
b. If no, clinical review required

7. Is the treatment being prescribed by, or in consultation with, a neurologist?

a. If yes, approve for 6 months
b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication Food and Drug Administration (FDA) approved or supported by major compendia?

a. If yes, continue to #2
b. If no, clinical review required

2. Were updated chart notes (within the past 12 months) with documentation of a positive response to therapy defined as a decrease in frequency of "OFF" episodes received? (Provide supporting documentation)

a. If yes, continue to #3
b. If no, clinical review required

3. Is the treatment being prescribed by or in consultation with a neurologist?

a. If yes, approve for 12 months reauthorization
b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Nourianz [istradefylline] tablets. Kyowa Kirin Inc., Bedminster, NJ; June 2024.
2. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 25 July. 2019].
3. Fox, Susan H., et al. "International Parkinson and movement disorder society evidence-based medicine review: Update on treatments for the motor symptoms of Parkinson's disease." Movement Disorders 33.8 (2018): 1248-1266.

Last Reviewed: 9/18/19, 5/20/20, 11/17/21, 3/17/23, 3/15/24, 3/21/25
Effective Date: 10/15/19, 7/1/20, 1/1/22, 4/15/24

Nuplazid® (pimavanserin tartrate)
Prior Authorization Guidelines

Affected Medication(s)

- Nuplazid oral capsule
- Nuplazid oral tablet

FDA Approved Indication(s)

- Treatment of hallucinations and delusions associated with Parkinson's disease psychosis

Dosing

- 34 mg orally once daily

Initial Authorization Criteria

1. Is the request for continuation of Nuplazid (pimavanserin tartrate) therapy?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Have the member's hallucinations or delusions developed after the onset of Parkinson's disease? (Provide documentation of onset of hallucinations or delusions in relation to onset of Parkinson's Disease)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Was an attempt made to reduce doses or discontinue medications that may contribute to, or cause, hallucinations and/or delusions or has rationale for no dose reduction/discontinuation been received? (Examples of medications include: dopamine agonists, amantadine, monoamine oxidase B inhibitors, and anticholinergics) (Provide documentation of attempted dose reduction, discontinuation, or rationale for avoidance)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is the treatment being prescribed by, or in consultation with, a neurologist?
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)

Last Reviewed: 11/21/18, 01/20/21, 5/19/21, 7/20/22, 7/21/23, 7/19/24, 7/18/25
Effective Date: 1/1/19, 8/15/24

a. If yes, continue to #2
b. If no, clinical review required

2. Has the member experienced a positive clinical response to therapy as defined by a reduction in the frequency and/or severity of hallucinations or delusions? (Provide supporting documentation)

    a. If yes, continue to #3
    b. If no, clinical review required

3. Is the treatment being prescribed by, or in consultation with, a neurologist?

    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Nuplazid [prescribing information]. San Diego, CA: Acadia Pharmaceuticals, Inc; January 2025.
2. Cummings J, Isaacson S, Mills R, et al. Pimavanserin for patients with Parkinson's disease psychosis: a randomized, placebo-controlled phase 3 trial. The Lancet. 2014 Feb 8; 383:533-540.
3. Connolly B, Fox SH. Treatment of cognitive, psychiatric, and affective disorders associated with Parkinson's disease. Neurotherapeutics 2014; 11:78.
4. Rabey JM, Treves TA, Neufeld MY, et al. Low-dose clozapine in the treatment of levodopa-induced mental disturbances in Parkinson's disease. Neurology 1995; 45:432.
5. Fernandez HH, Friedman JH, Jacques C, Rosenfeld M. Quetiapine for the treatment of drug-induced psychosis in Parkinson's disease. Mov Disord 1999; 14:484.
6. Parkinson Study Group. Low-dose clozapine for the treatment of drug-induced psychosis in Parkinson's disease. N Engl J Med 1999; 340:757.

Last Reviewed: 11/21/18, 01/20/21, 5/19/21, 7/20/22, 7/21/23, 7/19/24, 7/18/25
Effective Date: 1/1/19, 8/15/24

Octreotide Agents
Prior Authorization Guidelines

Affected Medication(s)

- Sandostatin injection solution
- Sandostatin LAR Depot intramuscular powder for suspension
- Octreotide acetate injection solution
- Mycapssa oral capsule

FDA Approved Indication(s)

- Sandostatin/octreotide injection:
  - 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 studies were not designed to show an effect on the size, rate of growth or development of metastases
- Mycapssa
  - Long-term maintenance treatment in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide

Dosing

- Refer to corresponding package insert for specific dosing recommendations

Initial Authorization Criteria

1. Is the request for continuation of Sandostatin (octreotide), Sandostatin LAR Depot (octreotide), octreotide acetate, or Mycapssa (octreotide) therapy?

   a. If yes, continue to Reauthorization
   b. If no, continue to #2

2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)

   a. If yes, continue to #3
   b. If no, clinical review required

3. Is the member 18 years of age or older?

   a. If yes, continue to #4
   b. If no, clinical review required

4. What diagnosis is the medication being requested for? (Provide supporting documentation)

   a. Carcinoid tumors/Neuroendocrine tumors (e.g. GI tract, lung, thymus, pancreas, adrenal), continue to corresponding criteria

Last Reviewed: 12/19/18, 1/20/21, 1/20/23, 1/19/24, 1/17/25
Effective Date: 1/1/19, 3/15/23

b. Diarrhea associated with vasoactive intestinal peptide tumors (VIPomas) [pancreatic, neuroendocrine (islet cell) tumor, insulinoma, glucagonoma, somatostatinoma, and gastrinoma], continue to corresponding criteria
c. Acromegaly, continue to corresponding criteria
d. Other oncology indication, continue to corresponding criteria
e. Other non-oncology indication(s), continue to corresponding criteria

Carcinoid tumors/Neuroendocrine tumors (e.g. GI tract, lung, thymus, pancreas, adrenal)

1. Does the member meet one or more of the following conditions? (Provide supporting documentation)

    - Severe diarrhea/flushing episodes (carcinoid syndrome)
    - Requested use is to treat symptoms related to hormone hypersecretion in pancreatic tumors
    - Requested use is for primary treatment of unresected primary gastrinoma
    - Requested use is for management of locoregional advanced or metastatic disease of the
    - bronchopulmonary, thymic, gastrointestinal tract
    - Requested use is for tumor control of unresectable and/or metastatic tumors of the pancreas
    - Requested use is for management of pheochromocytoma or paraganglioma with unresectable or distant metastases

    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Diarrhea associated with vasoactive intestinal peptide tumors (VIPomas) [pancreatic, neuroendocrine (islet cell) tumor, insulinoma, glucagonoma, somatostatinoma, and gastrinoma]

1. Does the member have profuse watery diarrhea? (Provide supporting documentation)

    a. If yes, approve for 6 months
    b. If no, clinical review required

Acromegaly

1. Was baseline growth hormone (GH) and IGF-1 blood levels received? (Provide GH and IGF-1 serum levels for review)

    a. If yes, continue to #2
    b. If no, clinical review required

2. Did the member have an inadequate response to surgery and/or radiotherapy or is the member not a candidate for surgery and/or radiotherapy? (Provide documentation of inadequate response or rationale why member is not a candidate)

    a. If yes, continue to #3
    b. If no, clinical review required

3. Is the request for Mycapssa (octreotide)?

    a. If yes, continue to #4
    b. If no, approve for 6 months

4. Does the member have trial with inadequate response, intolerance, or contraindication to both Sandostatin LAR (octreotide) injection and Somatuline Depot (lanreotide) injection? (Provide supporting documentation)

    a. If yes, approve for 6 months
    b. If no, clinical review required

Oncology Indication

1. Is the medication being requested for an indication supported by National Comprehensive Cancer Network (NCCN) with an evidence level of 2A or higher? (Provide disease staging, all prior treatment history, pathology report, and anticipated treatment plan for review)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member have Karnofsky Performance Status greater or equal to 50% OR Eastern Cooperative Oncology Group (ECOG) performance status of 0-2? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the medication being prescribed by or in consultation with an oncologist?
    a. If yes, approve for 4 months unless otherwise specified
    b. If no, clinical review required

Other Non-Oncology Indication

1. Has the member tried and had an inadequate response OR does the member have a contraindication to all standard treatment options for the requested indication? (Provide documentation of inadequate response, contraindication, and/or intolerance)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the treatment being prescribed by or in consultation with an appropriate specialist?
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Does the member continue to meet the initial authorization criteria? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is there documentation of any of the following side effects from the medication? (Examples of unacceptable toxicity include the following: biliary tract abnormalities, hypothyroidism, goiter, sinus bradycardia, cardiac arrhythmias, cardiac conduction abnormalities, pancreatitis, etc.) (Provide supporting documentation of absence of unacceptable toxicities)
    a. If yes, clinical review required
    b. If no, continue to #3
3. Does the member have a positive clinical response to therapy defined by one of the following? (Provide supporting documentation)
    - Improvement in symptoms including reduction in symptomatic episodes (such as diarrhea, rapid gastric dumping, flushing, bleeding, etc.)
    - Stabilization of glucose levels

Last Reviewed: 12/19/18, 1/20/21, 1/20/23, 1/19/24, 1/17/25
Effective Date: 1/1/19, 3/15/23

- Decrease or stabilization in tumor size
- For acromegaly only: Reduction of growth hormone (GH) and/or IGF-I blood levels from baseline
- For neuroendocrine tumors of the pancreas only: Member has had disease progression and therapy will be continued in member with functional tumors in combination with systemic therapy

a. If yes, continue to #4
b. If no, clinical review required

4. Is the treatment being prescribed by or in consultation with an appropriate specialist?

a. If yes, approve for 6 months unless otherwise specified
b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Sandostatin LAR [package insert]. East Hanover, NJ; Novartis Pharmaceuticals Corporation; March 2021.
2. MYCAPSSA (octreotide) delayed-release capsules, [package insert]. Needham, MA: Chiasma, Inc.; 2022.
3. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 30 Nov. 2020].
4. Giustina A, Chanson P, Kleinberg D, et al. Expert consensus document: A consensus on the medical treatment of acromegaly. Nat Rev Endocrinol. 2014 Apr; 10(4):243-8. doi:10.1038/nrendo.2014.21. Epub 2014 Feb 25.
5. Katznelson L, Laws ER Jr, Melmed S, et al. Acromegaly: an endocrine society clinical practice guideline. J Clin Endocrinol Metab. 2014 Nov; 99(11):3933-51. doi: 10.1210/jc.2014- 2700. Epub 2014 Oct 30.
6. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Neuroendocrine and Adrenal Tumors. Version 3.2024. Available at https://www.nccn.org/professionals/physician_gls/pdf/neuroendocrine.pdf. Accessed January 9, 2025.
7. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Thymomas and Thymic Carcinomas. Version 1.2025. Available at https://www.nccn.org/professionals/physician_gls/pdf/thymic.pdf. Accessed January 9, 2025.
8. Samson, Susan L., et al. "Maintenance of acromegaly control in patients switching from injectable somatostatin receptor ligands to oral octreotide." The Journal of Clinical Endocrinology & Metabolism 105.10 (2020): e3785-e3797.
9. Fleseriu, Maria, et al. "A Pituitary Society update to acromegaly management guidelines." Pituitary 24.1 (2021): 1-13.

Last Reviewed: 12/19/18, 1/20/21, 1/20/23, 1/19/24, 1/17/25
Effective Date: 1/1/19, 3/15/23

Ogsiveo (nirogacestat hydrobromide)
Prior Authorization Guidelines

Affected Medication(s)

- Ogsiveo oral tablet

Indication(s)

- Treatment of adult patients with progressing desmoid tumors who require systemic treatment

Dosing:

- 150 mg orally twice daily until disease progression or unacceptable toxicity

Initial Authorization Criteria

1. Is the request for continuation of therapy with the same anti-cancer medication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the medication being requested to be used for an FDA approved indication? (Provide documentation of diagnosis)
    a. If yes, continue to #4
    b. If no, continue to #3
3. Is the medication being requested being used for an indication supported by the National Comprehensive Cancer Network (NCCN) with an evidence level of 2A or higher? (Provide disease staging, all prior treatment history, pathology report, and anticipated treatment plan for review)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have Karnofsky Performance Status greater or equal to 50% OR Eastern Cooperative Oncology Group (ECOG) performance status of 0-2? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have a previous trial with inadequate response, intolerance or contraindication to at least TWO of the following: imatinib, pazopanib, or sorafenib? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Is the medication being prescribed by or in consultation with an oncologist?
    a. If yes, approve for 4 months unless otherwise specified
    b. If no, clinical review required

Last Reviewed: 1/19/24, 1/17/25
Effective Date: 3/1/24

Reauthorization Criteria

1. Is the documented indication approved by the FDA or supported by the NCCN recommendation with an evidence level of 2A or higher? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is there clinical documentation confirming disease responsiveness to therapy provided? (Examples include reduction in tumor size, objective response, delay in progression, partial response, etc.) (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
3. Is the medication being prescribed by or in consultation with an oncologist?
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. OGSIVEO (nirogacestat) tablets, [package insert]. Stamford, CT: SpringWorks Therapeutics, Inc.; 2023.
2. Drugs@FDA: FDA Approved Drug Products. 2023. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 11 Dec. 2023].
3. Clinical Practice Guidelines in Oncology (NCCN Guidelines): Soft Tissue Sarcoma. Version 4.2024 National Comprehensive Cancer Network website. Available from https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed December 30, 2024.
4. Gounder M, Ratan R, Alcindor T, et al. Nirogacestat, a γ-Secretase Inhibitor for Desmoid Tumors. N Engl J Med. 2023;388(10):898-912.

Last Reviewed: 1/19/24, 1/17/25
Effective Date: 3/1/24

Ohtuvayre (ensifentrine)
Prior Authorization Guidelines

Affected Medication(s)

- Ohtuvayre (ensifentrine) nebulization solution

FDA Approved Indication(s)

- Maintenance treatment of chronic obstructive pulmonary disease (COPD) in adult patients with moderate to severe symptomatic COPD

Dosing

- 3 mg (one unit-dose ampule) twice daily, once in the morning and once in the evening, administered by oral inhalation using a standard jet nebulizer with a mouthpiece

Initial Authorization Criteria

1. Is the request for continuation of therapy with the same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member 18 years of age or older? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have documentation of moderate, severe, or very severe COPD (i.e. FEV1 of < 80% predicted)? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have a previous trial of at least 8 weeks with inadequate response, intolerance, or contraindication to a long-acting bronchodilator (LABA) AND a long-acting muscarinic antagonist (LAMA)? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Does the member have a baseline eosinophil count of at least 300 cells/mcL OR a baseline eosinophil count of at least 100 cell/mcL with a history of COPD exacerbations (i.e. one or more hospitalizations or ER visits for an exacerbation within the past 12 months)? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, continue to #8
7. Does the member have a previous trial of at least 8 weeks with inadequate response, intolerance, or contraindication to an inhaled corticosteroid (ICS)? (Provide supporting documentation)

Last Reviewed: 11/15/24, 11/21/25
Effective Date: 1/1/25

a. If yes, continue to #8
b. If no, clinical review required

8. Is the medication being prescribed by, or in consultation with, a pulmonologist or other respiratory specialist?

    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide supporting documentation)

    a. If yes, continue to #2
    b. If no, clinical review required

2. Does the member have a positive clinical response to therapy (e.g., reduction in exacerbations, positive change from baseline in post-bronchodilator FEV1)? (Provide supporting documentation)

    a. If yes, continue to #3
    b. If no, clinical review required

3. Is the medication being prescribed by, or in consultation with, a pulmonologist or other respiratory specialist?

    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. OHTUVAYRE (ensifentrine) inhalation suspension. [Prescribing Information]. Raleigh, NC: Verona Pharma Inc; July 2025.
2. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global Strategy for the Diagnosis, Management and Prevention of Chronic Obstructive Pulmonary Disease: 2025 Report. Available at: www.goldcopd.org www.goldcopd.org [Accessed 12 September 2025].

Oncology Agents
Prior Authorization Guidelines

Affected Medication(s)

- abiraterone oral tablet
- Abirtega (abiraterone oral tablet)
- Actimmune (interferon gamma-1b subcutaneous solution)
- Akeega (abiraterone-niraparib oral tablet)
- Afinitor (everolimus oral tablet)
- Afinitor Disperz (everolimus tablet for suspension)
- Alecensa (alectinib oral capsule)
- Alkeran (melphalan tablet)
- Alunbrig (brigatinib oral tablet)
- Avmapki Fakzynja Co-Pack (avutometinib capsule and defacinitib tablet)
- Ayvakit (avapritinib oral tablet)
- Balversa (erdafitinib oral tablet)
- bexarotene 1% gel
- bexarotene capsule
- Bilprevda (denosumab-nxxp vial)
- Bomyntra (denosumab-bnht vial)
- Bosulif (bosutinib oral capsule and tablet)
- Braftovi (encorafenib capsule)
- Brukinsa (zanubrutinib oral capsule)
- Cabometyx (cabozantinib oral tablet)
- Calquence (acalabrutinib oral tablet)
- Caprelsa (vandetanib oral tablet)
- Cometriq (cabozantinib oral capsule)
- Copiktra (duvelisib capsule)
- Cotellic (cobimetinib tablet)
- Danziten (nilotinib tablet)
- dasatinib tablet
- Daurismo (glasdegib tablet)
- Demser (metyrosine capsule)
- Emcyt (estramustine phosphate sodium capsule)
- Ensacove (ensartinib capsule)
- Erivedge (vismodegib capsule)
- Erleada (apalutamide tablet)
- erlotinib tablet
- etoposide capsule
- Mekinist (trametinib dimethyl sulfoxide tablet and oral solution)
- Mektovi (binimetinib tablet)
- melphalan tablet
- Modeyso (dordaviprone capsule)
- Myleran (busulfan tablet)
- Nerlynx (neratinib tablet)
- Nexavar (sorafenib tosylate tablet)
- Nilandron (nilutamide tablet)
- nilotinib hcl capsule
- nilotinib tartrate capsule
- nilutamide tablet
- Ninlaro (ixazomib capsule)
- Nubeqa (darolutamide tablet)
- Odomzo (sonidegib capsule)
- Ojemda (tovorafenib tablet and suspension)
- Ojjaara (momelotinib tablet)
- Orserdu (elacestrant)
- Osentvelt (denosumab-bmwo vial)
- pazopanib tablet
- Pemazyre (pemigatinib tablet)
- Piqray (alpelisib tablet)
- Pomalyst (pomalidomide capsule)
- Qinlock (ripretinib tablet)
- Retevmo (selpercatinib capsule and tablet)
- Revuforj (revumenib tablet)
- Rezlidhia (olutasidenib tablet)
- Romvimza (vimseltinib capsule)
- Rozlytrek (entrectinib capsule and oral pellets)
- Rubraca (rucaparib tablet)
- Rydapt (midostaurin capsule)
- sorafenib tablet
- Sprycel (dasatinib tablet)
- Stivarga (regorafenib tablet)
- sunitinib capsule
- Sutent (sunitinib malate capsule)
- Tabloid (thioguanine tablet)

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- everolimus tablet and tablet for suspension
- Exkivity (mobocertinib capsule)
- Fareston (toremifene citrate tablet)
- Fruzaqla (fruquintinib oral capsule)
- Fotivda (tivozanib capsule)
- Gavreto (pralsetinib capsule)
- gefitinib tablet
- Gilotrif (afatinib dimaleate tablet)
- Gleostine (lomustine capsule)
- Gleevec (imatinib tablet)
- Gomekli (mirdametinib capsule and soluble tablet)
- Hernexeos (zongertinib tablet)
- Hycamtin (topotecan capsule)
- Ibrance (palbociclib capsule and tablet)
- Ibtrozi (taletrectinib capsule)
- Iclusig (ponatinib hydrochloride tablet)
- Idhifa (enasidenib tablet)
- imatinib tablet
- Imbruvica (ibrutinib capsule, tablet, and suspension)
- Imkeldi (imatinib solution)
- Inluriyo (imlunestrant tablet)
- Inlyta (axitinib tablet)
- Inrebic (fedratinib capsule)
- Iressa (gefitinib tablet)
- Itovebi (inavolisib tablet)
- Jakafi (ruxolitinib tablet)
- Jaypirca (pirtobrutinib tablet)
- Kisqali (ribociclib tablet)
- Koselugo (selumetinib capsule and sprinkle capsule)
- Krazati (adagrasib tablet)
- lapatinib tablet
- Lazcluze (lazertinib tablet)
- Lenvima (lenvatinib capsule)
- Leukeran (chlorambucil tablet)
- Lonsurf (trifluridine/tipiracil tablet)
- Lorbrena (lorlatinib tablet)
- Lumakras (sotorasib tablet)
- Tabrecta (capmatinib tablet)
- Tafinlar (dabrafenib mesylate capsule and tablet for suspension)
- Tagrisso (osimertinib tablet)
- Talzenna (talazoparib capsule)
- Tarceva (erlotinib hydrochloride tablet)
- Targretin (bexarotene capsule and topical gel)
- Tasigna (nilotinib hydrochloride capsule)
- Tavalisse (fostamatinib disodium hexahydrate tablet)
- Tazverik (tazemetostat tablet
- temozolomide capsule
- Tepmetko (tepotinib tablet)
- Thalomid (thalidomide oral capsule)
- Tibsovo (ivosidenib tablet)
- Torpenz (everolimus tablet)
- Trelstar (triptorelin pamoate powder for IM injection)
- Tukysa (tucatinib tablet)
- Turalio (pexidartinib capsules)
- Tykerb (lapatinib ditosylate tablet)
- Valchlor (mechlorethamine hydrochloride topical gel)
- Vanflyta (quizartinib oral tablet)
- Venclexta (venetoclax tablet)
- Verzenio (abemaciclib tablet)
- Vitrakvi (larotrectinib tablet and oral solution)
- Vizimpro (dacomitinib tablet)
- Vonjo (pacritinib capsule)
- Voranigo (vorasidenib tablet)
- Votrient (pazopanib hydrochloride tablet)
- Welireg (belzutifan tablet)
- Wyost (denosumab-bbdz vial)
- Xalkori (crizotinib capsule and oral pellets)
- Xospata (gilteritinib tablet)
- Xpovio (selinexor tablet)
- Xtandi (enzalutamide capsule)
- Xgeva (denosumab vial)
- Yonsa (abiraterone acetate tablet)
- Zejula (niraparib tablet)
- Zelboraf (vemurafenib tablet)
- Zolinza (vorinostat capsule)
- Zydelig (idelalisib tablet)

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- Lynparza (olaparib tablet)
- Lytgobi (futibatinib tablet)
- Matulane (procarbazine capsule)
- Zykadia (ceritinib tablet)
- Zytiga (abiraterone acetate tablet)

Indication(s)

- Refer to major compendia for supported use

Dosing

- Refer to indication specific compendia supported dosing

Initial Authorization Criteria

1. Is the request for continuation of therapy with the same anti-cancer medication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the medication being requested to be used for an FDA approved indication? (Provide documentation of diagnosis)
    a. If yes, continue to #4
    b. If no, continue to #3
3. Is the medication being requested being used for an indication supported by the National Comprehensive Cancer Network (NCCN) with an evidence level of 2A or higher? (Provide disease staging, all prior treatment history, pathology report, and anticipated treatment plan for review)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have Karnofsky Performance Status greater or equal to 50% OR Eastern Cooperative Oncology Group (ECOG) performance status of 0-2? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is the medication being prescribed by or in consultation with an oncologist?
    a. If yes, approve for 4 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication approved by the FDA or supported by the NCCN recommendation with an evidence level of 2A or higher? (Provide documentation of diagnosis)
    a. If yes, continue to #2

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b. If no, clinical review required

2. Is there clinical documentation confirming disease responsiveness to therapy provided? (Examples include reduction in tumor size, objective response, delay in progression, partial response, etc.) (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
3. Is the medication being prescribed by or in consultation with an oncologist?
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. National Comprehensive Cancer Network. NCCN – NCCN Guidelines. Available at: https://www.nccn.org.

Last Reviewed: 1/16/19, 5/15/19, 7/17/19, 9/18/19, 11/20/19, 3/18/20, 5/20/20, 7/15/20, 9/16/20, 11/18/20, 1/20/21, 3/17/21, 5/19/21, 7/21/21, 9/15/21, 11/17/21, 3/16/22, 7/20/22, 9/21/22, 1/20/23, 3/17,2023, 5/19/23, 7/21/23, 11/17/23, 1/19/24, 3/15/24, 7/19/24, 9/20/24, 11/15/24, 1/17/25, 3/21/25, 5/16/25, 7/18/25, 9/19/25, 11/21/25

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Oral and Nasal CGRP Antagonists
Prior Authorization Guidelines

Affected Medication(s)

- Ubrelvy (ubrogepant) oral tablet
- Nurtec (rimegepant) oral disintegrating tablet
- Qulipta (atogepant) oral tablet
- Zavzpret (zavegepant) nasal spray

FDA Approved Indication(s)

- Ubrelvy: Acute treatment of migraine with or without aura in adults
- Nurtec ODT:
  - Acute treatment of migraine with or without aura in adults
  - Preventive treatment of episodic migraine in adults
- Qulipta: Preventive treatment of episodic or chronic migraine in adults
- Zavzpret: Acute treatment of migraine with or without aura in adults

Dosing

- Refer to package insert for recommended dosing for corresponding diagnosis

Initial Authorization Criteria

1. Is the request for continuation of a CGRP antagonist agent?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide diagnosis)
   a. If yes, continue to #3
   b. If no, clinical review required
3. Is the member 18 years of age or older?
   a. If yes, continue to #4
   b. If no, clinical review required
4. What is the requested diagnosis?
   a. Management of acute migraine, continue to #5
   b. Prevention of chronic/episodic migraine, continue to #8
5. Does the member have a previous trial with inadequate response to TWO triptan drugs (i.e. sumatriptan, rizatriptan, naratriptan, zolmitriptan, etc.)?
   a. If yes, continue to #7
   b. If no, continue to #6
6. Does the member have a contraindication to all triptan therapies? (Example of contraindications include: history of coronary artery disease, cardiac accessory conduction pathway disorders, history of stroke, transient

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ischemic attack, or hemiplegic or basilar migraine, peripheral vascular disease, ischemic bowel disease, uncontrolled hypertension, or severe hepatic impairment) (Provide supporting documentation)

   a. If yes, continue to #7
   b. If no, clinical review required

7. Will the requested oral or nasal CGRP antagonist be used in combination with another CGRP antagonist for acute migraine use?

   a. If yes, clinical review required
   b. If no, approve for 6 months unless otherwise specified

8. Has the member experienced 4 or more headache days per month? (Provide supporting documentation)

   a. If yes, continue to #9
   b. If no, clinical review required

9. Has the member had a two-month trial and failure or intolerance to (2) of the following alternative agents with differing mechanisms of action for migraine prophylaxis: topiramate, divalproex, metoprolol, propranolol, timolol, atenolol, nadolol. amitriptyline, nortriptyline, venlafaxine, duloxetine? (Provide supporting documentation)

   a. If yes, continue to #11
   b. If no, continue to #10

10. Does the member have contraindications to all of the following alternative agents used for migraine prophylaxis: topiramate, divalproex, metoprolol, propranolol, timolol, atenolol, nadolol, amitriptyline, nortriptyline, venlafaxine, duloxetine? (Provide supporting documentation)

    a. If yes, continue to #11
    b. If no, clinical review required

11. Does the member have a documented trial with insufficient response, intolerance, or contraindication to all injectable CGRP agents? (Provide supporting documentation)

    a. If yes, continue to #12
    b. If no, clinical review required

12. Will CGRP antagonist to be used in combination with Botox?

    a. If yes, clinical review required
    b. If no, continue to #13

13. Will the requested oral/nasal CGRP antagonist be used in combination with another CGRP antagonist for prophylactic use?

    a. If yes, clinical review required
    b. If no, approve for 6 months unless otherwise specified

Reauthorization Criteria

1. Is the documented indication Food and Drug Administration (FDA) approved or supported by major compendia?

   a. If yes, continue to #2
   b. If no, clinical review required

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2. Has the member demonstrated a positive clinical response to therapy?
    a. If yes, continue to #3
    b. If no, clinical review required

3. Will the requested oral or nasal CGRP antagonist be used in combination with another CGRP antagonist for the same intended use (ie prophylactic or acute use)?
    a. If yes, clinical review required
    b. If no, approve for 12 months unless otherwise specified

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Ubrelvy [prescribing information]. Allergan USA, Inc. Madison, NJ. March 2021.
2. Nurtec ODT [prescribing Information]. Biohaven Pharmaceuticals, Inc. New Haven, CT. December 2021.
3. Qulipta tablets [prescribing information]. Madison, NJ: AbbVie; September 2021.
4. Zavzpret nasal spray, [prescribing information]. New York, NY: Pfizer; 2023.
5. Ailani J, Burch RC, Robbins MS, on behalf of the Board of Directors of the American Headache Society. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. Headache. 2021;61(7):1021-1039.

Last Reviewed: 11/16/22, 7/21/23, 7/19/24, 1/17/25
Effective Date: 1/1/23, 9/15/23, 8/15/24, 2/1/25

Oral Fentanyl Products
Prior Authorization Guidelines

Affected Medication(s)

- Fentora (fentanyl citrate) buccal tablet
- Fentanyl citrate OTFC
- Fentanyl citrate buccal tablet

Indication(s)

- **Fentanyl citrate OTFC**: Management of breakthrough pain in cancer patients 16 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain
- **Fentora**: Management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain

Dosing

- Refer to corresponding package insert for dosing recommendations

Initial Authorization Criteria

1. Is the request for renewal of a previously approved oral fentanyl product prior authorization with the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of cancer diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member meet the appropriate age for the FDA approved use of the medication? (At least 16 years of age for Actiq and at least 18 years of age for all others)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the member's cancer pain inadequately controlled despite adherence to around the clock opioid therapy? (Provide documentation of current medication regimen and inadequately controlled pain)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have a trial with inadequate response to at least TWO other oral or parenteral short-acting narcotic products that are used for breakthrough pain in cancer patients? (examples: morphine, hydromorphone, and oxycodone)? (Provide documentation of medications tried and inadequate response)
    a. If yes, continue to #6
    b. If no, clinical review required

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6. Is the member considered opioid tolerant defined as those who are taking at least or an equivalent dose of another opioid for a week or longer? (Provide documentation of opioid tolerance)

    - 60 mg of oral morphine/day
    - 25 mcg of transdermal fentanyl/hour
    - 30 mg oral oxycodone/day
    - 8 mg oral hydromorphone/day
    - 60 mg hydrocodone/day

    a. If yes, continue to #7
    b. If no, clinical review required

7. Is the medication being prescribed by, or in consult with, an oncologist or palliative care provider?

    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide supporting documentation)

    a. If yes, continue to #2
    b. If no, clinical review required

2. Does the member demonstrate a positive clinical response to therapy as documented by a greater control of break-through pain? (Provide supporting documentation)

    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Fentora [package insert]. Salt Lake City, Utah: Cephalon, Inc.; September 2018.
2. Fentanyl Citrate OTFC [package insert]. Parsippany, NJ: Teva Pharmaceuticals; January 2024.

Last Reviewed: 11/21/18, 9/18/19, 7/21/21, 3/16/22, 5/19/23, 5/17/24, 5/16/25
Effective Date: 1/1/19, 10/15/19, 9/1/21, 5/1/22, 7/15/23, 8/1/24

Oral GnRH Antagonists
Prior Authorization Guidelines

Affected Medication(s)

- Myfembree (relugolix, estradiol, and norethindrone) tablets
- Oriahnn (elagolix, estradiol, and norethindrone) capsules
- Orilissa (elagolix) oral tablet

FDA Approved Indication(s)

Myfembree

- Management of moderate to severe pain associated with endometriosis in premenopausal patients
- Management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal patients

Oriahnn

- Management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in patients prior to menopause

Orilissa

- Management of moderate to severe pain associated with endometriosis

Dosing

- Myfembree:
  - One tablet (relugolix 40mg, estradiol 1mg and norethindrone acetate 0.5mg) one time daily
  - Note: Recommended total duration of treatment is 24 months
- Oriahnn:
  - One capsule (elagolix 300mg, estradiol 1mg, norethindrone acetate 0.5mg) by mouth in the morning and one capsule (elagolix 300mg) in the evening.
  - Note: Use of Oriahnn should be limited to 24 months due to risk of continued bone loss, which may not be reversible
- Orilissa:
  - 150 mg once daily. Maximum treatment duration: 24 months
  - 200 mg twice daily. Maximum treatment duration: 6 months

Initial Authorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required
2. Is the treatment prescribed by, or in consultation with, an obstetrics/gynecologist or an endocrinologist?
   a. If yes, continue to #3
   b. If no, clinical review required
3. Is the member premenopausal?
   a. If yes, continue to #4
   b. If no, clinical review required

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4. What is the requested diagnosis?
    a. Heavy menstrual bleeding associated with uterine fibroids, continue to #5
    b. Pain associated with endometriosis, continue to #7
5. Has the member previously had a 3-month trial with at least 2 different hormonal contraceptives? (May include oral combination, oral progestin only, and/or progestin-releasing IUD) (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Does the member have a previous trial with inadequate response, intolerance, or contraindication to tranexamic acid? (Provide supporting documentation)
    a. If yes, approve for 24 months
    b. If no, clinical review required
7. Does the member have a previous trial with inadequate response, intolerance, or contraindication to at least two non-steroidal anti-inflammatory drugs (NSAID)? (Provide supporting documentation)
    a. If yes, continue to #8
    b. If no, clinical review required
8. Has the member previously had a 3-month trial with at least one hormonal contraceptive? (May include oral combination, oral progestin only, and/or progestin-releasing IUD) (Provide supporting documentation)
    a. If yes, continue to #9
    b. If no, clinical review required
9. Is the request for Orilissa 200 mg tablets?
    a. If yes, approve for 6 months
    b. If no, approve for 24 months

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Drugs@FDA: FDA Approved Drug Products. 2020. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 14 July, 2020].
2. ORIAHNN (elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules), [package insert]. North Chicago, IL: Abvvie, Inc.; June 2023.
3. MYFEMBREE® (relugolix, estradiol, and norethindrone acetate) tablets, [package insert]. Marlborough, MA: Sumitomo Pharma America, Inc; July 2024.
4. ORILISSA (elagolix tablets) [package insert]. North Chicago, IL: AbbVie Inc.; June 2023.
5. Schlaff, William D., et al. "Elagolix for heavy menstrual bleeding in women with uterine fibroids." New England Journal of Medicine (2020).

Last Reviewed: 11/18/20, 1/19/22, 3/17/23, 3/15/24, 7/19/24, 7/18/25
Effective Date: 12/15/20, 3/1/22, 6/1/23, 4/15/24, 8/15/24

6. NG88, N. I. C. E. "Heavy Menstrual Bleeding: assessment and management National Institute for Health and Clinical Excellence (NICE); 2018."
7. American College of Obstetricians and Gynecologists. "ACOG committee opinion no. 557: management of acute abnormal uterine bleeding in nonpregnant reproductive-aged women." Obstetrics and gynecology 121.4 (2013): 891.
8. Neri, Manuela, et al. "Clinical Utility Of Elagolix As An Oral Treatment For Women With Uterine Fibroids: A Short Report On The Emerging Efficacy Data." International Journal of Women's Health 11 (2019): 535.
9. American College of Obstetricians and Gynecologists. ACOG Practice Bulletin. Management of Symptomatic Uterine Leiomyomas. June 2021. Available at: https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2021/06/management-of-symptomatic-uterine-leiomyomas. Accessed on December 9, 2022.
10. Falcone, Tommaso, and Rebecca Flyckt. "Clinical management of endometriosis." Obstetrics & Gynecology 131.3 (2018): 557-571.

Orfadin®, Nityr® (nitisinone)
Prior Authorization Guidelines

Affected Medication(s)

- Orfadin oral capsule
- Nityr oral tablet
- nitisinone capsule
- Orfadin oral suspension

Indication(s)

- For the treatment of adult and pediatric patients with hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine

Dosing:

- 0.5 mg/kg orally twice daily, maximum dose of 2 mg/kg daily

Initial Authorization Criteria

1. Is the request for continuation of nitisinone therapy?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is nitisinone being requested for an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is documentation confirming diagnosis of hereditary tyrosinemia type 1 provided? (Provide documentation of biochemical testing, clinical presentation, and/or DNA testing result)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is baseline urine or plasma succinylacetone level provided? (Provide baseline urine or plasma succinylacetone level for review)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is documentation of adherence to nutritional therapy provided? (Provide supporting documentation of restriction of tyrosine and phenylalanine adherence)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Is the member's current weight provided? (Provide member's weight for review)
    a. If yes, continue to #7

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b. If no, provider outreach required

7. Is the request for Nityr tablets or Orfadin suspension?

    a. If yes, continue to #8
    b. If no, continue to #9

8. Does the member have an intolerance to nitisinone capsules or is clinical rationale supporting inability to take nitisinone provided? (Provide supporting documentation of intolerance or clinical rationale)

    a. If yes, continue to #9
    b. If no, clinical review required

9. Is the treatment being prescribed by, or in consultation with, a provider that is specialized in treatment of hereditary tyrosinemia or related disorders?

    a. If yes, approve for 4 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is nitisinone being requested for an FDA approved or major compendia supported indication?

    a. If yes, continue to #2
    b. If no, clinical review required

2. Is documentation of adherence to nutritional therapy received? (Provide supporting documentation of restriction of tyrosine and phenylalanine adherence)

    a. If yes, continue to #3
    b. If no, clinical review required

3. Has documentation of significant clinical response to therapy been provided? (Provide supporting documentation of complete urine or plasma succinylacetone suppression confirmed by lab result)

    a. If yes, continue to #4
    b. If no, clinical review required

4. Is member's current weight provided? (Provide member's weight for review)

    a. If yes, continue to #5
    b. If no, provider outreach required

5. Is the treatment being prescribed by or in consultation with a provider that is specialized in treatment of hereditary tyrosinemia or related disorders?

    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as

medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Nitisinone (Nityr) oral tablet [package insert]. Cambridge, UK: Cycle Pharmaceuticals Ltd.; July 2022.
2. Nitisinone (Orfadin) oral capsule/suspension [package insert]. Waltham, MA: Sobi, Inc; June 2022.
3. Grompe MD, Hahn MD, PhD, Rand MD. Disorders of tyrosine metabolism. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed January 29, 2025.
4. DynaMed Plus [Internet]. Ipswich (MA): EBSCO Information Services. 1995 - . Record No. 916953, Hereditary tyrosinemia; [updated 2017 Jan 31, cited July 5, 2018]. Available at: http://www.dynamed.com/login.aspx?direct=true&site=DynaMed&id=916953. Registration and login required.

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Effective Date: 1/1/19, 9/1/21, 6/1/23

Orgovyx® (relugolix)
Prior Authorization Guidelines

Affected Medication(s)

- Orgovyx (relugolix) oral tablet

FDA Approved Indication(s)

- Treatment of adults with advanced prostate cancer

Dosing

- Loading dose of 360mg on the first day of treatment followed by 120mg taken orally one time daily at approximately the same time each day

Initial Authorization Criteria

1. Is the request for continuation of therapy with the same medication for the same indication?

    a. If yes, continue to Reauthorization
    b. If no, continue to #2

2. Is the medication being requested for an FDA approved indication? (Provide supporting documentation)

    a. If yes, continue to #4
    b. If no, continue to #3

3. Is the medication being requested for an indication supported by the National Comprehensive Cancer Network (NCCN) recommendation with an evidence level of 2A or higher? (Provide disease staging, all prior treatment history, pathology report, and anticipated treatment plan for review)

    a. If yes, continue to #4
    b. If no, clinical review required

4. Does the member have Karnofsky Performance Status greater or equal to 50% OR Eastern Cooperative Oncology Group (ECOG) performance status of 0-2? (Provide supporting documentation)

    a. If yes, continue to #5
    a. If no, clinical review required

5. Does the member have a previous trial with inadequate response, intolerance, or contraindication to leuprolide? (Provide supporting documentation)

    a. If yes, continue to #6
    b. If no, clinical review required

6. Is the medication being prescribed by, or in consultation with, an oncologist?

    a. If yes, approve for 4 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication approved by the FDA or supported by NCCN recommendation with an evidence level of 2A or higher? (Provide supporting documentation)

    a. If yes, continue to #2

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b. If no, clinical review required

2. Is there clinical documentation confirming disease responsiveness to therapy provided? (Example includes testosterone levels < 50ng/dL) (Provide supporting documentation)

    a. If yes, continue to #3
    b. If no, clinical review required

3. Is the medication being prescribed by or in consultation with an oncologist?

    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

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References:

1. ORGOVYX (relugolix) tablets, [package insert]. Marlborough, MA: Sumitomo Pharma America Inc; October 2024.
2. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 26 Jan. 2021].
3. Shore, Neal D., et al. "Oral relugolix for androgen-deprivation therapy in advanced prostate cancer." New England Journal of Medicine 382.23 (2020): 2187-2196.
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Effective Date: 5/1/21, 7/15/22

Oxervate® (cenegermin-bkbj)
Prior Authorization Guidelines

Affected Medication(s)

- Oxervate ophthalmic solution

FDA Approved Indication(s)

- Treatment of neurotrophic keratitis

Dosing

- One drop in affected eye(s) 6 times per day for 8 weeks

Initial Authorization Criteria

1. Is the medication being requested for an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the member 2 years of age or older?
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member have a diagnosis of neurotrophic keratitis (NK) stage 2 or stage 3? (Characterized as persistent corneal epithelial defect and/or corneal stroma involvement with presence corneal ulcer)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Has the member trialed both preservative-free artificial tears and topical antibiotic eye drops with inadequate response? (Provide documentation of previous medication history)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Has the member previously been treated with a course of Oxervate for the same eye? (Note: Re-treatment with Oxervate is not supported)
    a. If yes, clinical review required
    b. If no, continue to #6
6. Is the medication being prescribed by, or in consultation with, and ophthalmologist?
    a. If yes, approve for 8 weeks
    b. If no, clinical review required

Note:

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medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Drugs@FDA: FDA Approved Drug Products. 2018. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 5 Dec. 2018].
2. OXERVATE (cenegermin-bkbj) ophthalmic solution [package insert]. Boston, MA: Dompe US, Inc.; February 2025.
3. Sacchetti M, Lambiase A. Diagnosis and management of neurotrophic keratitis. Clin Ophthalmol. 2014;8:571–579. Published 2014 Mar 19. doi:10.2147/OPTH.S45921
4. Bonini S, Lambiase A, Rama P et al. Phase 2 randomized, double-masked, vehicle-controlled trial of recombinant human nerve growth factor for neurotrophic keratitis. Ophthalmology 2018;125:1332–1343.
5. Semeraro F, Forbice E, Romano V, et al. Neurotrophic Keratitis. Ophthalmologica 2014;231:191-197. doi: 10.1159/000354380
6. National Institute for Health and Care Excellence. Cenegermin for treating neurotrophic keratits. https://www.nice.org.uk/guidance/ta532. Published July, 2018. Accessed May 7, 2019.
7. Graham RH and Hendrix MA. Neurotrophic Keratitis Treatment and Management. Medscape. https://emedicine.medscape.com/article/1194889. Updated September 13, 2018. Accessed May 7, 2019.

Pulmonary Arterial Hypertension (PAH) Agents
Prior Authorization Guidelines

Affected Medication(s)

- Adcirca (tadalafil) oral tablet
- Adempas (riociguat) oral tablet
- Alyq (tadalafil) oral tablet
- Ambrisentan oral tablet
- Bosentan oral tablet
- Bosentan oral tablet for suspension
- Letairis (ambrisentan) oral tablet
- Opsumit (macitentan) oral tablet
- Opsynvi (macitentan-tadalafil) oral tablet
- Orenitram ER (treprostinil) oral tablet
- Revatio (sildenafil) oral tablet
- Revatio (sildenafil) oral powder for suspension
- Sildenafil oral tablet (20 mg tablet only)
- Sildenafil 10 mg/ml oral suspension
- Tadalafil oral tablet (20 mg tablet only)
- Tracleer (bosentan) oral tablet
- Tracleer (bosentan) oral tablet for suspension
- Tyvaso (treprostinil) inhalation solution
- Uptravi (selexipag) oral tablet
- Ventavis (iloprost) inhalation solution
- Winrevair (sotatercept-csrk) injection solution
- Yutrepia (treprostinil) inhalation powder

FDA Approved Indication(s)

- **Adcirca / Alyq**
  - Treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise ability
- **Adempas**
  - Treatment of adults with persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) (WHO Group 4) after surgical treatment, or inoperable CTEPH, to improve exercise capacity and WHO functional class
  - Treatment of adults with PAH (WHO Group 1), to improve exercise capacity, WHO functional class and to delay clinical worsening
- **Letairis**
  - Treatment of PAH (WHO Group 1):
    - To improve exercise ability and delay clinical worsening
    - In combination with tadalafil to reduce the risks of disease progression and hospitalization for worsening PAH, and to improve exercise ability
- **Opsumit**
  - Treatment of PAH (WHO Group I) to reduce the risk of disease progression and hospitalization for PAH
- **Opsynvi**

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- Treatment of adults with PAH, WHO Group I and WHO Functional Class (FC) II–III). Individually, macitentan reduces the risk of clinical worsening events and hospitalization, and tadalafil improves exercise ability.

- **Orenitram ER**
  - Treatment of PAH (WHO Group I) to delay disease progression and to improve exercise capacity
- **Revatio**
  - Treatment of PAH (WHO Group 1) in adults to improve exercise ability and delay clinical worsening
  - Treatment of PAH (WHO Group 1) in pediatric patients 1 to 17 years old to improve exercise ability and, in pediatric patients too young to perform standardized exercise testing, pulmonary hemodynamics thought to underlie improvements in exercise
- **Tracleer**
  - Treatment of PAH (WHO Group 1):
    - In adults to improve exercise ability and to decrease clinical worsening
    - In pediatric patients ages 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
- **Tyvaso**

  Inhaled:
  - Treatment of PAH (WHO Group I) in adult patients to improve exercise ability
  - Treatment of pulmonary hypertension associated with interstitial lung disease (WHO Group 3) to improve exercise ability.
- **Uptravi**
  - Treatment of pulmonary arterial hypertension (WHO Group I) to delay disease progression and reduce the risk of hospitalization for PAH
- **Ventavis**
  - Treatment of pulmonary arterial hypertension (WHO group I) in adult patients to improve a composite endpoint consisting of exercise tolerance, symptoms (NYHA Class), and lack of clinical deterioration
- **Winrevair**
  - Treatment of adults with pulmonary arterial hypertension (PAH, World Health Organization [WHO] Group 1) to increase exercise capacity, improve WHO functional class (FC), and reduce the risk of clinical worsening events
- **Yutrepia**
  - Treatment of PAH (WHO Group I) in adult patients to improve exercise ability
  - Treatment of pulmonary hypertension associated with interstitial lung disease (WHO Group 3) to improve exercise ability

Dosing

- Refer to corresponding package insert for specific dosing recommendations

Initial Authorization Criteria

1. Is the request for continuation of therapy with the same oral pulmonary arterial hypertension agent?

   a. If yes, continue to Reauthorization
   b. If no, continue to #2

2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the request for use to treat PAH World Health Organization (WHO) Group 1? (Provide documentation of PAH, WHO Group 1)
    a. If yes, continue to #7
    b. If no, continue to #4
4. Is the request for use to treat persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH), WHO Group 4? (Provide documentation of CTEPH WHO Group 4)
    a. If yes, continue to corresponding criteria
    b. If no, continue to #5
5. Is the request for Tyvaso for management of pulmonary hypertension associated with interstitial lung disease (WHO Group 3)? (Provide supporting documentation)
    a. If yes, continue to corresponding criteria
    b. If no, continue to #6
6. Is the request for a major compendia supported indication?
    a. If yes, continue to #9
    b. If no, clinical review required
7. Has the diagnosis been confirmed by right heart catheterization demonstrating mPAP $\geq$ 20 mmHg, PVR $\geq$ 3 Wood units, and PCWP $\leq$15 mmHg (or confirmed by another recommended test such as echocardiograph if catheterization cannot be performed)? (Provide supporting documentation)
    a. If yes, continue to #8
    b. If no, clinical review required
8. Does the member have WHO or New York Heart Association (NYHA) Functional Class II-IV symptoms? (Provide supporting documentation)
    a. If yes, continue to #9
    b. If no, clinical review required
9. Is the prescriber a relevant specialist (i.e. pulmonologist or cardiologist)?
    a. If yes, continue to criteria corresponding to diagnosis and requested agent
    b. If no, clinical review required

Chronic Thromboembolic Pulmonary Hypertension

1. Has the diagnosis been confirmed by ventilation/perfusion (V/Q) scan, right heart catheterization demonstrating mPAP $\geq$ 20 mmHg and PCWP $\leq$15 mmHg, and presumed to be caused by thromboembolic occlusion of the pulmonary vasculature? (Provide supporting documentation)
    a. If yes, continue to #2

b. If no, clinical review required

2. Is the member 18 years of age or older?

   a. If yes, continue to #3
   b. If no, clinical review required

3. Is the member status post pulmonary thromboendarterectomy, status post balloon pulmonary angioplasty, ineligible for surgery, or bridging definitive surgery? (Provide supporting documentation)

   a. If yes, continue to #4
   b. If no, clinical review required

4. Is the request for a female member with reproductive potential?

   a. If yes, continue to #5
   b. If no, continue to #6

5. Has a pregnancy test been obtained within 30 days prior to start of treatment to exclude pregnancy? (Provide supporting documentation)

   a. If yes, continue to #6
   b. If no, clinical review required

6. Will Adempas (riociguat) be used concomitantly with a PDE5 inhibitor or another organic nitrate?

   a. If yes, clinical review required
   b. If no, continue to #7

7. Is the medication being prescribed by, or in consultation with an appropriate specialist (i.e. pulmonologist or cardiologist)?

   a. If yes, approve for 6 months unless otherwise specified
   b. If no, clinical review required

<u>PAH: Phosphodiesterase-5 Enzyme (PDE5) Inhibitors: Adcirca (tadalafil), Alyq (tadalafil), tadalafil, Revatio (sildenafil), sildenafil</u>

1. Does the member currently take other organic nitrates in any form, regularly or intermittently? (Examples include isosorbide dinitrate, isosorbide mononitrate, and nitroglycerin) (Provide medication list for review)

   a. If yes, clinical review required
   b. If no, continue to #2

2. Will the requested PDE5 inhibitor be used concomitantly with Adempas (riociguat)? (Provide documentation of treatment plan)

   a. If yes, clinical review required
   b. If no, continue to #3

3. Is the request for Revatio (sildenafil) suspension?

   a. If yes, continue to #4
   b. If no, approve for 6 months

4. Is there documentation for why member is unable to take solid dosage form? (Provide documentation with rationale why the member is unable to take solid dosage form)
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

<u>PAH: Endothelin Receptor Antagonists/ERA-PDE5 Combinations: Letairis (ambrisentan), Opsumit (macitentan), Opsynvi (macitentan-tadalafil), Tracleer (bosentan)</u>

1. Does the member have documentation of inadequate response, contraindication, or intolerance to a PDE5 inhibitor (e.g. sildenafil) OR will the requested medication be taken along with a PDE5 inhibitor? (Provide documentation of inadequate response, contraindication, or intolerance)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the member a female of reproductive potential?
    a. If yes, continue to #3
    b. If no, continue to #4
3. Has a pregnancy test been obtained within 30 days prior to start of treatment to exclude pregnancy? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have preexisting moderate or severe hepatic impairment? (Provide documentation of hepatic status)
    a. If yes, clinical review required
    b. If no, continue to #5
5. Is the request for Letairis (ambrisentan)?
    a. If yes, continue to #6
    b. If no, continue to #7
6. Is the member 18 years of age or older?
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required
7. Is the request for Tracleer (bosentan)?
    a. If yes, continue to #8
    b. If no, continue to #9
8. Will Tracleer (bosentan) be used concurrently with cyclosporine or glyburide? (Provide documentation of medication list)
    a. If yes, clinical review required
    b. If no, approve for 6 months unless otherwise specified
9. Is the request for Opsumit (macitentan) or Opsynvi (macitentan-tadalafil)?
    a. If yes, continue to #10

b. If no, clinical review required

10. Is the member 18 years of age or older?

    a. If yes, continue to #11
    b. If no, clinical review required

11. Does the member have documentation of inadequate response, contraindication, or intolerance to ambrisentan or bosentan? (Provide documentation of inadequate response, contraindication, or intolerance)
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

PAH: Soluble Guanylate Cyclase Stimulator: Adempas (riociguat)

1. Is the member 18 years of age or older?

    a. If yes, continue to #2
    b. If no, clinical review required

2. Does the member have documentation of inadequate response, contraindication, or intolerance to a PDE5 inhibitor (e.g. sildenafil)? (Provide documentation of inadequate response, contraindication, or intolerance)

    a. If yes, continue to #3
    b. If no, clinical review required

3. Does the member have documentation of inadequate response, contraindication, or intolerance to an endothelin receptor antagonist (e.g. Tracleer, Opsumit, or Letairis)? (Provide documentation of inadequate response, contraindication, or intolerance)

    a. If yes, continue to #4
    b. If no, clinical review required

4. Is the member a female of reproductive potential?

    a. If yes, continue to #5
    b. If no, continue to #6

5. Has pregnancy test been obtained within 30 days prior to start of treatment to exclude pregnancy? (Provide supporting documentation)

    a. If yes, continue to #6
    b. If no, clinical review required

6. Will Adempas (riociguat) be used concomitantly with a PDE5 inhibitor or another organic nitrate? (Provide documentation of treatment plan)

    a. If yes, clinical review required
    b. If no, approve for 6 months unless otherwise specified

PAH: Prostanoids/Prostacyclins: Orenitram ER (treprostinil), Uptravi (selexipag), Tyvaso (treprostinil), Ventavis (iloprost), Yutrepia (treprostinil)

1. Does the member have documentation of inadequate response, contraindication, or intolerance to at least **two** of the following: PDE5 inhibitor, endothelin receptor antagonist, or Adempas (riociguat)? (Provide documentation of inadequate response, contraindication, or intolerance)

    a. If yes, continue to #2
    b. If no, clinical review required

2. Will the member be taking the requested agent in combination with another prostanoid/prostacyclin (e.g. epoprostenol, iloprost)? (Provide documentation of treatment plan)

    a. If yes, clinical review required
    b. If no, continue to #3

3. Does the member have severe hepatic impairment (Child Pugh Class C)? (Provide supporting documentation of hepatic status)

    a. If yes, clinical review required
    b. If no, approve for 6 months unless otherwise specified

<u>PAH: Activin Signaling Inhibitor: Winrevair (sotatercept-csrk)</u>

1. Is the member 18 years of age or older?

    a. If yes, continue to #2
    b. If no, clinical review required

2. Does the member have symptomatic PAH classified as WHO Functional Class II or III? (Provide supporting documentation)

    a. If yes, continue to #3
    b. If no, clinical review required

3. Is the member currently on at least two PAH therapies from separate drug classes? (i.e. PDE5 inhibitor, endothelin receptor antagonist, soluble guanylate cyclase stimulator) (Provide documentation of medication history)

    a. If yes, continue to #4
    b. If no, clinical review required

4. Is the member currently on a prostacyclin or prostanoid for treatment of PAH? (Provide treatment plan)

    a. If yes, continue to #6
    b. If no, continue to #5

5. Does the member continue to have a risk score of intermediate-high or high as defined by one of the risk assessment tools below despite a 6-month trial with stable doses of current PAH therapy? (Provide documentation of risk assessment)

        - ESC/ERS 2022 Guidelines
        - REVEAL 2.0
        - COMPERA 2 4-Risk Strata

    a. If yes, continue to #6
    b. If no, clinical review required

6. Has the member been adherent with greater than 75% utilization to current PAH therapy over the past 6 months? (Provide supporting documentation)

    a. If yes, continue to #7
    b. If no, clinical review required

7. Is the member's platelet count greater than or equal to 50,000 cells/mm3? (Provide supporting documentation

    a. If yes, approve for 6 months
    b. If no, clinical review required

Pulmonary Hypertension Associated with Interstitial Lung Disease: Tyvaso (treprostinil)

1. Has a diagnosis of pulmonary hypertension associated with interstitial lung disease (WHO group 3) been confirmed by right heart catheterization? (Provide supporting documentation)

    a. If yes, continue to #2
    b. If no, clinical review required

2. Has a diagnosis of interstitial lung disease been confirmed by a computed tomography of the chest? (Provide supporting documentation)

    a. If yes, continue to #3
    b. If no, clinical review required

3. Is the medication being prescribed by, or in consultation with, an appropriate specialist (i.e. pulmonologist, cardiologist, or rheumatologist)?

    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Other Indications

1. Has the member tried and had an inadequate response OR dose the member have a contradiction to ALL standard treatment options for the requested indication? (Provide all prior treatment history, contraindication if appropriate, and treatment plan)

    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)

    a. If yes, continue to #2
    b. If no, clinical review required

2. Does the member have a positive clinical response to therapy? (Examples include improvement in 6-minute walking distance and/or stabilization or improvement in WHO functional class) (Provide supporting documentation)

a. If yes, continue to #3
b. If no, clinical review required

3. Is the prescriber a relevant specialist (i.e. pulmonologist or cardiologist)?

a. If yes, approve for 12 months unless otherwise specified
b. If no, clinical review required

Note:

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References:

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2. Humbert, Marc, et al. "2022 ESC/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension." European Respiratory Journal (2022).
3. Adcirca (tadalafil) [package insert]. Indianapolis, IN: Eli Lilly and Company; November 2024.
4. Adempas (riociguat) [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc; January 2023.
5. Letairis (ambrisentan) [package insert]. Foster City, CA: Gilead Sciences, Inc; April 2025.
6. Opsumit (macitentan) [package insert]. South San Francisco, CA: Actelion Pharmaceuticals US; April 2025.
7. Opsynvi (macitentan) [package insert]. Titusville, NJ: Actelion Pharmaceuticals US; April 2025.
8. Orenitram ER (treprostinil) [package insert]. Research Triangle Park, NC: United Therapeutics Corp; November 2024.
9. Revatio (sildenafil) [package insert]. NY, NY: Pfizer Labs; January 2023.
10. Tracleer (bosentan) [package insert]. South San Francisco, CA: Actelion Pharmaceuticals US; May 2025.
11. Uptravi (selexipag) [package insert]. South San Francisco, CA: Actelion Pharmaceuticals US; July 2024.
12. Ventavis (iloprost) [package insert]. Titusville, NJ: Actelion Pharmaceuticals US, Inc.; July 2022.
13. Tyvaso (treprostinil) [package insert]. Research Triangle Park, NC: United Therapeutics Corp.; December 2024.
14. Winrevair (sotatercept-csrk) [package insert]. Rahway, NJ: Merck Sharp & Dohme LLC; May 2025.
15. Yutrepia (treprostinil) [package insert]. Morrisville, NC: Liquidia Technologies, Inc. June 2025.
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17. Klinger JR, Elliott CG, Levine DJ, et al. Therapy for Pulmonary Arterial Hypertension in Adults: Update of the CHEST Guideline and Expert Panel Report [published correction appears in Chest. 2021 Jan;159(1):457]. Chest. 2019;155(3):565-586.
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Effective Date: 1/1/19, 9/1/19, 7/15/22, 11/1/22, 11/20/23, 6/15/24, 8/15/24, 8/1/25

19. Maron BA. Revised Definition of Pulmonary Hypertension and Approach to Management: A Clinical Primer. J Am Heart Assoc. 2023;12(8):e029024.

Palforzia® (peanut allergen powder)
Prior Authorization Guidelines

Affected Medication(s)

- Palforzia oral capsule
- Palforzia powder sachet

FDA Approved Indication(s)

- Mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanuts. Approved for use in patients with a confirmed diagnosis of peanut allergy. To be used in conjunction with a peanut avoidant diet

Dosing

- Administered in 3 sequential phases: Initial Dose Escalation, Up-Dosing and Maintenance. Open capsule(s) or sachet and empty into a few spoonfuls of refrigerated or room temperature semisolid food, mix well. Maintenance dose is 300mg daily; package insert should be referenced for initial dose escalation and up-dosing schedule.

Initial Authorization Criteria

1. Is the request for continuation of Palforzia (peanut allergen powder) therapy?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member between 4 and 17 years of age at the start of therapy?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have a documented peanut allergy confirmed by peanut allergen skin testing ≥ 3mm compared to control or peanut-specific serum IgE ≥ 0.35kUA/L completed within 12 months?
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have a history of a previous systemic allergic reaction to peanuts requiring the use of epinephrine or resulting in ER visit/hospitalization?
    a. If yes, continue to #6
    b. If no, clinical review required
6. Is medical rationale provided for why adhering to a peanut avoidant diet alone is not sufficient therapy?
    a. If yes, continue to #7

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b. If no, clinical review required

7. Will the medication be used in combination with peanut avoidance?

   a. If yes, continue to #8
   b. If no, clinical review required

8. Will the first dose of each new up-dosing be administered under the supervision of a health care professional?

   a. If yes, continue to #9
   b. If no, clinical review required

9. Does the member have any of the following contraindications to therapy?

   - Uncontrolled asthma
   - A history of eosinophilic esophagitis
   - Other eosinophilic gastrointestinal disease
   - Chronic, recurrent, or severe gastroesophageal reflux disease (GERD)
   - Symptoms of dysphasia
   - Recurrent gastrointestinal symptoms of undiagnosed etiology

   a. If yes, clinical review required
   b. If no, continue to #10

10. Is the medication being prescribed by, or in consultation with, an allergist or immunologist?

    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)

   a. If yes, continue to #2
   b. If no, clinical review required

2. Does the member remain adherent to peanut avoidant diet?

   a. If yes, continue to #3
   b. If no, clinical review required

3. Has the member had a positive clinical response to therapy as defined by an improvement in quality of life? (Provide supporting documentation of positive clinical response)

   a. If yes, continue to #4
   b. If no, clinical review required)

4. For member's who have used epinephrine while on Palforzia treatment, has supporting documentation been provided that demonstrates benefits of continued therapy outweigh the risks?

   a. If yes, continue to #5
   b. If no, clinical review required

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5. Is the treatment being prescribed by or in consultation with an allergist or immunologist?

    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Palforzia [peanut allergen powder] capsules. Aimmune Therapeutics, Inc. Brisbane, CA; March 2023.
2. DailyMed – Palforzia-peanut allergen powder capsule. 2020. U.S. National Library of Medicine. National Institutes of Health. [online] Accessed 21 April. 2020]
3. Moore, Andrew. “The Current State of Oral Immunotherapy: AAAAI.” The American Academy of Allergy, Asthma & Immunology, 4 Feb. 2020, www.aaaai.org/conditions-and-treatments/library/allergy-library/oit.
4. Feuille E, Nowak-Wegrzyn A. Allergen-Specific Immunotherapies for Food Allergy. Allergy Asthma Immunol Res. 2018 May;10(3):189-206. https://doi.org/10.4168/aair.2018.10.3.189
5. Togias, Alkis, et al. "Addendum guidelines for the prevention of peanut allergy in the United States: report of the National Institute of Allergy and Infectious Diseases–sponsored expert panel." World Allergy Organization Journal 10.1 (2017): 1-18.

Last Reviewed: 7/15/20, 9/15/21, 9/21/22, 9/15/23, 9/20/24, 9/19/25
Effective Date: 8/15/20, 10/15/24

Parathyroid Hormone (PTH) Analog Agents
Prior Authorization Guidelines

Affected Medication(s)

- Bonsity (teriparatide) subcutaneous solution
- Forteo (teriparatide) subcutaneous solution
- teriparatide subcutaneous solution
- Tymlos (abaloparatide) subcutaneous solution

FDA Approved Indication(s)

- 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
  - Bonsity, Forteo, teriparatide, Tymlos
- To increase bone mass in men with primary or hypogonadal 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
  - Bonsity, Forteo, teriparatide
- 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
  - Bonsity, Forteo, teriparatide
- To increase bone density in men with osteoporosis 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.
  - Tymlos

Dosing

- Bonsity, Forteo, teriparatide: 20 mcg subcutaneously once daily
- Tymlos: 80 mcg subcutaneously once daily

NOTE: Parathyroid hormone analogs have a lifetime cumulative treatment duration of 2 years

Authorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required
2. Does the member have a documented diagnosis of osteoporosis as indicated by one or more of the following? (Provide supporting documentation including DXA report within 2 years)
   - Hip DXA (femoral neck or total hip) or lumbar spine T-score less than or equal to -2.5 and/or forearm DXA 33% (one-third) radius
   - T-score less than or equal to -1 or low bone mass AND a history of fragility fracture to the hip or spine

Last Reviewed: 11/7/18, 5/20/20, 5/18/22, 7/21/23, 7/19/24, 9/19/25
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- T-score between -1 and -2.5 with a FRAX 10-year probability for major fracture ≥20% or hip fracture ≥3%

a. If yes, continue to #3
b. If no, clinical review required

3. Does the member have a very high risk for fracture as defined by one or more of the following? (Provide supporting documentation)

- Multiple fragility fractures as an adult
- T score ≤ 2.0 plus a fragility fracture
- T-score ≤ 3.0 in the absence of fractures
- Fractures sustained while on approved osteoporosis therapy
- Fractures while on medications causing skeletal harm (i.e. long-term glucocorticoids)
- High risk for falls or history of injurious falls and very high fracture probability with a FRAX Score > 30% for major osteoporosis fracture or hip fracture > 4.5%

a. If yes, continue to #10
a. If no, continue to #4

4. Does the member have a high risk for fracture as defined by one or more of the following? (Provide supporting documentation)

- History of an osteoporotic fracture as an adult
- Parental history of hip fracture
- Low BMI
- Rheumatoid arthritis
- Alcohol intake of 3 or more drinks per day
- Current smoking
- History of oral glucocorticoids ≥ 5 mg/day of prednisone (or equivalent) for > 3 months in lifetime
- Early menopause

a. If yes, continue to #5
b. If no, clinical review required

5. Does the member have five years of continuous treatment with bisphosphonates? (Provide all prior treatment history)

a. If yes, continue to #9
b. If no, continue to #6

6. Does the member have a trial with insufficient response to at least 12 months of bisphosphonate therapy (oral or IV) as defined by a decrease in T-score from baseline or member had a fracture while on bisphosphonate therapy? (Provide past relevant medication list with documentation of response to therapy)

a. If yes, continue to #9
b. If no, continue to #7

7. Does the member have a contradiction or intolerance to oral bisphosphonates? (Provide supporting documentation)

a. If yes, continue to #7

b. If no, clinical review required

8. Does the member have a contraindication or intolerance to IV bisphosphonates? (Provide supporting documentation)
    a. If yes, continue to #9
    b. If no, clinical review required
9. Does the member have documentation of a trial with insufficient response, an intolerance, or a contraindication to a preferred denosumab agent as defined by a decrease in T-score from baseline or member had a fracture while on denosumab therapy? (Provide past relevant medication list with documentation of response to therapy)
    a. If yes, continue to #10
    b. If no, clinical review required
10. Is the request for teriparatide?
    a. If yes, continue to #12
    b. If no, continue to #11
11. Does the member have documentation of a trial with insufficient response, an intolerance, or a contraindication to teriparatide as defined by a decrease in T-score from baseline or member had a fracture while on teriparatide therapy? (Provide past relevant medication list with documentation of response to therapy)
    a. If yes, continue to #12
    b. If no, clinical review required
12. Is the member currently supplementing with at least 1,000 mg of calcium and 400 IU of vitamin D daily that will be continued throughout therapy? (Provide list of current relevant medications)
    a. If yes, continue to #13
    b. If no, clinical review required
13. Is the member's serum calcium within normal range? (Provide serum calcium level for review)
    a. If yes, continue to #14
    b. If no, clinical review required
14. Does the member have increased risk of osteosarcoma? (i.e. Paget's disease of bone, unexplained elevations of alkaline phosphatase, open epiphyses, bone metastases or skeletal malignancies, hereditary disorders predisposing to osteosarcoma, or prior external beam or implant radiation therapy involving the skeleton)
    a. If yes, clinical review required
    b. If no, continue to #15
15. Will the requested parathyroid hormone analog be used concurrently with denosumab, bisphosphonates, or another PTH analog?
    a. If yes, clinical review required
    b. If no, continue to #16
16. Is the treatment being prescribed by or in consultation with an endocrinologist or a rheumatologist?
    a. If yes, approve for 2 years or unless otherwise specified (lifetime therapy limit of 24 months)
    b. If no, clinical review required

Last Reviewed: 11/7/18, 5/20/20, 5/18/22, 7/21/23, 7/19/24, 9/19/25
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Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Forteo [package insert]. Indianapolis, IN; Eli Lilly and Company; June 2025.
2. Tymlos [package insert]. Waltham, MA; Radius Health; April 2025.
3. Bonsity [package insert]. Morristown, NJ: Alvogen, Inc.; June 2025.
4. Camacho PM, Petak SM, Binkley N, et al. AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS AND AMERICAN COLLEGE OF ENDOCRINOLOGY CLINICAL PRACTICE GUIDELINES FOR THE DIAGNOSIS AND TREATMENT OF POSTMENOPAUSAL OSTEOPOROSIS - 2016. Endocr Pract. 2016 Sep 2; 22(Suppl 4):1-42.
5. Qaseem A, Hicks LA, Etxeandia-Ikobaltzeta I, et al. Pharmacologic Treatment of Primary Osteoporosis or Low Bone Mass to Prevent Fractures in Adults: A Living Clinical Guideline From the American College of Physicians. *Ann Intern Med*. 2023;176(2):224-238.
6. Jeremiah MP, Unwin BK, Greenawald MH, et al. Diagnosis and Management of Osteoporosis. Am Fam Physician. 2015 Aug 15;92(4):261-8.
7. Camacho, Pauline M., et al. "American Association of Clinical Endocrinologists/American College of Endocrinology clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis—2020 update." Endocrine Practice 26 (2020): 1-46.
8. Humphrey MB, Russell L, Danila MI, et al. 2022 American College of Rheumatology Guideline for the Prevention and Treatment of Glucocorticoid-Induced Osteoporosis. *Arthritis Rheumatol*. 2023;75(12):2088-2102.

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Paroxysmal Nocturnal Hemoglobinuria (PNH) Agents
Prior Authorization Guidelines

Affected Medication(s)

- Empaveli (pegcetacoplan) subcuataneous solution
- Fabhalta (iptacopan) oral capsule
- Voydeya (danicopan) oral tablet

FDA Approved Indication(s)

- Empaveli: Treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH)
- Fabhalta: Treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH) and reduction of proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression
- Voydeya: Treatment of extravascular hemolysis (EVH) in adults with paroxysmal nocturnal hemoglobinuria (PNH) as add-on therapy to ravulizumab (Ultomiris) or eculizumab (Soliris)

Dosing

- Empaveli: 1,080 mg subcutaneously twice weekly administered via an infusion pump or Empaveli on-body injector
- Fabhalta: 200 mg by mouth twice daily
- Voydeya: 150 mg by mouth three times daily

Initial Authorization Criteria

1. Is the request for continuation of therapy with the same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member 18 years of age or older? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. What is the requested indication?
    a. Paroxysmal nocturnal hemoglobinuria (PNH), continue to #5
    b. Primary immunoglobulin A nephropathy (IgAN), continue to #13
5. Does the member have a documented diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) as confirmed by detection of PNH clones of at least 10% by flow cytometry and the presence of at least 2 different glycosylphosphatidylinositol protein deficiencies within at least 2 different cell lines? (Provide supporting documentation of diagnosis)
    a. If yes, continue to #6
    b. If no, clinical review required

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Effective Date: 6/15/24, 2/1/25

6. Does the member have a laboratory evidence of significant intravascular hemolysis (i.e., LDH ≥ 1.5x upper limit of normal) with symptomatic disease and at least one other indication for therapy regardless of transfusion dependence? (Provide supporting documentation of diagnosis)

    - Patient has symptomatic anemia (i.e., hemoglobin < 7 g/dL or hemoglobin < 10 g/dL, in at least two independent measurements in a patient with cardiac symptoms)
    - Presence of a thrombotic event related to PNH
    - Presence of organ damage due to chronic hemolysis (i.e. renal insufficiency, pulmonary insufficiency/hypertension)
    - Patient is pregnant and potential benefit outweighs potential fetal risk
    - Patient has disabling fatigue
    - Patient has abdominal pain requiring admission or opioid analgesia, dysphagia, or erectile dysfunction

    a. If yes, continue to #7
    b. If no, clinical review required

7. Has the member previously trialed Soliris or Ultomiris for at least 12 weeks with inadequate response, intolerance, or contraindication? (Provide supporting documentation)

    a. If yes, continue to #8
    b. If no, clinical review required

8. What is the requested medication?

    a. Fabhalta, continue to #9
    b. Voydeya, continue to #10
    c. Empaveli, continue to #11

9. Has the member previously trialed Empaveli for at least 12 weeks with inadequate response, intolerance, or contraindication? (Provide supporting documentation)

    a. If yes, continue to #11
    b. If no, clinical review required

10. Will Voydeya be used in combination with Ultomiris or Soliris? (Provide treatment plan for review)

    a. If yes, continue to #12
    b. If no, clinical review required

11. Will the requested medication to be used with other complement inhibitor therapy?

    a. If yes, clinical review required
    b. If no, continue to #12

12. Is the medication being prescribed by, or in consult with, a hematologist?

    a. If yes, approve for 6 months
    b. If no, clinical review required

13. Does the member have documentation of primary immunoglobulin A nephropathy as proven by biopsy? (Provide supporting documentation)

    a. If yes, continue to #14
    b. If no, clinical review required

14. Does the member have documentation of estimated glomerular filtration rate (eGFR) of 20 mL/min/1.73m^2 or greater? (Provide supporting documentation)

    a. If yes, continue to #15
    b. If no, clinical review required

15. Did the member have an inadequate response to a 12 week trial of the following classes of medications at maximally indicated doses unless intolerance or contraindication is present to all three classes? (Provide supporting documentation)

    - ACE-inhibitor (i.e. lisinopril, benazepril, enalapril) or ARB (i.e. irbesartan, losartan); AND
    - Sodium-glucose cotransporter-2 inhibitor (SGLT-2)

    a. If yes, continue to #16
    b. If no, clinical review required

16. Does the member have a previous trial with inadequate response, intolerance or contraindication to Filspari (sparsentan)?

    a. If yes, continue to #17
    b. If no, clinical review required

17. Will Fabhalta (iptacopan) be used concurrently with Filspari (sparsentan)?

    a. If yes, clinical review required
    b. If no, continue to #18

18. Is Fabhalta (iptacopan) prescribed by, or in consult with, a nephrologist?

    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide supporting documentation)

    a. If yes, continue to #2
    b. If no, clinical review required

2. What is the requested indication?

    a. Paroxysmal nocturnal hemoglobinuria (PNH), continue to #3
    b. Primary immunoglobulin A nephropathy (IgAN), continue to #8

3. Has the member developed a severe bone marrow failure syndrome, experienced spontaneous disease remission, or received a curative allogeneic stem cell transplant?

    a. If yes, clinical review required
    b. If no, continue to #4

4. Were updated chart notes (within past year) provided with documentation of significant clinical response to therapy received? (ex. decrease in serum LDH from baseline, stabilization or improvement in hemoglobin from baseline, decrease in transfusion requirement for baseline, reduction in thromboembolic events) (Provide supporting documentation)

    a. If yes, continue to #5

b. If no, clinical review required

5. Is the request for Voydeya?
    a. If yes, continue to #7
    b. If no, continue to #6
6. Will the requested medication to be used with other complement inhibitor therapy?
    a. If yes, clinical review required
    b. If no, continue to #7
7. Is the medication being prescribed by, or in consult with, a hematologist?
    a. If yes, approve for 12 months
    b. If no, clinical review required
8. Were updated chart notes provided with documentation of significant clinical response (ex. reduction in proteinuria, improved or stable kidney function compared to baseline) to therapy received? (Provide supporting documentation)
    a. If yes, continue to #9
    b. If no, clinical review required
9. Is the medication being prescribed by, or in consult with, a nephrologist?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. FABHALTA® (iptacopan) capsules, [package insert]. East Hanover, NJ: Novartis Pharmaceuticals; 2024.
2. EMPAVELI (pegcetacoplan) injection solution [package insert]. Waltham, MA: Apellis Pharmaceuticals Inc; February 2024.
3. VOYDEYA (danicopan) tablets [package insert]. Boston, MA: Alexion Pharmaceuticals; April 2024.
4. Drugs@FDA: FDA Approved Drug Products. 2022. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 17 Jan. 2024].
5. Sahin F, Akay OM, Ayer M, et al. Pesg PNH diagnosis, follow-up and treatment guidelines. Am J Blood Res. 2016;6(2):19-27. Published 2016 Aug 5.
6. Peffault de Latour R, Roeth A, Kulasekararaj A, et al. Oral Monotherapy with Iptacopan, a Proximal Complement Inhibitor of Factor B, Has Superior Efficacy to Intravenous Terminal Complement Inhibition with Standard of Care Eculizumab or Ravulizumab and Favorable Safety in Patients with Paroxysmal Nocturnal Hemoglobinuria and Residual Anemia: Results from the Randomized, Active-Comparator-Controlled, Open-Label, Multicenter, Phase III Apply-PNH Study. Blood. 2022;140(Supplement 2):LBA-2-LBA-2.
7. Stevens, Paul E., et al. "KDIGO 2024 clinical practice guideline for the evaluation and management of chronic kidney disease." Kidney international 105.4 (2024): S117-S314.

Last Reviewed: 5/17/24, 1/17/25
Effective Date: 6/15/24, 2/1/25

Penicillamine
Prior Authorization Guidelines

Affected Medication(s)

- Cuprimine (penicillamine) oral capsule
- Depen (penicillamine) oral titratable tablet
- penicillamine oral capsule/tablet

FDA Approved Indication(s)

- Indicated in the treatment of Wilson's disease, cystinuria, and in patients with severe, active rheumatoid arthritis who have failed to respond to an adequate trial of conventional therapy

Dosing

- See package insert for detail dosing information

Initial Authorization Criteria

1. Is the treatment being prescribed by, or in consultation with an appropriate specialist (Examples: GI specialist, hepatologist, or nephrologist)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for continuation of penicillamine therapy for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
3. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #4
    b. If no, clinical review required
4. What is the requested drug being used to treat? (Provide documentation of diagnosis)
    a. Wilson's disease, continue to #5
    b. Cystinuria, continue to #7
    c. Other indication, clinical review required
5. Is the request for penicillamine (Cuprimine) capsules?
    a. If yes, continue to #6
    b. If no, approve for 6 months unless otherwise specified
6. Has the member had a trial with insufficient response, intolerance, or contraindication to penicillamine (Depen) tablets? (Provide supporting documentation)
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

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7. Has the member had a trial with insufficient response or is resistant to conservative therapy such as increased fluid intake, sodium and protein restrictions? (Provide supporting documentation)
    a. If yes, continue to #8
    b. If no, clinical review required
8. Has the member had a trial with insufficient response, intolerance, or contraindication to potassium citrate or potassium bicarbonate AND tiopronin? (Provide supporting documentation)
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Has the member had a positive clinical response to therapy? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the request for continuation of penicillamine therapy for the treatment of Wilson's disease or cystinuria?
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Cuprimine (penicillamine) [Prescribing Information]. Bridgewater, NJ: Bausch Health US, LLC. November 2019.
2. Schilsky ML, Roberts EA, Bronstein JM, et al. A multidisciplinary approach to the diagnosis and management of Wilson disease: 2022 Practice Guidance on Wilson disease from the American Association for the Study of Liver Diseases. *Hepatology*. Published online December 7, 2022.
3. Pearle MS, Goldfarb DS, Assimos DG et al: Medical management of kidney stones: AUA Guideline. J Urol 2014; 192: 316.

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Effective Date: 1/15/21, 5/1/22, 6/15/24, 6/1/25

Phenoxybenzamine
Prior Authorization Guidelines

Affected Medication(s)

- Dibenzyline (phenoxybenzamine) oral capsule
- phenoxybenzamine oral capsule

FDA Approved Indication(s)

- Treatment of sweating and hypertension associated with pheochromocytoma

Dosing

- 20-40 mg orally two to three times daily

Initial Authorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member have confirmed pheochromocytoma by imaging? (Provide supporting documentation for review)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is phenoxybenzamine being requested as preoperative management? (Provide treatment plan/duration and planned surgical date)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is documentation with rationale to avoid other alpha-blockers received? (i.e. prazosin, terazosin, doxazosin)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is the treatment being prescribed by or in consultation with an endocrinologist?
    a. If yes, approve for 1 month unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Dibenzyline [package insert]. Bannockburn, IL: Advanz Pharma; December 2024.

Last Reviewed: 11/20/19, 5/19/21, 5/18/22, 5/19/23, 5/17/24, 5/16/25
Effective Date: 2/1/20, 6/15/21, 6/15/24, 6/1/25

2. Lenders JWM, Duh QY, Eisenhofer G, et al. Phenochromocytoma and paraganglioma: an endocrine society clinical practice guideline. The Journal of Clinical Endocrinology & Metabolism. 2014;6:1915-1942. Available at: https://doi.org/10.1210/jc.2014-1498.
3. Fassnacht, M., et al. "Adrenocortical carcinomas and malignant phaeochromocytomas: ESMO–EURACAN Clinical Practice Guidelines for diagnosis, treatment and follow-up." Annals of Oncology 31.11 (2020): 1476-1490.

Last Reviewed: 11/20/19, 5/19/21, 5/18/22, 5/19/23, 5/17/24, 5/16/25
Effective Date: 2/1/20, 6/15/21, 6/14/24, 6/1/25

Phenylketonuria Agents
Prior Authorization Guidelines

Affected Medication(s)

- Javygtor (sapropterin) powder for oral solution
- Javygtor (sapropterin) oral tablet
- Kuvan (sapropterin) powder for oral solution
- Kuvan (sapropterin) oral tablet
- Palynziq (pegvaliase-pqpz) subcutaneous syringe
- Sapropterin powder for oral solution
- Sapropterin oral tablet
- Sephience (sepiapterin) oral powder
- Zelvysia (sapropterin) powder for oral solution

FDA Approved Indication(s)

Palynziq

- To reduce blood phenylalanine concentrations in adult patients with phenylketonuria who have uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management

Sapropterin (Javygtor, Kuvan, Zelvysia):

- To reduce blood phenylalanine (Phe) levels in adult and pediatric patients 1 month of age or older with hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4) responsive phenylketonuria (PKU) in conjunction with a PHE-restricted diet

Sephience

- Treatment of hyperphenylalaninemia (HPA) in adult and pediatric patients 1 month of age and older with sepiapterin-responsive phenylketonuria (PKU) in conjunction with a phenylalanine restricted diet

Dosing

- See corresponding package insert for dosing

Initial Authorization Criteria

1. Is the request continuation of therapy with the same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member have a blood phenylalanine concentration of 360 micromol/L or greater? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required

Last Reviewed: 11/21/25
Effective Date: 1/1/26

4. Has the member had a trial with inadequate response to a phenylalanine-restricted diet and does the treatment plan include continuation of a phenylalanine-restricted diet in combination with the requested treatment? (i.e. foods with high protein such as meat, fish, eggs, and milk products should be avoided) (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is the request for sapropterin?
    a. If yes, continue to #10
    b. If no, continue to #6
6. Has the member had a previous trial of at least 8 weeks with inadequate response (defined as continued elevated blood phenylalanine concentration), intolerance, or contraindication to treatment with sapropterin? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Is the member 18 years of age or older and have a blood phenylalanine concentration of 600 micromol/L or greater?
    a. If yes, continue to #8
    b. If no, continue to #10
8. Is the request for Palynziq?
    a. If yes, continue to #10
    b. If no, continue to #9
9. Has the member had a previous trial of at least 16 weeks of Palynziq (pegvaliase-pqpz) 60 mg dose with inadequate response (defined as continued increased blood phenylalanine concentration), intolerance, or contraindication to treatment? (Provide supporting documentation)
    a. If yes, continue to #10
    b. If no, clinical review required
10. Does the treatment plan include monitoring blood phenylalanine concentration during initiation of treatment to confirm response and periodically thereafter? (Provide supporting documentation)
    a. If yes, continue to #11
    b. If no, clinical review required
11. Is the treatment being prescribed by or in consultation with a specialist experienced in treatment of hyperphenylalaninemia?
    a. If yes, approve for 4 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication Food and Drug Administration (FDA) approved or supported by major compendia? (Provide supporting documentation)
    a. If yes, continue to #2

b. If no, clinical review required

2. Were updated chart notes from after starting treatment and within 1 year provided with documentation of significant clinical response to therapy defined as a reduction in the blood phenylalanine level of at least 20% from pretreatment baseline? (Provide supporting documentation)

   a. If yes, continue to #3
   b. If no, clinical review required

3. Does the treatment plan include continuation of a phenylalanine-restricted diet in combination with the requested medication? (i.e. foods with high protein such as meat, fish, eggs, and milk products should be avoided) (Provide supporting documentation)

   a. If yes, continue to #4
   b. If no, clinical review required

4. Is the treatment being prescribed by or in consultation with a specialist experienced in treatment of hyperphenylalaninemia?

   a. If yes, approve for 12 months unless otherwise specified
   b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Palynziq (pegvaliase-pqpz) Injection [package insert]. Novato, CA: BioMarin Pharma, Inc; December 2022.
2. Kuvan (sapropterin dihydrochloride) [Prescribing Information]. Novato, CA: BioMarin Pharmaceutical, Inc. August 2024.
3. Sephience (sepiapterin) oral powder, [package insert]. Warren, NJ: PTC Therapeutics Inc.; 2025.
4. Drugs@FDA: FDA Approved Drug Products. 2018. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 17 Sep. 2018].
5. Van Wegberg, A. M. J., et al. "The complete European guidelines on phenylketonuria: diagnosis and treatment." Orphanet journal of rare diseases 12.1 (2017): 162.
6. Smith WE, Berry SA, Bloom K, et al. Phenylalanine hydroxylase deficiency diagnosis and management: A 2023 evidence-based clinical guideline of the American College of Medical Genetics and Genomics (ACMG). Genet Med. 2025;27(1):101289.

Prevymis® (letermovir)
Prior Authorization Guidelines

Affected Medication(s)

- Prevymis oral tablet
- Prevymis oral pellets

FDA Approved Indication(s)

- Prophylaxis of cytomegalovirus (CMV) infection and disease in adult and pediatric patients 6 months of age and older weighing at least 6 kg who are CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT)
- Prophylaxis of CMV disease in adult and pediatric patients 12 years of age and older weighing at least 40 kg who are kidney transplant recipients at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-])

Dosing

- See package insert for specific dosing recommendations
- HSCT: Once daily through day 100 post-transplantation. May be continued through day 200 for patients at risk for late CMV infection and disease
- Kidney Transplant: Once daily through day 200 post-transplantation

Authorization Criteria

1. Is the request for continuation of Prevymis (letermovir) therapy for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA-approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Has the current medication list been reviewed by the care team confirming no major drug interaction with Prevymis? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the treatment being prescribed by or in consultation with a hematologist/oncologist, transplant specialist, or infectious disease specialist?
    a. If yes, continue to #5
    b. If no, clinical review required
5. What indication is Prevymis (letermovir) being requested for?
    a. Prophylaxis of CMV in allogeneic HSCT recipients, continue to #6

Last Reviewed: 10/3/18, 7/21/21, 11/16/22, 9/15/2023, 9/20/24, 3/21/25
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b. Prophylaxis of CMV in adult kidney transplant recipients, continue to #8

6. Is Prevymis (letermovir) being initiated within 100 days of transplant? (Provide documentation of transplant date)

   a. If yes, continue to #7
   b. If no, clinical review required

7. Does the member meet one of the following criteria? (Provide documentation of CMV status for recipient or donor if applicable)

   - CMV-seropositive recipient OR
   - CMV seronegative recipient receiving a graft from seropositive donor (CMV D+/R-) who received a T cell-depleted allograft, an HLA-1 mismatched allograft, an umbilical cord blood allograft, or alemtuzumab

   a. If yes, approve for 4 months or up to 100 days from date of transplant
   b. If no, clinical review required

8. Has documentation with rationale for avoidance or contraindication to both ganciclovir and valganciclovir been received? (Provide supporting documentation)

   a. If yes, continue to #9
   b. If no, clinical review required

9. Is Prevymis (letermovir) being initiated within 200 days of transplant? (Provide documentation of transplant date)

   a. If yes, continue to #10
   b. If no, clinical review required

10. Is the member CMV-seronegative and received a transplant from a CMV-positive donor?

    a. If yes, approve for 7 months or up to 200 days from date of transplant
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide supporting documentation)

   a. If yes, continue to #2
   b. If no, clinical review required

2. Is the request for extending Prevymis prophylaxis through 200 days post-HSCT in patients at risk for late CMV infection and disease?

   a. If yes, continue to #3
   b. If no, clinical review required

3. Does the member have at least one of the following risk factors for late CMV infection and disease? (Provide supporting documentation)

   - HLA-related (sibling) donor with at least one mismatch at one of the following three HLA-gene loci: HLA-A, -B, or -DR
   - Haploidentical donor

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Effective Date: 1/1/19, 9/1/21, 11/20/23, 10/15/24, 4/1/25

- Unrelated donor with at least one mismatch at one of the following three HLA-gene loci: HLA-A, -B, or -DR
- Use of umbilical cord blood as stem cell source
- Use of ex vivo T-cell depleted grafts
- Receipt of anti-thymocyte globulin
- Receipt of alemtuzumab
- Use of systemic prednisone (or equivalent) at a dose of at least 1 mg/kg of bodyweight per day

a. If yes, continue to #4
b. If no, clinical review required

4. Is the treatment being prescribed by or in consultation with a hematologist/oncologist, transplant specialist, or infectious disease specialist?

a. If yes, approve for 4 months or up to 200 days post-transplant date
b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Letermovir (Prevymis) [package insert]. Rahway, NJ: Merck & Co., Inc.; December 2024.
2. Wingard JR, Marr KA, Thorner AR. Prevention of viral infections in hematopoietic cell transplant recipients. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed January 24, 2025.
3. Clinical Practice Guidelines in Oncology (NCCN Guidelines): Prevention and Treatment of Cancer-Related Infections Version 3.2024 National Comprehensive Cancer Network website. Available from https://www.nccn.org/professionals/physician_gls/pdf/infections.pdf. Accessed January 24, 2025

Last Reviewed: 10/3/18, 7/21/21, 11/16/22, 9/15/2023, 9/20/24, 3/21/25
Effective Date: 1/1/19, 9/1/21, 11/20/23, 10/15/24, 4/1/25

Primary Biliary Cholangitis
Prior Authorization Guidelines

Affected Medication(s)

- Iqirvo (elafibranor) oral tablet
- Livdelzi (seladelpar) oral capsule

FDA Approved Indication(s)

- For the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA/ursodiol) in adults with an inadequate response to UDCA/ursodiol, or as monotherapy in adults unable to tolerate UDCA

Dosing

- Iqirvo: 80 mg orally once daily
- Livdelzi: 10 mg orally once daily

Initial Authorization Criteria

1. Is the request for continuation of the same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member 18 years of age or older?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have a trial with insufficient response defined as greater than ALP 1.67x ULN or total bilirubin greater than 1x ULN but less than 2x ULN with at least 12 months of ursodiol at a dose of $\geq$ 13 mg/kg/day? (Provide relevant medication history and response to therapy)
    a. If yes, continue to #6
    b. If no, continue to #5
5. Does the member have an intolerance or contraindication to ursodiol? (Provide supporting documentation of intolerance or contraindication)
    a. If yes, continue to #7
    b. If no, clinical review required
6. Will the member continue therapy with ursodiol concurrently with the requested medication? (Provide treatment plan)
    a. If yes, continue to #7
    b. If no, clinical review required

Last Reviewed: 11/7/18, 1/20/21, 11/16/22, 11/17/23, 9/20/24, 11/15/24, 11/12/25
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7. Is the treatment being prescribed by, or in consultation with, a hepatologist or gastrointestinal (GI) specialist?
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the member 18 years of age or older?
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member having a positive clinical response to therapy as defined by a maintained reduction in alkaline phosphate (ALP) level from pretreatment level? (Provide updated ALP levels for review)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the treatment being prescribed by, or in consultation with, a hepatologist or gastrointestinal (GI) specialist?
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. IQIRVO (elafibranor) oral tablets [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc; 2024.
2. LIVDELZI (seladelpar) oral capsules [package insert]. Foster City, CA: Gilead Sciences, Inc; 2024.
3. Lindor KD, Bowlus CL, Boyer J, Levy C, Mayo M. Primary Biliary Cholangitis: 2018 Practice Guidance from the American Association for the Study of Liver Diseases. Hepatology. 2019 Jan;69(1):394-419.
4. Lindor KD, Bowlus CL, Boyer J, Levy C, Mayo M. Primary biliary cholangitis: 2021 practice guidance update from the American Association for the Study of Liver Diseases. Hepatology. 2022 Apr;75(4):1012-1013.

Last Reviewed: 11/7/18, 1/20/21, 11/16/22, 11/17/23, 9/20/24, 11/15/24, 11/12/25
Effective Date: 1/1/19, 10/15/24, 1/1/25, 1/1/26

Pulmozyme® (dornase alfa), Bronchitol® (mannitol)
Prior Authorization Guidelines

Affected Medication(s)

- Pulmozyme (dornase alfa) inhalation solution
- Bronchitol (mannitol) inhalation powder

FDA Approved Indication(s)

- Pulmozyme: For daily administration in conjunction with standard therapies for the management of cystic fibrosis (CF) patients to improve pulmonary function. In CF patients with an FVC ≥ 40% of predicted, daily administration of Pulmozyme has also been shown to reduce the risk of respiratory tract infections requiring parenteral antibiotics
- Bronchitol: Add-on maintenance therapy to improve pulmonary function in adult patients 18 years and older with Cystic Fibrosis. Note: Use only for adults who have passed the Bronchitol Tolerance Test

Dosing

- Pulmozyme: 2.5 mg inhaled once or twice daily
- Bronchitol: 400mg inhaled twice daily

Initial Authorization Criteria

1. Is the request for continuation of Pulmozyme or Bronchitol therapy for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA-approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member have a confirmed diagnosis of cystic fibrosis? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, continue to #6
4. Is the request for Bronchitol?
    a. If yes, continue to #5
    b. If no, continue to #7
5. Does the member have documentation of a previous trial with Pulmozyme in combination with hypertonic saline?
    a. If yes continue to #7
    b. If no, clinical review required
6. Has the member tried and had an inadequate response OR does the member have a contra indication to ALL standard treatment options for the requested indication? (Provide all prior treatment history, contraindication if appropriate, and treatment plan)
    a. If yes, continue to #7

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Effective Date: 6/15/21, 12/20/23, 10/15/24

b. If no, clinical review required

7. Is the treatment being prescribed by or in consult with a pulmonologist or cystic fibrosis specialist?
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA-approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the treatment being prescribed by or in consultation with a pulmonologist or cystic fibrosis specialist?
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is documentation provided that the member is experiencing successful response to therapy? (Provide updated clinical information for review such as reduction in CF exacerbations compared to baseline, improvement in CF symptoms, reduction in respiratory infections, improvement in FEV1, etc.)
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. BRONCHITOL® (mannitol) inhalation powder, [package insert]. Frenchs Forest NSW: Arna Pharma Pty Ltd; September 2024.
2. PULMOZYME® (dornase alfa) solution, [package insert]. San Francisco, CA: Genentech, Inc; 2020.
3. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 12 Jan. 2021].
4. Flume, Patrick A., et al. "Efficacy and safety of inhaled dry-powder mannitol in adults with cystic fibrosis: An international, randomized controlled study." Journal of Cystic Fibrosis (2021).
5. Bilton D, Robinson P, Cooper P, Gallagher CG, Kolbe J, Fox H, Jaques A, Charlton B; CF301 Study Investigators. Inhaled dry powder mannitol in cystic fibrosis: an efficacy and safety study. Eur Respir J. 2011 Nov;38(5):1071-80. doi: 10.1183/09031936.00187510. Epub 2011 Apr 8. PMID: 21478216.
6. Aitken, Moira L., et al. "Long-term inhaled dry powder mannitol in cystic fibrosis: an international randomized study." American journal of respiratory and critical care medicine 185.6 (2012): 645-652.
7. Bilton, Diana, et al. "Pooled analysis of two large randomised phase III inhaled mannitol studies in cystic fibrosis." Journal of Cystic Fibrosis 12.4 (2013): 367-376.
8. Mogayzel PJ Jr, Naureckas ET, Robinson KA, et al. Cystic fibrosis pulmonary guidelines. Chronic medications for maintenance of lung health. *Am J Respir Crit Care Med*. 2013;187(7):680-689.

Last Reviewed: 5/19/21, 11/16/22, 11/17/23, 9/20/24, 9/19/25
Effective Date: 6/15/21, 12/20/23, 10/15/24

9. Villanueva, Gemma, et al. "Diagnosis and management of cystic fibrosis: summary of NICE guidance." Bmj 359 (2017).

Pyrukynd® (mitapivat)
Prior Authorization Guidelines

Affected Medication(s)

- Pyrukynd (mitapivat) oral tablet

FDA Approved Indication(s)

- Treatment of hemolytic anemia in adults with pyruvate kinase (PK) deficiency

Dosing

- Starting dose of 5mg twice daily; can be titrated up to 50mg by mouth two times daily

Initial Authorization Criteria

1. Is the request for continuation of therapy with the same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is Pyrukynd (mitapivat) being requested for an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the patient 18 years of age or older?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have documentation of pyruvate kinase deficiency confirmed by biochemical (reduced PK activity in RBCs) or genetic testing (identifying a pathogenic PKLR gene mutation)? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have documentation of at least 2 variant alleles in the PKLR gene, of which at least 1 was a missense variant? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Is the member homozygous for the c.1436G>A (p.R479H) variant or have 2 non-missense variants (without the presence of another missense variant) in the PKLR gene? (Provide supporting documentation)
    a. If yes, clinical review required
    b. If no, continue to #7
7. Is the member's hemoglobin 10 g/dL or less? (Provide supporting documentation)
    a. If yes, continue to #8
    b. If no, clinical review required
8. Has the member previously had 6 or more transfusions in the past year or has severe symptomatic anemia? (Provide supporting documentation)

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a. If yes, continue to #9
b. If no, clinical review required

9. Is Pyrukynd (mitapivat) being prescribed by, or in consult with, a hematologist?

    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide supporting documentation)

    a. If yes, continue to #2
    b. If no, clinical review required

2. Were updated chart notes (within past year) provided with documentation of significant clinical response to prior therapy received? (i.e. improvement in hemoglobin by at least 1.5 g/dL from baseline or reduction in RBC transfusions from baseline) (Provide supporting documentation)

    a. If yes, continue to #3
    b. If no, clinical review required

3. Is Pyrukynd (mitapivat) being prescribed by, or in consult with, a hematologist?

    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. PYRUKYND® (mitapivat) tablets, [package insert]. Cambridge, MA: Agios Pharmaceuticals, Inc; 2025.
2. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 29 Mar. 2022].
3. van Beers, Eduard J., et al. "Mitapivat (AG-348) in Adults with Pyruvate Kinase Deficiency Who Are Not Regularly Transfused: A Phase 3, Randomized, Multicenter, Double-Blind, Placebo-Controlled Study (ACTIVATE) in Progress." Blood 134 (2019): 4791.
4. Lynch, Megan, et al. "Mitapivat (AG-348) in adults with Pyruvate Kinase deficiency who are regularly transfused: a phase 3, open-label, multicenter, study (ACTIVATE-T) in progress." Blood 134 (2019): 3526.
5. Al-Samkari H, Shehata N, Lang-Robertson K, et al. Diagnosis and management of pyruvate kinase deficiency: international expert guidelines. Lancet Haematol. 2024;11(3):e228-e239.

Last Reviewed: 5/18/22, 5/19/23, 5/17/24, 5/16/25
Effective Date: 7/15/22, 6/15/24

Recorlev® (levoketoconazole)
Prior Authorization Guidelines

Affected Medication(s)

- Recorlev (levoketoconazole) oral tablet

FDA Approved Indication(s)

- Treatment of endogenous hypercortisolemia in adult patients with Cushing's syndrome for whom surgery is not an option or has not been curative

Dosing

- Initial 150mg orally twice daily, titrated up to a max of 600mg twice daily

Initial Authorization Criteria

1. Is the request for continuation of therapy with the same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is Recorlev (levoketoconazole) being requested for an FDA approved or compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the patient 18 years of age or older?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have documentation of endogenous Cushing's syndrome with a mean Urinary Free Cortisol level (UFC) greater than or equal to 1.5x the upper limit of normal (normal range: 11 to 138 nmol/day or 4 to 50 µg/day)? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Has the member previously undergone pituitary surgery that was not curative or is the member not a candidate for surgery? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Has the member previously trialed a maximum tolerated dose of ketoconazole for at least 8 weeks with treatment failure or is there a documented intolerance or contraindication to ketoconazole? (Provide supporting documentation)
    a. If yes, clinical review required
    b. If no, continue to #7
7. Is Recorlev (levoketoconazole) being prescribed by, or in consult with, an endocrinologist?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Last Reviewed: 5/18/22, 5/19/23, 5/17/24, 5/16/25
Effective Date: 7/15/22, 6/15/24

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (within past year) provided with documentation of significant clinical response to prior therapy received? (i.e. decrease in mUFC from baseline that is maintained within normal range) (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is Recorlev (levoketoconazole) being prescribed by, or in consult with, an endocrinologist?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. RECORLEV (levoketoconazole) tablets, [package insert]. Chicago, IL: Xeris Pharmaceuticals, Inc; 2024.
2. DailyMed – Recorlev- levoketoconazole tablet. 2022. U.S. National Library of Medicine. National Institutes of Health. [online]
3. Lynnette K. Nieman, Beverly M. K. Biller, James W. Findling, M. Hassan Murad, John Newell-Price, Martin O. Savage, Antoine Tabarin, Treatment of Cushing's Syndrome: An Endocrine Society Clinical Practice Guideline, The Journal of Clinical Endocrinology & Metabolism, Volume 100, Issue 8, 1 August 2015, Pages 2807–2831, https://doi.org/10.1210/jc.2015-1818
4. Fleseriu, Maria, et al. "Consensus on diagnosis and management of Cushing's disease: a guideline update." The Lancet Diabetes & Endocrinology 9.12 (2021): 847-875.
5. Fleseriu, Maria, et al. "Efficacy and safety of levoketoconazole in the treatment of endogenous Cushing's syndrome (SONICS): a phase 3, multicentre, open-label, single-arm trial." The Lancet Diabetes & Endocrinology 7.11 (2019): 855-865.
6. Zacharieva, Sabina Z., et al. "MON-332 Safety and Efficacy of Levoketoconazole in the Treatment of Endogenous Cushing's Syndrome (LOGICS): A Double-Blind, Placebo-Controlled, Withdrawal Study." Journal of the Endocrine Society 4. Supplement 1 (2020): MON-332.

Last Reviewed: 5/18/22, 5/19/23, 5/17/24, 5/16/25
Effective Date: 7/15/22, 6/15/24

Relistor® (methylnaltrexone bromide)
Prior Authorization Guidelines

Affected Medication(s)

- Relistor (methylnaltrexone) oral tablet
- Relistor (methylnaltrexone) subcutaneous solution

FDA Approved Indication(s)

- For the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation
  - Relistor oral tablet and subcutaneous solution
- For the treatment of OIC in adult patients with advanced illness or pain caused by active cancer who require opioid dosage escalation for palliative care
  - Relistor subcutaneous solution

Dosing

- Refer to appropriate package insert for dosing recommendations

Initial Authorization Criteria

1. Is the request for continuation of therapy with the same opioid-induced constipation agent?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
   a. If yes, continue to #3
   b. If no, clinical review required
3. Does the member have a clinical diagnosis of opioid-induced constipation (OIC) as defined as the following? (Provide supporting documentation)
   - Loose stools are rarely present without the use of laxatives AND
   - More than 25% of spontaneous bowel movements (SBM) associated with two or more of the following:
     - less than 3 SBM per week
     - straining
     - hard or lumpy stools
     - sensation of incomplete evacuation or anorectal obstruction/blockage
     - manual maneuvers to facilitate defecation

   a. If yes, continue to #4
   b. If no, clinical review required
4. Has the member been taking opioids for at least 4 weeks duration? (Provide supporting documentation)
   a. If yes, continue to #5
   b. If no, clinical review required

Last Reviewed: 12/19/18, 7/17/19, 5/19/21, 3/17/23, 3/15/24, 3/21/25
Effective Date: 1/1/19, 9/1/19, 6/15/21, 6/1/23, 4/15/24, 4/1/25

5. Is the member taking opioids for non-cancer pain or pain associated with a prior cancer?
    a. If yes, continue to #7
    b. If no and request is for subcutaneous solution, continue to #6
    c. If no and request is for oral tablet, clinical review required
6. Is the member taking opioids due to advanced illness or pain caused by cancer and requires opioid dose escalation for palliative care? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Has the member tried laxatives (e.g. psyllium, methylcellulose) **AND** at least one of the following categories for a minimum of 2 weeks (administered on a regular schedule, not PRN) and had inadequate response? (Provide documentation of medications trialed with response)
        - Stool softener (e.g. docusate)
        - Osmotic laxative (e.g. polyethylene glycol, lactulose, magnesium citrate)
        - Stimulant laxative (e.g. senna, bisacodyl)
        - Lubricant (e.g. mineral oil)
    a. If yes, continue to #8
    b. If no, clinical review required
8. Will another opioid antagonist be coadministered with the requested medication?
    a. If yes, clinical review required
    b. If no, continue to #9
9. Does the member have known or suspected gastrointestinal obstruction or is at increased risk of recurrent obstruction?
    a. If yes, clinical review required
    b. If no, continue to #10
10. Has the member tried agents, Movantik (naloxegol) or Symproic (naldemedine), with inadequate response or has a contraindication to use of either? (Provide supporting documentation)
    a. If yes, approve for 4 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the member still on chronic opioid therapy that is per the FDA-approved indications? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required

Last Reviewed: 12/19/18, 7/17/19, 5/19/21, 3/17/23, 3/15/24, 3/21/25
Effective Date: 1/1/19, 9/1/19, 6/15/21, 6/1/23, 4/15/24, 4/1/25

3. Has beneficial response to requested medication (i.e. increased number of bowel movements from baseline) been documented by the prescriber? (Provide supporting documentation)
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Relistor (methylnaltrexone) [package insert]. Tarrytown, NY: Progenics Pharmaceuticals, Inc.; May 2024.
2. Camilleri M, Lembo A, Katzka D. Opioids in Gastroenterology: Treating Adverse Effects and Creating Therapeutic Benefits. Clin Gastroenterol Hepatol. 2017;15(9):1338-1349. https://doi.org/10.1016/j.cgh.2017.05.014
3. Davies, Andrew, et al. "MASCC recommendations on the management of constipation in patients with advanced cancer." *Supportive Care in Cancer* 28.1 (2020): 23-33.
4. Crockett SD, Greer KB, Heidelbaugh JJ, et al. American Gastroenterological Association Institute Guideline on the Medical Management of Opioid-Induced Constipation. *Gastroenterology*. 2019;156(1):218-226.

Last Reviewed: 12/19/18, 7/17/19, 5/19/21, 3/17/23, 3/15/24, 3/21/25
Effective Date: 1/1/19, 9/1/19, 6/15/21, 6/1/23, 4/15/24, 4/1/25

Revlimid (lenalidomide)
Prior Authorization Guidelines

Affected Medication(s)

- Revlimid (lenalidomide) capsule
- Lenalidomide capsule

Indication(s)

- Refer to major compendia for supported use

Dosing

- Refer to indication specific compendia supported dosing

Initial Authorization Criteria

1. Is the request for continuation of therapy with the same medication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the medication being requested to be used for an FDA approved indication? (Provide documentation of diagnosis)
    a. If yes, continue to #4
    b. If no, continue to #3
3. Is the medication being requested being used for an indication supported by the National Comprehensive Cancer Network (NCCN) with an evidence level of 2A or higher? (Provide disease staging, all prior treatment history, pathology report, and anticipated treatment plan for review)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the medication being prescribed by or in consultation with an oncologist?
    a. If yes, approve for 4 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication approved by the FDA or supported by the NCCN recommendation with an evidence level of 2A or higher? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is there clinical documentation confirming disease responsiveness to therapy provided? (Examples include reduction in tumor size, objective response, delay in progression, partial response, etc.) (Provide supporting documentation)

Last Reviewed: 9/19/25
Effective Date: 10/31/25

a. If yes, continue to #2
b. If no, clinical review required

3. Is the medication being prescribed by or in consultation with an oncologist?
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Revlimid [package insert]. Summit, NJ: Celgene Corporation; March 2023.
2. National Comprehensive Cancer Network. NCCN – NCCN Guidelines. Available at: https://www.nccn.org.

Last Reviewed: 9/19/25
Effective Date: 10/31/25

Rezdiffra (resmetiron)
Prior Authorization Guidelines

Affected Medication(s)

- Rezdiffra (resmetiron) oral tablet

FDA Approved Indication(s)

- Treatment of adults with noncirrhotic nonalcoholic steatohepatitis (NASH) (also known as metabolic associated steatohepatitis (MASH)) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) in combination with diet and exercise

Dosing

- Less than 100 kg: 80 mg once daily
- Greater than or equal to 100 kg: 100 mg once daily

Initial Authorization Criteria

1. Is the request for continuation of therapy with the same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member 18 years of age or older?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have a diagnosis of noncirrhotic nonalcoholic steatohepatitis (NASH)/metabolic associated steatohepatitis (MASH) with liver fibrosis consistent with stage F2 or F3 as either confirmed by biopsy or noninvasive assessment such as fibrosis-4 index (FIB-4), enhanced liver fibrosis test (ELF), vibration controlled transient elastography (VCTE), or magnetic resonance elastography (MRE)? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Will Rezdiffra be used in combination with health behavior and lifestyle modifications including physical activity goals, nutritional education, and behavior change to support weight loss? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Does the member have hypertension, dyslipidemia, or Type 2 diabetes mellitus? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, continue to #8

Last Reviewed: 7/19/24, 7/18/25
Effective Date: 8/15/24

7. Is there documentation that the member's hypertension, dyslipidemia, and/or Type 2 diabetes mellitus are being actively managed with medications or lifestyle modifications for each of these comorbidities? (Provide supporting documentation)
    a. If yes, continue to #8
    b. If no, clinical review required
8. Is the medication being prescribed by, or in consultation with, a hepatologist or gastroenterologist?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (within past year) provided with documentation of clinical response to therapy received? (i.e. decrease in fibrosis stage, resolution of NASH/MASH, etc.)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is there documentation that the member's comorbidities continue to be actively managed with medications or lifestyle modifications? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the treatment being prescribed by, or in consultation with, a hepatologist or gastroenterologist?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. REZDIFFRA (resmetiron) tablets [package insert]. West Conshohocken, PA: Madrigal Pharmaceuticals Inc; February 2025.
2. Drugs@FDA: FDA Approved Drug Products. 2024. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 1 April 2024].
3. Rinella ME, Neuschwander-Tetri BA, Siddiqui MS, et al. AASLD Practice Guidance on the clinical assessment and management of nonalcoholic fatty liver disease. *Hepatology*. 2023;77(5):1797-1835.
4. Cusi K, Isaacs S, Barb D, et al. American Association of Clinical Endocrinology Clinical Practice Guideline for the Diagnosis and Management of Nonalcoholic Fatty Liver Disease in Primary Care and Endocrinology Clinical

Settings: Co-Sponsored by the American Association for the Study of Liver Diseases (AASLD). *Endocr Pract*. 2022;28(5):528-562.
5. Harrison SA, Bedossa P, Guy CD, et al. A Phase 3, Randomized, Controlled Trial of Resmetirom in NASH with Liver Fibrosis. N Engl J Med. 2024;390(6):497-509.

Rezurock® (belumosudil)
Prior Authorization Guidelines

Affected Medication(s)

- Rezurock oral tablet

FDA Approved Indication(s)

- Adult and pediatric patients 12 years and older with chronic graft-versus-host disease after failure of at least two prior lines of systemic therapy

Dosing

- 200mg orally once daily

Initial Authorization Criteria

1. Has the requested medication previously been approved by OHSU for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member have a diagnosis of chronic graft vs host disease? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the member 12 years of age or older?
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have a documented trial with inadequate response to systemic steroids? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Does the member have documentation of an inadequate response, intolerance, or contraindication to at least TWO of the following: ruxolitinib, tacrolimus, cyclosporine, ibrutinib, imatinib, methotrexate, sirolimus, or mycophenolate mofetil? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Is the medication prescribed by, or in consultation with, a provider specializing in transplant or oncology?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Last Reviewed: 11/17/21, 3/17/23, 1/19/24, 1/17/25
Effective Date: 1/1/22, 3/1/24

Reauthorization Criteria

1. Is the documented indication Food and Drug Administration (FDA) approved or supported by major compendia?
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (within 1 year) with documentation of stability or improvement in chronic graft vs host disease? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the treatment being prescribed by, or in consultation with, a provider specializing in transplant or an oncologist?
    a. If yes, approve for 12 months reauthorization
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. REZUROCK (belumosudil) tablets. Warrendale, PA 15086; Kadmon Pharmaceuticals, LLC. 2024.
2. Drugs@FDA: FDA Approved Drug Products. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 24 August. 2021].
3. Clinical Practice Guidelines in Oncology (NCCN Guidelines): Hematopoietic Cell Transplant. Version 2.2024 National Comprehensive Cancer Network website. Available from https://www.nccn.org/professionals/physician_gls/pdf/hct. Accessed December 30, 2024.
4. Cutler, Corey, et al. "Belumosudil for chronic graft-versus-host disease (cGVHD) after 2 or more prior lines of therapy: the ROCKstar Study." Blood (2021).

Last Reviewed: 11/17/21, 3/17/23, 1/19/24, 1/17/25
Effective Date: 1/1/22, 3/1/24

Rivfloza™ (nedosiran)
Prior Authorization Guidelines

Affected Medication(s)

- Rivfloza (nedosiran) subcutaneous injection

FDA Approved Indication(s)

- To lower urinary oxalate levels in children 9 years of age and older and adults with primary hyperoxaluria type 1 (PH1) and relatively preserved kidney function

Dosing

- Children 9 to 11 years:
  - < 50 kg: 3.3 mg/kg once monthly, not to exceed 128 mg
  - ≥ 50 kg: 160 mg once monthly
- Adults and adolescents 12 years and older:
  - < 50 kg: 128 mg once monthly
  - ≥ 50 kg: 160 mg once monthly

Initial Authorization Criteria

1. Is the request for continuation of therapy with the same medication for the same indication?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
   a. If yes, continue to #3
   b. If no, clinical review required
3. Does the member have a documented diagnosis of primary hyperoxaluria type 1 as confirmed by genetic testing or biopsy? (Provide supporting documentation of diagnosis)
   a. If yes, continue to #4
   b. If no, clinical review required
4. Is the member 9 years of age or older? (Provide supporting documentation)
   a. If yes, continue to #5
   b. If no, clinical review required
5. Has the member had a liver transplant?
   a. If yes, clinical review required
   b. If no, continue to #6
6. Does the patient have documentation of estimated glomerular filtration rate (eGFR) of 30 mL/min/1.73m2 or greater? (Provide supporting documentation)
   a. If yes, continue to #7
   b. If no, clinical review required
7. Is Rivfloza (nedosiran) being prescribed by, or in consult with, a specialist in genetics, nephrology, or urology?
   a. If yes, approve for 6 months

Last Reviewed: 3/15/24, 3/21/25
Effective Date: 4/15/24, 4/1/25

b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (within past year) provided with documentation of significant clinical response to therapy received? (ex. decrease in urinary oxalate excretion from baseline, reduction in spot urinary oxalate:creatinine ratio from baseline, stabilization of GFR)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is Rivfloza (nedosiran) being prescribed by, or in consult with, a specialist in genetics, nephrology, or urology?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. RIVFLOZA (nedosiran) subcutaneous injection, [package insert]. Plainsboro, NJ: Novo Nordisk; 2023.
2. Drugs@FDA: FDA Approved Drug Products. 2024. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 6 Feb. 2024].
3. Groothoff JW, Metry E, Deesker L, et al. Clinical practice recommendations for primary hyperoxaluria: an expert consensus statement from ERKNet and OxalEurope. Nat Rev Nephrol. 2023;19(3):194-211.
4. Baum MA, Langman C, Cochat P, et al. PHYOX2: a pivotal randomized study of nedosiran in primary hyperoxaluria type 1 or 2. Kidney Int. 2023;103(1):207-217.

Last Reviewed: 3/15/24, 3/21/25
Effective Date: 4/15/24, 4/1/25

Rufinamide
Prior Authorization Guidelines

Affected Medication(s)

- Banzel (rufinamide) oral tablet
- Banzel (rufinamide) oral suspension
- rufinamide oral tablet
- rufinamide oral suspension

FDA Approved Indication(s)

- Adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) in adults and pediatric patients 1 year of age and older

Dosing

- Maximum dose of 45 mg/kg per day in two divided doses, not to exceed 3200 mg per day

Initial Authorization Criteria

1. Is the request for continuation of rufinamide (Banzel) therapy?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA-approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member currently taking at least one other antiepileptic drug with inadequate response? (i.e. valproic acid, lamotrigine, topiramate, felbamate, cannabidiol) (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Will the member continue therapy with at least one other antiepileptic drug in combination with rufinamide (Banzel)?
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have familial short QT syndrome?
    a. If yes, clinical review required
    b. If no. continue to #6
6. Is the treatment being prescribed by or in consultation with a neurologist?
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

Last Reviewed: 9/19/2018, 11/20/19, 7/21/21, 11/16/22, 9/15/23, 9/20/24, 9/19/25
Effective Date: 1/1/2019, 9/1/21, 10/15/24

1. Is the request for use to treat an FDA-approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (within 1 year) provided with documentation of significant clinical response to therapy defined as at least 20% reduction in seizure frequency? (Provide documentation of decreased seizure frequency)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the treatment being prescribed by or in consultation with a neurologist?
    a. If yes, approve for 12 months reauthorization unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Banzel (rufinamide) [Prescribing Information]. Woodcliff Lake, NJ: Eisai Inc. December 2021.
2. Banzel. Micromedex. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed June 25, 2018.
3. National Institute for Health and Care Excellence (NICE): Epilepsies: diagnosis and management. National Institute for Health and Care Excellence (NICE). London, United Kingdom. Available at: https://www.nice.org.uk/guidance/cg137/resources/epilepsies-diagnosis-and-management-35109515407813. Accessed June 27, 2018.
4. Biton V, Krauss G, Vasquez-Santana B, et al. A randomized, double-blind, placebo-controlled, parallel-group study of ralfinamide as adjunctive therapy for refractory partial-onset seizures. Epilepsia. 2011 Feb;52(2):234-42. Available at: https://www.ncbi.nlm.nih.gov/pubmed/20887365. Accessed August 6, 2018.
5. Ohtsuka Y, Yoshinaga H, Shirasaka Y, et al. Rufinamide as an adjuctive therapy for Lennox-Gastaut syndrome: a randomized double-blind placebo-controlled trial in Japan. Epilepsy Res. 2014 Nov;108(9):1627-36. Available at: https://www.ncbi.nlm.nih.gov/pubmed/25219353. Accessed August 6, 2018.
6. National Institute of Neurological Disorders and Stroke. Lennox-Gastaut Syndrome Information Page. Available at: https://www.ninds.nih.gov/Disorders/All-Disorders/Lennox-Gastaut-Syndrome-Information-Page.
7. Debopam Samanta, Management of Lennox-Gastaut syndrome beyond childhood: A comprehensive review, Epilepsy & Behavior, Volume 114, Part A, 2021,107612, ISSN 1525-5050, https://doi.org/10.1016/j.yebeh.2020.107612.

Last Reviewed: 9/19/2018, 11/20/19, 7/21/21, 11/16/22, 9/15/23, 9/20/24, 9/19/25
Effective Date: 1/1/2019, 9/1/21, 10/15/24

Samsca® (tolvaptan)
Prior Authorization Guidelines

Affected Medication(s)

- Samsca oral tablet
- tolvaptan oral tablet

FDA Approved Indication(s)

- Treatment of clinically significant hypervolemic and euvolemic hyponatremia (serum sodium <125 mEq/L or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction), including patients with heart failure and Syndrome of Inappropriate Antidiuretic Hormone (SIADH)

Dosing

- Initially: 15mg once daily
- Titrate as needed to a maximum of 60 mg once daily
- Do not administer for more than 30 days to minimize risk of liver injury

Authorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the member 18 years of age or older?
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member have a serum sodium level <125 mEq/L? (Provide serum sodium level for review)
    a. If yes, continue to #5
    b. If no, continue to #4
4. Does the member have symptomatic hyponatremia despite fluid restriction of <1000mL/day? (i.e. lethargy, weakness, irritability) (Provide documentation of fluid restriction)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Are drugs known to potentially cause SIADH being reviewed or discontinued when appropriate? (i.e. chlorpropamide, SSRIs, TCAs, carbamazepine, vincristine, nicotine, NSAIDs, etc.) (Provide documentation of medication reconciliation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Does the member have any of the following contraindications to therapy with Samsca (tolvaptan)?
    - Autosomal Dominant Polycystic Kidney Disease (ADPKD)
    - Urgent Need to Raise Serum Sodium Acutely

Last Reviewed: 11/21/18, 7/15/20, 11/18/20, 1/19/22, 1/20/23, 1/19/24, 1/17/25
Effective Date: 1/1/19, 8/15/20, 3/1/24

- Inability to Sense or Appropriately Respond to Thirst
- Hypovolemic Hyponatremia
- Concomitant Use of Strong CYP 3A Inhibitors
- Anuria

a. If yes, clinical review required
b. If no, continue to #7

7. Is the treatment being prescribed by, or in consultation with, an endocrinologist or nephrologist?

a. If yes, approve for 1 month
b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Samsca (tolvaptan) [package insert]. Rockville, MD: Otsuka America Pharmaceuticals; November 2022.
2. Verbalis JG, Goldsmith SR, Greenberg A, et al. Diagnosis, evaluation, and treatment of hyponatremia: expert panel recommendations. Am J Med. 2013;126(10 Suppl 1):S1-S42.Schrier RW, Gross P, Gheorghiade M, et al. Tolvaptan, a selective oral vasopressin V2-receptor antagonist, for hyponatremia. N Engl J Med 2006;355(20):2099-2112.
3. Verbalis, Joseph G., et al. "Diagnosis, evaluation, and treatment of hyponatremia: expert panel recommendations." The American journal of medicine 126.10 (2013): S1-S42.

Last Reviewed: 11/21/18, 7/15/20, 11/18/20, 1/19/22, 1/20/23, 1/19/24, 1/17/25
Effective Date: 1/1/19, 8/15/20, 3/1/24

Scemblix® (asciminib)
Prior Authorization Guidelines

Affected Medication(s)

- Scemblix oral tablet

FDA Approved Indication(s)

- Treatment of adults with:
  - Newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+CML) in chronic phase (CP)
  - Previously treated Ph+ CML in CP
  - PH+ CML with the T315I mutation

Dosing

- For newly diagnosed or previously treated patients: 80mg by mouth once daily, or 40mg orally twice daily
- For patients with the T315I mutation: 200mg twice daily

Initial Authorization Criteria

1. Is the request for continuation of therapy with Scemblix (asciminib) medication for the same indication?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2
2. Is the medication being requested for an FDA approved indication? (Provide supporting documentation)
   a. If yes, continue to #4
   b. If no, continue to #3
3. Is the medication being requested for an indication supported by the National Comprehensive Cancer Network (NCCN) recommendation with an evidence level of 2A or higher? (Provide disease staging, all prior treatment history, pathology report, and anticipated treatment plan for review)
   a. If yes, continue to #4
   b. If no, clinical review required
4. Does the member have Karnofsky Performance Status greater or equal to 50% OR Eastern Cooperative Oncology Group (ECOG) performance status of 0-2? (Provide supporting documentation)
   a. If yes, continue to #5
   b. If no, clinical review required
5. Does the member have T315I mutation? (Provide supporting documentation)
   a. If yes, continue to #6
   b. If no, continue to #8
6. Has the member previously trialed Iclusig with an inadequate response or clinically significant adverse effect? (Provide supporting documentation)
   a. If yes, continue to #8

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b. If no, continue to #7

7. Does the member have a contraindication to treatment with Iclusig?

   a. If yes, continue to #8
   b. If no, clinical review required

8. Is the medication being prescribed by, or in consultation with, an oncologist or hematologist?

   a. If yes, approve for 4 months
   b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication approved by the FDA or supported by NCCN recommendation with an evidence level of 2A or higher? (Provide supporting documentation)

   a. If yes, continue to #2
   b. If no, clinical review required

2. Is there clinical documentation confirming disease responsiveness to therapy provided? (Example: BCR-ABL1 ≤ 0.1%) (Provide supporting documentation)

   a. If yes, continue to #3
   b. If no, clinical review required

3. Is the medication being prescribed by or in consultation with an oncologist or hematologist?

   a. If yes, approve for 12 months
   a. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. SCEMBLIX (asciminib) tablets, [package insert]. East Hanover, NJ: Novartis Pharmaceuticals; October 2024.
2. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 9 Dec. 2021].
3. Clinical Practice Guidelines in Oncology (NCCN Guidelines): Chronic Myeloid Leukemia. Version 3.2025 National Comprehensive Cancer Network website. Available from https://www.nccn.org/professionals/physician_gls/pdf/cml.pdf Accessed January 24, 2025.

Last Reviewed: 1/19/22, 3/17/23, 3/15/24, 3/21/25
Effective Date: 3/1/22, 4/1/25

Sexual Dysfunction Agents
Prior Authorization Guidelines

Affected Medication(s)

- Addyi (flibanserin) oral tablet
- Avanafil oral tablet
- Caverject (alprostadil) powder for reconstitution and intracavernosal injection
- Cialis (tadalafil) oral tablet
- Tadalafil oral tablet
- Edex (alprostadil) injection
- Vardenafil oral tablet
- Vardenafil orally disintegrating tablet
- Stendra (avanafil) oral tablet
- Viagra (sildenafil) oral tablet
- Sildenafil oral tablet
- Vyleesi (bremelanotide) subcutaneous solution

FDA Approved Indication(s)

- For the treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD), as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is NOT due to a co-existing medical or psychiatric condition, problems within the relationship, or the effects of a medication or other drug substance
  - Addyi, Vyleesi
- For the treatment of erectile dysfunction
  - Avanafil, Caverject, Edex, Cialis, Sildenafil, Stendra, Tadalafil, Vardenafil, Viagra
- Adjunct to other diagnostic tests in the diagnosis of erectile dysfunction (ED)
  - Caverject
- For the treatment of signs and symptoms of benign prostatic hyperplasia (BPH)
  - Cialis, Tadalafil
- Treatment of erectile dysfunction and the signs and symptoms of benign prostatic hyperplasia (ED/BPH)
  - Cialis, Tadalafil

Dosing

- Refer to corresponding package insert for specific dosing recommendations

Initial Authorization Criteria

1. Is the request for continuation of therapy with the same agent used for the same indication?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
   a. If yes, continue to #3
   b. If no, clinical review required

Last Reviewed: 12/19/18, 7/17/19, 3/18/20, 7/21/21, 11/16/22, 11/17/23, 9/20/24, 1/17/25
Effective Date: 1/1/19, 5/1/20, 1/1/23, 12/20/23, 10/15/24, 2/1/25

3. Which diagnosis is the medication being requested for?
    a. Erectile disorder, continue to corresponding criteria
    b. Female sexual interest/arousal disorder, continue to corresponding criteria
    c. As an adjunct to other diagnostic tests for diagnosis of erectile dysfunction, approve for one dose
    d. Benign prostatic hyperplasia, continue to corresponding criteria
    e. Other indication, continue to corresponding criteria

Erectile Disorder

1. Does the member experience one or more of the following symptoms on at least 75% of sexual activity for a duration of 6 months or greater? (Provide supporting documentation)

    - Marked difficulty in obtaining an erection during sexual activity
    - Marked difficulty in maintaining an erection until the completion of sexual activity
    - Marked decrease in erectile rigidity

    a. If yes, continue to #2
    b. If no, clinical review required
2. Do the above symptoms cause the member clinically significant distress? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Have other causes of sexual dysfunction been ruled out such as nonsexual mental disorder, severe relationship distress, other significant stressor, substance/medication side effect, and/or other medical condition (Provide supporting documentation)
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Female Sexual Interest/ Arousal Disorder

1. Does the member demonstrate a lack of, or significantly reduced, sexual interest/arousal as manifested by at least 3 of the following? (Provide supporting documentation)

    - Absent/reduced interest in sexual activity
    - Absent/reduced sexual/erotic thoughts or fantasies
    - No/reduced initiation of sexual activity, and typically unreceptive to a partner's attempts to initiate
    - Absent/reduced sexual excitement/pleasure during sexual activity in almost all or all (approximately 75%–100%) sexual encounters (in identified situational contexts or, if generalized, in all contexts)
    - Absent/reduced sexual interest/arousal in response to any internal or external sexual/erotic cues (e.g., written, verbal, visual)
    - Absent/reduced genital or non-genital sensations during sexual activity in almost all or all (approximately 75%–100%) sexual encounters (in identified situational contexts or, if generalized, in all contexts)

    a. If yes, continue to #2
    b. If no, clinical review required

2. Have the above symptoms persisted for a duration of 6 months or longer? (Provide supporting documentation of symptom duration)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Do the member's sexual symptoms cause the member clinically significant distress? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Have other causes of sexual dysfunction been ruled out such as nonsexual mental disorder, severe relationship distress, other significant stressor, substance/medication side effect, and/or other medical condition? (Provide supporting documentation)
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Benign Prostatic Hyperplasia

1. Does the member have documentation of a trial with inadequate response or intolerance to at least one alpha-adrenergic blocker (tamsulosin, doxazosin, terazosin, alfuzosin) AND one 5-alpha reductase inhibitor (finasteride or dutasteride)? (Provide supporting documentation of trials with inadequate response, intolerances, or contraindications)
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Other Indications

1. Has the member tried and had an inadequate response OR does the member have a contraindication to ALL standard treatment options for the requested indication? (Provide all prior treatment history, contraindication if appropriate, and treatment plan)
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member demonstrate a positive clinical response from therapy as defined by one of the below? (Provide supporting documentation)
    - For erectile disorder: Improvement in obtaining and maintaining an erection
    - For female sexual interest/arousal disorder: Improvement in sexual interest and/or sexual arousal
    - For benign prostatic hyperplasia: Improvement in urinary frequency, urinary urgency, nocturia, and/or incomplete emptying

Last Reviewed: 12/19/18, 7/17/19, 3/18/20, 7/21/21, 11/16/22, 11/17/23, 9/20/24
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- For other indications: Clinical documentation confirming disease responsiveness to therapy provided

a. If yes, approve for 12 months unless otherwise specified
b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Addyi (flibanserin) [Prescribing Information]. Bridgewater, NJ: Sprout Pharmaceuticals, Inc. September 2021.
2. Caverject (alprostadil) [Prescribing Information]. New York, NY: Pharmacia and Upjohn Company LLC. March 2019.
3. Stendra (avanafil) [Prescribing Information]. Cranford, NJ: Mist Pharmaceuticals, LLC. November 2021.
4. Cialis (tadalafil) [Prescribing Information]. Indianapolis, IN CT: Eli Lilly and Company. April 2022.
5. Viagra (sildenafil) [Prescribing Information]. New York, NY: Pfizer Laboratories Div Pfizer Inc. July 2021.
6. Sexual Dysfunctions, Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition. May 2013
7. McVary KT, Roehrborn CG, Avins AL, et al. Update on AUA guideline on the management of benign prostatic hyperplasia. J Urol 2011; 185:1793.
8. Burnett AL, Nehra A, Breau RH et al: Erectile dysfunction: AUA guideline. J Urol 2018; 200: 633.

Last Reviewed: 12/19/18, 7/17/19, 3/18/20, 7/21/21, 11/16/22, 11/17/23, 9/20/24
Effective Date: 1/1/19, 5/1/20, 1/1/23, 12/20/23, 10/15/24, 2/1/25

Signifor® (pasireotide)
Prior Authorization Guidelines

Affected Medication(s)

- Signifor subcutaneous solution

FDA Approved Indication(s)

- For treatment of adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative

Dosing

- 0.3 to 0.9 mg by subcutaneous injection twice a day

Initial Authorization Criteria

1. Is the request for continuation of Signifor (pasireotide) therapy?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Did the member either have pituitary surgery that was not curative or is the member not a candidate for surgery? (Provide supporting documentation confirming persistent hypercortisolism)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the requested medication being prescribed or in consultation with an endocrinologist?
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member demonstrate a positive clinical response to therapy as defined by a reduction in 24-hour urinary free cortisol levels or improvement in signs and symptoms of Cushing's disease? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required

Last Reviewed: 11/7/18, 7/21/21, 11/16/22, 11/17/23, 9/20/24, 9/19/25
Effective Date: 1/1/19, 10/15/24

3. Is the requested medication being prescribed or in consultation with an endocrinologist?
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Signifor [package insert]. Lebanon, NJ: Recordati Rare Diseases Inc.,; April 2025.
2. Biller BMK, Grossman AB, Steward PM, et al. Treatment of adrenocorticotropin-dependent Cushing's syndrome: a consensus statement. J Clin Endocrinol Met. 2008;93(7):2454-2462.
3. Nieman LK, Biller BMK, Findling JW, et al. The diagnosis of Cushing's syndrome: An Endocrine Society Practice Guideline. J Clin Endocrinol Metab. 2008;93(5):1526–1540.
4. Nieman LK, Biller BMK, Findling JW, et al. Treatment of Cushing's syndrome: An Endocrine Society Clinical Practice Guideline. The J Clin Endocrinol Metab. 2015;100(8):2807-2831.

Last Reviewed: 11/7/18, 7/21/21, 11/16/22, 10/15/2023, 11/17/23, 9/20/24, 9/19/25
Effective Date: 1/1/19, 10/15/24

Sirturo® (bedaquiline fumarate), Pretomanid
Prior Authorization Guidelines

Affected Medication(s)

- Sirturo (bedaquiline) oral tablet
- Pretomanid oral tablet

FDA Approved Indication(s)

- Sirturo: As part of combination therapy in the treatment of pediatric patients ≥5 years of age (weighing ≥15 kg) and adults with pulmonary multi-drug resistant tuberculosis (MDR-TB). Reserve for use when an effective treatment regimen cannot otherwise be provided
- Pretomanid: Part of a combination regimen with bedaquiline and linezolid for the treatment of adults with pulmonary extensively drug resistant (XDR), treatment-intolerant or nonresponsive multidrug-resistant (MDR) tuberculosis (TB)

Dosing

Sirturo

- Children ≥5 years and Adolescents:
  Weight 15 kg to <30 kg:
  Weeks 1 and 2: Oral: 200 mg once daily.
  Weeks 3 to 24: Oral: 100 mg 3 times weekly (Total weekly dose: 300 mg/week)

  Weight ≥30 kg:
  Weeks 1 and 2: Oral: 400 mg once daily.
  Weeks 3 to 24: Oral: 200 mg 3 times weekly (Total weekly dose: 600 mg/week)

- Adults: 400 mg orally once daily for the first two weeks, followed by 200 mg orally three times per week (with at least 48 hours between doses) for 22 weeks (total duration of 24 weeks)

Pretomanid

- 200 mg orally once daily for 26 weeks (in combination with bedaquiline and linezolid)

Authorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required
2. Does the patient have documentation of resistance to, intolerance to, or contraindication to quad therapy with isoniazid, rifampin, ethambutol, pyrazinamide? (Provide supporting documentation)
   a. If yes, continue to #3
   b. If no, clinical review required
3. Is the request for one of the following treatment regimens? (Provide documentation of susceptible isolate and planned treatment regimen)

Last Reviewed: 11/21/18, 7/15/20, 9/15/21, 3/17/23, 3/15/24, 3/21/25
Effective Date: 1/1/19,8/15/20, 11/1/21, 4/15/24

- Pretomanid + Sirturo + linezolid
- Sirturo + at least 3 additional antituberculotic agents active against member's *M. tuberculosis* isolate

a. If yes, continue to #4
b. If no, clinical review required

4. Is the treatment being prescribed by, or in consultation with, an infectious disease specialist or pulmonologist?

a. If yes, approve for up to 6 months
b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Sirturo [package insert]. Titusville, NJ: Janssen Products LP. August 2024.
2. Pretomanid (pretomanid) oral tablet [package insert]. New York, NY: Mylan Laboratories; November 2024.
3. World Health Organization (WHO). WHO consolidated guidelines on tuberculosis. Module 4: treatment: drug-susceptible tuberculosis treatment. Geneva, Switzerland: WHO; 2022.Centers for Disease Control and Prevention (CDC). Provisional CDC guidance for the use of Pretomanid as component by a regimen [Bedaquiline, Pretomanid, the Linezolid (BPaL)] to treatments drug-resistant tuberculosis condition. Atlanta, GA: CDC; 2023.
4. Nahid, Payam, et al. "Treatment of drug-resistant tuberculosis. An official ATS/CDC/ERS/IDSA clinical practice guideline." American journal of respiratory and critical care medicine 200.10 (2019): e93-e142.
5. Saukkonen, JJ, et al. "Updates on the Treatment of Drug-Susceptible and Drug-Resistant Tuberculosis: An Official ATS/CDC/ERS/IDSA Clinical Practice Guideline." American Journal of Respiratory and Critical Care Medicine. 211.1 (2024)

Last Reviewed: 11/21/18, 7/15/20, 9/15/21, 3/17/23, 3/15/24, 3/21/25
Effective Date: 1/1/19, 8/15/20, 11/1/21, 4/15/24

Skyclarys® (omaveloxolone)
Prior Authorization Guidelines

Affected Medication(s)

- Skyclarys (omaveloxolone) oral capsule

FDA Approved Indication(s)

- Treatment of Friedreich's ataxia (FA) in adults and adolescents aged 16 and older

Dosing

- 150 mg orally once daily

Initial Authorization Criteria

1. Is the request for continuation of therapy with the same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is Skyclarys® (omaveloxolone) being requested for an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member between ages 16 and 40?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member Friedreich's ataxia as confirmed by genetic testing? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have a stable modified Friedreich's Ataxia Rating Scale (mFARS) score between 20 and 80? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Does the member have a left ventricular ejection fraction of at least 40%? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Is the treatment being prescribed by, or in consultation with, a clinical geneticist or neurologist?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide supporting documentation)

Last Reviewed: 5/19/23, 7/19/24, 7/18/25
Effective Date: 7/15/23, 8/15/24

a. If yes, continue to #2
b. If no, clinical review required

2. Were updated chart notes (within past year) provided with documentation of clinical response to prior therapy received?

   a. If yes, continue to #3
   b. If no, clinical review required

3. Is the treatment being prescribed by, or in consultation with, a clinical geneticist or neurologist?

   a. If yes, approve for 12 months
   b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Skyclarys (omaveloxolone) capsules, [package insert]. Plano, TX: Reata Pharmaceuticals, Inc.; 2024.
2. Drugs@FDA: FDA Approved Drug Products. 2023. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 22 Mar. 2023].
3. Lynch, D. R., Chin, M. P., Delatycki, M. B., Subramony, S. H., Corti, M., Hoyle, J. C., Boesch, S., Nachbauer, W., Mariotti, C., Mathews, K. D., Giunti, P., Wilmot, G., Zesiewicz, T., Perlman, S., Goldsberry, A., O'Grady, M., & Meyer, C. J. (2021). Safety and Efficacy of Omaveloxolone in Friedreich Ataxia (MOXIe Study). Annals of neurology, 89(2), 212–225.
4. Lynch, D. R., Chin, M. P., Boesch, S., Delatycki, M. B., Giunti, P., Goldsberry, A., Hoyle, J. C., Mariotti, C., Mathews, K. D., Nachbauer, W., O'Grady, M., Perlman, S., Subramony, S. H., Wilmot, G., Zesiewicz, T., & Meyer, C. J. (2023). Efficacy of Omaveloxolone in Friedreich's Ataxia: Delayed-Start Analysis of the MOXIe Extension. Movement disorders : official journal of the Movement Disorder Society, 38(2), 313–320.
5. Corben, L. A., Collins, V., Milne, S., Farmer, J., Musheno, A., Lynch, D., Subramony, S., Pandolfo, M., Schulz, J. B., Lin, K., Delatycki, M. B., & Clinical Management Guidelines Writing Group (2022). Clinical management guidelines for Friedreich ataxia: best practice in rare diseases. Orphanet journal of rare diseases, 17(1), 415.

Sodium phenylbutyrate and Glycerol phenylbutyrate
Prior Authorization Guidelines

Affected Medication(s)

- Buphenyl (sodium phenylbutyrate) oral powder
- Buphenyl (sodium phenylbutyrate) oral tablet
- Glycerol phenylbutyrate
- Olpruva (sodium phenylbutyrate) for oral suspension
- Pheburane (sodium phenylbutyrate) oral pellets
- Ravicti (glycerol phenylbutyrate) oral solution
- Sodium phenylbutyrate oral powder
- Sodium phenylbutyrate oral tablet

FDA Approved Indication(s)

Buphenyl:

- Adjunctive therapy in the chronic management of patients with urea cycle disorders involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS)
    - Indicated in all patients with neonatal-onset deficiency (complete enzymatic deficiency, presenting within the first 28 days of life)
    - Indicated in patients with late-onset disease (partial enzymatic deficiency, presenting after the first month of life) who have a history of hyperammonemic encephalopathy

Olpruva:

- Adjunctive therapy in the chronic management of adult and pediatric patients weighing 20 kg or greater with a BSA of 1.2 m^2 or greater, with urea cycle disorders involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS)

Pheburane:

- Adjunctive therapy in the chronic management of patients with urea cycle disorders involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS)

Ravicti:

- Chronic management of patients 2 months of age and older with urea cycle disorders (UCDs) who cannot be managed by dietary protein restriction and/or amino acid supplementation alone
    - Must be used with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements)

Dosing

- Refer to drug specific package insert for dosing recommendations

Initial Authorization Criteria

1. Has the requested medication previously been approved by OHSU for the same indication?
    a. If yes, continue to Reauthorization

Last Reviewed: 11/21/18, 1/20/21, 3/16/22, 3/15/23, 5/19/23, 7/21/23, 7/19/24, 7/18/25, 11/21/25
Effective Date: 1/1/19, 3/1/21, 4/15/22, 9/15/23, 8/15/24, 1/1/26

b. If no, continue to #2

2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)

   a. If yes, continue to #3
   b. If no, clinical review required

3. Is the diagnosis confirmed by blood, enzyme, or genetic testing? (Provide lab result for review)

   a. If yes, continue to #4
   b. If no, clinical review required

4. Is the baseline plasma ammonia level provided? (Provide lab result for review)

   a. If yes, continue to #5
   b. If no, clinical review required

5. Has the member tried a protein restrictive diet and has the member remained adherent to the protein restrictive diet? (Provide documentation of restrictive diet)

   a. If yes, continue to #6
   b. If no, clinical review required

6. Is the requested medication Olpruva, Pheburane, or Ravicti (glycerol phenylbutyrate)?

   a. If yes, continue to #7
   b. If no, continue to #8

7. Does the member have a previous trial with inadequate response, intolerance, or contraindication to sodium phenylbutyrate? (Provide documentation of trial, intolerance, or contraindication)

   a. If yes, continue to #8
   b. If no, clinical review required

8. Is the treatment being initiated by a provider that specializes in the treatment of inherited metabolic disorders? (Examples include a medical geneticist or an endocrinologist)

   a. If yes, approve for 6 months unless otherwise specified
   b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)

   a. If yes, continue to #2
   b. If no, clinical review required

2. Is the member adherent to a protein restrictive diet? (Provide documentation of restrictive diet)

   a. If yes, continue to #3
   b. If no, clinical review required

Last Reviewed: 11/21/18, 1/20/21, 3/16/22, 5/19/23, 7/21/23, 7/19/24, 7/18/25, 11/21/25
Effective Date: 1/1/19, 3/1/21, 4/15/22, 9/15/23, 8/15/24, 1/1/26

3. Does the member show a positive clinical response to therapy as defined by normalized plasma ammonia levels? (Provide documentation of normalized plasma ammonia levels)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the treatment being initiated by a provider that specializes in the treatment of inherited metabolic disorders? (Examples include a medical geneticist or an endocrinologist)
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Buphenyl (sodium phenylbutyrate) [Prescribing Information]. Lake Forest, IL: Horizon Pharma, Inc. October 2024.
2. Ravicti (glycerol phenylbutyrate) [Prescribing Information]. Lake Forest, IL: Horizon therapeutics, LLC. September 2021.
3. Olpruva (sodium phenylbutyrate kit) [Prescribing Information]. Newton, MA: Acer Therapeutics Inc. December 2024.
4. Pheburane (sodium phenybutyrate pellet) [Prescribing Information]. Bryn Mawr, PA: Medunik USA, Inc. December 2024.
5. Lee, B. Urea cycle disorder: clinical features and diagnosis. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed June 2025.
6. Lee, B. Urea cycle disorder: management. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed June 2025.

Last Reviewed: 11/21/18, 1/20/21, 3/16/22, 5/19/23, 7/21/23, 7/19/24, 7/18/25, 11/21/25
Effective Date: 1/1/19, 3/1/21, 4/15/22, 9/15/23, 8/15/24, 1/1/26

Sohonos® (palovarotene)
Prior Authorization Guidelines

Affected Medication(s)

- Sohonos (palovarotene) oral capsule

FDA Approved Indication(s)

- For the reduction in volume of new heterotopic ossification (HO) in adults and pediatric patients aged 8 years and older for females and 10 years and older for males with fibrodysplasia ossificans progressiva (FOP)

Dosing

- Refer to package insert for dosing recommendations

Initial Authorization Criteria

1. Is the request for continuation Sohonos (palovarotene) therapy for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #3
2. Is Sohonos® (palovorotene) being requested for an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
3. Is the member at least 8 years of age for females or at least 10 years of age for males?
    a. If yes, continue to #5
    b. If no, clinical review required
4. Does the member have documentation of FOP diagnosis, with the R206H ACVR1 mutation or other FOP variants reported to be associated with progressive heterotopic ossification? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
5. Is the treatment dose appropriate?
    a. If yes, continue to #7
    b. If no, clinical review required
6. Is the treatment being prescribed by, or in consultation with, an endocrinologist or appropriate specialist?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #2

Last Reviewed: 11/17/23, 9/20/24, 9/19/25
Effective Date: 12/20/23, 10/15/24

b. If no, clinical review required

2. Were updated chart notes (within past year) provided with documentation of clinical response to prior therapy received?
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the treatment being prescribed by, or in consultation with, an endocrinologist or appropriate specialist?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. SOHONOS (palovarotene) capsules [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc; arch 2025.
2. Drugs@FDA: FDA Approved Drug Products. 2022. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 21 Sept. 2023].
3. Pignolo RJ, Hsiao EC, Al Mukaddam M, et al. Reduction of New Heterotopic Ossification (HO) in the Open-Label, Phase 3 MOVE Trial of Palovarotene for Fibrodysplasia Ossificans Progressiva (FOP). J Bone Miner Res. 2023;38(3):381-394.
4. Kaplan FS, et al. The medical management of fibrodysplasia ossificans progressiva: current treatment considerations. Proc Intl Clin Council FOP 2. 2022: 1-127.

Last Reviewed: 11/17/23, 9/20/24, 9/19/25

Effective Date: 12/20/23, 10/15/24

Somavert® (pegvisomant)
Prior Authorization Guidelines

Affected Medication(s)

- Somavert subcutaneous powder for solution

FDA Approved Indication(s)

- Treatment of acromegaly in patients who have had an inadequate response to surgery or radiation therapy, or for whom these therapies are not appropriate

Dosing

- Loading Dose: 40 mg subcutaneously
- Maintenance Dose: 10 mg subcutaneously once daily, starting the day after loading dose administration

Initial Authorization Criteria

1. Is the request for continuation of Somavert (pegvisomant) therapy?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member have an elevated insulin like growth factor-1(IGF-1) level for age and gender? (Provide baseline IGF-1 level for review)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have a trial with inadequate response to, or documentation supporting they are not a candidate for either surgery or radiation therapy? (Provide documentation of inadequate response or rationale for avoiding therapy)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have a trial with inadequate response to, intolerance, or contraindication to a first generation somatostatin receptor ligand (i.e. octreotide)? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Does the member have a trial with inadequate response to, intolerance, or contraindication to cabergoline? (Note: cabergoline is only indicated if IGF1 <2.5 times the upper limit of normal) (Provide supporting documentation)
    a. If yes, continue to #7

Last Reviewed: 11/21/18, 7/21/21, 3/17/23, 3/15/24, 3/21/25
Effective Date: 1/1/19, 4/15/24

b. If no, clinical review required

7. Is the treatment being prescribed by, or in consultation with, an endocrinologist?
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Has the member had a positive clinical response to therapy as defined as either a decrease in or normalization in insulin like growth factor for age and gender (IGF-1)? (Provide documentation of IGF-1 value for review)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the treatment being prescribed by, or in consultation with, an endocrinologist?
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Somavert (pegvisomant) Product Information, Pharmacia & Upjohn Company LLC. New York, NY. April 2024.
2. Fleseriu M, Biller BMK, Freda PU, et al. A Pituitary Society update to acromegaly management guidelines. Pituitary. 2021;24(1):1-13.
3. Melmed S, Colao A, Molitch M, et al. Guidelines for Acromegaly Management: An Update. J Clin Endocrinol Metab. 2009;94:1509-1517.
4. Katznelson, Laurence, et al. "Acromegaly: an endocrine society clinical practice guideline." The Journal of Clinical Endocrinology & Metabolism 99.11 (2014): 3933-3951.
5. Melmed, Shlomo, et al. "A consensus statement on acromegaly therapeutic outcomes." Nature Reviews Endocrinology 14.9 (2018): 552-561.

Last Reviewed: 11/21/18, 7/21/21, 3/17/23, 3/15/24, 3/21/25
Effective Date: 1/1/19, 4/15/24

Spevigo (spesolimab-sbzo)
Prior Authorization Guidelines

Affected Medication(s)

- Spevigo (spesolimab-sbzo) injection solution

FDA Approved Indication(s)

- Treatment of generalized pustular psoriasis (GPP) in adults and pediatric patients 12 years of age and older and weighing at least 40 kg

Dosing

- Loading dose, if needed: 600 mg subcutaneously one time
- Maintenance dose: 300 mg subcutaneously every 4 weeks

Initial Authorization Criteria

1. Is the request for continuation of therapy with the same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member 12 years of age or older?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have a diagnosis of generalized pustular psoriasis and a history of at least two flares of moderate-to-severe intensity in the past? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have a Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score of 0 or 1? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Did the member have an inadequate response to a 12-week trial with TWO of the following systemic therapies: methotrexate, cyclosporine, or acitretin? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Does the member have documentation of an inadequate response, intolerance, or contraindication to a Cimzia (certolizumab pegol), a preferred adalimumab biosimilar, Skyrizi (risankizumab),Selarsdi (ustekinumab-aekn), Stelara (ustekinumab), or Yesintek (ustekinumab-kfce)? (Provide supporting documentation)
    a. If yes, continue to #8

Last Reviewed: 7/19/24, 7/18/25
Effective Date: 8/15/24, 8/1/25

b. If no, clinical review required

8. Is the treatment being prescribed by, or in consultation with, a dermatologist?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (within past year) provided with documentation of significant clinical response to therapy received? (i.e. reduction of flares, improvement of GPPGA score)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the treatment being prescribed by, or in consultation with, a clinical geneticist or neurologist?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. SPEVIGO (spesolimab-sbzo) injection solution [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals Inc; December 2024.
2. Drugs@FDA: FDA Approved Drug Products. 2024. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 10 April 2024].
3. Robinson A, Van Voorhees AS, Hsu S, et al. Treatment of pustular psoriasis: from the Medical Board of the National Psoriasis Foundation. J Am Acad Dermatol. 2012;67(2):279-288.
4. Gooderham MJ, Van Voorhees AS, Lebwohl MG. An update on generalized pustular psoriasis. Expert Rev Clin Immunol. 2019;15(9):907-919

Last Reviewed: 7/19/24, 7/18/25

Effective Date: 8/15/24, 8/1/25

Spravato® (esketamine)
Prior Authorization Guidelines

Affected Medication(s)

- Spravato nasal spray

FDA Approved Indication(s)

- For treatment-resistant depression (TRD) in adults in conjunction with an oral antidepressant
- Depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior

NOTE: The use of Spravato beyond 4 weeks has not been systematically evaluated in the treatment of depressive symptoms in patients with MDD with acute suicidal ideation or behavior

Dosing

Treatment-resistant depression (TRD):

- Induction: 56 mg twice weekly; may increase to 84 mg twice weekly based on efficacy and tolerability
- Maintenance: Starting week 5, continue previous administered dose (56 mg or 84 mg) and decrease dosing frequency to once weekly. Starting week 9 and after, continue established dose (56 mg or 84 mg) and adjust dosing to the least frequency to maintain remission/response; once weekly or once every 2 weeks

Major depressive disorder (MDD) with acute suicidal ideation or behavior:

- 84 mg twice weekly for 4 weeks, may be reduced to 56 mg twice per week based on tolerability. Use beyond 4 weeks has not been systematically evaluated in the treatment of depressive symptoms in patients with MDD with suicidal ideation or behavior.

NOTE: Spravato must be administered under the direct supervision of a healthcare provider

Initial Authorization Criteria

1. Is the request for continuation of Spravato (esketamine) therapy?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member 18 years of age or older?
    a. If yes, continue to #4
    b. If no, clinical review required
4. What is the diagnosis that Spravato (esketamine) is being used for? (Provide documentation of diagnosis)
    a. Treatment-resistant depression (TRD), continue to #5
    b. Major depressive disorder (MDD) with acute suicidal ideation or behavior, continue to #7
    c. Other indication, clinical review required

Last Reviewed: 9/18/2019, 11/18/20, 1/19/22, 3/17/23, 9/15/2023, 9/20/24, 9/19/25
Effective Date: 10/15/2019, 1/15/21, 3/1/22, 11/20/23, 10/15/24

5. Does the member have a previous trial with inadequate response to at least two antidepressants from at least two different classes when titrated up to the maximum indicated doses for a trial lasting a minimum of 8 weeks OR a contraindication to all classes? (Examples: SSRI, SNRI, TCA, bupropion) (Provide supporting documentation)

    a. If yes, continue to #6
    b. If no, clinical review required

6. Does the member have a previous trial with inadequate response, intolerance, or contraindication to at least two augmentation therapies with trials lasting a minimum of 4 weeks in conjunction with an oral antidepressant? Augmentation therapies include atypical antipsychotics, lithium, or a second antidepressant within an alternative class. (Provide supporting documentation)

    a. If yes, continue to #8
    b. If no, clinical review required

7. Does the member have active suicidal ideation and urgent symptom control is considered necessary? (Provider supporting documentation)

    a. If yes, continue to #8
    b. If no, clinical review required

8. Will Spravato be used in conjunction with an oral antidepressant? (Provide supporting documentation)

    a. If yes, continue to #9
    b. If no, clinical review required

9. Is the treatment being prescribed by, or in consultation with, a mental health specialist and will Spravato be administered under the direct supervision of a healthcare provider?

    a. If yes, approve for the following:
        - Treatment-resistant depression: 6 months
        - Major depressive disorder (MDD) with acute suicidal ideation or behavior: 1 month
    b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication Food and Drug Administration (FDA) approved or supported by major compendia?

    a. If yes, continue to #2
    b. If no, clinical review required

2. What is the diagnosis that Spravato (esketamine) is being used for? (Provide documentation of diagnosis)

    a. Treatment-resistant depression (TRD), continue to #3
    b. Major depressive disorder (MDD) with acute suicidal ideation or behavior, clinical review required
    c. Other indication, clinical review required

3. Were updated chart notes (within the past 12 months) with documentation of a positive response to therapy defined as a decrease in depressive symptoms provided? (Provide supporting documentation)

Last Reviewed: 9/18/2019, 11/18/20, 1/19/22, 3/17/23, 9/15/2023, 9/20/24, 9/19/25
Effective Date: 10/15/2019, 1/15/21, 3/1/22, 11/20/23, 10/15/24

a. If yes, continue to #4
b. If no, clinical review required

4. Will Spravato be used in conjunction with an oral antidepressant? (Provide supporting documentation)

    a. If yes, continue to #5
    b. If no, clinical review required

5. Is the treatment being prescribed by, or in consultation, with a mental health specialist and will Spravato be administered under the direct supervision of a healthcare provider?

    a. If yes, approve for 12 months reauthorization
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Esketamine. Drugs@FDA: FDA. Approved Drug Products 2019. Accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=211243. Accessed August 13, 2019.
2. Lexicomp Online [internet database]. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. Updated periodically. Accessed August 13, 2019.
3. Esketamine nasal spray device (Spravato) [package insert]. Titusville, NJ. Janssen Pharmaceuticals, Inc.; May 2025.
4. American Psychological Association. *Clinical Practice Guideline for the Treatment of Depression Across Three Age Cohorts*. Washington, DC: American Psychological Association; 2019. https://www.apa.org/depression-guideline/guideline.pdf
5. Spravato (esketamine) REMS website. https://www.spravatorems.com/. Updated March 2019. Accessed August 14, 2019.
6. Daly EJ, Trivedi MH, Janik A, et al. Efficacy of Esketamine Nasal Spray Plus Oral Antidepressant Treatment for Relapse Prevention in Patients With Treatment-Resistant Depression: A Randomized Clinical Trial. *JAMA Psychiatry*. 2019. doi: 10.1001/jamapsychiatry.2019.1189.

Last Reviewed: 9/18/2019, 11/18/20, 1/19/22, 3/17/23, 9/15/2023, 9/20/24, 9/19/25
Effective Date: 10/15/2019, 1/15/21, 3/1/22, 11/20/23, 10/15/24

Sucraid® (sacrosidase)
Prior Authorization Guidelines

Affected Medication(s)

- Sucraid (sacrosidase) oral solution

FDA Approved Indication(s)

- For treatment of genetically determined sucrase deficiency, which is part of congenital sucrase-isomaltase deficiency (CSID)

Dosing

- Patients ≤ 15 kg body weight: 1 mL (1 scoop or 28 drops) orally with each meal or snack
- Patients > 15 kg body weight: 2 mL (2 scoops or 56 drops) orally with each meal or snack

Initial Authorization Criteria

1. Is the request for continuation of Sucraid (sacrosidase) therapy?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member 5 months of age or older?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have a diagnosis of congenital sucrose-isomaltase deficiency (CSID) confirmed by one of the following? (Provide supporting documentation)
    - Genetic testing of the sucrase-isomaltase (SI) gene indicates a pathogenic mutation
    - Positive sucrose breath test
    - Small bowel biopsy showing low sucrose activity and normal amounts of other disaccharides
    - Meets all of the following criteria:
        - Stool pH< 6
        - Increase in breath hydrogen of >10ppm when challenged with sucrose after fasting
        - Negative lactose breath test

    a. If yes, continue to #5
    b. If no, clinical review required
5. Is the requested medication being prescribed by, or in consultation with, a gastroenterologist or genetic specialist?
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Last Reviewed: 7/21/23, 7/19/24, 7/18/25
Effective Date: 9/15/23, 8/15/24

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member demonstrate a positive clinical response to therapy such as fewer stools or lower total symptom score compared to baseline? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the requested medication being prescribed by, or in consultation with, a gastroenterologist or genetic specialist?
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Sucraid [package insert]. Vero Beach, FL: QOL Medical, LLC; August 2024.
2. Naim HY, Heine M, Zimmer KP. Congenital sucrose-isomaltase deficiency: Heterogeneity of inheritance, trafficking, and function of an intestinal enzyme complex. J Pediatr Gastroenterol Nutr. 2012;55:S13-S20.
3. Cohen SA. The clinical consequences of sucrose-isomaltase deficiency. Mol Cell Pediatr. 2016;3:5.
4. Gericke B, Amiri M, Scott CR, Naim HY. Molecular pathogenicity of novel sucrose-isomaltase mutations found in congenital sucrose-isomaltase deficiency patients. Biochim Biophys Acta Mol Basis Dis. 2017;1863:817-826.

Last Reviewed: 7/21/23, 7/19/24, 7/18/25
Effective Date: 9/15/23, 8/15/24

Sunosi® (solriamfetol)
Prior Authorization Guidelines

Affected Medication(s)

- Sunosi® 75mg and 150mg oral tablets

FDA Approved Indication(s)

- Improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA)

Dosing

- 37.5mg – 150mg once daily

Initial Authorization Criteria

1. Is the request for continuation of Sunosi® (solriamfetol) therapy?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member 18 years of age or older?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the treatment prescribed by or in consultation with a sleep specialist (e.g. neurology, pulmonology)?
    a. If yes, continue to #5
    b. If no, clinical review required
5. Has this member's diagnosis been confirmed by overnight polysomnogram, and for narcolepsy a multiple sleep latency test (MSLT)? Note: narcolepsy may be confirmed by low levels of orexin or hypocretin within cerebrospinal fluid (<110pg/mL or less than one third of the normative value of the lab)
    a. If yes, continue to #6
    b. If no, clinical review required
6. What is the underlying condition causing excessive daytime sleepiness?
    a. Narcolepsy, continue to #7
    b. Obstructive sleep apnea, continue to #8
    c. Other, clinical review required

Last Reviewed: 1/20/21, 5/18/22, 7/21/23, 7/19/24, 7/18/25
Effective Date: 3/1/21, 8/15/24, 8/1/25

7. Has this member had a documented trial with insufficient response, intolerance, or contraindication to at least one medication in each of the following groups?

    - Group 1: Modafinil or Armodafinil
    - Group 2: Stimulants (e.g. Methylphenidate, dextroamphetamine/amphetamine, etc)

    a. If yes, continue to #10
    b. If no, clinical review required

8. Does this member have evidence of current use or a history of intolerance to a primary treatment for obstructive sleep apnea (e.g. CPAP, mandibular device, surgical intervention)?

    a. If yes, continue to #9
    b. If no, clinical review required

9. Has this member had a documented trial with insufficient response, intolerance, or contraindication to modafinil or armodafinil?

    a. If yes, continue to #10
    b. If no, clinical review required

10. Have all other causes of excessive daytime sleepiness been ruled out or treated (e.g. restless leg syndrome, periodic limb movements, substance abuse, etc.)?

    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)

    a. If yes, continue to #2
    b. If no, clinical review required

2. Were updated chart notes provided with documentation of significant clinical response to therapy (e.g. reduction in Epworth Sleepiness Scale [ESS])?

    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Morgenthaler TI, Kapur VK, Brown T, et al. Practice parameters for the treatment of narcolepsy and other hypersomnias of central origin. Sleep. 2007;30(12): 1705-1711.

Last Reviewed: 1/20/21, 5/18/22, 7/21/23, 7/19/24, 7/18/25
Effective Date: 3/1/21, 8/15/24, 8/1/25

2. Billiard M, Bassetti C, Dauvilliers Y, et al. EFNS guidelines on management of narcolepsy. Eur J Neurol. 2006;13(10):1035-1048.
3. Barateau L, Lopez R, Dauvilliers Y. Treatment options for narcolepsy. CNS Drugs. 2016;30:369-379.
4. Barateau L, Dauvilliers Y. Recent advances in treatment for narcolepsy. Ther Adv Neurol Disord. 2019;12:1-12.
5. Thorpy M, Bogan R. Update on the pharmacologic management of narcolepsy: mechanisms of action and clinical implications. Sleep Medicine. 2020;68:97-109.
6. Thorpy MJ, Shapiro, C, Mayer G, et al. A randomized study of solriamfetol for excessive sleepiness in narcolepsy. Ann Neurol. 2019;85:359-370.
7. Schweitzer P, Rosenburg R, Zammit G, et al. Solriamfetol for excessive sleepiness in obstructive sleep apnea (TONES 3): a randomized controlled trial. Am J Respir Crit Care Med. 2019;199(11): 1421 - 1431.
8. Malhotra A, Shapiro C, Pepin JL, et al. Long-term study of the safety and maintenance of efficacy of solriamfetol (JZP-110) in the treatment of excessive sleepiness in participants with narcolepsy aor obstructive sleep apnea. SleepJ. 2020;43(2):1-11.
9. Strollo PJ, Hedner J, Collop N, et al. Solriamfetol for the treatment of excessive sleepiness in OSA: a placebo-controlled randomized withdrawal study. Chest. 2019; 155(2):364-374.
10. Sunosi (solriamfetol) [Prescribing Information]. New York, NY: Axsome Therapeutics, Inc. July 2023.

Symlinpen® (pramlintide acetate)
Prior Authorization Guidelines

Affected Medication(s)

- Symlinpen subcutaneous solution

FDA Approved Indication(s)

- An adjunctive treatment in patients with type 1 or type 2 diabetes who use mealtime insulin therapy and who have failed to achieve desired glucose control despite optimal insulin therapy

Dosing

- Type 2 diabetes:
  - Initiate 60 mcg before each meal
  - May titrate to 120 mcg before each meal
- Type 1 diabetes:
  - Initiate 15 mcg before each meal
  - May titrate up to 60 mcg before each meal

Initial Authorization Criteria

1. Is the request for continuation of Symlinpen (pramlintide acetate) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
   a. If yes, continue to #3
   b. If no, clinical review required
3. Is the member currently taking mealtime insulin and plans to remain on mealtime insulin throughout therapy with Symlinpen (pramlintide acetate)? (Provide documentation of relevant medication history and treatment plan)
   a. If yes, continue to #4
   b. If no, clinical review required
4. Has the member failed to achieve glucose control despite insulin adherence and titration? (Provide documentation of insulin titration and response to dosing titration)
   a. If yes, continue to #5
   b. If no, clinical review required
5. Does the member have an HbA1c that is greater than 7% and less than or equal to 9%? (Provide HbA1C result for review)
   a. If yes, continue to #6
   b. If no, clinical review required

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6. Does the member have a history of recurrent hypoglycemia requiring assistance in the past 6 months or a history of hypoglycemia unawareness? (Provide documentation of relevant past medical history including any hypoglycemia episodes requiring assistance)
    a. If yes, clinical review required
    b. If no, approve for 6 months unless otherwise specified

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the member currently taking insulin and plans to remain on insulin throughout therapy with Symlinpen (pramlintide acetate)? (Provide documentation of treatment plan)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member show a positive clinical response to therapy defined as an HbA1c of less than or equal to 9%? (Provide documentation of HbA1c result for review)
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Symlin/SymlinPen [package insert]. San Diego, CA: Amylin Pharmaceuticals, Inc.; December 2019.

American Diabetes Association Professional Practice Committee. 9. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes-2025. Diabetes Care. 2025;48(1 Suppl 1):S181-S206.

Last Reviewed: 11/21/18, 5/19/21, 11/16/22, 11/17/23, 9/20/24, 9/19/25
Effective Date: 1/1/19, 10/15/24

Tavneos® (avacopan)
Prior Authorization Guidelines

Affected Medication(s)

- Tavneos oral tablet

FDA Approved Indication(s)

- Adjunctive treatment of severe active antineutrophil cytoplasmic autoantibody-associated vasculitis (granulomatosis with polyangiitis and microscopic polyangiitis) in combination with standard therapy, including glucocorticoids, in adults

Dosing

- 30 mg orally twice daily

Initial Authorization Criteria

1. Is the request a renewal of a previously approved Tavneos (avacopan) prior authorization and provided indication is the same as previous approval?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member have a diagnosis of granulomatosis with polyangiitis or microscopic polyangiitis? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the member 18 years of age or older?
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have a positive test for anti-PR3 or anti-MPO? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Does the member have at least 1 major item, or 3 non-major items, or the 2 renal items of proteinuria and hematuria on Birmingham Vasculitis Activity Score (BVAS)? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Does the member have a recent documented trial of at least 3 months with inadequate response to a maximally indicated dose of systemic steroids? (Provide supporting documentation)
    a. If yes, continue to #9

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b. If no, continue to #8

8. Is use of systemic steroids contraindicated or has the member had clinically significant adverse effects from a systemic steroid trial? (Provide supporting documentation)
    a. If yes, continue to #9
    b. If no, clinical review required
9. Is Tavneos prescribed in combination with either cyclophosphamide or rituximab?
    a. If yes, continue to #10
    b. If no, clinical review required
10. Is the medication prescribed by, or in consultation with, a rheumatologist?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication Food and Drug Administration (FDA) approved or supported by major compendia?
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (within 1 year) demonstrating at least a 50% reduction in BVAS from baseline or remission? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the treatment being prescribed by, or in consultation with, a rheumatologist?
    a. If yes, approve for 12 months reauthorization
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. TAVNEOS (avacopan) capsules, [package insert]. Cincinnati, OH: ChemoCentyx, Inc; 2024.
2. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 23 Nov. 2021].
3. Kidney Disease: Improving Global Outcomes (KDIGO) ANCA Vasculitis Work Group. KDIGO 2024 Clinical Practice Guideline for the Management of Antineutrophil Cytoplasmic Antibody (ANCA)-Associated Vasculitis [published correction appears in Kidney Int. 2024 Jul;106(1):160-163. doi: 10.1016/j.kint.2024.04.003]. Kidney Int. 2024;105(3S):S71-S116. doi:10.1016/j.kint.2023.10.008

Last Reviewed: 1/19/22, 3/17/23, 1/19/24, 1/17/25
Effective Date: 3/1/22, 3/1/24

4. Yates, Max, et al. "EULAR/ERA-EDTA recommendations for the management of ANCA-associated vasculitis." Annals of the rheumatic diseases 75.9 (2016): 1583-1594.

Tegsedi® (inotersen sodium), Wainua™ (eplontersen)
Prior Authorization Guidelines

Affected Medication(s)

- Tegsedi subcutaneous solution
- Wainua subcutaneous solution

FDA Approved Indication(s)

- Treatment of polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults

Dosing

- Tegsedi: 284 mg subcutaneously once weekly
- Wainua: 45 mg subcutaneously once monthly

Initial Authorization Criteria

1. Is the request for continuation of a previously approved agent?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member 18 years of age or older?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have documentation confirming the presence of a transthyretin (TTR) mutation? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have documentation of a biopsy that was found to be positive for amyloid deposits? (Provide documentation of biopsy)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Does the member meet the diagnosis and clinical requirements for at least one of the following below? (Provide supporting documentation)
    - Subjective patient symptoms are suggestive of neuropathy
    - Abnormal nerve conduction studies are consistent with polyneuropathy
    - Abnormal neurological examination is suggestive of neuropathy

    a. If yes, continue to #7
    b. If no, clinical review required

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7. Is the treatment being prescribed by, or in consultation with, a neurologist, geneticist, or provider who specializes in the management of amyloidosis?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Has the member demonstrated a positive clinical response to therapy defined as an improvement in neuropathy symptoms? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the treatment being prescribed by, or in consultation with, a neurologist, geneticist, or provider who specializes in the management of amyloidosis?
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Tegsedi (inotersen sodium) subcutaneous injection [package insert]. Waltham, MA: Akcea Therpeutics, Inc; January 2024.
2. WAINUA™ (eplontersen) subcutaneous injection [package insert]. Wilmington, DE: AstraZeneca; September 2024.
3. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 8 Jan, 2019].
4. Ando Y, Coelho T, Berk JL, Cruz MW, Ericzon BG, Ikeda SI, et al. Guideline of transthyretin-related hereditary amyloidosis for clinicians. Orphanet Journal of Rare Diseases. 2013;8(1):1-18.
5. Hawkins PN, Ando Y, Dispenzeri A, Gonzalez-Duarte A, Adams D, Suhr OB. Evolving landscape in the management of transthyretin amyloidosis. Annals of Medicine. 2015;47(8):625-38.
6. Ando Y, Adams D, Benson MD, et al. Guidelines and new directions in the therapy and monitoring of ATTRv amyloidosis. Amyloid. 2022;29(3):143-155.

Last Reviewed: 3/20/19, 7/21/21, 3/17/23, 3/15/24, 3/21/25
Effective Date: 5/1/19, 6/1/23, 4/15/24

Testosterone Products
Prior Authorization Guidelines

Affected Medication(s)

- Androderm (testosterone) transdermal patch
- Androgel (testosterone) 1% packet (25 mg/2.5g)
- Androgel 1.62% gel packet
- Azmiro (testosterone cypionate)
- Jatenzo (testosterone undecanoate) oral capsule
- Testosterone 1% packet (25 mg/2.5g)
- Testosterone 1.62% packet
- Testosterone 10 mg gel pump
- Testosterone 30 mg/1.5mL pump
- Tlando (testosterone undecanoate) oral capsule
- Xyosted (testosterone) subcutaneous solution

FDA Approved Indication(s)

- Primary hypogonadism (congenital or acquired): Testicular failure due to conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals
- Hypogonadotropic hypogonadism (congenital or acquired): Gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation

Dosing

- Refer to corresponding package insert for dosing recommendations

Initial Authorization Criteria

1. Is the request for continuation of therapy with the same testosterone therapy for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member have a trial with insufficient response, intolerance, or contraindication to generic intramuscular testosterone? (Provide documentation of trial with insufficient response or intolerance)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have a trial with insufficient response, intolerance, or contraindication to at least one of the following products?
    - Testosterone 50 mg/5g gel
    - Testosterone 1% packet (50 mg/5g)

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- Testosterone 12.5 mg/1.25g gel pump
- Testosterone 1.62% gel pump

a. If yes, continue to #5
b. If no, clinical review required

5. What indication is the testosterone medication being requested for?

    a. Hypogonadism, continue to corresponding criteria
    b. Gender affirming treatment, continue to corresponding criteria

Hypogonadism

1. Is the member currently taking testosterone replacement therapy? (Provide documentation of testosterone replacement therapy history)

    a. If yes, continue to #2
    b. If no, continue to #3

2. Does the member have a testosterone level that was taken in the morning that is either within normal range or below normal (below normal range: total testosterone < 300 ng/dL or free testosterone <5 ng/dL)? (Provide documentation of testosterone level)

    a. If yes, continue to #4
    b. If no, clinical review required

3. Does the member have documentation of TWO baseline testosterone levels, taken in the mornings of different days, that are below normal range (total testosterone< 300 ng/dL or free testosterone <5ng/dL)? (Provide documentation of testosterone levels)

    a. If yes, continue to #4
    b. If no, clinical review required

4. Does the member have at least TWO signs/symptoms of hypogonadism (If member is currently on testosterone therapy, did they experience at least TWO signs/symptoms before initiation of therapy)? (Examples include sleep disturbances, gynecomastia, decreased lean body mass, visceral obesity, hot flashes, changes in mood, cognitive impairment, insulin resistance, anemia, and low bone mineral density) (Provide supporting documentation of signs/symptoms)

    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Gender Affirming Treatment

1. Does the member have a diagnosis of gender identity disorder by a qualified mental health professional? (Provide supporting documentation)

    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)

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a. If yes, continue to #2
b. If no, clinical review required

2. Is the medication being used for gender affirming care?

    a. If yes, approve for 12 months
    b. If no, continue to #3

3. Does the member have a positive clinical response to therapy as defined by a total serum testosterone level that is within normal range? (Provide documentation of testosterone levels)

    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Androderm [prescribing information] Actavis Pharma, Inc. October 2016.
2. AndroGel 1% [prescribing information] AbbVie Inc. October 2016.
3. Jatenzo [testosterone undecanoate] capsules. Clarus Therapeutics, Inc. Northbrook, IL; 2019
4. Xyosted [prescribing information] Antares Pharma, Inc. September 2018.
5. Bhasin S, Brito JP, Cunningham GR, et al. Testosterone Therapy in Men With Hypogonadism: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab 2018; 103:1715.
6. Olson-Kennedy J, Rosenthal SM, Hastings J, et al. UCSF Transgender Care & Treatment Guidelines: Health consideration for gender non-forming children and transgender adolescents. 2016 Jun. Available at: https://transcare.ucsf.edu/guidelines/youth

Last Reviewed: 12/19/18, 3/20/19, 5/20/20, 9/15/21, 7/20/22, 11/17/23, 9/20/24, 1/17/25
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Therapeutic Immunomodulators
Prior Authorization Guidelines

Affected Medication(s)

- Abrilada (adalimumab-afzb)
- Adalimumab-aacf
- Adalimumab-aaty
- Adalimumab-adaz
- Adalimumab-adbm
- Adalimumab-fkip
- Adalimumab-ryvk
- Actemra (tocilizumab)
- Actemra Actpen (tocilizumab)
- Amjevita (adalimumab-atto)
- Bimzelx (bimekizumab)
- Cimzia (certolizumab pegol)
- Cosentyx (secukinumab)
- Cyltezo (adalimumab-adbm)
- Enbrel (etanercept)
- Entyvio (vedolizmab)
- Hadlima (adalimumab-bwwd)
- Hulio (adalimumab-fkjp)
- Humira (adalimumab)
- Hyrimoz (adalimumab-adaz)
- Idacio (adalimumab-aacf)
- Ilumya (tildrakizumab)
- Imuldosa (ustekinumab-srlf)
- Kevzara (sarilumab)
- Kineret (anakinra)
- Omvoh (mirikiuzumab-mrkz)
- Orencia (abatacept)
- Otezla (apremilast) oral tablet
- Otezla XR (apremilast) oral tablet
- Otulfi (ustekinumab-aauz)
- Pyzchiva (ustekinumab-ttwe)
- Selarsdi (ustekinumab-aekn)
- Siliq (brodalumab)
- Simlandi (adalimumab-ryvk)
- Simponi (golimumab)
- Skyrizi (risankizumab)
- Sotyktu (deucravacitinib)
- Starjemza (ustekinumab-hmny)
- Stelara (ustekinumab)
- Steqeyma (ustekinumab-stba)
- Taltz (ixekizumab)
- Tremfya (guselkumab)
- Tyenne (tocilizumab)
- Ustekinumab
- Ustekinumab-aauz
- Ustekinumab-aekn
- Ustekinumab-ttwe
- Vesipity (etrasimod)
- Wezlana (ustekinumab-auub)
- Yesintek (Ustekinumab-kfce)
- Yuflyma (adalimumab-aaty)
- Yusimry (adalimumab-aqvh)
- Zymfentra (infliximab-dyyb)

FDA Approved Indication(s)

- Drug Compendia supported indications may be covered

Drug Name	RA	JIA	PsA	AS	SpA	Crohn	UC	Ps	HS	Uveitis	Other
Cimzia	X	X	X	X	X	X		X			
Adalimumab-adaz	X	X	X	X		X	X	X	X	X	
Adalimumab-adbm	X	X	X	X		X	X	X	X	X	
Hyrimoz	X	X	X	X		X	X	X	X	X	
Cyltezo	X	X	X	X		X	X	X	X	X	
Simponi	X		X	X			X				
Skyrizi			X			X	X	X			
Steqeyma			X			X	X	X			
Yesintek			X			X	X	X			
Kevzara	X	X									
Taltz			X	X	X			X			
Bimzelx			X	X	X			X	X		
Cosentyx			X	X	X			X	X		X
Enbrel	X	X	X	X				X			
Entyvio						X	X				
Non-preferred adalimumab biosimilars	X	X	X	X		X	X	X	X	X	
Humira	X	X	X	X		X	X	X	X	X	
Actemra	X	X									X
Tyenne	X	X									X

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Ilumya								X			
Kineret	X										X
Omvoh						X	X				
Orencia	X	X	X								X
Otezla			X					X			X
Otezla XR			X					X			X
Siliq								X			
Sotyktu								X			
Stelara			X			X	X	X			
Tremfya			X			X	X	X			
Non-preferred ustekinumab biosimilars			X			X	X	X			
Velsipity							X				
Zymfentra						X	X				

Dosing

- Refer to corresponding package insert for information

Initial Authorization Criteria

1. Is the request for continuation of therapeutic immunomodulatory therapy?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA-approved indication or a major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Will the requested medication be used concurrently with any other biologic therapy? (Examples: Enbrel, Actemra, Cimzia, Simponi, Orencia, Taltz, Cosentyx, Otezla, etc)
    a. If yes, clinical review required
    b. If no, continue to #4
4. What is the diagnosis that the medication is being requested for?
    a. Rheumatoid arthritis, continue to corresponding criteria
    b. Juvenile idiopathic arthritis, continue to corresponding criteria
    c. Ankylosing spondylitis/nr-axSpA, continue to corresponding criteria
    d. Psoriatic arthritis, continue to corresponding criteria
    e. Crohn's disease, continue to corresponding criteria
    f. Ulcerative colitis, continue to corresponding criteria
    g. Plaque psoriasis, continue to corresponding criteria
    h. Hidradenitis suppurativa, continue to corresponding criteria
    i. Uveitis, continue to corresponding criteria
    j. Other indication not listed, continue to corresponding criteria

Rheumatoid Arthritis (RA)

1. Is the diagnosis of rheumatoid arthritis (RA) confirmed by ACR/EULAR classification criteria AND has the diagnosis been documented for greater for 6 months? (Provide supporting documentation)

    a. If yes, continue to #2
    b. If no, clinical review required

2. Does the member have moderate to severe active RA confirmed by one of the tests below and despite the current RA management regimen? (Provide test result for review and provide current RA regimen)

    - Patient Activity Scale (PAS) or PASII of 3.7 or higher
    - Routine Assessment of Patient Index Data 3 (RAPID3) of 2.0 or higher
    - Clinical Disease Activity Index (CDAI) of 10 or higher
    - Disease Activity Score (DAS) 28 erythrocyte sedimentation rate (ESR) of 3.2 or higher
    - Simplified Disease Activity Index (SDAI) of 11 or higher

    a. If yes, continue to #3
    b. If no, clinical review required

3. Did the member have an inadequate response to a 12 week trial of methotrexate? (Provide documentation of inadequate response to methotrexate)

    a. If yes, continue to #6
    b. If no, continue to #4

4. Does the member have a contraindication or history of intolerance to methotrexate? (Provide documentation of contraindication and/or intolerance. Note: 1. Alcohol consumption is not considered a contraindication 2. Nausea to oral formulation is not considered an intolerance)

    a. If yes, continue to #5
    b. If no, clinical review required

5. Did the member have a contraindication to all OR an inadequate response to one 12 week trial with the following disease-modifying antirheumatic drugs: leflunomide, sulfasalazine, or hydroxychloroquine? (Provide documentation of contraindication or inadequate response to therapy)

    a. If yes, continue to #6
    b. If no, clinical review required

6. Is the request for a preferred adalimumab biosimilar, Cimzia (certolizumab pegol), or Simponi (golimumab)?

    a. If yes, continue to #10
    b. If no, continue to #7

7. Does the member have a documented inadequate response, contraindication, or intolerance to TWO of the following agents: preferred adalimumab biosimilar, Cimzia (certolizumab pegol), Rinvoq (upadacitinib), Simponi (golimumab), or Xeljanz/Xeljanz XR (tofacitinib citrate)? (Provide documentation of inadequate responses, contraindications, and/or intolerances)

    a. If yes, continue to #8
    b. If no, clinical review required

8. Is the request for Kevzara (sarilumab)?

    a. If yes, continue to #10
    b. If no, continue to #9

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9. Does the member have a documented inadequate response, contraindication, or intolerance to Kevzara (sarilumab)? (Provide documentation of inadequate responses, contraindications, and/or intolerances)

    a. If yes, continue to #10
    b. If no, clinical review required

10. Is the medication being prescribed by or in consultation with a rheumatologist?

    a. If yes, approve 6 months unless otherwise specified
    b. If no, clinical review required

Juvenile Idiopathic Arthritis (JIA/PJIA)

1. Does the member have moderate to severe active polyarticular JIA defined as greater or equal to 5 swollen joints and at least 3 joints with limitation in motion? (Provide documentation of affected joints and current treatment regimen)

    a. If yes, continue to #2
    b. If no, clinical review required

2. Did the member have an inadequate response to a 12 week trial of methotrexate? (Provide documentation of trial with inadequate response)

    a. If yes, continue to #5
    b. If no, continue to #3

3. Does the member have a contraindication or history of intolerance to methotrexate? (Provide documentation of contraindication and/or intolerance. Note: 1. Alcohol consumption is not considered a contraindication 2. Nausea to oral formulation is not considered an intolerance)

    a. If yes, continue to #4
    b. If no, clinical review required

4. Did the member have a contraindication or history of intolerance to leflunomide? (Provide documentation of contraindication and/or intolerance)

    a. If yes, continue to #5
    b. If no, deny. Clinical criteria not met

5. Is the request for a preferred adalimumab biosimilar or Cimzia (certolizumab pegol)?

    a. If yes, continue to #7
    b. If no, continue to #6

6. Does the member have documentation of an inadequate response, intolerance, or contraindication to preferred adalimumab biosimilar or Cimzia (certolizumab pegol)? (Provide documentation of inadequate response, contraindication, and/or intolerance)

    a. If yes, continue to #7
    b. If no, clinical review required

7. Is the request for Kevzara (sarilumab)?

    a. If yes, continue to #9
    b. If no, continue to #8

8. Does the member have a documented inadequate response, contraindication, or intolerance to Kevzara (sarilumab)? (Provide documentation of inadequate responses, contraindications, and/or intolerances)

a. If yes, continue to #9
b. If no, clinical review required

9. Is the medication being prescribed by or in consultation with a rheumatologist?

    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Ankylosing Spondylitis (AS)/nr-axSpA

1. Does the member currently have active AS despite a current treatment regimen as defined by the below? (Provide supporting documentation)
    - Bath ankylosing spondylitis disease activity index (BASDAI) greater or equal to 4 OR
    - Ankylosing Spondylitis Disease Activity Score (ASDAS) greater or equal to 2.1 AND
    - Elevated CRP, positive MRI, or Radiographic sacroiliitis

    a. If yes, continue to #2
    b. If no, clinical review required

2. Did the member have an inadequate response or intolerance to TWO separate 4 week trials of prescription strength oral nonsteroidal anti-inflammatory drugs (NSAIDs)? (Provide documentation of NSAIDs tried, examples: ibuprofen, naproxen, diclofenac, meloxicam, etc.)

    a. If yes, continue to #4
    b. If no, continue to #3

3. Does the member have a contraindication to oral NSAIDs? (Provide documentation of contraindication)

    a. If yes, continue to #4
    b. If no, clinical review required

4. Does the member have isolated sacroiliitis or enthesitis disease? (Provide supporting documentation)

    a. If yes, continue to #5
    b. If no, continue to #7

5. Did the member have an inadequate response to a parenteral glucocorticoid injection? (Provide documentation of trial with inadequate response)

    a. If yes, continue to #10
    b. If no, continue to #6

6. Does the member have a contraindication to a parenteral glucocorticoid injection? (Provide documentation of contraindication)

    a. If yes, continue to #10
    b. If no, clinical review required

7. Does the member have predominantly active axial or peripheral disease? (Provide supporting documentation)

    a. If axial, continue to #10
    b. If peripheral, continue to #8

8. Did the member have an inadequate response to a 12-week trial with sulfasalazine? (Provide documentation of trial with inadequate response)

a. If yes, continue to #10
b. If no, continue to #9

9. Does the member have a contraindication or history of intolerance to sulfasalazine? (Provide documentation of contraindication and/or intolerance)

    a. If yes, continue to #10
    b. If no, clinical review required

10. Is the request for a preferred adalimumab biosimilar, Cimzia (certolizumab pegol), or Simponi (golimumab)?

    a. If yes, continue to #16
    b. If no, continue to #11

11. Does the member have a documented inadequate response, intolerance, or contraindication to TWO of the following agents: a preferred adalimumab biosimilar, Cimzia (certolizumab pegol), or Simponi (golimumab)? (Provide documentation of inadequate responses, contraindications, and/or intolerances)

    a. If yes, continue to #12
    b. If no, clinical review required

12. Is the request for Taltz (ixekizumab)?

    a. If yes, continue to #16
    b. If no, continue to #13

13. Does the member have a documented inadequate response, intolerance, or contraindication to Taltz (ixekizumab)? (Provide documentation of inadequate response, contraindication, and/or intolerance)

    a. If yes, continue to #14
    b. If no, clinical review required

14. Is the requested medication Cosentyx (secukinumab)?

    a. If yes, continue to #15
    b. If no, continue to #16

15. Does the member have a contraindication to intravenous Cosentyx (secukinumab)? (Provide documentation of contraindication. Note: Intravenous Cosentyx approved for use in adults only)

    a. If yes, continue to #15
    b. If no, clinical review required

16. Is the medication being prescribed by or in consultation with a rheumatologist?

    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

<u>Psoriatic Arthritis (PsA)</u>

1. Does the member currently have active PsA defined as greater or equal to 3 swollen joints AND greater or equal to 3 tender or painful joints despite the current treatment regimen? (Provide documentation of affected joints and current treatment regimen)

    a. If yes, continue to #2
    b. If no, clinical review required

2. Did the member have a contraindication or an inadequate response to a 12 week trial with one of the following: methotrexate, leflunomide, cyclosporine, sulfasalazine? (Provide documentation of trial with inadequate response or contraindication)

    a. If yes, continue to #3
    b. If no, clinical review required

3. Is the request for a preferred adalimumab biosimilar, Cimzia (certolizumab pegol), Simponi (golimumab), Skyrizi (risankizumab), Steqeyma (ustekinumab-stba), or Yesintek (ustekinumab-kfce)?

    a. If yes, continue to #9
    b. If no, continue to #4

4. Does the member have a documented inadequate response, contraindication, or intolerance to TWO of the following agents: a preferred adalimumab biosimilar, Cimzia (certolizumab pegol), Simponi (golimumab), Skyrizi (risankizumab), Steqeyma (ustekinumab-stba), or Yesintek (ustekinumab-kfce)? (Provide documentation of inadequate responses, contraindications, and/or intolerances)

    a. If yes, continue to #5
    b. If no, clinical review required

5. Is the request for Taltz (ixekizumab)?

    a. If yes, continue to #9
    b. If no, continue to #6

6. Does the member have a documented inadequate response, contraindication, or intolerance to BOTH of the following agents: Taltz (ixekizumab) and Xeljanz (tofacitinib)? (Provide documentation of inadequate responses, contraindications, and/or intolerances)

    a. If yes, continue to #7
    b. If no, clinical review required

7. Is the requested medication Cosentyx (secukinumab)?

    a. If yes, continue to #8
    b. If no, continue to #9

8. Does the member have a contraindication to intravenous Cosentyx (secukinumab)? (Provide documentation of contraindication. Note: Intravenous Cosentyx approved for use in adults only)

    a. If yes, continue to #9
    b. If no, clinical review required

9. Is the medication being prescribed by or in consultation with a rheumatologist or dermatologist?

    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

<u>Crohn's Disease (CD)</u>

1. Does the member currently have active CD defined as a Crohn's Disease Activity Index (CDAI) greater than 220 despite the current treatment regimen? (Provide documentation of CDAI and current treatment regimen)

    a. If yes, continue to #2
    b. If no, clinical review required

2. Did the member have an inadequate response to TWO of the following oral agents for a minimum trial of 12 weeks each: 6-mercaptopurine, azathioprine, corticosteroid, methotrexate, mesalamine? (Provide documentation of 12 week trials with inadequate responses)
    a. If yes, continue to #4
    b. If no, continue to #3
3. Does the member have a contraindication or history of intolerance to at least TWO of the following oral agents: 6-mercaptopurine, azathioprine, corticosteroids, methotrexate, mesalamine, sulfasalazine? (Provide documentation of contraindications and/or intolerances)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the medication being requested a preferred adalimumab biosimilar, Cimzia (certolizumab pegol), Skyrizi (risankizumab), Steqeyma (ustekinumab-stba), or Yesintek (ustekinumab-kfce)?
    a. If yes, continue to #9
    b. If no, continue to #5
5. Does the member have a documented inadequate response, contraindication, or intolerance to TWO of the following agents: a preferred adalimumab biosimilar, Cimzia (certolizumab pegol), Skyrizi (risankizumab), Steqeyma (ustekinumab-stba), or Yesintek (ustekinumab-kfce)? (Provide documentation of inadequate responses, contraindications, and/or intolerances)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Is the requested medication Zymfentra (infliximab-dyyb)?
    a. If yes, continue to #7
    b. If no, continue to #9
7. Does the member have a contraindication to maintenance dosing of intravenous infliximab or an infliximab biosimilar? (Provide documentation of contraindication)
    a. If yes, continue to #8
    b. If no, clinical review required
8. Has the member received three intravenous induction doses of an infliximab product prior to initiation and does the member have a positive response to treatment? (Provide supporting documentation)
    a. If yes, continue to #9
    b. If no, clinical review required
9. Is the medication being prescribed by or in consultation with a gastroenterologist?
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

<u>Ulcerative Colitis (UC)</u>

1. Does the member currently have active Ulcerative Colitis? (Provide documentation of diagnosis confirmed by endoscopy, colonoscopy, or sigmoidoscopy with Mayo score of greater than 2)
    a. If yes, continue to #2

b. If no, clinical review required

2. Is the medication being requested a preferred adalimumab biosimilar, Simponi (golimumab), Skyrizi (risankizumab), or Stelara (ustekinumab)?

    a. If yes, continue to #7
    b. If no, continue to #3

3. Does the member have a documented inadequate response, intolerance, or contraindication to TWO of the following: a preferred adalimumab biosimilar, Simponi (golimumab), Skyrizi (risankizumab), Steqeyma (ustekinumab-stba), or Yesintek (ustekinumab-kfce)? (Provide documentation of inadequate responses, contraindications, and/or intolerances)

    a. If yes, continue to #4
    b. If no, clinical review required

4. Is the requested medication Zymfentra (infliximab-dyyb)?

    a. If yes, continue to #5
    b. If no, continue to #7

5. Does the member have a contraindication to maintenance dosing of intravenous infliximab or an infliximab biosimilar? (Provide documentation of contraindication)

    a. If yes, continue to #6
    b. If no, clinical review required

6. Has the member received three intravenous induction doses of an infliximab product prior to initiation and does the member have a positive response to treatment? (Provide supporting documentation)

    a. If yes, continue to #7
    b. If no, clinical review required

7. Is the medication being prescribed by, or in consultation with, a gastroenterologist?

    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

<u>Plaque Psoriasis (Ps)</u>

1. Does the member currently have moderate to severe chronic Ps defined as having functional impairment (e.g. inability to use hands or feet or activities of daily living, or significant facial involvement preventing normal social interaction) AND one or more of the following: 1. At least 10% body surface area involvement AND/OR 2. Hand, foot or mucous membrane involvement? (Provide documentation of functional impairment and body area involvement)

    a. If yes, continue to #2
    b. If no, clinical review required

2. Did the member have an inadequate response to TWO separate 12 week trials with TWO of the following systemic therapies: methotrexate, cyclosporine, phototherapy? (Provide documentation of 12 week trials with inadequate responses)

    a. If yes, continue to #3
    b. If no, clinical review required

3. Is the medication being requested Cimzia (certolizumab pegol), a preferred adalimumab biosimilar, Skyrizi (risankizumab), Steqeyma (ustekinumab-stba), or Yesintek (ustekinumab-kfce)
    a. If yes, continue to #8
    b. If no, continue to #4
4. Is the request for Taltz (ixekizumab)?
    a. If yes, continue to #5
    b. If no, continue to #6
5. Does the member have documentation of an inadequate response, intolerance, or contraindication to ONE of the following agents: a preferred adalimumab biosimilar, Cimzia (certolizumab pegol), Skyrizi, (risankizumab), Steqeyma (ustekinumab-stba), or Yesintek (ustekinumab-kfce)? (Provide documentation of inadequate response, contraindication, and/or intolerance)
    a. If yes, continue to #8
    b. If no, clinical review required
6. Does the member have documentation of an inadequate response, intolerance, or contraindication to TWO of the following agents: a preferred adalimumab biosimilar, Cimzia (certolizumab pegol), Skyrizi (risankizumab), Steqeyma (ustekinumab-stba), or Yesintek (ustekinumab-kfce)? (Provide documentation of inadequate response, contraindication, and/or intolerance)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Does the member have documentation of an inadequate response, intolerance, or contraindication to Taltz (ixekizumab)? (Provide documentation of inadequate response, contraindication, and/or intolerance)
    a. If yes, continue to #8
    b. If no, clinical review required
8. Is the treatment being prescribed by or in consultation with a dermatologist?
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

<u>Hidradenitis Suppurativa</u>

1. Does the member have Hurley stage II or III Hidradenitis Suppurativa? (Provide documentation of Hurley stage)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Did the member have a previous inadequate response to oral antibiotics? (Provide documentation of oral antibiotic regimen trialed and inadequate response)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the request for a preferred adalimumab biosimilar?
    a. If yes, continue to #5
    b. If no, continue to #4

4. Does the member have documentation of inadequate response, intolerance, or contraindication to a preferred adalimumab biosimilar? (Provide documentation of inadequate response, contraindication, and/or intolerance)

    a. If yes, continue to #5
    b. If no, clinical review required

5. Is the treatment being prescribed by or in consultation with a dermatologist?

    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Uveitis

1. Does the member have a diagnosis of non-infectious intermediate, posterior uveitis or panuveitis?

    a. If yes, continue to #2
    b. If no, clinical review required

2. Does the member have an inadequate response, intolerance, or contraindication to at least TWO of the following: cyclosporine, systemic glucocorticoids, and/or an antimetabolite (mycophenolate, methotrexate, or azathioprine)? (Provide documentation of inadequate responses, contraindications, and/or intolerances)

    a. If yes, continue to #3
    b. If no, clinical review required

3. Is the request for a preferred adalimumab biosimilar?

    a. If yes, continue to #5
    b. If no, continue to #4

4. Does the member have documentation of an inadequate response, intolerance, or contraindication to a preferred adalimumab biosimilar? (Provide documentation of inadequate response, contraindication, and/or intolerance)

    a. If yes, continue to #5
    b. If no, clinical review required

5. Is the treatment being prescribed by or in consultation with an ophthalmologist?

    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Other Indications

1. Is the request for an FDA approved indication?

    a. If yes, continue to #3
    b. If no, continue to #2

2. Is the requested use supported by major compendia not otherwise excluded by plan design?

    a. If yes, continue to #3
    b. If no, clinical review required

3. Has the member tried and had an inadequate response OR does the member have a contraindication to ALL standard treatment options for the requested indication? (Provide documentation of inadequate responses, contraindications, and/or intolerances)

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a. If yes, continue to #4
b. If no, clinical review required

4. Is the treatment being prescribed by or in consultation with an appropriate specialist?

    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication FDA-approved or supported by major compendia? (Provide documentation of diagnosis)

    a. If yes, continue to #2
    b. If no, clinical review required

2. Were updated chart notes (dated within 1 year) provided with documentation of significant clinical response to therapy? (Provide supporting documentation)

    a. If yes, continue to #3
    b. If no, clinical review required

3. Is the request for Humira or a non-preferred adalimumab biosimilar?

    a. If yes, continue to #4
    b. If no, continue to #5

4. Does the member have documentation of an inadequate response, intolerance, or contraindication to two different preferred adalimumab biosimilars? (Provide documentation of inadequate response, contraindication, and/or intolerance)

    a. If yes, continue to #7
    b. If no, clinical review required

5. Is the request for Stelara or a non-preferred Ustekinumab biosimilar?

    a. If yes, continue to #6
    b. If no, continue to #7

6. Does the member have documentation of an inadequate response, intolerance, or contraindication to two different preferred ustekinumab biosimilars? (Provide documentation of inadequate response, contraindication, and/or intolerance)

    a. If yes, continue to #7
    b. If no, clinical review required

7. Will the requested medication be used with other biologic therapy? (Examples: Enbrel, Actemra, Cimzia, Simponi, Orencia, Taltz, Cosentyx, Otezla, etc)

    a. If yes, clinical review required
    b. If no, continue to #6

8. Is the treatment being prescribed by or in consultation with an appropriate specialist?

    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

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Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

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2. Adalimumab-adaz [Prescribing Information]. Princeton, NJ: Sandoz. Mar 2023.
3. Actemra (tocilizumab) [Prescribing Information]. South San Francisco, CA: Genentech. June 2022.
4. Amjevita (adalimumab-atto) [Prescribing Information]. Thousand Oaks, CA: Amgen Inc. Aug 2023.
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6. Cimzia (certolizumab pegol) [Prescribing Information]. Smyrna, GA: UCB Inc. March 2021.
7. Cosentyx (secukinumab) [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. December 2021.
8. Cyltezo (adalimumab-adbm) [Prescribing Information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc. Sep 2023.
9. Enbrel (etanercept) [Prescribing Information]. Thousand Oaks, CA: Amgen. June 2022.
10. Hadlima (adalimumab-bwwd) [Prescribing Information]. Jersey City, NJ: Organon LLC. Jul 2023
11. Hulio (adalimumab-fkjp) [Prescribing Information]. Morgantown, WV: Mylan Specialty L.P. Aug 2023
12. Humira (adalimumab) [Prescribing Information]. North Chicago, IL: AbbVie Inc. February 2021.
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15. Ilumya (tildrakizumab-asmn) [Prescribing Information]. Cranbury, NJ: Sun Pharma Global FZE. April 2022.
16. Kevzara (sarilumab) [Prescribing Information]. Bridgewater, NJ: Sanofi-aventis U.S. LLC. April 2018.
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19. Orencia (abatacept) [Prescribing Information]. Princeton, NJ: E.R. Squibb & Sons L.L.C. December 2021.
20. Otezla (apremilast) [Prescribing Information]. Summit, NJ: Celgene. February 2021.
21. Selarsdi (ustekinumab-aekn) [Prescribing Information]. Leesburg, VA: Alvotech USA Inc. February 2025.
22. Siliq (brodalumab) [Prescribing Information]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC. June 2020.
23. Simlandi (adalimumab-ryvk) [Prescribing Information]. Leesburg, VA: Alvotech USA. February 2023.
24. Simponi (golimumab) [Prescribing Information]. Horsham, PA: Janssen Biotech Inc. September 2019.

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26. Skyrizi (risankizumab-rzaa) [Prescribing Information]. North Chicago, IL: AbbVie Inc. June 2024.
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Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Care Research (Hoboken). 2016;68(2):151-66. Available at: http://onlinelibrary.wiley.com/doi/10.1002/acr.22708/full.

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Tobi Podhaler® (tobramycin)
Prior Authorization Guidelines

Affected Medication(s)

- Tobi Podhaler inhalation capsule

FDA Approved Indication(s)

- For the management of cystic fibrosis patients with *Pseudomonas aeruginosa*

Dosing

- Tobi Podhaler
  - For adults and children 6 years of age and older: Inhale contents of four 28 mg capsules twice daily via podhaler device in cycles of 28 days on drug, 28 days off of drug

Initial Authorization Criteria

1. Is the request for continuation of Tobi Podhaler therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
   a. If yes, continue to #3
   b. If no, clinical review required
3. Does the member have a diagnosis of cystic fibrosis and a positive culture demonstrating infection with *Pseudomonas aeruginosa*? (Provide supporting documentation of diagnosis and positive culture for *Pseudomonas aeruginosa*)
   a. If yes, continue to #4
   b. If no, clinical review required
4. Does the member have baseline FEV1 greater than or equal to 25%? (Provide baseline FEV1 for review)
   a. If yes, continue to #5
   b. If no, clinical review required
5. Has the member had a medical rationale for avoiding therapy with generic tobramycin inhaled solution? (Provide documentation of medical rationale for avoidance)
   a. If yes, approve for 6 months unless otherwise specified
   b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
   a. If yes, continue to #2

Last Reviewed: 12/19/18, 11/18/20, 9/15/21, 3/17/23, 3/15/24, 3/21/25
Effective Date: 1/1/19, 1/15/21, 4/15/24

b. If no, clinical review required

2. Does the member have a positive response to therapy as defined by stability in their disease state? (Provide supporting documentation for review)
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Tobi Podhaler (tobramycin) [Prescribing Information]. Morgantown, WV: Mylan Specialty LP. February 2023.
2. Mogayzel Jr, Peter J., et al. "Cystic Fibrosis Foundation pulmonary guideline. Pharmacologic approaches to prevention and eradication of initial Pseudomonas aeruginosa infection." *Annals of the American Thoracic Society* 11.10 (2014): 1640-1650.

Last Reviewed: 12/19/18, 11/18/20, 9/15/21, 3/17/23, 3/15/24, 3/21/25
Effective Date: 1/1/19, 1/15/21, 4/15/24

Tolvaptan
Prior Authorization Guidelines

Affected Medication(s)

- Jynarque oral tablet
- Tolvaptan oral tablet

FDA Approved Indication(s)

- To slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD)

Dosing

- Initially: 60 mg orally per day as 45 mg taken on waking and 15 mg taken 8 hours later
- Titrate to 90 mg taken on waking and 30 mg taken 8 hours later if tolerated
- Refer to package insert for dose adjustments for patients taking moderate CYP 3A inhibitors

Initial Authorization Criteria

1. Is the request for continuation oftolvaptan therapy for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member 18 years of age or older?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have a diagnosis of autosomal dominant polycystic kidney disease confirmed by ultrasonography, MRI/CT scan, or genetic testing? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is the member at risk of rapidly-progressing autosomal dominant polycystic kidney disease (ADPKD) defined by any of the following? (Provide supporting documentation)
        - MAYO class 1D or 1E
        - MAYO class 1C with additional evidence of rapid disease progression
        - eGFR decline ≥ 3.0 mL/min/1.73 m^2 over a period of ≥ 4 years
        - An ultrasound determined kidney length of > 16.5 cm
        - PROPKD score >6
        - Age of ≤ 55 with CKD stage 3
    a. If yes, continue to #6

Last Reviewed: 11/21/18, 11/18/20, 9/15/21, 1/20/23, 1/19/24, 3/21/25, 7/18/25
Effective Date: 1/1/19, 3/15/23, 3/1/24, 8/1/25

b. If no, clinical review required

6. Does the member have a contraindication to Jynarque (tolvaptan)? (Contraindications include: History of signs or symptoms of significant liver impairment or injury, use of Jynarque with strong CYP 3A inhibitors, uncorrected abnormal blood sodium concentrations, unable to sense or respond to thirst, hypovolemia, uncorrected urinary outflow obstruction, or anuria)

   a. If yes, clinical review required
   b. If no, continue to #7

7. Does the member have baseline liver function (ALT and AST) and bilirubin levels within normal range? (Provide documentation of AST, ALT and bilirubin levels taken within the previous 3 months for review)

   a. If yes, continue to #8
   b. If no, clinical review required

8. Is the treatment being prescribed by or in consultation with a nephrologist?

   a. If yes, approve for 6 months unless otherwise specified
   b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)

   a. If yes, continue to #2
   b. If no, clinical review required

2. Has the member had a positive clinical response to therapy as defined by a slowing in the decline in kidney function and/or an improvement in kidney pain? (Provide supporting documentation of positive clinical response)

   a. If yes, continue to #3
   b. If no, clinical review required

3. Has the member experienced an increase in ALT, AST, or bilirubin to greater than 2 times the upper limit of normal? (Provide updated ALT, AST, and bilirubin levels for review)

   a. If yes, clinical review required
   b. If no, continue to #4

4. Is the treatment being prescribed by or in consultation with a nephrologist?

   a. If yes, approve for 12 months unless otherwise specified
   b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

Last Reviewed: 11/21/18, 11/18/20, 9/15/21, 1/20/23, 1/19/24, 3/21/25, 7/18/25
Effective Date: 1/1/19, 3/15/23, 3/1/24, 8/1/25

References:

1. Jynarque [package insert]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; May 2025.
2. Kidney Disease: Improving Global Outcomes (KDIGO) ADPKD Work Group. KDIGO 2025 Clinical Practice Guideline for the Evaluation, Management, and Treatment of Autosomal Dominant Polycystic Kidney Disease (ADPKD). *Kidney Int*. 2025;107(2S):S1-S239.Srivastava A, Patel N. Autosomal dominant polycystic kidney disease. American Academy of Family Physician. 2014;90(5):303-307
3. Torres VE, Chapman AB, Devuyst O, et al. Tolvaptan in patients with autosomal dominant polycystic kidney disease. The New England Journal of Medicine. 2012;367:2407-18.
4. Müller, Roman-Ulrich, et al. "An update on the use of tolvaptan for autosomal dominant polycystic kidney disease: consensus statement on behalf of the ERA Working Group on Inherited Kidney Disorders, the European Rare Kidney Disease Reference Network and Polycystic Kidney Disease International." Nephrology Dialysis Transplantation 37.5 (2022): 825-839.

Last Reviewed: 11/21/18, 11/18/20, 9/15/21, 1/20/23, 1/19/24, 3/21/25, 7/18/25
Effective Date: 1/1/19, 3/15/23, 3/1/24, 8/1/25

Transthyretin Stabilizer Agents
Prior Authorization Guidelines

Affected Medication(s)

- Attruby (acoramidis) oral tablet
- Vyndaqel (tafamidis meglumine) oral capsule
- Vyndamax (tafamidis) oral capsule

FDA Approved Indication(s)

- Treatment of the cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization

Dosing

- Attruby: 712 mg (two 356 mg tablets) orally twice daily
- Vyndaqel: 80 mg (four 20-mg capsules) orally one time daily
- Vyndamax: 61 mg (one capsule) orally one time daily
- Vyndamax and Vyndaqel are not substitutable on a per mg basis

Initial Authorization Criteria

1. Is the request for continuation of therapy with the same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member 18 years of age or older?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have documentation confirming the presence of a transthyretin (TTR) mutation or TTR precursor protein? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have documentation of a biopsy that was found to be positive for amyloid deposits? (Provide documentation of biopsy)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Does the member have cardiomyopathy caused by transthyretin-mediated amyloidosis? (Provide supporting documentation)
    a. If yes, continue to #7

Last Reviewed: 11/20/19, 7/21/21, 7/20/22, 7/21/23, 7/19/24, 1/17/25
Effective Date: 1/1/20, 9/1/21, 8/15/24, 2/1/25

b. If no, clinical review required

7. Does the member have NYHA Class III or IV heart failure?

    a. If yes, clinical review required
    b. If no, continue to #8

8. Has the member had a liver transplant?

    a. If yes, clinical review required
    b. If no, continue to #9

9. Is the request for Attruby?

    a. If yes, clinical review required
    b. If no, continue to #10

10. Does the member have documentation of an inadequate response, intolerance, or contraindication to Attruby? (Provide supporting documentation)

    a. If yes, clinical review required
    b. If no, continue to #11

11. Is the requested medication being prescribed by, or in consultation with, a cardiologist?

    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)

    a. If yes, continue to #2
    b. If no, clinical review required

2. Has the member demonstrated a positive clinical response to therapy defined as an improvement or stabilization in cardiomyopathy symptoms? (Provide supporting documentation)

    a. If yes, continue to #3
    b. If no, clinical review required

3. Is the requested medication being prescribed by, or in consultation with, a cardiologist?

    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

Last Reviewed: 11/20/19, 7/21/21, 7/20/22, 7/21/23, 7/19/24, 1/17/25
Effective Date: 1/1/20, 9/1/21, 8/15/24, 2/1/25

References:

1. VYNDAQEL (tafamidis meglumine) and VYNDAMAX (tafamidis) oral capsules [package insert]. New York, NY: Pfizer Labs; 2019.
2. ATTRUBY™ (acoramidis) oral capsule [package insert]. Palo Alto, CA: BridgeBio Pharma; 2024
3. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 30 July. 2019].
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5. Maurer MS, Schwartz JH, Gundapaneni B, Elliott PM, Merlini G, Waddington-Cruz M, Kristen AV, Grogan M, Witteles R, Damy T, Drachman BM, Shah SJ, Hanna M, Judge DP, Barsdorf AI, Huber P, Patterson TA, Riley S, Schumacher J, Stewart M, Sultan MB, Rapezzi C; ATTR-ACT Study Investigators. Tafamidis Treatment for Patients with Transthyretin Amyloid Cardiomyopathy. N Engl J Med. 2018 Sep 13;379(11):1007-1016. doi: 10.1056/NEJMoa1805689. Epub 2018 Aug 27.
6. Kittleson MM, Maurer MS, Ambardekar AV, et al. Cardiac Amyloidosis: Evolving Diagnosis and Management: A Scientific Statement From the American Heart Association [published correction appears in Circulation. 2021 Jul 6;144(1):e10] [published correction appears in Circulation. 2021 Jul 6;144(1):e11]. Circulation. 2020;142(1):e7-e22.
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Last Reviewed: 11/20/19, 7/21/21, 7/20/22, 7/21/23, 7/19/24, 1/17/25
Effective Date: 1/1/20, 9/1/21, 8/15/24, 2/1/25

Truqap (capivastertib)
Prior Authorization Guidelines

Affected Medication(s)

- Truqap oral tablet

Indication(s)

- Treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN-alterations as detected by an FDA-approved test following progression on at least one endocrine-based regimen in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy

Dosing:

- 400 mg orally twice daily, with or without food, for 4 days followed by 3 days off until disease progression or unacceptable toxicity

Initial Authorization Criteria

1. Is the request for continuation of therapy with the same anti-cancer medication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the medication being requested to be used for an FDA approved indication? (Provide documentation of diagnosis)
    a. If yes, continue to #4
    b. If no, continue to #3
3. Is the medication being requested being used for an indication supported by the National Comprehensive Cancer Network (NCCN) with an evidence level of 2A or higher? (Provide disease staging, all prior treatment history, pathology report, and anticipated treatment plan for review)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have Karnofsky Performance Status greater or equal to 50% OR Eastern Cooperative Oncology Group (ECOG) performance status of 0-2? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have an identified alteration in PIK3CA only?
    a. If yes, continue to #6
    b. If no, continue to #7
6. Does the member have a previous trial with inadequate response, intolerance or contraindication to Piqray (alpelisib)? (Provide supporting documentation)
    a. If yes, continue to #7

Last Reviewed: 1/19/24, 3/21/25
Effective Date: 3/1/24

b. If no, clinical review required

7. Is the medication being prescribed by or in consultation with an oncologist?

    a. If yes, approve for 4 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication approved by the FDA or supported by the NCCN recommendation with an evidence level of 2A or higher? (Provide documentation of diagnosis)

    a. If yes, continue to #2
    b. If no, clinical review required

2. Is there clinical documentation confirming disease responsiveness to therapy provided? (Examples include reduction in tumor size, objective response, delay in progression, partial response, etc.) (Provide supporting documentation)

    a. If yes, continue to #2
    b. If no, clinical review required

3. Is the medication being prescribed by or in consultation with an oncologist?

    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Truqap (capivasertib) tablets, [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2024.
2. Drugs@FDA: FDA Approved Drug Products. 2023. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 11 Dec. 2023].
3. Clinical Practice Guidelines in Oncology (NCCN Guidelines): Breast Cancer. Version 6.2024 National Comprehensive Cancer Network website. Available from https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed January 29, 2025.
4. Turner NC, Oliveira M, Howell SJ, et al. Capivasertib in Hormone Receptor-Positive Advanced Breast Cancer. N Engl J Med. 2023;388(22):2058-2070.

Last Reviewed: 1/19/24, 3/21/25
Effective Date: 3/1/24

Tryngolza (olezarsen)
Prior Authorization Guidelines

Affected Medication(s)

- Tryngolza (olezarsen) subcutaneous injection

FDA Approved Indication(s)

- As adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS)

Dosing

- 80 mg subcutaneously once monthly

Initial Authorization Criteria

1. Is the request for continuation of therapy with the same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member have documentation of genetically confirmed Familial Chylomicronemia Syndrome (type 1 Hyperlipoproteinemia)? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have a baseline triglyceride level of at least 880 mg/dL? (Provide lab results)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is the member working with a dietician to manage this condition? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Is the member adherent to a very low-fat diet with less than 20 g of fat per day or no more than 15-20% of daily calories and will continue a very low-fat diet concurrently with Tryngolza (crinercerfont)? (Provide nutrition plan)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Is Tryngolza (crinercerfont) being prescribed by, or in consultation with, an endocrinologist or other specialist with experience treating familial chylomicronemia syndrome?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Last Reviewed: 3/21/25
Effective Date: 4/1/25

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (within past year) provided with documentation of significant clinical response to therapy received? (i.e. decrease in fasting triglycerides)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member continue to be adherent to a very low-fat diet with less than 20 g of fat per day or no more than 15-20% of daily calories? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is Tryngolza (crinercerfont) being prescribed by, or in consultation with, an endocrinologist or other specialist with experience treating familial chylomicronemia syndrome?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. TRYNGOLZA (olezarsen) injection solution, [package insert]. Carlsbad, CA: Ionis Pharmaceuticals, Inc.; 2025.
2. Drugs@FDA: FDA Approved Drug Products. 2025. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 19 Jan 2025]
3. Williams L, Rhodes KS, Karmally W, et al. Familial chylomicronemia syndrome: Bringing to life dietary recommendations throughout the life span. J Clin Lipidol. 2018;12(4):908-919.
4. Stroes ESG, Alexander VJ, Karwatowska-Prokopczuk E, et al. Olezarsen, Acute Pancreatitis, and Familial Chylomicronemia Syndrome. N Engl J Med. 2024;390(19):1781-1792.

Upneeq® (oxymetazoline hydrochloride)
Prior Authorization Guidelines

Affected Medication(s)

- Upneeq ophthalmic solution

FDA Approved Indication(s)

- Treatment of acquired blepharoptosis in adults

Dosing

- Instill one drop into affected eye(s) once daily

Initial Authorization Criteria

1. Is the request for continuation of Upneeq (oxymetazoline ophthalmic solution) therapy?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member 18 years of age or older?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have blepharoptosis that is caused by any of the following?
        - Congenital ptosis
        - Horner syndrome
        - Myasthenia gravis
        - Mechanical cause ptosis
    a. If yes, clinical review required
    b. If no, continue to #5
5. Does the member's blepharoptosis cause functional impairment? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Does the member meet one of the following? (Provide supporting documentation)
        - Marginal reflex distance-1 (MRD-1) ≤ 2mm
        - Inability to detect ≤ 8 of 17 points in the top 2 rows on the Leicester Peripheral Field Test (LPFT)
    a. If yes, continue to #7
    b. If no, clinical review required

Last Reviewed: 7/21/21, 3/17/23, 3/15/24, 3/21/25
Effective Date: 9/1/21, 4/15/24

7. Is the treatment being initiated by, or in consultation with, an ophthalmologist?
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member show a positive clinical response to therapy as defined by an improvement in visual field deficit? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the treatment being prescribed by or in consultation with an ophthalmologist?
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. UPNEEQ (oxymetazoline hydrochloride ophthalmic solution), [package insert]. Bridgewater, NJ: RVL Pharmaceuticals, Inc.; 2024.
2. Finsterer, Josef. "Ptosis: causes, presentation, and management." Aesthetic plastic surgery 27.3 (2003): 193-204.
3. Kersten, Robert C., Carlo de Conciliis, and Dwight R. Kulwin. "Acquired ptosis in the young and middle-aged adult population." Ophthalmology 102.6 (1995): 924-928.
4. Slonim, Charles B., et al. "Association of oxymetazoline hydrochloride, 0.1%, solution administration with visual field in acquired ptosis: a pooled analysis of 2 randomized clinical trials." JAMA ophthalmology 138.11 (2020): 1168-1175.

Last Reviewed: 7/21/21, 3/17/23, 3/15/24, 3/21/25
Effective Date: 9/1/21, 4/15/24

Vascepa® (icosapent ethyl)
Prior Authorization Guidelines

Affected Medication(s)

- Vascepa oral capsule
- Icosapent ethyl capsule

FDA Approved Indication(s)

- As an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (≥ 150 mg/dL) and
  - Established cardiovascular disease OR
  - Diabetes mellitus and 2 or more additional risk factors for cardiovascular disease
- As an adjunct to diet to reduce TG levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia

Dosing

- Twice daily of a total 4 gram per day taken with food

Initial Authorization Criteria

1. Is the request for continuation of therapy with the same medication for the same indication?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
   a. If yes, continue to #3
   b. If no, clinical review required
3. What is the requested drug being used for? (Provide documentation of diagnosis)
   a. Hypertriglyceridemia, continue to #4
   b. Atherosclerotic cardiovascular disease prevention, continue to #5
   c. Other indication, clinical review required
4. Does the member have a triglyceride level of 500 mg/dL or greater confirmed by labs within 6 months? (Provide lab for review)
   a. If yes, approve for 24 months unless otherwise specified
   b. If no, clinical review required
5. Does the member have Triglyceride level 150 mg/dL or greater (confirmed by labs within the last 6 months) and one of the following? (Provide supporting documentation)
   - Established cardiovascular disease
   - Type 2 diabetes with 2 or more additional risk factors for cardiovascular disease

Last Reviewed: 11/18/20, 1/19/22, 7/20/22, 7/21/23, 7/19/24, 1/17/25
Effective Date: 12/15/20, 3/1/22, 9/1/22, 8/15/24, 2/1/25

a. If yes, continue to #6

b. If no, clinical review required

6. Is the member currently on maximally tolerated statin therapy with plans to continue therapy? (Provide supporting documentation)
   a. If yes, approve for 24 months unless otherwise specified
   b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)

   a. If yes, continue to #2
   b. If no, clinical review required

2. Has this member been seen within the past 12 months for treatment of hypertriglyceridemia or prevention of atherosclerotic cardiovascular disease?

   a. If yes, approve for 24 months unless otherwise specified
   b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Vascepa (icosapent ethyl) [Prescribing Information]. Bridgewater, NJ: Amarin Pharma, Inc. July 2020.
2. Bhatt DL, Steg PG, Miler M, et al. Cardiovascular Risk Reduction with Icosapent Ethyl for Hypertriglyceridemia. New England Journal of Medicine. 2019;380(1):11-22.
3. Orringer, CE, Jacobson, TA, Maki, KC. National Lipid Association Scientific Statement on the use of icosapent ethyl in statin-treated patients with elevated triglycerides and high or very-high ASCVD risk. J Clin Lipidol. 2019;13(6):860-72.
4. Virani, Salim S., et al. "2021 ACC expert consensus decision pathway on the management of ASCVD risk reduction in patients with persistent hypertriglyceridemia: a report of the American College of Cardiology Solution Set Oversight Committee." Journal of the American College of Cardiology 78.9 (2021): 960-993.

Last Reviewed: 11/18/20, 1/19/22, 7/20/22, 7/21/23, 7/19/24, 1/17/25
Effective Date: 12/15/20, 3/1/22, 9/1/22, 8/15/24, 2/1/25

Veltassa® (patiromer)
Prior Authorization Guidelines

Affected Medication(s)

- Veltassa powder for suspension

FDA Approved Indication(s)

- Treatment of hyperkalemia in adults and pediatric patients 12 years and older
  Note: Should not be used as an emergency treatment for life-threatening hyperkalemia

Dosing

- Initially 8.4 g once daily
- Titrate as needed to maximum of 25.2 g once daily to reach desired serum potassium concentration

Initial Authorization Criteria

1. Is the request for continuation of Veltassa (patiromer) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
   a. If yes, continue to #3
   b. If no, clinical review required
3. Is the member 18 years of age or older?
   a. If yes, continue to #4
   b. If no, clinical review required
4. Is the baseline potassium level received? (Provide documentation of lab)
   a. If yes, continue to #5
   b. If no, clinical review required
5. Have potentially hyperkalemia contributing medications such as NSAIDs, ACEI, ARB, or aldosterone antagonists been reduced to lowest effective dose or discontinued if clinically appropriate? (Provide documentation of dose reduction/discontinuation or rationale why patient is not a candidate to do so)
   a. If yes, continue to #6
   b. If no, clinical review required
6. Does the member follow a low potassium diet? (Provide documentation of diet with 3 or less grams of potassium per day)
   a. If yes, continue to #7
   b. If no, clinical review required
7. Does the member have a trial with inadequate response, intolerance, or contraindication to treatment with sodium polystyrene sulfonate or Lokelma? (Provide documentation of trial, intolerance, or contraindication)

Last Reviewed: 11/21/18, 5/19/21, 11/16/22, 11/17/23, 9/20/24, 9/19/25
Effective Date: 1/1/19, 6/15/21, 10/15/24

a. If yes, continue to #8
b. If no, clinical review required

8. Is the treatment being prescribed by, or in consultation with, a nephrologist or cardiologist?

    a. If yes, approve for 6 months unless otherwise indicated
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia indication? (Provide documentation of diagnosis)

    a. If yes, continue to #2
    b. If no, clinical review required

2. Does the member have a positive response to therapy as defined as a decrease in serum potassium? (Provide documentation of decrease in serum potassium compared to pre-treatment)

    a. If yes, continue to #3
    b. If no, clinical review required

3. Is the treatment being prescribed by, or in consultation with, a nephrologist or cardiologist?

    a. If yes, approve for 12 months unless otherwise indicated
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Veltassa [Prescribing Information] King of Prussia, PA: Vifor Pharma, Inc; January 2025.
2. Bakris GL, Pitt B, Weir MR, et al. Effect of patiromer on serum potassium levels in patients with hyperkalemia and diabetic kidney disease: The AMETHYST-DN randomized clinical trial. JAMA. 2015; 314(2):151-161.
3. Weir MR, Bakris GL, Bushinsky DA, et al; for the OPAL-HK Investigators. Patiromer in patients with kidney disease and hyperkalemia receiving RAAS inhibitors. N Engl J Med. 2015; 372(3):211-221.
4. Clase, Catherine M., et al. "Potassium homeostasis and management of dyskalemia in kidney diseases: conclusions from a Kidney Disease: Improving Global Outcomes (KDIGO) Controversies Conference." Kidney international 97.1 (2020): 42-61.

Last Reviewed: 11/21/18, 5/19/21, 11/16/22, 11/17/23, 9/20/24, 9/19/25
Effective Date: 1/1/19, 6/15/21, 10/15/24

Verquvo® (vericiguat)
Prior Authorization Guidelines

Affected Medication(s)

- Verquvo oral tablet

FDA Approved Indication(s)

- Reduce 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%

Dosing

- Initial: 2.5 mg once daily with meals
- Target maintenance dose: 10 mg once daily

Initial Authorization Criteria

1. Is the request for continuation of Verquvo (vericiguat) therapy?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA-approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member aged 18 years of age or older?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have NYHA class II-IV heart failure with a left ventricular ejection fraction of 45% or less? (Provide lab for review)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have a worsening heart failure event defined as one of the following?
    - History of a previous heart failure hospitalization within the last 6 months
    - Use of outpatient IV diuretics for heart failure within the last 3 months

    a. If yes, continue to #6
    b. If no, clinical review required
6. Is the member currently taking a drug from each of the following classes at the maximum tolerated dose unless contraindicated? (Provide supporting documentation)
    - Beta Blocker: carvedilol 25mg twice daily, metoprolol succinate 200mg/day
    - ACE inhibitor/ARB/ARNI: captopril 50mg three times daily, enalapril 10mg twice daily, lisinopril 20-40mg/day, ramipril 5mg twice daily, losartan 150mg/day, Entresto sacubitril 97mg/valsartan 103mg twice daily

Last Reviewed: 5/19/21, 7/20/22, 7/21/23, 7/19/24, 7/18/25
Effective Date: 6/15/21, 9/1/22, 8/15/24

- Mineralocorticoid receptor agonist: spironolactone 25mg/day

a. If yes, continue to #7
b. If no, clinical review required

7. Does the member have documentation of an inadequate response, intolerance, or contraindication to Jardiance (empagliflozin) or Farxiga (dapagliflozin)?

a. If yes, continue to #8
b. If no, clinical review required

8. Is the treatment being prescribed by or in consult with a cardiologist?

a. If yes, approve for 6 months unless otherwise specified
b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA-approved or major compendia supported indication? (Provide documentation of diagnosis)

a. If yes, continue to #2
b. If no, clinical review required

2. Is the treatment being prescribed by or in consultation with a cardiologist?

a. If yes, continue to #3
b. If no, clinical review required

3. Is documentation provided that the member is experiencing successful response to Verquvo? (Provide updated clinical information for review such as reduction in HF hospitalizations compared to baseline, improvement in HF symptoms, reduction in need for IV diuretics etc.)

a. If yes, approve for 12 months unless otherwise specified
b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. VERQUVO (vericiguat) tablets, [package insert]. Rahway, NJ: Merck Sharp Dohme.; November 2024.
2. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 22 MAR. 2021].
3. Armstrong PW, Roessig L, Patel MJ, Anstrom KJ, Butler J, Voors AA, Lam CSP, Ponikowski P, Temple T, Pieske B, Ezekowitz J, Hernandez AF, Koglin J, O'Connor CM. A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial of the Efficacy and Safety of the Oral Soluble Guanylate Cyclase Stimulator: The VICTORIA Trial. JACC Heart Fail. 2018 Feb;6(2):96-104. doi: 10.1016/j.jchf.2017.08.013. Epub 2017 Oct 11. PMID: 29032136.
4.

Last Reviewed: 5/19/21, 7/20/22, 7/21/23, 7/19/24, 7/18/25
Effective Date: 6/15/21, 9/1/22, 8/15/24

Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines [published correction appears in Circulation. 2022 May 3;145(18):e1033 [published correction appears in Circulation. 2022 Sep 27;146(13):e185.] [published correction appears in Circulation. 2023 Apr 4;147(14):e674.]. Circulation. 2022;145(18):e895-e1032.Authors/Task Force Members:, McDonagh TA, Metra M, et al. 2023 Focused Update of the 2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure: Developed by the task force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC) With the special contribution of the Heart Failure Association (HFA) of the ESC. *Eur J Heart Fail*. 2024;26(1):5-17.

Vigabatrin
Prior Authorization Guidelines

Affected Medication(s)

- Sabril oral tablet
- Sabril oral packet
- Vigabatrin oral tablet
- Vigabatrin oral packet
- Vigadrone oral packet
- Vigafyde oral solution
- Vigpoder oral packet

FDA Approved Indication(s)

- Adjunctive therapy in patients 2 years of age or older with refectory complex partial seizures who had an inadequate response to several alternative treatments
  - Sabril, vigabatrin, Vigadrone, Vigpoder
- As monotherapy in infants 1 month to 2 years of age with infantile spasms for whom the potential benefits outweigh the potential risk of vision loss
  - Sabril, vigabatrin, Vigadrone, Vigafyde, Vigpoder

Dosing

Refractory Complex Partial Seizures:

- Pediatric (≥2 years of age to adolescents ≤16 years):
  - 10 to 15kg: 175mg twice daily initially, maintenance dose 525mg twice daily
  - >15 to 20kg: 225mg twice daily initially, maintenance dose 650mg twice daily
  - >20 to 25kg: 250mg twice daily initially, maintenance dose 750mg twice daily
  - >25kg to 60kg: 250mg twice daily initially, maintenance dose 1000mg twice daily
- Adolescents ≤16 years and weighing >60 kg or Adolescents ≥17 years:
  - 500 mg twice daily initially, maintenance 1,500 mg twice daily

Infantile Spasms: maximum daily dose of 150 mg/kg

Initial Authorization Criteria

1. Is the request for continuation of vigabatrin therapy for the same indication?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2
2. Review submitted diagnosis and verify criteria below:
   a. Refractory complex partial seizures, continue to corresponding criteria
   b. Infantile Spasm, continue to corresponding criteria
   c. Other indication, clinical review required

Refractory Complex Partial Seizures

1. Did the member have inadequate seizure control with at least TWO of the following anticonvulsants in the past: felbamate, lamotrigine, levetiracetam, oxcarbazepine, gabapentin, topiramate, tiagabine, zonisamide, or lacosamide? (Provide history of seizure therapy)

Last Reviewed: 10/3/18, 11/20/19, 7/20/22, 5/19/23, 3/15/24, 9/20/24, 9/19/25
Effective Date: 1/1/19, 1/1/20, 9/1/22, 7/1/23, 4/15/24, 10/15/24

a. If yes, continue to #2
b. If no, clinical review required

2. Is documentation provided that indicates potential benefits from treatment outweigh the risk of vision loss? (Documentation must confirm member was educated on the risk of vision loss)

    a. If yes, continue to #3
    b. If no, clinical review required

3. Was a baseline vision assessment completed?

    a. If yes, continue #4
    b. If no, clinical review required

4. Is the medication being prescribed by or in consultation with a neurologist who is certified with the Vigabatrin REMS program?

    a. If yes, approve for 12 months, unless otherwise specified
    b. If no, clinical review required

Infantile Spasms

1. Does documentation indicate potential benefits from treatment outweigh the risk of vision loss? (Documentation must confirm that member's parent or guardian was educated on the risk of vision loss)

    a. If yes, continue to #2
    b. If no, clinical review required

2. Is the medication being prescribed by or in consultation with a neurologist who is certified with the Vigabatrin REMS program?

    a. If yes, approve for 2 months, unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is vigabatrin being prescribed for an FDA-approved indication or major compendia supported use? (Provide documentation of diagnosis)

    a. If yes, continue to #2
    b. If no, clinical review required

2. Were updated chart notes provided (within 1 year) of clinical response to therapy with documentation of a routine vision assessment performed every 3 months? (Provide documentation of reduction in seizures/infantile spasms)

    a. If yes, continue to #3
    b. If no, clinical review required

3. Is the medication being prescribed by or in consultation with a neurologist who is certified with the Vigabatrin REMS program?

    a. If yes, approve for 12 months, unless otherwise specified
    b. If no, clinical review required

Last Reviewed: 10/3/18, 11/20/19, 7/20/22, 5/19/23, 3/15/24, 9/20/24, 9/19/25
Effective Date: 1/1/19, 1/1/20, 9/1/22, 7/1/23, 4/15/24, 10/15/24

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Sabril (vigabatrin) [Prescribing Information]. Deerfield, IL: Lundbeck. February 2022.
2. Sabril. Micromedex. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com.
3. Vigadrone [package insert]. Maple Grove, MC: Upsher-Smith Laboratories, LLC; July 2025.
4. Vigafyde [package insert]. Parsippany, NJ: Pyros Pharmaceuticals, Inc; February 2025.
5. Glaze, MD. Management and prognosis of infantile spasms. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com.
6. National Institute for Health and Care Excellence (NICE): Epilepsies: diagnosis and management. National Institute for Health and Care Excellence (NICE). London, United Kingdom. Available at: https://www.nice.org.uk/guidance/cg137/resources/epilepsies-diagnosis-and-management-35109515407813.
7. Kanner AM, Ashman E, Gloss D, et al. Practice guideline update summary: Efficacy and tolerability of the new antiepileptic drugs II: Treatment-resistant epilepsy: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology and the American Epilepsy Society. *Neurology*. 2018;91(2):82-90.

Last Reviewed: 10/3/18, 11/20/19, 7/20/22, 5/19/23, 3/15/24, 9/20/24, 9/19/25
Effective Date: 1/1/19, 1/1/20, 9/1/22, 7/1/23, 4/15/24, 10/15/24

Vijoice® (alpelisib)
Prior Authorization Guidelines

Affected Medication(s)

- Vijoice (alpelisib) oral tablet
- Vijoice (alpelisib) granule packet

FDA Approved Indication(s)

- Treatment of adult and pediatric patients 2 years of age and older with severe manifestations of PIK3CA-Related Overgrowth Spectrum (PROS)

Dosing

- Adult: 250mg once daily until disease progression or unacceptable toxicity
- Pediatric: Initial dose of 50mg once daily, with a potential to increase to 125mg once daily after 24 weeks in patients 6-17 years old

Initial Authorization Criteria

1. Is the request for continuation of Vijoice (alpelisib) therapy?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA-approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member aged 2 years of age or older?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have documentation of PIK3CA-Related Overgrowth Spectrum (PROS) with confirmed PIK3CA gene mutation? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have severe clinical manifestations resulting from a lesion associated with PROS and is the lesion both inoperable and causing functional impairment? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Has the member previously trialed sirolimus for at least 6 months with inadequate response or does the member have a documented intolerance or contraindication to sirolimus? (Note: inadequate response defined as continuing to have severe clinical manifestations resulting from the lesion with the lesion being inoperable and causing functional impairment despite current treatment)
    a. If yes, continue to #7

Last Reviewed: 7/20/22, 7/21/23, 7/19/24, 7/18/25
Effective Date: 9/1/22,8/15/24

b. If no, clinical review required

7. Is Vijoice (alpelisib) being prescribed by, or in consult with, a specialist with experience in the treatment of PROS?
   a. If yes, approve for 6 months
   b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA-approved or major compendia supported indication? (Provide documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required
2. Is the treatment being prescribed by, or in consultation with, a specialist with experience in the treatment of PROS?
   a. If yes, continue to #3
   b. If no, clinical review required
3. Were updated chart notes (within the past year) provided with documentation of significant clinical response to therapy defined by the following? (Provide supporting documentation)
   - ≥20 % reduction from baseline in the sum of measurable target lesion volume confirmed by imaging
   - Absence of a ≥20% increase from baseline in any target lesion, progression of non-target lesions, or appearance of new lesion

   a. If yes, approve for 12 months
   b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. VIJOICE® (alpelisib) tablets, [package insert]. East Hanover, NJ: Novartis Pharmaceuticals; July 2024.
2. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 26 May. 2022].
3. Canaud, G., et al. "LBA23 EPIK-P1: Retrospective chart review study of patients (pts) with PIK3CA-related Overgrowth Spectrum (PROS) who have received alpelisib (ALP) as part of a compassionate use programme." Annals of Oncology 32 (2021): S1297.
4. Douzou S, Rawson M, Faivre L, et al. A standard of care for individuals with PIK3CA related disorders: an international expert consensus statement. Clinical Genetics. 2022; 101:32-47.
5. Canuad G, Hammill AM, Adams D, Vikkula M, and Keppler-Noreuil KM. A review of mechanisms of disease across PIK3CA-related disorders with vascular manifestations. Orphanet J Rare Dis. 2021;16:306.

Last Reviewed: 7/20/22, 7/21/23, 7/19/24, 7/18/25
Effective Date: 9/1/22, 8/15/24

6. Parker, Victoria ER, et al. "Safety and efficacy of low-dose sirolimus in the PIK3CA-related overgrowth spectrum." Genetics in Medicine 21.5 (2019): 1189-1198.

Last Reviewed: 7/20/22, 7/21/23, 7/19/24, 7/18/25
Effective Date: 9/1/22, 8/15/24

Vivjoa® (oteseconazole)
Prior Authorization Guidelines

Affected Medication(s)

- Vivjoa oral capsule

FDA Approved Indication(s)

- Reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVCC who are not of reproductive potential

Dosing

- Vivjoa only regimen: 600mg on day 1, 450mg on day 2, then 150mg once weekly for 11 weeks starting on day 14
- Fluconazole/Vivjoa regimen: fluconazole 150mg on day 1, 4, and 7. Vivjoa 150mg once daily for 7 days on days 14-20. Then, Vivjoa 150mg once weekly for 11 weeks starting on day 28.

Initial Authorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member have a diagnosis of recurrent vulvovaginal candidiasis defined by 3 or more episodes of vulvovaginal candidiasis in a 12 month period? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member a female of reproductive potential?
    a. If yes, clinical review required
    b. If no, continue to #4
4. Has the member trialed a minimum of 6-months of fluconazole therapy with persistent recurrent vulvovaginal candidiasis? (Provide supporting documentation)
    a. If yes, approve for 6 months
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. VIVJOA™ (oteseconazole) capsules, [package insert]. Durham, NC: Mycovia Pharmaceuticals, Inc.; April 2024.

Last Reviewed: 9/21/22, 9/15/23, 9/20/24, 9/19/25
Effective Date: 11/1/22, 10/15/24

2. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 3 Aug. 2022].
3. Martens, Mark G., et al. "Phase 3 Study of the Safety and Efficacy of Oteseconazole in Treatment of Recurrent Vulvovaginal Candidiasis and Efficacy vs Fluconazole in Treatment of Acute Vulvovaginal Candidiasis Infections." American Journal of Obstetrics and Gynecology (2022).
4. Pappas, Peter G., et al. "Clinical practice guideline for the management of candidiasis: 2016 update by the Infectious Diseases Society of America." Clinical Infectious Diseases 62.4 (2016): e1-e50.

VMAT2 Inhibitors
Prior Authorization Guidelines

Affected Medication(s)

- Austedo (deutetrabenazine) oral tablet
- Austedo XR (deutetrabenazine) oral tablet
- Tetrabenazine oral tablet
- Xenazine (tetrabenazine) oral tablet
- Ingrezza (valbenazine) oral capsule
- Ingrezza (valbenazine) sprinkle capsule

FDA Approved Indication(s)

- **Austedo, Austedo XR:**
  - For the treatment of chorea associated with Huntington's disease
  - For the treatment of tardive dyskinesia in adults
- **Xenazine (tetrabenazine):**
  - For the treatment of chorea associated with Huntington's disease
- **Ingrezza:**
  - For the treatment of adults with chorea associated with Huntington's disease
  - For the treatment of tardive dyskinesia in adults

Dosing

- Refer to package insert for recommended dosing

Initial Authorization Criteria

1. Is the request for continuation of vesicular monoamine transporter 2 (VMAT2) inhibitor therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
   a. If yes, continue to #3
   b. If no, clinical review required
3. What is the diagnosis the medication is being requested for?
   a. Chorea associated with Huntington's disease, continue to corresponding criteria
   b. Tardive dyskinesia, continue to corresponding criteria
   c. Other indication, continue to corresponding criteria

Chorea associated with Huntington's Disease

1. Does the member have a diagnosis of Huntington's disease as defined by ALL of the following? (Provide supporting documentation)
   - DNA testing showing CAG expansion of $\geq$ 36
   - Family history (if known)

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- Classic presentation (choreiform movements, psychiatric problems, and dementia)

a. If yes, continue to #2
b. If no, clinical review required

2. Is the member's chorea causing functional impairment in activities of daily life? (Provide supporting documentation)

a. If yes, continue to #3
b. If no, clinical review required

3. Is Austedo (deutetrabenazine), Austedo XR, or Ingrezza (valbenazine) being requested?

a. If yes, continue to #4
b. If no, continue to #5

4. Does the member have a trial with insufficient response, intolerance, or contraindication to tetrabenazine? (Provide documentation of trial with inadequate response, intolerance, or contraindication)

a. If yes, continue to #5
b. If no, clinical review required

5. Does the member have any of the following contraindications to the requested treatment?

- Suicidal, or have untreated or inadequately treated depression
- Hepatic impairment
- Taking concurrently with monoamine oxidase inhibitors (MAOIs) or reserpine
- Taking concurrently with other VMAT2 inhibitors

a. If yes, clinical review required
b. If no, continue to #6

6. Is the treatment being prescribed by, or in consultation with, a neurologist?

a. If yes, approve for 3 months unless otherwise specified
b. If no, clinical review required

<u>Tardive dyskinesia</u>

1. Has the patient been taking a dopamine receptor blocking agent for at least 3 months that contributed to the diagnosis? (Provide current/past medication history)

a. If yes, continue to #2
b. If no, clinical review required

2. Does the member have a diagnosis of moderate to severe tardive dyskinesia as defined by an Abnormal Involuntary Movement Scale (AIMS) score of ≥8 or an Extrapyramidal Symptom Rating Scale (ESRS) score of ≥20? (Provide supporting documentation and movement scale score)

a. If yes, continue to #3
b. If no, clinical review required

3. Is Austedo (deutetrabenazine) or Austedo XR being requested?

a. If yes, continue to #4
b. If no, continue to #5

4. Does the member have a trial with insufficient response, intolerance, or contraindication to Ingrezza (valbenazine)? (Provide documentation of trial with inadequate response, intolerance, or contraindication)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have any of the following contraindications to the requested treatment?
    - Suicidal, or have untreated or inadequately treated depression
    - Hepatic impairment
    - Taking concurrently with monoamine oxidase inhibitors (MAOIs) or reserpine
    - Taking concurrently with other VMAT2 inhibitors

    a. If yes, clinical review required
    b. If no, continue to #6
6. Is the treatment being prescribed by, or in consult with, a psychiatrist or neurologist?
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Other Indications

1. Has the member tried and had an inadequate response OR does the member have a contraindication to ALL standard treatment options for the requested indication? (Provide all prior treatment history, contraindication if appropriate, and treatment plan)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member have any of the following contraindications to the requested treatment?
    - Suicidal, or have untreated or inadequately treated depression
    - Hepatic impairment
    - Taking concurrently with monoamine oxidase inhibitors (MAOIs) or reserpine
    - Taking concurrently with other VMAT2 inhibitors

    a. If yes, clinical review required
    b. If no, approve for 6 months unless otherwise specified

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required

Last Reviewed: 11/7/18, 7/21/21, 11/16/22, 11/17/23, 5/17/24, 5/16/25
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2. Does the member demonstrate a positive clinical response to therapy as defined by a decrease in chorea causing functional impairment OR an improvement in AIMS score of 2 or more points or improvement in ESRI score of 4 or more points compared to baseline? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the treatment being prescribed by, or in consult with, a neurologist or psychiatrist?
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Ingrezza Prescribing Information. San Diego, CA: Neurocrine Biosciences, Inc. August 2022. Available at http://www.ingrezza.com.
2. Smith HS, Cox LR, Smith BR. Dopamine receptor antagonists. Annals of Palliative Medicine. July 2012; 1(2). DOI: 10.3978/j.issn.2224-5820.2012.07.09.
3. Bhidayasiri R, Fahn S, Weiner WJ, et al. Evidence-based guideline: Treatment of tardive syndromes. Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2013; 31: 463-469.
4. Xenazine (tetrabenazine) [Prescribing Information]. Deerfield, IL: Lundbeck Pharmaceuticals LLC. September 2017.
5. Austedo (deutetrabenazine) [Prescribing Information]. North Wales, PA: Teva Neuroscience, Inc. May 2022.
6. Xenazine. Micromedex. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com.
7. Arya, D., Khan, T., Margolius, A., & Fernandez, H. (2019). Tardive Dyskinesia: Treatment Update. Current Neurology and Neuroscience Reports, 19(9). doi: 10.1007/s11910-019-0976-1

Last Reviewed: 11/7/18, 7/21/21, 11/16/22, 11/17/23, 5/17/24, 5/16/25
Effective Date: 1/1/19, 12/20/23, 6/15/24

Vowst® (fecal microbiota spores, live-brpk)
Prior Authorization Guidelines

Affected Medication(s)

- Vowst (fecal microbiota spores, live-brpk) oral capsules

FDA Approved Indication(s)

- To prevent the recurrence of Clostridioides difficile infection (CDI) in individuals 18 years of age and older following antibiotic treatment for recurrent CDI (rCDI)

Dosing

- 4 capsules orally once daily for 3 consecutive days

Initial Authorization Criteria

1. Is Vowst (fecal microbiota spores, live-brpk) being requested for an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the member 18 years of age or older?
    a. If yes, continue to #3
    b. If no, clinical review required
3. Has the member had a previous treatment course of Vowst for recurrent CDI?
    a. If yes, clinical review required
    b. If no, continue to #4
4. Has the member had 3 or more episodes of CDI within the past 12 months that were treated with oral vancomycin and/or Dificid (fidaxomicin)? (CDI defined as diarrhea for 2+ days and a confirmatory C. difficile toxin assay) (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Will the member have completed antibiotic treatment for recurrent CDI within 2 to 4 days prior to starting Vowst with resolution of active CDI? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Does the treatment plan include the use of magnesium citrate on the day before and at least 8 hours prior to taking the first dose of Vowst?
    a. If yes, continue to #7
    b. If no, clinical review required
7. Is the treatment being prescribed by, or in consultation with, a gastroenterologist or infectious disease specialist?
    a. If yes, approve for 7 days
    b. If no, clinical review required

Last Reviewed: 7/21/23, 7/19/24, 7/18/25
Effective Date: 9/15/23, 8/15/24

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. VOWST (fecal microbiota spores, live-brpk) capsules, [package insert]. Cambridge, MA: Seres Therapeutics, Inc; 2025.
2. Drugs@FDA: FDA Approved Drug Products. 2023. https://www.fda.gov/vaccines-blood-biologics/vowst [online] Available at: https://www.fda.gov/vaccines-blood-biologics/vowst [Accessed 14 Jun. 2023].
3. Kelly CR, Fischer M, Allegretti JR, et al. ACG Clinical Guidelines: Prevention, Diagnosis, and Treatment of Clostridioides difficile Infections [published correction appears in Am J Gastroenterol. 2022 Feb 1;117(2):358]. Am J Gastroenterol. 2021;116(6):1124-1147.
4. McDonald LC, Gerding DN, Johnson S, et al. Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA). Clin Infect Dis. 2018;66(7):e1-e48.
5. Johnson S, Lavergne V, Skinner AM, et al. Clinical Practice Guideline by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA): 2021 Focused Update Guidelines on Management of Clostridioides difficile Infection in Adults. Clin Infect Dis. 2021;73(5):e1029-e1044.

Last Reviewed: 7/21/23, 7/19/24, 7/18/25

Effective Date: 9/15/21, 8/15/24

Voxzogo® (vosoritide)
Prior Authorization Guidelines

Affected Medication(s)

- Voxzogo (vosoritide subcutaneous solution)

FDA Approved Indication(s)

- To increase linear growth in pediatric patients with achondroplasia who are 5 years of age and older with open epiphyses

Dosing

- Refer to package insert for weight based dosing

Initial Authorization Criteria

1. Is the request for continuation of a previously approved Voxzogo (vosoritide) prior authorization with the same indication as the previous approval?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member age 5 to 17 years old?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have a diagnosis of achondroplasia confirmed by molecular testing of FGFR3 gene? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is the member's baseline height and growth velocity provided and is the member's growth velocity at least 1.5cm/yr? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Is there documentation of open epiphyses? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, clinical review required

Last Reviewed: 3/16/22, 3/17/23, 3/15/24, 3/21/25
Effective Date: 4/15/22, 4/15/24

7. Has the member previously had or planning to have limb lengthening surgery? (Provide supporting documentation)
    a. If yes, clinical review required
    b. If no, continue to #8
8. Is the medication being prescribed by, or in consultation with, a pediatric endocrinologist, orthopedist, or other prescriber specialized in the treatment of achondroplasia?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is Voxzogo (vosoritide) being requested for an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is there documentation of continued open epiphyses? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Has there been an increase in growth velocity compared to baseline and does the member's growth velocity remain greater than 1.5cm/yr? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the medication being prescribed by, or in consultation with, a pediatric endocrinologist, orthopedist, or other prescriber specialized in the treatment of achondroplasia?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. VOXZOGO (vosoritide) for injection, [package insert]. Novato, CA: BioMarin Pharmaceutical, Inc; 2024.
2. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 09 Dec. 2021].
3. Pauli, Richard M. "Achondroplasia: a comprehensive clinical review." Orphanet Journal of Rare Diseases 14.1 (2019): 1-49.
4. Ornitz, David M., and Laurence Legeai-Mallet. "Achondroplasia: Development, pathogenesis, and therapy." Developmental dynamics 246.4 (2017): 291-309.

Last Reviewed: 3/16/22, 3/17/23, 3/15/24, 3/21/25
Effective Date: 4/15/22, 4/15/24

Vykat XR (diazoxide choline)
Prior Authorization Guidelines

Affected Medication(s)

- Vykat XR (diaxozide choline) oral tablet

FDA Approved Indication(s)

- Treatment of hyperphagia in adults and pediatric patients 4 years of age and older with Prader-Willi syndrome (PWS)

Dosing

- Refer to package insert for dosing recommendations

Initial Authorization Criteria

1. Is the request for continuation of therapy with the same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member have documentation of genetically confirmed Prader-Willi Syndrome? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Has the member been assessed at baseline using the caregiver Hyperphagia Questionnaire for Clinical Trials (HQ-CT) assessment? (Provide baseline score)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is Vykat XR (diazoxide choline) being prescribed by, or in consultation with, an endocrinologist or other specialist with experience treating Prader-Willi Syndrome?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (within past year) provided with documentation of significant clinical response to therapy received? (i.e. improvement in Hyperphagia Questionnaire for Clinical Trials (HQ-CT) assessment)
    a. If yes, continue to #3

Last Reviewed: 7/18/25
Effective Date: 8/1/25

b. If no, clinical review required

3. Is Vykat XR (diazoxide choline) being prescribed by, or in consultation with, an endocrinologist or other specialist with experience treating Prader-Willi Syndrome?

   a. If yes, approve for 12 months
   b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. VYKAT™ XR (diazoxide choline) extended-release tablets [package insert]. Redwood City, CA: Soleno Therapeutics, Inc; 2025.
2. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 17 Apr. 2025].
3. Butler MG, Miller JL, Forster JL. Prader-Willi Syndrome - Clinical Genetics, Diagnosis and Treatment Approaches: An Update. Curr Pediatr Rev. 2019;15(4):207-244.
4. Miller JL, Gevers E, Bridges N, et al. Diazoxide choline extended-release tablet in people with Prader-Willi syndrome: results from long-term open-label study. Obesity (Silver Spring). 2024;32(2):252-261.

Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase)
Prior Authorization Guidelines

Affected Medication(s)

- Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase, human recombinant) subcutaneous injection prefilled syringe

FDA Approved Indication(s)

- Treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive
- Treatment of adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP)

Dosing

- Generalized myasthenia gravis (gMG): 1,000 mg / 10,000 units (1,000 mg efgartigimod alfa and 10,000 units hyaluronidase) administered subcutaneously cycles of once weekly injections for 4 weeks
- Chronic inflammatory demyelinating polyneuropathy (CIDP): 1,000 mg / 10,000 units (1,000 mg efgartigimod alfa and 10,000 units hyaluronidase) administered subcutaneously once weekly

Note:

- Vial is to be administered by a healthcare professional only
- Prefilled syringe may be administered by patients and/or caregivers after proper instruction

Initial Authorization Criteria

1. Is the request for continuation of therapy with the same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Will the requested medication be used concurrently with any other biologic therapy?
    a. If yes, clinical review required
    b. If no, continue to #4
4. What is the diagnosis that the medication is being requested for?
    a. Generalized myasthenia gravis (gMG), continue to corresponding criteria
    b. Chronic inflammatory demyelinating polyneuropathy (CIDP), continue to corresponding criteria

Generalized myasthenia gravis (gMG)

1. Does the member have Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of Class II to IV disease? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required

Last Reviewed: 9/19/25
Effective Date: 10/31/25

2. Does the member have a positive serologic test for anti-acetylcholine receptor (AChR) antibodies? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Has the member had a thymectomy? (Note: Applicable only to patients with thymomas OR non-thymomatous patients who are 50 years of age or younger)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have an MG-Activities of Daily Living (MG-ADL) total score of 5 or greater? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Will the member avoid medications known to worsen or exacerbate symptoms of MG (e.g., certain antibiotics, beta-blockers, botulinum toxins, hydroxychloroquine, etc.)? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Has the member had an inadequate response, intolerance, or contraindication to pyridostigmine? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Has the member had an inadequate response, intolerance, or contraindication to a trial of at least six months with concurrent use of an oral corticosteroid with an immunosuppressive therapy (e.g., corticosteroids plus an immunosuppressant such as azathioprine, cyclosporine, mycophenolate, etc.) or has the member required at least one acute or chronic treatment with plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG) in addition to immunosuppressant therapy?
    a. If yes, continue to #8
    b. If no, clinical review required
8. Does the patient have an immunoglobulin G (IgG) deficiency requiring supplementation with IgG?
    a. If yes, clinical review required
    b. If no, continue to #9
9. Is Vyvgart Hytrulo being prescribed by, or in consultation with, a neurologist or specialist experienced in treating myasthenia gravis?
    a. If yes, approve for 4 weeks
    b. If no, clinical review required

Chronic inflammatory demyelinating polyneuropathy (CIDP)

1. Does the member have confirmation of CIDP based on electrodiagnostic testing indicating demyelination with one of the following: (Provide test results)
    - Partial motor conduction block in at least 2 motor nerves or in 1 nerve plus one other demyelination criterion listed here in at least 1 other nerve
    - Distal CMAP duration increase in at least 1 nerve plus one other demyelination criterion listed here in at least 1 other nerve

- Abnormal temporal dispersion conduction must be present in at least 2 motor nerves
- Reduced motor conduction velocity in at least 2 motor nerves
- Prolonged distal motor latency in at least 2 motor nerves
- Absent F wave in at least 2 motor nerves plus one other demyelination criterion listed here in at least 1 other nerve
- Prolonged F wave latency in at least 2 motor nerves

a. If yes, continue to #2
b. If no, clinical review required

2. Has the member's disease course been progressive or relapsing and remitting for at least two months? (Provide supporting documentation)

a. If yes, continue to #3
b. If no, clinical review required

3. Does the member have decreased or absent deep tendon reflexes in upper or lower limbs? (Provide supporting documentation)

a. If yes, continue to #4
b. If no, clinical review required

4. Does the member have baseline strength or weakness documented using an objective clinical measuring tool? (Examples: 6-minute walk test, Rankin, Modified Rankin, Medical Research Council Muscle Strength, or other test) (Provide supporting documentation)

a. If yes, continue to #5
b. If no, clinical review required

5. Has the member had an inadequate response, intolerance, or contraindication to a trial of at least three months with plasma exchange (PE) therapy or immunoglobulin?

a. If yes, continue to #6
b. If no, clinical review required

6. Does the patient have an immunoglobulin G (IgG) deficiency requiring supplementation with IgG?

a. If yes, clinical review required
b. If no, continue to #7

7. Is Vyvgart Hytrulo being prescribed by, or in consultation with, a neurologist or specialist experienced in treating CIDP?

a. If yes, approve for 4 months
b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported? (Provide supporting documentation)

a. If yes, continue to #2
b. If no, clinical review required

2. What is the diagnosis that the medication is being requested for?

a. Generalized myasthenia gravis (gMG), continue to corresponding criteria

b. Chronic inflammatory demyelinating polyneuropathy (CIDP), continue to corresponding criteria

Generalized myasthenia gravis (gMG)

1. Will the next cycle of Vyvgart Hytrulo be initiated at least 50 days after the start of the last cycle of treatment?
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (after most recent treatment) provided with documentation of significant clinical response to therapy received? (Ex. improvement from baseline in Myasthenia Gravis-Specific Activities of Daily Living scale (MG-ADL) total score or Quantitative Myasthenia Gravis (QMG) total score) (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Did member experience new or worsening disease activity at least 4 weeks after the last dose, requiring continuous treatment?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is Vyvgart Hytrulo being prescribed by, or in consult with, a specialist experienced in treating myasthenia gravis?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Chronic inflammatory demyelinating polyneuropathy (CIDP)

1. Were updated chart notes (within past year) provided with documentation of significant clinical response to therapy received? (Ex. Improvement on objective clinical measuring tool such as 6-minute walk test, Rankin, Modified Rankin, Medical Research Council Muscle Strength, or other test)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is Vyvgart Hytrulo being prescribed by, or in consult with, a specialist experienced in treating CIDP?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. VYVGART HYTRULO (efgartigimod alfa and hyaluronidase) subcutaneous injection, [package insert]. Boston, MA: argenx US, Inc.; April 2025.

2. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis: Executive summary. Neurology. 2016;87(4):419-425.
3. Narayanaswami P, Sanders DB, Wolfe G, et al. International Consensus Guidance for Management of Myasthenia Gravis: 2020 Update. Neurology. 2021;96(3):114-122.
4. Howard JF Jr, Bril V, Vu T, et al. Safety, efficacy, and tolerability of efgartigimod in patients with generalised myasthenia gravis (ADAPT): a multicentre, randomised, placebo-controlled, phase 3 trial. *Lancet Neurol*. 2021;20(7):526-536.

Wake Promoting Agents
Prior Authorization Guidelines

Affected Medication(s)

- Lumryz (sodium oxybate) packets for oral suspension
- Wakix (pitolisant hydrochloride) oral tablets
- Xyrem® (sodium oxybate) 500 mg/mL oral solution
- Sodium oxybate 500 mg/mL solution
- Xywav® (sodium oxybate) 500 mg/mL oral solution

FDA Approved Indication(s)

- Lumryz, Xyrem, Xywav: Treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy
- Wakix:
  - Treatment of cataplexy or excessive daytime sleepiness (EDS) in adults with narcolepsy
  - Treatment of excessive daytime sleepiness (EDS) in pediatric patients 6 years of age and older with narcolepsy
- Xywav: Treatment of idiopathic hypersomnia in adults

Dosing

- Refer to corresponding package insert for dosing recommendations

Initial Authorization Criteria

1. Is the request for continuation of a previously approved agent for the same indication?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
   a. If yes, continue to #3
   b. If no, clinical review required
3. Is the requested drug FDA approved for this patient's age? (Note: policy covered agents have different FDA approved ages)
   a. If yes, continue to #4
   b. If no, clinical review required
4. Is the treatment prescribed by or in consultation with a sleep specialist (e.g. neurology, pulmonology)?
   a. If yes, continue to #5
   b. If no, clinical review required
5. Has this member's diagnosis been confirmed by overnight polysomnogram and multiple sleep latency test (MSLT)? (Note: narcolepsy may be confirmed by low levels of orexin or hypocretin within cerebrospinal fluid (<110pg/mL or less than one third of the normative value of the lab))
   a. If yes, continue to #6

Last Reviewed: 1/20/21, 5/18/22, 3/17/23, 7/21/23, 7/19/24, 7/18/25
Effective Date: 3/1/21, 7/15/22, 6/1/23, 9/15/23, 8/15/24, 8/1/25

b. If no, clinical review required

6. What is the predominant symptom causing this request?

    a. Excessive daytime somnolence, continue to #7
    b. Cataplexy, approve for 3 months
    c. Idiopathic hypersomnia, continue to #7
    d. Other, clinical review required

7. Has this member had a documented trial with insufficient response, intolerance, or contraindication to at least one medication in each of the following groups? (Note: Requests for idiopathic hypersomnia do not require trial of solriamfetol (Sunosi))

    - Group 1: Modafinil or Armodafinil
    - Group 2: Stimulants (e.g. Methylphenidate, dextroamphetamine/amphetamine, etc.)
    - Group 3: Solriamfetol (Sunosi®)

    a. If yes, continue to #8
    b. If no, clinical review required

8. Have all other causes of excessive daytime sleepiness been ruled out or treated (e.g. obstructive sleep apnea, restless leg syndrome, periodic limb movements, substance abuse, etc.)?

    a. If yes, approve for 3 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)

    a. If yes, continue to #2
    b. If no, clinical review

2. Were updated chart notes provided with documentation of significant clinical response to therapy (e.g. reduction in cataplexy events or reduction in Epworth Sleepiness Scale [ESS])?

    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Morgenthaler TI, Kapur VK, Brown T, et al. Practice parameters for the treatment of narcolepsy and other hypersomnias of central origin. Sleep. 2007;30(12): 1705-1711.

Last Reviewed: 1/20/21, 5/18/22, 3/17/23, 7/21/23, 7/19/24, 7/18/25
Effective Date: 3/1/21, 7/15/22, 6/1/23, 9/15/23, 8/15/24, 8/1/25

2. Billiard M, Bassetti C, Dauvilliers Y, et al. EFNS guidelines on management of narcolepsy. Eur J Neurol. 2006;13(10):1035-1048.
3. Barateau L, Lopez R, Dauvilliers Y. Treatment options for narcolepsy. CNS Drugs. 2016;30:369-379.
4. Barateau L, Dauvilliers Y. Recent advances in treatment for narcolepsy. Ther Adv Neurol Disord. 2019;12:1-12.
5. Thorpy M, Bogan R. Update on the pharmacologic management of narcolepsy: mechanisms of action and clinical implications. Sleep Medicine. 2020;68:97-109.
6. Bogan RK, Thorpy MJ, Dauvilliers Y, et al. Efficacy and safety of calcium, magnesium, potassium and sodium oxybates (lower-sodium oxybate [LXB]; JZP-258) in a placebo-controlled, double-blind, randomized withdrawal study in adults with narcolepsu with cataplexy. SleepJ. 2020:1-13.
7. Dauvilliers Y, Bassetti C, Lammars GJ, et al. Pitolisant versus placebo or modafinil in patients with narcolepsy: a double-blind, randomised trial. Lancet Neurol. 2013; 12:1068-1075.
8. Dauvilliers Y, Arnulf I, Szakacs Z, et al. Long-term use of pitolisant to treat patients with narcolepsy: Harmony III study. SleepJ. 2019; 42(11):1-11.
9. Szakacs A, Dauvilliers Y, Mikhaylov V, et al. Safety and efficacy of pitolisant on cataplexy in patients with narcolepsy: a randomised, double-blind, placebo-controlled trial. Lancet Neurol. 2017;16:200-207.
10. Wakix (pitolisant) [Prescribing Information]. Plymouth Meeting, PA. Harmony Biosciences, LLC. May 2025.
11. Xyrem (sodium oxybate) [Prescribing Information]. Palo Alto, CA. Jazz Pharmaceuticals, Inc. April 2023.
12. Xywav (calcium, magnesium, potassium and sodium oxybate) [Prescribing Information]. Palo Alto, CA. Jazz Pharmaceuticalsm Inc. April 2023.
13. Dauvilliers, Yves, et al. "Safety and efficacy of lower-sodium oxybate in adults with idiopathic hypersomnia: a phase 3, placebo-controlled, double-blind, randomised withdrawal study." The Lancet Neurology 21.1 (2022): 53-65.
14. Lumryz (sodium oxybate for suspension, extended release) [Prescribing Information]. Chesterfield, MO. Avadel CNS Pharmaceuticals, LLC. April 2025.

Wegovy® (semaglutide)
Prior Authorization Guidelines

Affected Medication(s)

- Wegovy subcutaneous solution

FDA Approved Indication(s)

- In combination with a reduced calorie diet and increased physical activity to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and either obesity or overweight
- In combination with a reduced calorie diet and increased physical activity to reduce excess body weight and maintain weight reduction long term in adults and pediatric patients aged 12 years and older with obesity and adults who are overweight in the presence of at least one weight-related comorbid condition
- Treatment of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH), with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) in adults

Dosing

- Initiation: 0.25 mg subcutaneously once weekly, titrated to maintenance dose
- Maintenance: 1.7 or 2.4 mg subcutaneously once weekly

Initial Authorization Criteria

1. Is the request for continuation of Wegovy (semaglutide) therapy for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. What indication is the medication being requested for?
    a. Weight Management, clinical review required
    b. Risk reduction of major adverse cardiovascular events, continue to corresponding criteria
    c. Metabolic dysfunction-associated steatohepatitis (MASH), continue to corresponding criteria
    d. Heart failure with preserved ejection fraction, continue to corresponding criteria

Risk reduction of major adverse cardiovascular events

1. Is the member 45 years of age or older?
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member have a BMI of 27 kg/m^2 or greater AND established cardiovascular disease (history of myocardial infarction, stroke, or symptomatic peripheral arterial disease)? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required

Last Reviewed: 5/17/24, 5/16/25, 9/19/25
Effective Date: 6/15/24, 6/1/25, 10/31/25

3. Is the member's current cardiovascular-related drug regimen (i.e. statin, antiplatelet, ACE-I, etc.) optimized and is the member adherent to this therapy? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the treatment plan include health behavior and lifestyle modifications including physical activity goals, nutritional education, and behavior change? (Provide supporting documentation)
    a. If yes, approve for 6 months
    b. If no, clinical review required

Metabolic dysfunction-associated steatohepatitis (MASH)

1. Does the member have a diagnosis of noncirrhotic nonalcoholic steatohepatitis (NASH) with liver fibrosis consistent with stage F2 or F3 as either confirmed by biopsy or noninvasive assessment such as fibrosis-4 index (FIB-4), enhanced liver fibrosis test (ELF), vibration controlled transient elastography (VCTE), or magnetic resonance elastography (MRE)? (Provide supporting documentation)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Have all other causes of hepatic steatosis been ruled out? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member enrolled in a program to address health behavior and lifestyle modifications including physical activity goals, nutritional education, and behavior change to support weight loss? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is there documentation that, if present, the member's hypertension, dyslipidemia, and/or Type 2 diabetes mellitus are being actively managed with medications or lifestyle modifications for each of these comorbidities? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is the member currently on a GLP-1 medication?
    a. If yes, clinical review required
    b. If no, approve for 6 months

Heart failure with preserved ejection fraction

1. Does the member have a BMI of 30 kg/m^2 or greater?
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member have a diagnosis of heart failure with New York Heart Association (NYHA) Class II-IV symptoms? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required

3. Does the member have a left ventricular ejection fraction of at least 45%? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have an HbA1C of 6.5% or greater? (Provide lab results)
    a. If yes, clinical review required
    b. If no, continue to #5
5. Is the member currently on a GLP-1 medication?
    a. If yes, clinical review required
    b. If no, continue to #6
6. Is the medication being prescribed by, or in consultation with, a cardiologist?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. What indication is the medication being requested for?
    a. Risk reduction of major adverse cardiovascular events, continue to #3
    b. Metabolic dysfunction-associated steatohepatitis (MASH), continue to #5
    c. Heart failure with preserved ejection fraction, continue to #8
3. Is there clinical documentation confirming positive response to therapy as defined as 5% weight loss or more from baseline? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the treatment plan include on-going, age-appropriate health behavior and lifestyle modifications? (Provide supporting documentation)
    a. If yes, approve for 12 months
    b. If no, clinical review required
5. Were updated chart notes (within past year) provided with documentation of significant clinical response to therapy received? (i.e. decrease in fibrosis stage, resolution of NASH, etc.)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Is there documentation that the member's comorbidities continue to be actively managed with medications or lifestyle modifications? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, clinical review required

7. Is the medication being prescribed by, or in consultation with, a hepatologist or gastroenterologist?
    a. If yes, approve for 12 months
    b. If no, clinical review required
8. Were updated chart notes (within past year) provided with documentation of clinical response? (Provide updated clinical information for review such as improvement in HF symptoms etc.)
    a. If yes, continue to #9
    b. If no, clinical review required
9. Is the medication being prescribed by, or in consultation with, a cardiologist?
    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Wegovy (semaglutide) [Prescribing Information]. Plainsboro, NJ: Novo Nordisk, Inc. August 2025.
2. Lincoff, A. Michael, et al. "Semaglutide and cardiovascular outcomes in obesity without diabetes." New England Journal of Medicine 389.24 (2023): 2221-2232.
3. Cusi K, Isaacs S, Barb D, et al. American Association of Clinical Endocrinology Clinical Practice Guideline for the Diagnosis and Management of Nonalcoholic Fatty Liver Disease in Primary Care and Endocrinology Clinical Settings: Co-Sponsored by the American Association for the Study of Liver Diseases (AASLD). Endocr Pract. 2022;28(5):528-562.
4. Kosiborod MN, Abildstrøm SZ, Borlaug BA, et al. Semaglutide in Patients with Heart Failure with Preserved Ejection Fraction and Obesity. *N Engl J Med*. 2023;389(12):1069-1084.

Xermelo® (telotristat ethyl)
Prior Authorization Guidelines

Affected Medication(s)

- Xermelo oral tablet

FDA Approved Indication(s)

- For the treatment of carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in adults inadequately controlled by SSA therapy

Dosing

- 250 mg three times daily

Initial Authorization Criteria

1. Is the request for continuation of Xermelo (telotristat) therapy?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member have at least a 1-month trial with insufficient response to a somatostatin analog (SSA) (i.e. octreotide, lanreotide) at the maximum indicated dose? (Provide documentation of relevant past medication history and insufficient response)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is Xermelo (telotristat) being prescribed in combination with a somatostatin analog (SSA)? (Provide documentation of treatment regimen)
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
2. Does the member demonstrate a positive clinical response to therapy defined as a reduction in bowel movement frequency or a reduction in urinary 5-hydroxyindoleacetic acid (5-HIAA) levels? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required

Last Reviewed: 11/7/18, 1/20/21, 3/17/23, 3/15/24, 3/21/25
Effective Date: 1/1/19, 3/1/21, 6/1/23, 4/15/24

3. Is Xermelo (telotristat) being prescribed in combination with a somatostatin analog (SSA) unless an intolerance or contraindication is present? (Provide documentation of treatment regimen)

    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Xermelo Prescribing Information. The Woodlands, TX: Lexicon Pharmaceuticals, Inc; October 2022. Available at: www.xermelo.com.
2. Kulke MH, Horsch D, Caplin ME, et al. Telotristat ethyl, a tryptophan hydroxylase inhibitor for the treatment of carcinoid syndrome. J Clin Oncol. 2016; 25(1): 14-23.
3. National Comprehensive Cancer Network. Neuroendocrine Tumors Version 4.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/neuroendocrine.pdf
4. Kunz PL, Reidy-Lagunes D, Anthony LB, et al. North American Neuroendocrine Tumor Society (NANETS) guidelines: consensus guidelines for the management and treatment of neuroendocrine tumors. Pancreas. 2013; 42: 557-577.

Last Reviewed: 11/7/18, 1/20/21, 3/17/23, 3/15/24, 3/21/25
Effective Date: 1/1/19, 3/1/21, 6/1/23, 4/15/24

Xifaxan® (rifaximin)
Prior Authorization Guidelines

Affected Medication(s)

- Xifaxan oral tablet

FDA Approved Indication(s)

- For the treatment of travelers' diarrhea (TD) caused by noninvasive strains of *Escherichia coli* in adults and pediatric patients 12 years of age and older
- For reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults
- For the treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults

Dosing

- Travelers' diarrhea: 200mg by mouth three times daily for 3 days
- Hepatic encephalopathy: 550mg by mouth twice daily or 400mg by mouth three times daily
- Irritable bowel syndrome with diarrhea: 550mg by mouth three times daily for 14 days
- Small intestinal bacterial overgrowth: 550mg by mouth three times daily for 14 days

Initial Authorization Criteria

1. Is the request for continuation of Xifaxan (rifaximin) therapy for treatment of hepatic encephalopathy?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. What is the diagnosis that Xifaxan is being prescribed for?
    a. Travelers' diarrhea, continue to corresponding criteria
    b. Hepatic encephalopathy, continue to corresponding criteria
    c. Irritable bowel syndrome with diarrhea, continue to corresponding criteria
    d. Small intestinal bacterial overgrowth (SIBO), continue to corresponding criteria
    e. Other indication, clinical review required

Travelers' diarrhea

1. Is the member 12 years of age or older?
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member have a trial with insufficient response, contraindication, or intolerance to azithromycin for the treatment of travelers' diarrhea? (Provide relevant past medication history or documentation of contraindication/intolerance)
    a. If yes, approve for 3 days

Last Reviewed: 11/7/18, 7/21/21, 7/20/22, 7/21/23, 7/19/24, 7/18/25
Effective Date: 1/1/19, 9/1/21, 9/1/22, 9/15/23, 8/15/24

b. If no, clinical review required

Hepatic encephalopathy

1. Is the member 18 years of age or older?
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member have a trial with insufficient response to lactulose in the past 30 days up to the maximum indicated dose? (Insufficient response defined as continued altered mental status) (Provide relevant past medication history)
    a. If yes, continue to #3
    b. If no, continue to #4
3. Will the member continue to take lactulose concurrently with Xifaxan?
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required
4. Does the member have an intolerance or contraindication to lactulose? (Provide documentation of contraindication/intolerance)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have altered mental status?
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Irritable bowel syndrome with diarrhea

1. Is the member 18 years of age or older?
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member have a trial with insufficient response, intolerance, or contraindication to loperamide at the maximal indicated dose? (Provide relevant past medication history or documentation of contraindication/intolerance)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member have a trial with insufficient response, intolerance, or contraindication to an antispasmodic agent at the maximal indicated dose? (i.e. dicyclomine) (Provide relevant past medication history or documentation of contraindication/intolerance)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Has the member had 3 or more previous Xifaxan (rifaximin) treatment courses for irritable bowel syndrome with diarrhea? (Provide relevant past medication history)

a. If yes, clinical review required
b. If no, approve for 14 days

Small intestinal bacterial overgrowth (SIBO)

1. Does the member have a diagnosis of small intestinal bacterial overgrowth (SIBO) confirmed by a positive carbohydrate breath test or a jejunal aspirate culture? (Provide supporting documentation)?
    a. If yes, continue to #2
    b. If no, clinical review required
2. Does the member have a trial with insufficient response, intolerance, or contraindication to ONE of the following: amoxicillin/clavulanate, ciprofloxacin, trimethoprim-sulfamethoxazole, metronidazole, doxycycline, or tetracycline? (Provide relevant past medication history or documentation of contraindication/intolerance)
    a. If yes, approve for 14 days
    b. If no, continue to #3
3. Does the member have methane-predominant bacterial overgrowth and Xifaxan will be used in combination with neomycin? (Provide supporting documentation)
    a. If yes, approve for 14 days
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is Xifaxan (rifaximin) being used concurrently with lactulose unless a contraindication or intolerance is present? (Provide current treatment regimen or documentation of contraindication/intolerance)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member responding positively to therapy as defined by a decrease in symptoms? (Provide supporting documentation)
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

Last Reviewed: 11/7/18, 7/21/21, 7/20/22, 7/21/23, 7/19/24, 7/18/25
Effective Date: 1/1/19, 9/1/21, 9/1/22, 9/15/23, 8/15/24

1. Xifaxan Prescribing Information. Bridgewater, NJ: Salix Pharmaceuticals; November 2024.
2. Vilstrup H, Amodio P, Bajaj J, et al. Hepatic encephalopathy in chronic liver disease: 2014 practice guideline by AASLD-EASL. Hepatology. 2014; 60 (2): 715-735.
3. Weinberg DS, Smalley W, Heidelbaugh JJ, Shahnaz S. American Gastroenterological Association Institute guideline on the pharmacological management of irritable bowel syndrome. Gastroenterology. 2014; 147: 1146-1149.
4. Riddle M, Connor B, Beeching N, et al. Guidelines for the prevention and treatment of travelers' diarrhea: a graded expert panel report. J Travel Med. 2017 Apr 1;24(suppl_1):S57-S74.
5. Centers for Disease Control and Prevention (CDC). CDC Yellow Book 2026: health information for international travel. Oxford University Press, 2025.
6. Pimentel, Mark, et al. "ACG clinical guideline: small intestinal bacterial overgrowth." Official journal of the American College of Gastroenterology| ACG 115.2 (2020): 165-178.

Last Reviewed: 11/7/18, 7/21/21, 7/20/22, 7/21/23, 7/19/24, 7/18/25
Effective Date: 1/1/19, 9/1/21, 9/1/22, 9/15/23, 8/15/24

Xolremdi (mavorixafor)
Prior Authorization Guidelines

Affected Medication(s)

- Xolremdi (mavorixafor) oral capsules

FDA Approved Indication(s)

- Treatment of WHIM syndrome (warts, hypogammaglobulinemia, infections and myelokathexis) in patients at least 12 years of age to increase the number of circulating mature neutrophils and lymphocytes

Dosing

- Less than or equal to 50 kg: 300 mg orally once daily
- Greater than 50 kg: 400 mg orally once daily

Initial Authorization Criteria

1. Is the request for continuation of therapy with the same medication for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member 12 years of age or older?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have documentation of a genotype-confirmed variant of CXCR4 consistent with WHIM syndrome? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the patient have documentation of absolute neutrophil count less than or equal to 400 cells/μL? (Provide supporting documentation)
    a. If yes, clinical review required
    b. If no, continue to #6
6. Is Xolremdi (mavorixafor) being prescribed by, or in consult with, an immunologist, hematologist, or provider specialized in treating WHIM syndrome?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide supporting documentation)

Last Reviewed: 9/20/24, 9/19/25
Effective Date: 10/15/24

a. If yes, continue to #2
b. If no, clinical review required

2. Were updated chart notes (within past year) provided with documentation of clinical response to prior therapy received? (i.e. increase in ANC, decrease in yearly infections, improvement in warts) (Provide supporting documentation)

    a. If yes, continue to #3
    b. If no, clinical review required

3. Is the treatment being prescribed by, or in consultation with, an immunologist, hematologist, or provider specialized in treating WHIM syndrome?

    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. XOLREMDI (mavorixafor) tablets [package insert]. Boston, MA: X4 Pharmaceuticals, Inc; 2024.
2. Drugs@FDA: FDA Approved Drug Products. 2024. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 15 May. 2024].
3. Badolato R, Donadieu J; WHIM Research Group. How I treat warts, hypogammaglobulinemia, infections, and myelokathexis syndrome. Blood. 2017;130(23):2491-2498.
4. Badolato R, Alsina L, Azar A, et al. Phase 3 randomized trial of mavorixafor, CXCR4 antagonist, in WHIM syndrome. Blood. Published online April 21, 2024.

Yorvipath (palopegteriparatide)
Prior Authorization Guidelines

Affected Medication(s)

- Yorvipath (palopegteriparatide) injection solution

FDA Approved Indication(s)

- Treatment of hypoparathyroidism in adults

Dosing

- Refer to package insert for recommended dosing

Initial Authorization Criteria

1. Is the request for continuation of Yorvipath (palopegteriparatide) therapy for the same indication?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member diagnosed with hypocalcemia due to chronic hypoparathyroidism (i.e. not acute post-surgical hypoparathyroidism)? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Have other causes of hypocalcemia (e.g. hyperthyroidism, Paget disease, malnutrition, chronic kidney disease, treatment with bisphosphonates) been ruled out?
    a. If yes, continue to #5
    b. If no, clinical review required
5. Has the member been adherent to minimum 1,000 mg of elemental calcium and 400 IU of vitamin D supplementation daily for a minimum of 6 months and unable to maintain normal serum-albumin corrected calcium? (Provide supporting documentation)
    a. If yes, continue to #6
    b. If no, clinical review required
6. Will the member continue calcium and vitamin D supplementation concurrently with Yorvipath until stable albumin-corrected serum calcium concentration has been achieved?
    a. If yes, continue to #7
    b. If no, clinical review required
7. Is the member's serum albumin corrected calcium greater than or equal to 7.8 mg/dL? (Provide lab values within the past 30 days)
    a. If yes, continue to #8

Last Reviewed: 11/15/24, 11/21/25
Effective Date: 1/1/25, 1/1/26

b. If no, clinical review required

8. Is the member's serum 25-hydroxyvitamin D ≥ 20 ng/mL (75 nmol/L)? (Provide lab values within the past 30 days)
    a. If yes, continue to #9
    b. If no, clinical review required
9. Is the treatment being prescribed by, or in consultation with, an endocrinologist?
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Are the member's serum calcium levels regularly monitored and appropriate dosage adjustments made to meet the patient specific therapeutic goal? (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member demonstrate a positive clinical response to therapy as defined by one of the following: (Provide labs results for review)
    - Albumin-Corrected Serum Calcium greater than 8.3 mg/dL within the last 90 days
    - Albumin-Corrected Serum Calcium greater than 10.7 mg/dL within the last 90 days and Yorvipath dose is being decreased

    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the treatment being prescribed by, or in consultation with, an endocrinologist?
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. YORVIPATH (palopegteriparatide) injection, [package insert]. Princeton, NJ: Ascendis Pharma; 2024.
2. Brandi ML, Bilezikian JP, Shoback D, et al. Management of Hypoparathyroidism: Summary Statement and Guidelines. J Clin Endocrinol Metab. 2016;101(6):2273-2283.

Zelapar® (selegiline hydrochloride)
Prior Authorization Guidelines

Affected Medication(s)

- Zelapar oral disintegrating tablet

FDA Approved Indication(s)

- As an adjunct in the management of patients with Parkinson's disease being treated with levodopa/carbidopa who exhibit deterioration in the quality of their response to this therapy

Dosing

- Initially, 1.25 mg once daily for at least 6 weeks
- May increase dose to 2.5 mg once daily after initial 6 weeks

Initial Authorization Criteria

1. Is the request for continuation of Zelapar (selegiline hydrochloride) therapy?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member currently on levodopa/carbidopa therapy that will be continued concurrently with requested medication? (Provide relevant medication history and treatment plan)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Is the member experiencing a deterioration in the quality of their clinical response to levodopa/carbidopa? (Provide supporting documentation of a decline in response to levodopa/carbidopa demonstrated by at least 3 hours of "off" time per day)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have a trial with inadequate response to, or rationale for avoiding therapy with, BOTH generic selegiline oral tablets/capsules and generic rasagiline oral tablets? (Provide supporting documentation of trials with inadequate responses)
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)

Last Reviewed: 11/21/18, 1/20/21, 5/19/23, 5/17/24, 5/16/25
Effective Date: 1/1/19, 3/1/21

a. If yes, continue to #2
b. If no, clinical review required

2. Is the member currently on levodopa/carbidopa therapy that will be continued concurrently with requested medication? (Provide relevant medication history and treatment plan)

   a. If yes, continue to #3
   b. If no, clinical review required

3. Does the member have a positive clinical response to therapy as defined by a decrease in frequency or duration of "off" episodes? (Provide supporting documentation of a decrease in frequency or duration of off episodes)

   a. If yes, approve for 12 months unless otherwise specified
   b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Zelapar (selegiline) [prescribing information.] Bridgewater, NJ: Bausch Health US, LLC; June 2021.

Last Reviewed: 11/21/18, 1/20/21, 5/19/23, 5/17/24, 5/16/25
Effective Date: 1/1/19, 3/1/21, 6/15/24

Zepbound® (tirzepatide)
Prior Authorization Guidelines

Affected Medication(s)

- Zepbound subcutaneous solution

FDA Approved Indication(s)

- Indicated in combination with a reduced-calorie diet and increased physical activity:
  - To reduce excess body weight and maintain weight reduction long term in adults with obesity or adults with overweight in the presence of at least one weight-related comorbid condition
  - To treat moderate to severe obstructive sleep apnea (OSA) in adults with obesity

Dosing

- Initial dose: 2.5 mg subcutaneously once weekly
- Maintenance dose: 5mg, 7.5mg, 10mg, 12.5mg or 15mg subcutaneously once weekly

Initial Authorization Criteria

1. Is the request for continuation of Zepbound (tirzepatide) therapy for the same indication?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
   a. If yes, continue to #3
   b. If no, clinical review required
3. What indication is the medication being requested for?
   a. Weight Management, clinical review required
   b. Obstructive sleep apnea, continue #4
4. Does the member have moderate to severe sleep apnea defined by an CMS Apnea-Hypopnea index score of 15 or greater on polysomnogram testing? (CMS AHI measuring 4% or greater oxygen desaturation) (Provide supporting documentation)
   a. If yes, continue to #5
   b. If no, clinical review required
5. Does the member have a BMI of 30 kg/m^2 or greater? (Provide supporting documentation)
   a. If yes, continue to #6
   b. If no, clinical review required
6. Does the member have at least a 6-month trial of ALL of the following lifestyle modifications with continued symptoms? (Provide supporting documentation)
   - Reduced calorie diet (must provide documentation of recent consult with registered dietician)
   - Increased exercise (at least 150 minutes/week of moderate intensity physical activity)
   - Changing sleep position for positional OSA

Last Reviewed: 1/17/25, 11/21/25
Effective Date: 3/1/25, 1/1/26

- Avoidance of alcohol and other sedating medications

a. If yes, continue to #7
b. If no, clinical review required

7. Has the member been adherent with positive airway pressure (PAP) therapy (CPAP, BiPAP, autotitrating PAP), defined as use for greater than 4 hours/night for at least 70% of nights, for at least the last 3 months with inadequate effect (i.e. ongoing sleep apnea symptoms)? (Provide supporting documentation of adherence and ongoing symptoms)

    a. If yes, continue to #8
    b. If no, clinical review required

8. Does the member have diagnosis of diabetes?

    a. If yes, clinical review required
    b. If no, continue to #9

9. Is the member currently on a GLP-1 medication?

    a. If yes, clinical review required
    b. If no, continue to #10

10. Does the member have history of OSA related surgery?

    a. If yes, clinical review required
    b. If no, continue to #11

11. Is the treatment being prescribed by a practice that the member has an established relationship with and has seen the member for in person appointments at least every 12 months?

    a. If yes, approve for 12 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)

    a. If yes, continue to #2
    b. If no, clinical review required

2. What indication is the medication being requested for?

    a. Weight Management, clinical review required
    b. Obstructive sleep apnea, continue #3

3. Were updated chart notes (within the past 12 months) provided with documentation of response to therapy defined by AHI Score <15 or at least a 50% reduction in AHI Score from baseline? (Provide supporting documentation)

    a. If yes, continue to #4
    b. If no, clinical review required

4. Does member remain adherent with positive airway pressure (PAP) therapy (CPAP, BiPAP, autotitrating PAP), defined as use for greater than 4 hours/night for at least 70% of nights over the past 3 months? (Provide supporting documentation)

    a. If yes, continue to #5
    b. If no, clinical review required

5. Is the member adherent to BOTH of the following lifestyle modifications for the past 12 months? (Provide supporting documentation)

    - Reduced calorie diet
    - Increased exercise (at least 150 minutes/week of moderate intensity physical activity)

    a. If yes continue to #6
    b. If no, clinical review required

6. Is the treatment being prescribed by a practice that the member has an established relationship with and has seen the member for in person appointments at least every 12 months?

    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Zepbound [package insert]. Indianapolis, IN; Lilly USA, LLC; December 2024. Accessed January 2025.
2. Garvey, W. Timothy, et al. "Tirzepatide once weekly for the treatment of obesity in people with type 2 diabetes (SURMOUNT-2): a double-blind, randomised, multicentre, placebo-controlled, phase 3 trial." *The Lancet* 402.10402 (2023): 613-626.
3. Wadden, Thomas A., et al. "Tirzepatide after intensive lifestyle intervention in adults with overweight or obesity: the SURMOUNT-3 phase 3 trial." Nature medicine 29.11 (2023): 2909-2918.
4. Aronne, Louis J., et al. "Continued treatment with tirzepatide for maintenance of weight reduction in adults with obesity: the SURMOUNT-4 randomized clinical trial." Jama 331.1 (2024): 38-48.
5. Malhotra, Atul, et al. "Tirzepatide for the treatment of obstructive sleep apnea: Rationale, design, and sample baseline characteristics of the SURMOUNT-OSA phase 3 trial." *Contemporary Clinical Trials* 141 (2024): 107516.

Zeposia® (ozanimod)
Prior Authorization Guidelines

Affected Medication(s)

- Zeposia (ozanimod) capsule

FDA Approved Indication(s)

- For treatment of adult patients with relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
- For treatment of adult patients with moderately to severely active ulcerative colitis (UC)

Dosing

- 0.92 mg orally once daily

Initial Authorization Criteria

1. Is the request for continuation therapy?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Will the requested medication be used concurrently with other biologic or MS therapy? (examples: Enbrel, Dupixent, Cosentyx, Cimzia, Skyrizi, Otezla, Gilenya, etc)
    a. If yes, clinical review required
    b. If no, continue to #4
4. What is the diagnosis that the medication is being requested for?
    a. Multiple sclerosis, continue to corresponding criteria
    b. Ulcerative colitis, continue to corresponding criteria
    c. Other indication, clinical review required

Multiple Sclerosis (MS)

1. Is an MRI result consistent with multiple sclerosis received? (Provide MRI for review)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the member 18 years of age or older?
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member have a history of inadequate response, intolerance or contraindication to at least one drug from each of the following groups? (Provide supporting documentation)

Last Reviewed: 11/16/22, 7/21/23, 3/15/24, 3/21/25
Effective Date: 1/1/23, 9/15/23, 4/15/24, 4/1/25

- Glatiramer acetate
- Dimethyl fumarate or Teriflunomide
- Fingolimod

a. If yes, continue to #4
b. If no, clinical review required

4. Will the requested medication be used with other disease-modifying therapy for multiple sclerosis?
   a. If yes, clinical review required
   b. If no, continue to #5
5. Is the requested multiple sclerosis agent being prescribed by or in consultation with a neurologist?
   a. If yes, approve for 12 months unless otherwise specified
   b. If no, clinical review required

Ulcerative Colitis (UC)

1. Does the member currently have active Ulcerative Colitis? (Provide documentation of diagnosis confirmed by endoscopy, colonoscopy, or sigmoidoscopy with Mayo score of greater than 2)
   a. If yes, continue to #2
   b. If no, clinical review required
2. Does the member have a documented inadequate response, intolerance, or contraindication to TWO of the following: preferred adalimumab biosimilar, Simponi (golimumab), Skyrizi (risankuzumab), or Stelara (ustekinumab)? (Provide documentation of inadequate responses, contraindications, and/or intolerances)
   a. If yes, continue to #3
   b. If no, clinical review required
3. Is the medication being prescribed by, or in consultation with, a gastroenterologist?
   a. If yes, approve for 6 months unless otherwise specified
   b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required
2. Will the updated chart note (dated within 1 year) provided with documentation of significant clinical response to therapy? (Provide supporting documentation)
   a. If yes, continue to #3
   b. If no, clinical review required
3. Will the requested medication be used concurrently with other biologic or MS therapy? (examples: Enbrel, Dupixent, Cosentyx, Cimzia, Skyrizi, Otezla, Gilenya, etc)

Last Reviewed: 11/16/22, 7/21/23, 3/15/24, 3/21/25
Effective Date: 1/1/23, 9/15/23, 4/15/24, 4/1/25

a. If yes, clinical review required
b. If no, continue to #4

4. Is the treatment being prescribed by or in consultation with an appropriate specialist?

a. If yes, approve for 12 months unless otherwise specified
b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Zeposia (ozanimod) [Prescribing Information]. Summit, NJ: Celgene Corporation. August 2024.
2. Rae-Grand A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis. Neurology. 2018;90(17):777-788. Available at: http://n.neurology.org/content/neurology/90/17/777.full.pdf.
3. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology 2020;158:1450-1461. Available at: https://www.gastrojournal.org/article/S0016-5085(20)30018-4/pdf
4. Harbord M, Eliakim R, Bettenworth D, et al. Third European Evidence-based Consensus on Diagnosis and Management of Ulcerative Colitis. Part 2: Current Management. Journal of Crohn's and Colitis. 2017;11(7):769-84. Available at: https://academic.oup.com/ecco-jcc/article/11/7/769/2962457.

Last Reviewed: 11/16/22, 7/21/23, 3/15/24, 3/21/25
Effective Date: 1/1/23, 9/15/23, 4/15/24, 4/1/25

Zilbrysq® (zilucoplan)
Prior Authorization Guidelines

Affected Medication(s)

- Zilbrysq (zilucoplan) subcutaneous injection

FDA Approved Indication(s)

- Treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive

Dosing

- Subcutaneous daily dose:
  - Less than 56 kg: 16.6 mg
  - 56 to 77 kg: 23 mg
  - 77 kg or greater: 32.4 mg

Initial Authorization Criteria

1. Is the request for continuation of therapy with the same medication for the same indication?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
   a. If yes, continue to #3
   b. If no, clinical review required
3. Is the member 18 years of age or older? (Provide supporting documentation)
   a. If yes, continue to #4
   b. If no, clinical review required
4. Does the member have Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of Class II to IV disease? (Provide supporting documentation)
   a. If yes, continue to #5
   b. If no, clinical review required
5. Does the member have a positive serologic test for anti-acetylcholine receptor (AChR) antibodies? (Provide supporting documentation)
   a. If yes, continue to #6
   b. If no, clinical review required
6. Has the member had a thymectomy? (Note: Applicable only to patients with thymomas OR non-thymomatous patients who are 50 years of age or younger)
   a. If yes or N/A, continue to #7
   b. If no, clinical review required
7. Does the member have MG-Activities of Daily Living (MG-ADL) total score of ≥6? (Provide supporting documentation)

Last Reviewed: 3/15/24, 3/21/25
Effective Date: 4/15/24

a. If yes, continue to #8
b. If no, clinical review required

8. Will the member avoid or use with medications known to worsen or exacerbate symptoms of MG (e.g., certain antibiotics, beta-blockers, botulinum toxins, hydroxychloroquine, etc.)? (Provide supporting documentation)

    a. If yes, continue to #9
    b. If no, clinical review required

9. Has the member had an inadequate response after a minimum one-year trial with two (2) or more immunosuppressive therapies (e.g., corticosteroids plus an immunosuppressant such as azathioprine, cyclosporine, mycophenolate, etc.) or did the member require chronic treatment with plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG) in addition to immunosuppressant therapy? (Provide supporting documentation)

    a. If yes, continue to #10
    b. If no, clinical review required

10. Is Zilbrysq (zilucoplan) being prescribed by, or in consult with, a specialist experienced in treating myasthenia gravis?

    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported? (Provide supporting documentation)

    a. If yes, continue to #2
    b. If no, clinical review required

2. Has the member developed a severe bone marrow failure syndrome, experienced spontaneous disease remission, or received a curative allogeneic stem cell transplant?

    a. If yes, clinical review required
    b. If no, continue to #3

3. Were updated chart notes (within past year) provided with documentation of significant clinical response to therapy received? (Ex. improvement from baseline in Myasthenia Gravis-Specific Activities of Daily Living scale (MG-ADL) total score or Quantitative Myasthenia Gravis (QMG) total score) (Provide supporting documentation)

    a. If yes, continue to #4
    b. If no, clinical review required

4. Is Zilbrysq (zilucoplan) being prescribed by, or in consult with, a specialist experienced in treating myasthenia gravis?

    a. If yes, approve for 12 months
    b. If no, clinical review required

Note:

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medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. ZILBRYSQ (zilucoplan) subcutaneous injection, [package insert]. Smyrna, GA.: UCB, Inc; 2024.
2. Drugs@FDA: FDA Approved Drug Products. 2022. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 17 Jan. 2024].
3. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis: Executive summary. Neurology. 2016;87(4):419-425.
4. Narayanaswami P, Sanders DB, Wolfe G, et al. International Consensus Guidance for Management of Myasthenia Gravis: 2020 Update. Neurology. 2021;96(3):114-122.
5. Howard JF Jr, Bresch S, Genge A, et al. Safety and efficacy of zilucoplan in patients with generalised myasthenia gravis (RAISE): a randomised, double-blind, placebo-controlled, phase 3 study. Lancet Neurol. 2023;22(5):395-406.

Last Reviewed: 3/15/24, 3/21/25
Effective Date: 4/15/24

Zokinvy® (lonafarnib)
Prior Authorization Guidelines

Affected Medication(s)

- Zokinvy oral capsule

FDA Approved Indication(s)

- Patients 12 months of age and older with a body surface area of 0.39m^2 and above:
  - To reduce risk of mortality in Hutchinson-Gilford Progeria Syndrome
  - For Treatment of processing-deficient Progeroid Laminopathies with either:
    - Heterozygous LMNA mutation with progerin-like protein accumulation.
    - Homozygous or compound heterozygous ZMPSTE24 mutations.

Dosing

- Start at 115 mg/m^2 twice daily with morning and evening meals. After 4 months, increase to 150 mg/m^2 twice daily.

Initial Authorization Criteria

1. Is the request for renewal of a previously approved Zokinvy (lonafarnib) prior authorization with the same indication?

   a. If yes, continue to Reauthorization
   b. If no, continue to #2

2. Is this being requested for an FDA or major compendia supported indication?

   a. If yes, continue to #3
   b. If no, clinical review required

3. Does the member have a confirmed diagnosis of one of the following? (Provide supporting documentation)
   - HGPS confirmed by G608G mutation in the lamin A gene
   - Processing-deficient Progeroid Laminopathy with either of the following:
     - Heterozygous LMNA mutation with progerin-like protein accumulation.
     - Homozygous or compound heterozygous ZMPSTE24 mutations.

   a. If yes, continue to #4
   b. If no, clinical review required

4. Is the member 12 months of age or older?

   a. If yes, continue to #5
   b. If no, clinical review required

5. Is the member's BSA (or height and weight) provided and is dosing consistent with FDA approved dosing? (Provide BSA for review)

   a. If yes, continue to #6
   b. If no, clinical review required

Last Reviewed: 7/21/21, 3/17/23, 1/19/24, 1/17/25
Effective Date: 9/1/21

6. Is there documentation of baseline monitoring and planned ongoing monitoring of all of the following? (Provide baseline labs and monitoring plan for review)
    - Comprehensive metabolic panel
    - CBC
    - Ophthalmological evaluation
    - Blood pressure

    a. If yes, continue to #7
    b. If no, clinical review required

7. Does the member's baseline monitoring meet all of the following? (Provide baseline labs for review)
    - APC >1,000/ml
    - Platelets >75,000/ml (transfusion independent)
    - Hemoglobin >9g/dl
    - Creatinine ≤ 1.5 ULN for age or GFR >70ml/min/1.73m^2
    - Bilirubin ≤ 1.5 ULN for age
    - ALT and AST <5 x normal range for age

    a. If yes, continue to #8
    b. If no, clinical review required

8. Is there documentation of avoidance of strong CYP3A inhibitors/inducers, midazolam, lovastatin, simvastatin, or atorvastatin? (Provide supporting documentation)

    a. If yes, continue to #9
    b. If no, clinical review required

9. Is the member a female of reproductive potential?

    a. If yes, continue to #10
    b. If no, continue to #11

10. Does the member have documentation of a negative pregnancy test and documentation of contraceptive use throughout planned treatment? (Provide supporting documentation)

    a. If yes, continue to #11
    b. If no, clinical review required

11. Is the requested medication being prescribed by, or in consultation with, a specialist with experience in treating progeria and/or progeroid laminopathies?

    a. If yes, approve for 4 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is Zokinvy (lonafarnib) being requested for an FDA approved or major compendia supported indication? (Provide supporting documentation)

    a. If yes, continue to #2

b. If no, clinical review required

2. Is there documentation of disease stabilization compared to natural disease progression? (Provide supporting documentation)

   a. If yes, continue to #3
   b. If no, clinical review required

3. Is the requested medication being prescribed by, or in consultation with, a specialist with experience in treating progeria and/or progeroid laminopathies?

   a. If yes, approve for 12 months
   b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. ZOKINVY (lonafarnib) capsules, [package insert]. Palo Alto, CA: Eiger Biopharmaceuticals, Inc.; 2024.
2. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 5 FEB. 2021].
3. Gordon, Leslie B., et al. "Impact of farnesylation inhibitors on survival in Hutchinson-Gilford progeria syndrome." Circulation 130.1 (2014): 27-34.
4. Gordon, Leslie B., et al. "Association of lonafarnib treatment vs no treatment with mortality rate in patients with Hutchinson-Gilford progeria syndrome." Jama 319.16 (2018): 1687-1695.
5. Gordon, Leslie B., et al. "Clinical trial of the protein farnesylation inhibitors lonafarnib, pravastatin, and zoledronic acid in children with Hutchinson-Gilford progeria syndrome." Circulation 134.2 (2016): 114-125.
6. Gordon, Leslie B., et al. "Clinical trial of a farnesyltransferase inhibitor in children with Hutchinson–Gilford progeria syndrome." Proceedings of the National Academy of Sciences 109.41 (2012): 16666-16671.

Last Reviewed: 7/21/21, 3/17/23, 1/19/24, 1/17/25
Effective Date: 9/1/21

Zontivity® (vorapaxar)
Prior Authorization Guidelines

Affected Medication(s)

- Zontivity oral tablet

FDA Approved Indication(s)

- Reduction of thrombotic cardiovascular events in patients with a history of myocardial infarction (MI) or with peripheral arterial disease (PAD). ZONTIVITY has been shown to reduce the rate of a combined endpoint of cardiovascular death, MI, stroke, and urgent coronary revascularization

Dosing

- 2.08 mg orally once daily

Initial Authorization Criteria

1. Is the request for continuation of Zontivity (vorapaxar) therapy?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Does the member have documentation of a previous myocardial infarction or current peripheral artery disease? (Provide relevant medical history)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Will the member concurrently be taking aspirin and/or clopidogrel with the requested medication? (Provide documentation of treatment plan)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Does the member have history of a stroke, transient ischemic attack (TIA), intracranial hemorrhage (ICH), or active pathological bleeding? (Provide supporting documentation)
    a. If yes, clinical review required
    b. If no, continue to #6
6. Is the treatment being prescribed by, or in consultation with, a cardiologist?
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

Last Reviewed: 11/21/18, 1/20/21, 5/18/22, 7/21/23, 7/19/24, 7/18/25
Effective Date: 1/1/19, 7/15/22, 8/15/24

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Will the member concurrently be taking aspirin and/or clopidogrel with the requested medication? (Provide documentation of treatment plan)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Has the member had a stroke, transient ischemic attack (TIA), or intracranial hemorrhage (ICH) while taking Zontivity?
    a. If yes, clinical review required
    b. If no, continue to #4
4. Does the member have an absence of serious adverse reactions from therapy (i.e. bleeding)?
    a. If yes, continue to #5
    b. If no, clinical review required
5. Is the treatment being prescribed by, or in consultation with, a cardiologist?
    a. If yes, approve for 12 months unless otherwise specified
    b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Zontivity [prescribing information]. Parsippany, NJ: Aralez Pharmaceuticals Us Inc.; April 2021.
2. Morrow D, Braunwald E, Bonaca M, et. al. Vorapaxar in the Secondary Prevention of Atherothrombotic Events. New England Journal of Medicine 2012;366:1404-13.
3. Smith S, Benjamin E, Bonow R, et. al. AHA/ACCF Secondary Prevention and Risk Reduction Therapy for Patients with Coronary and Other Atherosclerotic Vascular Disease: 2011 Update: A Guideline From The American Heart Association and American College of Cardiology Foundation. Circulation 2011;124:2458-2473.
4. Morrow D, Scirica B, Fox K, et. al. Evaluation of a novel antiplatelet agent for secondary prevention in patients with a history of atherosclerotic disease: Design and rationale for the Thrombin-Receptor Antagonist in Secondary Prevention of Atherothrombotic Ischemic Events (TRA 2°P)-TIMI trial. American Heart Journal 2009;158:335-341.e.3.
5. Gornik HL, Aronow HD, Goodney PP, et al. 2024 ACC/AHA/AACVPR/APMA/ABC/SCAI/SVM/SVN/SVS/SIR/VESS Guideline for the Management of Lower Extremity Peripheral Artery Disease: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines [published correction appears in Circulation. 2025 Apr

Last Reviewed: 11/21/18, 1/20/21, 5/18/22, 7/21/23, 7/19/24, 7/18/25
Effective Date: 1/1/19, 7/15/22, 8/15/24

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Ztalmy® (ganaxolone)
Prior Authorization Guidelines

Affected Medication(s)

- Ztalmy oral suspension

FDA Approved Indication(s)

- Treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) in patients 2 years of age and older

Dosing

- 28kg or less: 6mg/kg orally three times daily through day 7; then 11 mg/kg three times daily through day 14; then 16 mg/kg three times daily through day 21; and 21 mg/kg three times daily thereafter
- Greater than 28kg: 150 mg/3 mL orally 3 times daily through day 7; then 300 mg/6 mL three times daily through day 14; then 450 mg/9 mL three times daily through day 21; and 600 mg/12 mL three times daily thereafter

Initial Authorization Criteria

1. Is the request for continuation of Ztalmy (ganaxolone) therapy?
    a. If yes, continue to Reauthorization
    b. If no, continue to #2
2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the member currently 2 years of age or older?
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member currently have confirmed diagnosis of cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder confirmed by genetic testing? (Provide supporting documentation)
    a. If yes, continue to #5
    b. If no, clinical review required
5. Has the member previously trialed at least 2 regimens containing two or more of the following used in combination? (Provide supporting documentation)
        i. Clobazam, valproate, topiramate, levetiracetam, vigabatrin
    a. If yes, continue to #6
    b. If no, clinical review required

Last Reviewed: 9/21/22, 9/15/23, 9/20/24, 9/19/25
Effective Date: 11/1/22, 10/15/24

6. Does the member continue to have uncontrolled seizures despite previous therapy? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, clinical review required
7. Is the medication prescribed by, or in consultation with, a neurologist? (Provide supporting documentation)
    a. If yes, approve for 6 months
    b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication Food and Drug Administration (FDA) approved or supported by major compendia?
    a. If yes, continue to #2
    b. If no, clinical review required
2. Were updated chart notes (within 1 year) with documentation of significant clinical response to therapy received? (Significant clinical response is defined by a decrease in seizure frequency compared to pre-treatment baseline) (Provide supporting documentation)
    a. If yes, continue to #3
    b. If no, clinical review required
3. Is the treatment being prescribed by, or in consultation with, a neurologist?
    a. If yes, approve for 12 months reauthorization
    b. If no, clinical review required

Note:

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References:

1. ZTALMY® (ganaxolone) oral suspension, [package insert]. Radnor, PA: Marinus Pharmaceuticals, Inc.; April 2025.
2. Drugs@FDA: FDA Approved Drug Products. 2019. accessdata.fda.gov. [online] Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [Accessed 3 Aug. 2022].
3. Knight, Elia M. Pestana, et al. "Safety and efficacy of ganaxolone in patients with CDKL5 deficiency disorder: results from the double-blind phase of a randomised, placebo-controlled, phase 3 trial." The Lancet Neurology 21.5 (2022): 417-427.
4. Leonard, Helen, et al. "CDKL5 deficiency disorder: clinical features, diagnosis, and management." The Lancet Neurology (2022).
5. Olson, Heather E., et al. "Current neurologic treatment and emerging therapies in CDKL5 deficiency disorder." Journal of neurodevelopmental disorders 13.1 (2021): 1-11.

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Effective Date: 11/1/22, 10/15/24

Zurzuvae™ (zuranolone)
Prior Authorization Guidelines

Affected Medication(s)

- Zurzuvae oral capsule

FDA Approved Indication(s)

- For treatment of postpartum depression (PPD) in adults

Dosing

- 50 mg orally once daily in the evening for 14 days
- The safety and effectiveness of Zurzuvae use beyond 14 days in a single treatment course have not been established.

Initial Authorization Criteria

1. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
    a. If yes, continue to #2
    b. If no, clinical review required
2. Is the member 18 years of age or older?
    a. If yes, continue to #3
    b. If no, clinical review required
3. Has the member experienced a major depressive episode with onset no earlier than the third trimester of pregnancy and no later than four weeks after delivery? (Provide supporting documentation)
    a. If yes, continue to #4
    b. If no, clinical review required
4. Does the member have a confirmed diagnosis of severe PPD documented by a standardized evidence-based depression rating scale that reliably measures depressive symptoms? (Provide test result for review)
    - Edinburgh postnatal Depression Scale (EPDS) ≥ 19
    - Patient Health Questionnaire-9 (PHQ-9) ≥ 20
    - Beck Depression Inventory (BDI-II) ≥ 29
    - Hamilton Rating Scale for Depression ≥ 19
    - Montgomery-Asberg Depression Rating Scale ≥ 35

    a. If yes, continue to #5
    b. If no, clinical review required
5. Is urgent symptom control necessary due to risk of harm to mother/baby? (Provide supporting documentation)
    a. If yes, continue to #7
    b. If no, continue to #6

Last Reviewed: 1/19/24, 1/17/25
Effective Date: 3/1/24

6. Does the member have a previous trial with inadequate response to at least two antidepressants from at least two different classes for a minimum of 4 weeks OR a contraindication to all classes? (Examples: SSRI, SNRI, TCA, bupropion) (Provide supporting documentation)

    a. If yes, continue to #7
    b. If no, clinical review required

7. Is the treatment being prescribed by, or in consultation with, a mental health specialist?

    a. If yes, approve for 14 days
    b. If no, clinical review required

Note:

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References:

1. Zurzuvae (zuranolone) oral capsules [package insert]. Cambridge, MA: Sage Therapeutics, Inc.; November 2024.
2. Treatment and Management of Mental Health Conditions During Pregnancy and Postpartum: ACOG Clinical Practice Guideline No. 5. Obstet Gynecol. 2023;141(6):1262-1288.
3. Screening and Diagnosis of Mental Health Conditions During Pregnancy and Postpartum: ACOG Clinical Practice Guideline No. 4. Obstet Gynecol. 2023;141(6):1232-1261.
4. Deligiannidis KM, Meltzer-Brody S, Maximos B, et al. Zuranolone for the Treatment of Postpartum Depression. Am J Psychiatry. 2023;180(9):668-675.
5. Deligiannidis KM, Meltzer-Brody S, Gunduz-Bruce H, et al. Effect of Zuranolone vs Placebo in Postpartum Depression: A Randomized Clinical Trial [published correction appears in JAMA Psychiatry. 2022 Jul 1;79(7):740] [published correction appears in JAMA Psychiatry. 2023 Feb 1;80(2):191]. JAMA Psychiatry. 2021;78(9):951-959.