Medicaid Prior Authorization Criteria
Last Revised 2/2020
Important:
Medical policies:

- are not the same as medical advice and do not guarantee any results or outcomes or coverage. If you are a member, please talk about any health care questions with your health care provider.
- do not determine benefits. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied.
- are interpreted and applied at the sole discretion of the Plan, and are subject to state and federal laws.
- explain when certain medical services are medically necessary and whether or not they are investigational (new). For more information about medical necessity and investigational (research) criteria, please see these specific policies. Our coverage guidelines are written to cover a given condition for the majority of people. Each individual’s unique, clinical circumstances may be considered.
- are based on constantly changing medical science. We reserve the right to review and update our policies periodically.
All Diagnoses
Initial Criteria:
1. Is the requested agent indicated for or supported for use in the submitted diagnosis for the member's age?
   If yes, continue to #2. If no, do not approve.

2. Is the request for maintenance of remission in a patient who already achieved remission with of the requested product or has already initiated therapy?
   If yes, continue to renewal criteria. If no, continue to #3.

3. Does the member have a history of COPD?
   If yes, do not approve. If no, continue to #4.

4. Has the treatment been initiated by or is an appropriate specialist currently supervising it?
   • Juvenile Idiopathic Arthritis: Rheumatologist
   • Psoriatic Arthritis: Dermatologist or Rheumatologist
   • Rheumatoid Arthritis: Rheumatologist
   If yes, continue to indication. If no, do not approve.

Juvenile Idiopathic Arthritis
Initial Criteria:
1. Does the member have juvenile idiopathic arthritis with active systemic features of JIA, with a physician global assessment of 5 or higher (or any systemic activity in the absence of active joint involvement)?
   If yes, continue to #9. If no, continue to #2.

2. Does the member have juvenile idiopathic arthritis without active systemic features of JIA?
   If yes, continue to #3. If no, do not approve.

3. Has the member tried and failed either: Intra-articular glucocorticoid injections (if fewer than 4 joints affected) OR NSAIDS for at least one month?
   If yes, continue to #4. If no, do not approve.

4. Has the member had at least a 3 month trial of methotrexate?
If yes, continue to #7. If no, continue to #5.

5. Does the member have a contraindication to methotrexate?
   If yes, continue to #6 If no, do not approve.

6. Has the member failed a 3 month trial of sulfasalazine or leflunomide?
   If yes, continue to #7. If no, do not approve.

7. Has the member tried and failed a TNF inhibitor?
   If yes, continue to #8. If no, do not approve.

8. Has the member tried and failed Actemra?
   If yes, continue to #12. If no, do not approve.

9. Has the member tried and failed systemic corticosteroids?
   If yes, continue to #10. If no, do not approve.

10. Does the member have a physician global assessment of less than 5 with continued joint involvement after 2 weeks of steroids?
    If yes, continue to #11. If no, continue to #12.

11. Has the member tried and failed ALL of the following:
    a. methotrexate or leflunomide for at least 3 months or contraindication to both.
    b. Kineret
    c. Actemra
    If yes, continue to #12. If no, do not approve.

12. Approve for 6 months

Juvenile Idiopathic Arthritis
Renewal Criteria:
1. Has the member experienced 20% or greater improvement in tender joint count and swollen joint count, or a reduction in systemic effects of JIA?
   If yes, approve for 12 months. If no, do not approve.

Psoriatic Arthritis
Initial Criteria:
1. Does the member have psoriatic arthritis based on at least 3 out of 5 of the following?
   - Psoriasis (1 point for personal or family history, 2 points for current)
   - Psoriatic nail dystrophy
   - Negative test result for RF
   - Dactylitis (current or history)
- Radiological evidence of juxta-articular new bone formation
  If yes, continue to #2. If no, do not approve.

2. Is the member transitioning to the requested treatment from a different biologic product?
   If yes, continue to #4. If no, continue to #6.

3. Has the member failed or have contraindications to conventional management with all of the following?
   - NSAIDs, and
   - Methotrexate or other DMARD such as leflunomide, sulfasalazine, or cyclosporine
     If yes, continue to #4. If no, do not approve.

4. Has the member tried and failed or have a contraindication to infliximab?
   If yes, continue to #5. If no, do not approve.

5. Approve for Orencia IV for 6 months.

Psoriatic Arthritis
Renewal Criteria:
1. Has the member experienced 20% or greater improvement in tender joint count and swollen joint count?
   If yes, approve for 12 months. If no, do not approve.

Rheumatoid Arthritis
Initial Criteria
1. Does the member have a baseline of moderate to high disease activity of rheumatoid arthritis measured as such by an accepted assessment instrument (PAS, PASII, RAPID3, CDAI, DAS28, SDAI)?
   If yes, continue to #2. If no, do not approve.

2. Is the member transitioning to the requested treatment from a different biologic product?
   If yes, continue to #5. If no, continue to #3.

3. Has the member tried and failed or have contraindications to methotrexate dosed at least 20mg per week for at least 8 weeks?
   If yes, continue to #4. If no, do not approve.

4. Has the member tried and failed or have contraindications to the following: leflunomide, hydroxychloroquine, or sulfasalazine?
   If yes, continue to #5. If no, do not approve.
5. Has the member tried and failed or have a contraindication to infliximab?
   If yes, continue to #6.          If no, do not approve.

6. Is the requested product being prescribed along with at least one of the following DMARDs: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine, unless contraindicated?
   If yes, continue to #7.          If no, do not approve.

7. Approve for Orencia IV for 6 months.

**Rheumatoid Arthritis**

**Renewal Criteria:**

1. Has the member experienced 20% or greater improvement in tender joint count and swollen joint count?
   If yes, approve for 12 months.     If no, do not approve.
Generic Name: Acitretin

Brand Name: Soriatane

Created: 09/14/17

**Plaque psoriasis:**

**Initial criteria:**
1. Does the member have chronic, moderate to severe plaque psoriasis with functional impairment and one or more of the following:
   a. At least 10% body surface area involved
   b. Hand, foot or mucous membrane involvement

   If yes, continue to #2. If no, do not approve.

2. Has the treatment been prescribed or is it currently being supervised by a dermatologist?
   If yes, continue to #3. If no, do not approve.

3. Has the member tried and failed or have contraindications to **ALL** of the following:
   - High-potency topical corticosteroids (betamethasone dipropionate, clobetasol, fluocinonide)
   - At least one other topical agent: calcipotriene, tazarotene, anthralin
   - PUVA or UVB Phototherapy
   - Methotrexate
   - At least one other second line systemic agent such as cyclosporine

   If yes, continue to #4. If no, do not approve.

4. Approve for 6 months.

**Renewal Criteria:**

**Plaque Psoriasis**
1. Has the member experienced a 50% reduction in plaques and/or is there evidence of functional improvement?
   If yes, approve for 12 months. If no, do not approve.
Topical) PA Criteria

Generic Name  Adapalene 0.1% Gel
Adapalene-Benzoyl Peroxide 0.1-2.5% gel
Tretinoin 0.025% Cream

Created: 9/12/19 (implemented 1/1/20)

1. Does the member have acne conglobata or acne fulminans?
   If yes, continue to #2.   If no, continue to #3.

2. Do the chart notes document that the member has recurrent abscesses or communicating sinuses?
   If yes, continue to #5.   If no, continue to #3.

3. Does the member have severe cystic acne?
   If yes, continue to #4   If no, deny for unfunded condition.

4. Has the provider submitted documentation showing 1) persistent or recurrent inflammatory nodules and cysts AND 2) ongoing scarring?
   If yes, continue to #5.   If no, deny for BTL/GN

   Note: OHA requires this level of severity to be considered funded under the Prioritized List of Health Services.

5. Is the product formulary?
   If yes, approve x 12 months.   If no, continue to #6.

6. Have appropriate formulary alternatives been tried and failed?
   If yes, approved x 12 months.   If no, deny for non-formulary.
Initial Criteria:
1. Does the member have compensated cirrhosis?
   If yes, continue to #2.       If no, continue to #3

2. Is HBV DNA > 2000 IU/ml (10,000 or 10^4 copies/ml)?
   If yes, continue to #8.       If no, do not approve.

3. Does the member have decompensated cirrhosis with detectable HBV DNA?
   If yes, continue #8.          If no, continue to #4

4. Is the member HBeAg (+)?
   If yes, continue to #5.       If no, continue to #6

5. Does the member meet the following:
   a. HBV DNA ≥ 20,000 IU/mL
   b. Serum ALT is persistently elevated after 3-6 months of monitoring or liver biopsy shows ≥ moderate inflammation or significant fibrosis
   If yes, continue to #8.       If no, do not approve.

6. Is the member HBeAg (-)?
   If yes, continue to #7.       If unknown, request HBeAg, HBV DNA, serum ALT for past 3-6mo and liver biopsy if available from provider.

7. Does the member meet the following:
   a. HBV DNA > 2,000 IU/mL
   b. Serum ALT is persistently elevated after 3-6 months of monitoring or liver biopsy shows ≥ moderate inflammation or fibrosis
   If yes, continue to #8.       If no, do not approve.
8. Does the member have HIV co-infection and is NOT currently receiving HAART (antiretroviral) therapy?
   If yes, approve x 6 months. If no, continue to #9

9. Is the member nucleoside/nucleotide-naïve (has not been treated with any CHB therapy including tenofovir, entecavir or telbivudine)?
   If yes, do not approve and recommend tenofovir as the preferred formulary alternative.
   If no, continue to #10.

10. Approve for 24 weeks (6 months).

Renewal Criteria:
1. Does the member have evidence of treatment compliance evidenced by consistent monthly prescription fills?
   If yes, continue to #2. If no, fwd to RPh

2. Does the member have undetectable HBV DNA?
   If yes, approve for 12 months. If no, fwd to RPh
Generic Name Aflibercept

Brand Name Eylea

Created: 3/13/12
Reviewed: 9/13/12, 9/12/13, 11/13/2014
Updated: 7/9/15, 09/13/18, 5/9/19, 9/12/19

***Nonformulary for outpatient benefit. PA required on medical benefit.***

Initial criteria:
**Diabetic Macular Edema (DME) or Diabetic Retinopathy (DR)**
1. Does the member have diabetic macular edema or diabetic retinopathy in diabetic macular edema?  
   If yes, continue to #2. If no, do not approve.

2. Has the member tried and failed Avastin?  
   If yes, continue to #3. If no, do not approve.

3. Approve for 6 months, with the following renewal language: “Renewal after the initial 6 months requires either documentation that you will reduce the dosing frequency OR evidence of the medical necessity for more frequent treatments.”

Initial criteria:
**Macular Edema Following Retinal Vein Occlusion (RVO)**
1. Does the member have macular edema following retinal or branch retinal vein occlusion (RVO or BRVO)?  
   If yes, continue to #2. If no, do not approve.

2. Has the member tried and failed Avastin?  
   If yes, continue to #3. If no, do not approve.

3. Approve for 12 months.

Initial criteria:
**Neovascular (Wet) Age-Related Macular Degeneration (AMD)**
1. Does the member have exudative (wet) age-related macular degeneration (AMD)?  
   If yes, continue to #2. If no, do not approve.

2. Has the member tried and failed Avastin?  
   If yes, continue to #3. If no, do not approve.

3. Approve for 3 months with the following approval language: “Renewal after the initial 3 months requires either documentation that you will reduce the dosing frequency OR evidence of the medical necessity for more frequent treatments.”
Renewal criteria:
**Diabetic Macular Edema (DME) or Diabetic Retinopathy (DR) and Neovascular (Wet) Age-Related Macular Degeneration (AMD)**

1. Is the request for a dosing interval greater than 4 weeks?
   
   If yes, continue to #3.
   
   If no, continue to #2.

2. Is there documentation that extended interval dosing has been tried and failed?
   
   If yes, continue to #3
   
   If no, do not approve

3. Has the member demonstrated disease stabilization or clinical response?
   
   If yes, continue to #4.
   
   If no, do not approve.

4. Approve the requested quantity for 12 months.

Renewal criteria:
**Macular Edema Following Retinal Vein Occlusion (RVO)**

1. Has the member demonstrated disease stabilization or clinical response?
   
   If yes, continue to #2.
   
   If no, do not approve.

2. Approve the requested quantity for 12 months.
1. Does the member have a diagnosis of pinworm?
   If yes, continue to #2. If no, continue to #3.

2. Has the member tried and failed two doses of pyrantel (Pin-X/Reese’s Pinworm) dosed 2 weeks apart?
   If yes, approve x 1 day. If no, deny.

3. Is the prescriber an infectious disease specialist?
   If yes, continue to #4. If no, deny.

4. Is the use for a supported indication and used with an appropriate dose and duration?
   If yes, approve. If no, deny.
Generic Name: Alemtuzumab
Brand Name: Lemtrada

Created: 12/28/11
Revised: 9/12/13, 3/2/15, 03/10/16

***Nonformulary on outpatient benefit. PA required for medical benefit. ***

**Initial Criteria:**
1. Is Lemtrada being prescribed by a neurologist?  
   If yes, continue to #2.  
   If no, do not approve.

2. Is the request for the treatment of relapsing, remitting multiple sclerosis (RRMS)?  
   If yes, continue to #3.  
   If no, do not approve.

3. Has the member tried and failed ALL of the following?  
   a. Interferon (such as Rebif, Avonex, Extavia, Betaseron, Plegridy)  
   b. Copaxone  
   c. Tecfidera  
   d. Gilenya  
   e. Tysabri  
   If yes, approve x 12 months (5 doses).  
   If no, do not approve.

**Renewal Criteria:**
1. Is the request for a second year of Lemtrada?  
   If yes, continue to #2.  
   If no, do not approve. Only labeled for 2 years

2. Did the member show documented response to Lemtrada?  
   If yes, approve x 12 months for 3 additional doses  
   If no, do not approve.
Generic Name    Alglucosidase alfa

Brand Name      Lumizyme
                Myozyme

Created: 9/16/10
Reviewed: 12/2/11, 5/10/12, 9/12/13
Revised: 7/23/15, 03/09/17

*** Nonformulary on outpatient benefit. PA required for medical benefit ***

**Initial Criteria:**

1. Is the treatment being prescribed or supervised by a specialist in Pompe Disease, such as a metabolic disease specialist, medical geneticist, or pediatric cardiologist?
   - If yes, continue to #2
   - If no, do not approve.

2. Does the member have a diagnosis of infantile onset Pompe disease?
   - If yes, continue to #3
   - If no, do not approve.

3. Is the diagnosis confirmed by enzyme assay demonstrating a reduced acid alpha-glucosidase (GAA) enzyme activity OR by genetic testing for mutations in the GAA gene?
   - If yes, continue to #4
   - If no, do not approve.

4. Is there medical record documentation of clinical symptoms?
   - If yes, continue to #5
   - If no, do not approve.

5. Has the provider outlined objective, measurable treatment goals?
   - If yes, continue to #6
   - If no, do not approve.

6. Approve for 6 months.

**Renewal Criteria:**

1. Is there medical record documentation of meeting treatment goals, such as improved cardiac and skeletal muscle function or slowing of disease progression?
   - If yes, approve for 6 months
   - If no, do not approve.
Generic Name Alpha 1-Proteinase Inhibitor Human

Brand Name Prolastin, Aralast, Zemaira, Glassia
Reviewed: 12/2/11, 9/12/13

**Initial Criteria:**
1. Is the member a current smoker?
   - If yes, continue to #2.
   - If no, continue to #3.

2. Is the member enrolled in a smoking cessation program and abstinent for at least 6 months?
   - If yes, continue to #3.
   - If no, do not approve

3. Is the request from a pulmonologist?
   - If yes, continue to #4.
   - If no, do not approve.

4. Does the member have ZZ or Z/null AAT deficiency?
   - If yes, continue to #5.
   - If no, do not approve.

5. Does the member have an AAT serum level ≤ 11μM or 50mg/dL?
   - If yes, continue to #6.
   - If no, do not approve.

6. Does the member have a diagnosis of moderate emphysema and/or an FEV1 between 30-65%?
   - If yes, continue to #7.
   - If no, do not approve.

7. Is the member currently undergoing or has undergone?
   a. Pulmonary rehabilitation, **and**
   b. Weight loss and nutritional support, if indicated.
   - If yes, continue to #8.
   - If no, do not approve.

8. Has the provider outlined specific, measurable treatment goals such as?
   a. Slowing of FEV1 decline, **and**
   b. Lack of disease progression.
   - If yes, approve for 12 weeks.
   - If no, do not approve.

**Renewal Criteria:**
1. Is the member meeting treatment goals?
   - If yes, approve for 12 months
   - If no, do not approve.
Generic Name: Apremilast
Brand Name: Otezla

Created: 7/22/14
Reviewed: 01/08/15
Revised: 01/12/17, 11/14/2019

All diagnoses:
Initial Criteria:
1. Is the requested agent indicated for or supported for use in the submitted diagnosis for the member's age?
   If yes, continue to #2. If no, do not approve. Deny for investigational.

2. Has the treatment been initiated by or is an appropriate specialist currently supervising it?
   - Plaque Psoriasis: Dermatologist
   - Psoriatic Arthritis: Dermatologist or Rheumatologist
   - Behçet Disease: Dermatologist, Gastroenterologist, Neurologist, or Rheumatologist
   If yes, continue to diagnosis. If no, do not approve.

Psoriatic arthritis:
Initial Criteria:
1. Does the member have a diagnosis of psoriatic arthritis based on at least 3 out of 5 of the following?
   - Psoriasis (1 point for personal or family history, 2 points for current)
   - Psoriatic nail dystrophy
   - Negative rest result for RF
   - Dactylitis (current or history)
   - Radiological evidence of juxta-articular new bone formation
   If yes, continue to #2. If no, do not approve.

2. Has the member failed all of the following:
   a. NSAIDs, and
   b. At least two DMARDs such as methotrexate, sulfasalazine, leflunomide, or cyclosporine.
   If yes, continue to #3. If no, do not approve.

3. Is the request for combination therapy with a biologic, to control skin symptoms associated with psoriatic arthritis or psoriasis?
   If yes, continue to #3 under plaque psoriasis criteria. If no, continue to #4.
4. Approve for 6 months.

**Psoriatic arthritis:**

**Renewal Criteria:**
1. Has the member experienced 20% or greater improvement in tender joint count and swollen joint count?
   a. If yes, continue to #2. If no, do not approve.

2. Approve for 12 months.

**Plaque psoriasis:**

**Initial criteria:**
1. Does the member have chronic, moderate to severe plaque psoriasis with functional impairment and one or more of the following:
   a. At least 10% body surface area involved
   b. Hand, foot or mucous membrane involvement
      If yes, continue to #2. If no, do not approve.

   Plaque psoriasis without functional impairment and hand, foot or mucous membrane involvement or affecting < 10% of body surface area is not covered for treatment by the Oregon Health Plan.

2. Has the member tried and failed or have contraindications to **ALL** of the following:
   a. High-potency topical corticosteroids (betamethasone dipropionate, clobetasol, fluocinonide)
   b. At least one other topical agent: calcipotriene, tazarotene, anthralin
   c. PUVA or UVB Phototherapy
   d. Methotrexate
   e. At least one other systemic agent: cyclosporine or acitretin.
      If yes, continue to #3. If no, do not approve.

3. Is the requested drug intended for use in combination with a biologic?
   If yes, continue to #4. If no, continue to #6.

4. Does the member have persistent moderate to severe psoriasis on biologic therapy for at least 3 months, with at least 10% body surface area involved, or hand, foot or mucous membrane involvement AND documentation of functional impairment?
   If yes, continue to #5. If no, do not approve.
5. Has the member failed combination therapy with the biologic and one of the following: methotrexate, cyclosporine, or acitretin?  
   If yes, continue to #6.  If no, do not approve.

6. Approve for 6 months.

**Plaque Psoriasis:**

**Renewal Criteria:**

1. Has the member experienced a clinically significant response, such as PASI-75 (75% improvement) and/or is there evidence of functional improvement?  
   If yes, approve for 12 months.  If no, do not approve.

**Behçet’s Disease:**

**Initial Criteria:**

1. Does the member have active recurrent oral ulcers associated with Behçet’s disease?  
   If yes, continue to #2.  If no, do not approve.

2. Is the diagnosis of Behçet’s disease supported by at least THREE of the following manifestations:  
   a. Recurrent genital ulcerations  
   b. Eye lesions (uveitis or retinal vasculitis)  
   c. Skin lesions (erythema nodosum, pseudofolliculitis, papulopustular lesions, acneiform nodules) found in adult patients not being treated with corticosteroids  
   d. Positive "pathergy test" read by a physician within 24-48 hours of testing  
      If yes, continue to #3.  If no, do not approve.

3. Is the member currently receiving another biologic or systemic treatment for Behçet’s disease?  
   If yes, do not approve.  If no, continue to #4.

4. Has the member tried and failed ALL of the following:  
   a. Oral systemic or oral topical antibiotics (in mouthwash) – tetracycline (nonformulary), doxycycline, minocycline  
   b. Triamcinolone acetonide 0.1% in Orabase paste (nonformulary)  
   c. Corticosteroid (prednisone, dexamethasone) oral tablets or mouthwash  
   d. Colchicine  
      If yes, continue to #5.  If no, do not approve.

5. Approve for 6 months.
Behçet’s Disease:
Renewal Criteria:

1. Is there chart note documentation showing that symptoms have improved or stabilized with treatment?
   If yes, continue to #2.    If no, do not approve.

2. Approve 12 months.
Generic Name       Aprepitant
Brand Name         Emend

Revised: 12/24/09, 1/4/11, 11/15/16
Reviewed: 9/13/12, 9/12/13

1. Is the member currently receiving treatment with a moderate to highly emetogenic chemotherapeutic agent?
   If yes, continue to #2.                   If no, do not approve.

1. Is the member receiving concurrent treatment with IV or oral Zofran (ondansetron) or Kytril (granisetron) or Aloxi (palonosetron) and dexamethasone [verify with PA and claims profile]?
   If yes, continue to #3.                   If no, do not approve.

2. Is the request for suspension packets?
   If yes, continue to #4                    If no, continue to #5

3. Is the member unable to use capsules?
   If yes, continue to #5                    If no, deny for criteria not met.

4. Approve up to 5 cycles.
Generic Name  Atovaquone
Brand Name  Mepron

Created: 01/11/2018

1. Is atovaquone being prescribed by or supervised by an infectious disease or HIV specialist?
   a. If yes, continue to #2. If no, do not approve.

2. Is the member HIV positive?
   a. If yes, approve for life. If no, continue to #3.
   b.

3. Is the member immunocompromised due to stem cell transplant and requires pneumocystis prophylaxis?
   a. If yes, approve for 12 months If no, continue to #4.
   b.

4. Does the member have a diagnosis of active babesiosis diagnosed by viral infection–like symptoms and identification of babesial parasites in blood by smear evaluation or by PCR amplification of babesial DNA?
   a. If yes, approve for requested If no, do not approve.
   b. course up to 10 days.
Initial Criteria:

1. Does the member have a diagnosis of cystic fibrosis?
   If yes, continue to #2. If no, do not approve.

2. Is the member ≥ 7 years of age?
   If yes, continue to #3. If no, do not approve.

3. Is the member’s FEV1 between 25% and 75% predicted?
   If yes, continue to #4. If no, do not approve.

4. Does the member have documentation of *Pseudomonas aeruginos* infection?
   If yes, continue to #5. If no, do not approve.

5. Has the member failed or has documented resistance to tobramycin (TOBI)?
   If yes, approve for 12 months. If no, do not approve.

Renewal Criteria:

1. Has the member demonstrated compliance with therapy and a clinical response such as increased FEV1 from baseline or improvement in respiratory symptoms?
   If yes, approve for 12 months. If no, do not approve.
Generic Name       Becaplermin
Brand Name         Regranex

Revised: 12/24/09
Reviewed: 12/2/11, 7/12/12, 9/12/13

**Initial Criteria:**
1. Does the member have a diagnosis of diabetes mellitus?
   If yes, continue to #2.  If no, do not approve.

2. Is the request from a surgeon, podiatrist or endocrinologist?
   If yes, continue to #3.  If no, do not approve.

3. Approve x 3 months.

**Renewal Criteria:**
1. Is there documentation of a reduction in ulcer size by at least approximately 30%?
   If yes, continue to #2.  If no, do not approve.

2. Approve for an additional 2 months.
Generic Name  Belatacept
Brand Name  Nulojix

Created: 11/29/11
Revised: 9/12/13

*** Nonformulary on outpatient benefit. PA required on medical benefit. ***

1. Is the request from a nephrologist or transplant specialist?
   If yes, continue to #2.     If no, do not approve.

2. Is the request for prophylaxis of organ transplant in a member who had a kidney transplant?
   If yes, continue to #3.     If no, do not approve.

3. Has the member failed (acute rejection, side effects, or inability to comply with oral therapy) or has contraindications to tacrolimus and cyclosporine?
   If yes, continue to #4.     If no, do not approve.

4. Is the member Epstein-Barr virus positive?
   If yes, continue to #5.     If no, do not approve.

5. Will Nulojix be used in combination with basiliximab induction, mycophenolate mofetil, and corticosteroids?
   If yes, continue to #6.     If no, do not approve.

6. Approve for life.
Generic Name       Belimumab
Brand Name         Benlysta

Created: 9/19/11
Revised: 9/12/13, 11/9/17

*** IV is nonformulary on pharmacy benefit***

**Initial Criteria:**
1. Is Benlysta being prescribed by or in consultation with a rheumatologist?  
   If yes, continue to #2.  If no, do not approve.
2. Does the member have a diagnosis of active, autoantibody-positive systemic lupus erythematosus (SLE) and is currently receiving standard therapy (see number 3)?  
   If yes, continue to #3.  If no, do not approve.
3. Does the member have a Safety of Estrogen in Lupus Erythematosus National Assessment SLE Disease Activity Index (SELENA-SLEDAI) score of ≥ 6?  
   If yes, continue to #4.  If no, do not approve.
4. Does the member have severe active lupus nephritis or severe active central nervous system lupus?  
   If yes, do not approve.  If no, continue to #5.
5. Has the member failed all of the following (alone or in combination)?  
   - NSAIDs  
   - Corticosteroids  
   - Antimalarials (primarily hydroxychloroquine)  
   - Immunosuppressives (e.g. cyclophosphamide, cyclosporine, tacrolimus, leflunomide, azathioprine, mycophenolate, and methotrexate)  
   If yes, continue to #6.  If no, do not approve.
6. Is the member currently on another biologic and/or IV cyclophosphamide?  
   If yes, do not approve.  If no, continue to #7.
7. Has the prescriber outlined specific and measurable treatment goals to assess a 6 month trial?  
   If yes, approve for 6 months.  If no, request treatment plan.

**Renewal Criteria:**
1. Is there medical record documentation of any of the following?  
   - SELENA-SLEDAI score point reduction of 4 or more.
• Provider has indicated that there is no worsening of disease from baseline after treatment with belimumab.
• Bristish Isles Lupus Assessment Group (BILAG) Classic Index that measures organ specific changes in disease activity in the past 28 days that indicates no new BILAG A score and no more than one new BILAG B score compared with baseline.
• No worsening of disease activity requiring intensification of therapy with high-dose steroids or immunosuppressants.
• Experienced a dose reduction of steroid therapy.

If yes, approve for 6 month. If no, do not approve.
Generic Name       Benznidazole

Brand Name         Benznidazole

Created: 3/8/18

1. Has the member been diagnosed with Chagas disease via one of the following:
   a. T. cruzi confirmed by detection of T. cruzi trypomastigotes on microscopy;
      OR
   b. Detection of T. cruzi DNA by PCR assay; OR
   c. 2 positive diagnostic serologic tests using two different techniques and
      antigens showing IgG antibodies to T. cruzi.
      If yes, continue to #2.                       If no, deny

2. Is the request for infectious disease or cardiologist?
   If yes, continue to #3                        If no, deny

3. Approve x 60 days for one course of treatment.
1. Is the request from a pulmonologist or cardiologist?
   If yes, continue to #2.     If no, do not approve

2. Does the member have a diagnosis of pulmonary arterial hypertension WHO Group I diagnosed by right heart catheterization?
   If yes, continue to #3.     If no, do not approve. WHO Groups 2-5 not indicated.

3. Is the member currently on, has documented failure of or contraindication to, or is concurrently being prescribed sildenafil or tadalafil?
   If yes, approve for lifetime.     If no, pend for documentation of why sildenafil or tadalafil is not being used.
Generic Name  | OnobotulinumtoxinA  
|----------------|
| AbobotulinumtoxinA  
| IncobotulinumtoxinA  
| RimabotulinumtoxinB  

Brand Name  | Botox  
|----------------|
| Dysport  
| Xeomin  
| Myobloc  

Revised: 3/11/10, 12/2/10, 03/10/11, 9/29/11, 2/14/12, 7/18/12, 11/15/13, 1/14/14, 03/12/15, 03/09/17, 01/11/18, 7/12/18, 9/13/18, 09/12/19  
Reviewed: 9/12/13  

***Nonformulary on outpatient benefit. PA required for medical benefit. ***

**Abnormal Involuntary Movements:**

**Initial Criteria:**

1. Is the request made by or supervised by a neurologist, ophthalmologist, physiatrist, or other appropriate specialist?  
   If yes, continue to #2  
   If no, do not approve.

2. Does the member have functional impairment from dystonia related to one of the following diagnoses:  
   - Torsion dystonia  
   - Spasmodic torticollis  
   - Blepharospasm in a member at least 12 years old  
   - Congenital sternocleidomastoid torticollis  
   - If yes, continue to #9.  
   - If no, continue to #3.

3. Does the member have limb spasticity associated with cerebral palsy?  
   If yes, continue to #4.  
   If no, continue to #5.

4. Is abnormal muscle tone causing functional impairment or expected to result in joint contracture?  
   If yes, continue to #9.  
   If no, do not approve.

5. Does the member have functional impairment related to chronic limb spasticity from one of the following diagnoses?  
   - Hereditary spastic paraplegia  
   - Spastic hemiplegia due to stroke  
   - Traumatic brain or spinal cord injury with resultant paraplegia, hemiplegia, or quadriplegia  
   - Multiple sclerosis  
   - Neuromyelitis optica  
   - Other demyelinating diseases of the central nervous system
If yes, continue to #6. If no, do not approve.

6. Is abnormal muscle tone causing functional impairment or expected to result in joint contracture?
   If yes, continue to #7. If no, do not approve.

7. Has the member tried and failed or have contraindications to conventional non-pharmacologic treatment including physical therapy, splinting, bracing, or biofeedback which has been ineffective or cannot be maximized secondary to significant contracture?
   If yes, continue to #8. If no, do not approve.

8. Has the member tried and failed two oral pharmacologic agents, such as baclofen, dantrolene, tizanidine, and benzodiazepines?
   If yes, continue to #9. If no, do not approve.

9. Approve for 12 months.

Renewal Criteria:
1. Has the member met treatment goals on the current dose, including but not limited to the following?
   • Decrease in severity of abnormal movements or contractures such as head positioning, improved range of motion, or decreased spasticity
   • Decrease in pain
   • Decrease in disability, such as enhanced motor ability and functional skills, improved execution of tasks, or improvement in activities of daily living.
   If yes, approve for 12 months. If no, continue to #2.

2. Has the provider requested dose optimization or toxin change?
   If yes, continue to #3. If no, do not approve.

3. Approve for 6 months.

Chronic Migraine:
Initial Criteria:
1. Is the treatment is administered in consultation with a neurologist or headache specialist?
   If yes, continue to #2. If no, do not approve.

2. Is the member at least 18 years old?
   If yes, continue to #3. If no, do not approve.

3. Does the member have a diagnosis of chronic migraine, defined as headaches on at least 15 days per month of which at least 8 days are with migraine?
   If yes, continue to #4. If no, do not approve.
4. Has the condition has been appropriately managed for medication overuse?
   If yes, continue to #5.     If no, do not approve.

5. Has the member not responded to or have contraindications to at least three prior pharmacological prophylaxis therapies:
   - Beta Blockers such as propranolol, metoprolol, timolol, atenolol, nadolol, nebivolol, or pindolol
   - Anticonvulsants such as divalproex sodium, sodium valproate, topiramate, or carbamazepine
   - Tricyclic Antidepressants such as amitriptyline
   If yes, approve for 2 treatments     If no, do not approve.
   In 6 months.

Renewal Criteria:
1. Is there a documented positive response to therapy, defined as a reduction of at least 7 headache days per month compared to baseline headache frequency?
   If yes, approve 12 months.    If no, do not approve.

Urinary Incontinence/Overactive Bladder
Initial Criteria:
1. Does the member have a diagnosis of idiopathic detrusor over-activity (overactive bladder) or neurogenic detrusor over-activity (neurogenic bladder)?
   If yes, continue to #2    If no, do not approve.

2. Has the member failed at least two anticholinergic medications (such as oxybutynin or tolterodine)?
   If yes, approve one treatment in 3 months.     If no, do not approve.

Renewal Criteria:
1. Is there a documented positive response to therapy, defined as a reduction of urinary frequency of 8 episodes per day or urinary incontinence of 2 episodes per day compared to baseline frequency?
   If yes, approve for 12 months.    If no, do not approve.

Strabismus
Initial criteria:
1. Is the request made by or supervised by an ophthalmologist or neurologist?
   If yes, continue to #2.     If no, do not approve.

2. Does the member have functional impairment related to strabismus due to other neurologic disorders? (H50.89 only)*
   If yes, approve one injection for 3 months.     If no, do not approve.
Achalasia

**Initial criteria:**
1. Is the request made by or supervised by a gastroenterologist?
   - If yes, continue to #2.
   - If no, do not approve.

2. Does the member have a diagnosis of achalasia?
   - If yes, continue to #3.
   - If no, do not approve.

3. Has the member remained symptomatic after a prior pneumatic dilation or surgical myotomy?
   - If yes, continue to #4.
   - If no, do not approve.

4. Is the member a high surgical risk for pneumatic dilation or surgical myotomy?
   - If yes, continue to #6.
   - If no, continue to #5.

5. Has the member presented with atypical achalasia symptoms and botulinum toxin is needed to help guide therapy or confirm diagnosis?
   - If yes, continue to #6
   - If no, do not approve.

6. Approve for 3 months.

**Renewal Criteria:**
1. Has there been a response to botulinum toxin, such as reduction in symptoms of dysphagia or reflux?
   - If yes, approve for 12 months.
   - If no, do not approve.
Generic Name: Buprenorphine/Naloxone

Brand Name: Bunavail
Zubsolv

Created: 2/1/2020

Bunavail and Zubsolv are formulary only for the purposes of covering the first 30 days of MAT without prior authorization to comply with Oregon law. Continuation after 30 days will be scrutinized for medical rationale of why generic buprenorphine/naloxone products cannot be used. Therapy changes may be required.
Generic Name: Buprenorphine Implant
Brand Name: Probuphine (implant)
Created: 10/31/16.

*** Nonformulary on outpatient benefit. PA required for medical benefit ***

1. Is the member currently on or have they been maintained for at least 6 months on no more than 8mg/day of buprenorphine or buprenorphine/naloxone SL tablets?
   - If yes, go to #2
   - If no, deny*

2. Is the member clinically stable? Consider the following factors in determining clinical stability:
   - Provider overall assessment
   - Abstinent for at least 90 days with no need for supplemental dosing
   - No significant withdrawal symptoms or cravings
   - No reported hospitalizations (addictions or mental health issues), ER visits or crisis interventions in the last 90 days
   - Consistent participation in recommended behavioral health therapy/ peer support program and compliance with provider visits
   - If yes, go to #3
   - If no, deny*

3. Is there documented medical reasoning it would be clinically inappropriate to continue with maintenance therapy on SL buprenorphine or generic Suboxone?
   - If yes, approve x 6 months
   - If no, deny
*** Nonformulary on outpatient benefit. PA required for medical benefit ***

**Note:** In accordance with Oregon Law, starting 1/1/20 CareOregon will cover MAT in the first 30 days without clinical prior authorization. For Sublocade, this applies only through the medical benefit. CareOregon discourages starting Sublocade under this policy as criteria will still be applied to future doses and will likely require a therapy change for the member. CareOregon strongly recommends using generic Suboxone or buprenorphine to start MAT while the PA for Sublocade is requested.

1. Does the member have a diagnosis of opioid abuse disorder?
   - If yes, continue to #2
   - If no, deny.

2. Is the member currently on or have they been maintained for at least 3 months on no more than 24mg/day of buprenorphine or buprenorphine/naloxone SL tablets and/or film?
   - If yes, go to #3
   - If no, deny

3. Is the member clinically stable? Consider the following factors in determining clinical stability:
   - Provider comprehensive assessment and treatment plan
   - Consistent participation in recommended behavioral health therapy/ peer support program and compliance with provider visits
   - Subjects should have had no significant opioid craving (≤ 20 mm on the Opioid Craving Visual Analog Scale) or withdrawal (a score ≤ 1.2 on the Clinical Opiate Withdrawal Scale) after at least 3 months of SUBOXONE sublingual tablet and/or film therapy
   - No reported hospitalizations (addictions or mental health issues), ER visits or crisis interventions in the last 90 days
   - Majority of UDS negative
     - If yes, go to #4
     - If no, deny

4. Is there documented medical reasoning it would be clinically inappropriate to continue with maintenance therapy on SL buprenorphine or generic Suboxone?
   - If yes, continue to #5
   - If no, deny

5. Is the planned treatment for 300 mg Qmonth x 2 months then 100 mg Qmonth?
   - If yes, approve requested dose for 6 months
   - If no, deny*
Renewal Criteria

1. Has the member maintained abstinence with the use of Sublocade based on negative blood or urine toxicology screens, OR maintained ongoing participation in a comprehensive substance abuse program that includes psychosocial support?

   If yes, approve x 6 months.  
   If no, continue to #2

2. Is there evidence of significantly reduced utilization of acute care services (ED visits, inpatient, and/or detox services)? Refer to SAS or Popintel for hospitalization/ED visit information.

   If yes approve x 6 months  
   If no do not approve.
Initial Criteria:
1. Is Crysvita prescribed by an endocrinologist?
   If yes, continue to #2.  If no, do not approve.

2. Does the member have X-linked hypophosphatemia (XLH)
   If yes, continue to #3.  If no, do not approve

3. Is the request for a child <12 OR an adolescent 13 or older that is still growing (not achieved adult height and epiphyses have not fused)?
   If yes, continue to #5  If no, continue to #4

4. Adolescents/Adults: Has the member had pronounced functional impairment from skeletal pain or recurrent pseudofractures/stress fractures despite conventional therapy with oral phosphate supplementation and active vitamin D analogs?
   Is yes, consult with Medical Director  If no, deny for not medically necessary.
   For assessment of medical necessity to treat.

5. Does the member have any of the following contraindications?
   o Plan to concomitantly use oral phosphate and/or active vitamin D analogs
   o A serum phosphorus level WNL OR above normal
   o Severe renal impairment (GFR<30) or ESRD
     Is yes, deny.  If no, continue to #6

6. Approve x 12 months.

Renewal Criteria:
Kids:
1. Has the member shown improvement while on treatment by any of the following:
   a. Increased serum phosphorous
   b. Increased standing-height z score
   c. Improvement in objective scales RSS or RGI-C,
   d. Improvement in 6MWT.
If yes, continue to #2

If no, deny for not medically Necessary

2. Is the member age \( \leq 12 \) OR an adolescent 13 or older that is still growing (not achieved adult height and epiphyses have not fused)
   If yes, approve x 12 months
   If no, review as an adult.

Adults:

1. Is there clear documentation that the original treatment goals have been met (see question #4 of initial criteria)
   If yes, approve x 12 months.
   If no, deny for medical necessity
1. Does the member have a diagnosis of moderate to severe psoriasis that is funded on the OHP?
   If yes, continue to #2. If no, do not approve.

2. Has the member failed at least one ultra-high potency topical steroid?
   If yes, approve for lifetime. If no, do not approve.
Generic Name  Cabozantinib
Brand Name  Cabometyx

Created: 5/5/16

1. Does the member have a diagnosis of advanced renal cell carcinoma (RCC) who have received prior anti-angiogenic therapy
   If yes, continue to #2. If no, use general OHP Chemotherapy PA criteria

2. Is the request from an oncologist?
   If yes, continue to #3. If no, do not approve

3. Is there a medical reason stated that the alternative Inlyta cannot be used instead (including review of NCCN guidelines to ensure still equal recommendation for Inlyta and Cabometyx)?
   If yes, do not approve If yes, approve x 12 months.

Renewal Criteria:
1. Has there been evidence of tumor response?
   If yes, approve x 12 months. If no, do not approve
Generic Name  Candesartan, Candesartan/HCTZ  
Valsartan, Valsartan/HCTZ  

Brand Name  Atacand, Atacand-HCT  
Diovan, Diovan-HCT  

Created: 03/31/16

1. Is the request for the treatment of reduced ejection fraction (systolic) heart failure?
   If yes, continue to #2.  
   If no, continue to #3.

2. Is documentation of intolerance or failure of an ACEI included with the request?
   If yes, approve for lifetime  
   If no, deny

3. Is the request for the treatment of hypertension?
   If yes, continue to #4  
   If no, deny

4. Has the patient tried maximum tolerated doses of losartan AND irbesartan AND at least one medication from three of the following classes:
   a. Calcium channel blockers (amlodipine, nifedipine, diltiazem, verapamil)  
   b. Beta blockers (metoprolol, carvedilol, atenolol)  
   c. Alpha blockers (prazosin, terazosin, doxazosin)  
   d. Thiazides (chlorthalidone, HCTZ)  
   e. Other (clonidine, spironolactone)
   If yes, approve for lifetime  
   If no, deny and offer untried agents
Initial:
1. Is Cablivi being prescribed by a hematologist?
   If yes, continue to #2.    If no, do not approve.

2. Does the member have a diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP) including the following features?
   a. Thrombocytopenia
   b. Microscopic evidence of red blood cell fragmentation (e.g., schistocytes)
   If yes, continue to #3.    If no, do not approve.

3. Is Cablivi being administered in addition to plasma exchange and immunosuppressive therapy and planned to be continued for 30 days after discontinuation of plasma exchange?
   If yes, continue to #4.    If no, do not approve.

4. Approve for one month for up to 30-day supply.

Renewal:
1. Has the member received Cablivi in combination with plasma exchange and immunosuppressive therapy during plasma exchange and for 30 days beyond the last plasma exchange?
   If yes, continue to #2.    If no, do not approve.

2. Does the member have sign(s) of persistent underlying disease such as suppressed ADAMTS13 activity levels?
   If yes, continue to #3.    If no, do not approve.

3. Approve for one month for up to 28-day supply.
Generic Name: Capsaicin
Brand Name: Qutenza

Created: 7/15/10
Reviewed: 12/2/11, 7/12/12, 9/12/13

*** Nonformulary on outpatient benefit. PA required for medical benefit ***

1. Does the member have a diagnosis of postherpetic neuralgia?
   If yes, continue to #2. If no, do not approve.

2. Has the member failed ALL of the following?
   a. Capsaicin cream
   b. Tricyclic antidepressant (amitriptyline, nortriptyline, desipramine)
   c. Gabapentin
   d. Lyrica

   If yes, continue to #3. If no, do not approve.

3. Approve up to 4 patches x 3 months. Must be administered by a healthcare professional.
Generic Name  C1 inhibitor (human)

Brand Name  Cinryze

Created: 7/16/09
Revised: 01/25/12
Reviewed: 7/12/12, 9/12/13

*** Non-formulary on outpatient benefit. PA required on medical benefit ***

**Initial criteria:**
1. Does the member have a diagnosis of hereditary angioedema (HAE) confirmed by genetic testing or normal C1q lab levels with levels below the lab's normal reference range for both C4 and C1INH?
   If yes, continue to #2.     If no, do not approve.

2. Does the member have a history of at least two attacks per month which are considered severe with swelling of the face, throat or gastrointestinal tract that significantly interrupts usual daily activity despite short-term symptomatic treatment?
   If yes, continue to #3.     If no, do not approve.

3. Has the member been evaluated for triggers of HAE attacks and is maximally managed for avoidance of those triggers (such as stress, hormonal changes, dental surgery, trauma, medications including ACE inhibitors and estrogen)?
   If yes, continue to #4.     If no, do not approve.

4. Has the member failed treatment with androgen therapy (i.e. danazol)?
   If yes, continue to #5.     If no, do not approve and recommend a trial of danazol.

5. Is treatment with acute, abortive therapy an option for this member (Firazyr,Berinet)?
   If yes, do not approve     If no, continue to #6.

6. Review case with medical director for consideration of approval.
   Long-term prevention: 1000 units IV q 3-4 days.
   Short-term prevention: 1000 units per procedure.

**Renewal criteria:**
1. Has there been at least a 50% reduction in the number of angioedema attacks, significant improvement in the severity and duration of attacks, and clinical documentation of functional improvement?
   If yes, approve previous qty as above x 1 month.     If no, do not approve.
Generic Name   C1 inhibitor (human)

Brand Name   Haegarda

Created: 11/9/17

**Initial criteria:**
1. Does the member have a diagnosis of hereditary angioedema (HAE) confirmed by genetic testing or normal C1q lab levels with levels below the lab's normal reference range for both C4 and C1INH?
   - If yes, continue to #2.
   - If no, do not approve.

2. Does the member have a history of at least two attacks per month which are considered severe with swelling of the face, throat or gastrointestinal tract that significantly interrupts usual daily activity despite short-term symptomatic treatment?
   - If yes, continue to #3.
   - If no, do not approve.

3. Has the member been evaluated for triggers of HAE attacks and is maximally managed for avoidance of those triggers (such as stress, hormonal changes, dental surgery, trauma, medications including ACE inhibitors and estrogen)?
   - If yes, continue to #4.
   - If no, do not approve.

4. Has the member failed treatment with androgen therapy (i.e. danazol)?
   - If yes, continue to #5.
   - If no, do not approve and recommend a trial of danazol.

5. Is treatment with acute, abortive therapy an option for this member (Firazyr, Berinert)?
   - If yes, do not approve
   - If no, continue to #6.

6. Does the member weigh 100 kg or less?
   - If yes, continue to #8.
   - If no, continue to #7

7. Has the member tried and failed Cinryze IV?
   - If yes, continue to #8.
   - If no, deny for the alt.

8. All approvals subject to medical director review. Approvals will be limited to appropriate weight based dose every 3-4 days.

**Renewal criteria:**
1. Has there been at least a 50% reduction in the number of angioedema attacks, significant improvement in the severity and duration of attacks, and clinical documentation of functional improvement?
   - If yes, approve previous qty as above x 12
   - If no, do not approve.
months.
Initial Criteria:

1. Is there documentation to support the use of this new antibiotic such as extensive resistance to common antibiotic agents including ceftazidime alone? Such documentation may include or require Infectious Disease consult notes.

   If yes, continue to #2. If no, deny.

2. Approve for duration clinically necessary.
1. Is the member at high-risk for GI complications from long-term use of NSAIDs as defined as one of the following?
   a. History of GI bleed
   b. Active peptic ulcer documented through endoscopy
   c. High risk of GI bleed (at least 3 of the following):
      i. History of peptic ulcer disease
      ii. Age >65
      iii. Long-term use of oral steroids
      iv. Long-term use of anticoagulants or antiplatelets (eg warfarin or clopidogrel)
      v. Male gender
      vi. History of Dyspepsia

     If yes, continue to #2. If no, do not approve

2. Is the member currently on aspirin? (Concurrent use of aspirin with celecoxib eliminates any gastroprotective benefit of celecoxib.)
   If yes, do not approve. If no, continue to #3.

3. Has the member failed a trial meloxicam?
   If yes continue to #4 If no, do not approve

4. Approve for life.
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Created: 03/10/2016
Updated: 5/17/16, 7/18/16, 11/15/16, 1/25/17, 5/11/17, 11/09/17, 1/11/18, 3/8/18, 5/10/18, 11/8/18, 1/10/19, 3/14/19, 5/9/19, 7/11/19, 1/9/2020

***Office administered infusions/injections are nonformulary on outpatient benefit. PA required for medical benefit. ***
**Initial Criteria:**
1. Is the treatment being prescribed by a hematologist or oncologist, as appropriate, for the type of cancer?
   - If yes, continue to #2.
   - If no, do not approve.

2. Is the treatment supported for the diagnosis in the NCCN guidelines?
   - If yes, continue to #4.
   - If no, continue to #3.

3. Is the treatment being used according to the FDA indication?
   - If yes, continue to #4
   - If no, do not approve.

4. Does the request meet criteria for treatment coverage specified in Guideline Note 12 of the Prioritized List of Health Services, considering treatment of cancer with little or no benefit?
   - If yes, continue to #5
   - If no, do not approve.

5. Approve x 12 months.

**Renewal Criteria:**
1. Has there been evidence of tumor response?
   - If yes, approve x 12 months.
   - If no, do not approve.
Generic Name      Clobazam
Brand Name        Onfi

Created: 1/10/19
Revised: 5/9/19, 7/11/19

1. Is the member at least age 2?
   If yes, continue to #2.                                If no, do not approve.

2. Does the member have a diagnosis of Lennox-Gastaut syndrome, refractory epilepsy
   or Dravet syndrome?
   If yes, continue to #3.                                If no, do not approve.

3. Approve x life (note: generic required)
Generic Name: Clonazepam
Brand Name: Klonopin
Created: 6/23/16

Effective 6/1/18: PA removed; however CareOregon intends to bring back PA in 2019

1. Does the member have a seizure diagnosis?
   Yes, approve for life.   No, continue to #2

2. Does the member have a terminal illness or in palliative care?
   Yes, approved for life.   No, continue to #3

3. Is the request for short term use (4 weeks or less)?
   Yes, continue to #4.   No, continue to #5 (chronic use)

4. Is the member on opiates or other sedative hypnotics?
   Yes, deny   No, approve for 1 month every 120 days

5. For chronic use, are all of the following met?
   a. Used for a supported indication
   b. Supported and clear clinical rationale to support-long term clonazepam use
   c. No concurrent use of opioids or sedative/hypnotics
   Yes, approve for 12 months.   No, deny for not medically appropriate.
Generic Name   Collagenase clostridium histolyticum

Brand Name     Xiaflex

Created: 8/13/10
Reviewed: 12/2/11, 5/10/12, 9/12/13
Revised: 6/1/14, 6/10/16, 09/08/16

**Initial:**
1. Does the member have a diagnosis of Dupuytren’s contracture?
   - If yes, continue to #2.
   - If no, do not approve.

2. Approve up to 1 injection per cord, maximum 2 cords.

**Renewal for Dupuytren’s Contracture:**
1. Is the request to treat the same cord previously treated?
   - If yes, continue to #2.
   - If no, go to initial criteria.

2. Has there been at least 4 weeks between same cord treatments?
   - If yes, continue to #3.
   - If no, deny (unless SOC is beyond 4 week minimum)

3. Has there been a cumulative total of 3 or more treatment for the same cord already?
   - If yes, deny for exceed FDA max.
   - If no, continue to #4.

4. Is their documentation demonstrating the condition persists and requires additional therapy?
   - If yes, approve up 1 to injection per cord.
   - If no, deny.
   Max 2 cords (each cord must meet criteria)
1. Does the member have chronic iron overload due to blood transfusions or from non-transfusion-dependent thalassemia syndromes?  
   If yes, continue to #2  
   If no, do not approve.

2. Has the member tried and failed deferoxamine injections (though frequent injections required, it is significantly less expensive and no evidence it is less effective)?  
   If yes, approve for life.  
   If no, do not approve and approve deferoxamine injections.
Generic Name:  Defibrotide Sodium

Brand Name:  Defitelio

Date Created: 07/19/16

*** Nonformulary on outpatient benefit. PA required for medical benefit. ***

1. Is the request for PROPHYLAXIS of hepatic veno-occlusive disease from hematopoietic stem-cell transplantation (HSCT)?
   If yes, deny for investigational. If no, continue to #2.

2. Is the request for acute treatment of hepatic veno-occlusive disease from hematopoietic stem-cell transplantation (HSCT)?
   If yes, approve. If no, deny.

Note: CareOregon expects acute treatment would begin during an acute hospitalization where PA is not required for drugs. PA is only required for pre-planned hospitalizations or outpatient infusion services.
Generic Name: Denosumab
Brand Name: Prolia

Created 12/7/10
Revised: 11/29/11, 7/13/12, 11/8/12, 11/09/17, 05/10/18
Reviewed: 9/12/13

*** Nonformulary on outpatient benefit. PA required for medical benefit. ***

Created 12/7/10
Revised: 11/29/11, 7/13/12, 11/8/12, 11/09/17, 05/10/18, 9/13/18
Reviewed: 9/12/13

*** Nonformulary on outpatient benefit. PA required for medical benefit. ***

1. Is the member a post-menopausal female with osteoporosis with ONE of the following:
   a. Radiographic evidence of an osteoporotic fracture while compliant on an oral bisphosphonate for at least 12 months.
   b. High risk of fracture AND
      i. documented adverse event with an oral bisphosphonate despite proper administration, OR
      ii. contraindication (previous hypersensitivity, esophageal abnormality, hypocalcemia, inability to stand or sit upright for 30 minutes) to oral bisphosphonates.
   If yes, continue to #5. If no, continue to #2.

2. Does the member have glucocorticoid-induced osteoporosis (on prednisone 7.5mg/day or equivalent for at least 6 months) with ONE of the following?
   a. Radiographic evidence of an osteoporotic fracture while compliant on an oral bisphosphonate for at least 12 months.
   b. High risk of fracture AND
      i. documented adverse event with an oral bisphosphonate despite proper administration, OR
      ii. contraindication (previous hypersensitivity, esophageal abnormality, hypocalcemia, inability to stand or sit upright for 30 minutes) to oral bisphosphonates.
   If yes, continue to #5. If no, continue to #3.

3. Does the member have a diagnosis of ONE of the following?
   a. Non-metastatic prostate cancer and receiving androgen deprivation therapy (ADT).
   b. Breast cancer receiving adjuvant aromatase inhibitor (AI) therapy.
   c. Male with osteoporosis.
   If yes, continue to #4. If no, do not approve.
4. Is the member at high risk for fracture?  
   If yes, continue to #5.  
   If no, do not approve.

5. Has the member tried and failed or have contraindications to zoledronic acid?  
   If yes, continue to #6.  
   If no, do not approve.

6. Approve for 12 months.
Generic Name  Denosumab
Brand Name  Xgeva

Created: 3/10/11
Reviewed: 7/12/12, 9/12/13
Revised: 9/16/13, 2/17/15, 05/10/18

*** Nonformulary on outpatient benefit. PA required for medical benefit. ***

1. Does the member have a diagnosis of bone metastases from solid tumors or multiple myeloma?
   If yes, go to #2. If no, continue to #3.

2. Has an zoledronic acid been tried first or is there a contraindication to zoledronic acid that is not a contraindication to denosumab?
   If yes, approve x 12 months. If no, do not approve.

3. Does the member have a diagnosis of giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity?
   If yes, approve x 12 months. If no, continue to #4

4. Does the member have a diagnosis of hypercalcemia of malignancy (HCM)?
   If yes, continue to #5. If no, do not approve.

5. Has a bisphosphonate such as zoledronic acid (Zometa) or pamidronate (Aredia) been tried first or is there a contraindication to either?
   If yes, approve x 12 months. If no, do not approve.
Generic Name          Desmopressin acetate
Brand Name            DDAVP

Revised: 4/12/10, 9/12/13
Reviewed: 12/2/11, 9/13/12

1. Does the member have a diagnosis of Enuresis (bedwetting)?
   If yes, do not approve.              If no, continue to #2.

2. Does the member have a diagnosis of Diabetes Insipidus?
   If yes, continue to #4.              If no, continue to #3.

3. Does the member have a diagnosis of hemophilia A with factor VIII level greater than 5% or von Willebrand disease type 1 with factor VIII levels greater than 5%?
   If yes, continue to #4.              If no, do not approve.

4. Approve for life. For hemophilia A or von Willebrand’s, approve Stimate 0.15mg nasal spray.
Generic Name: dexamethasone ophthalmic insert

Brand Name: Dextenza

Reviewed: 7/11/2019, 11/14/19

*** Nonformulary on outpatient benefit. PA required for medical benefit. ***

Initial Criteria:
1. Is the diagnosis ocular pain and inflammation following ophthalmic surgery?
   If yes, continue to #2.  If no, deny.

2. Has the member failed steroid and non-steroid anti-inflammatory eye drops?
   If yes, approve 1x.  If no, deny.
Generic Name       Dimethyl fumarate
Brand Name         Tecfidera

Created: 5/9/13
Reviewed: 9/12/13

1. Is the member age 18 or older?
   If yes, continue to #2.          If no, do not approve.

2. Does the member have a diagnosis of relapsing, remitting multiple sclerosis?
   If yes, continue to #3.          If no, do not approve.

3. Is the request for monotherapy and is not intended to be used in combination with
   other MS agents?
   If yes, approve x life.          If no, do not approve.
1. Does the member have nausea and vomiting associated with HIV/AIDS or cancer **and** is undergoing chemotherapy or radiation therapy?
   - If yes, continue to #3.
   - If no, continue to #2.

2. Does the member have a diagnosis of HIV/AIDS anorexia associated with weight loss or cachexia?
   - If yes, continue to #4.
   - If no, forward to the PA Pharmacist.

3. Has the member tried and failed or does the member have a contraindication to the following?
   - i) At least **TWO** of the following formulary alternatives:
     1. dimenhydrinate, or
     2. meclizine, or
     3. metoclopramide, or
     4. promethazine, or
     5. prochlorperazine
     **AND**
   - ii) Oral Zofran (ondansetron):
     - If yes, continue to #5.
     - If no, do not approve.

4. Has the member tried and failed or have a contraindication to Megace (megestrol)?
   - If yes, continue to #5.
   - If no, do not approve.

5. Approve for 12 months.
1. Is Multaq being requested by or supervised by a cardiologist?
   If yes, continue to #2.                                          If no, do not approve.

2. Does the member meet any of the following exclusionary criteria?
   - symptomatic heart failure with recent decompensation requiring hospitalization
   - NYHA Class IV heart failure
   - Permanent atrial fibrillation that will not or cannot be cardioverted into normal sinus rhythm.
   If yes, do not approve.                                         If no, continue to #3.

3. Has the member tried and failed or have a contraindication to amiodarone?
   If yes, continue to #4.                                        If no, do not approve.

4. Approve for lifetime.
Generic Name: Dupilumab
Brand Name: Dupixent
Created: 3/14/18
Updated: 11/14/19

**Atopic dermatitis**

**Initial Criteria:**
1. Does the member have chronic, moderate to severe Atopic Dermatitis with functional impairment and one or more of the following:
   a. At least 10% body surface area involved
   b. Hand, foot or mucous membrane involvement
   If yes, continue to #2.  If no, do not approve.
2. Has the member failed topical steroids, UVB phototherapy, and topical tacrolimus (requires a prior authorization)?
   If yes, continue to #3.  If no, do not approve.
3. Has the member failed two of the following?
   a. Cyclosporine
   b. Azathioprine
   c. Methotrexate
   d. Mycophenolate
   If yes, continue to #4.  If no, do not approve.
   Deny for GN 21 not met
4. Is the request for every other week dosing?
   If yes, approve x 4 months.  If no, do not approve.

**Atopic dermatitis**

**Renewal Criteria:**
1. Has the member experienced a 50% reduction in eczema and/or is there evidence of significant functional improvement?
   If yes, approve for 12 months.  If no, do not approve.

**Severe asthma**

**Initial Criteria:**
1. Is the request from a pulmonologist?
   If yes, continue to #2.  If no, do not approve.
2. Does the member have severe asthma which is uncontrolled despite treatment with the following?
   a. High dose inhaled corticosteroid with a long acting beta agonist (such as AirDuo, Advair, or Symbicort)
   b. Leukotriene inhibitor (such as montelukast)
      If yes, continue to #3.  If no, do not approve.

3. Is the asthma defined as eosinophilic phenotype or oral corticosteroid dependent?
   a. Eosinophilic phenotype, continue to #4
   b. Oral corticosteroid dependent, continue to #6
   c. If neither, do not approve

4. In the past year has the member had frequent asthma exacerbations resulting in repeated use of health care services, such as urgent care or ED visits or hospitalization?
   If yes, continue to #5.  If no, do not approve.

5. Does the member have a recent eosinophil count of ≥150/µl?
   If yes, approve x 4 months.  If no, do not approve. Approval studies showed no efficacy in patients with eosinophils <150/µl.

6. Does the member require oral steroids to maintain asthma control?
   If yes, approve x 4 months.  If no, do not approve.

**Severe Asthma Renewal Criteria:**
1. Has the member had a reduction in asthma exacerbations or a decrease in oral corticosteroid dose and demonstrated sustained clinical improvement from baseline?
   If yes, approve for 6 months.  If no, do not approve.

**Chronic Rhinosinusitis with Nasal Polyps Initial Criteria:**
1. Is the request from an allergist or ENT?
   If yes, continue to #2.  If no, do not approve.

2. Does the member have recurrent nasal polyps after multiple prior sinus surgeries within the past 2 years?
   If yes, continue to #3.  If no, do not approve.

3. Has the member failed all of these treatments?
a. At least 2 prior intranasal corticosteroids  
b. Sinuva  
   If yes, continue to #4.  
   If no, do not approve.

4. Is the member currently adherent to a nasal corticosteroid?  
   If yes, continue to #5.  
   If no, do not approve.

5. Is the member at risk of another sinus surgery?  
   If yes, continue to #6.  
   If no, do not approve.

6. Is there a statement why sinus surgery is not medically appropriate?  
   If yes, send to medical director  
   If no, do not approve.

**Chronic Rhinosinusitis with Nasal Polyps**

**Renewal Criteria:**

1. Has the member had a clinically significant improvement in symptoms and reduced risk of needing surgery?  
   If yes, approve for 6 months.  
   If no, do not approve.
Initial:
1. Does the member have a diagnosis of atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy or paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis?
   If yes, continue to #2.  If no, continue to #3

2. Is the member being followed by a hematologist or a specialist in this area?
   If yes, submit for external specialist review and notify medical director team.  
   If no, do not approve.

3. Does the member have generalized myasthenia gravis with clinical classification II to IV?
   If yes, continue to #4.  If no, continue to #7

4. Is there documentation which confirms the diagnosis is anti-acetylcholine receptor antibody positive?
   If yes, continue to #5.  If no, pend for this information and if not available deny

5. Has the member tried and failed All of the following?
   a. Pyridostigmine; AND
   b. Corticosteroids; AND
   c. At least two immune modulating agents including azathioprine, mycophenolate, cyclosporine, and tacrolimus; AND
   d. Rituxan; AND
   e. IVIG
   If yes, continue to #6  If no, deny and require alts (listed in relative preference.  May need to approve alts if PA required)

6. Has a baseline MG Activities of Daily Living (MG-ADL) score been obtained?
   If yes, continue to #10  If no, pend for this information.

7. Does the member have neuromyelitis optica spectrum disorder (NMOSD) and is anti-aquaporin-4 antibody positive?
   If yes, continue to #8  If no, deny.
8. Is the request from a neurologist?  
   If yes, continue to #9  
   If no, deny

9. Has the member tried and failed azathioprine and rituximab (Rituxan)?  
   If yes, continue to #10  
   If no, deny

10. Has the case’s medical necessity been confirmed with external specialist (MRIoA) and medical director review?  
    Yes, approve x 6 months.  
    If no, have these activities completed

Renewal:  
1. Is there documentation which demonstrates a clinically significant and meaningful response to therapy?  
   Yes, review with medical director.  
   If no, deny.
Initial Criteria:
1. Is the member between ages 18 and 49?  
   If yes, continue to #2  
   If no, do not approve

2. Has treatment been initiated/supervised by an obstetrician/gynecologist?  
   If yes, continue to #3  
   If no, do not approve

3. Does the member have a diagnosis of endometriosis confirmed by laparoscopy?  
   If yes, continue to #4  
   If no, do not approve

4. Has the member failed a 3-month trial of or have contraindications to NSAIDs AND hormonal therapies (combined oral contraceptives, progestins, or levonorgestrel IUD, etc.)?  
   If yes, continue to #5  
   If no, do not approve

5. Has the member tried a GnRH agonist (Lupron, Synarel, Zoladex, etc.) in the past?  
   If yes, continue to #6  
   If no, do not approve

6. Is there documentation of a clinical response to a GnRH agonist?  
   If yes, continue to #7  
   If no, do not approve

7. Has the member reached the maximum length of therapy allowed for GnRH agonists (12 months)?  
   If yes, approve x 6 months  
   If no, do not approve

Renewal Criteria:  
1. Is the request for continuation of the 200 mg twice daily dose?  
   If yes, do not approve  
   If no, continue to #2

2. Has the member been using the medication for 24 months?  
   If yes, do not approve  
   If no, continue to #3

3. Is there documentation of symptom improvement?  
   If yes, approve x 18 months  
   If no, do not approve
Generic Name: Edaravone
Brand Name: Radicava

Appeals: Upheld denials may need to be forwarded to a specialist reviewer. P
Revised: 09/14/17

**Initial Criteria:**
1. Does the member have a diagnosis of ALS based on El Escorial revised criteria or Awaji criteria with disease duration of less than 2 years? 
   If yes, continue to #2  
   If no, do not approve.

2. Has the treatment been initiated by or is a neurologist currently supervising it? 
   If yes, continue to #3.  
   If no, do not approve.

3. Is there documentation that the member's FEV1 is ≥80% 
   If yes, continue to #4.  
   If no, do not approve.

4. Is there documentation that the member is mostly or entirely able to complete ADLs independently (able to dress and bathe themselves, feed themselves, turn in bed, and walk)?
   If yes, continue to #5.  
   If no, do not approve.

5. Does the member have reasonable, documented goals of treatment (such as maintaining independent ADLs)?
   If yes, continue to #6.  
   If no, do not approve.

6. Is the member currently taking or have a contraindication to riluzole?
   If yes, approve x 6 months.  
   If no, do not approve.

**Renewal Criteria:**
1. Is there documentation that the member is still able to complete independent ADLs? 
   If yes, approve for 6 months.  
   If no, continue to #2.

2. Is there documentation that the member is still meeting their goals of care?
   If yes, approve for 6 months.  
   If no, do not approve.
TPO-RA agents

Generic Name
Avatrombopag
Eltrombopag
Romiplostim

Brand Name
Doptelet
Promacta
Nplate

Created: 11/14/2019

*** Nplate is non-formulary for outpatient benefit. PA required for medical benefit

Initial criteria:
All diagnoses:
1. Has the treatment been initiated by or is an appropriate specialist currently supervising it?
   If yes, continue to #2.   If no, do not approve.

2. Is the product requested supported for the diagnosis at appropriate dose for the age of the member?
   If yes, continue to #3.   If no, do not approve.

3. Is the product requested to be used with another therapy in the TPO-ER class or Tavalisse?
   If yes, do not approve.   If no, continue to diagnoses.

Initial criteria:
Immune Thrombocytopenic Purpura (ITP):
1. Does the member have a diagnosis of immune thrombocytopenic purpura (ITP)?
   If yes, continue to #2.   If no, do not approve.

2. Is there medical record documentation of platelet count of less than 20,000 per mm3 or less than 30,000 per mm3 with symptoms of bleeding?
   If yes, continue to #3.   If no, do not approve.

3. Is there documentation of failure of or contraindication to TWO formulary alternatives:
   a. Systemic corticosteroids
   b. Immunoglobulin replacement (IVIG or Anti-D)
   c. Rituximab
   d. Splenectomy
   If yes, approve for 3 months.   If no, do not approve.
Renewal criteria:

ITP:
1. Is there medical record documentation of maintenance of platelet counts between 30,000 per mm³ and 150,000 per mm³ or a doubling of platelet counts from baseline with resolution of bleeding episodes.
   If yes, approve for 6 months. If no, do not approve.

Initial Criteria:

Aplastic anemia:
1. Does the member have a diagnosis of aplastic anemia?
   If yes, continue to #2. If no, do not approve.

2. Is there medical record documentation of platelet count of less than 30,000 per mm³?
   If yes, continue to #3. If no, do not approve.

3. Had the member failed immunosuppressive therapy with TWO of the following:
   a. antithymocyte globulin (ATG)
   b. cyclophosphamide
   c. cyclosporine
   d. mycophenolate mofetil
   e. sirolimus
   If yes, continue to #4. If no, do not approve.

4. Approve for 16 weeks.

Renewal criteria:

Aplastic anemia:
1. Is there medical record documentation that hematologic response has occurred after 16 weeks of therapy?
   If yes, approve for 6 months. If no, do not approve.

Initial criteria:

Thrombocytopenia in CLD:
1. Does the member have chronic liver disease, and scheduled to undergo an elective procedure at least 8 days from the request date?
   If yes, continue to #2. If no, do not approve.

2. Is there medical record documentation of platelet count of less than 50,000 per mm³?
   If yes, continue to #3. If no, do not approve.

3. Is the scheduled procedure high risk for bleeding, or does the member currently have bleeding symptoms?
   If yes, continue to #4. If no, do not approve.
4. Approve for one fill.
Generic Name  Entecavir
Brand Name   Baraclude

Created: 2/16/09
Revised: 9/16/10
Reviewed: 12/2/11, 7/12/12, 9/12/13

**Initial Criteria:**
1. Does the member have compensated cirrhosis?
   If yes, continue to #2.   If no, continue to #3.
2. Is HBV DNA > 2000 IU/ml (10,000 or 10^4 copies/ml)?
   If yes, continue to #8.   If no, do not approve.
3. Does the member have decompensated cirrhosis with detectable HBV DNA?
   If yes, continue #8.     If no, continue to #4.
4. Is the member HBeAg (+)?
   If yes, continue to #5.    If no, continue to #6.
5. Does the member meet the following:
   a. HBV DNA ≥ 20,000 IU/mL
   b. Serum ALT is persistently elevated after 3-6 months of monitoring or liver biopsy shows ≥ moderate inflammation or significant fibrosis
   If yes, continue to #8.     If no, do not approve.
6. Is the member HBeAg (-)?
   If yes, continue to #7.    If unknown, request HBeAg, HBV DNA, serum ALT for past 3-6mo and liver biopsy if available from provider.
7. Does the member meet the following:
   a. HBV DNA > 2,000 IU/mL
   b. Serum ALT is persistently elevated after 3-6 months of monitoring or liver biopsy shows ≥ moderate inflammation or fibrosis
   If yes, continue to #8.     If no, do not approve.
8. Does the member have HIV co-infection and is NOT currently receiving HAART (antiretroviral) therapy?
   If yes, do not approve     If no, continue to #9.
9. Approve for 6 months.

**Renewal Criteria:**
1. Does the member have evidence of treatment compliance evidenced by consistent monthly prescription fills?
   If yes, approve x 12mo.   If no, fwd to provider consult
Generic Name: Etelcalcetide
Brand Name: Parsabiv
Initial: 1/11/18

1. Does the member have a diagnosis of secondary hyperparathyroidism with a serum parathyroid hormone value of > 200pg/mL, chronic kidney disease, and receiving hemodialysis?
   If yes, continue to #2. If no, deny.

2. Does the member have a diagnosis of parathyroid carcinoma or primary hyperparathyroidism?
   If yes, deny. If no, continue to #3.

3. Is the member’s corrected serum Calcium greater than the lower limit of the facility’s reference range?
   If yes, continue to #4 If no, deny.

4. Has the member tried and failed Sensipar?
   If yes, continue to #5. If no, deny and recommend Sensipar.

5. Approve for 12 months with quantity limit #12/month (3 times weekly dosing)

Renewal Criteria:
1. A provider statement that the patient has shown improvement or beneficial response to therapy with supporting laboratory findings.
   a. Reduction in iPTH
   b. Current corrected Serum Calcium greater than the lower limit of facility’s reference range.
Generic Name  Evolocumab
Brand Name   Repatha

Created: 6/21/17
Updated: 5/9/19

Initial Criteria
1. Is request from a cardiologist, endocrinologist, or lipid specialist?
   If yes go to #2   If no, deny

2. Does the member have Homozygous Familial Hypercholesterolemia (HoFH) confirmed with a genetic test?
   If yes, approve x life.  If no, go to #3

3. Does the member have established Atherosclerotic Cardiovascular Disease (ASCVD)?
   If yes, go to #4.   No, go to #6.

4. Does the member have very high risk ASCVD as evidenced by either: 1) history of multiple major ASCVD events or 2) 1 major ASCVD event AND multiple high-risk conditions
   a. Major ASCVD Events
      i. Recent (past 12 months) acute coronary syndrome (ACS)
      ii. Prior myocardial infarction (other than recent ACS event listed above)
      iii. Prior ischemic stroke
      iv. Symptomatic peripheral arterial disease
   b. High-Risk Conditions
      i. Age ≥65 years
      ii. Heterozygous familial hypercholesterolemia (HeFH)
      iii. Prior coronary revascularization outside of the major ASCVD event(s)
      iv. Diabetes mellitus
      v. Hypertension
      vi. Chronic kidney disease (eGFR 15-59 mL/min/1.73m²)
      vii. Current smoking
      viii. LDL-C ≥100 mg/dL despite maximally tolerated statin and ezetimibe
      ix. History of congestive heart failure
   Yes, go to #5   No, go to #6
5. Does the member have an LDL greater than or equal to 70 mg/dL despite maximum tolerated dose of high intensity statin (atorvastatin 40-80 mg, rosuvastatin 20-40 mg) + ezetimibe?
   a) Yes, go to #11
   b) If physician states statin associated side effects prevent use of high intensity statin therapy, continue to #10
   c) No, deny and require alts OR state member is at goal

6. Does the member have Heterozygous Familial Hypercholesterolemia (HeFH)?
   Yes, go to #7   No, go to #8

7. Does the member have an LDL greater than or equal to 100 mg/dL despite maximum tolerated dose of high intensity statin (atorvastatin 40-80 mg, rosuvastatin 20-40 mg) + ezetimibe?
   a. Yes, go to approve
   b. If physician states statin associated side effects prevent use of high intensity statin therapy, continue to #10
   c. No, deny and require alts OR at goal

8. Does the member have a baseline LDL greater than or equal to 220mg/dL?
   Yes, go to #9   No, deny. Not guideline recommended.

9. Does the member have an LDL greater than or equal to 130 mg/dL despite maximum tolerated dose of high intensity statin (atorvastatin 40-80 mg, rosuvastatin 20-40 mg) + ezetimibe?
   a. Yes, go to #11
   b. If physician states statin associated side effects prevent use of high intensity statin therapy, continue to #10
   c. No, deny require alts OR at goal

10. Statin Intolerance: Is the patient unable to tolerate high-intensity statin therapy documented by one of the following?
    a. Severe statin-associated side effects (rhabdomyolysis, hepatotoxicity- small increases in transaminases are not considered severe)
    b. If statin-associated side effects are not severe, has re-challenge with an alternate statin been attempted AND have non-statin causes been addressed?
    c. Medical contraindication to be on a statin regimen due to non-modifiable factors?
       If yes, continue to #11   No, deny and recommend alt strategy above

11. Approve x 6 months

First Renewal Criteria (after original approval)
1. Is the patient continuing maximum adjunctive treatment (i.e. statin, Zetia/BAS, low fat diet, exercise)
   If yes, continue to #2. If no, do not approve.

2. Has the patient been adherent with Repatha?
   If yes, continue to #3. If no, do not approve.

3. Has there been a significant* LDL reduction while on Repatha? *Significant lowering of LDL-C is defined as a $\geq 30\%$ decrease in LDL-C.
   If yes, approve x life. If no, do not approve.
Generic Name  Epoetin alfa
Darbepoetin

Brand Name  Epogen
Procrit
Aranesp
Retacrit

Revised: 1/27/09, 12/28/11, 7/18/12, 11/23/15, 5/12/16, , 9/13/18
Reviewed: 9/12/13, 7/11/19

Note: Epogen and Procrit are non-formulary on the pharmacy benefit as of 10/1/18 (replaced by the biosimilar Retacrit).

**Initial Criteria:**
1. Does the member have anemia associated with **ONE** of the following conditions?
   a. Chronic renal failure (CRF), or
   b. Solid tumors or multiple myeloma or lymphoma or lymphocytic leukemia who is currently undergoing myelosuppressive chemotherapy.
      If yes, continue to #4. If no, continue to #2.

2. Does the member have anemia associated with HIV/AIDS Zidovudine therapy?
   If yes, continue to #5. If no, continue to #3.

3. Does the member have anemia associated with interferon-ribavirin treatment (Pegasys, Peg-Intron, ribavirin, Ribasphere, Copegus)?
   If yes, forward to PLAN for review. If no, continue to #6

4. Does the member meet **ALL** of the following criteria?
   a. Hgb < 10 g/dL or Hct < 30%, and
   b. transferrin saturation > 20% **AND** ferritin > 100 ng/ml
      If yes, continue to #8. If no, do not approve.

5. Does the member meet **ALL** of the following criteria?
   a. Hgb < 10 g/dL or Hct < 30%, and
   b. transferrin saturation ≥ 20%, and
   c. Endogenous erythropoietin ≤ 500 IU/L, and
   d. Zidovudine doses ≤ 4200mg per week
      If yes, continue to #8. If no, do not approve.
6. Is the request for pre-operative treatment to raise hemoglobin and hematocrit prior to scheduled surgical procedures AND member has religious beliefs that preclude blood product transfusions?
   If yes, continue to #7. If no, do not approve.

7. Is the member currently anemic by the following definition?:
   a. Men: Hemoglobin < 13 g/dL
   b. Women: Hemoglobin < 12 g/dL
   If yes, continue to #8. If no, do not approve.

8. Approve for 3 months.

**Renewal Criteria:**

1. Is the member currently on epoetin (Procrit, Epogen) or darbepoetin (Aranesp) therapy and has maintained adequate iron stores (transferring saturation > 20%)?
   If yes, continue to #2. If no, do not approve.

2. Has the member continued to see a response to treatment demonstrated by an increase from baseline Hb/Hct or maintenance at target Hb/Hct?
   If yes, continue to #3. If no, do not approve.

3. For chronic kidney disease and HIV/AIDS: Approve for 12 months.
   For anemia of cancer/chemotherapy: Approve for 6 months.
Generic Name  
Erenumab-aooe

Brand Name:  
Aimovig

Date Created: 7/12/18
Revised: 7/11/19

New Start:
1. Is the request for the prophylaxis of migraines?  
   Yes, continue to #2.  
   No, deny for not accepted indication.

2. Is the request from a neurologist or headache specialist?  
   Yes, continue to #3.  
   No, deny for not medically appropriate.

3. Have medication overuse headaches and hemiplegic migraines been ruled out?  
   Yes, continue to #4.  
   No, deny for medical necessity.

4. Is the member at least 18 years old?  
   Yes, continue to #5.  
   No, deny for investigational.

5. How many migraines lasting at least 4 hours does the member have each month?  
   a. 0-3: Deny for medical necessity  
   b. 4-14: Continue to episodic alts  
   c. 15+: Continue to chronic alts

6. Has the member failed a 3 month-trial of at least one medication in each of the following classes?  
   a. Beta-blockers: propranolol, atenolol, timolol, or nadolol.  
   b. Anticonvulsants: topiramate, divalproex, or gabapentin  
   c. TCA: amitriptyline, nortriptyline, or desipramine.  
      Yes, continue to #8.  
      No, deny for criteria not met.

7. Has the member failed a 3 month-trial of at least one medication in each of the following classes?  
   a. Beta-blockers: propranolol, atenolol, or nadolol.  
   b. Anticonvulsants: topiramate, divalproex, or gabapentin  
   c. TCA: amitriptyline, nortriptyline, or desipramine.  
   d. Botox (PA required)  
      Yes, approve x 6 months.  
      No, deny for criteria not met.
Initial Renewal:
1. Has the member demonstrated an objective response to treatment as defined as the following:
   a. Episodic Migraine: a reduction of at least 2 headache days per month.
   b. Chronic Migraine: a reduction of at least 50% headache days per month.
      Yes, approve x 12 months.     No, continue to #2
Generic Name  Ertugliflozin  
Ertugliflozin/metformin  

Brand Name  Steglatro  
Segluromet  

Revised: 1/10/19, 2/1/2020  

Initial Criteria:  
1. Does the member have a diagnosis of Type 2 Diabetes?  
   If yes, continue to #2.  
   If no, do not approve. Use in T1DM is investigational.  

2. Has the member failed, been intolerant to, or have a contraindication to metformin?  
   If yes, continue to #3  
   If no, do not approve and recommend metformin.  

3. Has the member tried and failed ONE of, or have a contraindication to both of the following: sulfonylureas, pioglitazone?  
   If yes, continue to #4.  
   If no, do not approve.  

4. Evaluate based on HbA1c  
   a. Is HbA1c ≤ 7.5%--------------------------> If yes, do not approve.  
   b. Is HbA1c >7.5% and <9.0%----------> If yes, approve x lifetime.  
   c. Is HbA1c ≥9.0%--------------------------> If yes, continue to #5  

5. Has the provider submitted an acceptable rationale for why insulin cannot be used?  
   If yes, approve x lifetime  
   If no, deny and offer insulin.
1. Is the member under the age of 65? 
   If yes, approve until age 65. 
   If not, see PA criteria for meds high risk in the elderly.
Generic Name    Etodolac
Brand Name       Lodine

Created: 5/12/15

The following is Step Therapy coded criteria:

1. Has the member tried and failed meloxicam?
   If yes, approve for life          If no, do not approve.
Generic Name  Exenatide  
Albiglutide  
Liraglutide  
Lixisenatide  
Dulaglutide  

Brand Name  Byetta, Bydureon  
Tanzeum  
Victoza  
Adlyxin  
Trulicity  

Reviewed: 9/13/12

Initial Criteria:

1. Does the member have a diagnosis of Type 2 Diabetes?  
   If yes, continue to #2.  
   If no, do not approve.

2. Has the member failed, been intolerant to, or have a contraindication to metformin?  
   If yes, continue to #3  
   If no, do not approve.

3. Has the member failed at least TWO, or have a contraindication to all of the following: sulfonylurea, pioglitazone, alogliptin (PA required), or Steglatro (PA required)?  
   If yes, continue to #4  
   If no, do not approve.

4. Has the member failed one of the following or have medically accepted rationale why insulin can’t be used?  
   • Basal insulin  
   • Insulin NPH  
   If yes, continue to #5.  
   If no, deny for criteria.

5. Evaluate based on HbA1c:  
   a. Is HbA1c ≤ 7.5%--------------------------> If yes, do not approve.  
   b. Is HbA1c >7.5% and <9.0%-------------> If yes, approve for 6 months.  
   c. Is HbA1c ≥9.0%-------------------------> If yes, continue to #6

6. Has the provider submitted an acceptable, medical rationale for why meal time insulin cannot be used?  
   If yes, approve for 6 months.  
   If no, deny for criteria not met.

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First Renewal Criteria:

1. Has the member been adherent, had at least a 10% reduction in HbA1c, or HbA1c < 7.5%?
   - If yes, continue to #2.
   - If no, deny.

2. Is the member currently using meal-time insulin such as Admelog, Humalog, Novolog, or Apidra?
   - If yes, continue to #3
   - If no, approve x 12 months

3. Has the prescriber submitted a clear plan to discontinue meal-time insulin or is meal-time insulin only being used for the largest meal of the day?
   - If yes, Approve x 12 months
   - If no, deny on medical appropriateness

Subsequent Renewal Criteria (applies only after a full response to GLP1 identified via 10% reduction):

1. Has at least one A1c been obtained in the previous 6 months?
   - A1c less than 9%. Approve x 12 months
   - A1c less than, or equal to, 9%. Approve and recommend addition of basal or meal time insulin as appropriate.
1. Does the member have a diagnosis of acute herpes zoster or acute herpes simplex?  
   If yes, continue to #2.  
   If no, continue to #4.

2. Is the member Immune compromised (HIV, cancer, transplant, etc.)?  
   If yes, continue to #6.  
   If no, continue to #3.

3. Does the member have **ONE** of the following complications?  
   a. Herpetic gingivostomatitis, or  
   b. Herpes keratitis (ophthalmologic complications), or  
   c. Herpes encephalopathy (neurologic complications), or  
   d. Member is less than 2 years of age.  
   If yes, continue to #7.  
   If no, do not approve.

4. Does the member have a diagnosis of acute genital herpes?  
   If yes, continue to #7.  
   If no, continue to #5.

5. Is the request for herpes simplex prophylaxis and the member meets one of the following criteria:  
   a. Member is pregnant and in the last trimester of pregnancy  
   b. Member is immunocompromised (HIV, cancer, transplant)  
   If yes, continue to #7.  
   If no, do not approve.

6. Does the member have HIV and is severely immunocompromised (CD4<200) and/or has disseminated zoster, multi-dermal zoster, or an outbreak on face or genitals?  
   If yes, continue to #8.  
   If no, continue to #7.

7. Has the member tried and failed or experienced intolerable side effects to acyclovir and valacyclovir?  
   If yes, continue to #8.  
   If no, do not approve.

8. Approve for duration:  
   - **For immunocompromised members:** Approve for life.  
   - **For Pregnant members:** May approve up to 3 months for members in the last trimester.  
   - **For all other members:** Approve for up to one month.
Initial Criteria:
1. Has the treatment been initiated by or is an appropriate specialist in the field of hematology or oncology supervising it?
   If yes, continue to #2. If no, do not approve.

2. Does the member have intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis as defined by NCCN standards?
   If yes, continue to #3. If no, do not approve.

3. Is the member ineligible for allogenic hematopoietic cell transplantation (HCT)?
   If yes, continue to #4. If no, do not approve.

4. Approve for 6 months.

Renewal Criteria:
1. Is there chart note documentation of response, such as a reduction of symptoms or spleen volume?
   If yes, approve for 12 months. If no, do not approve.
Generic Name  Ferric Carboxymaltose
Brand Name  Injectafer

Created: 11/15/13
Revised: 01/14/16
Reviewed: 7/11/19

***Nonformulary on outpatient benefit. PA required for medical benefit. ***

1. Does the member have a diagnosis of iron deficiency anemia and is intolerant to oral iron or has not responded to oral iron?
   If yes, continue to #2   If no, do not approve.

2. Has rationale been provided for use of Injectafer over the preferred IV iron agents (Venofer, Ferrlecit)?
   If yes, approve x 12 months.   If no, do not approve.
Myeloid growth factors (MGFs) are indicated for the prevention of neutropenic fever – not for the prevention of neutropenia itself. Neutropenia is an expected side effect of many antineoplastic drugs and chemotherapy regimens. MGFs reduce the duration of neutropenia, not the magnitude (known as the nadir). Clinical practice guidelines (NCCN, ESMO, ASCO) adopt the same stance regarding when prophylaxis with MGFs is appropriate using evidence-based recommendations. MGFs are also generally not recommended for the treatment of febrile neutropenia.

- Indicated when the risk of febrile neutropenia is ≥ 20%
- Indicated when the risk of febrile neutropenia is 10-20% plus a risk factor
- Indicated when a patient experienced febrile neutropenia with a previous chemotherapy regimen
- MGF’s may still be appropriate in cases where the risk of febrile neutropenia is <10% but clinicians should be providing justification in these cases

1. Is this request for prevention of febrile neutropenia in patients undergoing myelosuppressive chemotherapy?
   If yes, continue to #2 If no, continue to #3

2. Has the member received G-CSF in a previous chemotherapy cycle?
   If yes, continue to #12 If no, continue to #8

3. Is this request for the treatment of febrile neutropenia?
If yes, continue to #4

If no, continue to #6

Note: treatment of neutropenia without fever after chemotherapy is not an indication for G-CSF use and should be denied for appropriateness.

4. Is this request for filgrastim or any of its biosimilars?  
If yes, continue to #5  
If no, deny medically appropriate

Note: Pegfilgrastim is a long-acting, one-time injection so it is not appropriate for treating febrile neutropenia.

5. Does the patient have any of the following risk factors?  
a. Expected hospital stay >10 days  
b. Profound neutropenia (<100 cells/uL)  
c. Age>65  
d. Pneumonia or other clinically documented infection  
e. Sepsis syndrome  
f. Invasive fungal infections  
g. Prior episode of febrile neutropenia  
h. Developed fever after being hospitalized (i.e. hospital acquired infection)  
If yes, continue to #12  
If no, deny medically appropriate

6. Does the member have a diagnosis of neutropenia associated with Hepatitis C treatment?  
If yes, review for medical necessity.  
If no, continue to #7

7. Does the member have one of the following diagnoses/procedures for approval of the medication?  
a. Bone marrow transplant (allogenic or autologous).  
b. Autologous peripheral blood progenitor cells (PBPC) transplant.  
c. Severe chronic neutropenia.  
d. AIDS.  
e. Myelodysplastic syndromes.  
   If yes, continue to #9.  
   If no, deny medically appropriate

8. Search by Cancer Type and continue to #9
9. Is the member undergoing high risk chemotherapy as defined by the table, or is the stated risk of febrile neutropenia >20%?
   If yes, continue to #12
   If no, continue to #10

10. Is the member undergoing intermediate risk chemotherapy as defined by the table, or is the stated risk of febrile neutropenia 10-20%?
    If yes, continue to #11
    If no, review for appropriateness

These regimens were adopted from the NCCN guidelines on myeloid growth factors and every regimen they listed as being high or intermediate risk is reflected here. There are scenarios where other protocols will call for prophylaxis with G-CSF that isn’t explicitly listed in this criteria.

11. Does the member have at least one of the following?
    a. Prior chemotherapy or radiation therapy
    b. History of persistent neutropenia
    c. Bone marrow involvement by tumor
    d. Recent surgery and/or open wounds
    e. Liver dysfunction (bilirubin >2.0)
    f. Renal dysfunction (CrCl <50mL/min)
    g. Age >65 receiving full chemotherapy dose intensity (i.e. no dose adjustments have been made to reduce patient’s risk)
    h. Poor performance status (ECOG >3)
    i. HIV/AIDS
    j. Chronic immunosuppression

    If yes, continue to #12
    If no, review for appropriateness

12. Approve as follows:
• Nivestym/Udenyca- 12 months
• Neulasta OnPro- 12 months
• Leukine- 12 months.

Malignancy

Acute Lymphoblastic Leukemia (ALL)

• FLAG-IDA (fludarabine, cytarabine, ± idarubicin)
• Other protocols not specified by guidelines may call for G-CSF which should be approved

Intermediate Risk Chemotherapy

• None specified

Back to Criteria

Adenocarcinoma - Occult Primary

• None specified

Bladder Cancer

• Dose-dense MVAC (methotrexate, vinblastine, doxorubicin, cisplatin)

Intermediate Risk Chemotherapy

• Gemcitabine + docetaxel

• None specified

Bone Cancer

• VAI (vincristine, doxorubicin or dactinomycin, ifosfamide)
• VDC-IE (vincristine, doxorubicin or dactinomycin, and cyclophosphamide alternating with ifosfamide and etoposide)
• VIDE (vincristine, ifosfamide, doxorubicin or dactinomycin, etoposide)

Breast Cancer

• Dose-dense AC followed by T (doxorubicin, cyclophosphamide, paclitaxel)
• TAC (docetaxel, doxorubicin, cyclophosphamide)
• TC (docetaxel, cyclophosphamide)

Intermediate Risk Chemotherapy

• Docetaxel
• AC (doxorubicin, cyclophosphamide) + sequential docetaxel
• Paclitaxel every 21 days
• TCH (docetaxel, carboplatin, trastuzumab)

Cervical Cancer
• None specified

Colorectal Cancer
• None specified

• FOLFOX (fluorouracil, leucovorin, oxaliplatin)

Esophageal and Gastric Cancer
• None specified

• Irinotecan + cisplatin
• Epirubicin + cisplatin + 5-fluorouracil
• Epirubicin + cisplatin + capecitabine

Head and Neck Squamous Cell Carcinoma
• TPC (docetaxel, cisplatin, 5-fluorouracil)

Hodgkin Lymphoma
• Brentuximab vedotin + AVD (doxorubicin, vinblastine, dacarbazine)
• BEACOPP (bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, prednisone)

Kidney Cancer
• Doxorubicin/gemcitabine

Melanoma
• Any dacarbazine-based combination with IL-2

Multiple Myeloma
• DT-PACE (dexamethasone, thalidomide, cisplatin, doxorubicin, cyclophosphamide, etoposide) + bortezomib
Non-Hodgkin’s Lymphoma

- Dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin)
- ICE (ifosfamide, carboplatin, etoposide)
- Dose-dense CHOP-14 (cyclophosphamide, doxorubicin, vincristine, prednisone)
- MINE (mesna, ifosfamide, mitoxantrone, etoposide)
- DHAP (dexamethasone, cisplatin, cytarabine)
- ESHAP (etoposide, methylprednisolone, cisplatin, cytarabine)
- HyperCVAD (cyclophosphamide, vincristine, doxorubicin, dexamethasone)
- GDP (gemcitabine, dexamethasone, cisplatin/carboplatin)
- CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) – includes liposomal doxorubicin
- Venetoclax containing regimens

Non-Small Cell Lung Cancer

- None specified
- Cisplatin + paclitaxel
- Cisplatin + vinorelbine
- Cisplatin + docetaxel
- Cisplatin + etoposide
- Cisplatin + pemetrexed
- Carboplatin + pemetrexed
- Carboplatin + docetaxel
- Docetaxel
- FOLFIRINOX (5-fluorouracil, leucovorin, irinotecan, oxaliplatin)
- Etoposide + carboplatin
- None specified

Ovarian Cancer

- Topotecan
- Docetaxel

Pancreatic Cancer

- None specified

Small Cell Lung Cancer

- Topotecan

Soft Tissue Sarcoma

- MAID (mesna, doxorubicin, ifosfamide, dacarbazine)
• Doxorubicin
• Ifosfamide/doxorubicin

Testicular Cancer

• VeIP (vinblastine, ifosfamide, cisplatin)
• VIP (etoposide, ifosfamide, cisplatin)
• TIP (paclitaxel, ifosfamide, cisplatin)
• BEP (bleomycin, etoposide, cisplatin)
• Etoposide + cisplatin
• Docetaxel

Uterine Sarcoma

• None specified
• Docetaxel
**Generic Name** Dexamethasone Intravitreal Implant
Fluocinolone Intravitreal Implant

**Brand Name** Ozurdex
Iluvien
Retisert
Yutiq

Created: 03/12/2015
Revised: 01/11/2018, 5/9/2019

***Nonformulary on outpatient benefit. PA required for medical benefit. ***

1. Is the request from an ophthalmologist?
   If yes, continue to #2
   If no, do not approve.

2. Does the member have a diagnosis of chronic diabetic macular edema?
   If yes, continue to #6.
   If no, continue to #3.

3. Does the member have a diagnosis of macular edema due to central retinal vein occlusion?
   If yes, continue to #6.
   If no, continue to #4.

4. Does the member have a diagnosis of branch retinal vein occlusion?
   If yes, continue to #5.
   If no, continue to #7.

5. Is laser photocoagulation failed or unsuitable because of the extent of macular hemorrhage?
   If yes, continue to #6.
   If no, do not approve.

6. Has the member failed anti-VEGF therapy?
   If yes, continue to #11.
   If no, do not approve.

7. Does the member have chronic non-infectious uveitis?
   If yes, continue to #8
   If no, do not approve.

8. Has the member failed ONE of the following?
   • Both local and systemic corticosteroids.
   • Immunosuppressive agents.
   If yes, continue to #9
   If no, do not approve.

9. Is the request for Retisert implant?
   If yes, continue to #10.
   If no, continue to #11.

10. Is there documented failure of or contraindication to Yutiq?
    If yes, continue to #11.
    If no, do not approve.
11. Approve for 12 months.
Generic Name: Fluorouracil cream, solution
Brand Name: Efudex

Created: 8/1/11  
Revised: 5/21/12, 9/12/13, 8/14/14, 3/14/19  
Reviewed: 7/12/12

1. Does the member have a diagnosis of actinic keratosis?
   If yes, do not approve.  
   If no, continue to #2.

2. Does the member have a diagnosis of superficial basal cell carcinoma?
   If yes, approve x 3 months.  
   If no, continue to #3.

3. Does the member have a diagnosis of squamous cell carcinoma in situ (Bowen’s disease)?
   If yes, approve x 2 months.  
   If no, continue to 4.

4. Does the member have a diagnosis of anal intraepithelial neoplasia?
   If yes, approve x 4 months.  
   If no, do not approve.
Generic Name  Fluticasone/Salmeterol  
Brand Name  Advair HFA  
Created: 5/9/19  

1. Is the member’s age 12 or less?  
   If yes, approve until age 12.  
   If no, continue to #2  

2. Does the member have a documented medical reason generic Advair Diskus cannot be used?  
   If yes, approve x life.  
   If no, deny and offer alt.
Initial Criteria:

1. Does the member have a diagnosis for COPD or Asthma?
   If yes, continue to #2. If no, deny

2. Is there documentation of persistent symptoms or exacerbations while on a combined LABA/LAMA or LABA/ICS combination inhaler (Advair, Symbicort, Generic Air Duo, Air Duo, or Stiolo Respimat, Anoro Elipta, Dulera, or Breo Elipta, ect...)?
   If yes, approve for life If no, deny and offer alternatives
Generic Name: Fostamatinib
Brand Name: Tavalisse

Created: 7/12/18

**Initial criteria:**

**ITP:**
1. Does the member have a diagnosis chronic idiopathic thrombocytopenic purpura (ITP) for at least 3 months?
   - If yes, continue to #2.
   - If no, do not approve.

2. Is Tavalisse being prescribed by a hematologist?
   - If yes, continue to #3.
   - If no, do not approve.

3. Is there medical record documentation of platelet count of less than 20,000 per mm3 or less than 30,000 per mm3 with symptoms of bleeding?
   - If yes, continue to #4.
   - If no, do not approve.

4. Is there documentation of failure of or contraindication to THREE formulary alternatives:
   - a. Systemic corticosteroids
   - b. Immunoglobulin replacement (PA required)
   - c. Splenectomy
   - d. Rituxan (PA required)
   - If yes, approve for 6 months.
   - If no, do not approve.

**Renewal criteria:**

**ITP:**
1. Is there medical record documentation of the following?:
   - a. Maintenance of platelet counts between 30,000 per mm3 and 150,000 per mm3 or a doubling of platelet counts from baseline with resolution of bleeding episodes.
   - If yes, approve for 6 months.
   - If no, do not approve.
Generic Name Glucarpidase
Brand Name Voraxaze

Created: 9/26/12
Reviewed: 9/12/13

*** Nonformulary on outpatient benefit. PA required for medical benefit. ***

1. Does the member have impaired kidney function and is currently on high dose methotrexate (≥ 1g/m2) and the intent is to treat toxic plasma methotrexate levels? If yes, approve qty requested. If no, do not approve.
GROWTH HORMONE

Generic Name    Somatrem
    Somatropin

Brand Name    Genotropin – Subcutaneous   Omnitrope - Subcutaneous
    Humatrope – Subcutaneous   Saizen - Subcutaneous
    Norditropin - Subcutaneous   Seristim LQ - Subcutaneous
    Nutropin - Subcutaneous   Tev-Tropin - Subcutaneous
    Nutropin AQ – Subcutaneous   Zorbtive - Subcutaneous
    Nutropin Depot – Intramuscular

Revised: 8/27/10, 9/29/10, 11/2/10, 2/15/12, 9/26/12, 7/8/13, 1/25/17, 5/9/19
Reviewed: 9/12/13

- All preparations of Serostim are not covered
- GH is not covered for members who are 18 years or older. GH for adults is on line 650. Guideline note 74 now states “Treatment with growth hormone should continue only until adult height as determined by bone age is achieved.”

Initial Criteria:

The following are required for all covered indications:

Note: All other indications that are not included in this policy are either considered investigational/experimental or not funded by OHP.

1. Does the member meet one of the following?
   a) the member < 18 years old OR
   b) bone age is less than or equal to 15 for females or 16 for males?
      If yes, continue to #2   If no, do not approve.

2. Is this an initial PA request? (Verify both rx and medical claims history)
   If yes, continue to #3   If no, continue to renewal criteria.

3. Is the prescriber a pediatric endocrinologist or pediatric nephrologist?
   If yes, continue to #4   If no, do not approve.

4. Does the member have evidence of short stature or growth failure by one of the following:
   - Height standard deviation score (SDS) of more than 3 SD below the mean for chronological age or sex; OR
• Height for age/sex is below the 3rd percentile (or greater than 2 SD below the mean and untreated growth velocity (GV) is below the 25th percentile* (must have at least one year of growth data); OR
• Severe growth rate deceleration (GV measured over one year of more than 2 SD below the mean for age and sex)

If yes, continue to #5 If no, do not approve.

5. Does the member have a funded condition under the Prioritized List of Health Services?
   If yes, continue to #6 If no, do not approve.

6. Does the member have documented biochemical GHD by ONE of the following tests:
   a. Two growth hormone (GH) stimulation tests < 10 ng/mL (microgram/L)
   b. One GH stimulation test < 15 ng/mL and IGF – 1 below normal for bone age and sex

If yes, continue to #2 If no, do not approve

7. For members over 12 years of age, is there evidence of non-closure of epiphyses confirmed by X-ray?
   If yes, approve for 12 months If no, do not approve

Renewal criteria:
1. Does the member meet ALL of the following criteria:
   a. Evidence of GV greater than 2.5 cm/year, AND
   b. For members over 12 years old, non-closure of epiphyses confirmed by X-ray, AND
   c. Bone age suggests has not reached height potential defined as bone age for male has not exceed 16 years of age (required annually when chronological age reaches 15) and bone age for female has not exceed 14 years of age (required annually when chronological age reaches 13).

If yes, approve for 12 months. If no, do not approve.
Generic Name        Herpes Zoster Vaccine
Brand Name          Shingrix Vaccine

Created: 1/8/2016
Updated: 3/8/18 (Zostavax removed in preference for Shingrix)

1. Is the member age 50 or older?
   If yes, continue to #2
   If no, review for unique circumstances justifying medical necessity

2. Is the request for Zostavax (not Shingrix)?
   If yes, deny and offer Shingrix
   If no, approve Shingrix x 2 doses.
Generic Name     lanadelumab-flyo
Brand Name       Takhzyro
Created: 1/10/19

**Initial criteria:**
1. Does the member have a diagnosis of hereditary angioedema (HAE) confirmed by genetic testing or normal C1q lab levels with levels below the lab’s normal reference range for both C4 and C1INH?
   - If yes, continue to #2.
   - If no, do not approve.

2. Does the member have a history of at least two attacks per month which are considered severe with swelling of the face, throat or gastrointestinal tract that significantly interrupts usual daily activity despite short-term symptomatic treatment?
   - If yes, continue to #3.
   - If no, do not approve.

3. Has the member been evaluated for triggers of HAE attacks and is maximally managed for avoidance of those triggers (such as stress, hormonal changes, dental surgery, trauma, medications including ACE inhibitors and estrogen)?
   - If yes, continue to #4.
   - If no, do not approve.

4. Has the member failed treatment with androgen therapy (i.e. danazol)?
   - If yes, continue to #5.
   - If no, do not approve and recommend a trial of danazol.

5. Is treatment with acute, abortive therapy an option for this member (Firazyr, Berinert)?
   - If yes, do not approve
   - If no, continue to #6.

6. All approvals subject to medical director review.

**Renewal criteria:**
1. Has the patient been attack free for greater than 6 months?
   - If yes, continue to #2
   - If no, continue to #3

2. Is the request for the extended dosing interval of 300 mg every 4 weeks or is there a statement explaining why they wish to keep the dosing interval every 2 weeks?
   - If yes, approve x 12 months
   - If no, pend for documentation of why 4-week interval would not be appropriate.
3. Has there been at least a 50% reduction in the number of angioedema attacks, significant improvement in the severity of attacks, and clinical documentation of functional improvement?
   If yes, approve x 6 months                      If no, do not approve.
Generic Name  ibalizumab-uiyk
Brand Name  Trogarzo
Created: 5/10/18

Initial Criteria:
1. Is the request for the treatment of HIV in an adult?
   Yes, continue to #2.    No, deny.
2. Is the request from an HIV or Infectious Disease specialist?
   Yes, continue to #3.    No, deny.
3. Does the member have demonstrated resistance to at least one drug in three classes (NRTI, NNRTI, and PI)?
   Yes, continue to #4    No, deny
4. Is there documentation that existing therapy has failed or is failing with viral load > 1,000?
   Yes, continue to #5    No, deny
5. Will the medication be used concurrently with additional antiretrovirals?
   Yes, continue to #6    No, deny
6. Does the member have a history of non-adherence with oral HIV meds in the last 6 months (at least 90% of medication taken on time)?
   Yes, require treatment plan to address and review with plan medical director
   No, approve x 6 months per label dosing.

Renewal Request:
1. Is this a request for a second induction dose within 6 months or last induction dose?
   Yes, deny.    No, continue to #2
2. Is there demonstrated viral suppression with documented viral load <200?
   Yes, approve x 12 months    No, deny for not medically appropriate
Generic Name: Ibrutinib
Brand Name: Imbruvica
Created: 09/14/17

**Cancer**

**Initial Criteria:**
1. Is the treatment being prescribed by a hematologist or oncologist for a type of cancer?
   - If yes, continue to #2.
   - If no, continue to #5.

2. Is the treatment supported for the diagnosis in the NCCN guidelines?
   - If yes, continue to #4.
   - If no, continue to #3.

3. Is the treatment being used according to the FDA indication?
   - If yes, continue to #4
   - If no, do not approve.

4. Does the request meet criteria for treatment coverage specified in Guideline Note 12 of the Prioritized List of Health Services, considering treatment of cancer with little or no benefit?
   - If yes, approve for 12 months
   - If no, do not approve.

**Cancer**

**Renewal Criteria:**
1. Is there evidence of tumor response and resolution or improvement of disease-related signs and symptoms?
   - If yes, approve for 12 months.
   - If no, do not approve.

**Chronic Graft vs Host Disease**

**Initial Criteria:**
1. Is the treatment being prescribed by a hematologist/oncologist or transplant specialist for the treatment of chronic graft vs host disease?
   - If yes, continue to #2.
   - If no, continue to #5.

2. Is the condition refractory to systemic corticosteroids?
   - If yes, continue to #3.
   - If no, do not approve.

3. Has the member tried and failed another systemic immunosuppressant, such as a calcineurin inhibitor?
   - If yes, continue to #4
   - If no, do not approve.

4. Approve for 6 months.
**Chronic Graft vs Host Disease**

**Renewal Criteria:**

1. Is there documentation of clinical response?
   - If yes, approve for 12 months.
   - If no, do not approve.
Generic Name  
Insulin Lispro  
Insulin Lispro Protamine and Insulin Lispro  
Insulin Aspart Protamine and Insulin Aspart  
Insulin Regular  
Insulin NPH  
Insulin NPH and Insulin Regular

Brand Name  
Humalog Pen 75/25  
Humalog 75/25 Kwikpen  
Humulin 70/30 Kwikpen  
Novolog Mix 70/30 Penfill  
Novolog Mix 70/30 Flexpen  
Novolin R InnoLet  
Novolin R Penfill  
Novolin N Innolet  
Novolin N Penfill  
Novolin 70/30 Innolet  
Novolin 70/30 Penfill

Created: 1/5/09  
Revised: 4/6/09, 9/19/11, 6/1/14, 3/1/17  
Reviewed: 9/13/12, 7/15/13, 9/12/13

1. Does the member have diabetes mellitus (Type I and Type II) and require Insulin therapy?  
   If yes, continue to #2.  If no, do not approve.

2. Is the member under the age of 19?  
   If yes, approve until age 19.  If no, continue to #3.

3. Does the member meet either one of the following criteria?  
   • Member demonstrates an inability to draw insulin from a multidose vial into a syringe documented by provider  OR  
   • Use short acting insulin analogs in intensive multi-dose therapy (i.e. greater than 4 times a day injections)  OR  
   • Member has uncontrolled diabetes due to poor compliance evident by claims history

   If yes, approve for life  If no, do not approve.
Generic: Insulin Glargine 300 units/mL
Brand: Toujeo SoloStar
Created: 3/9/17

1. Does the member have diabetes mellitus (Type I or Type II) and require insulin therapy?
   If yes, continue to #2. If no, do not approve.

2. Is the member over age 18?
   If yes, continue to #3. If no, do not approve. Toujeo should not be used in children. Recommend Basaglar.

3. Is the request based on the units/day of basal insulin?
   If yes, evaluate based on a-c. If no, continue to #4.
   a. Member takes ≤ 80 units of basal insulin per day
      i. If yes, do not approve. Recommend Basaglar.
   b. Member takes >80 units/day but ≤ 200 units/day of basal insulin
      i. If yes, approve for lifetime
   c. Member takes >200 units/day of basal insulin?
      i. If yes, do not approve. Toujeo was not studied in patients with insulin resistance (total daily insulin dose >200 units/day) and is not intended to be a replacement for those requiring U-500 insulin.

4. Does the member have a failure of or contraindication to Basaglar? Failure requires HbA1c not at goal after 3 months of basal insulin therapy.
   If yes, approve for lifetime. If no, continue to #5.

5. Does the member have nocturnal hypoglycemia after other inventions have been made to address hypoglycemia?
   If yes, approve for lifetime. If no, do not approve and recommend Basaglar.
Generic Insulin Glargine + Lixisenatide

Brand Soliqua

Created: 9/14/17

Initial Criteria:

1. Does the member have a diagnosis of Type 2 Diabetes?
   If yes, continue to #2. If no, do not approve.

2. Has the member failed, been intolerant to, or have a contraindication to metformin?
   If yes, continue to #3 If no, do not approve.

3. Has the member failed, been intolerant to, or have a contraindication to a sulfonylurea?
   If yes, continue to #4 If no, do not approve.

4. Has the member failed basal insulin at a dose of at least 40 units?
   If yes, continue to #5. If no, deny. Basal dose should be pushed before adding GLP1 in this combo form.

5. Evaluate based on HbA1c
   a. Is HbA1c ≤ 7.5%--------------------------> If yes, do not approve.
   b. Is HbA1c >7.5% and <9.0%---------> If yes, approve for 6 months.
   c. Is HbA1c ≥9.0%-------------------------> If yes, continue to #7

6. Has the provider submitted an acceptable, medical rationale for why meal time insulin cannot be used?
   If yes, approve for 6 months. If no, deny for criteria not met.

First Renewal Criteria:

1. Has the member been adherent, had at least a 10% reduction in HbA1c, or HbA1c < 7.5% or FBS ≤ 120g/dl?
   If yes, approve for 12 months. If no, evaluate below.

Subsequent Renewal Criteria (applies only after a full response to GLP1 identified via 10% reduction):

1. Has at least one A1c been obtained in the previous 6 months?
   i. A1c <9%. Approve x 12 months
   ii. A1c ≥9%. Approve and recommend addition of basal or meal time insulin as appropriate.
Generic Name: Insulin Human NPH U500

Brand Name: Humulin U500 Pens

Note: Pens preferred vs vials due to risk of waste with vials

Created: 5/11/17

Initial Criteria:
1. Does the member have a diagnosis of diabetes mellitus?  
   If yes, continue to #2.  If no, do not approve.

2. Is it medically safe and appropriate for a U500 product?  This edit is bypassable by dispensing pharmacy with proper verification of U500 selection to ensure appropriate product selection.  In most situations, total insulin usage should be 200 units or greater.
   If yes, approve x life.  If no, deny for not medically appropriate.
Generic Name  Interferon Alfa-2b
                      Interferon Alfa-N3

Brand Name  Intron A
                      Alferon-N

Revised: 4/7/08, 1/4/11, 9/12/13, 01/12/17
Reviewed: 7/12/12

**Initial Criteria**

1. Is the treatment being prescribed for a type of cancer?
   a. If yes, continue to #2   If no, continue to #6

2. Is the treatment being prescribed by a hematologist or oncologist?
   If yes, continue to #3.   If no, do not approve.

3. Is the treatment supported for the diagnosis in the NCCN guidelines
   If yes, continue to #5.   If no, continue to #4.

4. Is the treatment being used according to the FDA indication?
   If yes, continue to #5   If no, do not approve.

5. Does the request meet criteria for treatment coverage specified in Guideline Note 12 of the Prioritized List of Health Services, considering treatment of cancer with little or no benefit?
   If yes, approve for 12 months   If no, do not approve.

6. Does the member have a diagnosis of chronic hepatitis B?
   If yes, continue to #7   If no, continue to #16.

7. Is the treatment being prescribed by a hepatologist or gastroenterologist?
   If yes, continue to #8   If no, do not approve.

8. Does the member have decompensated cirrhosis?
   If yes, do not approve.   If no, continue to #9.

9. Does the member have compensated cirrhosis?
   If yes, continue to #10   If no, continue to #11.

10. Is HBV DNA > 2000 IU/ml (10,000 or 10^4 copies/ml)?
    If yes, continue to #15   If no, do not approve.

11. Is the member HBeAg (+)?
    If yes, continue to #12   If no, continue to #13

12. Does the member meet the following:
a. HBV DNA $\geq 20,000$ IU/mL
b. Serum ALT* is persistently elevated after 3-6 months of monitoring or liver biopsy shows $\geq$ moderate inflammation or significant fibrosis  
   If yes, continue to z                                                                 If no, do not approve.

13. Is the member HBeAg (-)?  
   If yes, continue to #14                                                                 If no, do not approve.

14. Does the member meet the following:  
   a. HBV DNA $> 2,000$ IU/mL  
   b. Serum ALT* is persistently elevated after 3-6 months of monitoring or liver biopsy shows $\geq$ moderate inflammation or significant fibrosis  
      If yes, continue to #15.                                                                 If no, do not approve.

15. Has the member received previous treatment with interferon?  
   If yes, do not approve.                                                                 If no, approve for 12 months.

16. Does the member have a diagnosis of condyloma acuminatum?  
   If yes, continue to #17                                                                 If no, do not approve.

17. Has the member failed or have contraindications to ALL of the following?  
   a. Cryotherapy, and  
   b. Trichloroacetic acid, and  
   c. Surgical excision, and  
   d. Podophyllum resin, and  
   e. Podofilox, and  
   f. Imiquimod  
      If yes, approve vials for 3 weeks.                                                                 If no, do not approve.
Generic Name               Interferon alfacon-1

Brand Name                  Infergen

Created: 09/12/2013

**Initial Criteria:**

1. Is the member at least 18 years of age?
   - If yes, continue to #2.
   - If no, do not approve.

2. Is the request for treatment of Chronic Hepatitis C with compensated liver disease?
   - If yes, continue to #3.
   - If no, do not approve.

3. Is the request for continuation of therapy? (Member is currently (prior 12 weeks) on HCV treatment according to Rx profile)
   - If yes, continue to #10.
   - If no, continue to #4.

4. Does the member have a history of previous interferon-ribavirin combination treatment? Verify by reviewing member’s Rx profile for combination interferon-based hepatitis C drugs (Rebetron, PEG-Intron, Pegasys, interferon-alpha) history. Does not include interferon monotherapy.
   - If yes, review for medical necessity.
   - If no, continue to #5.

5. Does the member have any of the following contraindications to the use of interferon-ribavirin therapy?
   a. decompensated cirrhosis
   b. autoimmune hepatitis
   - If yes, do not approve.
   - If no, continue to #6.

6. Does the member have a detectable HCV RNA (viral load) > 50IU/mL?
   - If yes, continue to #7.
   - If no, do not approve.

7. Does the member have a documented HCV Genotype?
   - If yes, continue to #8.
   - If no, do not approve.

8. Has the member failed or have a contraindication/adverse reaction to peginterferon alfa-2a (Pegasys)?
   - If yes, continue to #9.
   - If no, do not approve.

9. Approve for 16 weeks with the following response:
Continuation of Therapy:

1. Does the member have undetectable HCV RNA OR at least a 2-log reduction (+/- one standard deviation) in HCV RNA measured at 12 weeks?
   - If yes, continue to #2.
   - If no, do not approve.

2. Approve as follows.
   a. For genotype 1 or 4, approve for an additional 36 weeks or for up to a total of 48 weeks of therapy (whichever is the lesser of the two). (max daily dose=1400mg).
   b. For genotype 2 or 3, approve for an additional 12 weeks or for up to a total of 24 weeks of therapy (whichever is the lesser of the two). (max daily dose = 800mg).
   c. For HIV co-infection, approve for an additional 36 weeks or for up to a total of 48 weeks of therapy (whichever is the lesser of the two). (max daily dose=1400mg).
Generic Name  Interferon Alfa-N3
Brand Name  Alferon N

Reviewed: 12/2/11, 7/12/12
Revised: 9/12/13

1. Is the member age 18 years or older?
   If yes, continue to #2.  If no, do not approve.

2. Does the member have a diagnosis of Condyloma Acuminata?
   If yes, continue to #3.  If no, do not approve.

3. Has the member tried and failed or have contraindications to ALL of the following?
   a. Cryotherapy, and
   b. Trichloroacetic acid, and
   c. Surgical excision, and
   d. Podophyllum resin, and
   e. Podofilox, and
   f. Aldara.
      If yes, approve for 2 months.  If no, do not approve.
Generic Name  Interferon gamma-1b
Brand Name  Actimmune

Revised: 6/2/08
Reviewed: 12/2/11, 7/12/12, 9/12/13

1. Does the member have a diagnosis of Chronic Granulomatous Disease or Malignant osteopetrosis?
   If yes, continue to #2. If no, do not approve.

2. Approve for lifetime.
1. Does the member have acne conglobata or acne fulminans?  
   If yes, continue to #3.  If no, continue to #2.

2. Does the member have severe cystic acne?  
   If yes, continue to #4

3. Do the chart notes document that the member has recurrent abscesses or communicating sinuses?  
   If yes, continue to #5.  If no, continue to #4.

4. Has the provider submitted documentation showing 1) persistent or recurrent inflammatory nodules and cysts AND 2) ongoing scarring.  
   If yes, continue to #5.  If no, deny for BTL/GN

5. Has the member tried and failed a 3 month course of doxycycline?  
   If yes, continue to #6.  If no, do not approve.  Admin auth 3 months of doxycycline hyclate tablets GPI 040000201003**.

6. Has the member tried and failed a topical antibiotic such as clindamycin 1% solution?  
   If yes, continue to #7.  If no, do not approve.

7. Is there chart note documentation of activation of the iPLEDGE program?  
   If yes, continue to #8.  If no, do not approve.

8. Does the member have symptoms of depression, mood disturbance, psychosis, or aggression? (See note 3)  
   If yes, do not approve.  Not medically appropriate.  If no, continue to #9.

9. Approve for 20 weeks.
Note:

1) Acne conglobata is a severe form of nodular acne that is most commonly seen in young males. Lesions are most prominent on the back, chest, and buttocks, but can also appear in other sites. Large draining lesions, sinus tracts, and severe scarring may occur. Systemic symptoms are absent. (UpToDate). Assertions of acne conglobata must document this presentation and meet Guideline Note 132. Isotretinoin has been known to cause or exacerbate acne conglobata.

2) Acne fulminans is a disorder characterized by an acute eruption of large, inflammatory nodules and friable plaques with erosions, ulcers, and hemorrhagic crusts. This rare condition primarily affects adolescent males with preexisting acne vulgaris. Acne fulminans may be triggered by isotretinoin therapy or may occur spontaneously. The pathogenesis is unclear. Lesions usually involve the trunk but may be present elsewhere. Acne fulminans may occur in association with systemic symptoms. (UpToDate).

3) A comorbid mental health concern as an argument to cover isotretinoin for acne would be not medically appropriate. Psychiatric disorders including depression, psychosis, aggression, violent behavior, and rarely suicide ideation/attempt have occurred with isotretinoin use; monitoring recommended and discontinuation may be necessary. If the member has underlying mental health issues that are uncontrolled, a referral to a mental health professional may be necessary.

4) The maximum duration of therapy on the FDA label is 20 weeks
Generic Name  
Itraconazole capsule  
Itraconazole oral solution

Brand Name  
Sporanox Capsule  
Sporanox Oral Solution

Revised: 11/21/08, 09/08/16  
Reviewed: 12/2/11, 7/12/12, 9/12/13

**Initial Criteria:**

1. Does the member have **one** of the following diagnoses?
   a. Blastomycosis, or
   b. Histoplasmosis, or
   c. Aspergillosis.
      - If yes, approve for requested course up to 12 months.
      - If no, continue to #2.

2. Does the member have a diagnosis of onychomycosis?
   - If yes, continue to #3.
   - If no, continue to #5

3. Does the member meet **both** of the following criteria?
   a. Member is immunocompromised (drug-induced, HIV, etc) or has diabetes, and
   b. Member has a history of cellulitis or severe infection or severe functional impairment secondary to onychomycosis.
      - If yes, continue to #4.
      - If no, do not approve.

4. Has the member tried and failed or have contraindications to terbinafine?
   - If yes, approve for 3 months
   - If no, do not approve.

5. Does the member have a diagnosis of candidiasis of the mouth and esophagus?
   - If yes, continue to #6.
   - If no, continue to #8.

6. Is the member immunocompromised?
   - If yes, continue to #7.
   - If no, do not approve.

7. Has the member failed or have contraindications to fluconazole?
   - If yes, approve oral solution for 2 weeks.
   - If no, do not approve.

8. Does the member have a diagnosis of febrile neutropenia?
   - If yes, approve for 1 month.
   - If no, do not approve.
**Generic Name**
Intravenous Immune Globulin (IVIG)
Immune Globulin, Intramuscular
Immune Globulin, Subcutaneous

**Brand Name**
Bivigam
Carimune NF
Cuvitru
Flebogamma
GamaStan S/D
Gammagard
Gammagard S/D
Gammaked
Gammaphlex
Gamunex-C
Hizentra
HyQvia
Octagam
Privigen

Revised: 7/15/10, 12/2/10, 2/15/12, 9/26/12, 9/12/13, 09/13/18
Reviewed: 12/2/11, 7/12/12

**Allogenic Bone Marrow Transplant**

**Initial Criteria:**
1. Is immune globulin being prescribed by or supervised by a hematologist, oncologist, transplant specialist, or infectious disease specialist for the prevention of bacterial infections?
   - If yes, continue to #2.  
   - If no, do not approve.

2. Does the member have severe hypogammaglobulinemia with IgG levels less than 400 mg/dL after receiving an allogenic bone marrow transplant?
   - If yes, continue to #3.  
   - If no, do not approve.

3. Approve as follows:
   - Within 100 days of transplant: 500mg/kg/week for adults and adolescents, and 400mg/kg/month for children until 100 days post transplant.
   - After 100 days of transplant: 500mg/kg every 3-4 weeks for 3 months.

**Allogenic Bone Marrow Transplant**

**Renewal Criteria:**
1. Has there been clinical response to treatment such as a reduction in recurrent infections, or a statement of medical necessity to continue to maintain IgG levels above 400mg/dL?
   - If yes, approve for 3 months.  
   - If no, do not approve.
**Autoimmune Hemolytic Anemia, Warm Type**

**Initial Criteria:**

1. Is immune globulin being prescribed by or supervised by a hematologist?
   - If yes, continue to #2.
   - If no, do not approve.

2. Does the member have a diagnosis of autoimmune hemolytic anemia warm type, characterized by a predominance of IgG antibodies?
   - If yes, continue to #3.
   - If no, do not approve.

3. Has the member failed corticosteroids for at least 3 weeks?
   - If yes, continue to #4.
   - If no, do not approve.

4. Has the member failed a second line therapy from the following:
   a. Splenectomy
   b. Immunomodulators (azathioprine, danazol, cyclosporine, cyclophosphamide, or mycophenolate)
   c. Rituxan
   - If yes, continue to #5.
   - If no, do not approve.

5. Approve for 3 months.

**Autoimmune Hemolytic Anemia, Warm Type**

**Renewal Criteria:**

1. Has the member had response to treatment, such as resolution of anemia?
   - If yes, continue to #2.
   - If no, do not approve.

2. Has the member failed to produce a sustained response to therapy?
   - If yes, continue to #3.
   - If no, do not approve.

3. Approve for 12 months.

**Autoimmune Mucocutaneous Blistering Diseases**

**Initial Criteria:**

1. Is immune globulin being prescribed by or supervised by a dermatologist?
   - If yes, continue to #2.
   - If no, do not approve.

2. Does the member have one of the following diagnoses confirmed by biopsy and pathology?
   a. Pemphigus vulgaris
   b. Pemphigus foliaceous
   c. Bullous pemphigoid
3. Has the member tried and failed or have a contraindication to systemic corticosteroids?
   If yes, continue to #4.  If no, do not approve.

4. Has the member failed one of the following immunosuppressants?
   a. Azathioprine
   b. Cyclophosphamide
   c. Cyclosporine
   d. Methotrexate
   e. Mycophenolate
   If yes, continue to #7.  If no, continue to #5.

5. Does the member have rapidly progressive disease in which a clinical response cannot be achieved quickly enough using conventional agents?
   If yes, continue to #6.  If no, do not approve.

6. Does the provider have a treatment plan to use IVIG only until conventional agents take effect?
   If yes, continue to #8.  If no, do not approve.

7. Is the IVIG therapy intended for short term therapy only (up to 3 months)?
   If yes, continue to #8.  If no, do not approve.

8. Approve for 3 months.

**Chronic B-Cell Lymphocytic Leukemia with Hypogammaglobulinemia**

**Initial Criteria:**

1. Is immune globulin being prescribed by or supervised by a hematologist, oncologist, or infectious disease specialist?
   If yes, continue to #2.  If no, do not approve.

2. Does the member have CLL with hypogammaglobulinemia (IgG level less than 600mg/dL) at baseline?
   If yes, continue to #3.  If no, do not approve.

3. Does the member have either of the following?
   a. Evidence of specific antibody deficiency
   b. History of a serious bacterial infection that required IV antibiotic therapy or hospitalization
   If yes, continue to #4.  If no, do not approve.
4. Approve for 3 months.

**Chronic B-Cell Lymphocytic Leukemia with Hypogammaglobulinemia**

**Renewal Criteria:**

1. Is there chart note documentation of regular monitoring of IgG trough levels, blood cell counts, and serum chemistry, with improvement from baseline?  
   - If yes, continue to #2.  
   - If no, do not approve.

2. Has the member experienced a reduction in the number and/or severity of difficult to treat infections?  
   - If yes, approve for 12 months.  
   - If no, do not approve.

**Chronic Inflammatory Demyelinating Polyradiculoneuropathy (CIDP) / Multifocal Motor Neuropathy (MMN)**

**Initial Criteria:**

1. Is immune globulin being prescribed by or supervised by a neurologist?  
   - If yes, continue to #2  
   - If no, do not approve.

2. Has the condition persisted for longer than 2 months?  
   - If yes, continue to #3.  
   - If no, do not approve.

3. Is there documentation of a baseline strength and weakness using an objective clinical measuring tool, such as Inflammatory Neuropathy Cause and Treatment Score (INCAT), Medical Research Council (MRC), 6-minute timed walking test, Rankin, or Modified Rankin?  
   - If yes, continue to #4.  
   - If no, do not approve.

4. Has the diagnosis been made on the basis of electrophysiologic findings that support the diagnosis and rule out other possible conditions that may not respond to IVIG treatment?  
   - If yes, continue to #5.  
   - If no, do not approve.

5. Is the diagnosis multifocal motor neuropathy?  
   - If yes, continue to #7.  
   - If no, continue to #6.

6. Has the member failed one of the following, or have contraindications to both of the following to treat chronic inflammatory demyelinating polyradiculoneuropathy?  
   - a. Corticosteroids  
   - b. Plasmapheresis  
   - If yes, continue to #6.  
   - If no, do not approve.

7. Approve for 3 months.

**Chronic Inflammatory Demyelinating Polyradiculoneuropathy (CIDP) / Multifocal Motor Neuropathy (MMN)**
Renewal Criteria:
1. Has the member displayed an improvement from baseline strength and weakness using an objective clinical measuring tool?  
   If yes, continue to #2.  If no, do not approve.

2. Approve 6 months.

Disseminated encephalomyelitis, acute
Initial Criteria:
1. Is immune globulin being prescribed by or supervised by a neurologist?  
   If yes, continue to #2.  If no, do not approve.

2. Is the member under the age of 18?  
   If yes, continue to #3.  If no, do not approve.

3. Has the member tried and failed or have contraindication to intravenous corticosteroids?  
   If yes, continue to #4.  If no, do not approve.

4. Approve for 3 months.

Fetal and Neonatal Alloimmune Thrombocytopenia
Initial Criteria:
1. Is immune globulin being prescribed by or supervised by a hematologist, immunologist, obstetrician or neonatologist?  
   If yes, continue to #2.  If no, do not approve.

2. Is the member a neonate with neonatal alloimmune thrombocytopenia?  
   If yes, continue to #5.  If no, continue to #3.

3. Is the member a pregnant woman who has experienced a previous pregnancy affected by fetal alloimmune thrombocytopenia?  
   If yes, continue to #7.  If no, continue to #4.

4. Has a cordocentesis revealing fetal platelets less than 20 x 10^9/L been performed?  
   If yes, continue to #7.  If no, do not approve.

5. Is the neonate severely thrombocytopenic with a platelet count less than 30 x 10^9/L and/or symptomatic?  
   If yes, continue to #6.  If no, do not approve.

6. Has the neonate failed, have a contraindication to, or is intolerant to platelet transfusions?  
   If yes, continue to #7.  If no, do not approve.

7. Approve for 3 months or for the duration of pregnancy.
**Guillain-Barre Syndrome**

1. Is immune globulin being prescribed by or supervised by a neurologist?
   - If yes, continue to #2
   - If no, do not approve.

2. Has the disorder been diagnosed during the first 2 weeks of the illness, and IVIG is to be initiated within 4 weeks of onset?
   - If yes, continue to #3
   - If no, do not approve.

3. Does the member have severe disease with significant weakness such as inability to stand or walk without aid, respiratory or bulbar weakness, or Miller-Fisher syndrome (MFS)?
   - If yes, continue to #4
   - If no, do not approve.

4. Is IVIG to be used along with plasmapheresis?
   - If yes, do not approve.
   - If no, continue to #5.

5. Approve for 1 month.

**HIV, Pediatric**

**Initial Criteria:**

1. Is the immune globulin being prescribed by or supervised by an immunologist or an infectious diseases provider?
   - If yes, continue to #2
   - If no, do not approve.

2. Is the member less than 13 years old and infected with HIV?
   - If yes, continue to #3
   - If no, do not approve.

3. Is the member on highly active antiretroviral therapy (HAART)?
   - If yes, continue to #4
   - If no, do not approve.

4. Is the CD4+ count greater than 200/mm^3?  
   - If yes, continue to #5
   - If no, do not approve.

5. Does the member meet one of the following criteria?
   - Hypogammaglobulinemia defined as serum IgG concentration less than 400 mg/dL.
   - Recurrent serious bacterial infections, defined as two or more infections such as bacteremia, meningitis, or pneumonia in a 1-year period.
   - Failure to form antibodies to common antigens, such as measles, pneumococcal, and/or Haemophilus influenzae type b vaccine.
   - Living in areas where measles is highly prevalent and who have not developed an antibody response after two doses of measles, mumps, and rubella virus vaccine live.
   - HIV-infected children who are exposed to measles (single dose indicated).
• HIV-infected children with chronic bronchiectasis that is suboptimally responsive to antimicrobial and pulmonary therapy. If yes, approve for up to 12 months. If no, do not approve.

**HIV, Pediatric**

**Renewal Criteria:**
1. Has the member demonstrated a clinical response to therapy, such as reduction of recurrent infections?
   If yes, approve for 12 months. If no, do not approve.

**Idiopathic Inflammatory Myopathies (Dermatomyositis and Polymyositis)**

**Initial Criteria:**
1. Is immune globulin being prescribed by or supervised by a neurologist or rheumatologist?
   If yes, continue to #2 If no, do not approve.

2. Does the member have a diagnosis of an idiopathic inflammatory myopathy confirmed by biopsy (muscle or skin) or by the presence of a pathognomonic skin rashes (heliotrope rash, Gottron’s papules, and/or Gottron’s sign)?
   If yes, continue to #3. If no, do not approve.

3. Does the member have severe active illness with muscle weakness?
   If yes, continue to #4. If no, do not approve.

4. Has the member failed or have a contraindication to corticosteroids?
   If yes, continue to #5. If no, do not approve.

5. Has the member failed immunosuppressants, such as methotrexate, azathioprine, mycophenolate mofetil, cyclosporine, or cyclophosphamide?
   If yes, continue to #6 If no, do not approve.

6. Approve for 3 months.

**Idiopathic Inflammatory Myopathies (Dermatomyositis and Polymyositis)**

**Renewal Criteria:**
1. Has the member had a response to treatment, with improvement in functioning and/or in CPK?
   If yes, continue to #2. If no, do not approve.

2. Approve for 12 months.

**Immune Thrombocytopenic Purpura (ITP)**

**Initial Criteria:**
1. Is immune globulin being prescribed by or supervised by a hematologist?
   If yes, continue to specific diagnosis. If no, do not approve.
**Pediatric ITP**

1. Does the member have persistent (3-12 months) or chronic (greater than 12 months) ITP?
   
   If yes, continue to #3.  
   If no, continue to #2.

2. Does the member present with significant acute mucous membrane bleeding or other noncutaneous bleeding?
   
   If yes, continue to #4.  
   If no, do not approve.

3. Does the member have significant ongoing bleeding?
   
   If yes, continue to #4.  
   If no, do not approve.

4. Has the member failed corticosteroids?
   
   If yes, continue to #6.  
   If no, continue to #5.

5. Are corticosteroids contraindicated, or does the provider make a statement that a rapid increase in platelets is required?
   
   If yes, continue to #6.  
   If no, do not approve.

6. Approve for 3 months.

**ITP in pregnancy**

1. Is the member a pregnant woman with ITP?
   
   If yes, continue to #2  
   If no, do not approve.

2. Does the member require treatment based on one of the following conditions?
   
   a. Previously delivered an infant with autoimmune thrombocytopenia.
   
   b. Platelet count of less than $10 \times 10^9$/L during the third trimester
   
   c. Platelet count of less than $30 \times 10^9$/L associated with bleeding
   
   d. Platelet count of less than $75 \times 10^9$/L at time of delivery, to achieve minimum platelet counts recommended to undergo the procedures
   
   e. Past history of splenectomy.
   
   If yes, continue to #3.  
   If no, do not approve.

3. Has the member failed corticosteroids?
   
   If yes, continue to #5.  
   If no, continue to #4.

4. Are corticosteroids contraindicated, or does the provider make a statement that a rapid increase in platelets is required?
   
   If yes, continue to #5.  
   If no, do not approve.

5. Approve for appropriate duration for pregnancy term.
Adult ITP

1. Does the member have persistent or chronic ITP for longer than 6 months?  
   If yes, continue to #3. If no, continue to #2.

2. Does the member require acute treatment under one of the following conditions?  
   a. Platelet count less than $20 \times 10^9$/L, considered to be at risk for bleeding  
   b. Platelet count less than $30 \times 10^9$/L with acute bleeding  
   c. Member is preparing to undergo surgery, such as a splenectomy, with platelet count less than $75 \times 10^9$/L.  
      If yes, continue to #4. If no, do not approve.

3. Are the platelet counts persistently at or below $20 \times 10^9$/L?  
   If yes, continue to #4. If no, do not approve.

4. Has the member failed corticosteroids?  
   If yes, continue to #6. If no, continue to #5.

5. Are corticosteroids contraindicated, or does the provider make a statement that a rapid increase in platelets is required?  
   If yes, continue to #6. If no, do not approve.

6. Approve for 3 months.

Immune Thrombocytopenic Purpura (ITP)  
Renewal Criteria:

1. Has the member experienced a reduction of bleeding episodes and/or increased quality of life?  
   If yes, continue to #2. If no, do not approve.

2. Is there documentation of medical necessity to continue in order to prevent bleeding episodes?  
   If yes, approve 12 months. If no, do not approve.

Kawasaki Disease, Mucocutaneous Lymph Node Syndrome (MCLS)  
Initial Criteria:

1. Is immune globulin being prescribed by or supervised by a pediatric cardiologist or a pediatric infectious diseases physician?  
   If yes, continue to #2. If no, do not approve.

2. Has the diagnosis been confirmed by the presence of fever for at least 5 days with four of the following clinical signs:  
   - Mucous membrane changes such as a red tongue and dry fissured lips;  
   - Swelling of the hands and feet;  
   - Enlarged lymph nodes in the neck;
• Diffuse red rash covering most of the body;
• Redness of the eyes.
  If yes, continue to #3. If no, do not approve.

3. Is the treatment being initiated within 10 days of onset of fever?
  If yes, continue to #4. If no, do not approve.

4. Is the treatment being administered with aspirin, or if contraindicated with an alternative antiplatelet agent?
  If yes, continue to #5. If no, do not approve.

5. Approve for 1 month.

**Kidney transplant**

*Initial criteria:*

1. Is immune globulin being prescribed by or supervised by a transplant specialist?
   If yes, continue to #2. If no, do not approve.

2. Is IVIG being used for the prevention of acute humoral rejection in renal transplant?
   If yes, continue to #3. If no, continue to #4.

3. Is the member at high risk of antibody mediated rejection?
   If yes, continue to #5. If no, do not approve.

4. Has the member experienced an antibody mediated rejection?
   If yes, continue to #5. If no, do not approve.

5. Approve 1 month.

**Myasthenia Gravis**

*Initial Criteria:*

1. Is immune globulin being prescribed by or supervised by a neurologist?
   If yes, continue to #2. If no, do not approve.

2. Does the member have acute decompensated myasthenic crisis with respiratory failure or impending respiratory failure with severe bulbar symptoms?
   If yes, continue to #8. If no, continue to #3.

3. Does the member require stabilization of myasthenia gravis before surgery, such as for thymectomy?
   If yes, continue to #8. If no, continue to #4.
4. Is IVIG being used in a treatment plan including a specific supported immunosuppressive therapy, and is intended to bridge until the immunosuppressant takes effect?  
   If yes, continue to #5.  
   If no, continue to #6.

5. Is there documentation of trial and failure of or contraindication to corticosteroids?  
   If yes, continue to #9.  
   If no, do not approve.

6. Is IVIG being used for maintenance?  
   If yes, continue to #7.  
   If no, do not approve.

7. Is there a contraindication to ALL of the following immunosuppressants?  
   1. Corticosteroids  
   2. Azathioprine  
   3. Cyclosporine  
   4. Mycophenolate mofetil  
   5. Methotrexate  
   6. Tacrolimus  
   7. Cyclophosphamide  
   If yes, continue to #9.  
   If no, do not approve.

8. Is there a contraindication to plasmapheresis, such as poor venous access?  
   If yes, continue to #9.  
   If no, do not approve.

9. Approve for 3 months.

**Myasthenia Gravis**  
**Renewal Criteria:**  
1. Is the request for renewal of maintenance therapy?  
   a. If yes, continue to #2.  
      If no, evaluate on initial criteria.  
2. Has the member demonstrated a response in reduction of number of myasthenic crises or improvement in function?  
   a. If yes, continue to #3.  
      If no, do not approve.
3. Approve for 6 months.

**Primary Immunodeficiencies**  
**Initial Criteria:**  
1. Is the immune globulin being prescribed by or supervised by an allergist, immunologist, otolaryngologist or an infectious diseases provider?  
   If yes, continue to #2.  
   If no, do not approve.

2. Has the member been diagnosed with selective IgG subclass deficiency with deficiency of 1 or more IgG subclasses (e.g. IgG1, IgG2, IgG3, or IgG4) > 2 standard deviations (SD) below age-specific mean, assessed on 2 separate occasions during infection free period?
If yes, continue to #9. If no, continue to #3.

3. Has the member been diagnosed with specific antibody deficiency (SAD) AND normal levels of immunoglobulin and normal levels of IgG subclasses?
   If yes, continue to #9. If no, continue to #4.

4. Has the member been diagnosed with CVID or unspecified hypogammaglobulinemia?
   If yes, continue to #5. If no, continue to #6.

5. Does the member have at least one of the following?
   a. Reduced total serum IgG level
   b. Reduced IgG1 and IgG3 subclass levels
   c. Reduced IgG1 alone
   d. Markedly impaired antibody response to protein (e.g., tetanus, diphtheria) antigen OR a polysaccharide antigen (pneumococcus)
   If yes, continue to #9. If no, do not approve.

6. Does the member have hypogammaglobulinemia, X-linked agammaglobulinemia (Bruton’s agammaglobulinemia, congenital agammaglobulinemia), severe combined immunodeficiency (SCID), Wiskott-Aldrich syndrome, Hyper-IgM syndromes (X-linked or autosomal recessive), or another humoral immunodeficiency?
   If yes, continue to #7. If no, do not approve and check other diagnoses.

7. Does the member have agammaglobulinemia with ONE of the following?
   a. Total IgG < 200 mg/dL (at baseline prior to immune globulin therapy), OR
   b. Patients with an abnormal Bruton tyrosine kinase (BTK) gene/absence of BTK protein, OR
   c. Absence of B lymphocytes
   If yes, continue to #10. If no, continue to #8.

8. Does the member have hypogammaglobulinemia with a total IgG < 600mg/dL (at baseline prior to immune globulin therapy)?
   If yes, continue to #9. If no, do not approve.

9. Has the member had poor antibody response to vaccines (and/or absent isohaemagglutinins); i.e. absence of protective levels despite vaccination)?
   If yes, continue to #10. If no, do not approve.

10. Does the member have evidence of recurrent, persistent, severe, difficult-to-treat infections (e.g. recurring otitis media, bronchiectasis, recurrent infections requiring IV antibiotics, etc.) despite aggressive management and treatment with antibiotics?
    If yes, approve for 12 months. If no, do not approve.
**Primary Immunodeficiencies**

**Renewal Criteria:**

1. Is there chart note documentation of regular monitoring of IgG trough levels, blood cell counts, and serum chemistry, with improvement from baseline?
   - If yes, continue to #2.
   - If no, do not approve.

2. Has the member experienced a reduction in the number and/or severity of difficult to treat infections?
   - If yes, approve for 12 months.
   - If no, do not approve.
IV Antibiotics- Medical Benefit

Established: 2/1/19

Brand
- Xerava
- Nuzyra
- Zerbaxa
- Xenleta

Generic
- Eravacycline
- Omadacycline
- IV Doxycycline
- Ceftolozane/tazobactam
- Lefamulin

Any IV antibiotic that requires PA and does not have its own criteria falls to this policy. The plan will require evidence to support the use of the IV antibiotic is medically appropriate and necessary.
Initial:
1. Is the prescriber a cardiologist?
   If yes, continue to #2       If no, do not approve.

2. Is the member <18 years of age with a diagnosis of dilated cardiomyopathy?
   If yes, continue to #7       If no, continue to #3

3. Does the member have a diagnosis of stable, symptomatic chronic heart failure?
   If yes, continue to #4       If no, do not approve.

4. Is the patient's ejection fraction <35%?
   If yes, continue to #5       If no, do not approve.

5. Is the member's resting heart rate at least 70 beats per minute?
   If yes, continue to #6       If no, do not approve

6. Is the member on maximum tolerated doses of ALL of the following classes (formulary options of evidence supported medications and max doses shown)?
   a) Beta-Blocker [metoprolol succinate (200mg/day), carvedilol (25mg twice daily)]
   b) ACE-i/ARB [captopril (50mg three times daily), enalapril (10mg twice daily), lisinopril (20-40mg/day), ramipril (5mg twice daily), losartan (150mg/day)],
   c) Mineralocorticoid receptor antagonist [spironolactone (25 mg/day)]

   If yes, continue to #7.       If no, deny for criteria not met

7. Is the request for oral solution?
   If yes, continue to #8.       If no, approve for lifetime.

8. Is the member physically unable to take solid dosage forms?
   If yes, approve x life.       If no, deny and offer tablets
Generic Name  Ivacaftor
Ivacaftor/Lumacaftor
Ivacaftor/Lumacaftor/elexacaftor

Brand Name  Kalydeco (including packets)
Orkambi
Orkambi Packets
Symdeko
Trikafta

Created: 05/21/12
Reviewed: 9/12/13, 7/22/14
Revised: 11/12/15, 05/12/16, 02/03/17, 11/09/17, 1/11/18, 5/10/18, 1/10/19, 1/9/2020

Initial Criteria:
1. Does the member have a diagnosis of cystic fibrosis?
   If yes, continue to #2.   If no, do not approve.

2. Is the request from a pulmonologist?
   If yes, continue to #3   If no, do not approve.

3. Is the requested product appropriate in the patient’s age?
   If yes, continue to #4   If no, do not approve.

4. Does the member have an FDA indicated mutation confirmed with an FDA-cleared genetic test?
   If yes, continue to #5.   If no, do not approve.

5. Is the member on all of (or have contraindication to) the following and compliant for at least 6 months?
   • Pulmozyme, AND
   • nebulized hypertonic saline, AND
   • inhaled or oral antibiotics (if appropriate, such as pseudomonas positive)
   If yes, approve x 3 months .   If no, do not approve.

Renewal Criteria:
1. Is this the first renewal following the original 3 month approval?
   If yes, continue to #2   If no, continue to #3

2. Did the member demonstrate a documented objective response by one of the following?
   • A lack of decline in FEV1 verified with documentation
• A reduction in the incidence of pulmonary exacerbations
• A significant improvement in BMI by 10% from baseline
  If yes, continue to #3     If no, deny for not medically necessary

3. Is the request for Symdeko?
   If yes, continue to #4     if no, continue to #5

4. Has there been monitoring of liver function testing completed?
   If yes, continue to #5     if no, review case with medical director

5. Has the member shown compliance with fill history and documentation of ongoing oversight and cystic fibrosis management by the prescriber?
   If yes, approve x 6 months.     If no, review case with Medical Director.
Generic name  Lacosamide

Brand name  Vimpat

Created: 5/7/09
Revised: 9/15/10, 9/26/12, 01/11/18
Reviewed: 12/2/11, 9/12/13

1. Is the member at least 4 years of age?
   If yes, continue to #2.  
   If no, do not approve.

2. Does the member have a diagnosis of partial-onset seizures?
   If yes, continue to #3.  
   If no, do not approve.

3. Has the member failed to achieve successful control of their seizures with at least **TWO** other antiepileptic drugs, such as carbamazepine, oxcarbazepine, phenytoin, topiramate, or valproic acid?
   If yes, continue to #4.  
   If no, do not approve.

4. Is the request for oral solution?
   If yes, continue to #5.  
   If no, approve tablets for lifetime.

5. Is the member unable to take solid oral dosage forms?
   If yes, approve for lifetime.  
   If no, do not approve and approve the tablets for lifetime.
Generic Name  Lansoprazole
Brand Name  Prevacid, First-Lansoprazole

Revised: 7/14/09, 7/6/11, 9/19/11, 9/26/12, 9/12/13, 12/26/14, 11/6/15

1. Is the member’s age less than 19?
   If yes, continue to #5  If no, continue to #2.

2. Is the diagnosis GERD?
   If yes, continue to #3  If no, continue to #4

3. Does the request meet at least ONE of the following?:
   a.) Continuation of PPI therapy beyond 8 weeks (including other PPIs)?
   OR
   b). The request for more than 8 weeks or unspecified duration?

   If yes, deny. Chronic GERD therapy  If no, continue to #5.
   not covered per Guideline Note #144.

4. Does the member have a documented and medically appropriate diagnosis which is
currently funded by the Oregon Health Plan (OHP) Prioritized List?
   If yes, continue to #5.  If no, deny.

5. Is the request for oral capsules )?
   If yes, continue to #8.  If no, continue to #6.

6. Is the member unable to swallow pills or does the member require drug administration
through a G-tube or NG-tube?
   If yes, continue to #7.  If no, do not approve.

7. Has the member failed ALL of the following?
   a. cimetidine liquid or ranitidine syrup AND
   b. omeprazole suspension or (First-omeprazole)

   If yes, approve First-Lansoprazole.  If no, do not approve

8. Has the member tried and failed prescription omeprazole AND pantoprazole?
   If yes, continue to #9.  If no, do not approve.
9. Approve with the following durations:
   - Kids: approve until age 19.
   - Adults with a covered diagnosis (not GERD): max 12 months
   - Adults with GERD: 8 weeks.
Generic Name  Letermovir
Brand Name  Prevymis
Created: 5/10/18

**Initial Criteria:**
1. Has Prevymis been prescribed by or supervised by a hematologist/oncologist, transplant specialist, or infectious disease?
   If yes, continue to #2 If no, do not approve.

2. Is the member treated with any of the following therapy?
   a. Pimozide
   b. Ergot alkaloids
   c. Pitavastatin or simvastatin along with cyclosporine
   If yes, do not approve. If no, continue to #3.

3. Is the request for CMV prophylaxis following allogenic hematopoietic stem cell transplant (HSCT)?
   If yes, continue to #4. If no, do not approve.

4. Was prophylaxis initiated OR will be initiated immediately within 28 days following transplant?
   If yes, continue to #5. If no, do not approve.

5. Is the member (transplant recipient) OR the donor CMV-seropositive?
   If yes, continue to #6. If no, do not approve.

6. Has the prescriber given a statement why prophylaxis with ganciclovir/valganciclovir is not medically appropriate?
   If yes, continue to #7. If no, do not approve.

7. Is there documentation of a plan to monitor the member for CMV reactivation while on Prevymis therapy?
   If yes, approve for 100 days. If no, do not approve.
Generic Name  
Leuprolide in Atrigel  
Leuprolide Acetate  
Leuprolide Acetate and Norethindrone Acetate  
Histrelin Implant  
Triptorelin  
Goserelin Implant

Brand Name  
Eligard  
Lupron  
Lupron Depot  
Lupron Depot-PED  
Lupaneta Kit  
Supprelin LA  
Trelstar  
Triptodur  
Zoladex

Created: 01/11/18  
Reviewed: 7/11/19

***Lupron and Lupaneta may be covered with PA on the outpatient benefit. All others are nonformulary on outpatient benefit. PA for all required for medical benefit.***

All Diagnoses  
Initial Criteria:
1. Is the diagnosis a type of cancer?  
   If yes, continue to cancer criteria.  
   If no, continue to #2.

2. Is the requested agent indicated for or supported for use in the submitted diagnosis for the member's age?  
   If yes, continue to #3.  
   If no, do not approve.

3. Has the treatment been initiated by or is an appropriate specialist currently supervising it?  
   - Cancer: Hematologist/Oncologist  
   - Endometriosis: Obstetrician/Gynecologist  
   - Gender Dysphoria: Pediatric Endocrinologist  
   - Leiomyoma: Obstetrician/Gynecologist  
   - Precocious Puberty: Pediatric Endocrinologist  
   If yes, continue to #4.  
   If no, do not approve.

4. Is the request for a leuprolide containing product?  
   If yes, continue to #6.  
   If no, continue to #5.
5. Has a leuprolide product been tried and failed or is there a contraindication to leuprolide?
   a. If yes, continue to #6. If no, do not approve.

6. Proceed to specific criteria for the submitted indication.

**Cancer**

**Initial Criteria:**
1. Is the medication being prescribed by an oncologist for a cancer diagnosis?
   If yes, continue to #2 If no, do not approve.

2. Is the member new to CareOregon and already receiving the medication for a cancer diagnosis?
   If yes, approve for 12 months. If no, continue to #3.

3. Is the treatment supported for the diagnosis in the NCCN guidelines?
   If yes, continue to #5. If no, continue to #4.

4. Is the treatment being used according to the FDA indication for the requested product?
   If yes, continue to #5. If no, do not approve.

5. Does the request meet criteria for treatment coverage specified in Guideline Note 12 of the Prioritized List of Health Services, considering treatment of cancer with little or no benefit?
   If yes, approve for 12 months. If no, do not approve.

6. Approve for 12 months.

**Cancer**

**Renewal Criteria:**
1. Is the requested medication being continued by an oncologist for a cancer diagnosis?
   a. If yes, approve for 12 months. If no, do not approve.

**Endometriosis**

**Initial Criteria:**
1. Does the member have a diagnosis of endometriosis confirmed by laparoscopy?
   If yes, continue to #2. If no, do not approve.

2. Has the member tried and failed or have contraindications to hormonal therapies (combined oral contraceptives, progestins, or levonorgestrel IUD)?
   If yes, continue to #3. If no, do not approve.

3. Is the request for initial treatment (member is treatment naïve)?
If yes, continue to #5. If no, continue to #4.

4. Is the request for Lupaneta or is norethindrone add-back therapy also prescribed?
If yes, continue to #5
If no, do not approve.

5. Approve for 6 months.

**Endometriosis**

**Renewal Criteria:**
1. Is the request for Lupaneta or is norethindrone add-back therapy also prescribed?
   If yes, continue to #2.
   If no, do not approve.

2. Has the total length of use of GnRH agonist therapy been less than 12 months?
   If yes, continue to #3.
   If no, do not approve.

3. Approve for 6 months.

**Gender Dysphoria**

**Initial Criteria:**
1. Is the request for use in delaying the onset of puberty and/or continued pubertal development in a child or adolescent (younger than 18 years of age) with a diagnosis of gender dysphoria?
   If yes, continue to #2.
   If no, do not approve.

2. Is the use for delaying the onset of puberty?
   If yes, continue to #3.
   If no, continue to #5.

3. Has the member reached Tanner stage 2, with documentation that the first physical changes of puberty have occurred?
   If yes, continue to #4.
   If no, do not approve.

4. Is there documentation that the member has had a comprehensive mental health evaluation and has fulfilled eligibility and readiness criteria?
   If yes, continue to #8.
   If no, do not approve.

5. Is the request for continued delay of pubertal development in an adolescent who started titrating cross-sex hormones before age 18 but after reaching Tanner stage 5 in the gender they were assigned at birth?
   If yes, continue to #6.
   If no, do not approve.

6. Has it been more than two years from initiation of cross-sex hormones?
   If yes, do not approve.
   If no, continue to #7.

7. Has it been more than one year from initiation of cross-sex hormones?
Gender Dysphoria

Renewal Criteria:
1. Is the use for delaying the onset of puberty?
   If yes, continue to #2. If no, continue to #4.

2. Is the member age less than 17?
   If yes, continue to #7. If no, continue to #3.

3. Is member age less than 18?
   If yes, approve until the member turns 18. If no, do not approve.

4. Is the request for continued delay of pubertal development in an adolescent who started titrating cross-sex hormones before age 18 but after reaching Tanner stage 5 in the gender they were assigned at birth?
   If yes, continue to #5. If no, do not approve.

5. Has it been more than two years from initiation of cross-sex hormones?
   If yes, do not approve. If no, continue to #6.

6. Has it been more than one year from initiation of cross-sex hormones?
   If yes, approve until two years of cross-sex hormone therapy has been completed.
   If no, continue to #7.

7. Approve for 12 months.

Leiomyoma (Uterine Fibroids)

Initial Criteria:
1. Does the member have a diagnosis of uterine leiomyoma (fibroids)?
   If yes, continue to #2. If no, do not approve.

2. Is the request for preoperative hematologic treatment of anemia caused by fibroids?
   If yes, continue to #3. If no, do not approve.

3. Is the request for initial treatment (member is treatment naïve)?
   If yes, approve for 3 months. If no, do not approve.

Precocious Puberty
Initial Criteria:
1. Is the request being initiated by or supervised by a pediatric endocrinologist?
   If yes, continue to #2. If no, do not approve.

2. Does the member have a diagnosis of central precocious puberty?
   If yes, continue to #3. If no, do not approve.

3. Is the member age less than 11 for females and 12 for males?
   If yes, approve up to 12 months or until age 11 for females and age 12 for males.

Precocious Puberty
Renewal Criteria:
1. Does the member have a diagnosis of central precocious puberty?
   If yes, continue to #2. If no, do not approve

2. Is the member age less than 11 for females and 12 for males?
   If yes, approve up to 12 months or until age 11 for females and age 12 for males.
Generic Name: Levoleucovorin
Brand Name: Fusilev, Khapzory
Created: 09/14/17, 11/8/18

**Initial Criteria:**
1. Is the treatment being prescribed by a hematologist or oncologist, as appropriate, for the type of cancer?
   If yes, continue to #2. If no, do not approve.

2. Is the treatment supported for the diagnosis in the NCCN guidelines?
   If yes, continue to #4. If no, continue to #3.

3. Is the treatment being used according to the FDA indication?
   If yes, continue to #4. If no, do not approve.

4. Does the request meet criteria for treatment coverage specified in Guideline Note 12 of the Prioritized List of Health Services, considering treatment of cancer with little or no benefit?
   If yes, continue to #5. If no, do not approve.

5. Is there documentation of trial and failure of or contraindication to leucovorin calcium?
   If yes, continue to #6. If no, do not approve.

6. Approve for 12 months.

**Renewal Criteria:**
1. Has there been evidence of tumor response?
   If yes, approve for 12 months. If no, do not approve.
Generic Name: Mecasermin

Brand Name: Increlex

Revised: 11/21/08, 9/12/13
Reviewed: 12/2/11, 9/13/12

Initial Criteria:

1. Is the member age 2-18 years old?
   - If yes, continue to #2
   - If no, do not approve.

2. Is the prescriber a pediatric endocrinologist?
   - If yes, continue to #3.
   - If no, do not approve.

3. Does the member have primary IGF-1 deficiency due to growth hormone insensitivity syndrome?
   - If yes, continue to #5.
   - If no, continue to #4.

4. Does the member have a growth hormone gene deletion and has developed neutralizing antibodies to growth hormone?
   - If yes, continue to #5.
   - If no, do not approve.

5. Have secondary causes of IGF-1 deficiency been ruled out, such as growth hormone deficiency, malnutrition, hypothyroidism, or chronic corticosteroid therapy?
   - If yes, continue to #6.
   - If no, do not approve.

6. Is there evidence of non-closure of the epiphyseal plate?
   - If yes, continue to #7.
   - If no, do not approve.

7. Does the member have a suspected neoplasia?
   - If yes, do not approve.
   - If no, continue to #8.

8. Approve for 12 months.

Renewal Criteria:

1. Does the member meet **ALL** of the following criteria:
   a. Evidence of GV greater than 2.5 cm/year, **AND**
   b. Non-closure of epiphyses confirmed by X-ray, **AND**
   c. Bone age suggests that height potential has not been achieved defined as bone age for male has not exceeded 16 years of age (required annually when
chronological age reaches 15) and bone age for female has not exceeded 14 years of age (required annually when chronological age reaches 13)

If yes, approve for 12 months. If no, do not approve.
OHP Interleukin-5 Antagonist PA Criteria

Generic Name: Benralizumab
Mepolizumab
Reslizumab

Brand Name: Fasenra
Nucala
Cinqair

Created: 3/21/16
Revised: 3/12/18, 05/10/18, 3/14/19

All Diagnoses

Initial Criteria:
1. Is the requested agent indicated for or supported for use in the submitted diagnosis for the member’s age?
   If yes, continue to #2. If no, do not approve.

2. Has the treatment been initiated by or is an appropriate specialist currently supervising it?
   a. Eosinophilic asthma: pulmonologist
   b. Eosinophilic granulomatosis with polyangiitis (Churg–Strauss): pulmonologist, rheumatologist, or vasculitis specialist.
   If yes, continue to #3. If no, do not approve.

3. Is the member a current smoker?
   If yes, continue to #4. If no, continue to #5.

4. Is the member enrolled in a smoking cessation program?
   If yes, continue to #5. If no, do not approve.

5. Continue to appropriate diagnosis.

Eosinophilic Asthma

Initial Criteria:
1. Does the member have a diagnosis of moderate to severe asthma with an eosinophilic phenotype?
   If yes, continue to #2. If no, do not approve.

2. Is the member’s recent eosinophil count of ≥ 300 cells/µL in last 4 weeks?
   If yes, continue to #3. If no, do not approve.

3. Has the member failed the following agents including as combination therapy?
a. High dose inhaled corticosteroid with a long acting beta agonist (such as AirDuo, Advair, or Symbicort).
b. Long acting muscarinic antagonist (such as Spiriva)
c. Leukotriene inhibitor (such as montelukast)
   If yes, continue to #4. If no, do not approve.

4. Does the member have a history of compliance with asthma medications (above)?
   If yes, continue to #5. If no, do not approve.

5. In the past year has the member had frequent asthma exacerbations resulting in repeated use of health care services, such as urgent care or ED visits or hospitalization?
   If yes, approve x 4 months. If no, do not approve.

Renewal Criteria:
1. Has the member had a reduction in asthma exacerbations necessitating frequent office visits, ED / urgent care visits, hospitalizations, oral steroids and demonstrated sustained clinical improvement from baseline?
   If yes, approve for 6 months If no, do not approve.

Eosinophilic granulomatosis with polyangiitis
Initial Criteria:
1. Does the member have a diagnosis of symptomatic eosinophilic granulomatosis with polyangiitis?
   If yes, continue to #2. If no, do not approve.

2. Is there documentation of systemic involvement, aside from asthma or ear, nose, and throat manifestations)?
   If yes, continue to #3. If no, do not approve.

3. Has the member tried and failed to induce remission with a course of oral or pulse corticosteroids, or failed to taper after 3-4 months?
   If yes, continue to #4. If no, do not approve.

4. Has the member failed an immunosuppressant such as cyclophosphamide, azathioprine, or methotrexate?
   If yes, continue to #5. If no, do not approve.

5. Approve for 6 months.
Generic Name    Mesalamine

Brand Name
Mesalamine 800mg DR (generic AsacolHD)
Mesalamine 1.2 g (generic Lialda)
Delzicol
Apriso
Pentasa

Revised: 3/14/19

**Initial Criteria:**

1. Does the member have Crohn’s disease?
   If yes, continue to #4
   If no, continue to #2

2. Does the member have ulcerative colitis?
   If yes, continue to #3
   If no, review if disease state is supported

3. Is the disease described as active in the small bowel (proximal to the colon)?
   If yes, continue to #5
   If no, continue to #4

4. Has the member failed or is intolerant to **ONE** of the following: sulfasalazine OR balsalazide? Note: documentation of poor disease control from non-compliance of multi-day dosing of these medications will qualify, but adequate trial must first be tried.
   If yes, continue to #5
   If no, do not approve and recommend untried agents.

5. Is the request for Pentasa?
   If yes, continue to #6
   If no, continue to #7

6. Does the member meet one of the following:
   a. Failed one of: generic oral mesalamine product (Lialda, Asacol, etc) or Apriso; OR
   b. Provider states full GI tract involvement requires Pentasa release mechanism
   If yes, continue to #7
   If no, deny and require the alts

7. Approve x life.
Generic Name: Midostaurin
Brand Name: Rydapt
Created: 07/13/17

**Initial Criteria**

5. Is the treatment being prescribed by a hematologist or oncologist for a type of cancer?
   - If yes, continue to #2.
   - If no, continue to #5.

6. Is the treatment supported for the diagnosis in the NCCN guidelines?
   - If yes, continue to #4.
   - If no, continue to #3.

7. Is the treatment being used according to the FDA indication?
   - If yes, continue to #4
   - If no, do not approve.

8. Does the request meet criteria for treatment coverage specified in Guideline Note 12 of the Prioritized List of Health Services, considering treatment of cancer with little or no benefit?
   - If yes, approve for 12 months
   - If no, do not approve.

9. Is the treatment being prescribed by a hematologist, oncologist, or immunologist?
   - If yes, continue to #6
   - If no, do not approve.

10. Does the member have a diagnosis of aggressive systemic mastocytosis (ASM)?
    - If yes, continue to #7
    - If no, continue to #9.

11. Is the aggressive systemic mastocytosis without the D816V c-Kit mutation as determined with an FDA-approved test or with c-Kit mutational status unknown?
    - If yes, continue to #8
    - If no, continue to #10.

12. Has the member failed imatinib?
    - If yes, continue to #10
    - If no, do not approve and offer imatinib.

13. Does the member have systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL)?
    - If yes, continue to #10
    - If no, do not approve.

14. Approve for 6 months.

**Renewal Criteria**

**Cancer:**
1. Is there evidence of tumor response and resolution or improvement of disease-related signs and symptoms?
   If yes, approve for 12 months. If no, do not approve.

Renewal Criteria
Systemic Mastocytosis:
2. Is there documentation of a positive hematological response?
   If yes, approve for 12 months. If no, do not approve.
Generic Name: Miltefosine
Brand Name: Impavido

Created: 7/19/16

1. Is the request for treatment of visceral, cutaneous, and/or mucosal leishmaniasis?  
   If yes, continue to #2.  If no, deny.

2. Is the request from or in consultation with an Infectious Disease specialist?  
   If yes, continue to #3.  If no, deny.

3. Has the member tried and failed IV amphotericin B or Ambisome?  
   If yes, approve for maximum 28 days  If no, deny.
MIGRAINE TREATMENTS

Generic Name
- Sumatriptan
- Naratriptan
- Rizatriptan
- Zolmitriptan
- Dihydroergotamine

Brand Name
- Imitrex
- Amerge
- Maxalt
- Zomig
- Migranal

Created: 12/14/09
Revised: 9/28/11, 1/22/16
Reviewed: 9/13/12, 9/12/13

Quantity Limit Explanation:

According to product labeling, the safety and effectiveness of treating more than 4 headaches in a 30-day period with sumatriptan (oral and nasal spray), naratriptan, rizatriptan, frovatriptan, almotriptan, and zolmitriptan nasal spray have not been established.

Medical Necessity Quantity exception criteria:
1. Is the request for more than 4 treatment days per month?
   If yes, do not approve and recommend reevaluation of migraine prophylaxis.

Prophylaxis indications:
   a. 2 or more attacks per month that produce disability that lasts 3 or more days per month
   b. Contraindication or failure of acute treatments
   c. Use of abortive medication more than twice per week
   d. Presence of uncommon migraine (hemiplegic migraine, prolonged aura, migrainous infarction).

Common prophylactic medications for migraine include:
   a. Beta blockers: propranolol
   b. Calcium channel blockers: verapamil
   c. Tricyclic antidepressants: amitriptyline, nortriptyline
   d. Divalproex sodium
   e. Topiramate
Generic Name        Mometasone Nasal Implant
Brand Name          Sinuva

Currently reviewed by Medical Director Team with case-by-case review
Nasal Corticosteroids

Generic Name
- Beclomethasone
- Budesonide
- Flunisolide
- Mometasone
- Triamcinolone

Brand Name
- Beconase AQ,
- Rhinocort AQ,
- Nasarel, Nasalide,
- Nasonex,
- Nasacort AQ
- Nasacort 24 hr OTC

Revised: 12/21/09, 9/19/11, 9/12/13, 1/11/18
Reviewed: 5/10/12

Note: Fluticasone is available without PA. Nasacort 24hr OTC is available with Step Therapy off fluticasone (fluticasone criteria also apply).

1. Does the member have a diagnosis of chronic sinusitis?
   - If yes, continue to #5.
   - If no, continue to #2.

2. Does the member have a diagnosis of allergic rhinitis?
   - If yes, continue to #3.
   - If no, do not approve.

3. Does the member have any of the following complications?
   a. Periorbital inflammation or other ocular complications (chronic eye swelling)
   b. History of sinus surgery or frequent sinus procedures (e.g. fistula drainage)
   c. Wegener's Granulomatosis
   - If yes continue to #5.
   - If no, continue to #4

4. Does the member have a diagnosis of asthma?
   - If yes, continue to #5.
   - If no, do not approve

5. Approve generic flunisolide 29mcg (Nasarel) or generic flunisolide 0.025% (Nasarel) for life. If request for Nasacort 24 Hr OTC and fluticasone failed, approve for life.
Generic Name  Netupitant/Palonosetron
Rolapitant

Brand Name  Akynzeo
Varubi

Created: 2/17/15
Revised: 03/10/16

***Nonformulary for outpatient benefit. PA required on medical benefit.***

1. Is the member currently receiving treatment with a moderate to highly emetogenic chemotherapeutic agent?
   If yes, continue to #2. If no, do not approve.

2. Is the member receiving concurrent treatment dexamethasone?
   If yes, continue to #3. If no, do not approve.

3. Is the member receiving a 5-hydroxytryptamine-3 receptor antagonist such as ondansetron, dolasetron, granisetron, or palonosetron (included in Akynzeo)?
   If yes, continue to #4 If no, do not approve.

4. Approve for requested duration of chemotherapy.
Generic Name  Ocrelizumab
Brand Name    Ocrevus
Created: 7/13/17

*** Non-formulary for outpatient benefit. PA required for medical benefit ***

1. Is the request from a neurologist?
   If yes, continue to #2.        If no, deny.

2. Does the member have Relapsing Remitting Multiple Sclerosis (RRMS)?
   If yes, continue to #4.        If no, continue to #3

3. Does the member have primary or secondary progressive MS?
   If yes, deny for Guideline Note #95 not met.
   If no, deny for investigational

Guideline Note #95 states that primary progressive or secondary progressive MS are
not covered for immune modifying treatment therapies.

4. Deny Ocrevus and offer Rituxan. While using Rituxan is off label for MS, it has
   established safety and efficacy data. Rituxan is nearly identical Ocrevus and therefore
   the P&T Committee has assessed Ocrevus to offer no advantage vs Rituxan. If Rituxan failed,
   Ocrevus would not be an appropriate choice and other MS therapies should be considered.
Generic Name  Ocriplasmin
Brand Name  Jetrea

Created: 5/9/13  
Reviewed: 9/12/13

***Nonformulary for outpatient benefit. PA required on medical benefit.***

1. Does the member have a diagnosis of symptomatic vitreomacular adhesion?  
   If yes, approve x 1.  
   If no, do not approve.
Somatostatin Analogs

Generic Name     Octreotide
                 Octreotide acetate
                 Lanreotide
                 Pasireotide diaspartate
                 Pasireotide

Brand Name       Sandostatin
                 Sandostatin LAR
                 Somutuline
                 Signifor
                 Signifor LAR

Revised: 11/09/17, 11/8/18

***Depot products nonformulary for outpatient benefit. PA required on medical benefit.***

Initial Criteria:
1. Is the request prescribed by or supervised by an endocrinologist?
   If yes, continue to #2   If no, continue to #8.

2. Is the request for Signifor or Signifor LAR?
   If yes, continue to #3.   If no, continue to #8.

3. Is the request for the treatment of Cushing’s Disease?
   If yes, continue to #4.   If no, continue to #5.

4. Is pituitary surgery not an option or has it not been curative?
   If yes, approve for 3 months.   If no, do not approve.

5. Does the member have a diagnosis of acromegaly confirmed by elevated IGF-1 levels?
   If yes, continue to #6.   If no, continue to #8.

6. Is the acromegaly moderate to severe or symptomatic?
   If yes, continue to #7.   If no, do not approve.

7. Does the member have persistent disease after surgery or considered not to be a candidate for surgery?
   If yes, continue to #12.   If no, do not approve.

8. Is the treatment being prescribed by an oncologist for a type of cancer?
   If yes, continue to #9.   If no, do not approve.
9. Is the treatment supported for the diagnosis in the NCCN guidelines?
   If yes, continue to #11. If no, continue to #10.

10. Is the treatment being used according to the FDA indication?
    If yes, continue to #11. If no, do not approve.

11. Does the request meet criteria for treatment coverage specified in Guideline Note 12 of the Prioritized List of Health Services, considering treatment of cancer with little or no benefit?
    If yes, continue to #12. If no, do not approve.

12. Is the request for octreotide or octreotide LAR?
    If yes, continue to #16. If no, continue to #13.

13. Is the request for Somatuline?
    If yes, continue to #14. If no, continue to #15.

14. Has the member tried and failed or have a contraindication to octreotide?
    If yes, continue to #16. If no, do not approve and offer octreotide.

15. Has the member tried and failed or have a contraindication to Sandostatin/Sandostatin LAR AND Somatuline?
    If yes, continue to #16. If no, do not approve and offer all untried agents.

16. Is the requested product supported for the submitted indication?
    If yes, continue to #17. If no, do not approve

17. Approve for 12 months.

**Renewal Criteria:**

1. Does the member have Cushing's Disease?
   If yes, continue to #2. If no, continue to #3.

2. Has the member had a response of a significant reduction in normalization of mean 24 hour urine-free cortisol?
   If yes, approve for life. If no, do not approve.

3. Does the member have acromegaly?
   If yes, continue to #4. If no, continue to #5.
4. Has the member had a reduction in or has reached a target goal of GH or an age-normalized serum IGF-1 value?
   If yes, approve for 12 months. If no, do not approve.

5. Does the member have a cancer diagnosis?
   If yes, continue to #6. If no, do not approve.

6. Has the member reached treatment goals such as:
   • Symptom control, such as reduction in diarrhea episodes or carcinoid symptoms
   • Tumor control and disease stabilization
   If yes, approve for 12 months. If no, do not approve.
Opioids PA criteria

The following criteria apply to all reviews including PA required, Quantity limit exceeded, and formulary exception.

Representative Brand Names: Oxycontin, Duragesic, MS Contin, Dilaudid, Vicodin, Norco, Opana ER, Avinza

Representative Generic Names: oxycodone, morphine, fentanyl, hydromorphone, codeine, hydrocodone/APAP

Updated: 2/1/18 (in effective since 2/1/18, but online criteria error prevented posting until 3/1/19)

1. Is this a renewal request for a medication previously approved by CareOregon?
   If yes, continue to #2  If no, continue to #5

Taper Check

2. Was the original approval subject to expectations of a taper?
   If yes, continue to #3  If no, continue to #10

3. Has the member tapered as expected?
   If yes, continue to #10  If no, continue to #4

4. Has the provider submitted an updated plan to continue tapering?
   If yes, approve x 3 months  If no, deny.

Initial

5. Is the diagnosis covered under Oregon Medicaid?
   If yes, continue to #6.   If no, deny

6. Is the opioid for back pain?
   If yes, continue to #7.   If no, continue to #8.

7. By applicable scenario, are all sub-criteria met for management of back pain?
   a. Acute First 90 days:
      i. Immediate-Release opiate only
      ii. Non-opiates such as NSAIDs, APAP, muscle relaxants failed
   b. Chronic (beyond 90 days)
      i. Documentation that a taper plan is in place to discontinue opiates within 6 months. Taper plan itself is not required for submission so long as provider documents such a plan is in place.
      ii. Not a new start to this medication (unless switching is necessary in order to facilitate taper)
   If yes, continue to #8  If no, deny for Guideline Note #60 not met.
8. Are opioids relatively contraindicated for the indication including, but not limited to the following?:
   a. Treatment of an inappropriate condition (i.e., migraines, central pain syndrome/fibromyalgia)?
   b. Concomitant prescribing of a benzodiazepine
   c. Extended-release opioids for acute pain
      If yes, deny not medically appropriate. If no, continue to #9

9. Product specific/request type questions:
   a. Morphine ER
      i. Have short acting opioids been failed?
   b. Oxycontin:
      i. Short-acting opioids AND
      ii. Morphine ER (which also requires PA)
   c. Fentanyl Patch:
      i. Has Morphine ER been failed?
   d. Fentanyl Q48?
      i. Morphine ER failed
      ii. Fentanyl Q72H failed?
   e. Non-formulary meds: have formulary alternatives been tried and failed?
   f. All other formulary opioids
      i. No specific criteria
      ii. Non-opioid alts (NSAIDs, APAP)
      If yes, continue to #10 If no, deny.

Following Applies to both initial and renewal
10. Does the member have active cancer pain or is the member in a palliative care program?
    If yes, go to approval If no, continue to #11.

11. Has member actively participated in non-medication modalities?
    If yes, continue to #12 If no, deny

12. Has the member’s function been improved while on opioids?
    If yes, continue #13 If no, deny.

13. Has the member’s risk been assessed for ALL of the following?
    a. Risk of abuse
    b. Risk of respiratory adverse events
    c. Mental Health/Depression screening
    d. Urine drug screen
    e. PDMP report
    If yes, approve per below If no, deny
**Approval Durations/Language:**

a) Acute-Back Pain
   a. Duration: Up to 12 total weeks of therapy
   b. Language: “Per Oregon Medicaid Guideline Notes, no additional opioid therapy may be reauthorized.”

b) Chronic Back Pain (taper only)
   a. Duration: As needed for taper.
   b. Language: “Per Oregon Medicaid rules, opioids for chronic back pain are expected to be discontinued.”

c) Covered, non-back pain diagnoses (no taper involvement)
   a. Duration: 12 months.
   b. Language: " Renewal of this medication will require documentation of: 1) engagement in non-medication pain management modalities, including evaluation of function and quality of life using validated assessment tools 2) risk assessment results 3) mental health screening 4) Oregon Prescription Drug Monitoring Program (PDMP) query 5) recent Urine Drug Screen and 6) co-prescribing naloxone rescue kit for MED > 50.”

d) Taper plans (for chronic use not related to back pain)
   a. Duration: max 12 months or as appropriate for taper plan.
   b. Language: State reauthorization specifics required including any non-taper plan related renewals like language shown above.
1. Is the diagnosis Acute Otitis Externa (AOE)?
   If yes, continue to #2. If no, continue to #4.

2. Has the member failed treatment with neomycin/polymyxin B/HC otic?
   If yes, continue to #6. If no, continue to #3.

3. Does the member have a perforated tympanic membrane or tympanostomy tubes?
   If yes, continue to #6. If no, do not approve

4. Does the member have a diagnosis of Chronic Suppurative Otitis Media (CSOM)?
   If yes, deny for below the line If no, continue to #5.
   diagnosis.

5. Is the diagnosis Acute Otitis Media with tympanostomy tubes (AOMT) or post-operative tympanostomy tube otorrhea and/or granulation tissue?
   If yes, approve If no, continue to #8.
   #1 bottle (7.5ml) for 7 days.

6. Has the member failed a trial of ofloxacin otic OR ciprofloxacin 0.2% otic?
   If yes, continue to #7. If no, do not approve

7. Approve #1 bottle (7.5ml) for 7 days.

8. Is the request for prophylaxis following tympanostomy tube placement?
   If yes, do not approve If no, do not approve.
Generic Name  Omalizumab
Brand Name  Xolair
Revised: 1/14/09, 5/1/17, 11/9/17
Reviewed: 12/2/11, 9/12/13, 3/14/19

**Initial Criteria:**

1. Is Xolair being requested by a pulmonologist or immunologist?
   - If yes, continue to #2.
   - If no, do not approve.

2. Is the member ≥ 6 years?
   - If yes, continue to #3.
   - If no, do not approve.

3. Does the member have a diagnosis of moderate to severe persistent asthma?
   - If yes, continue to #4.
   - If no, do not approve.

4. Is the member a current smoker?
   - If yes, do not approve.
   - If no, continue to #5.

5. Does the member have a positive skin test or RAST to a perennial aeroallergen?
   - If yes, continue to #6.
   - If no, do not approve.

6. Is the member’s baseline IgE serum level within FDA label?
   - a. Age 6-11: 30-1,300 IU/mL
   - b. Age 12 and up: 30-700
   - If yes, continue to #7.
   - If no, do not approve.

7. Have the provider and member taken all steps to reduce and maximally manage environmental allergens and other triggers (e.g., tobacco smoke, dust mites, pets, molds, occupational exposures, GERD)?
   - If yes, continue to #8.
   - If no, do not approve.

8. Has the member failed the following agents including as combination therapy?
   - a. High dose inhaled corticosteroid with a long acting beta agonist (such as AirDuo, Advair, or Symbicort).
   - b. Long acting muscarinic antagonist (such as Spiriva)
   - c. Leukotriene inhibitor (such as montelukast)
   - If yes, continue to #9.
   - If no, do not approve.
9. Has the member tried and failed or have contraindications to allergen immunotherapy?
   If yes, continue to #10. If no, do not approve.

10. Does the member have a history of compliance with asthma medications?
    If yes, continue to #11. If no, do not approve.

11. In the past year has the member had frequent asthma exacerbations resulting in repeated use of health care services, such as urgent care or ED visits or hospitalization?
    If yes, approve for 4 months. If no, do not approve.

**Renewal Criteria:**
1. Has the member had a reduction in asthma exacerbations necessitating frequent office visits, ED / urgent care visits, hospitalizations, oral steroids and demonstrated sustained clinical improvement from baseline while on Xolair?
   If yes, approve for 6 months If no, do not approve.
Oral Nutritional Supplements

Generic Name  Lactose – Free Food, Lactose – Free Food/Fiber Nutritional Supplement


Revised: 6/7/10, 6/14/11, 5/21/12, 6/1/14, 03/10/16
Reviewed: 9/12/13

Age ≥ 6 years:
1. Is the nutritional supplement to be administered via enteral tube feeding (e.g. G-tube, NG-tube)?
   If yes, close request If no, continue to #2.
2. Is the member currently on oral nutritional supplements?
   If yes, continue to #3. If no, continue to #4.
3. Has there been an annual assessment by the MD or RD for continued use and documentation indicates there is weight maintenance (no continued weight loss or low serum protein)?
   If yes, approve for life. If no, do not approve.
4. Does the member have a nutritional deficiency identified by any ONE of the following?
   • Total protein < 5.6g/dl or albumin < 3.4g/dl or
   • Registered Dietician assessment in the past 3 months indicates sufficient caloric/protein intake is not obtainable through regular, liquefied or pureed foods (i.e., liquefied/pureed foods have been tried and failed)
   If yes, continue to #6. If no, continue to #5.
5. Does the member meet BOTH of the following criteria?
   a. Prolonged history (years) of malnutrition and diagnosis or symptoms of cachexia and member resides in a home, nursing facility, or chronic home care facility.
   b. Obtaining criteria from question #4 would be futile and invasive.
   If yes, continue to #6. If no, do not approve.
6. Does the member have an unplanned weight loss of ≥ 10%* and ONE of the following criteria?
• Severe trauma resulting in increased metabolic need (e.g., severe burn, major bone fracture), or
• Malabsorption difficulty (e.g., Crohn's disease, short-gut syndrome, bowel resection, fistula, gastric bypass, cystic fibrosis, renal dialysis, dysphagia, achalasia), or
• Diagnosis that requires additional calories (cancer, AIDS, Pulmonary insufficiency MS, ALS, Parkinson's, cerebral palsy, Alzheimer's)

*Weight loss criteria may be waived if body weight is being maintained by supplements due to member's medical condition (e.g., renal failure, AIDS)

If yes, approve for life. If no, do not approve.

**Age < 6 years:**

1. Is the nutritional supplement to be administered via enteral tube feeding (e.g. G-tube, NG-tube)?
   - If yes, close request
   - If no, continue to #2.

2. Is the request for Infant formula or nutritional supplements available through WIC? (note: WIC eligibility is for children less than age 5, proceed to #4 if 5 years old)
   - If yes, continue to #3.
   - If no, continue to #4.

3. Is member unable to obtain formula type or quantity required through WIC program?
   - If yes, forward to RPh.
   - If no, do not approve.

4. Is the member currently on oral nutritional supplements?
   - If yes, continue to #5.
   - If no, continue to #6.

5. Has there been an annual assessment by the MD or RD for continued use and documentation indicates there is weight maintenance?
   - If yes, approve x 12 mo.
   - If no, do not approve.

6. Does the member have a diagnosis of failure to thrive?
   - If yes, continue to #7.
   - If no, do not approve.

7. Does the member have a nutritional deficiency identified by any ONE of the following?
   • Total protein < 5.6g/dl or Albumin < 3.4g/dl, or
   • Registered dietician assessment in the past 3 months indicates sufficient caloric/protein intake is not attainable through regular, liquified or purified foods.
   - If yes, approve x 12 months.
   - If no, continue to #8.

8. Does the member meet ONE of the following criteria?
• Severe trauma resulting in increased metabolic need (e.g., severe burn, major bone fracture), or
• Malabsorption difficulty (e.g., Crohn’s disease, short-gut syndrome, bowel resection, fistula, gastric bypass, cystic fibrosis, renal dialysis, dysphagia, achalasia), or
• Diagnosis that requires additional calories (cancer, AIDS, Pulmonary insufficiency MS, ALS, Parkinson’s, cerebral palsy, Alzheimer’s)

If yes, approve x 12 months.  
If no, do not approve.
Quantity Exception Criteria

1. Is the member older than 1 year of age?  
   If yes, then continue to #2.    If no, then do not approve.

2. Is Tamiflu being used to treat influenza?  
   If yes, and the member has exceeded the annual quantity limit of 2 treatments/20 capsules) which does not require PA, review for clinical appropriateness.    If no, continue to #3.

3. Is Tamiflu being used for influenza prophylaxis (prevention)?  
   If yes, continue to #4.    If no, continue to #5

4. Has the member been exposed to the influenza virus (household or community outbreak)?  
   If yes, continue to #5.    If no, do not approve.

5. Does the member have any of the following that places them at high risk for developing influenza complications?  
   a. ≥ 65 years of age  
   b. Pregnancy (category C)  
   c. Children meeting the age limit or teenagers who are receiving long-term aspirin treatment and may be at risk for developing Reye’s syndrome.  
   d. Cardiovascular disease except hypertension  
   e. Chronic pulmonary disease (asthma or COPD)  
   f. Weakened immune system due to HIV/AIDS, immunosuppressive medications (e.g. transplant, steroids, TNFs), chemotherapy or radiation therapy  
   g. Renal disease  
   h. Hematological disorders (i.e. anemia)  
   i. Metabolic disease such as diabetes mellitus  
   j. Any muscle or nerve condition (e.g. spinal cord injuries, seizures, or cerebral palsy) or cognitive dysfunction that can lead to difficulty breathing or swallowing and increase the aspiration risk  
   k. Residents of nursing homes or other long-term care facilities  
   l. Currently resides with or cares for high-risk people (meeting one of the above criteria)  
   If yes, continue to #6.    If no, do not approve.
6. Approve with the following duration:
   a. 10 day therapy for household or community outbreaks.
   b. 30 days for institutional outbreaks. If an extension needed then the provider needs to submit another prior authorization request.

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Body Weight</th>
<th>Recommended Dose for 5 days</th>
<th>Number of Bottles of the Oral Suspension (6mg/ml)</th>
<th>Number of Capsules (30mg, 45mg, 75mg)</th>
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<tbody>
<tr>
<td></td>
<td>≤ 15kg</td>
<td>30mg BID</td>
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<td>10 of 30mg</td>
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<tr>
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<td>16 to 23kg</td>
<td>45mg BID</td>
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<td>24 to 40kg</td>
<td>60mg BID</td>
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<tr>
<td></td>
<td>&gt; 40kg</td>
<td>75mg BID</td>
<td>3</td>
<td>10 of 75mg</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Prophylaxis for Household Outbreaks</th>
<th>Body Weight</th>
<th>Recommended Dose for 10 days</th>
<th>Number of Bottles of the Oral Suspension (6mg/ml)</th>
<th>Number of Capsules (30mg, 45mg, 75mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>≤ 15kg</td>
<td>30mg QD</td>
<td>1</td>
<td>10 of 30mg</td>
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</tr>
<tr>
<td></td>
<td>&gt; 40kg</td>
<td>75mg QD</td>
<td>3</td>
<td>10 of 75mg</td>
</tr>
</tbody>
</table>
Generic Name Oxandrolone

Brand Name Oxandrin

Revised: 11/21/08, 01/14/16, 05/09/19
Reviewed: 12/2/11, 9/13/12, 9/12/13

Initial Criteria:
1. Does the member have any of the following contraindications to use of oxandrolone?
   a. Known or suspected carcinoma of the prostate or breast in males
   b. Carcinoma of the breast in females with hypercalcemia
   c. Pregnancy
   d. Nephrosis, the nephrotic phase of nephritis
   e. Hypercalcemia
   f. Severe hepatic dysfunction
   g. Severe renal dysfunction
      If yes, do not approve. If no, continue to #2.

2. Is oxandrolone being used as adjunctive therapy to promote weight gain after weight loss following extensive surgery, chronic infections, or severe trauma, or in a member without definite pathophysiologic reasons fails to gain or to maintain normal weight?
   If yes, continue to #3. If no, continue to #5.

3. Has the member experienced a weight loss of at least 10% in less than 4 months and has a BMI less than 20?
   If yes, approve for 4 weeks. If no, do not approve.

4. Is oxandrolone being used offset the protein catabolism associated with prolonged administration of corticosteroids?
   If yes, continue to #6. If no, continue to #5.

5. Does the member have a diagnosis of bone pain associated with osteoporosis?
   If yes, continue to #6. If no, do not approve.

6. Approve for 12 months

Renewal Criteria:
1. Is there documentation of increase in or maintenance of (no continued loss) weight/BMI?
   If yes, approve for 6 months. If no, do not approve.
Generic Name          Oxybutynin Patch
Brand Name            Oxytrol For Women OTC
Created: 1-14-14

2. Does the member have an above the line diagnosis (ATL)?
   If yes, continue to #2.     If no, do not approve.

3. Has the member tried and failed oxybutynin IR OR is unable to use oral oxybutynin IR?
   If yes, continue to #3.     If no, do not approve.

3. Approve for life at an NDC specific level for the OTC product “Oxytrol For Women”
Generic Name    Palivizumab

Brand Name    Synagis

Revised: 11/20/09, 9/16/10, 10/18/10, 01/10/11, 10/4/11, 10/21/11, 7/18/12, 10/9/12, 9/12/13, 08/19/14

The following are based off the American Academy of Pediatrics 2014 Synagis Guidelines:

1. Does the member meet **ANY** of the following?
   a. Current age** < 12 months at the start of RSV season and gestational age <29 weeks, 0 days, **or**
   b. Preterm infants who develop Chronic lung disease (CLD) of prematurity defined as birth at gestational age of <32 weeks, 0 days’ gestation and a requirement for >21% oxygen for at least 28 days after birth **AND** one of the following:
      i. Current age <12 months**; OR
      ii. Current age 12-24 months** AND continued medical need for supplemental oxygen, chronic corticosteroids, or diuretic therapy during the 6 month period before the start of the RSV season
   c. Current age < 12 months** with hemodynamically significant congenital heart disease (CHD) **and** at least one of the following:
      i. acyanotic heart disease who are receiving medication to control CHF and will require cardiac surgical procedures **or**
      ii. moderate to severe pulmonary hypertension, **or**
   d. Current age ≤ 12 months** with congenital abnormalities of the airway or neuromuscular disease that impairs the ability to clear secretions from the upper airways. **or**
   e. Age less than 24 months** who will be profoundly immunocompromised during RSV season (such as chemotherapy, or post solid organ or stem cell transplant)

   If yes, continue to #2. If no, deny.

** All referenced ages above are as of start of season.

2. Approve Synagis at a dose of 15mg/kg for up to a maximum of 5 total monthly doses until March 31 (projected end of RSV season). Qualifying infants born during RSV season may require fewer doses. If any infant or young child receiving monthly palivizumab prophylaxis experiences a breakthrough RSV hospitalization, monthly prophylaxis should be discontinued.
Generic Name: Pancrelipase
(Lipase-Amylase-Protease)

Brand Name: Creon
Pancreaze
Zenpep

Created: 03/09/17
Updated: 10/25/18

1. Is the request for Viokace (non-formulary)?
   If yes, continue to #2
   If no, continue to #3.

2. Is the member taking a PPI? (omeprazole or pantoprazole)
   If yes, continue to #3.
   If no, do not approve.

3. Does the member have a diagnosis of cystic fibrosis?
   If yes, continue to #8.
   If no, continue to #4.

4. Has the member had a pancreatectomy?
   If yes, continue to #8.
   If no, continue to #5.

5. Does the member have a diagnosis of exocrine pancreatic cancer?
   If yes, continue to #8.
   If no, continue to #6.

6. Does the member have a diagnosis of chronic pancreatitis confirmed by imaging?
   If yes, continue to #8.
   If no, continue to #7.

7. Does the member have exocrine pancreatic insufficiency confirmed with one of the following methods?
   - Confirmed steatorrhea with fecal fat determination
   - Measurement of fecal elastase
   - Secretin or CCK pancreatic function testing
   If yes, continue to #8.
   If no, do not approve.

8. Approve for lifetime.
Rare Conditions PA Policy

Brand
Onpattro
Revcovi
Oxervate
Gamifant
Ultomiris
Zolgensma
Vyndaqel
Vyndamax

Generic
Patisiran
Elapegademase
Cenergermin
Emapalumab-lzsg
Ravulizumab-cwvz
Onasemnogene abeparvovec
Tafamidis meglumine
Tafamidis

Created: 1/10/19

Policy: Due to the rare condition these drugs are used for, all reviews are subject to an evaluation of medical necessity/appropriateness by a CareOregon Medical Director. CareOregon does not maintain official criteria, but prior authorization is required.
Generic Name Paricalcitol
Brand Name Zemplar

Revised: 9/25/09
Reviewed: 12/2/11, 9/12/13

1. Does the member have Stage 3 (GFR 30-59), Stage 4 (GFR 15-29), or Stage 5 (GFR < 15 or dialysis) chronic kidney disease?
   If yes, continue to #2. If no, do not approve.

2. Does the member have iPTH values > 70 pg/mL if Stage 3, > 110 pg/mL if Stage 4, or > 300 pg/ml if Stage 5 on dialysis, corrected calcium levels < 9.5 mg/dL, and serum phosphorus levels < 4.6mg/dL?
   If yes, continue to #3. If no, do not approve.

3. Has the member tried and failed or have contraindications to Rocaltrol (calcitriol)?
   If yes, continue to #4. If no, do not approve.

4. Approve x lifetime with quantity limit #12/month.
Generic Name: Patiromer
Sodium Zirconium Cyclosilicate

Brand Name: Veltassa
Lokelma

Created: 3/21/16
Updated: 11/8/18

**Initial:**
1. Does the member have hyperkalemia based on potassium labs (vs reference ranges)?
   If yes, continue to #2
   If no, do not approve.

2. Has the member failed ALL of the following?
   a) Dietary modifications; and
   b) Dose modification (or discontinuation) of ACE-inhibitor, ARB, or other
      hyperkalemia causing agent; and
   c) Diuretics
   If yes, approve x 6 months.
   If no, do not approve.

**Renewal:**
1. Has the member shown a meaningful response to therapy (such as returning to normal
   potassium levels or a significant drop from baseline)?
   If yes, approve x 12 months.
   If no, do not approve.
Generic Name    Pegademase bovine
Brand Name      Adagen

Created: 9/15/10
Reviewed: 12/2/11, 5/10/12
Revised: 9/12/13

*** Nonformulary on outpatient benefit. PA required for medical benefit ***

Initial Criteria:
1. Does the member have a diagnosis of adenosine deaminase deficiency with severe
combined immunodeficiency disease (SCID)?
   If yes, continue to #2.  If no, do not approve.

2. Is there medical record documentation of diagnostic confirmation of disease by
   immunologic, imaging, or genetic studies?
   If yes, continue to #3.  If no, do not approve.

3. Has the member failed or is not a candidate for bone marrow transplant?
   If yes, continue to #4.  If no, do not approve.

4. Is the member age 18 or younger?
   If yes, continue to #5.  If no, do not approve.

5. Does the member have any of the following contraindications?
   a. Use as preparatory therapy or support therapy for bone marrow transplant.
   b. Severe thrombocytopenia
   If yes, do not approve.  If not, continue to #6.

6. Is there documentation of objective, measurable treatment goals?
   If yes, continue to #7.  If no, request from provider.

7. Approve x 12 months.

Renewal Criteria:
1. Is there medical record documentation of stabilization of disease progression, such as
diminished frequency of opportunistic infections or fewer complications of infections?
   If yes, approve x 12 months.  If no, do not approve.
1. Does the member have minimally classic and occult lesions of wet macular degeneration?
   If yes, continue to #2 If no, do not approve.
   Does not meet Guideline Note 46.

2. Has the member tried and failed Avastin?
   If yes, approve for 12 months If no, do not approve.
Generic Name Pegloticase
Brand Name Krystexxa

Created: 5/19/11
Reviewed: 7/12/12
Revised: 9/12/13

*** Nonformulary for outpatient benefit. PA required on medical benefit ***

**Initial Criteria:**
1. Is request for adult member with chronic gout with symptomatic hyperuricemia and one of the following:
   a. Minimum 2 acute attacks in the past 12 months
   b. At least 1 gout tophus
   c. Gouty arthritis
      If yes, continue to #2.    If no, do not approve.

2. Is requested by a rheumatologist or nephrologist?
   If yes, continue to #3.    If no, do not approve.

3. Has member failed (defined as at least 2 acute attacks per year while on treatment) or have contraindication to all conventional therapies at maximum tolerable dose including:
   a. allopurinol or probenecid
   b. combination or allopurinol/Uloric and probenecid
   c. Uloric
   d. Colcrys
      If yes, continue to #4.    If no, do not approve and recommend untried medication(s)

4. Does member have glucose-6-phosphate dehydrogenase (G6PD) deficiency?
   If yes, do not approve.    If no, continue to #5

5. Approve x 3 months.

**Renewal Criteria:**
1. Has member achieved serum uric acid level of less than <6mg/dL?
   If yes, approve x 6 months.    If no, do not approve.
Generic Name       Pentosan Polysulfate Sodium

Brand Name         Elmiron

Created: 7/15/13
Revised: 09/14/17

**Initial Criteria:**

1. Is the prescriber a urologist?
   If yes, continue to #2. If no, do not approve.

2. Does the member have a substantiated diagnosis of interstitial cystitis?
   If yes, continue to #3. If no, do not approve.

3. Is there documentation of failure of comprehensive non-medication therapies such as fluid management, bladder training with urge suppression and symptom management (muscle stretching, application of heat/cold, avoidance of pain triggers)?
   If yes, continue to #4. If no, do not approve.

4. Has the member tried and failed or have a contraindication to a TCA (at maximum tolerated doses) such as amitriptyline (25-100 mg/d), nortriptyline (25-150 mg/d), imipramine (25-200 mg/d) or desipramine (12.5-200 mg/d)?
   If yes, approve for 6 months. If no, do not approve.

**Renewal Criteria:**

1. Has the member been adherent and had an improvement in symptoms, such as a reduction in bladder pain?
   If yes, approve for life. If no, do not approve.
Generic Name   Tacrolimus
Brand Name      Protopic
Initial: 03/14/2019

**Initial Criteria:**
1. Does the member have chronic, severe atopic dermatitis at baseline with functional impairment and one or more of the following:
   a. At least 10% body surface area involved
   b. Hand, foot or mucous membrane involvement
      If yes, continue to #2  If no, do not approve.

2. Has the treatment been prescribed or is it currently being supervised by a dermatologist?
   If yes, continue to #3.  If no, do not approve.

3. Has the member tried and failed ALL of the following:
   - High-potency topical corticosteroids (augmented betamethasone 0.05% cream, desoximetasone 0.025% cream, or clobetasol), and
   - UVB Phototherapy
      If yes, continue to #4.  If no, do not approve.

4. Approve for 6 months.

**Renewal Criteria:**
1. Has the member experienced a 50% reduction in eczema, BSA <10%, or an improvement in functional impairment?
   If yes, approve x 12 months  If no, do not approve
Generic Name: Plerixafor  
Brand Name: Mozobil

Created: 10/16/15  
Revised: 11/03/16, 01/12/17

***Nonformulary on outpatient benefit. PA required for medical benefit. ***

Criteria:

1. Is the request for pre-transplant hematopoietic stem cell mobilization in non-Hodgkin lymphoma and multiple myeloma?  
   If yes, continue to #2.  
   If no, do not approve.

2. Has the member had an unsuccessful mobilization with G-CSF (filgrastim) with or without cyclophosphamide?  
   If yes, continue to #5.  
   If no, continue to #3.

3. Is the request for just-in-time or rescue treatment, requested before the mobilization to be used in the mobilization protocol if necessary?  
   If yes, continue to #4.  
   If no, do not approve.

4. Has the provider documented a treatment protocol that specifies that Mozobil will only be used in case of mobilization failure in order to salvage the attempt in one of these clinical scenarios?  
   a. Peripheral blood CD34+ counts plateaued at < 10 × 10^9/L or declined without reaching a maximum of 10 × 10^9/L after recovery of white blood cell counts following chemotherapy  
   b. The number of CD34+ cells collected was < 0.3 × 10^6 per kilogram of body weight per day for 2 consecutive days  
   c. A progressive decline in daily collection yield.  
      If yes, continue to #5  
      If no, do not approve.

5. Will Mozobil be used in conjunction with filgrastim for four days prior to the first evening dose and each day prior to apheresis while using Mozobil?  
   If yes, approve for up to 4 doses  
   If no, do not approve over 4 days.
Generic Name: Polidocanol
Brand Name: Varithena
Created: 09/22/14

**Nonformulary on outpatient benefit. PA required for medical benefit.***

1. Is the request for the treatment of incompetent great saphenous veins, accessory saphenous veins and visible varicosities of the great saphenous vein system above and below the knee; improves symptoms of superficial venous incompetence and the appearance of visible varicosities.
   - If yes, continue to #2.
   - If no, do not approve.

2. Is the condition causing or contributing to cellulitis or abscesses.
   - If yes, continue to #5.
   - If no, continue to #3.

3. Is the member using for cosmetic purposes only?
   - If yes, deny for benefit exclusion.
   - If no, continue to #4

4. Does the current prioritized list indicate this is a covered condition?
   - If yes, continue to #5.
   - If no, deny for below the line.

5. Approve x 12 months.
Generic Name  Posaconazole tablet
Posaconazole oral suspension

Brand Name  Noxafil Tablet
Noxafil Oral Suspension

Reviewed: 7/12/12, 9/12/13
Revised: 09/08/16, 11/09/17

1. Is treatment being initiated by an Infectious Disease specialist?
   If yes, continue to #2. If no, do not approve.

2. Does the member have a diagnosis or suspicion of a zygomycete infection (e.g. Rhizopus, Mucor, Absidia)?
   If yes, continue to #8. If no, continue to #3.

3. Is the request for the treatment of oropharyngeal candidiasis in members with HIV/AIDS?
   If yes, continue to #10. If no, continue to #4.

4. Is the request for primary prophylaxis of Aspergillus in patients with prolonged neutropenia due to intensive chemotherapy for acute myelogenous leukemia or advanced myelodysplastic syndrome?
   If yes, continue to #5. If no, continue to #6.

5. Has the member failed an adequate trial of voriconazole?
   If yes, approve for 6 months If no, do not approve.
   at a time until myeloid reconstitution has occurred.

6. Is the request for primary prophylaxis of Aspergillus in an allogenic stem cell transplant recipient?
   If yes, continue to #7. If no, do not approve.

7. Has the member failed an adequate trial of voriconazole?
   If yes, approve for 3 months. If no, do not approve.

8. Has the member failed an adequate trial of amphotericin B and/or itraconazole therapy?
   If yes, approve posaconazole If no, continue to #9.

9. Is the member stepping down from amphotericin B treatment?
   If yes, approve posaconazole If no, do not approve.
10. Has the member previously failed treatment with fluconazole, itraconazole oral solution, and voriconazole despite at least 200mg/d of fluconazole or 200mg/day itraconazole or 400mg/day voriconazole, intolerable side effects, or drug interactions?
   If yes, approve posaconazole   If no, do not approve.
Generic Name  Pregabalin
Brand Name  Lyrica (capsule and solution)

Revised: 12/20/07, 9/19/11, 9/26/12, 11/8/12, 9/12/13, 9/2/16

1. Does the member have a diagnosis of partial seizure disorder?
   If yes, approve for life. If no, continue to #2.

2. Is the diagnosis Fibromyalgia?
   If yes, do not approve. If no, continue to #3.

3. Is the diagnosis Diabetic Peripheral Neuropathy (DPN), Postherpetic Neuralgia, or neuropathic pain associated with spinal cord injury?
   If yes, continue to #4. If no, deny for investigational.

4. Is the request for DPN or Spinal cord injury?
   If yes, continue to #5 If no, continue to #6

5. Has the member tried and failed ALL of the following (at maximum tolerated doses):
   - TCAs - amitriptyline (25-100 mg/d), nortriptyline (25-150 mg/d), imipramine (25-200 mg/d) or desipramine 12.5-200 mg/d)
   - SNRIs – venlafaxine (150-225 mg/d) or duloxetine (60 mg/d)
   - Gabapentin – (1,800-3,600 mg/d)
   If yes, approve for 4 months If no, do not approve.

6. Is the request for the treatment of postherpetic neuralgia?
   If yes, continue to #7. If no, do not approve.

7. Has the patient failed ALL of the following (at maximum tolerated doses)?
   a. TCAs - amitriptyline (25-150 mg/d), nortriptyline (25-150 mg/d), imipramine (25-200 mg/d) or desipramine 12.5-200 mg/d)
   b. Gabapentin – (1800-3600 mg/d)
   c. Capsaicin cream – (applied 3-4 times daily)
   If yes, approve for 4 months If no, do not approve

**Lyrica Soln:**
1. Does the member meet the criteria listed above?
   If yes, continue to #2. If no, do not approve.
2. Is the member unable to swallow capsules?
   If yes, approve as above.  If no, do not approve.

**Lyrica Renewal Criteria:**

1. For treatment of DPN, postherpetic neuralgia, or spinal cord injury, did the prescriber submit documentation of improvement in pain or functioning since starting Lyrica?
   If yes, approve for lifetime  If no, do not approve.
Generic Name Rabeprazole
Brand Name Aciphex

Created: 10/1/14
Revised: 12/26/14, 12/1/15

1. Is the member's age less than 19?
   If yes, continue to #5
   If no, continue to #2.

2. Is the diagnosis GERD?
   If yes, continue to #3
   If no, continue to #4

3. Does the request meet at least ONE of the following?:
   a. Continuation of PPI therapy beyond 8 weeks (including other PPIs)?
   OR
   b. The request for more than 8 weeks or unspecified duration?

   If yes, deny. Chronic GERD therapy
   If no, continue to #5.
   not covered per Guideline Note #144.

4. Does the member have a documented and medically appropriate diagnosis which is currently funded by the Oregon Health Plan (OHP) Prioritized List?
   If yes, continue to #5.
   If no, deny.

5. Has the member tried and failed prescription omeprazole AND pantoprazole at twice daily dosing?
   If yes, continue to #6.
   If no, do not approve.

6. Approve with the following durations:
   b. Adults with a covered diagnosis (not GERD): max 12 months
   c. Adults with GERD: 8 weeks.
Generic Name Ranibizumab

Brand Name Lucentis

Created: 9/19/11
Revised: 3/13/12, 10/2/12, 05/14/15, 3/9/17, 6/7/17, 7/13/17, 3/14/19
Reviewed: 9/12/13

***Nonformulary for outpatient benefit. PA required on medical benefit.***

**Initial Criteria:**

1. Does the member have a diagnosis of:
   a. Exudative (Wet) Age-Related Macular Degeneration (AMD) or
   b. Macular Edema Following Retinal Vein Occlusion (RVO)?
   c. Diabetic Macular Edema with or without diabetic retinopathy?
   d. Myopic choroidal neovascularization (mCNV).
   e. Diabetic Retinopathy (DR)

   If yes, continue to #2

   If no, do not approve.

2. Has the member tried and failed Avastin?
   If yes, approve for 12 months.
   If no, do not approve.

**Renewal Criteria:**

1. Has the member demonstrated disease stabilization or clinical response?
   If yes, approve for 12 months.
   If no, do not approve.
1. Does the member have a diagnosis of hepatic encephalopathy associated with chronic liver disease?
   If yes, continue to #2. If no, do not approve.

2. Has the member failed a trial of lactulose?
   If yes, continue to #3. If no, do not approve.

3. Approve x life.
Generic Name: Riociguat
Brand Name: Adempas
Revised: 1-14-14, 11/8/18

1. Is Adempas being prescribed by a pulmonologist or cardiologist?
   If yes, continue to #2. If no, do not approve.

2. Does the member have WHO group 1 (pulmonary arterial hypertension) or WHO group 4 (chronic thromboembolic pulmonary hypertension) pulmonary hypertension?
   WHO group 1, continue to #3. If no, do not approve.
   WHO group 4, continue to #4.

3. Has the member failed or is a poor candidate for a PDE-5 inhibitor (e.g. sildenafil or tadalafil)?
   If yes, approve for lifetime. If no, do not approve.

4. Approve for lifetime.
Generic Name | Rituximab
---|---
Rituximab and Hyaluronidase Human

Brand Name | Rituxan
---|---
Rituxan Hycela
Truxima (biosimilar)
Ruxience (biosimilar)

Revised: 5/13/10, 7/14/11, 9/20/11, 9/12/13, 05/12/16, 11/15/16, 09/14/17, 03/14/19, 9/12/19, 11/14/19

**Nonformulary on outpatient benefit. PA required for medical benefit.**

All Diagnoses:
Initial Criteria:
1. Is the request for maintenance of remission in a patient who already achieved remission with Rituxan or has already initiated therapy for a supported indication?
   - If yes, continue to renewal criteria.
   - If no, continue to #2.

2. Has the treatment been initiated by or is an appropriate specialist currently supervising it?
   - ANCA vasculitis: Rheumatologist or Nephrologist
   - Cancer: Hematologist or Oncologist
   - Immune Thrombocytopenic Purpura (ITP): Hematologist
   - Lupus Nephritis: Rheumatologist or Nephrologist
   - Multiple Sclerosis: Neurologist
   - Neuromyelitis Optica (NMO): Neurologist
   - Pemphigoid Diseases/Pemphigus Vulgaris: Dermatologist
   - Primary Autoimmune Hemolytic Anemia (AIHA): Hematologist
   - Rheumatoid Arthritis: Rheumatologist
   - If yes, continue to #3.
   - If no, do not approve.

3. Has a baseline screening for hepatitis B (HBsAg and anti-HBc) been completed?
   - If yes, continue to #4.
   - If no, do not approve.

4. Does the member have a severe, active current infection?
   - If yes, do not approve.
   - If no, continue to #5.

5. Is Rituxan being prescribed with biologic DMARD or targeted synthetic DMARD?
   - If yes, do not approve.
   - If no, proceed to indication.

ANCA-Associated Vasculitis
Initial Criteria:
1. Does the member have a diagnosis of an ANCA-associated vasculitide confirmed with biopsy and/or ANCA testing?
If yes, continue to #2. If no, do not approve.

2. Is the condition life or organ threatening?
   If yes, continue to #4. If no, continue to #3.

3. Has the member failed a combination of corticosteroids and an immunosuppressant such as azathioprine, methotrexate, or mycophenolate?
   If yes, continue to #4. If no, do not approve.

4. Has the member failed or have a contraindication to the use of cyclophosphamide with corticosteroids?
   If yes, continue to #5. If no, do not approve.

5. Will Rituxan be used with corticosteroids?
   If yes, approve for 6 months. If no, do not approve.

**ANCA-Associated Vasculitis**

**Renewal Criteria:**

1. Has there been a resolution or improvement in disease-related signs and symptoms or has member achieved remission?
   If yes, approve for 12 months If no, do not approve.

**Cancer**

**Initial Criteria:**

1. Is the treatment supported for the diagnosis in the NCCN guidelines for the drug and dosage form?
   If yes, continue to #3. If no, continue to #2.

2. Is the treatment being used according to the FDA indication for the drug and dosage form?
   If yes, continue to #3. If no, do not approve.

3. Does the request meet criteria for treatment coverage specified in Guideline Note 12 of the Prioritized List of Health Services, considering treatment of cancer with little or no benefit?
   If yes, approve for 12 months If no, do not approve.

**Cancer:**

**Renewal Criteria:**

1. Is there evidence of tumor response and resolution or improvement of disease-related signs and symptoms?
   If yes, approve for 12 months If no, do not approve.

**Immune Thrombocytopenic Purpura (ITP)**

**Initial Criteria:**

1. Does the member have persistent or chronic ITP for longer than 6 months?
   If yes, continue to #3. If no, continue to #2.
2. Does the member require acute treatment under one of the following conditions?
   a. Platelet count less than 20 x 10^9/L, considered to be at risk for bleeding
   b. Platelet count less than 30 x 10^9/L with acute bleeding
   c. Member is preparing to undergo surgery, such as a splenectomy, with platelet count less than 75 x 10^9/L.
      If yes, continue to #4.   If no, do not approve.

3. Are the platelet counts persistently at or below 20 x 10^9/L?
   If yes, continue to #4.   If no, do not approve.

4. Has the member failed corticosteroids?
   If yes, continue to #6.   If no, continue to #5.

5. Are corticosteroids contraindicated, or does the provider make a statement that a rapid increase in platelets is required?
   If yes, continue to #6.   If no, do not approve.

6. Approve for 6 months

**Immune Thrombocytopenic Purpura (ITP)**
**Renewal Criteria:**
3. Has the member experienced a reduction of bleeding episodes and/or increased quality of life?
   If yes, continue to #2.   If no, do not approve.

4. Is there documentation of medical necessity to continue in order to prevent bleeding episodes?
   a. If yes, approve 12 months.   If no, do not approve.

**Multiple Sclerosis**
**Initial Criteria:**
1. Does the member have a diagnosis of relapsing-remitting multiple sclerosis?
   If yes, continue to #3.   If no, continue to #2.

2. Does the member have a diagnosis of primary progressive multiple sclerosis?
   If yes, continue to #3.   If no, do not approve.

3. Approve for 12 months.

**Multiple Sclerosis:**
**Renewal Criteria:**
1. Is Rituxan being used as the only disease modifying agent for multiple sclerosis?
   If yes, approve for 12 months.   If no, do not approve.
Neuromyelitis Optica (NMO)
Initial Criteria:
1. Does the patient have a diagnosis of neuromyelitis optica (NMO) or neuromyelitis optica spectrum disorder (NMOSD)?
   If yes, continue to #2.   If no, do not approve.

2. Has the member tried and failed mycophenolate mofetil and azathioprine (with or without concurrent prednisone)?
   If yes, continue to #3.   If no, do not approve.

3. Approve for 12 months.

Neuromyelitis Optica (NMO)
Renewal Criteria:
1. Has the provider documented a reduction in relapse rate since initiation of rituximab therapy?
   If yes, approve for 12 months   If no, do not approve.

Pemphigoid Diseases:
Initial Criteria:
1. Is Rituxan being prescribed by or supervised by a dermatologist?
   If yes, continue to #2.   If no, do not approve.

2. Does the member have pemphigus disease confirmed clinically, histologically and immunopathologically?
   a. Bullous pemphigoid
   b. Epidermolysis bullosa acquisita
   c. Mucous membrane pemphigoid, including ocular cicatricial pemphigoid
   If yes, continue to #3.   If no, do not approve.

3. Has the member tried and failed or have a contraindication to systemic corticosteroids?
   If yes, continue to #4.   If no, do not approve.

4. Has the member failed another systemic agent, such as colchicine, dapsone, azathioprine, cyclophosphamide, cyclosporine, methotrexate, or mycophenolate?
   If yes, continue to #5.   If no, do not approve.

5. Approve for 6 months.

Pemphigoid Diseases:
Renewal Criteria:
1. Has the member had a clinical response, such as complete epithelialization and absence of new and/or established lesions?
   If yes, approve for 12 months   If no, do not approve.
**Pemphigus Vulgaris**

**Initial Criteria:**

1. Is Rituxan being prescribed by or supervised by a dermatologist?  
   If yes, continue to #2.  
   If no, do not approve.

2. Does the member have moderate to severe pemphigus vulgaris confirmed by biopsy and pathology?  
   If yes, continue to #3.  
   If no, do not approve.

3. Has the member tried and failed systemic corticosteroids?  
   If yes, continue to #4.  
   If no, do not approve.

4. Has the member failed one of the following immunosuppressants?  
   a. Azathioprine  
   b. Cyclophosphamide  
   c. Cyclosporine  
   d. Methotrexate  
   e. Mycophenolate  
   If yes, continue to #5.  
   If no, do not approve.

5. Is Rituxan being prescribed in combination with a systemic corticosteroid?  
   If yes, continue to #7.  
   If no, do not approve.

6. Approve for 6 months.

**Pemphigus Vulgaris**

**Renewal Criteria:**

1. Has the member had a clinical response, such as complete epithelialization and absence of new and/or established lesions?  
   If yes, continue to #5.  
   If no, continue to #2.

2. Has the member had a relapse of pemphigus?  
   If yes, continue to #3.  
   If no, do not approve.

3. Does the treatment plan include resuming or increasing systemic corticosteroids?  
   If yes, continue to #4.  
   If no, do not approve.

4. Is the requested dose more than 16 weeks from the previous infusion?  
   If yes, continue to #6.  
   If no, do not approve.

5. Has the member successfully tapered off corticosteroids or is there a statement addressing why corticosteroids are still required?
6. Approve 12 months.

**Primary Autoimmune Hemolytic Anemia (AIHA):**

**Initial Criteria:**

1. Does the member have cold AIHA?
   - If yes, continue to #2.  
   - If no, continue to #3.

2. Does the member have symptomatic anemia, transfusion dependence, and/or disabling circulatory symptoms?
   - If yes, continue to #5.  
   - If no, do not approve.

3. Does the member have warm AIHA?
   - If yes, continue to #4.  
   - If no, do not approve.

4. Has the member failed corticosteroids for at least 3 weeks?
   - If yes, continue to #5.  
   - If no, do not approve.

5. Approve for 6 months.

**Primary Autoimmune Hemolytic Anemia (AIHA):**

**Renewal Criteria:**

1. Has there been a resolution or improvement in anemia and symptoms or has member achieved remission with the previous treatment?
   - If yes, approve for 12 months  
   - If no, do not approve.

**Rheumatoid Arthritis**

**Initial Criteria:**

1. Does the member have a baseline of moderate to high disease activity of rheumatoid arthritis measured as such by an accepted assessment instrument (PAS, PASII, RAPID3, CDAI, DAS28, SDAI)?
   - If yes, continue to #2.  
   - If no, do not approve.

2. Is the member transitioning to the requested treatment from a different biologic product?
   - If yes, continue to #6.  
   - If no, continue to #3.

3. Has the member tried and failed or have contraindications to methotrexate dosed at least 20mg per week for at least 8 weeks?
   - If yes, continue to #4.  
   - If no, do not approve.

4. Has the member tried and failed or have contraindications to the following: leflunomide, hydroxychloroquine, or sulfasalazine?
If yes, continue to #5. If no, do not approve.

5. Has the member tried and failed or have contraindications to the following: infliximab, Humira, or Enbrel?  
   If yes, continue to #6. If no, do not approve.

6. Is the requested product being prescribed along with at least one of the following DMARDs: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine, unless contraindicated?  
   If yes, continue to #7. If no, do not approve.

7. Approve Rituxan IV for 6 months.

**Rheumatoid Arthritis**

**Renewal Criteria:**

1. Is there medical record documentation of a 20% or greater improvement in tender joint count and swollen joint count?  
   If yes, approve for 12 months. If no, do not approve.
Generic Name  Romosozumab-aqqg
Brand Name  Evenity
Created: 7/11/19

***Nonformulary on pharmacy benefit. PA required on medical benefit***

1. Does the member have any of the following contraindications:
   a. Uncorrected hypocalemia or
   b. A stroke or MI within the last 12 months

   If yes, deny for not medically appropriate          If no, continue to #2.

2. Is the member a post-menopausal female with high risk of fracture defined by ONE of the following:
   a. history of osteoporotic fracture
   b. multiple risk factors for fracture (such as bone mineral density less than -2.5, previous minimal trauma fracture as an adult, low weight or body mass index, history of hip fracture in a first degree relative, tall stature or use of tobacco)
   c. failure of other available osteoporosis therapies

   If yes, continue to #3.          If no, deny.

3. Has the member had a documented adverse even with a bisphosphonate despite proper administration or contraindication

   If yes, continue to #4.          If no, deny.

4. Has the member tried and failed or have a contraindication to Prolia?

   If yes, continue to #5.          If no, deny and recommend Prolia (with PA)

5. Approve for 12 months (maximum approved duration by the FDA).
Generic Name  Ruxolitinib
Brand Name    Jakafi
Created: 7/11/19

**Cancer**

**Initial Criteria:**

5. Is the treatment supported for the diagnosis in the NCCN guidelines for the drug and dosage form?
    - If yes, continue to #3.
    - If no, continue to #2.

6. Is the treatment being used according to the FDA indication for the drug and dosage form?
    - If yes, continue to #3.
    - If no, do not approve.

7. Does the request meet criteria for treatment coverage specified in Guideline Note 12 of the Prioritized List of Health Services, considering treatment of cancer with little or no benefit?
    - If yes, approve for 12 months
    - If no, do not approve.

**Cancer**

**Renewal Criteria:**

2. Is there evidence of tumor response and resolution or improvement of disease-related signs and symptoms?
    - If yes, approve for 12 months
    - If no, do not approve.

**Acute Graft versus Host Disease**

**Initial Criteria:**

1. Has the treatment been initiated by or is an appropriate specialist in the field of transplant currently supervising it?
    - If yes, continue to #2.
    - If no, do not approve.

2. Does the member have at least grade 2 disease?
    - If yes, continue to #3
    - If no, do not approve.

3. Has the member tried and failed oral steroids?
    - If yes, approve for 1 month
    - If no, do not approve.
Generic Name: Saproterin

Brand Name: Kuvan

Created: 3/13/12
Revised: 9/12/13

**Initial Criteria:**

7. Is prescribed by a metabolic specialist?
   - If yes, continue to #2. If no, do not approve.

8. Does member have diagnosis of tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU)?
   - If yes, continue to #3. If no, do not approve.

9. Is member currently on a phenylalanine-restricted diet and unable to achieve target blood phenylalanine (Phe) level?
   - If yes, continue to #4. If no, do not approve and recommend a phenylalanine-restricted diet.

10. Is member’s baseline blood Phe level provided in the request?
    - If yes, continue to #5. If no, please request.

11. Approve x 2 months.

**Renewal Criteria:**

1. Does member have documented one of the following treatment response:
   - a. ≥ 30% decrease in blood Phe level compared with baseline
   - b. At least 20% decrease in blood Phe level compared with baseline with one of the following:
     - i. Increased dietary Phe tolerance
     - ii. Improved neurocognitive and/or psychosocial functioning
     - iii. Improved blood Phe stability
   - If yes, approve x life. If no, do not approve.
Generic Name
Sildenafil
Tadalafil

Brand Name
Revatio,
Adcirca,

Revised: 09/25/09, 9/11/14, 11/8/18
Reviewed: 9/13/12, 9/12/13

**Initial Criteria:**
1. Is the drug being requested by a pulmonologist or cardiologist?
   If yes, continue to #2.
   If no, do not approve.

2. Does the member have a diagnosis of pulmonary arterial hypertension WHO Group I
diagnosed by right heart catheterization?
   If yes, continue to #3.
   If no, do not approve. WHO Groups 2-5 not indicated.

3. Is the request for generic sildenafil?
   If yes, approve for lifetime.
   If no, continue to #4.

4. Has the member failed generic sildenafil or the prescriber provided rationale why
sildenafil cannot be used?
   If yes, approve generic tadalafil for lifetime.
   If no, do not approve.
Generic Name: Siponimod
Brand Name: Mayzent

Created: 7/11/19

**Initial Criteria:**
1. Is the request from a neurologist?
   - If yes, continue to #2.
   - If no, deny.

2. Is the member 18 or older?
   - If yes, continue to #3.
   - If no, deny.

3. Does the member have RRMS?
   - If yes, continue to #4.
   - If no, continue to #5.

4. Has the member failed all of the following: Glatiramer, Rituxan, Tecfidera, and Extavia?
   - If yes, continue to #6.
   - If no, deny

5. Does the member have SPMS?
   - If yes, continue to #6.
   - If no, deny.

6. Has the member had at least one relapse within the past 2 years?
   - If yes, continue to #7.
   - If no, deny.

7. Has the provider submitted CYP2C9 testing?
   - If yes, continue to #8.
   - If no, deny.

8. Is the dose requested in line with labeling for the member's specific CYP2C9 results?
   - If yes, approve for lifetime
   - If no, deny.
Generic Name: Sipuleucel-T

Brand Name: Provenge

Created: 7/14/11
Revised: 7/13/12, 9/12/13, 9/11/14

***Nonformulary on outpatient benefit. PA required for medical benefit. ***

1. Does the member have a diagnosis of asymptomatic or minimally symptomatic hormone refractory metastatic prostate cancer?
   If yes, continue to #2. If no, do not approve.

2. Does the member meet any of exclusion criteria listed below?
   If yes, do not approve. If no, continue to #3.

3. Does the member have a testosterone level of < 50 ug or below lowest level of normal?
   If yes, continue to #4. If no, do not approve.

4. Does the member have evidence of tumor progression while on hormonal therapy?
   If yes, continue to #5. If no, do not approve.

5. Is the request for treatment with Provenge alone (no other simultaneous chemotherapy or other immunosuppressive therapy)?
   If yes, continue to #6. If no, do not approve.

6. Approve 3 infusions x lifetime.
Generic Name        Alogliptin
Brand Name           Nesina

Revised: 11/19/09, 9/19/11, 9/12/13, 9/14/17, 7/12/18, 2/1/2020
Reviewed: 9/13/12

1. Does the member have a diagnosis of Type 2 Diabetes?
   If yes, continue to #2.                               If no, do not approve. Use in T1DM is investigational.

2. Has the member failed, been intolerant to, or have a contraindication to metformin?
   If yes, continue to #3                               If no, do not approve and recommend metformin.

3. Has the member tried and failed one of, or have a contraindication to both of the following: sulfonylureas, pioglitazone?
   If yes, continue to #4.                               If no, do not approve.

4. Evaluate based on HbA1c
   a. Is HbA1c ≤ 7.5%-----------------------------> If yes, do not approve.
   b. Is HbA1c >7.5% and <9.0%----------> If yes, approve x lifetime.
   c. Is HbA1c ≥9.0%-------------------------> If yes, continue to #5

5. Has the provider submitted an acceptable rationale for why insulin cannot be used?
   If yes, approve x lifetime                        If no, deny and offer insulin.
Generic Name Nicotine Oral Inhaler
           Nicotine Nasal Spray

Brand Name Nicotrol Inhaler
           Nicotrol NS

Created: 5/17/16

1. Has the member failed or have a significant contraindication to all of the following formulary alternatives: bupropion (Zyban), nicotine gum, patch and lozenge? If yes, continue to #2 If no, do not approve and recommend all untried agents.

2. Has the member failed combination therapy with nicotine replacement with bupropion? If yes, continue to #3 If no, do not approve and recommend combination therapy

3. Is the member enrolled in a counseling program? If yes, continue to #4. If no, do not approve.

4. Approve for 12 months (quantity limits may apply).
Generic Name: Pegvisomant

Brand Name: Somavert

Created: 03-05-14
Revised: 03/09/17

**Initial Criteria:**
1. Does the member have a diagnosis of acromegaly confirmed by elevated IGF-1 levels?
   - If yes, continue to #2.
   - If no, do not approve.

2. Is the acromegaly moderate to severe or symptomatic?
   - If yes, continue to #3.
   - If no, do not approve.

3. Does the member have persistent disease after surgery or considered not to be a candidate for surgery?
   - If yes, continue to #4
   - If no, do not approve.

4. Is the request for combination therapy with a somatostatin receptor ligand, such as octreotide, lanreotide, or pasireotide?
   - If yes, continue to #6
   - If no, continue to #5

5. Has the member tried and failed or have a contraindication to a somatostatin receptor ligand, such as octreotide, lanreotide, or pasireotide?
   - If yes, approve for 6 months.
   - If no, do not approve.

6. Has the member failed or have contraindications to combination therapy with a somatostatin receptor ligand and a dopamine agonist, such as cabergoline or bromocriptine?
   - If yes, approve for 6 months.
   - If no, do not approve.

**Renewal Criteria:**
1. Has the member had a reduction in or reached a target goal of an age-normalized serum IGF-1 value?
   - If yes, approve for 6 months.
   - If no, do not approve.
Generic Name  Sacubitril/valsartan
Brand Name  Entresto

Created: 11/23/15  Revised: 2/1/2020

1. Is the request from a cardiologist?
   If yes, continue to #2.  
   If no, deny.

2. Is the request for symptomatic congestive heart failure, in a pediatric patient with systemic left ventricular dysfunction?
   If yes, approve x lifetime.  
   If no, continue to #3.

3. Is the request for an adult with NYHA Class II to IV heart failure with reduced ejection fraction (EF≤40%)?
   If yes, continue to #4.  
   If no, deny.

4. Is the member on maximum tolerated doses of ALL of the following classes?
   a. Beta-Blocker [metoprolol succinate (200mg/day), carvedilol (25mg twice daily)] bisoprolol NF (10mg/day)
   b. ACE-i/ARB [captopril (50mg three times daily), enalapril (10mg twice daily), lisinopril (20mg/day), ramipril (5mg twice daily), losartan (150mg/day)], perindopril (8mg/day), trandopril (4mg/day), valsartan (160mg twice daily), candesartan (32mg/day)
   c. Mineralcorticoid receptor antagonist [spironolactone (25 mg/day)] eplerenone (50 mg/day)
   If yes, continue to #5.  
   If no, deny.

5. Is the plan clear to discontinue existing ACEi or ARB therapy before beginning Entresto (contraindicated to be on both)?
   If yes, approve x life.  
   If no, contact provider to verify plan intent.
Generic Name: Sebelipase alfa
Brand Name: Kanuma
Created: 3/21/16

***Non-formulary for pharmacy benefit***

**Initial:**
1. Is the diagnosis lysosomal acid lipase (LAL) confirmed by genetic testing?
   - If yes, continue to #2.
   - If no, deny.

2. Is the request from an appropriate specialist such as hepatologist?
   - If yes, continue to #3.
   - If no, deny.

3. Is there documented liver involvement/disease such as elevated LFTs (ALT/AST 3x above normal limit) and poorly controlled lipids?
   - If yes, approve x 20 weeks.
   - If no, deny.

**Renewal:**
1. Has there been a documented response to therapy such as normalization or improvement in liver enzyme function tests (LFTs)?
   - If yes, approve x 12 months.
   - If no, deny.
Generic Name  Sevelamer carbonate tablets

Brand Name  Renvela Tablets

Created 5/9/2019

1. Has the patient tried and failed or are they unable to take calcium acetate? Note: coded via step therapy logic
   If yes, approve x lifetime  If no, deny

Please note, criteria for sevelamer powder, lanthanum chews, and generic Renagel (sevelamer hcl) are listed elsewhere.
Generic Name  Sevelamer powder
Lanthanum Chews
Sevelamer HCl

Brand Name  Renvela Packets
Fosrenol
Renagel

Created 5/9/2019

1. Does the patient have hyperphosphatemia associated with chronic kidney disease?
   If yes, continue to #2  If no, deny

2. Has the patient tried and failed or are they unable to take calcium acetate?
   If yes, continue to #2  If no, deny

3. Has the prescriber provided rationale for why sevelamer carbonate tablets are not appropriate?
   If yes, approve x lifetime  If no, deny
Generic Name  Sofosbuvir/Velpatasvir,  Ribavirin  Sofosbuvir/Velpatasvir/Voxilaprevir  Glecaprevir/pibrentasvir

Brand Name  Epclusa, Mavyret, Vosevi, Ribavirin

Created: 07/11/14
Updated: 11/5/14, 5/13/15, 11/23/15, 3/9/16, 7/18/16, 9/8/16, 1/1/17, 6/1/17, 11/9/17, 1/1/18, 1/1/19, 1/10/19, 3/1/19, 1/1/20

New Starts Only:
1. What is the diagnosis being treated?  
   Record ICD10 and Continue to #2

2. Is the request for treatment of chronic Hepatitis C Infection (B18.2)?  
   If yes, continue to #3  
   If no, deny

3. Is expected survival from non-HCV-associated morbidities more than 1 year?  
   If yes, continue to #4.  
   If no, do not approve.

4. Has ALL of the following pre-treatment testing been documented?  
   a. Genotype testing in past 3 years is required if the patient has cirrhosis, any  
      prior treatment experience and if prescribed a regimen which is not pan-  
      genotypic.
   b. Current HBV status of patient (Treatment can re-activate HepB)
   c. Pregnancy test (past 30 days) for a woman of child-bearing age
   d. History of previous HCV treatment and outcome
   e. Presence or absence of cirrhosis as clinically determined (e.g. clinical,  
      laboratory, radiologic evidence, etc)
      
   If yes, continue to #5.  
   If no, do not approve.

5. Which regimen is requested?  
   Document and go to #6

6. Does the patient have complications of cirrhosis (ascites, portal hypertension,  
   hepatic encephalopathy, hepatocellular carcinoma, esophageal varices)?  
   If yes, continue to #7  
   If no, continue to #8

7. Is the regimen prescribed by, OR is the patient in the process of establishing care  
   with or in consultation with a hepatologist, gastroenterologist, or infectious disease  
   specialist?
8. Is there attestation that the patient and provider will comply with all case management interventions to promote the best possible outcome for the patient and adhere to monitoring requirements required by the Oregon Health Authority, including measuring and reporting of a post-treatment viral load?

Case management includes assessment of treatment barriers and offer of patient support to mitigate potential barriers to regimen adherence as well as facilitation of SVR12

   If yes, continue to #9. If no, deny

9. Is the prescribed drug Zepatier for genotype 1a OR Daklinza/Sovaldi for genotype 3 infection?

   If yes, continue to #10 If no, continue to #11

10. Has the patient had a baseline NS5a resistance test that documents a resistant variant to one of the agents in #16? Note: Baseline NS5A resistance testing is required.

   If yes, deny. If no, document test result and continue to #11

11. Does the prescribed regimen include a NS3/4a protease inhibitor (elbasvir, glecaprevir, simeprevir, paritaprevir, voxilaprevir)?

   If yes, continue to #12 If no, continue to #13.

12. Does the patient have moderate-severe hepatic impairment (Child-Pugh B or Child- Pugh C)?

   If yes, deny. If no, continue to #13.

13. Is the prescribed regimen for the retreatment after failure of a DAA due to noncompliance or lost to follow-up?

   If yes, review with medical director. If no, continue to #14

14. Is the prescribed drug regimen a recommended regimen based on the patient’s genotype, treatment status (retreatment or treatment naïve) and cirrhosis status (see Table 1)?

   If yes, approve. If no, deny.

### Approved Regimens

<table>
<thead>
<tr>
<th>Treatment History</th>
<th>Cirrhosis Status</th>
<th>Recommended Regimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotype 1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| DAA-Treatment naive                      | Non-cirrhotic or compensated cirrhosis | Epclusa x 12 weeks  
|                                          |                                      | Mavyret x 8 weeks |
|                                          | Decompensated Cirrhosis              | Epclusa + RBV x 12 weeks |
| Treatment Experienced (Prior PEG/RBV)   | Non-cirrhotic                        | Epclusa x 12 weeks  
|                                          |                                      | Mavyret x 8 weeks |
|                                          | Compensated cirrhosis                | Epclusa x 12 weeks  
|                                          |                                      | Mavyret x 12 weeks |
| Treatment Experienced (prior sofosbuvir)| Non-cirrhotic or compensated cirrhosis | Epclusa x 12 weeks  
|                                          |                                      | Mavyret x 12 weeks |
| Treatment Experienced (Prior NS3A/4A inhibitor) | Non-cirrhotic or compensated cirrhosis | Epclusa x 12 weeks  
|                                          |                                      | Mavyret x 12 week |
| Treatment Experienced (prior NS5A-containing regimen) | Non-cirrhotic or compensated cirrhosis | Mavyret x 16 weeks |
| **Genotype 2**                           |                                        |                     |
| Naive                                    | Non-cirrhotic or compensated cirrhosis | Epclusa x 12 weeks  
|                                          |                                      | Mavyret x 8 weeks |
|                                          | Decompensated                        | Epclusa + RBV x 12 weeks |
| Treatment Experienced (Prior PEG/RBV)   | Non-cirrhotic                        | Epclusa x 12 weeks  
|                                          |                                      | Mavyret x 8 weeks |
|                                          | Compensated cirrhosis                | Epclusa x 12 weeks  
|                                          |                                      | Mavyret x 12 weeks |
| Treatment Experienced (SOF +RBV)        | Non-cirrhotic or compensated cirrhosis | Epclusa x 12 weeks  
|                                          |                                      | Mavyret x 12 weeks |
| Treatment Experienced (prior NS5A-containing regimen) | Non-cirrhotic or compensated cirrhosis | Vosevi x 12 weeks |
| **Genotype 3**                           |                                        |                     |
| Naive                                    | Non-cirrhotic or compensated cirrhosis | Epclusa x 12 weeks  
|                                          |                                      | Mavyret x 8 weeks |
|                                          | Decompensated                        | Epclusa + RBV x 12 weeks |
| Treatment Experienced (Prior PEG/RBV) | Non-cirrhotic or compensated cirrhosis | Epclusa x 12 weeks  
Mavyret x 16 weeks |
| Treatment Experienced (SOF +RBV) | Non-cirrhotic or compensated cirrhosis | Mavyret x 16 weeks |
| Treatment Experienced (prior NS5A-containing regimen) | Non-cirrhotic or compensated cirrhosis | Vosevi x 12 weeks |
| **Genotype 4** | | |
| Treatment Naïve | Non-cirrhotic or compensated cirrhosis | Epclusa x 12 weeks  
Mavyret x 8 weeks |
| Treatment Experienced (prior PEG/RBV only) | Non-cirrhotic | Epclusa x 12 weeks  
Mavyret x 8 weeks |
| | Compensated cirrhosis | Epclusa x 12 weeks  
Mavyret x 12 weeks |
| Treatment Experienced (prior NS5A-containing regimen OR sofosbuvir) | Non-cirrhotic or compensated cirrhosis | Vosevi x 12 weeks |
| **Genotypes 5/6** | | |
| Treatment Naïve | Non-cirrhotic or compensated cirrhosis | Epclusa x 12 weeks  
Mavyret x 8 weeks |
| Treatment Experienced (prior PEGIFN/RBV only) | Non-cirrhotic | Epclusa x 12 weeks  
Mavyret x 8 weeks |
| | Compensated Cirrhosis | Epclusa x 12 weeks  
Mavyret x 12 weeks |
| | Decompensated cirrhosis | Epclusa + RBV x 12 weeks |
| Experienced (prior DAA-containing regimen, including NS5A) | Non-cirrhotic or compensated cirrhosis | Vosevi x 12 weeks |

** No baseline NS5A RAVs. For genotype 1a patients with baseline NS5A RAVs, extend duration to 16 weeks.
Evidence is insufficient if the addition of RBV may benefit subjects with GT3 and cirrhosis. If RBV is not used with regimen, then baseline RAV testing should be done prior to treatment to rule out the Y93 polymorphism.
Generic Name: Tenofovir Alafenamide/Emtricitabine
Brand Name: Descovy

Created: 11/14/19

Summary of intent: CareOregon prefers the use of Truvada for PrEP. For active HIV treatment Descovy or Truvada are equally preferred when used as part of a supported regimen.

1. Is Descovy being used as part of a regimen for active HIV treatment?
   If yes, approve x life. If no, continue to #2

2. Is Descovy being used for pre-exposure prophylaxis (PrEP)?
   If yes, continue to #3. If no, deny for investigational use.

3. Does the member have a medical contraindication to using Truvada, such as documented renal insufficiency?
   If yes, approve x life. If no, deny and require Truvada.
Generic Name  Teriflunomide
Brand Name  Aubagio

Created: 3/28/13
Reviewed: 9/12/13, 9/12/15

1. Does the member have a diagnosis of relapsing remitting multiple sclerosis?
   If yes, continue to #2.    If no, do not approve.

2. Is the request for monotherapy and is not intended to be used in combination with other MS agents?
   If yes, approve x life.    If no, do not approve.
Generic Name Abaloparatide
Brand Name Tymlos

1. Does the member have any of the following exclusionary criteria that places them at increased baseline risk for osteosarcoma: Paget’s disease of bone, unexplained elevations of alkaline phosphatase, open epiphyses, or prior external beam or implant radiation therapy involving the skeleton)?
   If yes, do not approve. If no, continue to #2.

2. Is the member a post-menopausal female with ONE of the following:
   - Radiographic evidence of an osteoporotic fracture while compliant on a bisphosphonate for ≥ 12 months
   - High risk of fracture AND a) documented adverse event with a bisphosphonate despite proper administration or b) contraindication to bisphosphonate.
   If yes, continue to #5. If no, continue to #3.

3. Is the member a male or female with steroid-induced osteoporosis and ALL of the following:
   a. Steroid use for > 3 months at a dose of 5mg/d prednisone (or equivalent), and
   b. BMD T-score < -2.5, and
   c. ONE of the following:
      1. Radiographic evidence of an osteoporotic fracture while compliant on a bisphosphonate for ≥ 12 months (check refill history, member should have at least 6 consecutive month fills)
      2. Documented adverse event with a bisphosphonate despite proper administration or contraindication to bisphosphonate.
   If yes, continue to #5. If no, continue to #4.

4. Is the member a male with a diagnosis of primary or hypogonadal osteoporosis and ALL of the following:
   a. History of osteoporotic fracture with radiographic evidence
   b. Multiple fracture risk factors
   c. Compliant on bisphosphonate for ≥ 12 months (check refill history, member should have at least 6 consecutive month fills) or history of a serious adverse event despite proper administration or contraindication to bisphosphonate therapy.
   If yes, continue to #5. If no, do not approve.

5. Has the member tried and failed or have a contraindication to Prolia?
   If yes, continue to #6 If no, do not approve, recommend Prolia (with PA)
6. Approve for 2 years
Generic Name  Testosterone Transdermal
               Testosterone Gel
               Methyltestosterone

Brand Name    Vogelxo
               Androgel
               Android, Methitest, Testred

Revised: 7/28/08, 5/19/11, 9/20/11, 01/08/15, 05/14/15, 8/1/15, 01/14/16, 11/15/16,
           2/1/18, 05/09/19
Reviewed: 9/13/12, 9/12/13, 7/18/16, 7/11/19

***Aveed nonformulary on outpatient benefit. PA required for medical benefit. ***

All diagnoses:
Initial criteria:
1. Is there chart note documentation of trial and failure of or contraindication to injectable
   testosterone?
   If yes, continue to specific diagnosis.   If no, do not approve.

AIDS Wasting Syndrome
Initial criteria:
1. Does the member have a diagnosis of AIDS wasting syndrome, defined by an
   involuntary loss of more than 10 percent of body weight?
   If yes, approve for life.   If no, do not approve.

Breast Cancer
Initial criteria:
1. Is testosterone being used for the palliation of inoperable metastatic (skeletal)
   mammary cancer in a member who is 1 to 5 years postmenopausal?
   If yes, approve for life   If no, do not approve.

Gender Dysphoria:
Initial criteria:
1. Does the member have a diagnosis of gender dysphoria?
   If yes, approve for life.   If no, do not approve.

Hypogonadism:
Initial criteria:
1. Is the member male and 18 years of age or older?
   If yes, continue to #2.   If no, do not approve.
2. Does the member have one of the following hypogonadism diagnoses?
   a. Primary Hypogonadism (congenital or acquired) as defined as testicular failure
      due to such conditions as cryptorchidism, bilateral torsion, orchitis, vanishing
testis syndrome, orchidectomy, Klinefelter’s syndrome, chemotherapy, trauma, or toxic damage from alcohol or heavy metals; OR
b. Hypogonadotropic Hypogonadism (congenital or acquired): as defined by idiopathic gonadotropin or luteinizing hormone releasing hormone (LHRH) deficiency, or pituitary-hypothalamic injury from tumors, trauma or radiation.
   If yes, continue to #3. If no, do not approve.

3. Does the member have any of the following contraindications?
   a. Breast cancer or known or suspected prostate cancer
   b. Elevated hematocrit (>50%)
   c. Untreated severe obstructive sleep apnea
   d. Severe lower urinary tract symptoms
   e. Uncontrolled or poorly-controlled heart failure
      If yes, do not approve. If no, continue to #4.

4. Has the member experienced a major cardiovascular event (such as a myocardial infarction, stroke, acute coronary syndrome) in the past six months?
   If yes, do not approve. If no, continue to #5.

5. Does the member have uncontrolled or poorly-controlled benign prostate hyperplasia or is at a higher risk of prostate cancer, such as elevation of PSA after initiating testosterone replacement therapy?
   If yes, do not approve. If no, continue to #6.

6. Is the member new to CareOregon and already receiving testosterone replacement for at least 6 months or an existing member with documented use of testosterone replacement for at least 6 months?
   If yes, continue to #8. If no, continue to #7.

7. Has the member had TWO morning (between 8 a.m. to 10 a.m.) tests (at least 1 week apart) at baseline demonstrating low testosterone levels as defined by the following criteria?
   Total serum testosterone level less than 300ng/dL (10.4nmol/L); OR
   Total serum testosterone level less than 350ng/dL (12.1nmol/L) AND free serum testosterone level less than 50pg/mL (or 0.174nmol/L).
   If yes, continue to #8. If no, do not approve.

8. Approve for lifetime.
**VMAT2 Inhibitor Criteria**

Generic Name: Tetrabenazine
Valbenazine

Brand Name: Xenazine
Ingrezza

Created: 05/09/2019

**All diagnoses:**

**Initial criteria:**

1. Has the treatment been initiated by or is an appropriate specialist currently supervising it?
   a. Huntington’s Chorea: neurologist
   b. Tardive Dyskinesia: neurologist or psychiatrist (PMHNP and other mid-level excluded)
   If yes, continue to #2.  If no, do not approve.  Not medically appropriate.

2. Is the drug requested indicated for or supported for the submitted diagnosis?
   If yes, continue to #3.  If no, do not approve.

3. Is the request for Ingrezza?
   If yes, continue to #5.
   If no, continue to #5.

4. Has the member tried and failed or have contraindications to tetrabenazine that are not also contraindications to Ingrezza?
   If yes, continue to diagnosis.  If no, do not approve.

5. Does the member have any of the following contraindications?
   a. With Huntington’s disease and actively suicidal, or in patients with untreated or inadequately treated depression.
   b. Hepatic impairment
   c. Taking monoamine oxidase inhibitors (MAOIs) in the past 14 days.
   d. Taking reserpine in the last 20 days.
   e. Taking another VMAT2 inhibitor (tetrabenazine, deutetetabenazine, or valbenazine)
   If yes, do not approve.  If no, continue to #6.

6. Is the dose of tetrabenazine requested greater than 50mg per day?
   If yes, continue to #7.  If no, continue to diagnosis.
7. Has the member been tested and genotyped to determine if they are poor metabolizers (PMs) or extensive metabolizers (EMs) by their ability to express the drug metabolizing enzyme, CYP2D6?
   If yes, continue to diagnosis. If no, do not approve, request testing or reduced dose.

**Huntington’s Chorea**

**Initial criteria:**
1. Is the diagnosis Huntington’s Chorea?
   If yes, continue to #2. If no, do not approve. (See note below)

2. Did the provider submit medical record documentation on the degree of chorea and impact on functional ability and/or quality of life as a baseline?
   If yes, continue to #3. If no, do not approve.

3. Did the provider submit medical record documentation of an assessment of mental status specifically for depression and suicidality?
   If yes, continue to #4. If no, do not approve.

4. Approve for 2 months.

**Huntington’s Chorea: Renewal Criteria:**
1. Is there documentation of a clinical response such as improvement in chorea, ability to perform activities of daily living, reduction in falls, or increase in quality of life?
   If yes, continue to #2. If no, do not approve.

2. Has there been close observation for the emergence or worsening of depression, suicidality, or unusual changes in behavior while on therapy?
   If yes, continue to #3. If no, do not approve.

3. Is the requested maintenance dose properly adjusted based on current medication regimen and metabolizer status? (If tetrabenazine dose over 50mg per day, CYP2D6 genotyping is required.)
   If yes, approve for 12 months. If no, do not approve.

**Tardive Dyskinesia:**

**Initial criteria:**
1. Does the member have a documented clinical diagnosis of tardive dyskinesia (TD) including the following:
   a. At least one month of past or current exposure to a dopamine receptor blocker.
   b. Dyskinetic or dystonic involuntary movements.
   c. Exclusion of other causes of abnormal movements.
   If yes, continue to #2. If no, do not approve.
2. Is there clear documentation that the tardive dyskinesia causes significant functional impairment?
   If yes, continue to #3. If no, do not approve.

3. Did the provider submit medical record documentation on the degree of tardive dyskinesia with the AIMS scale as a baseline?
   If yes, continue to #4. If no, do not approve.

4. Did the provider submit documentation that medication(s) precipitating the tardive dyskinesia has been discontinued, but tardive dyskinesia persists?
   If yes, continue to #7. If no, continue to #5.

5. Has the member had an 8-week trial of at least TWO other agents within the same therapeutic category at a clinically effective and maximum tolerated dose for the member’s primary neuropsychiatric diagnoses?
   If yes, continue to #7. If no, continue to #6.

6. Did the provider submit documentation that medication(s) precipitating the tardive dyskinesia are medically necessary?
   If yes, continue to #7. If no, do not approve.

7. Has the member tried and failed or have a contraindication to clonazepam?
   If yes, continue to #8. If no, do not approve.

8. Approve for 3 months.

**Tardive Dyskinesia:**

**Renewal Criteria:**

1. Is there documentation of BOTH of the following:
   a. follow-up AIMS assessment showing improvement from baseline, AND
   b. documentation of improved functioning, such as ability to perform activities of daily living, reduction in falls, increase in quality of life?
   If yes, continue to #2. If no, do not approve.

2. Is the requested maintenance dose properly adjusted based on current medication regimen and metabolizer status? (If tetrabenazine dose over 50mg per day, CYP2D6 genotyping is required.)
   If yes, continue to #3. If no, do not approve.

3. Approve for 12 months.
Generic Tetracycline Bismuth Subsalicylate

**H. Pylori Bismuth quadruple therapy**

Created: 1/9/2020

1. Is the diagnosis *H. pylori*?
   If yes, continue to #4. If no, continue to #2

2. Is the diagnosis covered by the Prioritized List of Health Services?
   If yes, continue to #3. If no, deny for BTL

3. Has doxycycline and other formulary antibiotics been tried and failed OR demonstrated why not medically appropriate?
   If yes, approve an appropriate treatment duration
   If no, deny for criteria not met.

4. Was the diagnosis of *H. pylori* confirmed via endoscopy, urea breath test, or stool antigen assay?
   If yes, continue to #5. If no, deny for medical appropriateness

5. Has the member tried and failed Clarithromycin + Amoxicillin + Metronidazole + a PPI (“concomitant therapy”)?
   a. Note: Concomitant therapy is supported first-line by 2017 ACG Practice Guidelines. Only triple therapy clarithromycin regimens are discouraged due to concerns for elevated macrolide resistance.
   If yes, approve for 14 days. If no, deny for criteria not met.
Generic Name  Tigecycline

Brand Name  Tygacil

Created: 5/27/09  Reviewed: 7/12/12, 9/12/13

1. Is the member being treated by an Infectious Disease Specialist?
   If yes, continue to #2  If no, do not approve.

2. Is the member ≥ 18 years old?
   If yes, continue to #3  If no, do not approve.

3. Does the member have a diagnosis of complicated skin and skin structure infections (CSSIs), complicated intra-abdominal infections (CIABs), or community acquired pneumonia (CAP) that is resistant to standard therapies?
   1. CSSIs: vancomycin, beta lactam
   2. CIABs: imipenim/cilastim
   3. CAP: severe infection requiring IV therapy and resistant to a beta-lactam, such as cefotaxime, ceftriaxone plus azithromycin or Zosyn and a fluoroquinolone such as levofloxacin or moxifloxacin

   If yes, approve the duration  If no, do not approve.

   requested.
Generic Name  Tiotropium

Brand Name  Spiriva Respimat

Created: 1/10/19

Initial Criteria:
1. Does the member have a diagnosis of asthma or COPD/emphysema?
   If asthma, approve x lifetime.  If COPD/emphysema, continue to #2.

2. Has the member tried and failed Incruse Ellipta?
   If yes, approve x lifetime.  If no, deny for PA criteria not met.
Generic Name  Tobramycin nebules
Brand Name  Tobi

Created: 5/9/19

1) Does the member have a diagnosis of cystic fibrosis?
   Yes, approve x lifetime.   No, continue to #2.

2) Is the request from a pulmonologist or infectious disease specialist with a diagnosis of lower respiratory tract infection?
   Yes, approve x 12 months   No, deny
Generic Name: Tolvaptan

Brand Name: Jynarque

Created: 9/13/18

**Initial Criteria:**

1. Is the member at least 18 years old and less than or equal to 50 years old?
   - If yes, continue to #2.
   - If no, do not approve.

2. Is Jynarque being prescribed by a nephrologist?
   - If yes, continue to #3.
   - If no, do not approve.

3. Does the member have a diagnosis of typical ADPKD with PDK1 mutation?
   - If yes, continue to #4.
   - If no, do not approve.

4. Is the member’s GFR greater than 25 ml/min?
   - If yes, continue to #5.
   - If no, do not approve.

5. Does the member have stage 3 CKD?
   - If yes, continue to #6.
   - If no, do not approve.

6. Does the member have a diagnosis of rapidly progressing ADPKD as defined by either a confirmed GFR decline of at least 5 ml/min per year over 1 year and/or 2.5 ml/min per year over a period of 5 years or a total kidney volume increase of at least 5% per year confirmed by at least 3 repeated ultrasound or MRI measurements taken at least 6 months apart?
   - If yes, continue to #7.
   - If no, do not approve.

7. Does the member documentation of no liver impairment (including normal baseline ALT/AST)?
   - If yes, approve for 12 months.
   - If no, do not approve.

**Renewal Criteria:**

1. Is there evidence of current GFR greater than 25 ml/min and continued monitoring by nephrologist?
   - If yes, approve x 12 months.
   - If no, do not approve.
### Biologics Prior Authorization Criteria

#### Tumor Necrosis Factor (TNF) Inhibitors

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<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
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<tbody>
<tr>
<td>Etanercept</td>
<td>Enbrel</td>
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<tr>
<td>Adalimumab</td>
<td>Humira</td>
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<td>Golimumab</td>
<td>Simponi Aria</td>
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<tr>
<td>Infliximab</td>
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<td>Infliximab-adba</td>
<td>Renflexis</td>
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<td>Infliximab-dyyb</td>
<td>Inflectra</td>
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#### Interleukin 17/23 Antagonists

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<tr>
<th>Generic Name</th>
<th>Brand Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Secukinumab</td>
<td>Cosentyx</td>
</tr>
<tr>
<td>Tildrakizumab-asmn</td>
<td>Ilumya</td>
</tr>
<tr>
<td>Brodalumab</td>
<td>Siliq</td>
</tr>
<tr>
<td>Risankizumab</td>
<td>Skyrizi</td>
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<tr>
<td>Ixekizumab</td>
<td>Taltz</td>
</tr>
<tr>
<td>Guselkumab</td>
<td>Tremfya</td>
</tr>
</tbody>
</table>

Created: 01/09/18  
Updated: 5/10/18, 7/11/19, 11/14/19

***Infliximab, Ilumya, and Simponi Aria are nonformulary for outpatient benefit.***  
***PA required on medical benefit.***

#### All Diagnoses:  
**Initial Criteria:**
1. Is the requested agent indicated for or supported for use in the submitted diagnosis for the member’s age? See grid below. Link.
   If yes, continue to #2. If no, do not approve. Deny for investigational.

2. Is the request for maintenance of remission in a patient who already achieved remission with the requested product or has already initiated therapy?
   If yes, continue to renewal criteria If no, continue to #3.
   for the submitted diagnosis.

3. Has the risk of infections been addressed by the following?
   • Initial testing for latent TB and treatment, if necessary, before starting therapy.
   • No current active infection at initiation of therapy.
   • Risks and benefits documented in cases of chronic or recurrent infection.
   If yes, continue to #4. If no, do not approve.

4. Has the treatment been initiated by or is an appropriate specialist currently supervising it?
   • Ankylosing Spondylitis and Axial Spondyloarthritis: Rheumatologist
   • Crohn’s Disease: Gastroenterologist
   • Hidradenitis Suppurativa: Dermatology
   • Juvenile Idiopathic Arthritis: Rheumatologist
   • Plaque Psoriasis: Dermatologist
   • Psoriatic Arthritis: Dermatologist or Rheumatologist
   • Rheumatoid Arthritis: Rheumatologist
   • Ulcerative Colitis: Gastroenterologist
   • Uveitis: Ophthalmologist or Rheumatologist
   If yes, continue to #5. If no, do not approve.

5. Is the requested agent to be used in combination with another biologic or Otezla?
   If yes, do not approve. If no, continue to #6.

6. Is the request for a TNF inhibitor?
   If yes, continue to #8. If no, continue to #7.

7. Has the member tried and failed at least ONE or have contraindications to ALL tumor necrosis factor (TNF) inhibitors that are supported for the diagnosis and the age of the member?
   If yes, continue to #11. If no, do not approve.

8. Is the request for infliximab?
   If yes, continue to #11. If no, continue to #9.

9. Has the member tried and failed or have contraindications to infliximab?
   If yes, continue to #11. If no, continue to #10.
10. Is infliximab supported for use in diagnosis for the age of the member.
   If yes, do not approve. If no, continue to #11.

11. Proceed to specific criteria for the submitted indication.

**Ankylosing Spondylitis and Axial Spondyloarthritis**

**Initial Criteria:**

1. Does the member have ankylosing spondylitis or axial spondyloarthritis (radiographic or non-radiographic)? Diagnosis is definitive if the following are met:
   a. Back pain and stiffness for more than 3 months AND
   b. Signs of active inflammation on MRI OR radiological evidence of sacroiliitis OR HLA-B27 positive
   If yes, continue to #2. If no, do not approve.

2. Does the member have moderate to severe active disease at baseline, evidenced by a Bath AS Disease Activity Index (BASDAI) score of at least 4?
   If yes, continue to #3. If no, do not approve.

3. Is the member transitioning to the requested treatment from a different biologic product?
   If yes, continue to #5. If no, continue to #4.

4. Has the member tried and failed conventional therapy with both of the following:
   • At least two NSAIDs for 3 months at maximum recommended or tolerated anti-inflammatory dose unless contraindicated, and
   • Physical therapy/exercise program
   If yes, continue to #5. If no, do not approve.

5. Is the request for Cosentyx?
   If yes, continue to #6. If no, continue to #7.

6. Has the provider requested a loading dose? (induction dosing 150 mg at weeks 0, 1, 2, 3, and 4)
   If yes, do not approve. If no, continue to #7.

7. Approve for 12 months for infliximab, 6 months for all else.

**Ankylosing Spondylitis and Axial Spondyloarthritis**

**Renewal Criteria:**
1. Does the member have significant improvement in signs and symptoms of AS/SpA and/or functioning, such as 50% relative change or 2-point improvement in BASDAI?
   - If yes, approve for 12 months.
   - If no, do not approve.

**Crohn’s Disease**

**Initial Criteria:**

1. Does the member have a diagnosis of severe fistulizing Crohn’s disease?
   - If yes, continue to #8.
   - If no, continue to #2.

2. Does the member have moderate to severe Crohn’s disease?
   - If yes, continue to #3.
   - If no, do not approve.

3. Is the member transitioning to the requested treatment from a different biologic product?
   - If yes, continue to #8.
   - If no, continue to #4.

4. Is the request for induction of remission?
   - If yes, continue to #5.
   - If no, continue to #6.

5. Has the member failed to achieve remission with a systemic corticosteroid?
   - If yes, continue to #8.
   - If no, do not approve.

6. Is the member currently stable on steroids and considered steroid-dependent?
   - If yes, continue to #7.
   - If no, do not approve.

7. Has the member tried azathioprine, 6-mercaptopurine, or methotrexate for maintenance?
   - If yes, continue to #8.
   - If no, do not approve.

8. Is the request for Stelara?
   - If yes, continue to #9.
   - If no, continue to #10.

9. Has the member tried and failed ALL of the following biologics?
   a. Infliximab, AND
   b. Humira, AND
   c. An anti-integrin alpha-4
   - If yes, continue to #10.
   - If no, do not approve.

10. Approve for 12 months for infliximab, 6 months for all else.

**Crohn’s Disease**

**Renewal Criteria:**
1. Has the member experienced a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission?
   If yes, approve for 12 months. If no, do not approve.

**Hidradenitis Suppuritiva**

**Note:** This criteria is for infliximab infusions. Humira would require all this AND a reason infliximab cannot be used (or previously failed). If a member is already on Humira, a change to infliximab will not be required.

**Initial Criteria:**
1. Has the treatment been prescribed by, or in consultation with, OHSU dermatology? (CareOregon is actively partnering with OHSU dermatology for this complex disease state to ensure optimal management for our members).
   If yes, continue to #3. If no, continue to #2.

2. Do **ALL** of the following apply?
   a) The request is from an MD with a specialty in dermatology; AND
   b) There is a valid reason a consultation with OHSU is not possible (untimely access and lack of telemedicine consult); AND
   c) The provider has detailed a plan of treatment which include evaluation for possible surgery within a year of starting infliximab.
   If yes, continue to #3. If no, do not approve. Recommend consult

3. Does the member have a diagnosis of moderate to severe hidradenitis suppurativa (Hurley II/Hurley III stage), characterized by recurrent, painful, and suppurating lesions recurring at least twice in 6 months?
   If yes, continue to #4. If no, do not approve.

4. Has the member tried and failed a 3 month treatment course of **ALL** of the following:
   - Oral antibiotics, such as clindamycin and rifampin, dapsone, or doxycycline (doxycycline has quantity limits)
   - Intralesional corticosteroid injections.
   - Antiandrogenic hormonal treatments for women (OCP or spironolactone)
   - Acitretin if not of child-bearing potential
   If yes, continue to #5. If no, do not approve and offer untried alts.

5. Approve for 12 months at 10 mg/kg weeks 0, 2, 6, and then every 6 weeks.

**Renewal criteria:**
1. Is there a valid, medical reason surgical intervention is not being pursued?
If yes, continue to #2. If no, pend for reason why not surgery

2. Has there been a significant treatment response as defined as ONE of the following:
   - A reduction of 25% or more in the total abscess and inflammatory nodule count; OR
   - No increase in abscesses and draining fistulas

   If yes, approve for 12 months. If no, do not approve.

**Juvenile Idiopathic Arthritis**

**Initial Criteria:**

1. Is the member transitioning to the requested treatment from a different biologic product?
   - If yes, continue to #7.
   - If no, continue to #2.

2. Does the member have juvenile idiopathic arthritis with active systemic features of juvenile idiopathic arthritis, with a physician global assessment of 5 or higher (or any systemic activity in the absence of active joint involvement)?
   - If yes, continue to #8.
   - If no, continue to #3.

3. Does the member have juvenile idiopathic arthritis without active systemic features of juvenile idiopathic arthritis?
   - If yes, continue to #4.
   - If no, do not approve.

4. Has the member tried and failed either: Intra-articular glucocorticoid injections (if fewer than 4 joints affected) OR NSAIDS for at least one month?
   - If yes, continue to #5.
   - If no, do not approve.

5. Has the member had at least a 3 month trial of methotrexate?
   - If yes, continue to #10.
   - If no, continue to #6.

6. Does the member have a contraindication to methotrexate?
   - If yes, continue to #7.
   - If no, do not approve.

7. Has the member failed a 3 month trial of sulfasalazine or leflunomide?
   - If yes, continue to #10.
   - If no, do not approve.

8. Has the member tried and failed systemic corticosteroids?
   - If yes, continue to #9.
   - If no, do not approve.

9. Has the member had at least a 3 month trial of methotrexate or leflunomide or contraindication to both?
   - If yes, continue to #10.
   - If no, do not approve.
10. Approve for 12 months for infliximab, 6 months for all else.

**Juvenile Idiopathic Arthritis**

**Renewal Criteria:**
1. Has the member experienced 20% or greater improvement in tender joint count and swollen joint count or has there been an improvement in functional ability?
   - If yes, approve for 12 months.
   - If no, do not approve.

**Plaque Psoriasis**

**Initial Criteria:**
1. Does the member have chronic, moderate to severe plaque psoriasis at baseline with functional impairment and one or more of the following:
   a. At least 10% body surface area involved
   b. Hand, foot or mucous membrane involvement
      - If yes, continue to #2
      - If no, do not approve.

Plaque psoriasis without functional impairment and hand, foot or mucus membrane involvement or affecting < 10% of body surface area is not covered for treatment by the Oregon Health Plan.

2. Is the member transitioning to the requested treatment from a different biologic product?
   - If yes, continue to #4.
   - If no, continue to #3.

3. Has the member tried and failed or have contraindications to ALL of the following:
   - High-potency topical corticosteroids, such as augmented betamethasone cream 0.05%, desoximetasone 0.25% cream, or clobetasol, and
   - At least one other topical agent: calcipotriene, tazarotene, anthralin, tar, and
   - PUVA or UVB Phototherapy, and
   - Methotrexate, and
   - At least one other second line systemic agent, such as cyclosporine or acitretin.
      - If yes, continue to #4.
      - If no, do not approve.

4. Is the dosing within plan quantity limits (in criteria below)?
   - If yes, continue to #5.
   - If no, do not approve.

5. Is the request for Cosentyx?
   - If yes, continue to #6.
   - If no, continue to #7.

6. Has the prescriber submitted a treatment plan that documents a trial of dose reduction to 150mg after 3 months?
If yes, continue to #7                  If no, do not approve.

7. Approve for 12 months for infliximab, 3 months for all else

**Plaque Psoriasis**

**Renewal Criteria:**

1. Has the member experienced a clinically significant response, such as PASI-75 (75% improvement) and/or is there evidence of functional improvement?
   If yes, continue to #2.                           If no, continue to #4.

2. Is the request for renewal for Cosentyx?
   If yes, continue to #3.                           If no, continue to #7.

3. Is the request for a dose reduction to 150mg or maintenance at 150mg every 4 weeks?
   If yes, continue to #7.                           If no, do not approve.

4. Is the request for renewal for Stelara?
   If yes, continue to #5.                           If no, do not approve.

5. Is member weight greater than 100kg?
   If yes, continue to #6.                           If no, do not approve.

6. Is the request for a dose increase to 90mg every 12 weeks?
   If yes, continue to #7.                           If no, do not approve.

7. Approve for 12 months.

**Psoriatic Arthritis**

**Initial Criteria:**

1. Does the member have psoriatic arthritis based on at least 3 out of 5 of the following?
   - Psoriasis (1 point for personal or family history, 2 points for current)
   - Psoriatic nail dystrophy
   - Negative test result for RF
   - Dactylitis (current or history)
   - Radiological evidence of juxta-articular new bone formation
   If yes, continue to #2                           If no, do not approve.

2. Is the member transitioning to the requested treatment from a different biologic product?
   If yes, continue to #4.                           If no, continue to #3.

3. Has the member failed or have contraindications to conventional management with all of the following?
   - NSAIDs, and
• Methotrexate or other DMARD such as leflunomide, sulfasalazine, or cyclosporine.
  If yes, continue to #4. If no, do not approve

4. Is the request for Cosentyx?
  If yes, continue to #5. If no, continue to #6.

5. Has the provider requested a loading dose? (induction dosing 150 mg at weeks 0, 1, 2, 3, and 4.)
  If yes, do not approve. If no, continue to #6.

6. Approve for 12 months for infliximab, 6 months for all else.

Psoriatic Arthritis
Renewal Criteria:
1. Has the member experienced 20% or greater improvement in tender joint count and swollen joint count?
   a. If yes, continue to #2. If no, do not approve.

2. Approve for 12 months

Rheumatoid Arthritis
Initial Criteria:
1. Does the member have a baseline of moderate to high disease activity of rheumatoid arthritis measured as such by an accepted assessment instrument (PAS, PASII, RAPID3, CDAI, DAS28, SDAI)?
   If yes, continue to #2. If no, do not approve.

2. Is the member transitioning to the requested treatment from a different biologic product?
   If yes, continue to #5. If no, continue to #3.

3. Has the member tried and failed or have contraindications to methotrexate dosed at least 20mg per week for at least 8 weeks?
   If yes, continue to #4. If no, do not approve.

4. Has the member tried and failed or have contraindications to the following: leflunomide, hydroxychloroquine, or sulfasalazine?
   If yes, continue to #5. If no, do not approve.
5. Is the requested product being prescribed along with at least one of the following DMARDs: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine, unless contraindicated?
   If yes, continue to #6. If no, do not approve.

6. Is the request for infliximab?
   If yes, continue to #8. If no, continue to #7.

7. Has the member tried and failed or have a contraindication to infliximab?
   If yes, continue to #8. If no, do not approve.

8. Approve for 12 months for infliximab, 6 months for all else.

**Rheumatoid Arthritis**

**Renewal Criteria:**

1. Has the member experienced 20% or greater improvement in tender joint count and swollen joint count?
   If yes, approve for 12 months. If no, do not approve.

**Ulcerative Colitis**

**Initial Criteria:**

1. Does the member have a diagnosis of moderate to severe ulcerative colitis defined by the following criteria:
   - Moderate = greater than or equal to 4 stools daily.
   - Severe = greater than or equal to 6 bloody stools daily and evidence of toxicity such as fever, anemia, elevated ESR, or tachycardia.
   If yes, continue to #2. If no, do not approve.

2. Is the member transitioning to the requested treatment from a different biologic product?
   If yes, continue to #7. If no, continue to #3.

3. Is the request for induction of remission?
   If yes, continue to #4. If no, continue to #5.

4. Has the member failed to achieve remission with a systemic corticosteroid
   If yes, continue to #7. If no, do not approve.

5. Is the member currently stable on steroids and considered steroid-dependent?
   If yes, continue to #6. If no, do not approve.

6. Has the member tried azathioprine, 6-mercaptopurine, or a 5-ASA for maintenance?
   If yes, continue to #7. If no, do not approve.
7. Is the request for Stelara?
   If yes, continue to #8.  If no, continue to #9.

8. Has the member tried and failed or have a contraindication to ALL of the following?
   a. Infliximab, AND
   b. Humira, AND
   c. Entyvio
   If yes, continue to #9.  If no, do not approve.

9. Approve for 12 months for infliximab, 6 months for all else.

**Ulcerative Colitis**

**Renewal Criteria:**

1. Has the member demonstrated a significant response including the following:
   • Decrease in bloody stools per day and/or
   • Elimination of signs of toxicity
     If yes, approve for 12 months.  If no, do not approve.

**Non-infectious Uveitis**

**Initial Criteria:**

1. Does the member have a diagnosis of non-infectious, intermediate, posterior or panuveitis?
   If yes, continue to #2.  If no, do not approve.

2. Is the member transitioning to the requested treatment from a different biologic product?
   If yes, continue to #4.  If no, continue to #3.

3. Has the member failed one of each of the following?
   • Topical glucocorticoids for at least 1 month OR periocular steroid injections
     and
   • Oral corticosteroids, and
   • Immunomodulator: mycophenolate, tacrolimus, cyclosporine, azathioprine, or methotrexate.
     If yes, continue to #4.  If no, do not approve

4. Approve for 12 months for infliximab, 6 months for all else.

**Non-infectious Uveitis**

**Renewal Criteria:**
1. Is there documentation that disease activity has been controlled, such as a lack of inflammation, no new inflammatory vascular lesions, no vitreous haze or decreases in visual acuity?
   - If yes, approve for 12 months.
   - If no, do not approve.

**Quantity Limits:**

**Cosentyx:**
- Two syringes every 8 weeks (150mg every 4 weeks).
- Exceptions:
  - New starts:
    - Moderate to severe plaque psoriasis with or without psoriatic arthritis: Eight syringes in the first 28 day fill then two syringes every four weeks continuing for initial 3 month approval only.

**Enbrel:**
- Four syringes per 28 days all strengths.
- Exceptions:
  - New starts:
    - Moderate to severe plaque psoriasis: Eight syringes per 28 days are authorized for the initial 3 month approval.

**Humira:**
- Two syringes per 28 days all strengths.
- Exceptions:
  - New starts:
    - Crohn’s Disease or ulcerative colitis: One Crohn’s starter pack for a 28 day supply at initiation will be authorized.
    - Moderate to severe plaque psoriasis: One psoriasis starter pack for a 28 day supply at initiation will be authorized.
    - Ulcerative colitis: One Crohn’s starter pack or equivalent for a 28 day supply at initiation will be authorized.
    - Uveitis: One psoriasis starter pack or equivalent for a 28 day supply at initiation will be authorized.
    - Hidradenitis suppurativa: Four syringes per 28 days at initiation will be authorized.

**Infliximab:**
- 5mg/kg every 8 weeks.
- Exceptions:
  - New starts:
    - For all diagnoses, up to 5mg/kg on weeks 0, 2, and 6 at initiation will be authorized (8 doses over 12 months).
    - At least 12 weeks after initiation, quantity limit exceptions require documentation of medical necessity. Interval changes AND dose increases will not be approved at the same time in the same request.

**Siliq:**
- Two syringes per 28 days
- Exceptions:
- **New starts:**
  - **Moderate to severe plaque psoriasis:** Three syringes for a 28 day supply for the first fill

**Simponi Aria:**
- **2mg/kg every 8 weeks.**
- **Exceptions:**
  - Rheumatoid arthritis: 2mg/kg on weeks 0 and 4 at initiation will be authorized (4 doses over 6 months).

**Stelara:**
- **IV:** One weight based infusion.
- **SQ:** One 45mg syringe every 12 weeks.
- **Exceptions:**
  - Crohn’s Disease: One 90mg syringe every 8 weeks after induction
  - New starts:
    - Psoriatic arthritis and moderate to severe plaque psoriasis: Induction doses of one 45mg syringe will be authorized for new starts for 0 and 4 weeks on separate fills.
  - Moderate to severe plaque psoriasis with or without psoriatic arthritis: one 90mg syringe every 12 weeks only after failure of 3 months of 45mg dosing.

**Taltz:**
- One 80mg syringe every 28 days.
- **Exceptions:**
  - New starts:
    - Plaque psoriasis with or without psoriatic arthritis:
      - Three syringes for a 28 day supply, then
      - Two syringes per 28 days for initial 3 month approval.
    - Psoriatic arthritis:
      - Three syringes for a 28 day supply for first fill.

**Tremfya:**
- One syringe 100mg/ml syringe every 8 weeks.
- **Exceptions:**
  - New starts:
    - Induction doses of one 100mg syringe will be authorized for new starts for 0 and 4 weeks on separate fills.
DIL-6 Receptor Antagonists

Generic Name  Tocilizumab
Brand Name  Actemra (including Actpen)

Created: 1/18/13
Revised: 9/12/13, 04/02/14, 09/14/17, 05/10/18, 11/14/19

All Diagnoses:
Initial Criteria:
1. Is the requested agent indicated for or supported for use in the submitted diagnosis for the member's age?
   If yes, continue to #2. If no, do not approve.

2. Is the request for maintenance of remission in a patient who already achieved remission with the requested product or has already initiated therapy?
   If yes, continue to renewal criteria If no, continue to #3.
   for the submitted diagnosis.

3. Has the risk of infections been addressed by the following?
   • Initial testing for latent TB and treatment, if necessary, before starting therapy
   • No current active infection at initiation of therapy
   • Risks and benefits documented in cases of chronic or recurrent infection
   If yes, continue to #4. If no, do not approve.

4. Does the member have medical record documentation of all of the following?
   a. absolute neutrophil count (ANC) above 2000/mm3, and
   b. platelet count above 100,000/mm, and
   c. ALT or AST below 1.5 times the upper limit of normal (ULN)
   If yes, continue to #5. If no, do not approve.

5. Has the treatment been initiated by or is an appropriate specialist currently supervising it?
   If yes, continue to #6. If no, do not approve.

6. Is the requested agent to be used in combination with another biologic?
   If yes, do not approve. If no, continue to diagnosis.

Giant Cell Arteritis:
Initial Criteria:
1. Does the member have a diagnosis of giant cell arteritis diagnosed by temporal artery biopsy or imaging?
   If yes, continue to #2. If no, do not approve.
2. Has the member tried high dose steroids (starting with prednisone 60mg per day) to induce remission?
   If yes, continue to #3. If no, do not approve.

3. Is the member currently on steroids and has failed to respond or failed to maintain remission during a taper according to schedule?
   If yes, continue to #4. If no, do not approve.

4. Will the requested product be initiated in conjunction with a steroid taper?
   If yes, continue to #5. If no, do not approve.

5. Approve for 6 months.

**Giant Cell Arteritis:**

**Renewal Criteria:**

1. Is there medical record documentation of laboratory monitoring of neutrophils, platelets, liver function tests, and lipids?
   If yes, continue to #2. If no, do not approve.

2. Has the member achieved clinical response, including normalization of erythrocyte sedimentation rate and c-reactive protein, successful steroid taper, or sustained absence of signs and symptoms?
   If yes, approve for 12 months. If no, do not approve.

**Juvenile Idiopathic Arthritis:**

**Initial Criteria:**

1. Does the member have juvenile idiopathic arthritis with active systemic features of JIA, with a physician global assessment of 5 or higher (or any systemic activity in the absence of active joint involvement)?
   If yes, continue to #9. If no, continue to #2.

2. Does the member have juvenile idiopathic arthritis without active systemic features of JIA?
   If yes, continue to #3. If no, do not approve.

3. Has the member tried and failed either: Intra-articular glucocorticoid injections (if fewer than 4 joints affected) OR NSAIDS for at least one month?
   If yes, continue to #4. If no, do not approve.

4. Has the member had at least a 3 month trial of methotrexate?
   If yes, continue to #7. If no, continue to #5.

5. Does the member have a contraindication to methotrexate?
If yes, continue to #6  If no, do not approve.

6. Has the member failed a 3 month trial of sulfasalazine or leflunomide?
   If yes, continue to #7.  If no, do not approve.

7. Has the member tried and failed a TNF inhibitor?
   If yes, continue to #11.  If no, do not approve.

8. Has the member tried and failed systemic corticosteroids?
   If yes, continue to #9.  If no, do not approve.

9. Does the member have a physician global assessment of less than 5 with continued joint involvement after 2 weeks of steroids?
   If yes, continue to #10.  If no, continue to #11.

10. Has the member tried and failed ALL of the following:
    a. methotrexate or leflunomide for at least 3 months or contraindication to both.
    b. Kineret
   If yes, continue to #11.  If no, do not approve.

11. Approve for 6 months.

**Juvenile Idiopathic Arthritis:**
**Renewal Criteria:**
1. Is there medical record documentation of laboratory monitoring of neutrophils, platelets, liver function tests, and lipids?
   If yes, continue to #2.  If no, do not approve.

2. Has the member experienced 20% or greater improvement in tender joint count and swollen joint count or stabilization of active systemic activity?
   If yes, approve for 12 months.  If no, do not approve.

**Rheumatoid Arthritis:**
**Initial Criteria:**
1. Does the member have a baseline of moderate to high disease activity of rheumatoid arthritis measured as such by an accepted assessment instrument (PAS, PASII, RAPID3, CDAI, DAS28, SDAI)?
   If yes, continue to #2.  If no, do not approve.

2. Is the member transitioning to the requested treatment from a different biologic product?
   If yes, continue to #5.  If no, continue to #3.

3. Has the member tried and failed or have contraindications to methotrexate dosed at least 20mg per week for at least 8 weeks?
If yes, continue to #4. If no, do not approve.

4. Has the member tried and failed or have contraindications to the following: leflunomide, hydroxychloroquine, or sulfasalazine?
   If yes, continue to #5. If no, do not approve.

5. Has the member tried and failed or have a contraindication to infliximab?
   If yes, continue to #6. If no, do not approve.

6. Approve for 6 months.

Rheumatoid Arthritis:
Renewal Criteria:
1. Is there medical record documentation of laboratory monitoring of neutrophils, platelets, liver function tests, and lipids?
   If yes, continue to #2. If no, do not approve.

2. Has the member experienced 20% or greater improvement in tender joint count and swollen joint count?
   If yes, approve for 12 months. If no, do not approve.
Generic Name  Tolterodine
Brand Name  Detrol

Created: 9/26/12
Reviewed: 7/11/19

1. Does the member have a diagnosis of overactive bladder that is covered by the Prioritized List?
   If yes, continue to #2. If no, do not approve.

2. Has the member failed a trial of oxybutynin?
   If yes, approve x life. If no, do not approve.
Generic Name: Tranexamic acid  
Brand Name: Lysteda

Created: 01/03/17  
Updated: 05/10/18, 11/08/18

**Initial Criteria**
1. Does the member have an underlying bleeding disorder such as von Willebrand's or hemophilia?
   - If yes, approve for lifetime.  
   - If no, continue to #2.

2. Does the member have a diagnosis of menorrhagia or abnormal uterine bleeding?
   - If yes, continue to #3.  
   - If no, do not approve.

3. Is the diagnosis characterized by all of the following:
   - Profuse bleeding lasting more than 7 days or repetitive periods at less than 21-day intervals.
   - Bleeding causes major impairment or interferes with quality of life.
   - If yes, continue to #4  
   - If no, do not approve.

4. Has the member failed a 6 month trial of combination oral contraceptives, or if estrogens are contraindicated, a progestin such as medroxyprogesterone or progestin oral contraceptive?
   - If yes, continue to #5.  
   - If no, do not approve.

5. Approve for 6 months.

**Renewal Criteria**
1. For abnormal uterine bleeding, has there been a documented response, with reduction in the days or amount of bleeding, resolution of anemia, or improvement in ability to function?
   - If yes, approve for 12 months.  
   - If no, do not approve.

.
Initial Criteria:
1. Is medication being requested by a pulmonologist or cardiologist?  
   If yes, continue to #2.     If no, do not approve.

2. Does the member have a diagnosis of pulmonary arterial hypertension WHO Group 1 diagnosed by right heart catheterization?  
   If yes, continue to #3.     If no, do not approve.     WHO Groups 2-5 not indicated.

3. Is the member currently on, has a failure or contraindication to, or is concurrently being prescribed 1) sildenafil or tadalafil and 2) bosentan or ambrisentan?  
   If yes, continue to #4.     If no, pend for documentation of why sildenafil/tadalafil and bosentan/ambrisentan is not being used

4. Which drug is being requested?  
   Veletri, approve x 12 month  
   Remodulin, continue to #5  
   Uptravi, continue to #6

5. Is there documentation that subcutaneous treatment is medically necessary?  
   If yes, approve x 12 months.     If no, deny and offer Veletri.

6. Is there documentation that oral therapy is medically necessary?  
   If yes, approve x 12 months.     If no, deny and offer Veletri.

Renewal Criteria:
1. Is documentation provided showing the member is still being seen by the pulmonologist or cardiologist and has been adherent to therapy.  
   If yes, approve for 12 months.     If no, do not approve.
Generic Name: Triamcinolone ER suspension for IA injection

Brand Name: Zilretta

Created: 3/8/18

1. Does the member have X-ray confirmed osteoarthritis of the knee?  
   If yes, continue to #2.  
   If no, deny for not supported use.

2. Is there an acceptable medical reason of why Zilretta is necessary vs generic Triamcinolone IR injection?  
   If yes, continue to #3.  
   If no, deny and offer alt

3. Has the member previously been treated with Zilretta?  
   If yes, deny (not labeled for repeat injections)  
   If no, approve x 1 dose.
Generic Name       Trospium
Brand Name          Sanctura
Created: 7/11/2019

1. Does the member have a diagnosis of overactive bladder that is covered by the Prioritized List?
   If yes, continue to #2.                                      If no, do not approve.

2. Has the member failed a trial of oxybutynin?
   If yes, approve x life.                                      If no, do not approve.
Generic Name  Varenicline
Brand Name  Chantix

Revised: 4/6/09, 5/12/16, 1/10/19
Reviewed: 12/2/11, 9/13/12, 9/12/13

Chantix is available on the formulary with a qty limit of #2/day x 12 weeks (one treatment course in 365 days). Second treatment courses within a year require authorization with the following criteria:

**Quantity Exception Criteria:**
1. Is the request for ongoing treatment of Chantix®, following the initial 12-week treatment course (check claims history for previous Chantix® claims)?
   - If yes, deny.
   - If no, continue to #2.

2. Has the provider provided notes discussing smoking cessation and described a change from the previous quit attempt or additional services that will be provided during this treatment course?
   - If yes, approve for 12 weeks
   - If no, request additional information.
**Brand Name** Varizig  
**Generic Name** Varicella zoster immune globulin  

Created: 7/11/13  
Reviewed: 9/12/13  

*** Nonformulary on outpatient benefit. PA required for medical benefit ***

1. Was the member diagnosed with chicken pox and the exposure occurred within the last 4 days?

   If yes, continue to #2.     If no, do not approve.

1. Is the member in one of the following high risk categories?
   a. Immunocompromised children and adults
   b. Newborns of mothers with varicella before or after delivery
   c. Premature infants, neonates, and infants < 1 year
   d. Adults without evidence of immunity
   e. Pregnant woman

   If yes, approve x 1 dose.     If no, do not approve.
Anti-alpha-4-integrin Antibodies

Generic Name  Natalizumab
Vedolizumab

Brand Name  Tysabri
Entyvio

Created: 11/14/19

***Nonformulary for outpatient benefit. PA required on medical benefit.***

All Diagnoses:
Initial Criteria:
1. Is the requested agent indicated for or supported for use in the submitted diagnosis for the member's age? See grid below.
   If yes, continue to #2. If no, do not approve.

2. Is the request for maintenance of remission in a patient who already achieved remission with the requested product or has already initiated therapy?
   If yes, continue to renewal criteria. If no, continue to #3.
   for the submitted diagnosis.

3. Has the treatment been initiated by or is an appropriate specialist currently supervising it?
   a. Crohn's Disease: Gastroenterologist
   b. Multiple Sclerosis: Neurologist
   c. Ulcerative Colitis: Gastroenterologist
   If yes, continue to #3. If no, do not approve.

4. Is the requested agent to be used in combination with another biologic?
   If yes, do not approve. If no, continue to #6.

Initial Criteria:
Crohn's Disease
1. Does the member have a diagnosis of severe fistulizing Crohn's disease?
   If yes, continue to #8. If no, continue to #2.

2. Does the member have moderate to severe Crohn's disease?
   If yes, continue to #3. If no, do not approve.

3. Is the member transitioning to the requested treatment from a different biologic product?
   If yes, continue to #8. If no, continue to #4.

4. Is the request for induction of remission?
If yes, continue to #5. If no, continue to #6.

5. Has the member failed to achieve remission with a systemic corticosteroid?
   If yes, continue to #8. If no, do not approve.

6. Is the member currently stable on steroids and considered steroid-dependent?
   If yes, continue to #7. If no, do not approve.

7. Has the member tried azathioprine, 6-mercaptopurine, or methotrexate for maintenance?
   If yes, continue to #8. If no, do not approve.

8. Has the member failed at least TWO TNF inhibitors or have contraindications to all TNF inhibitors?
   If yes, continue to #9. If no, do not approve.

9. Approve for 6 months.

Renewal Criteria:
Crohn’s Disease

1. Has the member experienced a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission?
   If yes, continue to #2. If no, do not approve.

2. Approve 12 months.

Multiple Sclerosis:
Initial Criteria:

1. Does the member have a diagnosis of relapsing-remitting multiple sclerosis?
   If yes, continue to #2. If no, do not approve.

2. Has the member failed (continuation of clinical relapses, CNS lesion progression on MRI, or worsening disability) while adherent to therapy on one of the following, or have contraindications to all of the following?
   a. S1P receptor modulator
   b. Fumarate derivative
   If yes, continue to #3. If no, do not approve.

3. Is the requested product intended to be used concurrently with any of the following:
   a. Interferon beta
   b. Glatiramir acetate
   c. S1P receptor modulators
d. Fumarate derivatives
  e. Teriflunomide
  f. Cladribine
  If yes, do not approve.  
  If no, continue to #6.

4. Approve for 12 months

**Multiple Sclerosis:**

**Renewal Criteria:**

1. Is there documentation of benefit since initiation, such as delay in the accumulation of physical disability and/or reduction in the frequency of clinical exacerbations and no symptoms suggestive of PML?
   If yes, approve for 12 months.  
   If no, do not approve.

**Ulcerative Colitis**

**Initial Criteria:**

1. Does the member have a diagnosis of moderate to severe ulcerative colitis defined by the following criteria:
   a. Moderate = greater than or equal to 4 stools daily.
   b. Severe = greater than or equal to 6 bloody stools daily and evidence of toxicity such as fever, anemia, elevated ESR, or tachycardia.
   If yes, continue to #2.  
   If no, do not approve.

2. Is the member transitioning to the requested treatment from a different biologic product?
   If yes, continue to #7.  
   If no, continue to #3.

3. Is the request for induction of remission?
   If yes, continue to #4.  
   If no, continue to #5.

4. Has the member failed to achieve remission with a systemic corticosteroid?
   If yes, continue to #7.  
   If no, do not approve.

5. Is the member currently stable on steroids and considered steroid-dependent?
   If yes, continue to #6.  
   If no, do not approve.

6. Has the member tried azathioprine, 6-mercaptopurine, or a 5-ASA for maintenance?
   If yes, continue to #7.  
   If no, do not approve.

7. Has the member failed at least TWO TNF inhibitors or have contraindications to all TNF inhibitors?
   If yes, continue to #8.  
   If no, do not approve.
8. Approve for 6 months.

**Ulcerative Colitis**

**Renewal Criteria:**

1. Has the member demonstrated a significant response including the following:
   - Decrease in bloody stools per day and/or
   - Elimination of signs of toxicity
     If yes, continue to #2. If no, do not approve.

2. Approve for 12 months.
Generic Name  Velaglucerase alfa
Brand Name    Vpriv

Created: 07/15/10
Reviewed: 12/2/11, 5/21/12, 9/12/13
Revised: 5/21/12

*** Nonformulary on outpatient benefit. PA required for medical benefit ***

Initial criteria:
1. Does the member have diagnosis of type 1 Gaucher disease?
   If yes, continue to #2. If no, do not approve.

2. Has the diagnosis been confirmed by one of the following?
   a. Biochemical assay of glucocerebrosidase activity in WBCs or skin fibroblasts is
      less than or equal to 30% of normal activity
   b. Genotyping revealing 2 pathogenic mutations of the glucocerebrosidase gene
      If yes, continue to #3. If no, do not approve.

3. Does the severity of disease result in one or more of the following conditions:
   a. Moderate-to-severe anemia
   b. Thrombocytopenia with bleeding tendency
   c. Bone disease
   d. Significant hepatomegaly or splenomegaly
      If yes, continue to #4. If no, do not approve.

4. Is the member at least 4 years old?
   If yes, continue to #5. If no, do not approve.

5. Has the provider outlined objective, measurable treatment goals?
   If yes, approve 6 months. If no, request from provider.
   Approved dosing:
   60 units/kg IV every other week.
   Range 15-60 units/kg

Renewal criteria:
1. Is there any medical record documentation of stabilization of disease progression, such as:
   a. Improvement in hematologic markers, such as increased Hgb/Hct and/or platelet counts
   b. Reduction in spleen or liver volume
   c. Reduction in biochemical markers, such as chitotrisidase, ACE, acid phosphatase tartrate resistant (TRAP)
d. Reduction in skeletal markers, such as DEXA scan, bone pain, bone age (for member age 14 years or less).

If yes, approve x 6 months. If no, do not approve.
Generic Name    Vigabatrin
Brand name     Sabril

Created: 11/20/09
Reviewed: 12/2/11, 9/13/12, 9/12/13

1. Is the diagnosis complex partial seizures?
   If yes, continue to #2.    If no, continue to #4.

2. Is the request for monotherapy?
   If yes, do not approve. Does not
   meet PA criteria for medical
   necessity.    If no, continue to #3.

3. Has the member failed adjunctive treatment with at least two of the following:
   topiramate, felbamate, gabapentin, lamotrigine, tiagabine, levetiracetam,
   oxcarbazepine, zonisamide or lacosamide?
   If yes, continue to #5.    If no, do not approve.

4. Is the diagnosis infantile spasms and the member is between 1 month and 2 years of
   age?
   If yes, continue to #5.    If no, do not approve.

5. Approve with the following durations.
   Complex Partial Seizures: Approve for a 3 month trial
   Infantile spasms: Approve for 1 month trial

Renewal Criteria for Infantile Spasms:
1. Is the member less than two years of age?
   If yes, continue to #2.    If no, do not approve.

2. Has there been medical record documentation of a reduction in spasms or if this is not
   an initial renewal request, ongoing assessment that continuation of therapy is
   medically necessary?
   If yes, approve for 6 months or less if
   the member is close to 2 years of age.
   If no, do not approve.

Renewal Criteria for Complex Partial Seizures:
1. Has there been medical record documentation of a reduction in seizures?
   If yes, continue to #2.    If no, do not approve.

2. Has there been ongoing monitoring for vision loss (documentation that
   ophthalmologic examinations including visual field evaluation and dilated indirect
   ophthalmoscopy of the retina at baseline and at least every 3 months)?
   If yes, approve for 12 months.    If no, do not approve.
Generic Name  Vitamin K
Phytonadione

Brand Name  Mephyton

Created: 9/14/17

1. Is the member using acutely for elevated INR while on warfarin?
   If yes, approve up to 5 tablets per fill.  If no, evaluate medical necessity.
Generic Name Voretigine neparvovec-rzyl

Brand Name Luxturna

Created: 5/10/18

**Initial Criteria:**

9. Does the patient have retinal dystrophy with confirmed bi-allelic RPE65 mutations (documented genetic testing required)?
   - If yes, continue to #2.
   - If no, deny.

10. Is the request from a provider at a center of excellence who is trained for and following administration and treatment protocols for Luxturna?
    - If yes, continue to #3.
    - If no, deny.

11. Is the member greater than 1 year of age?
    - If yes, continue to #4.
    - If no, deny.

12. Has the patient been previously enrolled in clinical trials of gene therapy for retinal dystrophy RPE65 mutations or been previously treated with gene therapy for retinal dystrophy in the eye(s) receiving treatment?
    - If yes, deny.
    - If no, continue to #5.

13. Does the patient have other pre-existing eye conditions or complicating systemic diseases that would eventually lead to irreversible vision loss and prevent the patient from receiving full benefit from treatment (eg. severe diabetic retinopathy)?
    - If yes, deny.
    - If no, continue to #6.

14. Does the patient have a visual acuity of at least 20/800 OR have remaining light perception in the eye(s) receiving treatment?
    - If yes, continue to #7.
    - If no, deny

15. Does the patient have visual acuity of less than 20/60 OR a visual field of less than 20 degrees?
    - If yes, continue to #8.
    - If no, deny.

16. Does the provider document presence of neural retina and a retinal thickness >100 microns within the posterior pole as assessed by optical coherence tomography AND have sufficient viable retinal cells as assessed by the treating physician?
    - If yes, continue to #9.
    - If no, deny.

17. Has independent review agreed all criteria above are met?
    - If yes, approve.
    - If no, submit to MRloA for review.
Generic Name  Voriconazole
Brand Name  Vfend

Original date: 6/22/09
Reviewed: 12/2/11, 7/12/12, 9/12/13
Revised: 09/08/16, 11/9/17

1. Is treatment being initiated by an Infectious Disease specialist?
   If yes, continue to #2.   If no, do not approve.

2. Does the member have a diagnosis of esophageal candidiasis or candidemia (including disseminated candidiasis)?
   If yes, continue to #3.   If no, continue to #4.

3. Has the member failed treatment with fluconazole?
   If yes, continue to #6.   If no, do not approve

4. Does the member have a diagnosis of blastomycosis of the central nervous system and is stepping down from amphotericin B?
   If yes, approve for 12 months   If no, continue to # 5.

5. Does the member have a diagnosis of invasive aspergillosis or a serious infection caused by Scedosporium apiospermum or Fusarium species intolerant or refractory to other therapy?
   If yes, continue to #9.   If no, continue to #6.

6. Is the request for secondary prophylaxis in a member with successfully treated invasive pulmonary aspergillosis who will require subsequent immunosuppression?
   If yes, approve for the duration of immunosuppression.
   If no, continue to #7.

7. Is the request for primary prophylaxis of Aspergillus in patients with prolonged neutropenia due to intensive chemotherapy for acute myelogenous leukemia or advanced myelodysplastic syndrome?
   If yes, approve for 6 months at a time until myeloid reconstitution has occurred.
   If no, continue to #8.

8. Is the request for primary prophylaxis of Aspergillus in an allogenic stem cell transplant recipient?
   If yes, approve for 3 months   If no, do not approve.

9. Approve for the duration of therapy.
Generic Name       Zanamivir
Brand Name         Relenza

Revised: 5/23/08, 3/28/13
Reviewed: 12/2/11, 7/12/12, 9/12/13

Quantity Exception Criteria:
1. Is Relenza being used for influenza treatment?
   If yes, and the member has exceeded the annual quantity limit of 2 treatments or 2 inhalers which does not require a PA, forward to the pharmacist.
   If no, continue to #2.

2. Is Relenza being used for influenza prophylaxis (prevention)?
   If yes, continue to #3.
   If no, do not approve.

3. Has the member been exposed to the influenza virus (household or community outbreak)?
   If yes, continue to #4.
   If no, do not approve.

4. Does the member have any of the following that places them at high risk for developing complications?
   a. ≥ 65 years of age
   b. Pregnancy (category C)
   c. Children meeting the age limit or teenagers who are receiving long-term aspirin treatment and may be at risk for developing Reye’s syndrome.
   d. Chronic metabolic disease (i.e. diabetes)
   e. Cardiovascular disease except hypertension
   f. Weakened immune system due to HIV/AIDS, immunosuppressive medications, chemotherapy and radiation therapy.
   g. Renal disease
   h. Hematological disorders (i.e. anemia)
   i. Metabolic disease such as diabetes mellitus
   j. Any muscle or nerve condition (e.g. spinal cord injuries, seizures, or cerebral palsy) or cognitive dysfunction that can lead to difficulty breathing or swallowing and increase the aspiration risk
   k. Residents of nursing homes or other long-term care facilities
   l. Currently resides with or cares for high-risk people (meeting one of the above criteria)
   If yes, continue to #5.
   If no, do not approve.

5. Does the member have chronic pulmonary disease (COPD/asthma)?
   If yes, do not approve
   If no, continue to #6.
6. Approve with the following duration:
   a. 10 day therapy for household or community outbreaks.
   b. 30 days for institutional outbreaks. If an extension needed then the provider needs to submit another prior authorization request.
Utilization Management (UM) Coded Edits

The following are criteria for drugs that are coded on formulary with restrictions that allow some claims to PA without prior authorization if certain limits (such as age, previous drug failures) are able to be identified within the pharmacy claim history. Claims that do not pay are held to the following PA criteria:

Created: 7/19/16

**Actonel (risedronate)**

1. Has the member tried and failed alendronate?
   - If yes, approve x life.
   - If no, deny for not meeting ST.

**Diagnosis-inferred coded Antifungals** (Miconazole, Nystatin Bulk Powder, Nystatin Oral, Nystatin-TCA combo)

1. Does the member have a comorbid condition which makes them immunocompromised (such has history of RA, Psoriasis, active cancer, diabetes or HIV)?
   - If yes, approve x life.
   - If no, continue to #2

2. Is the member’s condition funded under OHP?
   - If yes, approve.
   - If no, deny.

**Budesonide (Pulmicort) Nebulizer Solution:**

1. Is the member age 12 or less?
   - If yes, approve until age 12.
   - If no, continue to #2.

   2. Is the rationale for avoiding inhalers based on technique difficulties?
      - If yes, continue to #3.
      - If no, continue to #4.

   3. Has the member tried and failed the use of a spacer-device?
      - If yes, approve x life.
      - If no, deny for criteria not met.

   4. Does the member have a documented reason inhaled corticosteroid steroid inhalers cannot be used (include severe/end stage COPD)?
      - If yes, approve x life.
      - If no, deny for criteria not met.

**Caffeine Citrate**

1. Is the member age 1 or less?
   - If yes, approve until age 1.
   - If no, deny.

**First-Omeprazole**

1. What is the member’s age?
Ages 0 – 12 years: Approve until age 12.
Ages 12-18 year: Continue to #5
Ages 19 and up: Continue to #2

2. Is the diagnosis GERD?
   If yes, continue to #3. If no, continue to #4.

3. Does the request meet at least ONE of the following?
   a) Continuation of PPI therapy beyond 8 weeks (including other PPIs)?
   Or
   b) The request is for more than 8 weeks or unspecified duration?
   If yes, deny. Chronic GERD Therapy
   If no, continue to #5
   Not Covered per Guideline Note #144

4. Does the member have a documented and medically appropriate diagnosis which is currently funded by the Oregon Health Plan (OHP) Prioritized List?
   If yes, continue to #5. If no, deny for BTL.

5. Has the member tried and failed one of each of the following:
   a. cimetidine liquid or ranitidine syrup AND
   b. omeprazole capsules (either swallowed whole or compounded into a suspension). If the member’s pharmacy refuses to compound based on interpretation of FDA ban on compounding “available products”, please consider this ground for not using compound if swallowing whole capsules is not medically an option.
   If yes, approve as follows: If no, deny for criteria not met.
   Ages 12-18 year: Approve until age 19
   Ages 19 & up AND not GERD: Evaluated for medical necessity for duration
   Ages 19 & up for GERD: 8 weeks

Fluoride Products (not containing other vitamins or minerals)
1. Is the members age less than 19?
   If yes, approve until age 19. If no, deny for OHP exclusion.
   OHP does not cover fluoride supplements for adults.

Griseofulvin Suspension
1. Is the member less than the age of 12?
   If yes, approve until age 12. If no, continue to #2.

2. Evaluate for whether condition meets ALL of the following:
   a) funded by the Prioritized list AND
   b) is an appropriate treatment choice for the indication AND
   c) there is no untried alternative covered on formulary without PA required (such as, but not limited to, terbinafine or fluconazole-available as a suspension without PA).
If yes, approve for appropriate treatment duration    If no, deny.

**Liquid products with age limit to allow for kids:**
**Suspension/Solution Products with age max of 12:**
Clindamycin, methylphenidate, nizatidine, propranolol, Trileptal, Vibramycin, Viread, Cipro, ondansetron, oseltamivir

1. Is the member less than the age of 12?
   If yes, no PA should be needed.    If no, continue to #2

2. Is there documentation that both of the following are met:
   a) documentation the member is unable to take solid dosage forms?
   b) the use is for a funded OHP condition by the prioritized list and is medically
      necessary/appropriate?
   If yes, approve x max 12 months    If no, deny for criteria not
   met and offer solid dosage
   form.

**Long Acting Stimulants**
Products: Generics of: Concerta, Ritalin LA, Metadate CD, Adderall XR.

1. Is the member less than age 19?
   If yes, approve until age 19.    If no, continue to #2.

2. Has the member tried and failed one of each of the following (note:
   compliance/convenience concerns do not satisfy failure):
   a. methylphenidate IR or dexamfetamine IR
   b. generic Adderall IR or dextroamphetamine IR
   If yes, approve for life.    If no, continue to #3.

3. Does the member have a history of stimulant abuse AND the provider states it would
   be inappropriate to use immediate release stimulants?
   If yes, continue to #4.    If no, deny for criteria not
   met.

4. Has the member tried and failed BOTH of the following non-stimulant alternatives:
   a. Strattera (covered directly by the State) **and**
   b. bupropion (covered directly by the State)
   If yes, continue to #5.    If no, deny for criteria not
   met.

5. Has the provider submitted a statement acknowledging there are continued risks to
   using even ER stimulants in patients which history of stimulant abuse?
   If yes, approve x life.    If no, pend for statement.

**Formulary Multivitamins**
1. Which type of multivitamin product is requested?
   a. Pre-natal: See separate Prenatal PA Criteria
   b. Combination with fluoride: continue to #2.
   c. Other (no fluoride, not prenatal): continue to #3

2. Is the member under the age of 3?
   If yes, approve until age of 3
   If no, deny for not FDA approved. For kids age less than 19, fluoride products alone covered.

3. Does the member have a documented vitamin-deficiency requiring multivitamin supplementation?
   If yes, approve as long as deficiency is expected to last.
   If no, deny for not FDA approved.

Formulary Prenatal Vitamins:
1. Does the member meet both of the following?
   a. Female Gender AND
   b. Age less than 50.
   If yes, approve until age 50.
   If no, continue to #2.

2. Does the member have a documented vitamin-deficiency requiring multi-vitamin supplementation?
   If yes, approve as long as deficiency is expected to last.
   If no, deny.

Vaccines:
Products: Any vaccine WITHOUT its own unique criteria.

1. Is the product coverable by the Vaccine-For-Children (VFC) Program?
   If yes, continue to #2.
   If no, continue to #3.

2. If the member age less than 19?
   If yes, deny and notify of VFC coverage through doctor’s office/clinic.
   If no, continue to #3.

3. Is the use (particularly member’s age) in accordance with CDC/ACIP vaccine recommendations?
   If yes, approve.
   If no, deny for not medically necessary/appropriate.

Viramune XR 100 mg:
1. Is the member less than 19 years of age?
If yes, approve until age 19. If no, deny. FDA label recommends higher dosages in adults.