CareOregon

Medicaid Prior Authorization Criteria
Last Revised 08/2018

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.

Generic Name: Abatacept IV

Brand Name: Orencia IV

Revised: 12/24/09, 1/4/11, 3/13/12, 7/13/12, 9/27/12, 9/12/13, 11/12/15, 09/14/17

*****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?
   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 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.

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.

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 #4. 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:
   a. Intra-articular glucocorticoid injections (if fewer than 4 joints affected) OR
   b. NSAIDS for at least one month?
   If yes, continue to #5. If no, do not approve.

4. Has the member tried and failed systemic corticosteroids?
   If yes, continue to #6. If no, do not approve.

5. Has the member tried and failed ALL of the following:
   a. methotrexate or leflunomide for at least 3 months or contraindication to both.

b. One TNF inhibitor or a contraindication to all.
If yes, continue to #8. If no, do not approve.

6. 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 #7. If no, continue to #8.

7. 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 #8. If no, do not approve.

8. 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 stabilization of active systemic activity?
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 or sulfasalazine.
   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.

Generic Name Acamprosate

Brand Name Campral

Revised: 12/24/09, 11/9/17
Reviewed: 12/24/11, 9/13/12

1. Does the member meet DSM-IV criteria for alcohol dependence?
   If yes, continue to #2. If no, do not approve.

2. Is the member currently abstinent from alcohol?
   If yes, continue to #3. If no, do not approve.

3. Has the member tried and failed naltrexone (Revia)?
   If yes, continue to #4. If no, do not approve

4. Approve for 12 months.

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.

Generic Name Adefovir
Telbivudine

Brand Name Hepsera
Tyzeka

Revised: 12/22/09, 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 10^4copies/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 tenofoviras the preferred formulary alternative. If no, continue to #10.

10. Approve for 24 weeks (6 months).

<u>Renewal Criteria</u>:

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

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

1. Does the member one of the following diagnoses?
    - Exudative (Wet) Age-Related Macular Degeneration (AMD); or
    - Diabetic Macular Edema; or
    - Diabetic Retinopathy in DME; or
    - 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, approve for life. If no, do not approve and recommend Avastin.

Generic Name: Albendazole

Brand Name: Albenza

Created: 7/19/16
Revised: 11/09/17

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.

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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 FEV_1 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

Psoriatic arthritis:
Initial Criteria:

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

2. 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 #3. If no, do not approve.

3. Has the member failed all of the following:
   - NSAIDs,
   - At least two DMARDs such as methotrexate, sulfasalazine, or leflunomide.

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

4. Approve for 6 months.

Psoriatic arthritis:
Renewal Criteria:

1. Does the member have documented, clear treatment response from therapy such as improved reduction in swollen joint counts, improved psoriasis, or functional improvement?
   If yes, approve for 12 months. If no, do not approve.

Plaque psoriasis:
Initial criteria:

4. 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.

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

6. 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 systemic agent: cyclosporine or acitretin.

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

5. Approve for 6 months.

Renewal Criteria:
Plaque Psoriasis

2. 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.

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.

Generic Name: Aztreonam

Brand Name: Cayston

Created: 9/15/10
Reviewed: 12/2/11, 7/12/12, 9/12/13
Revised: 10/2/12, 1/25/17

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.

Generic Name Bosentan

Brand Name Tracleer

Revised: 4/28/10, 9/11/14
Reviewed: 9/13/12, 9/12/13

1. Is Tracleer being requested by a pulmonologist or cardiologist?
   If yes, continue to #2. If no, do not approve

2. Is the member a current smoker?
   If yes, continue to #3. If no, continue to #4.

3. Is the member enrolled in a smoking cessation program?
   If yes, continue to #4. If no, do not approve.

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

5. Does the member meet all of the following criteria?
   a. Mean PAP ≥ 25 mm Hg at rest and
   b. Pulmonary Capillary Wedge Pressure ≤15 mm Hg at rest, and
   c. NYHA functional class II to IV symptoms
   If yes, continue to #6. If no, do not approve.

6. Has the member had a positive response to vasoreactivity testing such as?
   a. ≥ 25% reduction in mean PVR, or
   b. Fall in mean PAP of at least 10 and ≤ 40mm Hg, or
   c. Increase or unchanged cardiac output.
      If yes, do not approve. Calcium channel blocker is indicated. If no, continue to #7.

7. Has the member tried and failed or have contraindication to sildenafil?
   If yes, approve x 16 weeks. If no, do not approve.

Renewal Criteria:

1. Does the member meet any of the following treatment goals?
   a. A significant increase in the 6-minute walk test, or
   b. Decrease in dyspnea fatigue rating and other symptoms, or
   c. Evidence of hemodynamic improvement such as a reduction in mPAP and PVR, or
   d. Improvement in NYHA functional class, or

e. Lack of functional or hemodynamic deterioration

If yes, approve for 12 months. If no, do not approve.

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, 9/14/17, 1/11/18, 7/12/18

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 #12. 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 #6.

4. Is the member between 2 and 18 years old?
   If yes, continue to #5. If no, do not approve.

5. Is abnormal muscle tone causing functional impairment or expected to result in joint contracture?
   If yes, continue to #12. If no, do not approve.

6. 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 quadraplegia
- Multiple sclerosis
- Neuromyelitis optica
- Other demyelinating diseases of the central nervous system

If yes, continue to #7. If no, do not approve.

7. Is the member at least 18 years old?
   If yes, continue to #9. If no, continue to #8.

8. Is the request for Dysport for the treatment of lower limb spasticity in a member at least 2 years old?
   If yes, continue to #9. If no, do not approve.

9. Is abnormal muscle tone causing functional impairment or expected to result in joint contracture?
   If yes, continue to #10. If no, do not approve.

10. 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 #11. If no, do not approve.

11. Has the member tried and failed two oral pharmacologic agents, such as baclofen, dantrolene, tizanidine, and benzodiazepines?
    If yes, continue to #12. If no, do not approve.

12. 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:

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 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
   - Calcium Channel Blockers
   - Anticonvulsants such as divalproex sodium, sodium valproate, topiramate, or carbamazepine
   - Tricyclic Antidepressants such as amitriptyline

   If yes, approve for 2 treatments In 6 months. If no, do not approve.

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. Is the member at least 12 years old?
   If yes, continue to #3. If no, do not approve.

3. 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 Approve for 3 months. If no, do not approve.

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 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

Generic Name Buprenorphine Implant

Brand Name Sublocade (long-acting buprenorphine injection)

Created: 5/10/18.

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

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*

<u>Renewal Criteria</u>

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.

Generic Name Calcipotriene Cream
Calcipotriene Solution

Brand Name Dovenox Cream
Dovenox Solution

Created: 09/10/15

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

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.

Generic Name Ceftazidime/Avibactam
Brand Name Avycaz

Created: 07/23/15

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.

Generic Name Celecoxib

Brand Name Celebrex

Revised: 8/6/09, 9/19/11, 4/29/16, 7/12/18
Reviewed: 9/13/12, 9/12/13

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.

Generic Name	Chemotherapy #chemotherapy
Abraxane	Paclitaxel Protein
Adcetris	Brentuximab
Afinitor	Everolimus
Alcensa	Alectinib
Alimta	Pemetrexed
Aliqopa	Copanlisib
Alkeran	Melphalan
Arranon	Nelarabine
Arzerra	Ofatumumab
Atezolizumab	Tecentriq
Avastin	Bevacizumab
Bavencio	Avelumab
Beleodaq	Belinostat
Bendeka	Bendamustine
Blincyto	Blinatumomab
Bosulif	Bosutinib
Brigatinib	Alunbrig
Calquence	Acalabrutinib
Caprelsa	Vandetanib
Cometriq	Cabozantinib
Cotellic	Cobimetinib
Cyramza	Ramucirumab
Dacogen	Decitabine
Darzalex	Daratumumab
Docefrez	Docetaxel
Doxil	Doxorubicin Lipo
Durvalumab	Imfinzi
Eloxatin	Oxaliplatin
Empliciti	Elotuzumab
Erbitux	Cetuximab
Erivedge	Vismodegib
Erleada	Apalutamide
Erwinaze	Asparaginase
Evomela	Melphalan
Farydak	Panobinostat
Faslodex	Fulvestrant
Firmagon	Degarelix
Folotyn	Pralatrexate
Gazyva	Obinutuzumab
Gilotrif	Afatinib
Gleevec	Imatinib
Kyprolis	Carfilzomib
Lartruvo	Olaratumab
Lenvima	Lenvatinib
Lomustine	Gleostine
Lonsurf	Trifluridine-Tipiracil
Lynparza	Olaparib
Matulane	Procarbazine
Mekinist	Trametinib
Mylotarg	Gemtuzumab ozogamicin
Mvasi	Bevacizumab-awwb
Nexavar	Sorafenib
Nerlynx	Neratinib
Ninlaro	Ixazomib
Odomzo	Sonidegib
Ogivri	Trastuzumab-dkst
Oncaspar	Pegaspargase
Onivyde	Irinotecan Lipo
Opdivo	Nivolumab
Perjeta	Pertuzumab
Pomalyst	Pomalidomide
Portrazza	Necitumumab
Revlimid	Lenalidomide
Rubraca	Rucaparib
Sprycel	Dasatinib
Stivarga	Regorafenib
Sutent	Sunitinib
Sylatron	Peginterferon
Sylvant	Siltuximab
Synribo	Omacetaxine
Tafinlar	Dabrafenib
Tagrisso	Osimertinib
Tarceva	Erlotinib
Tasigna	Nilotinib
Taxotere	Docetaxel
Temodar	Temozolamide
Torisel	Temsirolimus
Treanda	Bendamustine
Trelstar	Triptorelin
Tykerb	Lapatinib
Unituxin	Dinutuximab
Vantas	Histrelin

- Halaven Eribulin
- Herceptin Trastuzumab
- Ibrance Palbociclib
- Iclusig Ponatinib
- Idhifa Enasidenib
- Imlygic Talimogene
- Inlyta Axitinib
- Iressa Gefitinib
- Istodax Romidepsin
- Ixempra Ixabepilone
- Jakafi Ruxolitinib
- Jevtana Cabazitaxel
- Kadcyla Ado-Trastuzumab
- Keytruda Pembrolizumab
- Kisqali Ribociclib
- Kymriah Tisagenlecleucel-t
- Vectibix Panitumumab
- Velcade Bortezomib
- Venclexta Venetoclax
- Verzenio Ademaciclib
- Votrient Pazopanib
- Vyxeos Daunorubicin/cytarabine
- Xalkori Crizotinib
- Xtandi Enzalutamide
- Yervoy Ipilimumab
- Yescarta Axicabtagene ciloleucel
- Yondelis Trabectedin
- Zaltrap Ziv-Aflibercept
- Zejula Niraparib
- Zelboraf Vemurafenib
- Zolinza Vorinostat
- Zydelig Idelalisib
- Zykadia Ceritinib
- Zytiga Abiraterone

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

*****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: 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)

Generic Name Daclizumab

Brand Name Zinbryta

Created: 11/15/16

1. Is the member ≥18 years old and has a diagnosis of relapsing-remitting multiple sclerosis?
   If yes, continue to #2 If no, deny.

2. Is treatment requested by or in consultation with a neurologist?
   If yes, continue to #3 If no, deny

3. Has the member failed* or have contraindications to treatment with one of the following?
   a. Interferon β (Avonex, Rebif, Plegridy, Extavia or Betaseron) **OR**
   b. Glatiramir acetate (Copaxone, Glatopa) **OR**
   c. Teriflunomide (Aubagio) **OR**
   d. Natalizumab (Tysabri)
   If yes, continue to #4 If no, deny

4. Has the member failed* or have contraindications to treatment with Dimethyl fumarate (Tecfidera)?
   If yes, continue to #5 If no, deny

5. Approve daclizumba (Zinbryta) 150 mg injection once a month for 12 months.

*Note: For treatment failure, all of the following must be documented in the medical record:
a. Member compliance with previous regimens
b. Continuation of clinical relapses or CNS lesion progression on MRI or worsening disability

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. *****

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 #4. If no, continue to #2.

2. 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 #3. If no, do not approve.

3. Is the member at high risk for fracture?

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

4. Has the member tried and failed or have contraindications to zoledronic acid?

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

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 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.

Generic Name Dronabinol

Brand Name Marinol

Reviewed: 12/2/11
Revised: 9/26/12, 9/12/13, 01/08/15

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.

Generic Name Dronedarone

Brand Name Multaq

Created: 01/14/16

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 Eculizumab

Brand Name Soliris

Revised: 6/2/08, 11/29/11, 3/8/18
Reviewed: 7/12/12, 9/12/13

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

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 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, deny for not accepted indication

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 #7 If no, pend for this information.

7. 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.

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.

Generic Name Eltrombopag

Brand Name Promacta

Created: 3/29/13
Reviewed: 9/12/13, 01/08/15
Updated: 8/31/15, 05/10/18

Initial criteria:
ITP:

1. Does the member have a diagnosis of relapsing or refractory idiopathic thrombocytopenic purpura (ITP)?
   If yes, continue to #2. If no, do not approve.

2. Is Promacta 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 TWO formulary alternatives:
   a. Systemic corticosteroids
   b. Immunoglobulin replacement
   c. Splenectomy

   If yes, approve for 3 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 Promacta 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 or equal to 20,000 per mm3?
   If yes, continue to #4 If no, do not approve.

4. Had the member failed immunosuppressive therapy with antithymocyte globulin (ATG) and cyclosporine?
   If yes, continue to #5 If no, do not approve.

5. Approve for 16 weeks.

Renewal criteria:
ITP:

1. Is there medical record documentation of ALL of the following?
    a. Liver enzymes and bilirubin lab tests every 2 weeks for the first 3 months and monthly thereafter according to the manufacturer's recommendation.
    b. 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.

Renewal criteria:
Aplastic anemia:

1. Is there medical record documentation of ALL of the following?
    a. Liver enzymes and bilirubin lab tests every 2 weeks for the first 3 months and monthly thereafter according to the manufacturer's recommendation.
    b. A hematologic response has occurred after 16 weeks of therapy?

If yes, approve for 6 months. If no, do not approve..

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 10^4copies/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

Initial Criteria

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

2. Does the patient have one of the following indications?
   a. Primary heterozygous familial hypercholesterolemia (HeFH)
   b. Primary hypercholesterolemia and atherosclerotic cardiovascular disease (ASCVD)
   c. Primary homozygous familial hypercholesterolemia (HoFH)

   If a, continue to #5 If no, do not approve.
   If b, continue to #3
   If c, continue to #10

3. Does the patient have ASCVD confirmed by one of the following:
   a. Acute coronary syndrome
   b. History of myocardial infarction
   c. Stable or unstable angina
   d. Coronary or other arterial revascularization
   e. Stroke, transient ischemic attack
   f. Peripheral arterial disease that is atherosclerotic in origin.

   If yes, continue to #4. If no, do no approve.

4. Does the member have one of the following?
   a. NYHA class III or IV, or last EF <30%
   b. BP >180/110
   If yes, continue to #6, If no, continue to #5

5. Does the member qualify for having additional high-risk factors?
   a. 1 Major Risk Factor
      i. Diabetes
      ii. Age 65 or older
      iii. MI or stroke in previous 6 months
      iv. Multiple MI or stroke (or combo of the two)
      v. Current Smoker
      vi. Symptomatic PAD
   b. 2 Minor Risk Factors

i. Non-MI related coronary revascularization
ii. Residual CAD with at least 40% in 2 large vessels
iii. HDL <40 for men, HDL < 50 for women
iv. hsCRP> 2.0 mg/L
v. LDL>=130
vi. Metabolic syndrome

If yes, continue to #7 If no, continue to #6

6. Does the patient have an LDL-C greater than or equal to 100 mg while on maximum therapy (not baseline LDL) including ALL of the following?
    a. Rosuvastatin 40 mg (other high potency statins/doses not accepted unless dose increases not tolerated)
    b. Ezetimibe
    c. BAS

    If yes, continue to #9.
    If no, do not approve.
    For stated statin contraindication, continue to #8

7. Does the patient have an LDL-C greater than or equal to 70 mg/dL while on maximum therapy (not baseline LDL) with ALL of the following?
    a. Rosuvastatin 40 mg (other high potency statins/doses not accepted unless dose increases not tolerated)
    b. Zetia

    If yes, continue to #9.
    If no, do not approve.
    For stated statin contraindication, continue to #8

8. Is the patient unable to tolerate high-intensity statin therapy documented by one of the following?
    c. Rhabdomyolysis
    d. If on a low- to moderate-intensity statin: unable to push dose to high intensity due to persistent myalgia or myositis
    e. If not on statin therapy: persistent myalgia or myositis despite a trial of a statin rechallenge with pravastatin or rosuvastatin.
    d. If member has any modifiable factors which have been appropriately modified to address statin intolerance?
    e. Is medically contraindicated to be on a statin regimen due to non-modifiable factors?

    If yes, continue to #9. If no, do not approve.

9. Will Repatha be used as adjunct to the following: a) statin and Zetia/BAS if not contraindicated, b) low-fat diet and c) exercise?

If yes, approve for 6 months. If no, do not approve.

10. Is HoFH diagnosis confirmed with a genetic test?

If yes, approve x life. If no, do not approve

First Renewal Criteria (after original approval)

1. Is the patient still 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 ≥ 30% decrease in LDL-C.

   If yes, approve x 12 months. If no, do not approve.

Subsequent Renewals (after first renewal showed LDL lowering)

1. Has the patient been adherent?

   If yes, approve x 12 months. If no, do not approve.

Generic Name Epoetin alfa
Darbepoetin

Brand Name Epogen
Procrit
Aranesp

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

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 Epoprostenol
Iloprost

Brand Name Flolan
Ventavis

Revised: 4/28/10
Reviewed: 9/13/12, 9/12/13

Initial Criteria:

1. Is drug being requested by a pulmonologist or cardiologist?
   If yes, continue to #2 — If no, do not approve.

2. Is the member a current smoker?
   If yes, continue to #3. — If no, continue to #4.

3. Is the member enrolled in a smoking cessation program?
   If yes, continue to #4. — If no, consult with provider.

4. Does the member have a diagnosis of pulmonary arterial hypertension WHO Group 1 diagnosed by right heart catheterization?
   If yes, continue to #5. — If no, do not approve. WHO Groups 2-5 not indicated.

5. Does the member meet ALL of the following criteria?
   a. Mean PAP ≥ 25 mm Hg at rest, and
   b. Pulmonary Capillary Wedge Pressure ≤15 mm Hg at rest, and
   c. NYHA Class functional class III to IV symptoms
   If yes, continue to #6. — If no, do not approve.

6. Has the member had a positive response to vasoreactivity testing such as?
   a. ≥ 25% reduction in mean PVR, or
   b. Fall in mean PAP of at least 10 and ≤ 40mm Hg, or
   c. Increase or unchanged cardiac output.
   If yes, do not approve. Calcium channel blocker indicated. — If no, continue to #7.

7. Has the member tried and failed or have contraindications to treatment with sildenafil, bosentan (Tracleer) or ambrisentan (Letairis)?
   If yes, approve x 16 weeks. — If no, do not approve.

Renewal Criteria:

1. Does the member meet any of the following treatment goals?
   a. A significant increase in the 6-minute walk test, or

b. Decrease in dyspnea fatigue rating and other symptoms, or
c. Evidence of hemodynamic improvement such as a reduction in mPAP and PVR, or
d. Improvement in NYHA functional class, or
e. Lack of functional or hemodynamic deterioration.

If yes, approve for 12 months. If no, do not approve.

Generic Name Erenumab-aooe

Brand Name: Aimovig

Date Created: 7/12/18

Note: If approved, it is plan policy to start with the 70 mg dose using the 140 mg dose packaging which supplies two 70 mg injections (a two month supply).

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, continue to #8. No, deny for criteria not met.

8. Is the dose for 70 mg once per month?
   Yes, approve x 6 months No, deny for medical necessity.

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 70 mg dose x 12 months. No, continue to #2
2. Did the member demonstrate a response, but not a full response as defined above?
   Yes, approve dose increase to 140 mg No, deny for medical necessity.*

Generic Name Ertugliflozin
Ertugliflozin/metformin

Brand Name Steglatro
Segluromet

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 have a contraindication/intolerance to OR failed to achieve HbA1c ≤ 7.5% with combination therapy of:
   a. Metformin
   b. sulfonylureas (glipizide, glimepiride)
   If yes, continue to #3 If no, do not approve and recommend all untried agents.

3. Has pioglitazone been tried and failed OR does the member have demonstrated risk factors for heart failure?
   If yes, continue to #4. If no, do not approve. Criteria not met.

4. Has renal function been assessed and is eGFR ≥ 60 mL/minute/1.73m^2?
   If yes, continue to #5 If no, do not approve. Ertugliflozin is not recommended per FDA approved label if eGFR < 60 and contraindicated if <30.

5. Is baseline HbA1c ≥ 10%?
   If yes, do not approve and recommend basal insulin, such as NPH or Basaglar. If no, approve x 6 months.

First Renewal Criteria:

1. Has the member met an HbA1c goal of ≤ 7.5% or had at least a 10% HbA1C reduction from baseline?
   If yes, approve x 12 months If no, do not approve.

Subsequent Renewal Criteria (applies only after a full response to SGLT 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	Estradiol Valerate Estradiol Cypionate
Brand Name	Depo-Estradiol Delestrogen

Created: 01/13/11
Updated: 7/13/17

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 Lixisenadtide
Brand Name	Byetta, Bydureon Tanzeum Victoza Adlyxin

Revised: 6/8/09, 1/25/12, 9/12/13, 9/22/14, 7/23/15, 5/11/17, 11/9/17, 7/12/18
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, 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 (A1c not 10% lower, A1c remains > 7.5% or FBS ≥ 120mg/dl) ONE, or have a contraindication to BOTH of the following?:
   - basal insulin
   - pioglitazone

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

5. Evaluate based on HbA1c
   a. Is HbA1c ≤ 7.5%----------> If yes, do not approve.
   b. Is HbA1c >7.5% and <10.0%----------> If yes, approve for 6 months.
   c. Is HbA1c ≥10.0%----------> 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.

7. Has the provider indicated they do not prefer to use basal insulin or pioglitazone due to weight ≥ 100kg or BMI ≥ 30?
   If yes, continue to #8. If no, do not approve.

8. Evaluate based on HbA1c

    a. Is HbA1c ≤ 7.5%----------> If yes, do not approve.
    b. Is HbA1c >7.5% ----------> If yes, approve for 6 months.

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):

2. Has at least one A1c been obtained in the previous 6 months?
   iii. A1c <9%. Approve x 12 months
   iv. A1c ≥9%. Approve and recommend addition of basal or meal time insulin as appropriate.

Generic Name Ezetimibe

Brand Name Zetia

Revised: 11/20/08, 8/31/11, 9/13/12, 4/28/15, 2/24/16
Reviewed: 9/12/13

1. Does the member have homozygous sitosterolemia?
   If yes, continue to #4. If no, continue to #2.
   .
2. Does the member have a contraindication to statins?

3. **If yes, continue to #3 If no, deny.** Has the member failed maximum tolerated doses of niacin, fibrate and a bile acid sequestrant (e.g. cholestyramine) unless contraindicated?
   If yes, continue to #4. If no, do not approve

   .
4. Approve for life.

Generic Name Famciclovir

Brand Name Famvir

Revised: 12/24/09, 9/19/11, 6/1/14, 6/20/16
Reviewed: 7/12/12, 9/12/13

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 .

Generic Name Ferric Carboxymaltose

Brand Name Injectafer

Created: 11/15/13
Revised: 01/14/16

*****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.

Generic Name	Filgrastim (G-CSF) Pegfilgrastim Sargramostim (GM-CSF) Tbo-filgrastim
Brand Name	Neulasta Leukine Zarxio

Revised: 11/20/08, 4/2/14, 11/23/15, 5/11/17
Reviewed: 12/2/11, 9/12/13, 8/1/15

1. Does the member have <u>one</u> of the following diagnoses/procedures for approval of the medication?
   a. Receiving myelosuppressive chemotherapy for non-myeloid malignancies.
   b. Bone marrow transplant (allogenic or autologous).
   c. Autologous peripheral blood progenitor cells (PBPC) transplant.
   d. Severe chronic neutropenia.
   e. AIDS.
   f. Myelodysplastic syndromes.

   If yes, continue to #2. If no, continue to #3.

2. Approve as follows:
   - Zarxio- 3 months.
   - Neulasta- 3 months with a Quantity limit of #1 syringe/month.
   - Leukine- 3 months.

3. Does the member have a diagnosis of neutropenia associated with Hepatitis C treatment?

   If yes, review for medical necessity. If no, do not approve.

Generic Name Dexamethasone Intravitreal Implant
Fluocinolone Intravitreal Implant

Brand Name Ozurdex
Iluvien
Retisert

Created: 03/12/2015
Revised: 01/11/2018

*****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 #5.

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 #. 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.

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

10. Is there documented failure of or contraindication to Ozurdex?
    If yes, continue to #11. If no, do not approve.

11. Approve for 12 months.
    Retisert: 30 months

Generic Name Fluorouracil cream, solution

Brand Name Efudex

Created: 8/1/11
Revised: 5/21/12, 9/12/13, 8/14/14
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 anal intraepithelial neosplasia?
   If yes, approve x 4 months. If no, do not approve.

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Generic Name Fluticasone/Salmeterol
Budesonide/formorterol

Brand Name Advair #Advair
Symbicort #Symbicort

Created: 9/14/17
Revisde: 7/12/18

Initial Criteria:

1. Is the member established and well controlled on the requested therapy?
   If yes, approve x 12 months. If no, continue to #2

2. Does the member have a diagnosis for COPD/emphysema?
   If yes, continue to #4. If no, continue to #3

3. Has the member tried and failed, or has a contraindication to, generic AirDuo (fluticasone/salmeterol)?
   If yes, approve x 12 months. If no, deny and offer the alt.

4. Has the member tried and failed, or has a contraindication to, LAMA/LABA combo therapy such as Anoro or Stiolto?
   If yes, continue to #5 If no, deny and offer the alts

5. Has the member tried and failed, or has a contraindication to, Trelegy (LABA/LAMA/ICS)?
   If yes, continue to #6. If no, deny and offer alt

6. Is the request for a higher dose steroid component not found in Trelegy?
   If yes, approve x life. If no, deny for lack of medical necessity

Generic Name Fluticasone/umeclidinium/vilanterol

Brand Name Trelegy Ellipta

Created: 3/8/18

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 Stiolto 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?:
   c. 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 Humatrope – Subcutaneous Norditropin - Subcutaneous Nutropin - Subcutaneous Nutropin AQ – Subcutaneous Nutropin Depot – Intramuscular	Omnitrope - Subcutaneous Saizen - Subcutaneous Seristim LQ - Subcutaneous Tev-Tropin - Subcutaneous Zorbtive - Subcutaneous

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

- **All preparations of Serostim are not covered**
- **GH is not covered for members who are 18 years or older. The clinical evidence show minimal benefit to enable member to attain or retain the capability for independence or self-care. OAR 410-141-0500(2)(a) and guideline note 74 in the Prioritized List of Health Services.**

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. Is the member < 18 years old?
   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 statue 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 one of the following diagnoses?
    a. Growth hormone deficiency
    b. Prader-Willi syndrome
    c. Turner's syndrome
    d. Chronic renal failure/insufficiency; pre-transplant
    e. Idiopathic short stature without GH deficiency

    If yes for a-d, continue to the specific criteria for the diagnosis.
    If yes for e, do not approve. Dx is not on the Prioritized List and is not covered per guideline note 74.
    If no, do not approve.

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

1. 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

    Note: GH stimulation test or IGF-1 are not needed for GHD if multiple pituitary hormone deficiencies exist (at least one other deficient hormone including Luteinizing hormone (LH), Follicle Stimulation Hormone (FSH), Thyroid stimulating hormone (TSH), and Adrenocorticortropic Hormone (ACTH).)
    Note: GH stimulation test or IGF – 1 levels are not needed for congenital GHD (low GH level detected during acute episode of hypoglycemia)

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

2. For members over 12 years of age, is there evidence of non-closure of epiphyses confirmed by X-ray?
    If yes, continue to #3 If no, do not approve

3. Approve for 12 months.

<u>Prader-Willi Syndrome</u>:

1. Does the member have a confirmed diagnosis of Prader-Willi syndrome (confirmed with genetic testing, decreased muscle tone by exam)?
    If yes, continue to #2 If no, do not approve

2. For members over 12 years of age, is there evidence of non-closure of epiphyses confirmed by X-ray?
   If yes, continue to #3 If no, do not approve

3. Approve for 12 months.

Turner's Syndrome:

1. Is the diagnosis confirmed by genetic testing?
   If yes, continue to #2 If no, do not approve
2. For members over 12 years of age, is there evidence of non-closure of epiphyses confirmed by X-ray?
   If yes, continue to #3 If no, do not approve
3. Approve for 12 months.

Pre-transplant chronic renal insufficiency:

1. Has the member's nutritional status been optimized and metabolic abnormalities (e.g. metabolic acidosis) been corrected?
   If yes, continue to #2 If no, do not approve

2. For members over 12 years of age, is there evidence of non-closure of epiphyses confirmed by X-ray?
   If yes, continue to #3 If no, do not approve

3. 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. 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.

High Risk in Elderly Meds (PA req age ≥ 65)

Generic Names: CHLORZOXAZONE, CLONAZEPAM, CYPROHEPTADINE, DIGOXIN TAB 250 MCG (0.25 MG) DISOPYRAMIDE, ESTRADIOL, GUANFACINE, INDOMETHACIN, MEGESTROL ACETATE, METHYLDOPA, TICLOPIDINE, TRIHEXYPHENIDYL, BENZTROPINE, ZOLPIDEM, CHLORPHENIRAMINE, DEXBROMPHENIRAMINE, DIPHENHYDRAMINE, GLYBURIDE, NIFEDIPINE IR, ARMOUR THYROID, PHENOBARBITAL, METHYLPHENIDATE HCL, NITROFURANTOIN

Created: 5/11/15
Revised: 7/30/15

Criteria:

1. Is age greater than or equal to 65?
   If yes, continue to #2. If no, criteria do not apply.

2. Is the member's diagnosis covered under the Oregon Health Plan according to the Prioritized List of Health Services?
   If yes, continue to #3. If no, do not approve

3. Is there sufficient clinical rationale for use of the high risk medication such as clear benefits outweighing increased risks?
   If yes, continue to #4. If no, deny exclusion.

4. Has the member failed at least 2 non-high risk alternatives **OR** there are no appropriate alternatives to offer (failure of 1 still required if 1 alternative available)?
   If yes, continue to #5. If no, deny for PA criteria not met

5. Approve x life.

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 Imiquimod

Brand Name Aldara, Zyclara

Created: 8/1/11
Revised: 7/13/12, 8/14/14
Reviewed: 9/12/13

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

2. Does the member have a diagnosis of external condyloma acuminatum (genital warts)?
   If yes, continue to #4. If no, continue to #3.

3. Does the member have a diagnosis of superficial basal cell carcinoma on trunk, neck, or extremities?
   If yes, approve x 12 weeks. If no, continue to #5 .

4. Has the member tried podofilox soln?
   If yes, approve x 4 months. If not, do not approve and recommend podofilox soln.

5. Does the member have a diagnosis of anal intraepithelial neosplasia?
   If yes, approve x 4 months. If no, do not approve.

Insulin Pens

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?
   v. A1c <9%. Approve x 12 months
   vi. A1c ≥9%. Approve and recommend addition of basal or meal time insulin as appropriate.

Generic Name: Insulin Human NPH U500 #Humulin #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 10^4copies/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 ≥ 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 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 ≥ 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.

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, subcutaneous
Brand Name	Carimune NF, Flebogamma, Gamimune N, Gammagard S/D, Gammar IV, Gammar-P IV, Iveegam, Octagam, Panglobulin, Polygam S/D, Venoglobulin, Gammaplex, Bivigam
	Hizentra, Hyqvia

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

IVIG may be considered medically necessary for the following conditions:

1. Primary Immunnodeficiencies supported by laboratory findings
    a. Congenital Agammaglobulinemia or X-linked Agammaglobulinemia:
        i. Deficits or absence of all 5 Ig classes- IgG, IgM, IgA, IgE, IgD
        ii. Very low or absent B-lymphocytes
        iii. Normal T lymphocytes
        iv. The physical examination of members with XLA usually reveals absent lymph nodes and tonsils
        v. Recurrent bacterial infections
        vi. Antimicrobials are often requried in addition to IVIG or SCIG

    b. Immune Globulin Subclass Deficiency
        i. Low IgA, IgG, and IgE with elevated IgM

    c. UNG (Uracil nucleoside Glycosylase) Deficiency
        i. Low IgA, IgG, and IgE with elevated IgM

    d. Hypgogammaglobulinemia
        i. Below normal IgG
        ii. Recurrent bacterial infections

    e. ICOS (Inducible T-cell co-stimulator) Deficiency
        i. Panhypogammaglobulinemia and impaired antibody production and low B-lymphocytes
    f. Common Variable Immunodeficiency (CVID; Acquired Hypogammaglobulinemia; Adult Onset Hypogammaglobulinemia; Dysgammaglobulinemia)
        i. Low to normal IgG and inability to produce a response to protein such as tetanus or carbohydrate antigens such as pneumovax, +
        ii. Severe, recurrent and/or chronic infections

g. Severe Combined Immunodeficiency (SCID) such as Wiskott-Aldrich Syndrome
    i. Low IgG, IgA and IgM
    ii. Absent or below normal B-lymphocytes and T-lymphocytes
    iii. IVIG or SCIG should be initiated before BMT and afterward as necessary

Approval duration: Lifetime.

2. . Immune Thrombocytopenic Purpura (ITP)

a. Acute ITP
    i. Indicated to manage an acute bleeding (platelet < 30,000) episode or increase platelet prior to major, invasive surgery (e.g., splenectomy).

b. Chronic Refractory ITP
    i. Indicated on when all of the following are met:
        1. Prior treatment with oral corticosteroids
        2. Platelets persistently < 20,000 or symptoms of bleeding

c. ITP in Pregnancy
    i. Women who have previously delivered children with autoimmune thrombocytopenia, or
    ii. Platelet < 30,000 associated with bleeding before vaginal delivery or C-section, or
    iii. Women with platelets < 75,000 during the current pregnancy, or
    iv. Women with history of splenectomy

Approval duration: Up to 3 months.

1. Chronic B-Cell Lymphocytic Leukemia with Hypogammaglobulinemia
    a. IgG < 600
    b. Evidence of specific antibody deficiency + repeated bacterial infections

    Approval duration: up to 3 months.

2. HIV
    a. < 13 years old, +
    b. Entry level CD4+ ≥ 200/mm3, +
    c. Clinically symptomatic
    Approval duration: up to 3 months.

3. Allogeneic Bone Marrow Transplant
    a. hematologic neoplasms +
    b. ≥ 20 years old +

c. Seropositive for CMV prior to transplant +
d. Seronegative donor, + for medicare members
e. Medicare covered transplant

Approval duration: up to 3 months.

4. Kawasaki Disease
   a. IVIG indicated during the 1st 10 days of diagnosis when combined with aspirin to reduce coronary aneurysms. There is no benefit if administered after 10 days from onset of symptoms.
   b. IVIG may be indicated after 10 days in pediatric members with persistent fever without explanation or aneurysms and ongoing systemic inflammation (as denoted by elevated erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) are present.

   Approval duration: up to 3 months.

5. Acute & Chronic Demyelinating Polyradiculoneuropathy Including Guillain-Barre Syndrome
   a. Other therapy has failed or is contraindicated + member has difficulty with venous access for plasmaphoresis, or
   b. Rapidly progressive form of disease with symptoms < 2 weeks or deteriorating ability to ambulate, or
   c. Deteriorating pulmonary function tests

6. Myasthenia Gravis
   a. Treatment of acute decompensation such as respiratory failure, or
   b. Other treatments have been unsuccessful or are contraindicated including plasma exchange, prednisone, azathioprine, cyclosporine, and cyclophosphamide

   Approval duration: As requested by provider up to 3 months.

7. Autoimmune Mucocutaneous Blistering Disease
   a. One of the following diagnoses, +
      ii. Pemphigus vulgaris
      iii. Pemphigus foliaceous
      iv. Bullous pemphigoid
      v. Mucous membrane pemphigoid
      vi. Epidermolysis bullous acquisita
   b. Failed conventional therapy (e.g., steroids, methotrexate, other immunosuppressant) or conventional therapy is contraindicated, or

c. Have rapidly progressive disease in which a clinical response could be affected quickly enough using conventional agents. IVIG should be administered only until conventional agents take effect.

Approval duration: As requested by provider up to 3 months.

8. Autoimmune Hemolytic Anemia, Warm Type
   a. Predominance of IgG antibodies (as opposed to predominance of IgM)
   b. Members ≤ 18 years + hepatomegaly or hepatosplenomegaly

   Approval duration: As requested by provider up to 3 months.

9. Polymyositis and Dermatomyositis
   a. Unresponsive to or intolerant of steroids, azathioprine, cyclosporine, and cyclophosphamide
   b. Associated with severe disability

   Dose: 2gm/kg/month up to 3 months. Records must show measurable, objective response within 3 months of initiation such as improvement in CPK levels, increase or stabilization of muscle strength, or EMG abnormalities.

   Approval duration: Up to 3 months.

12. Multifocal motor neuropathy (MMN)
    Approve x 3 months. Records must document response such as improvement in functional ability, such as grip strength.

    Approval duration: 3 months. Records must document response such as improvement in functional ability, such as grip strength for renewal request.

Generic Name Ivabradine

Brand Name Corlanor

Created: 6/25/15

Initial:

1. Does the member have a diagnosis of stable, symptomatic chronic heart failure?

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

2. Is the patients ejection fraction ≤35%?
   If yes, continue to #3 If no, do not approve.

3. Is the member's resting heart rate at least 70 beats per minute?
   If yes, continue to #4 If no, do not approve

4. 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) Mineralcorticoid receptor antagonist [spironolactone (25 mg/day)]

   If yes, approve x life If no, deny for criteria not met

Generic Name Ivacaftor
Ivacaftor/Lumacaftor

Brand Name Kalydeco
Orkambi
Symdeko

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

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 appropriate mutation identified in the FDA label (confirmed with a FDA-cleared genetic test) FDA expansion list too large to include. Must review FDA label directly. i.e. for Symdeko should have homozygous f508del or one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor
   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, go to #6 . If no, do not approve.

6. Is the request for Symdeko?
   If yes, go to #7 If no, approve x 3 months

7. Has the member failed Orkambi or is unable to tolerate it due to side effects?
   If yes, approve x 3 months If no, deny and offer Orkambi.

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 not covered per Guideline Note #144. If no, continue to #5.

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 Vantas Zoladex

Created: 01/11/18

*****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?

If yes, approve until two years of cross-sex hormone therapy has been completed. If no, continue to #8.

8. Approve for 12 months.

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. If no, do not approve.

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. If no, do not approve.

Generic Name: Levoleucovorin

Brand Name: Fusilev

Created: 09/14/17

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

Non-formulary on pharmacy 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?
   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/mcL 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. Approve for 6 months.

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

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. 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).1

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

Generic Name: Naltrexone Extended-Release Injection

Brand Name: Vivitrol

Revised: 8/5/08, 01/13/11, 9/12/13, 12/21/15
Reviewed: 9/13/12

***** Nonformulary on outpatient benefit. PA required for medical benefit. *****
Initial Criteria:

1. Does the member have a diagnosis of alcohol dependence ?
   If yes, continue to #3. If no, continue to #2.

2. Does the member have a diagnosis of opioid dependence ?
   If yes, continue to #5. If no, do not approve.

3. Has the member failed an adequate trial of oral naltrexone?
   If yes, continue to #6 If no, go to #4.

4. Has the provider established a case for clear cost-avoidance with Vivitrol due to a number of repeat hospitalizations for the member from their alcohol dependence AND a trial of oral naltrexone has been determined not appropriate?
   If yes, continue to #6 If no, do not approve

5. Has the member failed a trial of the following?
   a. Oral naltrexone
      AND
   b. Opioid based therapy (one of the following)
      i. MMT from a Federally Certified Medical Methadone Maintenance Clinic
         OR
      ii. Suboxone

   If yes, continue to #6 If no, do not approve.

6. Is there documentation that the member is engaged in a drug and alcohol treatment program with psychosocial support?
   If yes, approve X 6 months If no, do not approve.

Renewal Criteria:
Has the member maintained abstinence with the use of Vivitrol 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

1. Is there evidence of significantly reduced utilization of acute care services (ED visits, inpatient, and/or detox services)?
   If yes approve x 6 months If no do not approve.

Notes to Provider:

- FDA-Approved Indication: treatment of alcohol dependence in members who are able to abstain from alcohol in an outpatient setting prior to initiation of treatment with naltrexone injection.
- **Member should be abstinent from alcohol and opioids for a minimum of 7 days prior to receiving Vivitrol.**
- Efficacy promoting abstinence has not been demonstrated in members who have not completed detoxification and achieved alcohol abstinence prior to beginning Vivitrol treatment.
- Use of naltrexone in combination with other anti-alcoholic medications is not recommended.
- Acute hepatitis, acute liver disease or significant renal impairment are typically contra-indications for Vivitrol.

Dosing and Admin: 380 mg IM into the upper outer quadrant of a gluteal muscle,alternating buttocks, every 4 weeks.

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 Natalizumab

Brand Name Tysabri

Revised: 5/19/10, 9/12/13, 06/15/15
Reviewed: 12/2/11

****Non-formulary on pharmacy benefit. This is considered a medical benefit covered drug*****

Initial Criteria (Multiple Sclerosis):

1. Is the member ≥18 years old and has a diagnosis of relapsing-remitting multiple sclerosis?
   If yes, continue to #2. If no, do not approve.

2. Is treatment requested by or in consultation with a neurologist?
   If yes, continue to #3. If no, do not approve.

3. Has the member failed* or have contraindications to treatment **with one of the following?**
   a. Interferon beta (Avonex, Rebif, Plegridy, Extavia or Betaseron)
   OR
   b. Glatiramir acetate (Copaxone, Glatopa),Teriflunomide (Aubagio)

*Note: For treatment failure, all of the following must be documented in the medical record:

1. Member compliance with previous regimens
2. Continuation of clinical relapses **or** CNS lesion progression on MRI **or** worsening disability

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

4. Has the member failed* or have contraindications to treatment with one of the following:
   a. Fingolimod (Gilenya)
   b. Dimthyl Fumarate (Tecfidera)

*Note: For treatment failure, all of the following must be documented in the medical record:

i. Member compliance with previous regimens
ii. Continuation of clinical relapses **or** CNS lesion progression on MRI **or** worsening disability

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

5. Is Tysabri intended to be used concurrently with any of the following:

a. Interferon beta (Avonex, Plegridy, Rebif or Betaseron)
b. Glatiramir acetate (Copaxone)
c. Fingolimod (Gilenya),Teriflunomide (Aubagio), Dimethyl Fumarate (Tecfidera)

If yes, do not approve. Combination therapy is not FDA approved and increases risk of PML.

If no, continue to #5.

6. Approve natalizumab 300 mg infusion once a month for 12 months.

Renewal Criteria (MS):

1. Is there documentation of benefit since initiation of Tysabri, 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 x 12 months. If no, do not approve.

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Initial Criteria (Crohn's Disease):

1. Does the member have a diagnosis of moderate to severe Crohn's disease?

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

2. Does the member have an elevated baseline C reactive protein (CRP) level > 2.87ml/L?

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

3. Has the member failed or have contraindications to treatment with an adequate course of systemic corticosteroids at a prednisone equivalent of 40-60mg/day?

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

4. Has the member demonstrated treatment failure (e.g. active disease flares while stabilized for at least 2 months) or contraindications to all of the following:
   a. Azathioprine
   b. Mercaptopruine
   c. Cyclosporine
   d. Methotrexate
   e. Remicade
   f. Humira

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

5. Is Tysabri being prescribed as monotherapy or with either oral steroids or 5-Aminosalicylates (e.g. Asacol, Rowasa, Pentasa)?

If yes, continue to #6. If no, do not approve.

6. If the member is currently on oral steroids, does the provider have a taper schedule outlined for as soon as the member experiences clinical response?

   If yes or not applicable, continue to #7. If no, do not approve.

7. Approve x 6 months.

Renewal Criteria (Crohn's disease):

1. Is there demonstration of clinical response evidenced by at least one of the following:
   a. Reduction in CDAI or number of disease flares or improved quality of life
   b. If previously on oral steroids, they have been successfully discontinued
   c. No history of serious prior infection or evidence of liver toxicity since the previous authorization

   If yes, approve x 12 months. If no, do not approve.

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 #ocrelizumab

Brand Name Ocrevus #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

Created: 03/09/17
Revised: 11/09/17

*****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 #9.

2. Is the request for Signifor LAR?
   If yes, continue to #6. If no, continue to #3.

3. Is the request for Signifor?
   If yes, continue to #4. If no, continue to #6.

4. Is the request for the treatment of Cushing's Disease?
   If yes, continue to #5. If no, continue to #6.

5. Is pituitary surgery is not an option or has it not been curative?
   If yes, approve for 3 months. If no, do not approve.

6. Does the member have a diagnosis of acromegaly confirmed by elevated IGF-1 levels?
   If yes, continue to #7. If no, continue to #9.

7. Is the acromegaly moderate to severe or symptomatic?
   If yes, continue to #8. If no, do not approve.

8. Does the member have persistent disease after surgery or considered not to be a candidate for surgery?
   If yes, continue to #13. If no, do not approve.

9. Is the treatment being prescribed by an oncologist for a type of cancer?
   If yes, continue to #10. If no, do not approve.

10. Is the treatment supported for the diagnosis in the NCCN guidelines?
    If yes, continue to #12. If no, continue to #11.

11. Is the treatment being used according to the FDA indication?
    If yes, continue to #12. If no, do not approve.

12. 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 #13. If no, do not approve.

13. Is the request for octreotide or octreotide LAR?
    If yes, continue to #17. If no, continue to #14.

14. Is the request for Somatuline?
    If yes, continue to #15. If no, continue to #16.

15. Has the member tried and failed or have a contraindication to octreotide?
    If yes, continue to #17. If no, do not approve and offer octreotide.

16. Has the member tried and failed or have a contraindication to Sandostatin/Sandostatin LAR AND Somatuline?
    If yes, continue to #17. If no, do not approve and offer all untried agents.

17. Is the requested product supported for the submitted indication?
    If yes, continue to #18. If no, do not approve

18. 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 at least a 50% 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.

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Opioids PA criteria

Updated: 1/9/17

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/AAP

New Quantity Limit for IR opioids criteria belongs further below.

ALL (new start and renewal)

1. Is the diagnosis funded for coverage under Oregon Medicaid Prioritized List of Health Services?; And does Practice Guideline Note #60 apply?:
   a. Straight Above-The-Line (no applicable guideline notes)=>continue to #3
   b. Pairs to Lines Where Guideline Note #60 (Opioid Prescribing for Back Pain) => continue to #2
   c. Straight Below-The-Line=> Deny

2. Does the request meet Guideline Note #60 for Opioid Prescribing for Low Back Pain? **ALL** sub-provisions (i, ii, etc) must be met for a) or b) or c) as applicable by timing of use of opioids related to onset of pain/injury:
   a) Acute First 6 weeks:
      i. Immediate-Release opiate only
      ii. Non-opiates such as NSAIDs, APAP, muscle relaxants failed
      iii. Using other active interventions such as physical therapy
      iv. No current or history of opiate abuse.
   b) Acute 6 weeks to 90 days:
      i. All of the above from section “a) Acute First 6 weeks”
      ii. Demonstrated functional improvement by validated tools from first 6 weeks (see questions 8-10 below to assist evaluation)
      iii. Assessment of risk of opioid abuse (see questions 8-10 below to assist evaluation)
   c) Chronic (beyond 90 days)
      i. Member established on therapy of requested product prior to last 90 days. Members who initiated therapy in last 90 days (sections a and b above) will not be approved to continue into chronic use.
      ii. Documentation that a taper plan is in place to discontinue opiates by 1/1/2018. Taper plan itself is not required for submission so long as provider documents such a plan is in place.

If yes, continue to #3. If no, deny for Guideline Note #60 Not met.

3. Has CareOregon previously approved this opioid?

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

New Starts

4. Are the following clinical/quality/preferred alternatives met?

- Diagnosis not migraine
- Not on dual long acting opiates (including methadone)
- Have preferred alts been tried and failed? (may not apply to all requests)
    - Oxycontin or Fentanyl: failure of morphine ER tablets (generic MS Contin)
    - Non-formulary meds: assess appropriateness of formulary alts at the discretion of the plan.

If yes, continue to #11. If no, deny.

Renewal Criteria

5. Does the member have active cancer pain or is the member in a palliative care program?

If yes, continue to #11. If no, continue to #6.

6. Has the member experienced an overdose event in the last year, including ED or hospitalization?

If yes, deny If no, continue to #7

7. Has the member tried and failed non-medication modalities (failure: experienced little to no improvement in function or quality of life) Or is there a reason as to why member cannot participate in these activities?

If yes, continue to #8 If no, deny

8. Has the member's function improved while using opioids? This should include ONE of the following:

- PEG questionnaire
- FRQ questionnaire
- PDI (Pain Disability Index)
- Clear documentation of physician assessment of changes from baseline function.

If yes, continue to #9. If no, deny

9. Has the member's risk been assessed? This should include documentation of ALL of the following:

- Validated risk scoring tool such as ORT, CAGE-AID, SOAPP-R, COMM, DIRE, ORS, and AUDIT
- PDMP report

- Mental Health Screening such as PHQ-9, GAD-7, PC-PTSD, or mental health professional evaluation
- UDS

If yes, continue to #10. If no, deny

10. Are either of the following met?:
    a) UDS NOT consistent with what is prescribed; **or**
    b) PDMP report shows signs of fraud, waste, or abuse.
    If yes, deny. If no, continue to #11

11. Approve durations (assume above met):
- Straight Above-The-Line (no applicable guideline notes): 12 months with renewal criteria
- Acute Use, Pairs to Lines Where Guideline Note #60 (Opioid Prescribing for Back Pain):
  - Initial: 6 weeks
  - Renewal: additional 6 final weeks
- Chronic Use Per Guideline Note #60: 12 months OR 1/1/2018, whichever is earliest.
  - Durations may need to be reduced to coincide with CCO MED reduction efforts

QL Exception Criteria- for QLs based on 120 MED

Prescriptions written for "as needed" doses will require clear documentation of expected number of max tablets per day written in order to be reviewed for prior authorization.

First QL PA

1. Does member have active cancer pain or use for palliation/terminal care?
   Yes, approve x life. No, continue to #2.

2. Is member established on therapy?
   Yes, continue to #3. No, deny for not medically appropriate.

3. Does the member have a diagnosis of chronic back pain (dx pairs to GN 60) OR is straight BTL?
   Yes, continue to #4 No, continue to # 5

4. Is there documentation of plan to taper off opioids by end of 2017?
   Yes, approve x 6 months. No, deny for GN/BTL.

5. Is there a documented taper plan to taper below MED 120 in 6 months?
   Yes, approve x 6 months. No, deny for not medically appropriate.

Renewal for QL

1. Is diagnosis of chronic back pain (dx pairs to GN 60) OR is straight BTL?
   Yes, continue to #2. No, continue to #3

2. Has member demonstrated a taper from last approval AND plan to continue taper to be off by end of 2017?
   Yes, approve until end of 2017. No, deny for GN/BTL.

3. Is there a medical reason the member has not been successful to taper below MED 120 in last 6 months? Reasons may include acute pain such as severe fracture OR extremely high MED dose originally with continued successful taper but still above MED 120.
   Yes, approve x 6 months. No, deny for not medically appropriate.

Brand Name Ciprodex Otic

Generic Name Ciprofloxacin/dexamethasone

Revised: 1/22/10, 2/14/12, 7/12/18
Reviewed: 9/13/12, 9/12/13

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 diagnosis. If no, continue to #5.

5. Is the diagnosis Acute Otitis Media with tympanostomy tubes (AOMT) or post-operative tympanostomy tube otorrhea and/or granulation tissue?
   If yes, approve #1 bottle (7.5ml) for 7 days. If no, continue to #8.

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

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 combined treatment with high-dose, inhaled corticosteroids, long-acting beta agonist, and a long-acting muscarinic antagonist (Spiriva)?
   If yes, continue to #9. If no, do not approve.

9. Has the member tried and failed or have contraindications to second-line treatments including?
   a. Leukotriene inhibitor, **and**

b. 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 12 weeks. 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
Brand Name	Boost, Boost High Protein, Boost Plus, Ensure, Ensure Enlive, Ensure High Protein, Ensure Light, Ensure Plus, Ensure Plus HN, Jevity, Liquid Nutrition, Liquid Nutrition Plus, Nubasics, Nubasics Plus, Nutrition Plus, Osmolite, Pediasure, Pediasure with Fiber, Peptamen, Peptamen Junior, Promod, Resource, Resource Plus, Resource Diabetic

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.

Generic Name: Oseltamivir

Brand Name: Tamiflu

Revised: 5/23/08, 11/29/11
Reviewed: 7/12/12, 9/12/13

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.

Treatment

Body Weight	Recommended Dose for 5 days	Number of Bottles of the Oral Suspension (6mg/ml)	Number of Capsules (30mg, 45mg, 75mg)
≤ 15kg	30mg BID	1	10 of 30mg
16 to 23kg	45mg BID	2	10 of 45mg
24 to 40kg	60mg BID	2	20 of 30mg
> 40kg	75mg BID	3	10 of 75mg

Prophylaxis for Household Outbreaks

Body Weight	Recommended Dose for 10 days	Number of Bottles of the Oral Suspension (6mg/ml)	Number of Capsules (30mg, 45mg, 75mg)
≤ 15kg	30mg QD	1	10 of 30mg
16 to 23kg	45mg QD	2	10 of 45mg
24 to 40kg	60mg QD	2	20 of 30mg
> 40kg	75mg QD	3	10 of 75mg

Generic Name Oxandrolone

Brand Name Oxandrin

Revised: 11/21/08
Reviewed: 12/2/11, 9/13/12, 9/12/13
Revised: 01/14/16

Initial Criteria:

1. Does the member have a documented diagnosis of wasting syndrome (weight loss/cachexia) due to HIV/AIDS, cancer, severe COPD, chronic infection, extensive surgery, or trauma?
   If yes, continue to #2. If no, continue to #4.

2. Has the member experienced a weight loss of ≥ 10% in < 4 months and has a BMI < 20?
   If yes, continue to #3. If no, do not approve.

3. Has the member tried/failed or have contraindications to megestrol?
   If yes, continue to #7. If no, do not approve.

4. Is oxandrolone being used to offset protein breakdown (catabolism) that is associated with **chronic** corticosteroid use?
   If yes, continue to #7. 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. Has the member tried/failed or have contraindications to standard pain therapy including NSAIDs and opioids?
   If yes, continue to #7. If no, do not approve.

7. Does the member have any of the following contraindications to use of oxandrolone?

   Does the member have any of the following contraindications to use of oxandrolone?
   - Known or suspected carcinoma of the prostate or breast in males
   - Carcinoma of the breast in females with hypercalcemia
   - Hypercalcemia

- Nephrosis
  If yes, do not approve. If no, continue to #8.

8. Wasting syndrome: Approve for 4 weeks.
   All others: Approve for 12 months.

Renewal Criteria:
Cachexia/Wasting: Documentation of increase in or maintenance of (no continued loss) weight/BMI. Approve x 6 months.

Generic Name Oxybutynin Patch

Brand Name Oxytrol For Women OTC

Created: 1-14-14

1. Does the member have an above the line diagnosis (ATL)?
   If yes, continue to #2. If no, do not approve.

2. Has them 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

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 #9. If no, continue to #4.

4. Has the member had a pancreatectomy?
   If yes, continue to #9. If no, continue to #5.

5. Does the member have a diagnosis of exocrine pancreatic cancer?
   If yes, continue to #9. If no, continue to #6.

6. Does the member have a diagnosis of chronic pancreatitis?
   If yes, continue to #8. If no, continue to #7.

7. Does the member have a diagnosis of malabsorption from a chronic condition? (e.g. Crohn's Disease, celiac disease, bowel resection)
   If yes, continue to #8. If no, do not approve.
   Deny for investigational.

8. 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 pancreatic function testing
   - Imaging

   If yes, continue to #9. If no, do not approve.

9. Approve for lifetime.

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 .

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Generic Name: Patiromer

Brand Name: Veltassa

Created: 3/21/16

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.

Generic Name Pegaptanib

Brand Name Macugen

Created: 3/13/12
Reviewed: 9/13/12, 9/12/13
Revised: 01/11/18

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

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 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 $< 10 \times 10^9$/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 $< 0.3 \times 10^6$ 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 over 4 days. If no, do not approve

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 *Aspergillius* 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 at a time until myeloid reconstitution has occurred. If no, do not approve.

6. Is the request for primary prophylaxis of *Aspergillius* 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 not covered per Guideline Note #144. If no, continue to #5.

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:
   a. Kids: approve until age 19.
   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
Reviewed: 9/12/13

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

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 life. If no, do not approve.

Generic Name Rifaximin

Brand Name Xifaxan

Created: 5/13/10
Reviewed: 7/12/12, 9/12/13
Revised: 7/11/13, 6/1/14, 07/27/15

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

Created: 1-14-14

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 class IV pulmonary arterial hypertension- chronic thromboembolic PAH?
   If yes, continue to #3. If no, continue to #4.

3. Has the member failed surgical treatment or is not a surgical candidate?
   If yes, continue to #6. If no, do not approve.

4. Does the member have class I PAH?
   If yes, continue to #5. If no, do not approve.

5. Has the member failed or is a poor candidate for both of the following:
   a. A PDE-5 inhibitor (e.g.- sildenafil or tadalafil) **AND**
   b. An endothelin recepotor antagonist (e.g.- ambrisentan, bosentan, or macitentan)

   If yes, continue to #6. If no, do not approve.

6. Approve for 6 months.

Renewal Criteria:

1. Has the member had documented response to treatment?
   If yes, approve x 12 months. If no, do not approve.

Generic Name Rituximab
Rituximab and Hyaluronidase Human

Brand Name Rituxan
Rituxan Hycela

Revised: 5/13/10, 7/14/11, 9/20/11, 9/12/13, 05/12/16, 11/15/16, 09/14/17

Cancer
Initial Criteria:

1. Is the treatment being prescribed by a hematologist or oncologist, as appropriate, for a 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 for the drug and dosage form?
   If yes, continue to #4. If no, continue to #3.
3. Is the treatment being used according to the FDA indication for the drug and dosage form?
   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.

Rheumatoid Arthritis
Initial Criteria:

1. 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 #2.
2. Has the treatment been initiated by or is a rheumatologist currently supervising it?
   If yes, continue to #3. If no, do not approve.
3. 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 #4. If no, do not approve.

4. Is the member transitioning to the requested treatment from a different biologic product?
   If yes, continue to #8. If no, continue to #5.

5. 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 #6. If no, do not approve.

6. Has the member tried and failed or have contraindications to the following: leflunomide, hydroxychloroquine, or sulfasalazine?
   If yes, continue to #7. If no, do not approve.

7. Has the member tried and failed or have contraindications to the following: infliximab, Humira, or Enbrel?
   If yes, continue to #8. If no, do not approve.

8. 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 #9. If no, do not approve.

9. 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 or a reduction in specific, objective pain symptoms, and/or improved functioning?
   If yes, approve for 12 months. If no, do not approve.

Granulomatosis and Polyangiitis

Initial Criteria:

1. Does the member have a diagnosis of Wegener's Granulomatosis (WG) or Microscopic Polyangiitis (MPA)?
   If yes, continue to #2. If no, do not approve. .

2. Does the member have a contraindication to the use of cyclophosphamide?
   If yes, approve Rituxan IV If no, do not approve.

Granulomatosis and Polyangiitis

Renewal Criteria:

1. Has there been a resolution or improvement in disease-related signs and symptoms or has the member achieved remission?
   If yes, approve for 12 months. If no, do not approve.

Idiopathic Thrombocytopenic Purpura
Initial Criteria:

1. Does the member have a diagnosis of relapsing or refractory idiopathic thrombocytopenic purpura (ITP)?
   If yes, continue to # 2. If no, do not approve. .

2. Is the platelet count less than 20,000/microliter or are there symptoms of bleeding?
   If yes, continue to #3. If no, do not approve.

3. Has the member failed one of the following?
   - Adequate trial of corticosteroids
   - IVIG
   - Splenectomy

   If yes, approve Rituxan IV for 4 doses. If no, do not approve.

Idiopathic Thrombocytopenic Purpura
Renewal Criteria:

1. Has the member since relapsed with a platelet count less than 20,000/microliter?
   If yes, approve for 4 doses. 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 Rituxan IV for one dose in 6 months.

Multiple Sclerosis
Renewal Criteria:

1. Is the CD 19 count undetectable 1-4 weeks prior to the next dose (6 months after initial dose)?
   If yes, approve 500mg every 6 months for 12 months If no, approve 1,000mg once.

Neuromyelitis Optica (NMO)

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 Rituxan IV 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.

Generic Name Romiplostim

Brand Name Nplate

Created: 01/04/11
Reviewed: 7/12/12, 9/12/13
Updated: 05/10/18

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

Initial criteria:

1. Does the member have a diagnosis of chronic immune (idiopathic) thrombocytopenic purpura (ITP) at risk for bleeding?
   If yes, continue to #2. If no, do not approve.

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

3. Is the member at least 18 years of age?
   If yes, continue to #4. If no, do not approve.

4. 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 #5. If no, do not approve.

5. Is there documentation of failure of or contraindication to TWO of the following:
   a. Systemic corticosteroids
   b. Immunoglobulin replacement
   c. Splenectomy
   If yes, approve for 3 months. If no, do not approve.

Renewal criteria:

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.

Generic Name Saproterin

Brand Name Kuvan

Created: 3/13/12
Revised: 9/12/13

Initial Criteria:

1. Is prescribed by a metabolic specialist?
   If yes, continue to #2. If no, do not approve.

2. Does member have diagnosis of tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU)?
   If yes, continue to #3. If no, do not approve.

3. 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.

4. Is member's baseline blood Phe level provided in the request?
   If yes, continue to #5. If no, please request.

5. 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, Viagra
Adcirca, Cialis

Revised: 09/25/09, 9/11/14
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. Is the member a current smoker?
   If yes, continue to #3. If no, continue to #4.

3. Is the member enrolled in a smoking cessation program?
   If yes, continue to #4. If no, consult with provider.

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

5. Does the member meet all of the following criteria?
   a. Mean PAP ≥ 25 mm Hg at rest, and
   b. Pulmonary capillary wedge pressure ≤ 15mm Hg at rest
   c. NYHA functional class II or III symptoms
   If yes, continue to #6. If no, do not approve.

6. Has the member had a positive response to vasoreactivity testing such as:
   a. ≥ 25% reduction in mean PVR
   b. Fall in mean PAP of at least 10 and 40 mm Hg
   c. Increase or unchanged cardiac output
   If yes, do not approve. Calcium channel blocker indicated. If no, continue to #7.

7. Is the request for generic sildenafil?
   If yes, approve x 12 weeks. If no, continue to #8.

8. Has the member failed generic sildenafil or the provider provided rationale why sildenafil cannot be used?
   If yes, approve Revatio, Cialis, or Adcirca x 12 weeks. If no, do not approve.

Renewal Criteria:

1. Does the member meet any of the following treatment goals?
    a. A significant increase in the 6 minute walk test
    b. Decrease in dyspnea fatigue rating and other symptoms
    c. Evidence of hemodynamic improvement such as a reduction in mPAP and PVR
    d. Improvement in NYHA functional class
    e. Lack of functional or hemodynamic deterioration

    If yes, approve x 12 months. If no, do not approve.

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, 3/12/18, 7/12/18
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. Use in T1DM is investigational.

2. Has the member have a contraindication/intolerance to OR failed to achieve HbA1c ≤ 7% with combination therapy of:
   a. Metformin
   b. sulfonylureas (glipizide, glimepiride)
   If yes, continue to #3 If no, do not approve and recommend all untried agents.

3. Has pioglitazone been tried and failed OR does the member have demonstrated risk factors for heart failure?
   If yes, continue to #4. If no, do not approve. Criteria not met.

4. Is baseline HbA1c ≥ 10%?
   If yes, do not approve and recommend basal insulin, such as NPH or Basaglar. If no, approve x 6 months.

First Renewal Criteria:

1. Has the member met an HbA1c goal of ≤ 7.5% or had at least a 10% HbA1C reduction from baseline?
   If yes, approve x 12 months If no, do not approve.

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?
   vii. A1c <9%. Approve x 12 months
   viii. A1c ≥9%. Approve and recommend addition of basal or meal time insulin as appropriate.

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 bupriopion?
   - 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

5. Is the request for the treatment of NYHA Class II to IV chronic heart failure?
   If yes, continue to #2. If no, deny.

6. Does the member have an ejection fraction ≤40%?
   If yes, continue #3. If no, deny.

7. Is the request from a cardiologist?
   If yes, continue to #4. If no, deny.

   a. Is the member on maximum tolerated doses of ALL of the following classes? 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)
      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-fomulary for pharmacy benefit*****

Initial:

1. Is the diagnosis lyosomal 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 Daclatasvir,
Elbasvir/grazoprevir,
Sofosbuvir/Velpatasvir,
Ribavirin
Sofosbuvir/Velpatasvir/Voxilaprevir
Glecaprevir/pibrentasvir

Brand Name Daklinza, Zepatier, 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

Criteria shall apply to all Hepatitis C treatment regimens including non-formulary requests.

New Starts Only:

1. Is expected survival from non-HCV-associated morbidities more than 1 year?
   If yes, continue to #2. If no, do not approve.

2. Has ALL of the following pre-treatment testing been documented and submitted?
   a. Genotype testing (within 3 years)
   b. Baseline HCV RNA in past 6 months (must be quantifiable, not just detected)
   c. HIV status
   d. HBV status (Treatment can re-activate HepB)
   e. Pregnancy test (past 30 days) for a woman of child-bearing age
   f. History of previous HCV treatment and outcome
   If yes, continue to #3. If no, do not approve.

3. Does the member have HIV and treated by an HIV specialist?
   If yes, continue to #7 If no, continue to #4.

4. Does the member meet one of the following clinical scenarios?
   a. Cirrhotic (Stage F4) **OR** Metavir Stage F2 or F3 Fibrosis by one of the following:
      i. Biopsy
      ii. Elastography: Fibroscan or Shear Wave
      iii. Acoustic Radiation Force Impulse imaging (ARFI)
      OR
      iv. Serum Test: Fibrosure/Fibrotest, Fibrospect, Fibrometer, or ELF **AND** a reason one of the above tests (i-iii) cannot be used.

b. Clinical Diagnosis of Cirrhosis by:
    i. Clinical Markers (such as ascites, portal hypertension, encephalopathy, hepatocellular carcinoma, or varices)
    ii. Laboratory markers
    iii. Imaging (combination of a nodular liver and portal hypertension [ascites, encephalopathy, or varices])

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

Note on handling of ranges of tests:

- Fibrosis stage will be categorized as the higher F Stage
- At the discretion of the plan, a more specific test (such as Fibroscan, etc) may be required to evaluate a possible range. However, if that additional test also shows a range the highest F score will be used.
    - Ranges that include F0 will require a more specific confirmation test (IE- F0-F2)

5. Patients with the extrahepatic manifestations of hepatitis C infection listed below who have formal documentation from a relevant specialist that their condition is HCV related.
    i. Lymphoproliferative disease, including type 2 or 3 cryoglobulinemia with end-organ manifestations (i.e., leukocytoclastic vasculitis); or
    ii. Proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis; or
    iii. Porphyria cutanea tarda or lichen planus
    iv. Lymphomas (B-cell non-Hodgkin lymphoma)
    v. Type 2 Diabetes with insulin resistance

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

6. HCV infection in the transplant setting
    i. Listed patients who it is essential to eradicate the virus in order to realistically prevent a transplant or it is critical to prevent recurrent HCV infection post-transplant
    ii. Post-transplant patients

    If yes, continue to #7. If no, deny.

7. Is the treatment prescribed by a specialist (hepatology, gastroenterology, or infectious disease) OR a non-specialist with validated documentation of knowledge in HepC prescribing and ability to meet case management requirements (see question 10)?

    If yes, continue to #8 If no, deny

8. In the previous 6 months:

a. Has the patient actively abused alcohol (>14 drinks per week for men or >7 drinks per week for women or binge alcohol use [>4 drinks per occasion at least once a month]); **OR**
b. Has the patient been diagnosed with a substance use disorder; **OR**
c. Is the prescriber aware of current alcohol abuse or illicit injectable drug use?

If yes, continue to #9 If no, continue to #10

9. Is the patient enrolled in a treatment program under the care of an addiction/substance use treatment specialist?

If yes, continue to #10 If no, deny.

10. Will the patient and provider comply with all case management interventions and adhere to monitoring requirements required by the Oregon Health Authority, including measuring and reporting of a post-treatment viral load?

If yes, continue to #11 If no, deny

11. Is the prescribed drug for Zepatier for genotype 1a or Daklinza/Sovaldi for genotype 3 infection?

If yes, continue to #12 If no, continue to #13

12. Has the patient had a baseline NS5a resistance test show a resistant variant to one of the agents?

If yes, deny and recommend alternative regimen. If no, continue to #13

13. Does the patient have moderate-severe hepatic impairment (Child-Pugh B or Child-Pugh C)?

If yes, continue to #14 . If no, continue to #15

14. Does the prescribed regimen include a NS3/4a protease inhibitor?

If yes, deny alts should be offered. If no, continue to #15

15. Is the prescribed regimen for the retreatment after failure of a DAA due to noncompliance or lost to follow-up?

If yes, forward to medical director for review. If no, continue to #16

16. Does the request match one of the regimens below?

If yes, approve for duration noted. If no, deny criteria not met and cite alternative required.

Approved Regimens

Treatment History	Cirrhosis Status	Recommended Regimen
Genotype 1		
DAA-Treatment naive	Non-cirrhotic	Zepatier x 12 weeks** Epclusa x 12 weeks Mavyret x 8 weeks
	Compensated Cirrhosis	Zepatier x 12 weeks** Epclusa x 12 weeks Mavyret x 12 weeks
	Decompensated Cirrhosis	Epclusa + RBV x 12 weeks
Treatment Experienced (Prior PEG/RBV)	Non-cirrhotic	Zepatier x 12 weeks** Epclusa x 12 weeks Mavyret x 8 weeks
	Compensated Cirrhosis	Zepatier x 12 weeks** Epclusa x 12 weeks Mavyret x 12 weeks
Treatment Experienced (prior sofosbuvir)	Non-cirrhotic or compensated cirrhosis	Eplcusa x 12 weeks Vosevi x 12 weeks (GT 1a only without tx h/o NS5A inhibitor Mavyret x 12 weeks
Treatment Experienced (Prior NS3A/4A inhibitor	Non-cirrhotic or compensated cirrhosis	Epclusa x 12 weeks Zepatier + RBV x 12 weeks** Mavyret x 12 week
Treatment Experienced (prior NS5A-containing regimen	Non-cirrhotic or compensated cirrhosis	Vosevi x 12 weeks Mavyret x 16 weeks
Genotype 2		
Naive	Non-cirrhotic	Epclusa x 12 weeks Mavyret x 8 weeks
	Compensated cirrhosis	Epclusa x 12 weeks Mavyret x 12 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	Epclusa x 12 weeks Mavyret x 8 weeks

	Compensated cirrhosis	Epclusa +RBV x 12 weeks Mavyret x 12 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	Vosevi x 12 weeks 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	Zepatier x 12 weeks Epclusa x 12 weeks Mavyret x 8 weeks
	Compensated cirrhosis	Zepatier x 12 weeks Epclusa x 12 weeks Mavyret x 12 weeks
	Decompensated	Epclusa + RBV x 12 weeks
Treatment Experienced (prior PEG/RBV only)	Non-cirrhotic	Zepatier x 12 weeks Epclusa x 12 weeks Mavyret x 8 weeks
	Compensated cirrhosis	Zepatier x 12 weeks 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 or Experienced (prior PEGIFN/RBV only)	Non-cirrhotic or compensated cirrhosis	Epclusa x 12 weeks Mayvret x 8 weeks
	Compensated Cirrhosis	Epclusa x 12 weeks Mavyret x 12 weeks
	Decompensated cirrhosis	Epclusa + RBV x 12 weeks
Experienced (prior NS5Acontaining regimen OR sofosbuvir)	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 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

Revised: 11/20/09, 11/09/17
Reviewed: 12/2/11, 9/13/12, 9/12/13

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) 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 bisphosphonate1 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 bisphosphonate1 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. Approve for 2 years.

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Generic Name	Testosterone Transdermal Testosterone Gel Methyltestosterone
Brand Name	Androderm, 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
Reviewed: 9/13/12, 9/12/13, 7/18/16

1. Is the member new to CareOregon and already receiving testosterone replacement or an existing member with documented use of testosterone replacement?
   If yes, continue to #9. If no, continue to #2.

2. Does the member have a diagnosis of gender dysphoria?
   If yes, continue to #9 If no, continue to #3

3. Is the member male and ≥ 12 years old?
   If yes, continue to #4. If no, do not approve.

4. Does the member have a diagnosis of primary or secondary hypogonadism?
   If yes, continue to #5. If no, continue to #8.

5. Does the member have a total testosterone level < 300ng/dL on two separate draws?
   If yes, continue to #7. If no, continue to #6.

6. Does the member have a free testosterone level below the normal range for a member in his age group on two separate draws?
   If yes, continue to #7. If no, do not approve.

7. Is there documentation that the member is symptomatic?
   If yes, continue to #9 If no, do not approve.

8. 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, continue to #9. If no, continue to #4.

9. Is the request for topical testosterone?
   If yes, continue to #10 If no, approve for life.

10. Has the member tried and failed or have a contraindication to testosterone injections?
    If yes, approve for life. If no, deny.

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 requested. If no, do not approve.

Biologics Prior Authorization Criteria

Tumor Necrosis Factor (TNF) Inhibitors

Generic Name	Etanercept Adalimumab Golimumab Infliximab Infliximab-adba Infliximab-dyyb
Brand Name	Enbrel Humira Simponi Aria Remicade Inflectra

Interleukin 17/23 Antagonists

Generic Name	Secukinumab Brodalumab Ustekinumab Ixekizumab Guselkumab
Brand Name	Cosentyx Siliq Stelara Taltz Tremfya

Created: 01/09/18
Updated: 5/10/18

*****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 for the submitted diagnosis. If no, continue to #3.

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: Rheumatologist
   - Crohn's Disease: Gastroenterologist
   - 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 #10. If no, do not approve.

8. Has the member tried and failed or have contraindications to infliximab? See below for nonclinical contraindications.
   If yes, continue to #10. If no, continue to #9.

9. Is infliximab supported for use in diagnosis for the age of the member?
   If yes, do not approve. If no, continue to #10.

10. Proceed to specific criteria for the submitted indication.

Ankylosing Spondylitis

Crohn's Disease
Hidradenitis Suppurativa
Juvenile Idiopathic Arthritis
Plaque Psoriasis
Psoriatic Arthritis
Rheumatoid Arthritis
Ulcerative Colitis
Uveitis

Ankylosing Spondylitis

Initial Criteria:

1. Does the member have ankylosing spondylitis? Diagnosis is definitive if both are met:
    a. Radiological evidence of sacroilitis
    b. Clinical evidence with two of three:
        i. low back pain and stiffness for more than 3 months which improves with exercise but is not relieved by rest;
        ii. limitation of motion of the lumbar spine in the sagittal and frontal planes;
        iii. limitation of chest expansion relative to normal values correlated for age and sex

    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 **all** 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, **and**
    - For peripheral disease only: Sulfasalazine for at least 4 months at standard target dose or maximally tolerated dose.

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

5. Is the request for Cosentyx?
    a. 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 6 months.

Ankylosing Spondylitis

Renewal Criteria:

1. Does the member have significant improvement in signs and symptoms of AS 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 prednisone or methylprednisolone?
   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. Remicade, AND
   b. Humira, AND
   c. Entyvio or Tysabri
   If yes, continue to #10. If no, do not approve.

10. Approve for 6 months.

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.

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 #5. 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:
   a. Intra-articular glucocorticoid injections (if fewer than 4 joints affected) OR
   b. NSAIDS for at least one month?
   If yes, continue to #6. If no, do not approve.

5. Has the member tried and failed systemic corticosteroids?
   If yes, continue to #6. If no, do not approve.

6. Has the member had at least a 3 month trial of methotrexate or leflunomide or contraindication to both?
   If yes, continue to #7. If no, do not approve.

7. 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 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 3 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, 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 or sulfasalazine.

   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 6 months.

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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 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.

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 prednisone or methylprednisolone?
   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, mesalamine, or sulfasalazine for maintenance?
   If yes, continue to #7. If no, do not approve.

7. Is the request for infliximab?
   If yes, continue to #9. If no, continue to #8.

8. Has the member tried and failed or have a contraindication to infliximab?
   If yes, continue to #9. If no, do not approve.

9. 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, 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 (prednisolone acetate, fluprednate) for at least 1 month, **and**
   - Oral corticosteroids, **and**
   - Methotrexate

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

4. Approve for 6 months.

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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.

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 (7 doses over 6 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.

<u>Tremfya:</u>

- 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.

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Generic Name Toclizumab

Brand Name Actemra

Created: 1/18/13
Revised: 9/12/13, 04/02/14, 09/14/17, 05/10/18

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 for the submitted diagnosis. If no, continue to #3.

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.

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.

Juvenile Idiopathic Arthritis
Initial Criteria:

9. 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 #4. If no, continue to #2.

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

11. Has the member tried and failed either:
    a. Intra-articular glucocorticoid injections (if fewer than 4 joints affected) OR
    b. NSAIDS for at least one month?
    If yes, continue to #5. If no, do not approve.

12. Has the member tried and failed systemic corticosteroids?
    If yes, continue to #6. If no, do not approve.

13. Has the member tried and failed ALL of the following:
    a. methotrexate or leflunomide for at least 3 months or contraindication to both.
    b. One TNF inhibitor or a contraindication to all.
    If yes, continue to #8. If no, do not approve.

14. 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 #7. If no, continue to #8.

15. Has the member had at least a 3 month trial of methotrexate or leflunomide or contraindication to both?
    If yes, continue to #8. If no, do not approve.

16. Approve for 6 months.

Systemic Juvenile Idiopathic Arthritis
Renewal Criteria:

2. 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.

3. 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.

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.

Generic Name Tolterodine

Brand Name Detrol

Created: 9/26/12

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

Initial Criteria

1. Does the member have a bleeding disorder and the request is to prevent bleeding in a dental procedure?
   If yes, approve for 1 month. 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. Does the member have an underlying bleeding disorder such as von Willebrand's or hemophilia?
   If yes, approve for 12 months If no, continue to #4.

4. 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.
   - Anemia due to acute or chronic blood loss (hemoglobin less than 10 g/dL or hemoglobin less than 11 g/dL if use of iron is documented).
   - Bleeding causes major impairment or interferes with quality of life.

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

5. 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 #6. If no, do not approve.

6. Has the member failed a trial of naproxen given on a scheduled basis at maximum tolerated dose starting the first day of menses for 5 days or until menses cease?
   If yes, continue to #7 If no, do not approve.

7. 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.

Generic Name Treprostinil

Brand Name Remodulin, Tyvaso

Revised: 4/28/10
Reviewed: 9/13/12, 9/12/13

Initial Criteria:

1. Is Remodulin being requested by a pulmonologist or cardiologist?
   If yes, continue to #2. If no, do not approve.

2. Is the member a current smoker?
   If yes, continue to #3. If no, continue to #4.

3. Is the member enrolled in a smoking cessation program?
   If yes, continue to #4. If no, consult with provider.

4. Does the member have a diagnosis of pulmonary arterial hypertension WHO Group 1 diagnosed by right heart catheterization?
   If yes, continue to #5. If no, do not approve. WHO Groups 2-5 not indicated.

5. Does the member meet the ALL of the following criteria?
   a. Mean PAP ≥ 25 mm Hg at rest, and
   b. Pulmonary Capillary Wedge Pressure ≤15 mm Hg at rest, and
   c. NYHA functional class II to IV symptoms
   If yes, continue to #6. If no, do not approve.

6. Has the member had a positive response to vasoreactivity testing such as?
   a. ≥ 25% reduction in mean PVR, or
   b. Fall in mean PAP of at least 10 and ≤ 40mm Hg, or
   c. Increase or unchanged cardiac output.
   If yes, do not approve. Calcium channel blocker indicated. If no, continue to #7.

7. Has the member tried and failed or have contraindications to treatment with sildenafil, bosentan (Tracleer) or ambrisentan (Letairis)?
   If yes, approve x 16 weeks. If no, do not approve.

Renewal Criteria:

1. Does the member meet any of the following treatment goals?
   a. A significant increase in the 6-minute walk test, or
   b. Decrease in dyspnea fatigue rating and other symptoms, or

c. Evidence of hemodynamic improvement such as a reduction in mPAP and PVR, or
d. Improvement in NYHA functional class, or
e. Lack of functional or hemodynamic deterioration.

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 Varenicline

Brand Name Chantix

Revised: 4/6/09, 5/12/16
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 re-treatment (check claims history for previous Chantix claims)?
   If yes, continue to #2. If no, deny.

2. Has the provider outlined a different treatment plan to ensure successful smoking cessation (i.e. enhanced counseling, increased member motivation, enrollment in smoking cessation program)?
   If yes, continue to #3. If no, request additional information.

3. Is the member enrolled in a smoking cessation counseling program, such as Quit for Life?
   If yes, continue to #4. If no, request documentation of enrollment.

4. Approve for 12 weeks.

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.

Generic Name Vedolizumab

Brand Name Entyvio
Created: 10/30/14
Revised: 6/17/15

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

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. Has the member failed to achieve remission with prednisone, hydrocortisone, or methylprednisolone?

    If yes, continue to #3. If no, continue to #4.

3. Has the patient failed Humira and Remicade?

    If yes, continue to #5. If no, do not approve and recommend untried agents.

4. Is the request for maintenance of remission in a patient who already achieved remission with Entyvio?

    If yes, continue to renewal. If no, do not approve and recommend azathioprine, 6-mercaptopurine, or sulfasalazine for maintenance.

5. Is Entyvio being initiated or supervised by a gastroenterologist?

    If yes, approve x 14 weeks. If no, do not approve.

Renewal Criteria:

Ulcerative colitis

1. Has the member demonstrated a significant response including the following:
    a. Decrease in bloody stools per day and/or
    b. Elimination of signs of toxicity

    If yes, approve for 1 year. If no, do not approve.

Initial Criteria:
Crohn's Disease

1. Does the member have a diagnosis of moderate to severe Crohn's disease? (i.e. Crohn's Disease Activity Index (CDAI) 220-450)
   If yes, continue to #2. If no, do not approve.

   (Note: Moderate and Severe Disease: failed treatment for mild to moderate disease or has more prominent symptoms including fevers, significant weight loss, abdominal pain or tenderness, intermittent nausea or vomiting (without obstructive findings), or significant anemia, evidence of intestinal obstruction, cachexia, or evidence of abscess.)

2. Is the request for induction of remission?
   If yes, continue to #3. If no, continue to #5.

3. Has the member failed to achieve remission with prednisone or methylprednisolone?
   If yes, continue to #4. If no, do not approve.

4. Has the member failed at least TWO TNF-alpha inhibitors (e.g. Humira, Remicade, Cimzia)?

5. If yes, continue to #6. If no, do not approve .Is the request for maintenance of remission in a patient who already achieved remission with Entyvio?
   If yes, continue to renewal. If no, do not approve and recommend azathioprine, 6-mercaptopurine, or methotrexate for maintenance.

6. Is Entyvio being initiated or supervised by a gastroenterologist?
   If yes, approve for 14 weeks. If no, do not approve.

Renewal Criteria:
Crohn's Disease

1. Has the member experienced a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission?
   If yes, approve x 1 year. If no, do not approve.

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, oxcarbazapeine, 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 #Vitamin K
Phytonadione #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:

1. Does the patient have retinal dystrophy with confirmed bi-allelic RPE65 mutations (documented genetic testing required)?
   If yes, continue to #2. If no, deny.

2. 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.

3. Is the member greater than 1 year of age?
   If yes, continue to #4. If no, deny.

4. 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.

5. 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.

6. 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

7. 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.

8. 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.

9. Has independent review agreed all criteria above are met?
   If yes, approve. If no, submit to MRIoA 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 *Aspergillius* 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 *Aspergillius* 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 6 or less?
   If yes, approve until age 7. 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 – 6 years: Approve until age 7.
Ages 7-18 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 Not Covered per Guideline Note #144 If no, continue to #5

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 7-18 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 7?
If yes, approve until age 7. 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 6:
Clindamycin, methylphenidate, nizatidine, propranolol, Trileptal, Vibramycin, Viread, Cipro
Suspension/Solution Products with age max of 8:
Tamiflu

1. Is the request for Tamiflu Suspension?
If yes, continue to #2. If no, continue to #3.

2. Is the member less than the age of 9?
If yes, approve until age 9. If no, continue to #4

3. Is the member less than the age of 7?
If yes, approve until age of 7. If no, continue to #4

4. 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 dexmethylphenidate 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, approve x life. If no, deny for criteria not met.

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.