

“What’s New” Medical Pharmaceutical Policy May 2018 Updates

MBP 4.0 Intravenous Immune Globulin (IVIG)- Updated policy

- **Myasthenia Gravis**

The following criteria must be met:

1. Must be prescribed by a neurologist; AND
2. Documentation of therapeutic failure on, intolerance to, or contraindication to at least two standard treatments (e.g. cholinesterase inhibitors, azathioprine, corticosteroids) and /or a combination of these treatments for a minimum of 3 months; AND

Medical documentation of one of the following indications:

3. Diagnosis of acute myasthenic crisis with decompensation; OR
4. Use during postoperative period following a thymectomy; OR
5. Use prior to planned thymectomy

~~Note: For chronic forms of Myasthenia Gravis, treatment with IVIG is considered investigational and is not covered.~~

MBP 5.0 Remicade (infliximab), Inflectra (infliximab-dyyb), Renflexis (infliximab-abda)- Updated policy

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

GRANDFATHER PROVISION – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature

Remicade (infliximab), Inflectra (infliximab-dyyb) or Renflexis (infliximab-abda) will be considered medically necessary when all of the following criteria are met based on indication:

For Treatment of Rheumatoid Arthritis:

- Must be 18 years of age or greater **AND**
- Requesting provider must be a rheumatologist **AND**
- Diagnosis of moderate to severe rheumatoid arthritis according the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis

AND

- Medical record documentation that the infliximab product is **not being used concurrently with a TNF blocker or other biologic agent AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* **AND** Enbrel* **AND**
- Continuation of effective dose of methotrexate during infliximab therapy **AND**
- For new start Remicade or Renflexis requests, medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Inflectra*

Recommended guidelines for use in the treatment of rheumatoid arthritis

- 3 mg/kg given as an intravenous infusion followed with additional similar doses at 2 and 6 weeks after the first infusion then every 8 weeks thereafter. Infliximab should be given in combination with methotrexate.
- For patients who have an incomplete response, consideration may be given to adjusting the dose up to 10 mg/kg or treating as often as every 4 weeks.

For Treatment of Crohn’s Disease, Pediatric Crohn’s Disease, and/or Fistulizing Crohn’s Disease:

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- Must be 6 years of age or older; **AND**
 - Prescription is written by a gastroenterologist **AND**
 - Medical record documentation of a diagnosis of moderate to severe Crohn's disease **AND**
 - **Medical record documentation that the infliximab product is not being used concurrently with a TNF blocker or other biologic agent **AND****
 - One of the following:
 - Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Humira* **OR**
 - Physician documentation of Crohn's disease with actively draining fistulas.
- AND**
- For new start Remicade or Renflexis requests, medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Inflectra*

Recommended guidelines for use in the treatment of crohn's disease or fistulizing crohn's disease:

- 5 mg/kg given intravenously as an induction regimen at 0, 2, and 6 weeks followed by a maintenance regimen of 5 mg/kg every 8 weeks thereafter
- For adult members who respond and then lose response, consideration may be given to treatment with 10 mg/kg.

For Treatment of Ulcerative Colitis:

- Must be at least 6 years of age; **AND**
 - Must be prescribed by a gastroenterologist; **AND**
 - Physician provided documentation of a diagnosis of moderate to severe ulcerative colitis;
- AND**
- Physician provided documentation of failure on, intolerance to, or contraindication to adequate trials of conventional therapy that include corticosteroids, aminosalicylates and immunomodulators (eg, 6-mercaptopurine or azathioprine **AND**
 - **Medical record documentation that the infliximab product is not being used concurrently with a TNF blocker or other biologic agent **AND****
 - Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to at least a 12 week trial of Humira* **OR** medical record documentation of age < 18 years **AND**
 - For new start Remicade requests, medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Inflectra* **OR** medical record documentation of age <18 years **OR**
 - For new start Renflexis requests, medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3-month trial of Inflectra*

Recommended guidelines for the use in the treatment of ulcerative colitis

- 5 mg/kg as an intravenous infusion followed with additional similar doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter.

For Treatment of Ankylosing Spondylitis:

- Physician documentation of a diagnosis of ankylosing spondylitis **AND**
- Prescribing physician must be a rheumatologist **AND**
- Must be at least 18 years of age **AND**
- **Medical record documentation that the infliximab product is not being used concurrently with a TNF blocker or other biologic agent **AND****
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* **AND** Cosentyx* **Enbrel*** **AND**
- For new start Remicade or Renflexis requests, medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Inflectra*

Recommended guidelines for use in ankylosing spondylitis

- 5mg/kg at 0, 2 and 6 weeks, then every 6 weeks thereafter

For the treatment of Plaque Psoriasis:

- Prescribed by a dermatologist **AND**
- Insured individual must be at least 18 years of age **AND**
- Physician provided documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% body surface area involved or disease affecting crucial body areas such as the hands, feet, face, or genitals **AND**
- Medical record documentation that the infliximab product is **not** being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an inadequate response to, contraindication to, or failure on at least 3 months of Humira* **AND** Cosentyx* ~~Enbrel*~~ **AND**
- For new start Remicade or Renflexis requests, medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Inflectra*

Recommended guidelines for the use in the treatment of plaque psoriasis

- 5 mg/kg as an intravenous infusion followed with additional similar doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter.

For the treatment of Psoriatic Arthritis:

- Physician provided documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include the following:
 - Documentation of either active psoriatic lesions or a documented history of psoriasis **AND**
- Must be prescribed by a rheumatologist or dermatologist **AND**
- Must be at least 18 years of age **AND**
- Medical record documentation that the infliximab product is **not** being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an inadequate response to, contraindication to, or failure on 12 weeks of Humira* and Cosentyx* ~~Enbrel*~~ **AND**
- For new start Remicade or Renflexis requests, medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Inflectra*

Recommended guidelines for the use in the treatment of psoriatic arthritis

- 5 mg/kg as an intravenous infusion followed with additional similar doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter.

AUTHORIZATION DURATION: Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of the treated indication at six (6) months of infliximab therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of the treated indication while on infliximab therapy.

LIMITATIONS: Inflectra and Renflexis are not approved for the use in pediatric ulcerative colitis due to orphan drug exclusivity for Remicade

MBP 13.0 Viscosupplementation using hyaluronan injections (Euflexxa, Gel-One, GenVisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, Supartz FX, Visco-3) - Updated policy

Hyaluronan, also known as hyaluronic acid, is a naturally occurring macromolecule that is a major component of synovial fluid. In osteoarthritis, there are changes in the quality and quantity of hyaluronan in the synovial fluid and cartilage. Intra-articular injection of hyaluronan (~~FDA-approved products include Euflexxa, Synvisc, Synvisc One, Orthovisc, Supartz, Hyalgan, Monovisc, and Gel-One~~) has been proposed as a means of restoring viscoelasticity of the synovial fluid in patients with osteoarthritis. This treatment is also known as viscosupplementation.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

NOTE: ~~Euflexxa~~, Gelsyn-3, Synvisc, and Synvisc One are preferred agents and DO NOT Require Prior Authorization

~~Euflexxa~~, Gel-One, GenVisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, Supartz FX, and Visco-3 require Prior Authorization and will be considered medically necessary when all of the following criteria are met:

- Physician documented symptomatic osteoarthritis of the knee, defined as knee pain associated with radiographic evidence of osteophytes in the knee joint provided the clinical presentation is not that of "bone-on-bone", morning stiffness of less than or equal to 30 minutes in duration, crepitus on range of motion; **AND**
- Physician documented knee joint pain sufficient to interfere with ambulatory functional activities; **AND**
- Physician documentation of non-pharmacologic modalities, e.g., weight loss, quadriceps muscle strengthening, other physical therapy modalities, or exercises that have not promoted satisfactory symptomatic relief; **AND**
- Physician documentation that there has been no significant improvement following pharmacologic therapy with a full-dose nonsteroidal anti-inflammatory drug (NSAID) regimen, with or without supplemental acetaminophen, over a 10-12 week period of time or if NSAID's are contraindicated, a failure of daily acetaminophen regimen over a 4 to 6 week period; **AND**
- Physician documentation that there has been no significant improvement following standard dose intra-articular corticosteroid injection(s) e.g., a satisfactory clinical response of greater than or equal to 3 months; this requirement does not apply if the use of corticosteroids might increase the risk of local or systemic bacterial infection, e.g., diabetes mellitus; **AND**
- Physician documentation of failure on, intolerance to or contraindication to ~~Euflexxa~~, Gelsyn-3, Synvisc, and Synvisc One

AUTHORIZATION DURATION/QUANTITY LIMIT: Initial approval will be for **six (6) months** and will be **limited to one (1) treatment course** to the affected knee(s) (bilateral injections may be allowed if both knees meet the required coverage criteria). Subsequent approvals will be for six (6) months and will be limited to one (1) treatment course to the affected knee(s) when members meet the following criteria:

- Repeat treatment cycles are considered medically necessary when ALL of the following criteria are met:
 1. Medical record documentation of significant improvement in pain and function following the previous injection; **AND**
 2. Documented reduction of the doses of nonsteroidals or analgesics during the six month period following the last injection in the previous series as well as no need for accompanying intra-articular steroid injections; **AND**
 3. Six months or longer have elapsed since the last injection in the previous series.

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LIMITATIONS:

- Euflexxa treatment course is limited to 3 6 injections, one week apart, in a 42 6-month period
- Gel-One treatment course is limited to 1 2 injections in a 42 6-month period.
- Gelsyn-3 treatment course is limited to 3 injections in a 6-month period.
- GenVisc 850 treatment course is limited to 5 injections in a 6-month period.
- Hyalgan (sodium hyaluronate) treatment course is limited to 5 40 injections in a 42 6-month period.
- Hymovis treatment course is limited to 2 injections in a 6-month period.
- Monovisc treatment course is limited to 1 2 injections in a 42 6-month period.
- Orthovisc treatment course is limited to 4 8 injections in a 42 6-month period.
- Supartz treatment course is limited to 5 40 injections in a 42 6-month period.
- Synvisc (Hylan G-F 20) treatment course is limited to 3 6 injections in a 42 6-month period.
- Synvisc One treatment is limited to 1 2 injections in a 42 6-month period.
- Visco-3 treatment course is limited to 3 injections in a 6-month period.
- Treatment requires referral to, and should be rendered by a participating Orthopedic surgeon or Rheumatologist.
- Bilateral injections may be allowed if both knees meet the required coverage criteria.

MBP 40.0 Orenzia IV (abatacept)- Updated policy

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

GRANDFATHER PROVISION – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature

Orenzia IV (abatacept) will be considered medically necessary when all of the following criteria are met:

1. Rheumatoid arthritis that is refractory to DMARD therapy, including TNF(Tumor necrosis factor) antagonists:
 - Documentation of a diagnosis of moderate to severe RA in accordance with the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis; **AND**
 - Member must be at least 18 years old; **AND**
 - Must be prescribed by a rheumatologist; **AND**
 - Medical record documentation that Orenzia is not being used concurrently with a TNF blocker or other biologic agent **AND**
 - Documentation of inadequate response to minimum 3 month trial of one preferred TNF alpha inhibitor Enbrel OR Humira)
2. Polyarticular Juvenile Idiopathic Arthritis (PJIA)
 - Insured individual is 6 years of age or older ; **AND**
 - Medical record documentation of a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis or juvenile rheumatoid **AND**
 - Must be prescribed by a rheumatologist; **AND**
 - Medical record documentation that Orenzia is not being used concurrently with a TNF blocker or other biologic agent **AND**
 - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a minimum 4 month trial of one preferred TNF alpha inhibitor (Enbrel **OR** Humira)
3. Psoriatic Arthritis (PsA):

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- Prescription written by a rheumatologist **AND**
- Medical record documentation of a diagnosis of moderate to severe active psoriatic arthritis which must include the following:
 - Documentation of either active psoriatic lesions OR a documented history of psoriasis. **AND**
- ~~Medical record documentation of a diagnosis of active psoriatic arthritis AND~~
- Medical record documentation of age ≥ 18 years of age **AND**
- Medical record documentation that Orencia is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an inadequate response to a minimum 3 month trial of one preferred ~~TNF-alpha-inhibitor~~ biologic (Humira* **AND OR** Cosentyx* ~~Enbrel*~~)

MBP 54.0 Soliris (eculizumab)- Updated policy

Soliris (eculizumab) will be considered medically necessary when all of the following criteria are met **per indication:**

- ~~1. Soliris® is indicated for the reduction of hemolysis in the treatment of paroxysmal nocturnal hemoglobinuria (PNH) when all of the following criteria are met:~~

1. Paroxysmal Nocturnal Hemoglobinuria (PNH)

- Medical record documentation of a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)
- Physician provided documentation of flow cytometry confirming diagnosis AND
- Physician provided documentation of Soliris being prescribed by a hematologist AND
- Physician provided documentation of the insured individual being vaccinated with the meningococcal vaccine AND
- Physician documentation of one of the following:
 - member is transfusion-dependent (i.e., has at least 1 transfusion in the 24 months prior to initiation of eculizumab due to documented hemoglobin less than 7 g/dL in persons without anemic symptoms or less than 9 g/dL in persons with symptoms from anemia) prior to initiation of eculizumab treatment; **or**
 - there is a significant adverse impact on the insured individual's health such as end organ damage or thrombosis without other cause.

AUTHORIZATION DURATION: Approval will be given for six months. Additional coverage will only be provided when documentation of the following is provided:

- Member requires fewer transfusions or has stabilization of Hb levels **AND**
- Reduction in intravascular hemolysis as evidenced reduction in elevated LDH levels from baseline **AND**
- No recurrent infections

- ~~2. Soliris is indicated for the treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy.~~

2. Atypical Hemolytic Uremic Syndrome (aHUS)

- Medical record documentation of a diagnosis of atypical hemolytic uremic syndrome (aHUS) (Soliris is used to inhibit complement-mediated thrombotic microangiopathy)

AUTHORIZATION DURATION: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

3. Generalized Myasthenia Gravis (gMA)

- Medical record documentation supporting a confirmed diagnosis of Generalized Myasthenia Gravis **AND**
- Medical record documentation that member is anti-acetylcholine receptor (AChR) antibody positive **AND**
- Prescribed by or in consultation with a neuromuscular specialist **AND**
- Medical record documentation of Myasthenia Gravis Foundation of America Clinical Classification (MGFA) Class II to IV **AND ***
- Medical record documentation Myasthenia Gravis-Activities of Daily Living (MG-ADL) score of 6 or more at baseline **AND****
- Medical record documentation of age ≥ 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to corticosteroids **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to cholinesterase inhibitors **AND**
- Medical record documentation of therapeutic failure on intolerance to, or contraindication to at least two (2) non-steroidal immunosuppressive therapies **OR** has failed at least one (1) immunosuppressive therapy and required chronic plasmapheresis or plasma exchange (PE) **AND**
- Medical record documentation of failure on intolerance to, or contraindication to Rituxan **AND**
- Medical record documentation of failure on intolerance to, or contraindication to intravenous immunoglobulin (IVIG)

AUTHORIZATION DURATION: Initial approval will be given for six months.

Subsequent approvals will be for an additional six months and will require:

- Medical record documentation of continued disease improvement or lack of disease progression **AND**
 - Medical record documentation that the member is responding positively to therapy as evidenced by a 3-point reduction in MG-ADL total score**;
- The medication will no longer be covered if patient experiences toxicity or worsening of disease.

**Note: Class I Myasthenia gravis is indicated by any eye muscle weakness, possible ptosis (drooping or falling of the upper eyelid) and no other evidence of muscle weakness elsewhere. Class II to IV include muscle weakness in areas of the body beyond the eye.*

*Note: Corticosteroids: betamethasone, dexamethasone, methylprednisolone, prednisone
Cholinesterase inhibitors: pyridostigmine, neostigmine
Immunosuppressants: azathioprine, mycophenolate, cyclosporine, Rituxan*

Note: Dosing for MG is 900 mg IV every 7 days for the first 4 weeks, followed by a single dose of 1,200 mg 7 days after the fourth dose, and then 1,200 mg every 2 weeks thereafter. Max dosage is 1,200 mg per dose.

MG Activities of Daily Living (MG-ADL)**

Grade	0	1	2	3	Score
Talking	Normal	Intermittent slurring or nasal speech	Constant slurring or nasal, but can be understood	Difficult to understand speech	
Chewing	Normal	Fatigue with solid food	Fatigue with soft food	Gastric tube	
Swallowing	Normal	Rare episode of choking	Frequent choking necessitating changes in diet	Gastric tube	
Breathing	Normal	Shortness of breath with exertion	Shortness of breath at rest	Ventilator dependence	
Impairment of ability to brush teeth or comb hair	None	Extra effort, but no rest periods needed	Rest periods needed	Cannot do one of these functions	
Impairment of ability to arise from a chair	None	Mild, sometimes uses arms	Moderate, always uses arms	Severe, requires assistance	
Double vision	None	Occurs, but not daily	Daily, but not constant	Constant	
Eyelid droop	None	Occurs, but not daily	Daily, but not constant	Constant	

Total score _____

MBP 74.0 Cimzia (certolizumab pegol)- Updated policy

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

GRANDFATHER PROVISION – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature

Cimzia (certolizumab pegol) will be considered medically necessary when all of the following criteria are met:

1. Crohn's disease:

- Physician documentation for a diagnosis of moderate to severe Crohn's disease **AND**
- Prescription written by a gastroenterologist **AND**
- Insured individual is 18 years of age or older **AND**
- Medical record documentation that Cimzia is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on Humira* (*requires prior authorization)

QUANTITY LIMIT:

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New starts: One-week authorization for QL of 6 syringes (3 kits) per 28 days, Remainder of the 6-month authorization duration QL of 2 syringes (1 kit) per 28 days
Continued maintenance: QL of 2 syringes (1 kit) per 28 days

AUTHORIZATION DURATION:

Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of Crohn's disease at six (6) months of Cimzia therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of Crohn's disease while on Cimzia therapy.

2. Rheumatoid Arthritis

- Physician documentation for a diagnosis of moderate to severe rheumatoid arthritis (made in accordance with the American College of Rheumatology Criteria for the Classification of Diagnosis of Rheumatoid Arthritis); **AND**
- Prescription written by a rheumatologist **AND**
- Insured individual is 18 years of age or older **AND**
- Medical record documentation that Cimzia is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* **AND** Enbrel* (*requires prior authorization)

QUANTITY LIMIT:

New starts: One-week authorization for QL of 6 syringes (3 kits) per 28 days, Remainder of the 6-month authorization duration QL of 2 syringes (1 kit) per 28 days
Continued maintenance: QL of 2 syringes (1 kit) per 28 days

AUTHORIZATION DURATION:

Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of rheumatoid arthritis at six (6) months of Cimzia therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of rheumatoid while on Cimzia therapy.

3. Psoriatic Arthritis

- Must be ordered by a rheumatologist or dermatologist **AND**
- Insured individual is 18 years of age or older **AND**
- Physician documentation for a diagnosis of active psoriatic arthritis as evidenced by:
 - Documentation of either active psoriatic lesions or a history of psoriasis **AND**
- Medical record documentation that Cimzia is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* **AND** Cosentyx* ~~Enbrel*~~ (*requires prior authorization)

QUANTITY LIMIT:

New starts: One-week authorization for QL of 6 syringes (3 kits) per 28 days, Remainder of the 6-month authorization duration QL of 2 syringes (1 kit) per 28 days
Continued maintenance: QL of 2 syringes (1 kit) per 28 days

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AUTHORIZATION DURATION:

Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of psoriatic arthritis at six (6) months of Cimzia therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of psoriatic arthritis while on Cimzia therapy.

4. Ankylosing Spondylitis

- Must be ordered by a rheumatologist; **AND**
- Insured individual is 18 years of age or older; **AND**
- Physician documentation of a diagnosis of ankylosing spondylitis; **AND**
- Medical record documentation that Cimzia is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* **AND** Cosentyx* ~~Enbrel*~~ (*requires prior authorization)

QUANTITY LIMIT:

New starts: One-week authorization for QL of 6 syringes (3 kits) per 28 days, Remainder of the 6-month authorization duration QL of 2 syringes (1 kit) per 28 days

Continued maintenance: QL of 2 syringes (1 kit) per 28 days

AUTHORIZATION DURATION:

Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of ankylosing spondylitis at six (6) months of Cimzia therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of ankylosing spondylitis while on Cimzia therapy.

MBP 75.0 Stelara (ustekinumab)- Updated policy

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

GRANDFATHER PROVISION – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature

Stelara (ustekinumab) will be considered medically necessary when all of the following criteria are met:

1. For plaque psoriasis
 - Prescription must be written by a dermatologist **AND**
 - Member must be at least 18 years of age **AND**
 - Medical record documentation that the prescribed dosing is appropriate for patient's weight **AND**
 - Medical record documentation of moderate to severe plaque psoriasis characterized by $\geq 5\%$ of body surface area involved or disease affecting crucial body areas such as the hands, feet, face, or genitals **AND**

- **Medical record documentation that Stelara is not being used concurrently with a TNF blocker or other biologic agent AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* **AND Cosentyx* Enbrel***

*Requires Prior Authorization

AUTHORIZATION DURATION:

Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of plaque psoriasis at six (6) months of Stelara therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of plaque psoriasis while on Stelara therapy.

2. For psoriatic arthritis
 - Prescription must be written by a rheumatologist or a dermatologist **AND**
 - Member must be at least 18 years of age **AND**
 - Medical record documentation that the patient is going to receive a dose of 45 mg every 12 weeks OR medical record documentation that the patient has a co-existing diagnosis of moderate-to-severe plaque psoriasis and weighs > 100 kg. **AND**
 - Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include the following:
 - Documentation of either active psoriatic lesions or a documented history of psoriasis **AND**
 - **Medical record documentation that Stelara is not being used concurrently with a TNF blocker or other biologic agent AND**
 - Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* **AND Cosentyx* Enbrel***

*Requires Prior Authorization

AUTHORIZATION DURATION: Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of psoriatic arthritis at six (6) months of Stelara therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of psoriatic arthritis while on Stelara therapy.

3. For Crohn's disease (CD)
 - Prescription must be written by a gastroenterologist **AND**
 - Member must be at least 18 years of age **AND**
 - Medical record documentation of moderately to severely active Crohn's disease **AND**
 - **Medical record documentation that Stelara is not being used concurrently with a TNF blocker or other biologic agent AND**
 - Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3-month trial of three (3) of the following medications: Humira*, Cimzia*, Entyvio*, infliximab (Remicade or Inflectra) *, or Tysabri* **AND**

- Medical record documentation of Stelara 130mg vials as IV infusion (for induction therapy) OR Stelara 90mg syringes (for maintenance therapy) being prescribed.

*Requires Prior Authorization

Note to reviewer: Stelara 45mg syringe is not indicated for use in Crohn's disease.

AUTHORIZATION DURATION: If determined to be medically necessary, Stelara should be approved for an initial authorization duration of six **(6) months**. After the initial 6-month maintenance approval, subsequent approvals for coverage will be for a duration of twelve **(12) months** requiring medical record documentation of continued or sustained improvement in the signs and symptoms of Crohn's disease while on Stelara therapy.

MBP 112.0 Simponi Aria (golimumab)- Updated policy

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

GRANDFATHER PROVISION – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature

Simponi Aria (golimumab) will be considered medically necessary when all of the following criteria are met per indication:

Rheumatoid Arthritis

- Requesting provider must be a rheumatologist **AND**
- Medical record documentation of age ≥18 years **AND**
- Medical record documentation of a diagnosis of moderate to severe rheumatoid arthritis according to the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis **AND**
- Medical record documentation that Simponi Aria will be given in combination with methotrexate **AND**
- Medical record documentation that Simponi Aria is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an inadequate response to, contraindication to, or failure on 12 weeks of etanercept (Enbrel*) **AND** adalimumab (Humira*) therapy.

Psoriatic Arthritis

- Requesting provider must be a rheumatologist or dermatologist **AND**
- Medical record documentation of age ≥18 years **AND**
- Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis, which must include the following:
 - Documentation of active psoriatic lesions OR documentation of a history of psoriasis **AND**
- Medical record documentation that Simponi Aria is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an inadequate response to, contraindication to, or failure on 12 weeks of secukinumab (Cosentyx*) **AND** adalimumab (Humira*) therapy.

Ankylosing Spondylitis

- Requesting provider must be a rheumatologist **AND**
- Medical record documentation of age ≥18 years **AND**
- Medical record documentation of a diagnosis of ankylosing spondylitis **AND**

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- Medical record documentation that Simponi Aria is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an inadequate response to, contraindication to, or failure on 12 weeks of secukinumab (Cosentyx*) **AND** adalimumab (Humira*) therapy.

(*requires prior authorization)

AUTHORIZATION DURATION: Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms **of disease of rheumatoid arthritis** at six (6) months of Simponi Aria therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms **of disease of rheumatoid arthritis** while on Simponi Aria therapy.

MBP 126.0 Opdivo (nivolumab)- Updated policy

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

GRANDFATHER PROVISION – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature

Opdivo (nivolumab) will be considered medically necessary when all of the following criteria are met:

1. *Melanoma*

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 18 years of age **AND**
- Medical record documentation of one of the following:
 - A diagnosis of unresectable or metastatic melanoma **AND**
 - Opdivo is not being used in combination with any other agents for the treatment of unresectable or metastatic melanoma (with the exception of ipilimumab).

OR

- A diagnosis of completely resected (no evidence of disease) metastatic melanoma with distant metastases, which may include lymph nodes **AND**
- Medical record documentation of complete resection of distant metastases **AND**
- Opdivo is being used in the adjuvant setting **AND**
- Opdivo is being used as a single agent

**** (Note: The FDA-approved treatment duration for use of Opdivo in the adjuvant setting for completely resected metastatic melanoma is for up to 1 year, see specific reauthorization criteria below.)**

- ~~• Medical record documentation of a diagnosis of unresectable or metastatic melanoma **AND**~~
- ~~• Medical record documentation that Opdivo is not being used in combination with any other agents for the treatment of unresectable or metastatic melanoma (with the exception of ipilimumab).~~

2. *Non-Small Cell Lung Cancer (NSCLC)*

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 18 years of age **AND**

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- Medical record documentation of a diagnosis of metastatic non-small cell lung cancer (NSCLC) with disease progression while on or after platinum-based chemotherapy **AND**
- Medical record documentation that Opdivo is not being used in combination with any other agents for the treatment of metastatic non-small cell lung cancer (NSCLC)

3. *Renal Cell Carcinoma*

- Medical record documentation of use as a single agent for relapse or for surgically unresectable advanced or metastatic renal cell carcinoma **AND**
- Medical record documentation of a therapeutic failure on or intolerance to prior anti-angiogenic therapy, including, but not limited to, Sutent (sunitinib), Votrient (pazopanib), Inlyta (axitinib), Nexavar (sorafenib), Avastin (bevacizumab), Afinitor (everolimus), or Torisel (temsirolimus).

4. *Classical Hodgkin Lymphoma (CHL)*

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 18 years of age **AND**
- Medical record documentation of a diagnosis of classical Hodgkin lymphoma (CHL) that has relapsed or progressed after:
 - Autologous hematopoietic stem cell transplantation and post-transplantation brentuximab vedotin (Adcetris). OR
 - Three (3) or more lines of systemic therapy that includes autologous HSCT

5. *Squamous Cell Carcinoma of the Head and Neck (SCCHN)*

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 18 years of age **AND**
- Medical record documentation of a diagnosis of recurrent or metastatic squamous cell carcinoma of the head and neck **AND**
Medical record documentation of disease progression while on or after receiving a platinum-based therapy

6. *Urothelial Carcinoma*

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient > 18 years of age **AND**
- Medical record documentation of a diagnosis of locally advanced or metastatic urothelial carcinoma **AND** one of the following:
 - Disease progression during or following platinum-containing chemotherapy OR
 - Disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy**AND**
- Medical record documentation that Opdivo is NOT being used in combination with any other agent

7. *Colorectal Cancer*

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 12 years of age **AND**
- Medical record documentation of a diagnosis of metastatic colorectal cancer **AND**
- Medical record documentation of microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) disease **AND**

- Medical record documentation of progression following treatment with a fluoropyrimidine, oxaliplatin, or irinotecan

8. *Hepatocellular Carcinoma (HCC)*

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of hepatocellular carcinoma **AND**
- Medical record documentation of a therapeutic failure on or intolerance to sorafenib (Nexavar)

AUTHORIZATION DURATION: ~~Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.~~

****For adjuvant treatment of metastatic melanoma (completely resected melanoma):**

Initial approval will be for **6 months** or less if the reviewing provider feels it is medically appropriate. One subsequent approval will be for an additional **6 months** or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Authorization of Opdivo for the adjuvant treatment of metastatic melanoma should not exceed the FDA-approved treatment duration of 1 year (12 months). For requests exceeding the above limit, medical record documentation of the following is required:

- Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration

For all other indications:

Initial approval will be for **6 months** or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional **12 months** or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

MBP 131.0 Cosentyx (secukinumab) vials - Updated policy

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

GRANDFATHER PROVISION – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature

Cosentyx (secukinumab) vials will be considered medically necessary when all of the following criteria are met:

1. Plaque Psoriasis:

- Prescription must be written by a dermatologist **AND**
- Member must be 18 years of age or older **AND**
- Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by $\geq 5\%$ of body surface area involved or disease involving crucial body areas

such as the hands, feet, face, or genitals. **AND**

- Medical record documentation that Cosentyx is not being used concurrently with a TNF blocker or other biologic agent **AND**
- A therapeutic failure on, intolerance to, or contraindication to topical corticosteroids **AND** at least two to three months of systemic therapy (including but not limited to methotrexate and/or cyclosporine) or phototherapy **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy.
- ~~Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3-month trial of Humira* AND Enbrel*~~

2. Psoriatic Arthritis:

- Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include the following:
 - Documentation of either active psoriatic lesions or a documented history of psoriasis **AND**
- Prescription must be written by a rheumatologist or dermatologist **AND**
- Member must be at least 18 years of age **AND**
- Medical record documentation that Cosentyx is not being used concurrently with a TNF blocker or other biologic agent **AND**
- **For peripheral disease:** Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on methotrexate **AND** an adequate trial of at least two (2) formulary NSAIDs **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **OR**
- **For axial disease:** Medical record documentation of an intolerance to, contraindication to, or therapeutic failure to an adequate trial of at least two (2) formulary NSAIDs **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy
- ~~Medical record documentation of intolerance to, contraindication to, or therapeutic failure on a minimum 3-month trial of Humira* AND Enbrel*~~

3. Ankylosing Spondylitis:

- Medical record documentation of a diagnosis of ankylosing spondylitis **AND**
- Prescription must be written by a rheumatologist **AND**
- Member must be at least 18 years of age **AND**
- Medical record documentation that Cosentyx is not being used concurrently with a TNF blocker or other biologic agent **AND**
- A therapeutic failure on, contraindication to, or intolerance to an adequate trial of at least two (2) NSAIDs **OR** a therapeutic failure on or intolerance to prior biologic therapy **AND**
- ~~Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to a minimum 3-month trial of Humira* AND Enbrel* AND~~
- Medical record documentation that the medication is being dosed as 150 mg every 4 weeks with or without a loading dose of 150 mg at Weeks 0, 1, 2, 3, and 4.

MBP 158.0 Tepadina (thiotepa)- Updated policy

Tepadina (thiotepa) will be considered medically necessary when ALL of the following criteria are met:

- Prescription written by a pediatric hematologist/oncologist or pediatric transplant specialist **AND**
- Medical record documentation that the patient has a diagnosis of beta-thalassemia major **AND**
- Medical record documentation that the patient's disease is class 3 in severity as evidenced by the presence of ALL of the following:
 - Liver size > 2 cm

- Presence of liver fibrosis; and
- Inadequate iron chelation **AND**
- Medical record documentation that the patient is undergoing allogeneic hematopoietic progenitor stem cell transplant (HSCT) **AND**
- Medical record documentation that Tepadina is being used as part of a preparative regimen consisting of high-dose busulfan and cyclophosphamide **AND**
- Medical record documentation that the patient is under 18 years of age

OR

Requests for any of the following indications will be reviewed based on medical necessity:

- For treatment of adenocarcinoma of the breast or ovary
- For controlling intracavitary effusions secondary to diffuse or localized neoplastic diseases of various serosal cavities.
- For treatment of superficial papillary carcinoma of the urinary bladder.

AUTHORIZATION DURATION: Approved requests should be authorized one time for a total of **two doses**, with a quantity limit for an appropriate number of vials* of each strength based on the patient's weight (dose is 5mg/kg).

*Supplied as 15mg single-dose vial or 100mg single-dose vial

MBP 165.0 Rituxan Hycela (rituximab/hyaluronidase)- Updated policy

AUTHORIZATION DURATION: Initial approval will be for **6 months** or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional **12 months** or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Requests exceeding the maximum FDA-approved treatment duration (listed below) will require the following:

- Medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration **as listed in the chart below.**

Indication	Maximum Treatment Duration
Follicular Lymphoma (FL)	
Relapsed or Refractory	7 Weeks
Retreatment for Relapsed or Refractory	3 Weeks
Previously Untreated	21 Weeks (Seven 21-day cycles) for induction, up to 2 years for maintenance
Non-progressing after first line CVP chemotherapy	2 Years (16 doses given once weekly for 4 weeks in 6-month intervals)
Diffuse Large B-Cell Lymphoma (DLBCL)	21 Weeks (Seven 21-day cycles)
Chronic Lymphocytic Leukemia (CLL)	5 Months (Five 28-day cycles)

MBP 167.0 Vabomere (meropenem/vaborbactam)- New policy

DESCRIPTION:

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Vabomere (meropenem/vaborbactam) is an antibacterial drug containing a combination of meropenem, a penem antibacterial, and vaborbactam, a beta-lactamase inhibitor.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Vabomere (meropenem/vaborbactam) will be considered medically necessary when ALL of the following criteria are met:

- Prescribed by or in consultation with an infectious disease specialist **AND**
- Age of 18 years or greater **AND**
- Medical record documentation of a diagnosis of complicated urinary tract infections (cUTI) including pyelonephritis caused by the following susceptible microorganisms: *Enterobacter cloacae* species complex, *Escherichia coli*, or *Klebsiella pneumoniae* **AND**
- Medical record documentation of culture and sensitivity showing the patient's infection is not susceptible to alternative antibiotic treatments **OR** a documented history of previous intolerance to or contraindication to other antibiotics shown to be susceptible on the culture and sensitivity

AUTHORIZATION DURATION: Approvals will be made for a one-time authorization of 14 days.

QUANTITY LIMIT: 6 vials per day

MBP 169.0 Baxdela IV (delafloxacin) - New policy

DESCRIPTION:

Baxdela IV (delafloxacin) is a fluoroquinolone antibiotic that inhibits DNA gyrase (topoisomerase II) and topoisomerase IV enzymes, which are required for bacterial DNA replication, transcription, repair, and recombination.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Baxdela IV (delafloxacin) will be considered medically necessary when ALL of the following criteria are met:

- Medical record documentation that patient is greater than or equal to 18 years of age **AND**
- Medical record documentation of a diagnosis of acute bacterial skin and skin structure infections (ABSSSI)* caused by: *Staphylococcus aureus* (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates), *Staphylococcus haemolyticus*, *Staphylococcus lugdunensis*, *Streptococcus agalactiae*, *Streptococcus anginosus* Group (including *Streptococcus anginosus*, *Streptococcus intermedius*, and *Streptococcus constellatus*), *Streptococcus pyogenes*, *Enterococcus faecalis*, *Escherichia coli*, *Enterobacter cloacae*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa* **AND**
- Prescription written by or in consultation with Infectious Disease **AND**
- If Baxdela was initiated during an inpatient stay, medical record documentation of culture and sensitivity showing the patient's infection is not susceptible to alternative antibiotic treatments **OR** a documented history of previous intolerance to or contraindication to other antibiotics shown to be susceptible on the culture and sensitivity **AND**
- Medical record documentation of therapeutic failure on, intolerance to, contraindication to Baxdela tablets.

*Note to reviewer: ABSSSI is defined as a skin infection with a lesion surface area of at least 75 cm² and includes the three following types of infection: (1) cellulitis/erysipelas, (2) wound infections, and (3) major cutaneous abscesses.

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AUTHORIZATION DURATION: If approved, Baxdela IV will be authorized for 14 days, with a maximum of 28 doses.

MBP 170.0 Lutathera (lutetium Lu 177 dotatate)- New policy

DESCRIPTION:

Lutathera (lutetium Lu 177 dotatate) is a beta- and gamma-emitting radionuclide which binds to somatostatin receptors with highest affinity to subtype 2 receptors (SSRT2). Upon binding to somatostatin receptor expressing cells, including malignant somatostatin receptor-positive tumors, the compound is internalized. The beta emission from Lu 177 induces cellular damage by formation of free radicals in somatostatin receptor-positive cells and in neighboring cells.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Lutathera (lutetium Lu 177 dotatate) will be considered medically necessary when ALL of the following criteria are met:

- Prescribed by a hematologist/oncologist **AND**
- Patient is 18 years of age or older **AND**
- Medical record documentation of a diagnosis of gastroenteropancreatic neuroendocrine tumor (GEP-NET) (including foregut, midgut, and hindgut tumors) **AND**
- Medical record documentation of presence of somatostatin receptors on all lesions (somatostatin receptor positive disease) **AND**
- Medical record documentation that long-acting somatostatin analogs have been (or will be) discontinued at least 4 weeks prior to initiation of treatment with Lutathera

Note: Per the package labeling, short-acting somatostatin analogs may be used within 4 weeks of treatment with Lutathera but must be discontinued 24 hours prior to Lutathera treatment. Long-acting somatostatin analogs may be given between 4 and 24 hours after each Lutathera dose provided that it is again discontinued 4-weeks prior to retreatment with Lutathera. After completing Lutathera treatment, long-acting somatostatin analogs may be restarted for 18 months.

AUTHORIZATION DURATION: Approval will be for a one-time authorization of **4 visits (7 months)** of therapy. For requests exceeding the above limit, medical record documentation of the following is required:

- Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved labeling.

MBP 171.0 Varubi IV (rolapitant)- New policy

DESCRIPTION: Varubi IV (rolapitant) is a substance P/neurokinin (NK1) receptor antagonist that prevents delayed nausea and vomiting associated with emetogenic chemotherapy by selectively and competitively inhibiting the substance P/neurokinin 1 (NK1) receptor.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Varubi IV (rolapitant) will be considered medically necessary when ALL of the following criteria are met:

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- Medical record documentation that Varubi injectable emulsion is being used for the prevention of delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy OR
- Medical record documentation that Varubi is being used for the prevention of delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy for insured individuals who have a treatment failure or contraindication to ondansetron (Zofran) or granisetron (Kytril). Treatment failure is defined as allergy, intolerable side-effects, significant drug-drug interaction, or lack of efficacy.

The following antineoplastic agents are considered highly emetogenic (refer to NCCN for complete list):

- | | |
|--|--|
| <ul style="list-style-type: none"> • AC combination defined as any chemotherapy regimen that contains an anthracycline and cyclophosphamide • Carboplatin • Carmustine • Cisplatin • Cyclophosphamide at doses >1500 mg/m² • Dacarbazine • Dactinomycin | <ul style="list-style-type: none"> • Daunorubicin • Doxorubicin • Epirubicin • Ifosfamide • Irinotecan • Mechlorethamine • Methotrexate at doses > 250mg/m² • Oxaliplatin • Streptozotocin • Trabectedin |
|--|--|

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued symptom control and clinical benefit. Varubi will no longer be covered if patient experiences toxicity or worsening of symptoms.

MBP 172.0 Trisenox (arsenic trioxide)- New policy

DESCRIPTION:

Trisenox (arsenic trioxide) is an arsenical which induces apoptosis in APL cells via morphological changes and DNA fragmentation. It also damages or degrades the fusion protein promyelocytic leukemia (PML)-retinoic acid receptor (RAR) alpha.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Trisenox (arsenic trioxide) will be considered medically necessary when ALL of the following criteria are met:

- Prescription written by a hematologist or oncologist **AND**
- Medical record documentation of newly-diagnosed low-risk acute promyelocytic leukemia (APL) characterized by the presence of the t(15,17) translocation of PML/RAR-alpha gene expression **AND** that Trisenox is being used in combination with tretinoin **OR**
- Medical record documentation the Trisenox is being used for induction of remission and consolidation in patients with acute promyelocytic leukemia (APL) who are refractory to, or have relapsed from, retinoid and anthracycline chemotherapy, and whose APL is characterized by the presence of the t(15,17) translocation or PML/RAR-alpha gene expression

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the

reviewing provider feels it is medically appropriate. Trisenox will no longer be covered if patient experiences toxicity or worsening of disease.

MBP 168.0 Parsabiv (etelcalcetide)- New policy

DESCRIPTION:

Parsabiv (etelcalcetide), a calcium-sensing receptor agonist, is a synthetic peptide calcimimetic agent that allosterically binds and activates the calcium-sensing receptor (CaSR) on parathyroid chief cells. This action on the parathyroid gland sensitizes CaSR to promote negative feedback, thus decreasing PTH secretion and serum calcium and phosphorus levels.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Parsabiv (etelcalcetide) will be considered medically necessary when ALL of the following criteria are met:

- Medical record documentation that patient is ≥ 18 years of age **AND**
- Medical record documentation of a diagnosis of secondary hyperparathyroidism (SHPT) in patients with chronic kidney disease (CKD) **AND**
- Medical record documentation that the patient is on hemodialysis (HD) **AND**
- Medical record documentation that the patient does not have parathyroid carcinoma or primary hyperparathyroidism **AND**
- Medical record documentation that Parsabiv is not being used in combination with another calcimimetic (ie. Sensipar) **AND**
- Medical record documentation of baseline PTH level > 300 pg/mL **AND** corrected serum calcium ≥ 7.5 mg/dL **AND**
- Medical record documentation of failure on, intolerance to, or contraindication to Sensipar

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate.

REAUTHORIZATION CRITERIA: Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require:

- Medical record documentation of updated labs since the date of previous review showing the patient has had a clinically significant response to treatment with Parsabiv as evidenced by:
 - PTH level decreased from baseline **AND**
 - Corrected serum calcium ≥ 7.5 mg/dL

The following policies were reviewed with no changes:

- MBP 60.0 Cerezyme (imiglucerase)
- MBP 61.0 Flolan or Veletri (epoprostenol)
- MBP 63.0 Ixempra (ixabepilone)
- MBP 64.0 Arranon (nelarbine)
- MBP 65.0 Torisel (temsirolimus)
- MBP 67.0 Supprelin LA (histrelin acetate implant)
- MBP 79.0 Provenge (sipuleucel-T)
- MBP 81.0 Prolia (denosumab)
- MBP 83.0 Lumizyme (alglucosidase alfa)
- MBP 85.0 Cinryze (C1 esterase inhibitor, human)
- MBP 86.0 Kalbitor (ecallantide)

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- MBP 89.0 Xgeva (denosumab)
- MBP 90.0 Benlysta (belimumab)
- MBP 92.0 Off-label Drug Use for Oncologic Indications
- MBP 93.0 Nulojix (belatacept)
- MBP 95.0 Erwinaze (aspiraginase)
- MBP 96.0 Voraxaze (glucarpidase)
- MBP 99.0 Sandostatin LAR (Octreotide acetate)
- MBP 100.0 Elelyso (taliglucerase alfa)
- MBP 101.0 Zaltrap (ziv-aflibercept)
- MBP 102.0 Synribo (omacetaxine mepesuccinate)
- MBP 105.0 VPRIV (velaglucerase alfa)
- MBP 108.0 Kadcylla (ado-trastuzumab emtansine)
- MBP 111.0 Marqibo (vincristine sulfate liposome injection)
- MBP 117.0 Beleodaq (belinostat)
- MBP 118.0 Entyvio (vedolizumab)
- MBP 124.0 Ruconest (C1 esterase inhibitor, recombinant)
- MBP 127.0 Makena (hydroxyprogesterone caproate)
- MBP 129.0 Iluvien (fluocinolone acetonide)
- MBP 130.0 Mircera (methoxy polyethylene glycol-epoetin beta)