"What's New" Medical Pharmaceutical Policy June 2024 Updates

The following policy updates and reviews apply to all GHP members (Commercial, Marketplace, TPA, Medicare and Medicaid):

MBP 48.0 Rituxan (rituximab), Truxima (rituximab-abbs), Ruxience (rituximab-pvvr), Riabni (rituximab-arrx) – Updated Policy

3. **For Acute Lymphoblastic Leukemia, Hairy Cell Leukemia, and Chronic Lymphoid Leukemia:**
   Note: Prior authorization is not required for Ruxience, Riabni or Truxima for diagnosis codes C91.00 through C91.02, C91.10 through C91.12, or C91.40 through C91.42. In the event of a request for the rituximab reference product (i.e. Rituxan), OR in the event a requestor would like a medical necessity review completed, the following criteria would apply:
   - Medical record documentation of a diagnosis of Acute Lymphoblastic Leukemia, Hairy Cell Leukemia, or Chronic Lymphocytic Leukemia (CLL)

   AND
   - For rituximab reference product requests (i.e. Rituxan), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to rituximab-pvvr (Ruxience) AND rituximab-arrx (Riabni) AND rituximab-abbs (Truxima).

7. **For Hodgkin Lymphoma**
   Note: Prior authorization is not required for Ruxience, Riabni or Truxima for diagnosis codes C81.00 through C81.09. In the event of a request for the rituximab reference product (i.e. Rituxan), OR in the event a requestor would like a medical necessity review completed, the following criteria would apply:
   - Medical record documentation of a diagnosis of Hodgkin Lymphoma

   AND
   - For rituximab reference product requests (i.e. Rituxan), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to rituximab-pvvr (Ruxience) AND rituximab-arrx (Riabni) AND rituximab-abbs (Truxima).

MBP 234.0 Oxlumo (lumasiran) – Updated Policy

- Prescription written by or in consultation with an appropriate specialist (including but not limited to a nephrologist, urologist, geneticist, or hepatologist) **AND**
- Medical Record documentation of primary hyperoxaluria type 1 (PH1) as confirmed by ONE of the following:
  - Molecular genetic testing that confirms a mutation of alanin:glyoxylate aminotransferase (AGXT) gene* **OR**
  - A liver biopsy to confirm absent or significantly reduced alanin:glyoxylate aminotransferase (AGT)

AND
- Medical record documentation of metabolic screening that demonstrates ONE of the following:
  - Markedly increased urinary oxalate excretion (i.e. generally greater than 0.7 mmol/1.73 m^2 per day or greater than the upper limit of normal) **OR**
  - Increased urinary oxalate to creatinine ratio (i.e. greater than the age-specific upper limit of normal)

~~**AND**~~
- ~~Medical record documentation of sufficient kidney function as defined by ONE of the following:~~
  - ~~Medical record documentation patient has an eGFR ≥30 mL/min/1.73m^2 **OR**~~
  - ~~If eGFR is not calculated due to age limitations, a serum creatine within the normal age-specific reference range~~

AND
- Medical record documentation that the patient does not have a history of liver transplant.

*Note: AGXT genotypes include but are not limited to: PR/RR, PR/M, PR/N, M/M, M/N, N/N

AUTHORIZATION DURATION: Approval will be given for an **initial duration of six (6) months** or less if the reviewing provider feels it is medically appropriate. After the initial six (6) month approval, subsequent approvals will be for a **duration of twelve (12) months** or less if the reviewing provider feels it is medically appropriate, requiring medical record documentation of:

- ~~Sufficient kidney function as defined by ONE of the following:~~
  - ~~Medical record documentation patient has an eGFR ≥30 mL/min/1.73m^2~~ ~~**OR**~~
  - ~~If eGFR is not calculated due to age limitations, a serum creatine within the normal age-specific reference range~~

~~**AND**~~

- Medical record documentation that the patient does not have a history of liver transplant.

Ongoing subsequent approvals will be for a **duration of twelve (12) months** or less if the reviewing provider feels it is medically appropriate, requiring medical record documentation of:

- ~~Sufficient kidney function as defined by ONE of the following:~~
  - ~~Medical record documentation patient has an eGFR ≥30 mL/min/1.73m^2~~ ~~**OR**~~
  - ~~If eGFR is not calculated due to age limitations, a serum creatine within the normal age-specific reference range~~

~~**AND**~~

- Medical record documentation that the patient does not have a history of liver transplant.

MBP 239.0 Rybrevant (amivantamab-vmjw) – Updated Policy

- Medical record documentation that Rybrevant is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of with locally advanced or metastatic non-small cell lung cancer (NSCLC) **AND**
- Medical record documentation of epidermal growth factor receptor (EGFR) exon 20 insertion mutations as determined by an FDA approved test* **AND**
- One of the following:
  - Medical record documentation of disease progression on or following prior treatment with a platinum-based chemotherapy AND that Rybrevant will be used as a single agent

  OR
  - Medical record documentation that Rybrevant is being used as first line treatment AND that Rybrevant will be used in combination with carboplatin and pemetrexed

MBP 310.0 Ycanth (cantharidin) – New Policy

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

- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation of a diagnosis of molluscum contagiosum (MC) **AND**
- Medical record documentation of treatment failure of at least one other treatment modality (including but not limited to cryotherapy, curettage, or podofilox) or reason why other treatments cannot be used

AUTHORIZATION DURATION: 3 Months

QUANTITY LIMITS: 2 applicators per 21 days

MBP 315.0 Aphexda (motixafortide) – New Policy

Aphexda (motixafortide) will be considered medically when ALL of the following criteria are met:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Aphexda is prescribed by a hematologist or oncologist **AND**
- Medical record documentation that Aphexda will be used in combination with filgrastim for the mobilization and collection of hematopoietic stem cells for subsequent autologous stem cell transplantation **AND**
- Medical record documentation of therapeutic failure, intolerance, or contraindication to plerixafor

AUTHORIZATION DURATION: One (1) month

The following policies were reviewed with no changes:

- MBP 93.0 Nulojix (belatacept)
- MBP 128.0 Blincyto (blinatumomab)
- MBP 144.0 Tecentriq (atezolizumab)
- MBP 164.0 Vyxeos (daunorubicin-cytarabine liposomal)
- MBP 180.0 Kanuma (sebelipase alfa)
- MBP 211.0 Givlaari (givosiran)
- MBP 213.0 Sarclisa (isatuximab-irfc)
- MBP 216.0 Trodelvy (sacituzumab govitecan-hziy)
- MBP 219.0 Fetroja (cefiderocol)
- MBP 227.0 Danyelza (naxitamab-gqgk)
- MBP 229.0 Olinvyk (oliceridine)
- MBP 231.0 Margenza (margetuximab-cmkb)
- MBP 232.0 Cosela (trilaciclib)
- MBP 250.0 Kimmtrak (tebentafusp-tebn)
- MBP 275.0 Pedmark (sodium thiosulfate)
- MBP 276.0 Zynteglo (betibeglogene autotemcel)
- MBP 277.0 Elahere (mirvetuximab soravtansine-gynx)

The following policy was retired:

- MBP 233.0 Pepaxto (melphalan flufenamide) [withdrawn from market as of 2/23/24 [published in federal register 4/18/24]]

The following policy updates and reviews apply to Commercial, Marketplace, TPA, and Medicare GHP members only:

MBP 81.0 Prolia (denosumab) – Updated Policy

Prolia (denosumab) will be considered medically necessary for the commercial, exchange, and CHIP lines of business when all of the following criteria are met:

1. **For post-menopausal women at high risk for fractures:**
   - Physician provided documentation of a diagnosis of post-menopausal osteoporosis **AND**
   - One of the following:
     - Physician provided documentation of previous osteoporotic fracture **OR**
     - Physician provided documentation of high risk of fracture (defined as a spine or hip DXA T-score of less than or equal to -2.5, supporting clinical factors, and/or FRAX calculation showing a >3% probability of hip fracture OR >20% probability of major osteoporosis-related fracture) **OR**
     - Physician provided documentation of a failed attempt of therapy with or contraindication to one oral bisphosphonate

2. **For increasing bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer:**
   - Physician provided documentation that patient is receiving adjuvant aromatase inhibitor therapy for breast cancer; **AND**
   - One of the following:
     - Physician provided documentation of previous osteoporotic fracture* **OR**
     - Physician provided documentation of high risk of fracture (defined as a spine or hip DXA T-score of less than or equal to -2.5, supporting clinical factors, and/or FRAX calculation showing a >3% probability of hip fracture OR >20% probability of major osteoporosis-related fracture)

   AND
   - Physician provided documentation of a failed attempt of therapy with or contraindication to one oral bisphosphonate

3. **For increasing bone mass in men at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer:**
   - Physician provided documentation that patient is receiving adjuvant aromatase inhibitor therapy for breast cancer; **AND**
   - One of the following:
     - Physician provided documentation of previous osteoporotic fracture* **OR**
     - Physician provided documentation of high risk of fracture (defined as a spine or hip DXA T-score of less than or equal to -2.5, supporting clinical factors, and/or FRAX calculation showing a >3% probability of hip fracture OR >20% probability of major osteoporosis-related fracture)

   AND
   - Physician provided documentation of a failed attempt of therapy with or contraindication to one oral bisphosphonate

4. **For the treatment of men at high risk for fractures:**
   - Physician provided documentation of a diagnosis of osteoporosis **AND**
   - One of the following:
     - Physician provided documentation of previous osteoporotic fracture **OR**
     - Physician provided documentation of high risk of fracture (defined as spine or hip DXA T-score of less than or equal to -2.5, supporting clinical factors, and/or FRAX calculation showing a >3% probability of hip fracture OR >20% probability of major osteoporosis-related fracture) **OR**

- Physician provided documentation of a failed attempt of therapy with or contraindication to one oral bisphosphonate

5. **For the treatment of glucocorticoid-induced osteoporosis:**
   - Medical record documentation of a diagnosis of glucocorticoid-induced osteoporosis **AND**
   - Medical record documentation that the patient is initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone **AND**
   - Medical record documentation that the patient is going to remain on systemic glucocorticoid therapy for at least 6 months **AND**
   - One of the following:
     - Medical record documentation of previous osteoporotic fracture **OR**
     - Medical record documentation of high risk of fracture defined as DXA T-score of less than or equal to -2.0 at the lumbar spine, total hip, or femoral neck, supporting clinical factors and/or FRAX calculation showing a ≥3% probability of hip fracture OR ≥20% probability of major osteoporosis-related fracture; **OR**
     - Medical record documentation of a failure on, intolerance to, or contraindication to one oral bisphosphonate

*Note:
Per the American Association of Clinical Endocrinologists/American College of Endocrinology
Osteoporotic fracture (low-trauma fracture, fragility fracture) - A fracture usually sustained from force similar to a fall from a standing position or less that would not have occurred in healthy bone, excepting fractures of the skull, face, fingers, and toes.

Per UpToDate
Osteoporotic fracture (fragility fracture) – Fracture at the spine, hip, wrist, humerus, and pelvis, without measurement of BMD. Fractures occurring from a fall from a standing height or less, without major trauma such as a motor vehicle accident. Fractures at some skeletal sites (including the skull, cervical spine, hands, and feet) are not considered fragility fractures. Stress fractures are also not considered fragility fractures as they are due to repetitive injury, often in individuals with otherwise healthy bones. Rib fractures may present as fragility fractures but more commonly result from trauma.

MBP 141.0 Nucala ~~vial~~ (mepolizumab) – Updated Policy

Nucala ~~vial~~ (mepolizumab) will be considered medically necessary for the commercial, exchange, and CHIP lines of business when all of the following criteria are met:

Severe Eosinophilic Asthma

- Documentation of patient age ≥ 6 years **AND**
- Medical record documentation of a diagnosis of severe eosinophilic asthma AND that Nucala is being used as add-on maintenance treatment **AND**
- Prescription written by an allergist or pulmonologist **AND**
- Medical record documentation of a blood eosinophil count of either ≥ 300 cells/mcL during the 12-month period before screening and/or ≥ 150 cells/mcL within 3 months of the start of therapy **AND**
- Medical record documentation of:
  - Intolerance to or not well controlled or very poorly controlled symptoms* despite at least a 3 month trial of: high-dose inhaled corticosteroids and/or oral systemic corticosteroids plus a long-acting beta agonist **OR**
  - Two or more exacerbations in the previous 12 months requiring additional medical treatment (oral corticosteroids, emergency department or urgent care visits, or hospitalization) despite current therapy with high-dose inhaled corticosteroids plus a long-acting beta agonist **AND**

- Insured individual must be adherent with current therapeutic regimen and must demonstrate appropriate inhaler technique **AND**
- Known environmental triggers within the member's control have been eliminated **AND**
- Medical record documentation that the medication will not be used in combination with another biologic medication indicated for asthma treatment (e.g. Fasenra (benralizumab), Cinqair (reslizumab), Dupixent (dupilumab), Xolair (omalizumab), Tezspire (tezepelumab))

*****Measures of disease severity

Measure	Not Well Controlled	Very Poorly Controlled
Symptoms	> 2 days per week	Throughout the day
Nighttime awakenings	1-3x/week	≥ 4x/week
Interference with normal activity	Some limitation	Extremely limited
SABA use for symptom control (not to prevent exercise-induced bronchospasm)	> 2 days/week	Several times per day
FEV1 (% predicted) or peak flow (% personal best)	60-80%	< 60%
Asthma Control Test (ACT) Score	16-19	≤ 15

Eosinophilic Granulomatosis (EGPA)

- Prescription written by an allergist/immunologist, pulmonologist, and/or rheumatologist **AND**
- Medical record documentation that patient is ≥18 years of age **AND**
- Medical record documentation of eosinophilic granulomatosis (EGPA) confirmed by biopsy evidence of vasculitis AND at least four (4) of the following criteria:
    - Asthma (a history of wheezing or the finding of diffuse high-pitched wheezes on expiration)
    - Eosinophilia (blood eosinophil level of ≥10% or ≥1500 cells/microL on differential white blood cell count)
    - Mononeuropathy (including multiplex) or polyneuropathy
    - Migratory or transient pulmonary opacities detected radiographically
    - Paranasal sinus abnormality
    - Biopsy containing a blood vessel showing the accumulation of eosinophils in extravascular areas

  AND
- Medical record documentation of a therapeutic failure on, contraindication to, or intolerance to systemic glucocorticoid therapy AND at least one immunosuppressant therapy (cyclophosphamide, azathioprine, methotrexate) **AND**
- Medical record documentation that the medication will not be used in combination with Fasenra (benralizumab), Cinqair (reslizumab), Dupixent (dupilumab), Xolair (omalizumab), or Tezspire (tezepelumab)

Hypereosinophilic syndrome (HES)

- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of a diagnosis of hypereosinophilic syndrome (HES) for greater than or equal to 6 months **AND**
- Medical record documentation that member has been evaluated for and does NOT have an identifiable non-hematologic secondary cause* or FIP1 like 1-platelet derived growth factor receptor (FIP1L1-PDGFRα) kinase-positive hypereosinophilic syndrome (HES) **AND**
- Medical record documentation of a blood eosinophil count of 1,000 cells/mcL or higher **AND**
- Medical record documentation of at least two hypereosinophilic syndrome (HES) flares within the previous 12 months with a worsening of clinical symptoms of HES or increasing blood eosinophil level requiring an escalation in therapy **AND**

- Medical record documentation that member is on stable hypereosinophilic syndrome (HES) therapy including, but not limited to oral corticosteroids, immunosuppressives, or cytotoxic therapy **AND**
- Medical record documentation that the medication will not be used in combination with Fasenra (benralizumab), Cinqair (reslizumab), Dupixent (dupilumab), Xolair (omalizumab), or Tezspire (tezepelumab)

*Note: Non-hematologic secondary causes can include but are not limited to drug hypersensitivity, parasitic helminth infection, HIV infection, and non-hematologic malignancy

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

- Medical record documentation that Nucala is prescribed by or in consultation with an allergist, pulmonologist, immunologist, or otolaryngologist (ENT provider) **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) **AND**
- Medical record documentation that Nucala will be used as add-on maintenance treatment **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three (3) intranasal corticosteroids **AND**
- Medical record documentation that the medication will not be used in combination with Fasenra (benralizumab), Cinqair (reslizumab), Dupixent (dupilumab), Xolair (omalizumab), or Tezspire (tezepelumab)

MBP 141.0 Xolair (omalizumab) – Updated Policy

~~Xolair must be administered in a clinical setting equipped to manage life-threatening anaphylaxis. Patients should be observed for a minimum of two hours following administration of Xolair. It is also recommended by the FDA that patients on Xolair therapy should also carry and know how to initiate emergency self-treatment for anaphylaxis.~~

~~**EXCLUSIONS:**~~

~~Xolair has not been shown to be effective in patients age 12 and older with an IgE level less than 30 IU/ml or greater than 700 IU/ml, or in patients age 6 through 11 with an IgE level less than 30 IU/ml or greater than 1300 IU/ml~~

~~Xolair® has not been shown to alleviate acute asthma exacerbations and should not be used for treatment of acute bronchospasm or status asthmaticus.~~

~~Non-compliance with combination therapy including inhaled or systemic corticosteroids **and** a long-acting beta-agonist or leukotriene receptor antagonist.~~

3. For Nasal Polyps:

- Medical record documentation that Nucala is prescribed by or in consultation with an allergist, pulmonologist, immunologist, or otolaryngologist (ENT provider) **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of nasal polyps **AND**
- Medical record documentation that Xolair will be used as add-on maintenance treatment **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to ~~intranasal fluticasone and intranasal mometasone~~ three (3) intranasal corticosteroids (including but not limited to: beclomethasone, ciclesonide, fluticasone, mometasone, triamcinolone)

MBP 40.0 Orencia IV (abatacept) – Updated Policy

Orencia IV (abatacept) will be considered medically necessary for the commercial, exchange, and CHIP lines of business when all of the following criteria are met:

1. Rheumatoid arthritis (RA) 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 Orencia is not being used concurrently with a TNF blocker or other biologic agent **AND**
    - Documentation of inadequate response to minimum 3 month trial of two (2) of the following: Humira*, Rinvoq*, Enbrel* OR Xeljanz*

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 Orencia 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 two (2) of the following: Humira*, Enbrel*, OR Xeljanz*

3. Psoriatic Arthritis (PsA):
    - 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 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 two (2) of the following: Humira*, ~~AND~~ Cosentyx*, Enbrel*, Otezla*, Skyrizi*, Tremfya*, Rinvoq* OR Xeljanz/XR*

4. Prophylaxis of Acute Graft Versus Host Disease:
    - Prescription written by a hematologist, oncologist, or transplant specialist **AND**
    - Medical record documentation that the patient is 2 years of age and older **AND**
    - Medical record documentation that patient is undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor **AND**
    - Medical record documentation Orencia will be used in combination with a calcineurin inhibitor (i.e. cyclosporine, tacrolimus) and methotrexate **AND**
    - Medical record documentation that the member is receiving a Food and Drug Administration (FDA) approved dose**

*Prior authorization required

**Note: The FDA approved dose for prophylaxis of acute graft versus host disease:
- For patients 2 years to less than 6 years old: 15 mg/kg IV on the day before transplantation (Day -1), followed by 12mg/kg IV on Days 5, 14, and 28 after transplantation
- For patients 6 years and older: 10 mg/kg (maximum of 1,000 mg) IV on the day before transplantation (Day -1), followed by administration on Days 5, 14, and 28 days after transplantation

MBP 318.0 Casgevy (exagamglogene autotemcel) – New Policy

Casgevy (exagamglogene autotemcel) will be considered medically necessary when ALL of the following criteria are met:

Sickle Cell Disease

- Prescription written by a hematologist and/or stem cell transplant specialist **AND**
- Medical record documentation of age greater than or equal to 12 years and less than or equal to 65 years **AND**
- Medical record documentation of a diagnosis of severe sickle cell disease with all of the following:
  - Documentation of a βS/βS, βS/β0 or βS/β+ genotype **AND**
  - Documentation of greater than or equal to two (2) vaso-occlusive crises (VOCs) or events (VOEs)** per year in the previous two years **AND**
  - Documentation of therapeutic failure, contraindication, or intolerance to hydroxyurea

  AND
- Medical record documentation that the member has not had a prior hematopoietic stem cell transplant or hematopoietic stem-cell based gene therapy (i.e. Lyfgenia) **AND**
- Medical record documentation the member is a candidate for a hematopoietic stem cell transplant but ineligible due to absence of Human Leukocyte Antigen (HLA)-matched family donor* **AND**
- Medical record documentation that the member has a negative serology test for Human Immunodeficiency Virus (HIV)

Transfusion-Dependent β-thalassemia

- Prescription written by a hematologist and/or stem cell transplant specialist **AND**
- Medical record documentation of age greater than or equal to 12 years and less than or equal to 65 years **AND**
- Medical record documentation of a diagnosis of transfusion-dependent β-thalassemia AND medical record documentation of a history of ≥ 100 mL/kg/year or 10 units/year of packed red blood cell (RBC) transfusions in the prior 2 years **AND**
- Medical record documentation that the member has not had a prior hematopoietic stem cell transplant or hematopoietic stem-cell based gene therapy (i.e. Zynteglo) **AND**
- Medical record documentation the member is a candidate for a hematopoietic stem cell transplant but ineligible due to absence of Human Leukocyte Antigen (HLA)-matched family donor* **AND**
- Medical record documentation that the member has a negative serology test for Human Immunodeficiency Virus (HIV)

*Note to reviewer: The package insert recommends confirming that hematopoietic stem cell transplantation (HSCT) is appropriate prior to Casgevy since patients will be going through similar steps (mobilization, apheresis, and myeloablative) required for a HSCT. However, the clinical trials excluded patients who had a known and available HLA-matched related donor. Considering that HSCT has been available for longer and has more evidence supporting its use, it may be appropriate to require HSCT as an alternate to Casgevy. While it is possible for patients to have a matched unrelated donor, outcomes are best with matched related donors.

**Note to reviewer: In clinical trials, VOCs were defined as:

- Acute pain event requiring a visit to a medical facility and administration of pain medications (opioids or intravenous [IV] non-steroidal anti-inflammatory drugs [NSAIDs]) or RBC transfusions OR

- Acute chest syndrome OR
- Priapism lasting > 2 hours and requiring a visit to a medical facility OR
- Splenic sequestration.

AUTHORIZATION DURATION: One (1) time approval per lifetime; Requests for authorizations exceeding these limits 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.

MBP 319.0 Lyfgenia (lovotibeglogene autotemcel) – New Policy

Lyfgenia (lovotibeglogene autotemcel) will be considered medically necessary when ALL of the following criteria are met:

- Prescription written by a hematologist and/or stem cell transplant specialist **AND**
- Medical record documentation of age greater than or equal to 12 years and less than or equal to 65 years **AND**
- Medical record documentation of a diagnosis of severe sickle cell disease with all of the following:
    - Documentation of a βS/βS, βS/β0 or βS/β+ genotype **AND**
    - Documentation of greater than or equal to two (2) vaso-occlusive crises (VOCs) or events (VOEs)** per year in the previous two years **AND**
    - Documentation of therapeutic failure, contraindication, or intolerance to hydroxyurea

  AND
- Medical record documentation that the member has not had a prior hematopoietic stem cell transplant or hematopoietic stem-cell based gene therapy (i.e. Casgevy) **AND**
- Medical record documentation the member is a candidate for a hematopoietic stem cell transplant but ineligible due to absence of Human Leukocyte Antigen (HLA)-matched family donor* **AND**
- Medical record documentation that the member has a negative serology test for Human Immunodeficiency Virus (HIV)

*Note to reviewer: The package insert recommends confirming that hematopoietic stem cell transplantation (HSCT) is appropriate prior to Lyfgenia since patients will be going through similar steps (mobilization, apheresis, and myeloablative) required for a HSCT. However, the clinical trials excluded patients who had a known and available HLA-matched related donor. Considering that HSCT has been available for longer and has more evidence supporting its use, it may be appropriate to require HSCT as an alternate to Lyfgenia. While it is possible for patients to have a matched unrelated donor, outcomes are best with matched related donors.

**Note to reviewer: In clinical trials, VOCs were defined as:
an event with no medically determined cause other than a vaso-occlusion, requiring a ≥ 24-hour hospital or Emergency Room (ER) observation unit visit OR
at least 2 visits to a day unit or ER over 72 hours with both visits requiring intravenous treatment OR
4 priapism episodes that require a visit to a medical facility (with or without inpatient admission)

AUTHORIZATION DURATION: One (1) time approval per lifetime; Requests for authorizations exceeding these limits 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.

The following policies were reviewed with no changes:

- MBP 13.0 Viscosupplementation
- MBP 42.0 Boniva IV (ibandronate)
- MBP 76.0 Actemra IV (tocilizumab)
- MBP 212.0 Adakveo (crizanlizumab-tmca)
- MBP 274.0 Spevigo (spesolimab-sbzo)