“What’s New” Medical Pharmaceutical Policy June 2022 Updates
The following policy updates and reviews apply to all GHP members (Commercial, Marketplace, TPA, Medicare and Medicaid):

MBP 119.0 Keytruda (pembrolizumab) – Updated Policy

7. Gastric Cancer

- Prescription written by a hematologist/oncologist **AND**
- ~~Medical record documentation of one of the following:~~
  - ~~Medical record documentation of a diagnosis of recurrent locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma **AND**~~
  - ~~Medical record documentation that tumors express PD-L1 (combined positive score [CPS] greater than or equal to 1) as determined by an FDA-approved test **AND**~~
  - ~~Medical record documentation of disease progression on or after two or more prior lines of therapy (including fluoropyrimidine- and platinum-containing chemotherapy)* **AND**~~
  - ~~If patient has HER2-positive disease, medical record documentation of disease progression on or after HER2/neu-targeted therapy (including but not limited to trastuzumab (Herceptin)*~~

  ~~**OR**~~
- Medical record documentation of a diagnosis of locally advanced unresectable or metastatic HER-2 positive gastric or gastroesophageal junction adenocarcinoma **AND**
- Medical record documentation that Keytruda will be used as first-line treatment **AND**
- Medical record documentation that Keytruda will be used in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy

~~*Note to reviewer: Current recommendations intend Keytruda to be used as third-line treatment (i.e. patient is to have 2 prior lines of therapy, one of which must include HER2/neu-targeted therapy if the patient has HER-2 positive disease)~~

14. **Endometrial Carcinoma**

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of advanced endometrial carcinoma **AND**
- Medical record documentation of disease progression following at least one prior systemic therapy **AND**
- Medical record documentation that patient is not a candidate for curative surgery or radiation **AND**
- Medical record documentation of one of the following:
  - Medical record documentation that tumors are **not** microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) **AND**
  - Medical record documentation that Keytruda will be given in combination with lenvatinib (Lenvima)

  OR
  - Medical record documentation that Keytruda will be used as a single agent for treatment of tumors that are microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)

MBP 126.0 Opdivo (nivolumab) – Updated Policy

2. Non-Small Cell Lung Cancer (NSCLC)

OR

If the request is for neoadjuvant treatment of resectable NSCLC:

- Medical record documentation of resectable (tumor size greater than or equal to 4 centimeters or node-positive) non-small cell lung cancer (NSCLC) **AND**
- Medical record documentation that Opdivo will be used for neoadjuvant treatment in combination with platinum-doublet chemotherapy.

AUTHORIZATION DURATION:

****For Neoadjuvant NSCLC:** One approval will be given for up to **3 cycles for a total duration of 6 months**.
Authorization of Opdivo for the neoadjuvant treatment of NSCLC should not exceed the FDA-approved treatment duration of 3 cycles. 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

MBP 162.0 Yescarta (axicabtagene ciloleucel) – Updated Policy

Large B-Cell Lymphoma (second-line)

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is 18 years of age or older **AND**
- Medical record documentation of large B-cell lymphoma that is refractory to first-line chemoimmunotherapy OR that relapses within 12 months of first-line chemoimmunotherapy **AND**
- Medical record documentation that the member has not received prior treatment with CAR-T cell therapy or other genetically modified T cell therapy

Large B-Cell Lymphoma (third-line or beyond)

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is 18 years of age or older **AND**
- Medical record documentation of one of the following diagnoses:
  - Relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified **OR**
  - Relapsed or refractory primary mediastinal large B-cell lymphoma **OR**
  - Relapsed or refractory high-grade B-cell lymphoma **OR**
  - Relapsed or refractory diffuse large B-cell lymphoma (DLBCL) arising from follicular lymphoma

  AND
- Medical record documentation of a therapeutic failure on two or more previous lines of therapy **AND**
- Medical record documentation that the member has not received prior treatment with CAR-T cell therapy or other genetically modified T cell therapy

MBP 256.0 Carvykti (ciltacabtagene autoleucel) – New Policy

Carvykti (ciltacabtagene autoleucel) will be considered medically necessary when all of the following criteria are met:

- Medical record documentation that Carvykti is prescribed by a hematologist/oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of relapsed or refractory multiple myeloma **AND**
- Medical record documentation of at least four prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody **AND**
- Medical record documentation that the member has not received prior treatment with CAR-T cell therapy or other genetically modified T cell therapy

AUTHORIZATION DURATION: One-time authorization for one administration of Carvykti.

MBP 257.0 Opdualag (nivolumab and relatlimab-rmbw) – New Policy

Opdualag (nivolumab and relatlimab-rmbw) will be considered medically necessary when all of the following criteria are met:

- Medical record documentation that Opdualag is written by a hematologist or oncologist **AND**
- Medical record documentation that patient is greater than or equal to 12 years of age **AND**
- For patients greater than or equal to 12 years and less than 18 years of age:
    - Medical record documentation of weight greater than or equal to 40 kg

  AND
- Medical record documentation of a diagnosis of unresectable or metastatic melanoma

AUTHORIZATION DURATION: Initial approval will be for **12 months**. Subsequent approvals will be for an additional **12 months** 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.

QUANTITY LIMIT: 2 vials (40 mL) per 28 days

MBP 260.0 Vyvgart (efgartigimod alfa-fcab) – New Policy

Vyvgart (efgartigimod alfa-fcab) will be considered medically necessary 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 Vyvgart is prescribed by or in consultation with a neurologist **AND**
- Medical record documentation of a diagnosis of generalized myasthenia gravis (gMG) that is anti-acetylcholine receptor (AChR) antibody positive **AND**
- Medical record documentation of Myasthenia Gravis Foundation of America Clinical Classification (MGFA) Class II to IV **AND ***
- Medical record documentation of a baseline Myasthenia Gravis-Activities of Daily Living (MG-ADL) score of 5 or more **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 rituximab or rituximab biosimilar **AND**
- Medical record documentation of failure on intolerance to, or contraindication to intravenous immunoglobulin (IVIG)

AUTHORIZATION DURATION: Initial approval will be for 6 months. Subsequent approvals will be for 6 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 2-point reduction from baseline in Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score**

The medication will no longer be covered if patient experiences toxicity or worsening of disease.

The following policies were reviewed with no changes:

- MBP 108.0 Kadcyla (ado-trastuzumab emtansine)
- MBP 132.0 Avycaz (cetfazidime and avibactam)
- MBP 151.0 Spinraza (nusinersen)
- MBP 199.0 Zolgensma (onasemnogene abeparvovec-xioi)
- MBP 200.0 Polivy (polatuzumab vedotin-piiq)
- MBP 213.0 Sarclisa (isatuximab-irfc)
- MBP 217.0 Tepezza (teprotumumab-trbw)
- MBP 234.0 Oxlumo (lumasiran)

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

Note: For Medicaid GHP Family members please refer to the Pennsylvania Medical Assistance Statewide Preferred Drug List (PDL) https://papdl.com/preferred-drug-list for specific coverage information and policy criteria for any drug listed below.

MBP 22.0 Xolair (omalizumab) – Updated Policy

1. **Asthma:**
   - Must be prescribed by an allergist or pulmonologist **AND**
   - Insured individual must be compliant with current therapeutic regimen **AND**
   - Insured individual is at least 6 years of age **AND**
   - Physician provided documentation of a diagnosis of moderate to severe persistent asthma* with evidence of reversible airway disease [i.e. greater than 12% improvement in forced expiratory volume in one second (FEV_1) with at least 200 ml increase or at least a 20% or greater improvement in peak expiratory flow (PEF) after administration of albuterol] **AND**
   - Physician provided documentation of inadequate control or intolerance, despite a 3 month trial of: medium –high dose inhaled corticosteroids or systemic corticosteroids **and** long-acting beta agonists or leukotriene receptor antagonists **AND**
   - Physician provided documentation of an IgE level of greater than 30 IU/ml and less than 700 IU/ml for individuals age 12 and older OR IgE level of greater than 30 IU/ml and less than 1300 IU/ml for individuals age 6 through 11 **AND**
   - Physician provided documentation of evidence of a specific allergic reactivity to a perennial aeroallergen by positive skin or blood test for a specific IgE **AND**
   - Known environmental triggers within the member's control have been eliminated. **AND**
   - ~~Medical record documentation that Xolair is not being used in combination with Fasenra (benralizumab), Nucala (mepolizumab), or Cinqair (reslizumab)~~
   - Medical record documentation that Xolair will not be used in combination with another biologic medication indicated for asthma treatment (e.g. Tezspire, Nucala, Fasenra, Dupixent, Cinqair)

MBP 40.0 Orencia (abatacept) – Updated Policy

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 an FDA approved dose*

*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

AUTHORIZATION DURATION:

Prophylaxis of Acute Graft Versus Host Disease:

Authorization for prophylaxis of Acute Graft Versus Host Disease should not exceed the FDA-approved treatment duration of 28 days after transplantation. For requests exceeding 1 month auth duration, 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.

All other Indications:

Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or a lack of progression in the signs and symptoms of the targeted disease state at six (6) months of Orencia 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 targeted disease state while on Orencia therapy.

MBP 118.0 Entyvio (vedolizumab) – Updated Policy

Crohn's Disease

- Prescription written by a gastroenterologist **AND**
- Medical record documentation of age >18 years **AND**
- Medical record documentation of a diagnosis of moderate-to-severe Crohn's disease **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Humira* OR an infliximab* product.

MBP 141.0 Nucala (mepolizumab) – Updated Policy

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))
- ~~Medical record documentation that Nucala is not being used in combination with Fasenra (benralizumab), Cinqair (reslizumab), or Xolair (omalizumab).~~

MBP 145.0 Cinqair (reslizumab) – Updated Policy

- Documentation of patient age ≥ 18 years **AND**
- Patient must have severe persistent eosinophilic asthma **AND**
- Cinqair 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 ≥ 400 cells/mcL since the time of asthma diagnosis **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), Nucala (mepolizumab), Dupixent (dupilumab), Xolair (omalizumab)) **AND**
- ~~Medical record documentation that Cinqair is not being used in combination with Fasenra (benralizumab), Nucala (mepolizumab), or Xolair (omalizumab) **AND**~~
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to the use of Nucala

MBP 181.0 Site of Care Review Guidelines for Infusion Drugs and Specialty Medications – Updated Policy

II. Purpose/Objective:

To provide a policy of coverage regarding the use of hospital based outpatient facilities as a site of care for drugs that require administration via intravenous infusion or injection. This policy applies to these medications:

1. Abatacept (Orencia IV)
2. Agalsidase Beta (Fabrazyme)
3. Alglucosidase Alfa (Lumizyme)
4. Alpha1-Proteinase Inhibitor [Human] products
5. Anifrolumab-fnia (Saphnelo)
6. Avalglucosidase alfa-ngpt (Nexviazyme)
7. Belimumab (Benlysta IV)
8. Benralizumab (Fasenra)
9. C1 esterase Inhibitor [Human] (Cinryze)
10. Canakinumab (Ilaris)
11. Casimersen (Amondys 45)
12. Certolizumab (Cimzia)
13. Denosumab (Prolia, Xgeva)
14. Eculizumab (Soliris)
15. Edaravone (Radicava)
16. Elapegademase-lvlr (Revcovi)
17. Elosulfase alfa (Vimizim)

18. Eptinezumab (Vyepti)
19. Eteplirsen (Exondys 51)
20. Galsulfase (Naglazyme)
21. Golodirsen (Vyondys 53)
22. Golimumab (Simponi Aria)
23. Idursulfase (Elaprase)
24. Immune Globulin (IVIG)
25. Imiglucerase (Cerezyme)
26. Inebilizumab (Uplizna)
27. Infliximab & infliximab biosimilar products
28. Laronidase (Aldurazyme)
29. Mepolizumab (Nucala)
30. Omalizumab (Xolair)
31. Patisiran (Onpattro)
32. Ravulizumab (Ultomiris)
33. Sebelipase alfa (Kanuma)
34. Taliglucerase alfa (Elelyso)
35. Tildrakizumab (Ilumya)
36. Tocilizumab (Actemra IV)
37. Ustekinumab (Stelara)
38. Vedolizumab (Entyvio)
39. Velaglucerase alfa (Vpriv)
40. Vestronidase alfa-vjbk (Mepsevii)
41. Viltolarsen (Viltepso

MBP 173.0 Fasenra Prefilled Syringes (benralizumab) – Updated Policy

- Prescribed by an allergist/immunologist or pulmonologist **AND**
- Patient is 12 years of age or older **AND**
- Medical record documentation of a diagnosis of severe eosinophilic asthma AND that Fasenra is being used as add-on maintenance treatment **AND**
- Medical record documentation of blood eosinophil count ≥150 cells/microL (0.15 x 10E3/uL) within the past 3 months **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
- Medical record documentation that individual is adherent to current therapeutic regimen and has demonstrated appropriate inhaler technique **AND**
- Medical record documentation that 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. Xolair (omalizumab), Nucala (mepolizumab), Dupixent (dupilumab), Cinqair (reslizumab))
- ~~Medical record documentation that Fasenra is not being used in combination with Xolair (omalizumab), Nucala (mepolizumab), or Cinqair (reslizumab)~~

MBP 259.0 Tezspire (tezepelumab-ekko) – New Policy

- Prescription written by or in consultation with an allergist, immunologist, or pulmonologist **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of severe asthma **AND**
- Medical record documentation that Tezspire will be used as an add-on maintenance treatment **AND**
- Medical record documentation of one of the following:
    - Poor control or intolerance, despite a 3 month trial of: medium –high dose inhaled corticosteroids and another controller medication (long-acting beta agonists, long-acting muscarinic antagonist, or leukotriene receptor antagonists) with or without oral corticosteroids **OR**

- Two or more asthma exacerbations requiring systemic corticosteroid treatment or one asthma exacerbation resulting in hospitalization in the past 12 months despite current therapy to medium- high inhaled corticosteroids and another controller medication (long-acting beta agonists, long-acting muscarinic antagonist, or leukotriene receptor antagonists)

AND

- Medical record documentation that Tezspire will not be used in combination with another biologic medication indicated for asthma treatment (e.g. Xolair, Nucala, Fasenra, Dupixent, Cinqair)

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 disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

QUANTITY LIMITS: 1.91 mL (210 mg) every 28 days

Quantity limits were added to the following policies/products:

- MBP 47.0 Lucentis (ranibizumab): 0.1mL (1mg) per 30 days
- MBP 94.0 Eylea (aflibercept): 0.1mL (4mg) per 30 days
- MBP 251.0 Beovu (brolucizumab): 0.1mL (12mg) per 30 days
- MBP 252.0 Susvimo (ranibizumab implant): 0.2mL (2 vials) per 24 weeks (to allow 2mg per 24 weeks per treated eye)
- MBP 253.0 Vabysmo (faricimab): 0.1mL (12mg) per 30 days

The following policies were reviewed with no changes:

- MBP 59.0 White Blood Cell Stimulating Factors
- MBP 218.0 Vyepti (eptinezumab-jjmr)