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

**MBP 80.0 Xiaflex (collagenase clostridium histolyticum) – Updated Policy**

1. For treatment of Peyronie disease:
   - Medical record documentation of a diagnosis of moderate to severe Peyronie’s Disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy AND
   - Medical record documentation that Xiaflex will be used in combination with (or therapeutic failure on, intolerance to, or contraindication to) pentoxifylline

**MBP 119.0 Keytruda (pembrolizumab) – Updated Policy**

1. **Urothelial Carcinoma**
   - Prescription written by a hematologist/oncologist AND
   - Medical record documentation that patient is ≥ 18 years of age AND
   - Medical record documentation of locally advanced or metastatic urothelial carcinoma AND
   - Medical record documentation of 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 OR
     - Patient is not eligible cisplatin-containing chemotherapy* AND
     - Tumors express PD-L1 (combined positive score [CPS] greater than or equal to 10) as determined by an FDA-approved test OR
     - Patient is not eligible for any platinum-containing chemotherapy (regardless of PD-L1 status) OR
     - Patient has high-risk, non-muscle invasive bladder cancer (NMIBC)** AND
     - Patient’s disease is unresponsive to an adequate trial of Bacillus Calmette-Guerin (BCG) therapy** AND
     - Patient is ineligible for or has elected not to undergo cystectomy

*Note: In clinical trials, patients who were not considered cisplatin-eligible had the following characteristics: baseline creatinine clearance of <60 mL/min, ECOG performance status of 2, ECOG 2 and baseline creatinine clearance of <60 mL/min, other reasons (Class III heart failure, Grade 2 or greater peripheral neuropathy, and Grade 2 or greater hearing loss).

12. **Renal Cell Carcinoma (RCC)**
   - Prescription written by a hematologist/oncologist AND
   - Medical record documentation that patient is ≥ 18 years of age AND
   - Medical record documentation of diagnosis of advanced renal cell carcinoma AND
   - Medical record documentation that Keytruda is being used in combination with axitinib (Inlyta) OR lenvatinib (Lenvima) AND
   - Medical record documentation that Keytruda in combination with and axitinib (Inlyta) OR lenvatinib (Lenvima) is being used as first-line treatment for advanced disease

Note: In clinical trials, advanced disease included newly diagnosed or recurrent Stage IV renal cell carcinoma.

13. **Triple Negative Breast Cancer**
   - Prescription written by a hematologist/oncologist AND
   - Medical record documentation of age greater than or equal to 18 years AND
   - Medical record documentation of one of the following:
     - Medical record documentation of locally recurrent unresectable or metastatic triple-negative breast cancer (TNBC) AND both of the following:
       - Medical record documentation that tumors express PD-L1 [Combined Positive Score (CPS) greater than or equal to 10] as determined by an FDA approved test AND
       - Medical record documentation that Keytruda will be given in combination with chemotherapy (paclitaxel, paclitaxel protein-bound, or gemcitabine and carboplatin).

OR
Medical record documentation of high-risk, early-stage triple-negative breast cancer (TNBC) AND Medical record documentation that Keytruda will be given in combination with chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery

MBP 121.0 Dalvance (dalbavancin)
1. Medical record documentation that patient is ≥ 18 years of age AND
2. Medical record documentation of a diagnosis of an acute bacterial skin and skin structure infection (including cellulitis/erysipelas, wound infection, and major cutaneous abscess) caused by: Staphylococcus aureus, Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus dysgalactiae, Streptococcus anginosus, Streptococcus intermedius, Streptococcus constellatus, or Enterococcus faecalis (vancomycin susceptible strains) which has been diagnosed and documented with Infectious Disease consultation AND
3. If Dalvance was initiated during an inpatient stay, medical record documentation of a 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 OR
4. Medical record documentation of a prescribed dose of Dalvance (dalbavancin) that is consistent with the Food and Drug Administration (FDA) approved package labeling OR 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 that exceeds FDA approved labeling.

AUTHORIZATION LIMIT: If approved, Dalvance will be authorized for a treatment course of 2 doses within a 2 week period.

AUTHORIZATION DURATION/QUANTITY LIMIT:
For SINGLE dose regimen: Approval will be for one (1) week and will be limited to one (1) treatment course (up to 1,500 mg as a single dose) (Facets RX count 300, Darwin RX count 1).

For TWO-dose regimen: Approval will be for two (2) weeks and will be limited to two (2) treatment courses (up to 1,500 mg divided among two doses) (Facets RX count 300, Darwin RX count 2).

The following policies were reviewed with no changes:
- MBP 4.0 Intravenous Immune Globulin
- MBP 166.0 Adcetris (brentuximab vedotin)
- MBP 167.0 Vabomere (meropenem-vaborbactam)
- MBP 170.0 Lutathera (lutetium Lu 177 dotate)
- MBP 172.0 Trisenox (arsenic trioxide)
- MBP 182.0 Crysvita (burosumab-twza)
- MBP 187.0 Zemdri (plazomicin)
- MBP 189.0 Lumoxiti (moxetumomab pasudotox-tdfk)
- MBP 203.0 Nuzyra (omadacycline) Injection
- MBP 205.0 Zerbaxa (ceftolozane-tazobactam)
- MBP 210.0 Reblozyl (luspatercept-aamt)
- MBP 215.0 Recarbio (imipenem/ cilastatin/relebactam)
- MBP 221.0 Monjuvi (tafasitamab-cxix)
- MBP 222.0 Zepzelca (lurbirectedxin)
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](https://papdl.com/preferred-drug-list) for specific coverage information and policy criteria for any drug listed below.

**MBP 104.0 Emend IV (fosaprepitant) – Updated Policy**

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

1. Medical record documentation that Emend is being used for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy; OR
2. Medical record documentation that Emend is being used for the prevention of acute and 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.

**ADDITIONAL INFORMATION:**

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

- AC combination defined as any chemotherapy regimen that contains an anthracycline and cyclophosphamide
- Carboplatin
- Carmustine
- Cisplatin
- Cyclophosphamide at doses >1500 mg/m²
- Dacarbazine
- Daclomycin
- Daunorubicin
- Doxorubicin
- Epirubicin
- Ifosfamide
- Irinotecan
- Mechlorethamine
- Methotrexate at doses > 250mg/m²
- Oxaliplatin
- Streptozotocin
- Trabectedin

**MEDICARE BUSINESS SEGMENT:** Please refer to Pub 100-03 NCD, Transmittal 165 for additional chemotherapeutic regimens that are considered medically necessary for requiring Emend [http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=309&ncdver=2&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=Pennsylvania&KeyWord=Aprepitant&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAAABAAAAAA%3d%3d&].

**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.

**MBP 181.0 Site of Care – 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. Algglucosidase Alfa (Lumizyme)
4. Alpha1-Proteinase Inhibitor [Human] products
5. Belimumab (Benlysta IV)
6. Benralizumab (Fasenza)
7. C1 esterase Inhibitor [Human] (Cinryze)
8. Canakinumab (Ilaris)
9. Casimersen (Amondys 45) [effective 12/15/21]
10. Certolizumab (Cimzia)
11. Denosumab (Prolia, Xgeva)
12. Edaravone (Radicava) [effective 12/15/21]
13. Eptinezumab (Vyepti)
14. Eteplirsen (Exondys 51) [effective 12/15/21]
15. Galsulfase (Naglazyme)
16. Golodirsen (Vyondys 53) [effective 12/15/21]
17. Golimumab (Simponi Aria)
18. Immune Globulin (IVIG)
19. Imiglucerase (Cerezyme)
20. Infliximab & infliximab biosimilar products
21. Laronidase (Aldurazyme)
22. Mepolizumab (Nucala)
23. Omalizumab (Xolair)
24. Tiadakizumab (Ilumya)
25. Tocilizumab (Actemra IV)
26. Ustekinumab (Stelara)
27. Vedolizumab (Entyvio)
28. Viitolarren (Viltepso) [effective 12/15/21]
DESCRIPTION:
Specific intravenous and injectable drugs must meet applicable medical necessity criteria for coverage. If these criteria are met, this coverage policy will be used to determine the medical necessity of administration in the hospital based outpatient setting. If medical necessity criteria for administration in the hospital based outpatient setting are not met, an alternative less intensive site of care facility should be utilized.

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

Administration in the hospital based outpatient setting will be considered medically necessary and LIMITED to a duration of 60 days [for Xolair (omalizumab), a duration of up to 90 days if the reviewing provider determines it is medically appropriate] when one of the following criteria are met:

- This is the initial medication infusion OR
- Member is reinitiating treatment after not receiving any treatments for at least 6 months.

AUTHORIZATION DURATION: Initial approval will be for a duration of 60 days [for Xolair, up to 90 days]. Administration in the hospital based outpatient setting for longer than 60 days the initially approved amount will be required to meet the authorization criteria in the section below.

Administration in the hospital based outpatient setting will be considered medically necessary for a duration of greater than 60 days when one of the following criteria are met:

- The medication has a site of care restriction for administration per the FDA approved label OR
- Documented previous history of severe or potentially life-threatening adverse event during or following administration and the adverse event cannot be managed using pre-medication(s) or adjusting the rate of infusion OR
- All of the following:
  - All alternate non-hospital outpatient settings are not within a reasonable distance from the member's home (within 50 miles) AND
  - Home healthcare or infusion provider has determined that the patient, home caregiver, or home environment is not appropriate for home infusion or home infusion services are not available due to limited network access AND
  - For request of a provider administered drug, for which a self-administered formulation is available, including but not limited to abatacept, belimumab, benralizumab, certolizumab, golimumab, mepolizumab, omalizumab, tocilizumab, and ustekinumab: medical record documentation of a therapeutic failure of or intolerance to a 3 month trial of the self-administered formulation of the respective product.

- For IVIG any of the above criteria OR
  - Change of immune globulin products (one infusion will be permitted in the hospital outpatient setting) OR
  - Laboratory confirmed immunoglobulin A (IgA) deficiency with anti-IgA antibodies

- For Xgeva (denosumab) any of the above criteria OR
  - Patient is receiving Xgeva concomitantly with intravenous chemotherapy as part of the same encounter

AUTHORIZATION DURATION: Initial approval will be for the same length of time as the authorization of the specific drug being administered. Subsequent approvals will be required if the specific drug requires subsequent authorizations.

NOTE: To prevent a delay in care and allow adequate transition time for members to an alternate infusion site, members already established on therapy who do not meet any of the above criteria will be given a 60-day transition auth to allow them to continue receiving therapy at their current hospital based outpatient facility while they transition to a different infusion site.