Geisinger Health Plan

POLICIES AND PROCEDURE MANUAL

"What's New" Medical Pharmaceutical Policy June 2021 Updates

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

MBP 162.0 Yescarta (axicabtagene ciloleucel)- Updated policy

Yescarta (axicabtagene ciloleucel) will be considered medically necessary when ALL of the following criteria are met:
Large B-Cell Lymphoma

- 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 214.0 Vyondys 53 (golodirsen)- Updated policy

Vyondys 53 (golodirsen) will be considered medically necessary when ALL of the following criteria are met:

- Medical record documentation of interdisciplinary team involvement including, at a minimum, neurology, cardiology, pulmonology, and a genetic specialist (e.g. geneticist, genetic counselor, etc.) **AND**
- Medical record documentation of Duchenne's Muscular Dystrophy (DMD) confirmed by genetic testing **AND**
- Medical record documentation that the member has a confirmed mutation of the DMD gene that is amenable to exon 53 skipping confirmed by a genetic counselor **AND**
- Medical record documentation of a baseline evaluation, including a standardized assessment of motor function by a neurologist with experience treating Duchenne muscular dystrophy **AND**
- Medical record documentation that Vyondys 53 is being given concurrently with oral corticosteroids unless intolerant or contraindicated **AND**
- Medical record documentation that patient will receive a dose consistent with the FDA approved labeling (maximum dose of 30mg/kg infused once weekly)

Note: Exon Deletions* on the Duchenne Muscular Dystrophy Gene Theoretically Amenable to Exon 53 Skipping

3-52	4-52	5-52	6-52	9-52					
10-52	11-52	13-52	14-52	15-52	16-52	17-52	19-52		
21-52	23-52	24-52	25-52	26-52	27-52	28-52	29-52		
30-52	31-52	32-52	33-52	34-52	35-52	36-52	37-52	38-52	39-52
40-52	41-52	42-52	43-52	45-52	47-52	48-52	49-52		
50-52	52	54-58	54-61	54-63	54-64	54-66	54-76	54-77	

*The first number represents the first exon deleted. The last number is the last exon deleted. The dash (-) represents all exons in between the first and last exon deleted.

~~**Note**: In clinical trials, stable cardiac function was defined as left ventricular ejection fraction ≥50% based on screening echocardiogram and QTc<450 ms based on screening electrocardiogram and stable pulmonary function was defined as percent predicted forced vital capacity of at least 50% and no requirement for nocturnal ventilation.~~

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

3. For Nasal Polyps:
- Medical record documentation that Xolair is prescribed by or in consultation with an otolaryngologist **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

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.

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

MBP 181.0 Site of Care Review Guidelines for Infusion Drugs and Specialty Medications- Updated policy

I. Policy:
Site of Care Review Guidelines for Infusion Drugs and Specialty Medications

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) [effective 7/15/21]
3. Alglucosidase Alfa (Lumizyme) [effective 7/15/21]
4. Belimumab (Benlysta IV)
5. Benralizumab (Fasenra)
6. C1 esterase Inhibitor [Human] (Cinryze)
7. Canakinumab (Ilaris) [effective 8/15/21]
8. Certolizumab (Cimzia) [effective 8/15/21]
9. Denosumab (Prolia, Xgeva)
10. Eptinezumab (Vyepti) [effective 8/15/21]
11. Galsulfase (Naglazyme) [effective 7/15/21]
12. Golimumab (Simponi Aria)
13. Immune Globulin (IVIG)
14. Imiglucerase (Cerezyme) [effective 7/15/21]
15. Infliximab & infliximab biosimilar products
16. Laronidase (Aldurazyme) [effective 7/15/21]
17. Mepolizumab (Nucala)
18. Omalizumab (Xolair)
19. Tildrakizumab (Ilumya) [effective 8/15/21]
20. Tocilizumab (Actemra IV)
21. Ustekinumab (Stelara) [effective 8/15/21]
22. Vedolizumab (Entyvio)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than

3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.
7. Site of Care – choice of physical location for administration of intravenous infusions or injections. Site of care locations include hospital inpatient, hospital based outpatient facilities, physician's office, ambulatory infusion centers, or home infusion services.
8. Alternative less intensive site of care facilities include non-hospital affiliated outpatient infusion centers such as ambulatory infusion centers or physician's offices and home infusion
9. Hospital based outpatient facilities include ER services, intravenous drug infusions or injections, observation services, outpatient surgery, lab tests, or x-rays, or any other hospital services where the patient is not admitted as an inpatient.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient -

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 <u>LIMITED to a duration of 60 days</u> 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. Administration in the hospital based outpatient setting for longer than 60 days 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 <u>duration of greater than 60 days</u> 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, ~~and~~ 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.

OR

- 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

OR

- 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.