Geisinger Health Plan

POLICIES AND PROCEDURE MANUAL

Policy: MBP 181.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Site of Care Review Guidelines for Infusion Drugs and Specialty Medications

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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)
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. Eptinezumab (Vyepti)
17. Eteplirsen (Exondys 51)
18. Galsulfase (Naglazyme)
19. Golodirsen (Vyondys 53)
20. Golimumab (Simponi Aria)
21. Inebilizumab (Uplizna)
22. Immune Globulin (IVIG)
23. Imiglucerase (Cerezyme)
24. Infliximab & infliximab biosimilar products
25. Laronidase (Aldurazyme)
26. Mepolizumab (Nucala)
27. Omalizumab (Xolair)
28. Patisiran (Onpattro)
29. Ravulizumab (Ultomiris)
30. Tildrakizumab (Ilumya)
31. Tocilizumab (Actemra IV)
32. Ustekinumab (Stelara)
33. Vedolizumab (Entyvio)
34. Viltolarsen (Viltepso)

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 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 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 <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, 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.

LIMITATIONS: If none of the above criteria are met and the proposed hospital-based outpatient facility is considered a least costly site of care, the hospital outpatient infusion would be approved.

LINE OF BUSINESS:
This policy does not apply to the Medicaid or Medicare line of business. Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 9/18/18

Revised: 4/30/20 (addition of abatacept, belimumab, golimumab, tocilizumab, vedolizumab, denosumab, and summarized infliximab), 9/15/20 (addition of Cinryze, Nucala, Fasenra, Xolair, updated criteria), 5/18/21 (addition of Fabrazyme, Lumizyme, Ilaris, Cimzia, Vyepti, Naglazyme, Cerezyme, Aldurazyme, Ilumya, Stelara), 8/27/21 (addition of Alpha-1 products), 11/16/21 (addition of Amondys 45, Radicava, Exondys 51, Vyondys 53, Viltepso, Xolair verbiage changes), 1/18/22 (addition of Nexviazyme, Saphnelo, Soliris, Uplizna, Onpattro, Ultomiris)

Reviewed: 9/1/19