Pharmacy Medical Necessity Guidelines: Cerezyme® (imiglucerase), Elelyso® (taliglucerase alfa) and VPRIV® (velaglucerase alfa)

Effective: June 9, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	MED	Department to Review	PRECERT /MM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:

Commercial Products:
PRECERT:617.972.9409

Tufts Health Public Plans Products:
MM: 888.415.9055

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Cerezyme (imiglucerase for injection) is indicated for long-term enzyme replacement therapy for pediatric and adult patients with a confirmed diagnosis of Type 1 Gaucher disease that results in one or more of the following conditions: anemia, thrombocytopenia, bone disease, or hepatomegaly or splenomegaly.

Elelyso (taliglucerase alfa) for injection is a hydrolytic lysosomal glucocerebroside-specific enzyme indicated for the treatment of pediatric and adult patients with a confirmed diagnosis of Type 1 Gaucher disease.

VPRIV (velaglucerase alfa) is a hydrolytic lysosomal glucocerebroside-specific enzyme indicated for long-term enzyme replacement therapy for pediatric and adult patients with type 1 Gaucher disease.

Gaucher disease is a rare and debilitating genetic disorder in which patients lack the enzyme b-glucocerebrosidase, which is essential for the proper lipid metabolism. As a result of this missing enzyme, there is a build-up of the glycolipid glucocerebroside, which can cause a host of problems, most importantly, hepatomegaly (enlarged liver), splenomegaly (enlarged spleen), bone disease and severe anemia (low blood counts). The mainstay of treatment for this disease focuses on replacing the missing enzyme, which provides some relief, but is not a cure.

COVERAGE GUIDELINES

The plan may authorize coverage of Cerezyme (imiglucerase), Elelyso (taliglucerase alfa) or VPRIV (velaglucerase alfa) for Members when the following criteria are met:

1. Documented diagnosis of Type 1 Gaucher disease

AND

2. Documentation of one of the following:
   a. For Cerezyme, the Member is at least 2 years of age
   b. For Elelyso, the Member is at least 4 years of age
   c. For VPRIV, the Member is at least 4 years of age

AND

3. Documentation of one of the following:
   a. Anemia
   b. Bone disease
   c. Hepatomegaly or splenomegaly
   d. Thrombocytopenia

Dosing Recommendations: Symptomatic Members may receive doses up to, but not exceeding, 60 units/kg infused every 2 weeks.

LIMITATIONS

1. The plan does not cover enzyme replacement therapy for Type 2 or Type 3 Gaucher Disease.

CODES

The following HCPCS/CPT code(s) are:

Code	Description
J1786	Injection, imiglucerase, 10 units
J3060	Injection, taliglucerase alfa, 10 units
J3385	Injection, velaglucerase alfa, 100 units

REFERENCES

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3. Bracoud L, Ahmad H, Brill-Almon E, et al. Improving the Accuracy of MRI Spleen and Liver Volume Measurements: A Phase III Gaucher Disease Clinical Trial Setting as a Model. *J BCMD*. 2011; 46:47-52.
4. Cerezyme (imiglucerase) [package insert]. Cambridge, MA: Genzyme Corporation; April 2018.
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APPROVAL HISTORY

September 2001: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
1. December 14, 2004: Remove Type 3 Gaucher disease from Coverage Criteria. Add Type 3 to Coverage Limitations.
2. November 8, 2005: No changes.
3. September 12, 2006: Added generic descriptors for both Ceredase (alglucerase) or Cerezyme (imiglucerase) under I. Clinical Coverage Criteria.
4. September 11, 2007: No changes.
5. May 13, 2008: Changed criteria #1 for Children under the age of 18 to read as, "Documented diagnosis by a pediatric metabolic specialist of Type 1 Gaucher disease and one of the following:" Added "hepatosplenomegaly to coverage criteria #1 for Children under the age of 18. Removed statement ("And one or more of the following") between coverage criteria #1 and #2 for Children under the age of 18. Removed Dosing Criteria section and changed dose recommendation statement for children to read as, "Dosing Recommendations: Symptomatic members may receive doses up to, but not exceeding, 60units/kg infused every 2 weeks."
6. May 12, 2009: No changes.
7. January 1, 2010: Removal of Tufts Health Plan Medicare Preferred language (separate criteria have been created specifically for Tufts Health Plan Medicare Preferred).
8. May 11, 2010: No changes.
9. July 13, 2010: Added VPRIV (velaglucerase alfa) to pharmacy medical necessity guidelines.
10. January 1, 2011: Administrative Update: Added reimbursement codes J1786 and J3385.
11. July 12, 2011: No changes.
12. May 8, 2012: Administrative Update: Removed reimbursement codes J0205 and J1785. Removed Ceredase from Medical Necessity Guidelines, product is no longer available.
13. September 11, 2012: Added Elelyso (taliglucerase alfa) to the Medical Necessity Guideline.
14. January 1, 2013: Administrative Update: Added reimbursement code C9294.
15. September 10, 2013: No changes.
16. January 1, 2014: Administrative Update: Replaced reimbursement code C9294 with J3060.
17. September 9, 2014: No changes.
18. August 11, 2015: No changes.
19. January 1, 2016: Administrative change to rebranded template
20. July 12, 2016: No changes.
21. April 11, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
22. July 11, 2017: No changes.
23. July 10, 2018: No changes.
24. March 12, 2019: Updated Medical Necessity Guideline so the coverage criteria for members of all ages are the same but added age requirements for Cerezyme, Elelyso, and VPRIV. Removed the requirement that the diagnosis of Type 1 Gaucher disease is made by a specialist. Updated coverage criteria that to require documentation of one of the following: Anemia, bone disease, hepatomegaly or splenomegaly, or thrombocytopenia.
25. June 9, 2020: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards

adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.