Effective: January 1, 2023

Prior Authorization Required
If REQUIRED, submit supporting clinical documentation pertinent to service request.

Applies to:

Commercial Products
☐ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988
☐ Tufts Health Plan Commercial products; Fax 617-673-0988

CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products
☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0988
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0988
☒ Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.

Senior Products
☒ Harvard Pilgrim Health Care Stride Medicare Advantage; Fax 617-673-0956
☒ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956
☒ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956
☒ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Gaucher disease (GD) is a rare and debilitating genetic disorder in which patients lack the enzyme β-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.

Type 1 GD (GD1) is the most prevalent type in the United States, Europe, and Israel and occurs with greater frequency in the Ashkenazi Jewish population. In the United States, Europe, and Israel, approximately 90 percent of patients have GD1. GD1 is characterized by variability in signs, symptoms, severity, and progression, even among siblings with the same genotype and monozygotic twins. Symptomatic patients have visceral involvement, bone disease, and bleeding. Fatigue is common, and pubertal delay with associated delay in growth may occur. Bone disease is common in all patients, especially those who have undergone splenectomy. Variability is described in individuals homozygous for the c.1226A>G allele (p.N409S or N370S variant), ranging from clinically significant anemia, thrombocytopenia, hepatosplenomegaly, marrow infiltration, bony abnormalities, and osteopenia/osteoporosis, to essentially asymptomatic with no or mild hematologic and skeletal findings on examination.

Food and Drug Administration (FDA) 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.
STEP THERAPY:
Some medically administered Part B drugs may have additional requirements or limits on coverage. These requirements and limits may include step therapy. This is when we require you to first try certain preferred drugs to treat your medical condition before we will cover another non-preferred drug for that condition.

This policy supplements Medicare Local Coverage Determinations (LCDs) and National Coverage Determinations (NCDs) for the purpose of determining coverage under Medicare Part B medical benefits and applies a step therapy for Cerezyme (imiglucerase for injection).

This policy applies a step therapy Cerezyme (imiglucerase for injection). This list indicates the common uses for which Cerezyme (imiglucerase for injection) are prescribed. This list can change from time to time.

<table>
<thead>
<tr>
<th>Drug class</th>
<th>Nonpreferred product(s)</th>
<th>Preferred product(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gaucher disease</td>
<td>Cerezyme</td>
<td>Elelyso</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Vpriv</td>
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</tbody>
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Clinical Guideline Coverage Criteria

The Plan may cover Cerezyme when all the following clinical criteria is met:

1. History of prior treatment with Elelyso® (taliglucerase alfa) or Vpriv® (velaglucerase alfa) resulting in a substandard response to therapy

OR

2. History of intolerance or adverse event to treatment with Elelyso® (taliglucerase alfa) or Vpriv® (velaglucerase alfa)

OR

3. Rationale that treatment with Elelyso® (taliglucerase alfa) or Vpriv® (velaglucerase alfa is not clinically appropriate
   (Note: Convenience does not qualify as clinical rationale for inappropriateness of Elelyso or Vpriv)

OR

4. Continuation of prior therapy with Cerezyme (imiglucerase for injection) within the past 365 days

Limitations

- The plan does not cover enzyme replacement therapy for Type 2 or Type 3 Gaucher Disease.
- Any indications other than FDA-approved indications are considered experimental or investigational and will not be approved by the health plan

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>J1786</td>
<td>Injection, imiglucerase, 10 units</td>
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</tbody>
</table>

References:


Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)
September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better...
understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member’s benefit document, and in coordination with the Member’s physician(s) on a case-by-case basis considering the individual Member’s health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven 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 our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update 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 Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

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