

PREFERRED SPECIALTY MANAGEMENT POLICY

- POLICY:** Gaucher Disease – Enzyme Replacement Therapy Preferred Specialty Management Policy
- Cerezyme® (imiglucerase intravenous infusion – Genzyme)
 - Elelyso™ (taliglucerase alfa intravenous infusion – Pfizer)
 - Vpriv™ (velaglucerase alfa intravenous infusion – Shire)

REVIEW DATE: 08/31/2022

OVERVIEW

Cerezyme, Elelyso, and Vpriv are enzyme replacement therapy agents indicated for **long-term therapy in patients with a confirmed diagnosis of Type 1 Gaucher disease.**¹⁻³ The indication for Cerezyme specifies that it is used in Type 1 Gaucher disease that results in one or more of the following conditions: anemia, thrombocytopenia, bone disease, hepatomegaly, or splenomegaly. All of these agents have efficacy data to support use in both adult and pediatric patients.

POLICY STATEMENT

This Preferred Specialty Management program has been developed to encourage the use of the Preferred Product. For all medications (Preferred and Non-Preferred), the patient is required to meet the respective standard *Prior Authorization Policy* criteria. The program also directs the patient to try the Preferred Product prior to the approval of a Non-Preferred Product. Requests for Non-Preferred Products will also be reviewed using the exception criteria (below). Patients meeting the Prior Authorization criteria for a Non-Preferred Product who have not tried the Preferred Product will be offered a review for the Preferred Product. All approvals are provided for the duration noted below.

Documentation: Documentation is required for use of Cerezyme as noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to chart notes, prescription claims records, and prescription receipts.

Automation: None.

Preferred Products: Cerezyme
Non-Preferred Products: Elelyso, Vpriv

RECOMMENDED EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
Elelyso	<ol style="list-style-type: none"> 1. Approve for 1 year if the patient meets the following criteria (A <u>and</u> B): <ol style="list-style-type: none"> A) Patient meets the standard <i>Gaucher Disease – Enzyme Replacement Therapy – Elelyso Prior Authorization</i> criteria; AND B) Patient has tried Cerezyme [documentation required]. 2. For a patient who met criteria 1A but NOT 1B, offer to review for Cerezyme using the standard <i>Gaucher Disease – Enzyme Replacement Therapy – Cerezyme Prior Authorization</i> criteria. 3. If the patient is continuing therapy with Elelyso, approve for 1 year if the standard <i>Gaucher Disease – Enzyme Replacement Therapy – Elelyso Prior Authorization</i> criteria are met.
Vpriv	<ol style="list-style-type: none"> 1. Approve for 1 year if the patient meets the following criteria (A <u>and</u> B): <ol style="list-style-type: none"> A) Patient meets the standard <i>Gaucher Disease – Enzyme Replacement Therapy – Vpriv Prior Authorization</i> criteria; AND B) Patient has tried Cerezyme [documentation required]. 2. For a patient who met criteria 1A but NOT 1B, offer to review for Cerezyme using the standard <i>Gaucher Disease – Enzyme Replacement Therapy – Cerezyme Prior Authorization</i> criteria. 3. If the patient is continuing therapy with Vpriv, approve for 1 year if the standard <i>Gaucher Disease – Enzyme Replacement Therapy – Vpriv Prior Authorization</i> criteria are met.

REFERENCES

1. Cerezyme® intravenous infusion [prescribing information]. Cambridge, MA: Genzyme; May 2022.
2. Vpriv™ intravenous infusion [prescribing information]. Cambridge, MA: Shire; October 2021.
3. Elelyso™ intravenous infusion [prescribing information]. New York, NY: Pfizer Labs; June 2022.