Clover Health

EXCEPTIONS CRITERIA
GAUCHER DISEASE AGENTS

PREFERRED PRODUCT: ELELYSO

POLICY
This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the Gaucher disease products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Gaucher Disease Agents

	Product(s)
Preferred*	• **Elelyso** (taliglucerase alfa)
Targeted (non-preferred)	• **Cerezyme** (imiglucerase) • **VPRIV** (velaglucerase alfa)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

II. EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product.

Coverage for a targeted product is provided when either of the following criteria are met:

A. Member has received treatment with the targeted product in the past 365 days.
B. Member has had a documented inadequate response or an intolerable adverse event with the preferred product.
C. The member is less than 4 years of age and the requested product is Cerezyme.

REFERENCES

1. Elelyso [package insert]. New York, NY: Pfizer, Inc; July 2021.
2. Cerezyme [package insert]. Cambridge, MA: Genzyme Corporation; December 2021.
3. VPRIV [package insert]. Lexington, MA: Shire Human Genetic Therapies, Inc.; September 2021.