

This document applies to the following:

Product	Applies
Medicare Part B	<input checked="" type="checkbox"/>
Medicare Part B: Advanced Biosimilars First	<input checked="" type="checkbox"/>

Medicare Part B Step Therapy Gaucher Disease Agents

This document informs prescribers of preferred products and provides an exception process for non-preferred products through prior authorization.

These criteria were developed to align with the following: Medicare Part B and Medicare Part B Advanced Biosimilars First.

Plan Design Summary

This program applies to the Gaucher disease products specified in this document. Coverage for non-preferred 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 non-preferred product for the first time.

Step therapy is applied in addition to any applicable National Coverage Determination (NCD), Local Coverage Determination (LCD), and Medicare Part B utilization management (UM) programs implemented for the client.

Table. Gaucher Disease Agents

Medications considered preferred on your plan may still require a clinical prior authorization review.

	Products
Preferred	<ul style="list-style-type: none"> • Cerezyme (imiglucerase) • Elelyso (taliglucerase alfa)
Non-preferred	<ul style="list-style-type: none"> • VPRIV (velaglucerase alfa)

Reference number(s)
4219-D

Step Therapy Criteria

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

Coverage for a non-preferred product is provided when ANY of the following criteria is met:

- Member has received treatment with the non-preferred product in the past 365 days.
- The member has had a documented inadequate response or an intolerable adverse event with Cerezyme AND is between 2 and 4 years of age.
- Member has had a documented inadequate response or an intolerable adverse event with both of the preferred products, Cerezyme and Elelyso.

References

1. Elelyso [package insert]. New York, NY: Pfizer, Inc; January 2025.
2. Cerezyme [package insert]. Cambridge, MA: Genzyme Corporation; December 2024.
3. VPRIV [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; September 2024.