Reference number(s)
6444-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☑
Standard Control – Choice (SCCF)	☑
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☑
Advanced Control Specialty – Choice (ACSCF)	☑
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☑

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☐
Value Formulary Chart (VFC)	☑
Medical Benefit	☐
Medical Benefit: Advanced Biosimilars First	☐
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Gaucher Disease Agents

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

These criteria were developed to align with the following: Standard Control Formulary (SF), Standard Control Choice Formulary (SCCF), Advanced Control Specialty Formulary (ACSF), Advanced Control Specialty – Choice Formulary (ACSCF), Value Formulary (VF), and Value Formulary Chart (VFC).

Plan Design Summary

This program applies to the Gaucher disease products specified in this document. 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 all members requesting treatment with the targeted product.

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

Table. Gaucher Disease Agents

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

	Product(s)
Preferred	• Cerdelga (eliglustat) • Cerezyme (imiglucerase)

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	Product(s)
Target	• Elelyso (taliglucerase alfa) • VPRIV (velaglucerase alfa)

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 any of the following criteria are met:

- Member has had a documented inadequate response or an intolerable adverse event with both of the preferred products, Cerdelga and Cerezyme.
- Member has had a documented inadequate response or an intolerable adverse event with Cerezyme AND meets any of the following criteria:
    - Member is an indeterminate or ultra-rapid CYP2D6 metabolizer.
    - Member has pre-existing cardiac, renal, or hepatic disease.
    - Member has a clinically significant drug interaction with Cerdelga.
    - Member is 4 years of age or older but less than 18 years of age.

References

1. Cerdelga [package insert]. Cambridge, MA: Genzyme Corporation; January 2024.
2. Cerezyme [package insert]. Cambridge, MA: Genzyme Corporation; July 2024.
3. Elelyso [package insert]. New York, NY: Pfizer, Inc; July 2024.
4. VPRIV [package insert]. Lexington, MA: Shire Human Genetic Therapies, Inc., a Takeda company; July 2024

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