CVS Caremark®

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| Reference number(s) |
| 2301-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 Products

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: Managed Medicaid Template (MMT).

## 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 a targeted product.

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

### Table 1. Gaucher Disease Products (Enzyme Replacement Therapy)

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

|  | Products |
| --- | --- |
| Preferred\* | * Cerezyme (imiglucerase) |
| Targeted | * Elelyso (taliglucerase alfa) * VPRIV (velaglucerase alfa) |

### Table 2. Gaucher Disease Products (Substrate Reduction Therapy)

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

|  | Products |
| --- | --- |
| Preferred\* | * Cerdelga (eliglustat) |
| Targeted | * Zavesca (miglustat) * miglustat (generic) |

## Exception Criteria

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

### Enzyme Replacement Therapy

Coverage for a targeted product is provided when the member has had a documented inadequate response or an intolerable adverse event with the preferred product, Cerezyme.

### Substrate Reduction Therapy

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 the preferred product, Cerdelga.
* 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 the preferred product, Cerdelga.

## 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.
5. Zavesca [package insert]. Titusville, NJ: Actelion Pharmaceuticals US, Inc.; August 2022.
6. miglustat [package insert]. Baudette, MN: ANI Pharmaceuticals, Inc.; August 2022.