This policy applies to the following:

Standard Control (SF)	Managed Medicaid Template (MMT)	ACSF Chart (ACSFC)	✓	Medical Benefit	Medicare Part B
Standard Control – Choice (SCCF)	Marketplace (MF)	SF Chart (SFC)		Medical: Advanced Biosimilars First	Medicare Part B: Biosimilars First
Preferred Drug Plan Design (PDPD)	Aetna Health Exchange (AHE)	VF Chart (VFC)		Medical Benefit: Managed Medicaid	Medicare Part B: Advanced Biosimilars First
Advanced Control Specialty (ACSF)	IVL	New to Market (NTM)		Medical Benefit: Add-on	
Advanced Control Specialty – Choice (ACSCF)	Value (VF)				

Reference #

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# 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 all members requesting treatment with a targeted product.

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	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 the member has had a documented inadequate response or an intolerable adverse event with the preferred product.

## **REFERENCES**

Specialty Exceptions Gaucher's Disease Medical 4218-D P2024.docx

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#### This policy applies to the following:

Standard Control (SF)	Managed Medicaid Template (MMT)	ACSF Chart (ACSFC)	×	Medical Benefit	Medicare Part B
Standard Control – Choice (SCCF)	Marketplace (MF)	SF Chart (SFC)		Medical: Advanced Biosimilars First	Medicare Part B: Biosimilars First
Preferred Drug Plan Design (PDPD)	Aetna Health Exchange (AHE)	VF Chart (VFC)		Medical Benefit: Managed Medicaid	Medicare Part B: Advanced Biosimilars First
Advanced Control Specialty (ACSF)	IVL	New to Market (NTM)		Medical Benefit: Add-on	
Advanced Control Specialty – Choice (ACSCF)	Value (VF)				

1. Elelyso [package insert]. New York, NY: Pfizer, Inc; May 2023.

- 2. Cerezyme [package insert]. Cambridge, MA: Genzyme Corporation; December 2022.
- 3. VPRIV [package insert]. Lexington, MA: Shire Human Genetic Therapies, Inc., a Takeda company; September 2021.

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