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: Advanced Biosimilars First
	Preferred Drug Plan Design (PDPD)		Aetna Health Exchange (AHE)		VF Chart (VFC)		Medical Benefit: Managed Medicaid		
	Advanced Control Specialty (ACSF)		IVL		New to Market (NTM)		Medical Benefit: Add-on		
	Advanced Control Specialty – Choice (ACSCF)		Value (VF)						

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EXCEPTIONS CRITERIA

GAUCHER DISEASE AGENTS

PREFERRED PRODUCTS: CEREZYME AND 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*	• **Cerezyme** (imiglucerase) • **Elelyso** (taliglucerase alfa)
Targeted	• **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 is 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 both of the preferred products, Cerezyme and Elelyso.

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: Advanced Biosimilars First**
	Preferred Drug Plan Design (PDPD)		**Aetna Health Exchange (AHE)**		**VF Chart (VFC)**		**Medical Benefit: Managed Medicaid**		
	Advanced Control Specialty (ACSF)		**IVL**		**New to Market (NTM)**		**Medical Benefit: Add-on**		
	Advanced Control Specialty – Choice (ACSCF)		**Value (VF)**						

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REFERENCES

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: Takeda Pharmaceuticals U.S.A., Inc.; September 2021.