This policy applies to the following:

	Standard Opt-in		PDPD		Marketplace		Medical Benefit	✓	Medicare Part B
	Standard Opt-out		ACSF		MMT		Medical Benefit: Biosimilars First		Medicare Part B: Biosimilars First
	VF		Balanced		Medical Benefit: Managed Medicaid		Medical Benefit: Add-on		Medicare Part B: Add-on

Reference #
4219-D

POLICY Document for ELELYSO, CEREZYME AND VPRIV

The overall objective of this policy is to support the appropriate and cost effective use of the medication, specific to use of preferred medication options, and overall clinically appropriate use. This document provides specific information to each section of the overall policy.

Section 1: Preferred Product
- Policy information specific to preferred medications

Section 2: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

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 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	• **Elelyso** (taliglucerase alfa)
Targeted	• **Cerezyme** (imiglucerase) • **VPRIV** (velaglucerase alfa)

This policy applies to the following:

	Standard Opt-in		**PDPD**		**Marketplace**		**Medical Benefit**	✓	**Medicare Part B**	**Reference #**
	Standard Opt-out		**ACSF**		**MMT**		**Medical Benefit: Biosimilars First**		**Medicare Part B: Biosimilars First**	4219-D
	VF		**Balanced**		**Medical Benefit: Managed Medicaid**		**Medical Benefit: Add-on**		**Medicare Part B: Add-on**	

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 are 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 the preferred product.

REFERENCES

1. Elelyso [package insert]. New York, NY: Pfizer, Inc; October 2019.
2. Cerezyme [package insert]. Cambridge, MA: Genzyme Corporation; April 2018.
3. VPRIV [package insert]. Lexington, MA: Shire Human Genetic Therapies, Inc.; November 2019.

Section 2: Clinical Criteria

STANDARD MEDICARE PART B MANAGEMENT

UNIVERSAL CRITERIA

POLICY

The Specialty Universal Med B Criteria ensure appropriate utilization of Specialty medications and confirm that selection elements established in the FDA-approved product labeling and relevant compendia are followed. The criteria may be applied in situations where specific criteria are pending development.

Authorization of 12 months may be granted for a requested medication when clinically appropriate