

This policy applies to the following:

	Standard Opt-in		PDPD		Marketplace		Medical Benefit	✓	Medicare Part B	Reference # 4219-D
	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	

## 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)
<b>Preferred</b>	<ul style="list-style-type: none"> <li>• <b>ElELYSO</b> (taliglucerase alfa)</li> </ul>
<b>Targeted</b>	<ul style="list-style-type: none"> <li>• <b>Cerezyme</b> (imiglucerase)</li> <li>• <b>VPRIV</b> (velaglucerase alfa)</li> </ul>

#### 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.