POLICY Document for Cerezyme (imiglucerase)

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 both sections 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

Section 1: Preferred Product

EXCEPTIONS CRITERIA
Gaucher Disease

I. PREFERRED PRODUCT: ELELYSO

This policy informs prescribers of preferred products and provides an exception process for non-preferred products through prior authorization.

II. PLAN DESIGN SUMMARY

This program applies to the Gaucher disease products specified in this policy. Coverage for non-preferred 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 non-preferred product for an indication that is also FDA-approved for the preferred 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)
Non-preferred	• **Cerezyme** (imiglucerase) • **VPRIV** (velaglucerase alfa)

III. EXCEPTION CRITERIA

Coverage for a non-preferred product is provided when the member has experienced a confirmed adverse event with the preferred product.

Section 2: Clinical Criteria

CEREZYME (imiglucerase)

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
Cerezyme is indicated for long-term enzyme replacement therapy (ERT) for pediatric and adult patients with a confirmed diagnosis of type 1 Gaucher disease that results in one or more of the following conditions: anemia, thrombocytopenia, bone disease, hepatomegaly, or splenomegaly.

B. Compendial Uses
Gaucher disease type 3

II. CRITERIA FOR INITIAL APPROVAL

A. Gaucher disease type 1
Indefinite authorization may be granted for treatment of Gaucher disease type 1 when the diagnosis of Gaucher disease was confirmed by enzyme assay demonstrating a deficiency of beta-glucocerebrosidase (glucosidase) enzyme activity or by genetic testing

B. Gaucher disease type 3
Indefinite authorization may be granted for treatment of Gaucher disease type 3 when the diagnosis of Gaucher disease was confirmed by enzyme assay demonstrating a

deficiency of beta-glucocerebrosidase (glucosidase) enzyme activity or by genetic testing

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

REFERENCES:

SECTION 1

1. Elelyso [package insert]. New York, NY: Pfizer, Inc; December 2016.
2. Cerezyme [package insert]. Cambridge, MA: Genzyme Corporation; May 2011.
3. VPRIV [package insert]. Lexington, MA: Shire Human Genetic Therapies, Inc.; April 2015.

SECTION 2

1. Cerezyme [package insert]. Cambridge, MA: Genzyme Corporation; May 2011.
2. Altarescu G, Hill S, Wiggs E, et al. The efficacy of enzyme replacement therapy in patients with chronic neuronopathic Gaucher's disease. *J Pediatr.* 2001;138:539-547.
3. Erikson A, Forsberg H, Nilsson M, Astrom M, Mansson JE. Ten years' experience of enzyme infusion therapy of Norrbottnian (type 3) Gaucher disease. *Acta Paediatr*. 2006;95:312-317.
4. Pastores GM, Hughes DA. Gaucher Disease. [Updated February 26, 2015]. In: Pagon RA, Adam MP, Ardinger HH, et al, editors. GeneReviews® [Internet]. Seattle, WA: University of Washington, Seattle; 1993-2016.
5. Kaplan P, Baris H, De Meirleir L, et al. Revised recommendations for the management of Gaucher disease in children. *Eur J Pediatr.* 2013;172:447-458.