

<b>Policy Title:</b>	Cerezyme (imiglucerase), Elelyso (taliglucerase alfa), VPRIV (velaglucerase alfa) Intravenous		
		<b>Department:</b>	PHA
<b>Effective Date:</b>	01/01/2020		
<b>Review Date:</b>	04/19/2019, 9/18/2019, 12/18/2019, 1/29/2020, 2/04/2021, 1/27/2022, 1/19/2023		

**Purpose:** To support safe, effective and appropriate use of Cerezyme (imiglucerase), Elelyso (taliglucerase alfa), and VPRIV (velaglucerase alfa) to treat Gaucher’s disease.

**Scope:** Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

**Policy Statement:**

Medications to treat Gaucher’s disease are covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

**Procedure:**

Coverage of Cerezyme (imiglucerase), Elelyso (taliglucerase alfa), and VPRIV (velaglucerase alfa) will be reviewed prospectively via the prior authorization process based on criteria below.

**Coverage Criteria:**

- Patient must have a confirmed diagnosis of type 1 Gaucher disease (GD1) when the diagnosis of Gaucher disease was confirmed by enzyme assay demonstrating a deficiency of beta-glucocerebrosidase (glucosidase) enzyme activity or by genetic testing; AND
- Requests for Elelyso (taliglucerase alfa) or VPRIV (velaglucerase alfa) must have a documented failure, intolerance or contraindication to Cerezyme (imiglucerase); OR
- Patients that are currently on treatment with Elelyso (taliglucerase alfa) or VPRIV (velaglucerase alfa) can remain on treatment; OR
- MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements

**Continuation of Therapy Criteria:**

- The patient meets all initial criteria; AND
- Patient is tolerating and responding to medication (improvement in symptoms compared to pre-treatment baseline, such as e.g. bone pain, fatigue, dyspnea, angina, abdominal distension, diminished quality of life, etc.) and there continues to be a medical need for the medication.

**Coverage duration:** 6 months

\*\*\* Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable. \*\*\*

**Dosage/Administration:**

**Cerezyme:**

Indication	Dose	Maximum dose (1 billable unit = 10 units)
Type 1 Gaucher Disease	Initial dosages range from 2.5 U/kg of body weight 3 times a week to 60 U/kg once every 2 weeks based on disease severity.	700 billable units every 14 days

**Elelyso:**

Indication	Dose	Maximum dose (1 billable unit = 10 units)
Type 1 Gaucher Disease	Up to 60 units/kg every other week as a 60-120-minute intravenous infusion	700 billable units every 14 days

**VPRIV:**

Indication	Dose	Maximum dose (1 billable unit = 10 units)
Type 1 Gaucher Disease	Up to 60 units/kg every other week as a 60-minute intravenous infusion	72 billable units every 14 days

**Investigational use:** All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

**Applicable Codes:**

Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all-inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

<b>HCPCS/CPT Code</b>	<b>Description</b>
J1786	Injection, imiglucerase, 10 units
J3060	Injection, taliglucerase alfa, 10 units
J3385	Injection, velaglucerase alfa, 100 units

References:

1. Elelyso [package insert]. New York, NY: Pfizer, Inc.; September 2022.
2. Cerezyme [package insert]. Cambridge, MA: Genzyme Corporation; May 2022..
3. VPRIV [package insert]. Lexington, MA: Shire Human Genetic Therapies, Inc.; October 2022..