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|---|---|---|---|
| **Policy Title:** | Cerezyme (imiglucerase), Elelyso (taliglucerase alfa), VPRIV (velaglucerase alfa) | | |
| **Policy Number:** | 000664 | **Department:** | PHA |
| **Effective Date:** | 07/01/2019 | | |
| **Review Date:** | 04/19/2019 | | |
| **Revision Date:** | 04/19/2019 | | |

**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, Exchange, Integrity

**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.

***Criteria Coverage for Medicaid and Exchange:***

- Patient must have a confirmed diagnosis of type 1 Gaucher disease (GD1) or a diagnosis of type 3 Gaucher (GD3) and the diagnosis of Gaucher disease was confirmed by enzyme assay demonstrating a deficiency of beta-glucocerebrosidase (glucosidase) enzyme activity or by genetic testing;
- For patients requesting Elelyso (taliglucerase alfa) or VPRIV (velaglucerase alfa) they must have a documented failure, intolerance or contraindication to Cerezyme (imiglucerase);
- For patients that are currently on treatment with Elelyso (taliglucerase alfa) or VPRIV (velaglucerase alfa) they can remain on treatment as long as the medication was not obtained as samples or via manufacturer's patient assistance programs.

***Criteria Coverage for Integrity ONLY:***

- Patient must have a confirmed diagnosis of type 1 Gaucher disease (GD1) or a diagnosis of type 3 Gaucher (GD3) and the diagnosis of Gaucher disease was confirmed by enzyme assay demonstrating a deficiency of beta-glucocerebrosidase (glucosidase) enzyme activity or by genetic testing.

**Coverage durations:** 12 months

**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 one of the above listed resources. 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:

| HCPCS/CPT Code | Description |
|---|---|
| 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.; December 2016.
2. Cerezyme [package insert]. Cambridge, MA: Genzyme Corporation; April 2018.
3. VPRIV [package insert]. Lexington, MA: Shire Human Genetic Therapies, Inc.; April 2015.