Policy Title:	Cerezyme (imiglucerase), Elelyso (taliglucerase alfa), VPRIV (velaglucerase alfa) Intravenous		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	04/19/2019, 9/18/2019, 12/18/19		
Revision Date:	04/19/2019, 9/18/2019		

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, 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

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:

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.