UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Gaucher's Disease Agents- ARIZONA

Program	Prior Authorization
Medications	Cerdelga (eliglustat), Cerezyme (imiglucerase), Elelyso (taliglucerase alfa), Vpriv (velaglucerase alfa), Zavesca (miglustat)
Markets in Scope	Arizona

1. Background:

Cerdelga (eliglustat) is indicated for the long-term treatment of adult patients with Type 1 Gaucher's disease who are CYP2D6 extensive metabolizers (EMs), intermediate metabolizers (IMs), or poor metabolizers (PMs) as detected by an FDA-cleared test.

Cerezyme indicated for long-term enzyme replacement therapy for pediatric and adult patients with a confirmed diagnosis of Type 1 Gaucher's disease that results in one or more of the following conditions: anemia, thrombocytopenia, bone disease, hepatomegaly or splenomegaly.

Elelyso is a hydrolytic lysosomal glucocerebroside-specific enzyme indicated for the treatment of patients with a confirmed diagnosis of Type 1 Gaucher's disease.

Vpriv is a hydrolytic lysosomal glucocerebroside-specific enzyme indicated for long-term enzyme replacement therapy (ERT) for patients with Type 1 Gaucher's disease.

Zavesca (miglustat) is indicated as monotherapy for the treatment of adult patients with mild to moderate Type 1 Gaucher's disease for whom enzyme replacement therapy is not a therapeutic option (eg, due to allergy, hypersensitivity, or poor venous access).

2. Coverage Criteria:

A. Initial Authorization

1. Cerdelga will be approved based on **all** of the following criteria:

a. Diagnosis of Type 1 Gaucher's disease

-AND-

b. Patient is **one** of the following as detected by an FDA-cleared test:

(1) CYP2D6 extensive metabolizer,
(2) CYP2D6 intermediate metabolizer
(3) CYP2D6 poor metabolizer

-AND-

c. Patient has a history of failure, contraindication, or intolerance to Cerezyme

Authorization will be issued for 12 months.

2. Cerezyme will be approved based on the following criteria:

a. Diagnosis of Type 1 Gaucher's disease that results in one or more of the following conditions:

(1) Anemia
(2) Thrombocytopenia
(3) Bone disease
(4) Hepatomegaly or splenomegaly

Authorization will be issued for 12 months.

3. Vpriv or **Elelyso** will be approved based on **both** of the following:

a. Diagnosis of Type 1 Gaucher's disease

-AND-

b. Patient has a history of failure, contraindication, or intolerance to Cerezyme

Authorization will be issued for 12 months.

4. Zavesca will be approved based on **both** of the following criteria:

a. Diagnosis of mild to moderate Type 1 Gaucher's disease

-AND-

b. **One** of the following:

(1) Patient is unable to receive enzyme replacement therapy due to one of the following conditions:

a) Allergy or hypersensitivity to enzyme replacement therapy
b) Poor venous access
c) Unavailability of enzyme replacement therapy (e.g., Cerezyme, VPRIV)

-OR-

(2) Patient has a history of failure, contraindication, or intolerance to Cerezyme

Authorization will be issued for 12 months.

B. Reauthorization

1. **Cerdelga, Cerezyme, Elelyso, Vpriv, or Zavesca** will be approved based on the following criterion:

   a. Documentation of positive clinical response to therapy

Authorization will be issued for 12 months.

3. References:

1. Cerdelga Prescribing Information. Genzyme Ireland, Ltd. Waterford, Ireland. August 2014.
2. Cerezyme Prescribing Information. Genzyme Corporation. Cambridge, MA. March 2017.
3. Elelyso [prescribing information]. New York, NY: Pfizer Labs; December 2016.
4. Vpriv Prescribing Information. Shire Human Genetic Therapies Inc. Lexington, MA. November 2017.
5. Zavesca Prescribing Information. Actelion Pharmaceuticals US Inc. South San Francisco, CA. February 2016.

Program	Prior Authorization
Change Control	
11/2017	New program specific to Arizona
2/2018	Added Vpriv and Elelyso to criteria as these are reinsurable in AZ