

**Cerezyme (imiglucerase)
 Elelyso (taliglucerase alfa)
 VPRIV (velaglucerase alfa)
 Effective 10/01/2021**

Plan	<input checked="" type="checkbox"/> MassHealth <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX)		
Specialty Limitations	N/A		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

Cerezyme is a modified form of the enzyme glucocerebrosidase indicated for long-term enzyme replacement therapy for pediatric and adult patients diagnosed with Gaucher disease Type 1 that results in one or more of the following conditions: anemia, bone disease, hepatomegaly or splenomegaly or thrombocytopenia

Elelyso and VPRI are recombinant glucocerebrosidase-specific enzymes FDA approved to treat type 1 Gaucher’s disease in patients ≥4 years of age.

Coverage Guidelines

Authorization may be granted for members new to AllWays Health Partners who are currently receiving treatment with Cerezyme, Elelyso, or VPRIV, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

OR

Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:

1. The member diagnosed with Gaucher disease Type 1.
2. The diagnosis of Gaucher Type 1 has been confirmed by enzyme assay demonstrating deficiency of beta-glucocerebrosidase (glucosidase) enzyme activity or by genetic testing.
3. Documentation has been submitted of one of the following conditions:
 - Anemia
 - Bone disease
 - Hepatomegaly or splenomegaly



- Thrombocytopenia
4. For Cerezyme: The member is at least 2 years of age
 5. For Elelyso and VPRIV: The member is at least 4 years of age

Continuation of Therapy

Reauthorization requires physician documentation of improvement of member's condition.

Limitations

1. Initial approvals and reauthorizations will be granted for 12 months

References

1. Cerezyme (imiglucerase) [prescribing information]. Cambridge, MA: Genzyme Corporation; December 2020.
2. Elelyso (taliglucerase alfa) [prescribing information]. New York, NY: Pfizer Labs; November 2020
3. VPriv (velaglucerase alfa) [prescribing information]. Lexington, MA: Shire Human Genetic Therapies; December 2020
4. Biegstraaten M, Cox TM, Belmatoug N, et al. Management goals for type 1 Gaucher disease: An expert consensus document from the European working group on Gaucher disease. *Blood Cells Mol Dis* 2016
5. Shemesh E, Deroma L, Bembi B, et al. Enzyme replacement and substrate reduction therapy for Gaucher disease. *Cochrane Database Syst Rev* 2015; :CD010324
6. Ben Turkia H, Gonzalez DE, Barton NW, et al. Velaglucerase alfa enzyme replacement therapy compared with imiglucerase in patients with Gaucher disease. *Am J Hematol* 2013; 88:179
7. Niederau C, vom Dahl S, Häussinger D. First long-term results of imiglucerase therapy of type 1 Gaucher disease. *Eur J Med Res* 1998; 3:25
8. Pastores GM, Rosenbloom B, Weinreb N, et al. A multicenter open-label treatment protocol (HGT-GCB-058) of velaglucerase alfa enzyme replacement therapy in patients with Gaucher disease type 1: safety and tolerability. *Genet Med* 2014; 16:359

Review History

07/21/2021- Reviewed P&T, switch from CVS SGM to AllWays Health Partners custom policy: removed compendial use for Gaucher type 3, combined Cerezyme, Elelyso and VPRIV into one document, added required conditions and age requirements; overview and references updated. Effective 10/01/2021.

Disclaimer

AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.