Mass General Brigham
Health Plan

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

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview
Cerezyme is a modified form of the enzyme glucocerebrosidase indicted 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 the plan 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 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.