Elelyso (taliglucerase alfa)

Effective Date: January 1, 2021	Number: MG.MM.PH.226

Definition

Elelyso is an analogue of β-glucocerebrosidase produced via recombinant DNA technology in genetically modified carrot plant root cells. Elelyso differs from human glucocerebrosidase by two amino acids at the N terminal and seven amino acids at the C terminal end of the protein. Elelyso catalyzes the breakdown of glucocerebroside to glucose and ceramide.

Elelyso is indicated for the treatment of patients with a confirmed diagnosis of Type 1 Gaucher disease.

Length of Authorization

Coverage will be provided for 12 months

Dosing

- Each individual dose must not exceed 60 U/kg administered intravenously no more frequently than once every 2 weeks

Guideline

Gaucher Disease, Type 1

- Elelyso is prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders; **AND**
- Patient's diagnosis is established by one of the following:
    - Demonstration of deficient β-glucocerebrosidase activity in leukocytes or fibroblasts; **OR**
    - Molecular genetic testing documenting glucocerebrosidase gene mutation

Limitations/Exclusions

- Coverage is not recommended for circumstances not listed in the Guideline. Criteria will be updated as new published data are available.

Applicable Procedure Codes

J3060	Injection, taliglucerase, 200 units

Applicable NDC's

00069-0106-xx	Injection,taliglucerase, 200 unit vial

Applicable Diagnosis Codes

E75.22	Lipidosis (Gaucher Disease)

Revision History

1/1/2021	Criteria apply to Commercial, Medicare, and Medicaid members.

References

1. Elelyso® for injection [prescribing information]. New York, NY: Pfizer; December 2016.
2. Burrow TA, Barnes S, and Grabowski GA. Prevalence and management of Gaucher disease. Pediatric Health, Medicine and Therapeutics. 2011;2:59-73
3. Cox T. Gaucher disease: clinical profile and therapeutic development. Biologics: Targets & Therapy. 2010;4:299-313
4. Jmoudiak, M. and Futerman, AH. Gaucher disease: Pathological mechanisms and modern management. British Journal of Haematology. 2005;129(2):178–188
5. Grabowski GA. Lysosomal storage disease 1- phenotype, diagnosis, and treatment of Gaucher's disease. Lancet. 2008;372:1263-1271.
6. Zimran A. How I treat Gaucher disease. Blood. 2011;118:1463-1471.
7. Stirnemann J, Belmatoug N, Camou F, et al. A review of Gaucher disease pathophysiology, clinical presentation and treatments. *Int J Mol Sci*. 2017;18:441.
8. Baris HN, Cohen IJ, Mistry PK. Gaucher disease: The metabolic defect, pathophysiology, phenotypes and natural history. *Pediatr Endocrinol Rev*. 2014;12:72-81.