# SPECIALTY GUIDELINE MANAGEMENT

# **ELELYSO** (taliglucerase alfa)

### **POLICY**

### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

### A. FDA-Approved Indications

Elelyso is indicated for the treatment of patients 4 years and older with a confirmed diagnosis of type 1 Gaucher disease.

# B. Compendial Uses

Gaucher disease type 2

Gaucher disease type 3

All other indications are considered experimental/investigational and not medically necessary.

### II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: betaglucocerebrosidase enzyme assay or genetic testing results supporting diagnosis

### III. CRITERIA FOR INITIAL APPROVAL

## A. Gaucher disease type 1

Authorization of 12 months may be granted for treatment of Gaucher disease type 1 when the diagnosis of Gaucher disease was confirmed by enzyme assay demonstrating a deficiency of beta-glucocerebrosidase (glucosidase) enzyme activity or by genetic testing.

# B. Gaucher disease type 2

Authorization of 12 months may be granted for treatment of Gaucher disease type 2 when the diagnosis of Gaucher disease was confirmed by enzyme assay demonstrating a deficiency of beta-glucocerebrosidase (glucosidase) enzyme activity or by genetic testing.

### C. Gaucher disease type 3

Authorization of 12 months may be granted for treatment of Gaucher disease type 3 when the diagnosis of Gaucher disease was confirmed by enzyme assay demonstrating a deficiency of beta-glucocerebrosidase (glucosidase) enzyme activity or by genetic testing.

### IV. CONTINUATION OF THERAPY

Elelyso 2053-A SGM P2021.docx

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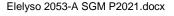


Reference	number
2053-A	

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for Gaucher disease type 1, type 2, or type 3 who are not experiencing an inadequate response or any intolerable adverse events from therapy.

### V. REFERENCES

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- 3. Pastores GM, Hughes DA. Gaucher Disease. [Updated June 21, 2018]. In: Pagon RA, Adam MP, Ardinger HH, et al, editors. GeneReviews® [Internet]. Seattle, WA: University of Washington, Seattle; 1993-2018.
- 4. Kaplan P, Baris H, De Meirleir L, et al. Revised recommendations for the management of Gaucher disease in children. *Eur J Pediatr.* 2013;172:447-458.
- 5. Vellodi A, Tylki-Szymanska A, Davies EH, et al. Management of neuronopathic Gaucher disease: revised recommendations. European Working Group on Gaucher Disease. *J Inherit Metab Dis.* 2009;32(5):660.
- 6. American Society of Health System Pharmacists. AHFS Drug Information. Bethesda, MD. Electronic version, 2021. Available with subscription. URL: http://online.lexi.com/crlsql/servlet/crlonline. Accessed January 28, 2021.
- 7. DRUGDEX System (electronic version). Micromedex Truven Health Analytics. Available with subscription. URL: www.micromedexsolutions.com. Accessed January 28, 2021.
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