SmartHealth Ascension

Idursulfase

(Elaprase®) J1743 (1mg)

Covered with prior authorization

Idursulfase (Elaprase®) may be authorized when the following criteria are met:

Individual has a diagnosis of mucopolysaccharidosis II (MPS II, Hunter syndrome) confirmed by:

- Deficiency in iduronate 2-sulfatase enzyme activity as measured in fibroblasts or leukocytes combined with normal enzyme activity level of another sulfatase, and documentation is provided; **OR**
- Pathologic iduronate 2-sulfatase gene mutation, and documentation is provided; **AND**
- The medication 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

Individual is 16 months of age or older

The individual has symptoms or testing related to MPS II including ONE of the following:

- FVC
- 6-minute walk test (6-MWT)
- Developmental delay or cognitive impairment
- Frequent infections
- Hearing loss
- Hepatosplenomegaly
- Hernias
- Impaired respiratory function
- Joint pain
- Skeletal deformities
- Sleep apnea
- Valvular heart disease

Exclusion criteria:
Requests for Idursulfase (Elaprase®) may not be approved for the following:

- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines

- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use

Initial authorization is up to 12 months.

Annual reauthorizations will require documentation to show clinically significant improvement or stabilization in clinical signs and symptoms of disease.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:

This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Dosing

The recommended dosage regimen of Elaprase is 0.5 mg per kg of body weight administered once weekly as an intravenous infusion. Elaprase is supplied as a sterile injection in a 5 mL Type I glass via

Elaprase® is a hydrolytic lysosomal glycosaminoglycan (GAG)-specific enzyme indicated for patients with Hunter syndrome (Mucopolysaccharidosis II, MPS II).

References:

1. Elaprase® [Prescribing Information]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc. 2023.
2. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
3. Muenzer J, Bodamer O, Burton B, et al. The role of enzyme replacement therapy in severe Hunter syndrome-an expert panel consensus. Eur J Pediatr. 2012; 171(1):181-188.
4. Scarpa M, Almássy Z, Beck M, et al. Mucopolysaccharidosis type II: European recommendations for the diagnosis and multidisciplinary management of a rare disease. Orphanet J Rare Dis. 2011; 6:72.
5. Wraith JE, Scarpa M, Beck M, et al. Mucopolysaccharidosis type II (Hunter syndrome): a clinical review and recommendations for treatment in the era of enzyme replacement therapy. Eur J Pediatr. 2008; 167(3):267-277.

Date	Summary of Changes
January 2023	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
January 2023	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.
March 2023	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team, or email your questions to smarthealthspecialty@ascension.org.