Elaprase® (idursulfase)

When requesting Elaprase® (idursulfase), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved Indication

Elaprase (idursulfase) is indicated for the treatment of individuals with mucopolysaccharidosis type II (MPS II; Hunter syndrome).

Coverage Guidelines

Mucopolysaccharidosis Type II (MPS II; Hunter syndrome)

The individual must meet **all** of the following criteria for approval:

- Diagnosis is confirmed by one of the following:
  - Laboratory test demonstrating deficient iduronate-2-sulfatase activity in leukocytes, fibroblasts, or plasma; OR
  - Molecular genetic test demonstrating iduronate-2-sulfatase gene mutation

- Elaprase 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.

Approval duration: 12 months

Dosing Recommendation

Approve up to 0.5 mg/kg administered intravenously no more frequently than once a week.

References

1. Elaprase® injection for intravenous use [prescribing information]. Lexington, MA: Shire Human Genetic Therapies, Inc.; November, 2018.
2. Scarpa M, Almassy 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.
3. Muenzer J, Beck M, Eng CM, et al. Multidisciplinary management of Hunter syndrome. *Pediatrics*. 2009;124:e1228-e1239.
4. Giugliani R, Federhen A, Munoz Rojas MV, et al. Mucopolysaccharidosis I, II, and VI: Brief review and guidelines for treatment. *Genet Mol Biol*. 2010;33:589-604.

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