

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:
 - o Laboratory test demonstrating deficient iduronate-2-sulfatase activity in leukocytes, fibroblasts, serum or plasma; OR
 - o Molecular genetic test demonstrating iduronate-2-sulfatase gene mutation
- Elaprase is prescribed by or in consultation with a geneticist, an endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders.

Approval duration: 12 months

Dosing Recommendation

The recommended dosage regimen of Elaprase is 0.5 mg per kg of body weight administered once weekly as an intravenous infusion.

References

1. Elaprase® injection for intravenous use [prescribing information]. Lexington, MA: Shire Human Genetic Therapies, Inc.; September 2021.
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.
5. D'Avanzo F, Rigon L, Zanetti A, Tomanin R. Mucopolysaccharidosis type II: One hundred years of research, diagnosis, and treatment. *Int J Mol Sci.* 2020;21:E1258.