Elaprase (idursulfase)

Effective Date: January 1, 2021  Number: MG.MM.PH.308

Definitions

Elaprase is human iduronate-2-sulfatase (idursulfase), produced in a human cell line using recombinant DNA technology. Idursulfase hydrolyzes the 2-sulfate esters of terminal iduronate sulfate residues from dermatan and heparin sulfate in lysosomes of various cell types. Elaprase is indicated for patients with Hunter syndrome (Mucopolysaccharidosis type II [MPS II]). Elaprase has been shown to improve walking capacity in patients ≥ 5 years of age. In patients 16 months to 5 years of age, no data are available to demonstrate improvement in disease-related symptoms or long-term clinical outcome; however, treatment has reduced spleen volume similar to that of patients ≥ 5 years of age.

Dosing

Each dose must not exceed 0.5 mg/kg administered intravenously no more frequently than once a week.

Length of Coverage

- Approvals will be granted for 12 months

Guideline

Mucopolysaccharidosis Type II (Hunter Syndrome)

- The diagnosis is established by one of the following:
Patient has a laboratory test demonstrating deficient iduronate-2-sulfatase activity in leukocytes, fibroblasts, serum, or plasma; OR
- Patient has a molecular genetic test demonstrating iduronate-2-sulfatase gene mutation; AND
- 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.

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

| J1743 | Injection, idursulfase, 1 mg; 1 mg = 1 billable unit |

Applicable NDC Codes

| 54092-0700-xx | Elaprase 6 mg/3 mL single-use vial for injection |

Applicable Diagnosis Codes

| E76.1 | Mucopolysaccharidosis, type II |

Revisions

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

REFERENCES