**Elaprase® (idursulfase)**  
**(Intravenous)**

**Last Review Date:** 10/02/2018  
**Date of Origin:** 01/01/2012  
**Dates Reviewed:** 12/2011, 02/2013, 02/2014, 12/2014, 10/2015, 10/2016, 10/2017, 10/2018

I. **Length of Authorization**  
Coverage will be provided for 12 months and may be renewed.

II. **Dosing Limits**

   A. **Quantity Limit (max daily dose) [Pharmacy Benefit]:**
      - Elaprase 6 mg vial: 10 vials per 7 days

   B. **Max Units (per dose and over time) [Medical Benefit]:**
      - 60 billable units every 7 days

III. **Initial Approval Criteria**

Coverage is provided in the following conditions:

**Hunter syndrome (Mucopolysaccharidosis II; MPS II) †**

- Patient is at least 16 months old: **AND**
- Patient has absence of severe cognitive impairment: **AND**
- Diagnosis has been confirmed by one of the following:
  - Deficient iduronate 2-sulfatase (I2S) enzyme activity in white cells, fibroblasts, or plasma in the presence of normal activity of at least one other sulfatase: **OR**
  - Detection of pathogenic mutations in the **IDS** gene by molecular genetic testing: **AND**
- Documented baseline value for urinary glycosaminoglycan (uGAG)
- Documented baseline values for one or more of the following:
  - Patients 5 years or greater: 6-minute walk test (6-MWT) and/or percent predicted forced vital capacity (FVC): **OR**
  - Patients < 5 years: spleen volume, liver volume, FVC, and/or 6-minute walk test

† FDA Approved Indication(s)
IV. Renewal Criteria

Authorizations can be renewed based on the following criteria:

- Patient continues to meet the criteria in section III: **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe hypersensitivity including anaphylactic and anaphylactoid reactions, antibody development and serious adverse reactions, acute respiratory complications, acute cardiorespiratory failure, etc.: **AND**
- Patient does not have progressive/irreversible severe cognitive impairment: **AND**
- Patient has a documented reduction in uGAG levels: **AND**
- Patient has demonstrated a beneficial response to therapy compared to pretreatment baseline in one or more of the following:
  - **Patients 5 years or greater**: stabilization or improvement in 6-MWT and/or FVC: **OR**
  - **Patients < 5 years**: spleen volume, and/or liver volume or stabilization/improvement in FVC and/or 6-MWT

V. Dosage/Administration

<table>
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<tr>
<th>Indication</th>
<th>Dose</th>
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<tr>
<td>Hunter Syndrome; MPS II</td>
<td>0.5 mg/kg of body weight administered once weekly as an intravenous infusion</td>
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</table>

VI. Billing Code/Availability Information

**Jcode:**

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

**NDC:**

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

VII. References


Appendix 1 – Covered Diagnosis Codes

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<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
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<tr>
<td>E76.1</td>
<td>Mucopolysaccharidosis, type II</td>
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Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

N/A

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<td>Noridian Healthcare Solutions, LLC</td>
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