Elaprase® (idursulfase)

Last Review Date: January 1, 2019  Number: MG.MM.PH.76

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Authorization

- Coverage will be provided for 12 months and may be renewed.

Dosing Limits

A. Max Units (per dose and over time) [Medical Benefit]:

- 60 billable units every 7 days

Dosing and Administration
Elaprase Package Insert

Guideline

Initial Criteria

Coverage is provided in the following conditions:

Hunter syndrome (Mucopolysaccharidosis II; MPS II) †

- Patient is at least 5 years 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)

**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 the following: 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

**Limitations/Exclusions**

Eleprase is considered investigational when used for any indication not listed above.

**Applicable Procedure Codes**

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<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>J1743</td>
<td>Injection, idursulfase, 1 mg; 1 mg = 1 billable unit</td>
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**Applicable NDC Codes**

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<tr>
<th>Code</th>
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<tr>
<td>54092-0700-xx</td>
<td>Elaprase 6 mg/3 mL single-use vial for injection</td>
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**Applicable Diagnosis Codes**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>E76.1</td>
<td>Mucopolysaccharidosis, type II</td>
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References


