Elaprase® (idursulfase)

Last Review Date: January 1, 2020  Number: MG.MM.PH.76

Medical Guideline Disclaimer
Property of EmblemHealth. All rights reserved. The treating physician or primary care provider must submit to EmblemHealth the clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request for prior authorization. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary. If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication. EmblemHealth Services Company LLC, ("EmblemHealth") has adopted the herein policy in providing management, administrative and other services to HIP Health Plan of New York, HIP Insurance Company of New York, Group Health Incorporated, GHI HMO Select, ConnectiCare, Inc., ConnectiCare Insurance Company, Inc. ConnectiCare Benefits, Inc., and ConnectiCare of Massachusetts, Inc. related to health benefit plans offered by these entities. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

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 above; **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**

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

**Applicable Procedure Codes**

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

**Applicable NDC Codes**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>54092-0700-xx</td>
<td>Elaprase 6 mg/3 mL single-use vial for injection</td>
</tr>
</tbody>
</table>

**Applicable Diagnosis Codes**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E76.1</td>
<td>Mucopolysaccharidosis, type II</td>
</tr>
</tbody>
</table>
Elaprase® (idursulfase)
Last review: January 1, 2020
Page 3 of 3

References


