Aldurazyme (laronidase solution)

Effective Date: January 1, 2021
Number: MG.MM.PH.303

Medical Guideline Disclaimer

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Definitions

Aldurazyme is human α-L-iduronidase produced in Chinese hamster ovary cells via recombinant DNA technology. Alpha-L-iduronidase catalyzes the hydrolysis of terminal α-L-iduronic acid from dermatan sulfate and heparin sulfate. Aldurazyme is indicated for patients with Hurler and Hurler-Scheie forms of Mucopolysaccharidosis type I and in patients with the Scheie form who have moderate to severe symptoms. The risks and benefits of treating mildly affected patients with the Scheie form have not been established.

Dosing

- Each dose must not exceed 0.58 mg/kg administered intravenously no more frequently than once weekly.

Length of Coverage

- Approval will be granted for 12 months

Guideline

Mucopolysaccharidosis Type I (Hurler Syndrome, Hurler-Scheie Syndrome, and Scheie Syndrome)

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

• Aldurazyme 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

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<tr>
<th>Procedure Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>J1931</td>
<td>Injection, laronidase, 0.1 mg; 1 billable unit = 0.1 mg</td>
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Applicable NDC’s

<table>
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<th>NDC Code</th>
<th>Description</th>
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<tr>
<td>58468-0070-xx</td>
<td>Aldurazyme 2.9 mg/5 mL single-dose vial</td>
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Applicable Diagnosis Codes

<table>
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<th>ICD-10 Description</th>
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<tbody>
<tr>
<td>E76.01</td>
<td>Hurler's syndrome</td>
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<tr>
<td>E76.02</td>
<td>Hurler-Scheie syndrome</td>
</tr>
<tr>
<td>E76.03</td>
<td>Scheie's syndrome</td>
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Revision History

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

REFERENCES