laronidase (Aldurazyme)

Commercial Medical Benefit Drug Policy

Place of Service
Home Infusion Administration
Infusion Center Administration
Office Administration
Outpatient Facility

Drug Details

USP Category: GENETIC OR ENZYME OR PROTEIN DISORDER: REPLACEMENT, MODIFIERS, TREATMENT
Mechanism of Action: exogenous enzyme replacement for alpha-L-iduronidase
HCPCS:
J1931:Injection, laronidase, 0.1 mg
How Supplied:
2.9 mg/5 mL (single-use vial)

Condition(s) listed in policy *(see coverage criteria for details)*

- Hurler Form of Mucopolysaccharidosis I (MPS I) OR Hurler-Scheie Form of MPS I OR Scheie Form with Moderate to Severe Symptoms of Mucopolysaccharidosis (MPS I)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Hurler Form of Mucopolysaccharidosis I (MPS I) OR Hurler-Scheie Form of MPS I OR Scheie Form with Moderate to Severe Symptoms of Mucopolysaccharidosis (MPS I)
Meets medical necessity if all the following are met:
1. Meets EITHER of the following:
   a. Documented reduced enzyme activity in alpha-L-iduronidase activity
   b. Genetic testing confirming diagnosis of MPS I

Covered Doses:

Up to 0.58 mg/kg given intravenously once weekly

Coverage Period:
Yearly

ICD-10:
E76.01, E76.02, E76.03

References

1. AHFS. Available by subscription at http://www.lexi.com
2. Aldurazyme (laronidase) Prescribing Information. Cambridge, MA: Genzyme Corp.; 12/2023.
3. DrugDex. Available by subscription at http://www.thomsonhc.com
4. Wang RY, Bodamer OA, et al. American College of Medical Genetics (ACMG) Work Group on Diagnostic Confirmation of Lysosomal Storage Diseases. Lysosomal storage diseases: diagnostic confirmation and management of presymptomatic individuals. Genet Med. 2011; 13(5):457-484.

Review History

Date of Last Annual Review: 2Q2025
Changes from previous policy version:

- No clinical change to policy following annual review.

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee