Laronidase (Aldurazyme®)	Place of Service Infusion Center Administration Home Infusion Administration Office Administration Outpatient Facility Infusion Administration* [*Prior authorization required – see section (1)] HCPCS: **J1931** per 0.1 mg

Conditions listed in policy (*see criteria for details*)

- Hurler form of Mucopolysaccharidosis (MPS I)
- Hurler-Scheie form of Mucopolysaccharidosis (MPS I)
- Scheie form with moderate to severe symptoms of Mucopolysaccharidosis (MPS I)

AHFS therapeutic class: Enzymes

Mechanism of action: Laronidase is a biosynthetic (recombinant DNA origin) replacement form of L-iduronidase, a lysosomal enzyme that catalyzes the hydrolysis of terminal α-l-iduronic acid residues of dermatan sulfate and heparan sulfate. In animal models of mucopolysaccharidosis I, intravenous laronidase was shown to decrease hepatic storage of glycosaminoglycans as well as their urinary excretion.

(1) Special Instructions and pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Aldurazyme® (laronidase) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

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)

1. Either of the following:
    a. Documented reduced enzyme activity in alpha-L-iduronidase activity, OR
    b. Genetic testing confirming diagnosis of MPS I

Covered Doses
Up to 0.58 mg/kg administered intravenously weekly

Coverage Period
Indefinite

ICD-10:
E76.01- E76.03

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Aldurazyme® (laronidase) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:
2.9 mg/5 mL (single-use vial)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- Aldurazyme® (laronidase) [Prescribing information]. Cambridge, MA: Genzyme Corp.; 12/2019.
- DrugDex®. Available by subscription at http://www.thomsonhc.com
- 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.

(7) Policy Update

Date of last review: 2Q2023
Date of next review: 2Q2024
Changes from previous policy version:

- No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee