

<b>Policy Name:</b>	<b>Aldurazyme (laronidase)</b>	<b>Policy #:</b>	<b>2472P</b>
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## Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Aldurazyme.

## Statement of the Policy

Health Alliance Medical Plans and Health Alliance Northwest will approve the use of Aldurazyme under the Specialty Medical benefit when the following criteria have been met.

## Criteria

### 1. Coverage Criteria for the Treatment of Mucopolysaccharidosis (MPS type I)

- 1.1 Documented diagnosis of MPS type I
  - Hurler syndrome
  - Hurler-Scheie syndrome
  - Scheie syndrome
- 1.2 Prescribed by a geneticist (gene doctor)
- 1.3 For a diagnosis of Scheie syndrome:
  - Provider's opinion that the disease is moderate-to-severe
  - Provider's opinion that the drug is needed to improve lung function and/or walking capacity (drug has not been evaluated for effects on the central nervous system)

### 2. Approval Period

- 2.1 12 months

## CPT Codes

96360 – 96361	Intravenous infusion, hydration
96365 – 96368	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug)
96379	Unlisted therapeutic, prophylactic, or diagnostic intravenous or intra-arterial injection or infusion

## HCPCS Codes

J1931	Injection, laronidase, 0.1 mg (Aldurazyme)
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## References

1. Aldurazyme (laronidase) [prescribing information]. Cambridge, MA: Genzyme; December 2019.
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3. Laraway S, Mercer J, Jameson E, et al. Outcomes of Long-Term Treatment with Laronidase in Patients with Mucopolysaccharidosis Type I. J Pediatr. 2016;178:219.
4. Sifuentes M, Doroshov R, Hoft R, et al. A follow-up study of MPS I patients treated with laronidase

enzyme replacement therapy for 6 years. *Mol Genet Metab.* 2007;90(2):171.

5. Wraith JE, Clarke LA, Beck M, et al. Enzyme replacement therapy for mucopolysaccharidosis I: a randomized, double-blinded, placebo-controlled, multinational study of recombinant human alpha-L-iduronidase (laronidase). *J Pediatr.* 2004;144(5):581.
6. Martins AM, Dualibi AP, Norato D, et al. Guidelines for the management of mucopolysaccharidosis type I. *J Pediatr.* 2009;155(4)(suppl):S32-S46.

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