Pharmacy Drug Policy & Procedure

Policy Name:	Aldurazyme (laronidase)	Policy #:	2472P

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 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 Initial: 12 months

2.2 Reauthorization:12 months with documented clinical benefit from therapy

CPT Codes

HCPCS Codes

J1931	Injection, laronidase, 0.1mg (Aldurazyme)

References

1. Aldurazyme (laronidase) [prescribing information]. Cambridge, MA: Genzyme; December 2023.
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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, Doroshow 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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