Mass General Brigham
Health Plan

Aldurazyme (laronidase)
Effective 09/01/2023

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit (NLX)		
Specialty Limitations	These medications have been designated specialty and must be filled at a contracted specialty pharmacy when obtained through the pharmacy benefit.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview
Aldurazyme is indicated for adult and pediatric patients with Hurler and Hurler-Scheie forms of Mucopolysaccharidosis I (MPS I) and for patients with the Scheie form who have moderate to severe symptoms.

Coverage Guidelines
Authorization may be granted for members new to General Brigham Health Plan who are currently receiving treatment with Aldurazyme excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members meeting ALL the following criteria:

1. Member has a diagnosis of mucopolysaccharidosis (MPS I)
2. Diagnosis of MPS I was confirmed by enzyme assay demonstrating a deficiency of alpha L-iduonidase enzyme activity and/or by genetic testing
3. Member has Hurler (i.e. severe MPS I) or Hurler Scheie (i.e. attenuated MPS I) OR the member has the Scheie form (Scheie syndrome/i.e. attenuated MPS I) with moderate to severe symptoms (e.g., normal intelligence, less progressive physical problems, corneal clouding, joint stiffness, valvular heart disease).

Continuation of Therapy
Reauthorization of 12 months may be granted for continued treatment in members requesting reauthorization for mucopolysaccharidosis I (MPS I) who have a clinically positive response to therapy, which shall include improvement, stabilization, or slowing of disease progression.

Limitations
Initial approvals and reauthorizations will be granted for 12 months.

References

1. Aldurazyme [package insert]. Cambridge, MA: Genzyme Corporation; December 2019.
2. 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;144:581-588.
3. Muenzer J, Wraith JE, Clarke LA; International Consensus Panel on Management and Treatment of Mucopolysaccharidosis I. Mucopolysaccharidosis I: management and treatment guidelines. Pediatrics. 2009 Jan;123(1):19-29.

Review History

07/12/2023 – Reviewed at July P&T; Switched from CVS Standard to custom criteria; Effective 9/1/23