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Clinical Policy Title:	laronidase
Policy Number:	RxA.010
Drug(s) Applied:	Aldurazyme®
Original Policy Date:	02/07/2020
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Mucopolysaccharidosis I: Hurler, Hurler-Scheie, and Scheie Forms (must meet all)**:**

1. Diagnosis of MPS I: confirmed by one of the following:
   a. Enzyme assay demonstrating deficiency of alpha-L-iduronidase activity;
   b. DNA testing;
2. Member has one of the following (a or b):
   a. Hurler or Hurler-Scheie form of MPS I;
   b. Scheie form of MPS I with moderate to severe symptoms;
3. Age ≥ 6 months;
4. Dose does not exceed 0.58 mg per kg per week (rounded up to the nearest whole vial).

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Mucopolysaccharidosis I: Hurler, Hurler-Scheie, and Scheie Forms (must meet all)**:**

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy as evidenced by improvement in the individual member's MPS I disease manifestation profile (see Appendix D for examples);
3. If request is for a dose increase, new dose does not exceed 0.58 mg per kg per week (rounded up to the nearest whole vial).

Approval Duration
Commercial: 6 months
Medicaid: 6 months

References

1. Muenzer J. The mucopolysaccharidoses: a heterogeneous group of disorders with variable pediatric presentations. J Pediatr. 2004; 144(5 Suppl): S27-S34. Available at: https://www.jpeds.com/article/S0022-3476(04)00097-6/fulltext. Accessed July 04, 2022.

Review/Revision History	Review/Revised Date	P&T Approval Date

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

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Policy established.	01/2020	02/07/2020
Policy was reviewed: 1) Continuation therapy criteria II.A.1. rephrased to "Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy." 2) Initial therapy and continued therapy approval updated from duration of request or 6 months (whichever is less) to "6 months". 3) References were updated.	01/20/2021	03/09/2021
Policy was reviewed: 1) Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 2) References were reviewed and updated.	11/19/2021	01/17/2022
Policy was reviewed: 1) Initial Approval Criteria I.A.2: Updated to add Member has one of the following (a or b): a. Hurler or Hurler-Scheie form of MPS I; b. Scheie form of MPS I with moderate to severe symptoms. 2) References were reviewed and updated.	07/04/2022	10/19/2022
Policy was reviewed.	10/19/2023	10/19/2023

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