Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Aldurazyme (laronidase)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***September 2009 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO	[ ] PPO	*Products*: [ ] Small [ ] Indiv. [ ] Large	*Exchange*: [ ] Shop [ ] Indiv.	[x] All
OTHER	[x] Self-funded/ASO				

PURPOSE

The purpose of this policy is to define the prior authorization process for Aldurazyme (laronidase).

Aldurazyme (laronidase) is a polymorphic variant of a human enzyme indicated for 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.

DEFINITIONS

Mucopolysaccharidosis I – a rare, autosomal recessive genetic disease caused by a defect in the gene coding for the lysosomal enzyme alpha-L-iduronidase resulting in inability to produce sufficient amounts of the enzyme

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002

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Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Aldurazyme (laronidase), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be prescribed by or in consultation with a physician who specializes in the treatment of inherited metabolic disorders
- Must have a confirmed diagnosis of Mucopolysaccharidosis, Type I (Hurler and Hurler-Scheie forms) or the Scheie form with moderate to severe symptoms

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 year
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Aldurazyme [package insert]. BioMatin/Genzyme LLC. Novato CA, April 2008.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

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DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/17, 02/18*

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