

POLICY AND PROCEDURE

POLICY NUMBER: *RX.PA.122.E*

REVISION DATE: *05/13*

PAGE NUMBER: 1 of 3

POLICY TITLE: *Naglazyme (galsulfase)*
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	<input type="checkbox"/> HMO <input type="checkbox"/> PPO <i>Products:</i> <input type="checkbox"/> Small <i>Exchange:</i> <input type="checkbox"/> Shop <input checked="" type="checkbox"/> All <input type="checkbox"/> Indiv. <input type="checkbox"/> Indiv. <input type="checkbox"/> Large
OTHER	<input checked="" type="checkbox"/> Self-funded/ASO

PURPOSE

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

Naglazyme (galsulfase) is a variant form of a polymorphic human enzyme indicated for patients with Mucopolysaccharidosis VI (MPS VI). Galsulfase (Naglazyme) has been shown to improve walking and stair-climbing capacity.

DEFINITIONS

Mucopolysaccharidosis VI – a progressive lysosomal storage disorder caused by a deficiency in the arylsulfatase B enzyme causing retention of glycosaminoglycans leading to multisystemic organ damage

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

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

The drug, Naglazyme (galsulfase), 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 VI (Maroteaux-Lamy syndrome)

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. Naglazyme [package insert]. BioMarin Pharmaceuticals. Novato CA, June 2005.

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
<i>Annual review</i>	<i>02/17, 02/18</i>

