

N-acetylgalactosamine-6-sulfate sulfatase (GALNS) – lysosomal enzyme responsible for degrading glycosaminoglycans keratin sulfate and chondroitin-6-sulfate.

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, Vimizim (elosulfase alfa), 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 diagnosis of Mucopolysaccharidosis type Morquio A syndrome. Diagnosis must be confirmed by one of the following methods:
 - GALNS enzyme activity assay (from leukocytes or fibroblasts) demonstrating a deficiency in GALNS activity. Documentation of laboratory result (including laboratory reference range) is required.
 - GALNS gene molecular analysis demonstrating mutation in both GALNS alleles. Documentation of laboratory result of GAA gene mutation analysis is required.

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 6 months
Reauthorization	Up to 1 year

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

REFERENCES

1. Vimizim [prescribing information]. Novato, CA: BioMarin Pharmaceutical, Inc.; 2014
2. Vimizim [AMCP Dosseier]. Novato, CA: BioMarin Pharmaceutical, Inc.; 2014.

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

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
<i>Annual review</i>	<i>02/17, 02/18</i>

