Gateway Health℠ It's Wholecare.

Updated: 06/2020
PARP Approved: 07/2020

Prior Authorization Criteria

Vimizim (Elosulfase alfa)

All requests for Vimizim (elosulfase alfa) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Coverage may be provided with a diagnosis of Mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome) and the following criteria is met:

- Member is 5 years of age or older.
- The diagnosis has been confirmed by biochemical/genetic confirmation by ONE of the following:
    - Absence or marked reduction in N-acetylgalactosamine 6-sulfatase (GALNS) enzyme activity.
    - Sequence analysis and/or deletion/duplication analysis of the GALNS gene for biallelic mutation.
- The medication is prescribed by a by or in association with a biochemical geneticist or metabolic physician.
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines.
- **Initial Duration of Approval:** 12 months
- **Reauthorization criteria**
    - Reauthorization benefit will be approved if there is documented, significant improvement with prior courses with treatment.
- **Reauthorization Duration of approval:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

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VIMIZIM
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

1. Does the member have a diagnosis of Mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome)? If yes, please answer the following questions:
   ☐ Yes ☐ No

   a. Is member 5 years of age or older?
      ☐ Yes ☐ No

   b. Has the diagnosis has been confirmed by biochemical/genetic confirmation by ANY of the following:
      i. Absence or marked reduction in N-acetylgalactosamine 6-sulfatase (GALNS) enzyme activity.
         ☐ Yes ☐ No

      ii. Sequence analysis and/or deletion/duplication analysis of the GALNS gene for biallelic mutation.
         ☐ Yes ☐ No

   c. Will the medication be prescribed by or in association with a biochemical geneticist or metabolic physician?
      ☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY			
Medication Name	**Strength/ Frequency**	**Dates of Therapy**	**Status (Discontinued & Why/Current)**

REAUTHORIZATION

Has there been documented, significant improvement with prior courses with treatment?

☐ Yes ☐ No

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date