

Gateway Health
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.

Drug Name Prior Authorization Criteria:

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.
- Documentation of a baseline 6-minute walk test.
- **Initial Duration of Approval:** 12 months
- **Reauthorization criteria**
 - Documentation of improved 6-minute walk test.
- **Reauthorization Duration of approval:** 12 months

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.