elosulfase alfa (Vimizim)

Commercial Medical Benefit Drug Policy

Place of Service
Home Infusion
Infusion Center Administration
Office Administration
Outpatient Facility Infusion Administration

Drug Details

USP Category: GENETIC OR ENZYME OR PROTEIN DISORDER: REPLACEMENT, MODIFIERS, TREATMENT
Mechanism of Action: Exogenous enzyme N-acetylgalactosamine-6-sulfatase
HCPCS:
J1322:Injection, elosulfase alfa, 1 mg
How Supplied:
5 mg/5 mL (single-use vials)

Condition(s) listed in policy *(see coverage criteria for details)*

- Mucopolysaccharidosis Type IVA (MPS IVA; Morquio A syndrome)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO, Shared Advantage, HMO (non-direct)** may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION

MCG Care Guidelines, 19th edition, 2015

ADMINISTRATION OF VIMIZIM IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted)*

1. Patient is initiating therapy (allowed for the first four infusions) or is being re-initiated on Vimizim after at least 6 months off therapy. *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

OR

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. Patient has experienced a previous severe adverse event on Vimizim based on documentation submitted.
3. Patient continues to experience moderate to severe adverse events on Vimizim based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.
4. Patient is clinically unstable based on documentation submitted.
5. Patient is physically or cognitively unstable based on documentation submitted.

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice.

Mucopolysaccharidosis Type IVA (MPS IVA; Morquio A syndrome)

Meets medical necessity if all the following are met:

1. Patients with documented clinical diagnosis of Mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome) based on clinical signs and symptoms
2. Either of the following:
   a. Documented reduced GALNS enzyme activity
   b. Genetic testing confirming diagnosis of MPS IVA

Covered Doses:

Up to 2 mg/kg given intravenously once weekly

Coverage Period:

Yearly, based on continued response to therapy

ICD-10:

E76.210

References

1. AHFS. Available by subscription at http://www.lexi.com
2. Akyol MU, Alden TD, Amartino H, et al; MPS Consensus Programme Steering Committee; MPS Consensus Programme Co-Chairs. Recommendations for the management of MPS IVA: systematic evidence- and consensus-based guidance. Orphanet J Rare Dis. 2019 Jun 13;14(1) :137.
3. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch

4. Hendriksz CJ, Berger KI, Giugliani R et al. International guidelines for the management and treatment of Morquio A syndrome. Am J Med Genet A. 2015 Jan;167A (1):11-25.
5. Vimizim (elosulfase alfa) Prescribing Information. BioMarin Pharmaceuticals, Novato, CA: 12/2019.

Review History

Date of Last Annual Review: 3Q2025
Changes from previous policy version:

- No clinical change following annual review.

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee