## elosulfase alfa (Vimizim)

## 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 California Code of Regulations (CCR), Title 22, Section 51303 and 51313 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.

## 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 or b):
   a. Documented reduced GALNS enzyme activity
   b. Genetic testing confirming diagnosis of MPS IVA

**Covered Doses:**



Blue Shield of California Promise Health Plan is an independent licensee of the Blue Shield Association

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: 10/2025.


## Review History

Date of Last Annual Review: 3Q2026
Changes from previous policy version:

- No clinical changes following annual review.

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