blue california
Promise Health Plan

## galsulfase (Naglazyme)

## Medical Benefit Drug Policy

Place of Service
Home Infusion Administration
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:** Hydrolytic lysosomal glycosaminoglycan (GAG)-specific enzyme.
**HCPCS:**
J1458:Injection, galsulfase, 1 mg
**How Supplied:**
5 mg/5 mL (single dose vial)

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

- Mucopolysaccharidosis VI (MPS VI, Maroteaux-Lamy 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 VI (MPS VI, Maroteaux-Lamy syndrome)**
**Meets medical necessity if all the following are met:**
1. Meets ONE of the following:
   a. Documented reduced enzyme activity in arylsulfastase B (ASB)
   b. Genetic testing confirming diagnosis of MPS VI

**Covered Doses:**
1 mg/kg given intravenously once weekly

**Coverage Period:**
Indefinite

**ICD-10:**
E76.29

## References


1. AHFS. Available by subscription at http://www.lexi.com.
2. DrugDex. Available by subscription at http://www.micromedexsolutions.com.
3. Naglazyme (galsulfase) Prescribing Information. BioMarin Pharmaceutical Inc., Novato, CA: 9/2024.


## Review History

Date of Last Annual Review: 2Q2025
Changes from previous policy version:

- No clinical change to policy following annual review.

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