

## **galsulfase (Naglazyme)**

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

1. Patient is initiating therapy with Naglazyme (allowed for first 4 doses) or is being re-initiated on Naglazyme 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 Naglazyme based on documentation submitted.
3. Patient continues to experience moderate to severe adverse events on Naglazyme 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 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 arylsulfatase 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*