Galsulfase (Naglazyme®)	Place of Service Home Infusion Administration Infusion Center Administration Office Administration Outpatient Facility Infusion Administration* [*Prior authorization required – see section (1)] HCPCS: J1458 per 1 mg

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

- Mucopolysaccharidosis VI (MPS VI, Maroteaux-Lamy syndrome)

AHFS therapeutic class: Enzymes

Mechanism of action: Hydrolytic lysosomal glycosaminoglycan (GAG)-specific enzyme

(1) Special Instructions and pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review.

****CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION ****

AAAAI Guidelines 2011, MCG™ Care Guidelines, 19th edition, 2015

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, Medi-Cal, ASO/Shared Advantage, HMO (non-direct contract)** 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.

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

1. **Patient is receiving the initial 4 infusions of Naglazyme 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.**

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Naglazyme® (galsulfase) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Mucopolysaccharidosis VI (MPS VI, Maroteaux-Lamy syndrome)

1. Either of the following:
   a. Documented reduced enzyme activity in arylsulfastase B (ASB), OR
   b. Genetic testing confirming diagnosis of MPS VI

Covered Doses
Up to 1 mg/kg IV weekly

Coverage Period
indefinite

ICD-10:
E76.29

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Naglazyme® (galsulfase) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:
5 mg/5 mL (single dose vial)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com.
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com.
- Harmatz P, Shediac R. Mucopolysaccharidosis VI: pathophysiology, diagnosis and treatment. Front Biosci (Landmark Ed). 2017 Jan 1;22:385-406. https://www.bioscience.org/2017/v22/af/4490/fulltext.htm Accessed 5/30/2019.
- Naglazyme® (galsulfase) [Prescribing information]. Novato, CA: Biomarin, Inc.. 12/2019.

(7) Policy Update

Date of last review: 2Q2023

Date of next review: 2Q2024

Changes from previous policy version:

- No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee