



Prior Authorization Approval Criteria
Department of Pharmacy Services

Generic Name: galsulfase

Brand Name: Naglazyme

Medication Class: Endocrine and Metabolic Agents

FDA Approved Uses: Enzyme replacement therapy for the treatment of mucopolysaccharidosis VI (MPS VI), also known as Maroteaux-Lamy syndrome.

Available Dosage Forms: 5mg/5ml solution in single use vials.

Usual Dose: 1 mg/kg intravenously infused over no less than 4 hours once a week.

Duration of Therapy: Drug therapy will be based on its potential benefit versus the severity and frequency of the infusion-related reaction encountered by the patient.

Criteria for Use: *(bullet points below are all inclusive unless otherwise noted)*

- Clinically diagnosed mucopolysaccharidosis VI (MPS VI).

Criteria for Continuation of Therapy:

- Drug therapy will be based on its potential benefit versus the severity and frequency of the infusion-related reaction encountered by the patient.

Cautions:

- Severe Infusion related symptoms: angioneurotic edema, hypotension, dyspnea, bronchospasm, respiratory distress, apnea, and urticaria.
- Common infusion related symptoms: fever, chills/rigors, headache, rash, and mild to moderate urticaria.
- Patients should be treated with an antihistamine with or without antipyretics 30 – 60 minutes prior to each galsulfase infusion because of the frequent occurrence of infusion reactions.
- Despite pretreatment, infusion reactions occurred in 30 of 55 patients treated with galsulfase.
- To minimize infusion reactions, the infusion rate should be given at a slower rate, and additional antihistamines or corticosteroids may be necessary.

Monitoring: Patients should be closely monitored for signs and symptoms of infusion related reactions.

Contraindications:

- No contraindications are specified in the product labeling.



Not Approved if:

- Does not meet the above stated criteria.

Notes:

- Primary endpoint in published studies has only been based on improvements in the 12 minute walk test and 3 minute stair climb and have been too short to assess the drugs potential impact on disease progression and organ damage.

P&T Approval: _____ Date: _____