

Naglazyme® (galsulfase)

When requesting Naglazyme® (galsulfase), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved Indication

Naglazyme (galsulfase) is indicated for the treatment of mucopolysaccharidosis type VI (MPS VI; Maroteaux-Lamy Syndrome).

Coverage Guidelines

Mucopolysaccharidosis Type VI (MPS VI; Maroteaux-Lamy Syndrome)

The individual must meet all of the following criteria for approval:

- Diagnosis is confirmed by one of the following:
 - o Laboratory test demonstrating deficient N-acetylgalactosamine 4-sulfatase (arylsulfatase B) activity in leukocytes or fibroblasts; OR
 - o Molecular genetic test demonstrating biallelic pathogenic or likely pathogenic N-acetylgalactosamine 4-sulfatase (arylsulfatase B) gene variants;
- Naglazyme is prescribed by or in consultation with a geneticist, an endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders.

Approval duration: 12 months

Dosing Recommendation

The recommended dosage regimen of Naglazyme is 1 mg per kg of body weight administered once weekly as an intravenous infusion.

References

1. Naglazyme® injection for intravenous use [prescribing information]. Novato, CA: BioMarin Pharmaceutical, Inc.; December 2019.
2. Harmatz PR, Shediach R. Mucopolysaccharidosis VI: Pathophysiology, diagnosis and treatment. *Front Biosci.* 2017;22:385-406.
3. Vairo F, Federhen A, Baldo G, et al. Diagnostic and treatment strategies in mucopolysaccharidosis VI. *Appl Clin Genet.* 2015;8:245-255.