Pharmacy Drug Policy & Procedure

Policy Name:	Naglazyme (galsulfase)	Policy #:	2479P

Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Naglazyme (galsulfase).

Statement of the Policy

Health Alliance Medical Plans will approve the use of Naglazyme (galsulfase) under the Specialty Medical benefit when the following criteria have been met.

Criteria

1. **Coverage Criteria for the Treatment of Maroteaux-Lamy syndrome (MPS type VI)**
   - 1.1 Diagnosis of Mucopolysaccharidosis (MPS type VI) with testing that shows evidence of gene mutation
   - 1.2 Prescribed by a geneticist (gene specialist)
2. **Approval Period**
   - 2.1 Initial: 12 months
   - 2.2 Reauthorization: 12 months with documented clinical benefit from therapy

CPT Codes

HCPCS Codes

J1458	Injection, galsulfase, 1mg (Naglazyme)

References

1. Naglazyme (galsulfase) [prescribing information]. Novato, CA: BioMarin Pharmaceutical Inc.; July 2024.
2. Brunelli MJ, Atallah ÁN, da Silva EM. Enzyme replacement therapy with galsulfase for mucopolysaccharidosis type VI. Cochrane Database Syst Rev 2016; 3:CD009806.
3. Giugliani R, Harmatz P, and Wraith JE, "Management Guidelines for Mucopolysaccharidosis VI," Pediatrics, 2007, 120(2):405-18.
4. Giugliani R, Lampe C, Guffon N, et al. Natural history and galsulfase treatment in mucopolysaccharidosis VI (MPS VI, Maroteaux-Lamy syndrome)--10-year follow-up of patients who previously participated in an MPS VI Survey Study. Am J Med Genet A. 2014;164A(8):1953-1964.
5. Harmatz P, Giugliani R, Schwartz I, et al. Enzyme replacement therapy for mucopolysaccharidosis VI: a phase 3, randomized, double-blind, placebo-controlled, multinational study of recombinant human N-acetylgalactosamine 4-sulfatase (recombinant human arylsulfatase B or rhASB) and follow-on, open-label extension study. J Pediatr 2006; 148:533.

6. Harmatz PR, Garcia P, Guffon N, et al. Galsulfase (Naglazyme®) therapy in infants with mucopolysaccharidosis VI. J Inherit Metab Dis. 2014;37(2):277-287.

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