Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

Naglazyme (galsulfase)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications	Dosing Limit
Naglazyme (galsulfase) 5 mg vial	1 mg/kg once per week

APPROVAL CRITERIA

Requests for Naglazyme (galsulfase) may be approved if the following criteria are met:

I. Individual has a diagnosis of Mucopolysaccharidosis VI (Maroteaux-Lamy syndrome) confirmed by (Akyol 2019, Wood 2012)**:**
   A. An increase in dermatan sulfate in the urine and a decrease in the activity of N-acetylgalactosamine-4-sulfatase (arylsulfatase B) enzyme as measured in fibroblasts or leukocytes combined with normal enzyme activity level of another sulfatase; **OR**
   B. Documented N-acetlygalactosamine-4-sulfatase (arylsulfatase B) gene mutation.

Naglazyme (galsulfase) may not be approved when the above criteria are not met and for all other indications.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

1. Akyol MU, Alden TD, Amartino H, et al. Recommendations for the management of MPS VI: systematic evidence and consensus-based guidance. *Orphanet J Rare Dis*. 2019;14(1):118. doi: 10.1186/s13023-019-1080-y.

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: August 31, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lehman TJA, Miller Nicole, Norquist B, et al. Diagnosis of the mucopolysaccharidoses. *Rheumatology*. 2011; 50:V41-V46.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
6. Valayannopoulos V, Nicely H, Harmatz P, Turbeville S. Mucopolysaccharidosis VI. *Orphanet J Rare Dis*. 2010; 5:5.
7. Wang RY, Bodamer OA, Watson MS, Wilcox WR. American College of Medical Genetics (ACMG) Work Group on Diagnostic Confirmation of Lysosomal Storage Diseases. Lysosomal storage diseases: diagnostic confirmation and management of presymptomatic individuals. *Genet Med*. 2011; 13(5):457-484.
8. Wood T, Bodamer OA, Burin MG, et al. Expert recommendations for the laboratory diagnosis of MPS VI. *Mol Genet Metab*. 2012; 106(1):73-82.