Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

*FHK- Florida Healthy Kids

Naglazyme (galsulfase)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Naglazyme (galsulfase)

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 (Valayannopoulos 2010, 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.

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

Key References:

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

*FHK- Florida Healthy Kids

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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.; 2018; 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.