Field Name	Field Description
Prior Authorization Group Description	**Mucopolysaccharidosis VI (Maroteaux-Lamy Syndrome) Agents**
Drugs	**Naglazyme (galsulfase)**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	"See Other Criteria"
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months Renewal: 12 months

Other Criteria	**Initial Authorization**
	• Diagnosis of Mucopolysaccharidosis VI as confirmed by one of the following:
	  o Enzyme assay demonstrating a deficiency in N-acetygalactosamine 4-sulfatase (arylsulfatase B) enzyme activity
	  o DNA testing
	• Patient's weight
	• Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines
	
	Reauthorization
	• Patient has demonstrated a beneficial response (i.e., stabilization or improvement in 12-minute walk test [12-MWT], 3-minute stair climb test, urinary glycosaminoglycan (GAG) levels, etc.)
	• Patient's weight
	• Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines

Revision/Review Date 11/2024	**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**