PRIOR AUTHORIZATION CRITERIA

BRAND NAME	**NAGLAZYME**
(generic)	**(galsulfase)**
Status: CVS Caremark Criteria	***MDC***
Type: Initial Prior Authorization	***Ref #577-A***

FDA-APPROVED INDICATION[1]
Naglazyme is indicated for patients with Mucopolysaccharidosis VI (MPS VI, Maroteaux-Lamy syndrome). Naglazyme has been shown to improve walking and stair-climbing capacity.

CRITERIA FOR APPROVAL

1	Does the patient have a diagnosis of mucopolysaccharidosis VI (MPS VI, Maroteaux-Lamy syndrome)? [If no, no further questions.]	Yes	No
2	Was the diagnosis confirmed by an enzyme assay demonstrating a deficiency of N-acetylgalactosamine 4-sulfatase (arylsulfatase B) enzyme activity OR by genetic testing?	Yes	No

Guidelines for Approval	
Duration of Approval	**12 Months**
Set 1: MPS VI	
Yes to question(s)	**No to question(s)**
1	None
2	

Mapping Instructions		
	Yes	**No**
1	Go to 2	Deny
2	Approve, 12 months	Deny

RATIONALE
These criteria meet the Medicare Part D definition of a medically accepted indication. This definition includes uses which are approved by the FDA or supported by a citation included, or approved for inclusion, in one of the Medicare approved compendia.

The intent of the criteria is to ensure that patients follow selection elements noted in labeling and/or practice guidelines in order to decrease the potential for inappropriate utilization.

REFERENCES
1. Naglazyme [package insert]. Novato, CA: BioMarin Pharmaceutical, Inc.; March 2013.

DOCUMENT HISTORY

Written:	Specialty Clinical Development (AC) 11/2009
Revised:	KR 08/2010; TG 07/2011, 09/2011 (CMS); AC 09/2012 (CMS); AS 09/2013 (CMS), IP 04/2014, 09/2014 (CMS), TS 04/2015, IP 08/2015 (CMS), TS 06/2016 (CMS), DK 04/2016, 07/2017 (CMS)
Reviewed:	CDPR/WLF 12/2009; KP 08/2010, 08/2011; DNC 07/2012, 06/2013; SES 04/2014, LCB 04/2015, ME 05/2016
External Review:	01/2010, 09/2010, 08/2011, 08/2012, 07/2013, 06/2014, 05/2015, 07/2016

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