PRIOR AUTHORIZATION CRITERIA

BRAND NAME	**KANUMA**
(generic)	**(sebelipase alfa)**
Status: CVS Caremark Criteria	***MDC***
Type: Initial Prior Authorization	***Ref #1314-A***

FDA-APPROVED INDICATION[1]
Kanuma is indicated for the treatment of patients with a diagnosis of lysosomal acid lipase (LAL) deficiency.

CRITERIA FOR APPROVAL

1	Does the patient have a diagnosis of lysosomal acid lipase (LAL) deficiency? [If no, no further questions.]	Yes	No
2	Was the diagnosis confirmed by an enzyme assay demonstrating a deficiency of lysosomal acid lipase enzyme activity OR by genetic testing?	Yes	No

Guidelines for Approval	
Duration of Approval	**12 Months**
Set 1: LAL Deficiency	
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. Kanuma [package insert]. Cheshire, CT: Alexion Pharmaceuticals Inc.; December 2015.

DOCUMENT HISTORY
Written: Specialty Clinical Development (TS) 12/2015
Revised: DK 04/2016, PK 02/2017, DK 07/2017 (CMS)
Reviewed: CDPR/LCB 12/2015, LMS 05/2016, LMS 03/2017
External Review: 12/2015, 07/2016, 05/2017