

PRIOR AUTHORIZATION CRITERIA

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

FDA-APPROVED INDICATION¹

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

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