

Sebelipase alfa (Kanuma®)

Place of Service

Office Administration  
Infusion Center Administration  
Home Infusion Administration  
Outpatient Facility Administration

HCPCS: J2840 per 1 mg

Condition listed in policy (see criteria for details)

- [Lysosomal Acid Lipase deficiency \(LAL-D\)](#)

AHFS therapeutic class: Enzymes

Mechanism of action: Hydrolytic lysosomal cholesteryl ester and triacylglycerol-specific enzyme

**(1) Special Instructions and Pertinent Information**

Covered under the Medical Benefit, please submit clinical information for prior authorization.

**(2) Prior Authorization/Medical Review is required for the following condition(s)**

All requests for Kanuma® (sebelipase alfa) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Lysosomal Acid Lipase deficiency (LAL-D) [Wolman's disease, Cholesterol Ester Storage Disease (CESD)]

1. Prescribed or diagnosed by metabolic specialist or hepatologist, **AND**
2. One of the following:
  - a. Deficient lysosomal lipase acid enzyme activity, or
  - b. Molecular genetic testing (2 mutations) confirming a diagnosis of LAL-D

**Covered Doses**

Up to 3 mg/kg IV every week

**Coverage period**

indefinite

**ICD-10:**

E75.5

**(3) The following condition(s) DO NOT require Prior Authorization/Preservice**

All requests for Kanuma® (sebelipase alfa) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

**(4) This Medication is NOT medically necessary for the following condition(s)**

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

#### **(5) Additional Information**

How supplied:

20 mg/10 ml (single-use vials)

#### **(6) References**

- AHFS®. Available by subscription at <http://www.lexi.com>
- American Academy of Allergy Asthma and Immunology. Guidelines for the Site of Care for Administration of IGIV Therapy. December 2011.
- DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
- Hoffman EP, Barr ML, Giovanni MA, Murray MF. Lysosomal Acid Lipase Deficiency. In GeneReview [Adam MP, Ardinger HH, Pagon RA, et al., editors]. Seattle, WA. September 1, 2016. <https://www.ncbi.nlm.nih.gov/books/NBK305870/>.
- Kanuma® (sebelipase alfa) [Prescribing Information]. Boston, MA : Alexion Pharmaceuticals, Inc. ; 11/2021.
- MCG™ Care Guidelines, 19th edition, 2015, Home Infusion Therapy, CMT: CMT-0009(SR)

#### **(7) Policy Update**

Date of last review: 3Q2023

Date of next review: 3Q2024

Changes from previous policy version:

- No clinical change to policy following routine annual review.

*BSC Drug Coverage Criteria to Determine Medical Necessity  
Reviewed by P&T Committee*