sebelipase alfa (Kanuma)

Medical Benefit Drug Policy

Place of Service

Office Administration
Infusion Center Administration
Home Infusion Administration
Outpatient Facility Administration

Drug Details

USP Category: GENETIC OR ENZYME OR PROTEIN DISORDER: REPLACEMENT, MODIFIERS, TREATMENT
Mechanism of Action: Hydrolytic lysosomal cholesteryl ester and triacylglycerol-specific enzyme
HCPCS:
J2840:Injection, sebelipase alfa, 1 mg
How Supplied:
20 mg/10 ml (single-use vials)

Condition(s) listed in policy *(see coverage criteria for details)*

- Lysosomal Acid Lipase deficiency (LAL-D)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Lysosomal Acid Lipase deficiency (LAL-D)
Meets medical necessity if all the following are met:

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

Covered Doses:

Blue Shield of California Promise Health Plan is an independent licensee of the Blue Shield Association

Up to 5 mg/kg given intravenously once weekly

Coverage Period:
Yearly, based on continued response to therapy

ICD-10:
E75.5

References

1. AHFS. Available by subscription at http://www.lexi.com
2. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
3. 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/.
4. Kanuma (sebelipase alfa) [prescribing information]. Boston, MA: Alexion Pharmaceuticals; July 2024.
5. MCG™ Care Guidelines, 19th edition, 2015, Home Infusion Therapy, CMT: CMT-0009(SR)

Review History

Date of Last Annual Review: 3Q2026
Changes from previous policy version:

- No clinical changes following annual review.

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee