

Market Applicability/Effective Date														
Market	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

\*FHK- Florida Healthy Kids

## Kanuma (sebelipase alfa)

DRUG.00093

Override(s)	Approval Duration
Prior Authorization	
Initial Request	6 months
Maintenance Therapy	1 year

Medications	Quantity Limit
Kanuma (sebelipase alfa)	N/A

### APPROVAL CRITERIA

- I. Initial treatment with Kanuma (sebelipase alfa) is considered **medically necessary** when used for the treatment of individuals *less than 4 years of age* when the following criteria are met:
  - A. Individual has a diagnosis of lysosomal acid lipase deficiency (LAL-D) disorder (also known as Wolman disease [WD]); **AND**
  - B. Diagnosis has been confirmed by **one** of the following:
    1. A dried blood spot test demonstrating deficient lysosomal acid lipase activity; **OR**
    2. Documented molecular genetic test revealing mutations in the lipase A, lysosomal acid type (LIPA) gene; **OR**
- II. Initial treatment with Kanuma (sebelipase alfa) is considered **medically necessary** when used for the treatment of individuals *4 years of age and older* when **all** the following criteria are met:
  - A. Individual has a diagnosis of lysosomal acid lipase deficiency (LAL-D) disorder (also known as cholesteryl ester storage disease [CESD]); **AND**
  - B. Diagnosis has been confirmed by **one** of the following:
    1. A dried blood spot test demonstrating deficient lysosomal acid lipase activity; **OR**
    2. Documented molecular genetic test revealing mutations in the LIPA gene;

**AND**

  - C. Individual has a baseline alanine aminotransferase (ALT) level greater than or equal to 1.5 times the upper limit of normal.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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Maintenance therapy with Kanuma (sebelipase alfa) for ongoing treatment of lysosomal acid lipase (LAL) disorder is considered **medically necessary** when the following criteria are met:

- A. Individual previously met criteria for initial therapy; **AND**
- B. Documentation of clinically improvement in symptoms or lab values is provided.

**Investigational and Not Medically Necessary:**

The use of Kanuma (sebelipase alfa) is considered **investigational and not medically necessary** for all other indications not listed above as medically necessary.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

**Key References:**

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2015. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed April 21, 2015.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2015; Updated periodically.

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