

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

*FHK- Florida Healthy Kids

Kanuma (sebelipase alfa)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Kanuma (sebelipase alfa)

APPROVAL CRITERIA

Requests for initiation of therapy with Kanuma (sebelipase alfa) may be approved if the following criteria are met:

- I. Individual is less than 4 years of age; **AND**
- II. Individual has a diagnosis of lysosomal acid lipase deficiency (LAL-D) disorder (also known as Wolman disease [WD]); **AND**
- III. Diagnosis has been confirmed by one of the following:
 - A. A dried blood spot test demonstrating deficient lysosomal acid lipase activity; **OR**
 - B. Documented molecular genetic test revealing mutations in the lipase A, lysosomal acid type (LIPA) gene;

OR

- IV. Individual is 4 years of age and older; **AND**
- V. Individual has a diagnosis of lysosomal acid lipase deficiency (LAL-D) disorder (also known as cholesteryl ester storage disease [CESD]); **AND**
- VI. Diagnosis has been confirmed by one of the following:
 - A. A dried blood spot test demonstrating deficient lysosomal acid lipase activity; **OR**
 - B. Documented molecular genetic test revealing mutations in the LIPA gene; **AND**
- VII. Individual has a baseline alanine aminotransferase (ALT) level greater than or equal to 1.5 times the upper limit of normal.

Continuing treatment with Kanuma (sebelipase alfa) may be approved when the following criteria are met:

- I. Individual has had a clinical improvement in symptoms or lab values.

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

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: June 15, 2018.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.
5. Burton BK, Blawani M, Feillet F, et al. A phase 3 trial of sebelipase alfa in lysosomal acid lipase deficiency. N Engl J Med. 2015; 373:1010-1020.
6. Hamilton J, Jones I, Srivastava R, Galloway P. A new method for the measurement of lysosomal acid lipase in dried blood spots using the inhibitor Lalistat 2. Clinica Chimica Acta. 2012; 413(15-16):1207-1210.
7. Online Mendelian Inheritance in Man (OMIM) #278000 Lysosomal Acid Lipase Deficiency. Available from: <http://omim.org/entry/278000>. Accessed on: June 15, 2018.

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