



Wolman's Disease
Kanuma (sebelipase alfa) J2840
Prior Authorization Request
Medicare Part B Form

Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.

<input type="checkbox"/>	Standard Request– (72 Hours)	<input type="checkbox"/>	Urgent Request (standard time frame could place the member's life, health or ability in serious jeopardy)
Date Requested _____			
Requestor _____ Clinic name: _____ Phone _____ / Fax _____			

MEMBER INFORMATION

*Name: _____ *ID#: _____ *DOB: _____

PRESCRIBER INFORMATION

*Name: _____ MD FNP DO NP PA *Phone: _____

*Address: _____ *Fax: _____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name: _____ Phone: _____

*Address: _____ Fax: _____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht: _____)	Frequency	End Date if known

Self-administered Provider-administered Home Infusion

Chart notes attached. **Other important information:** _____

Diagnosis: ICD10: _____ **Description:** _____

Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

New Start or Initial Request: (Clinical documentation required for all requests)

Patient is **less than 4 years of age**; AND

- Patient has a diagnosis of LAL-D disorder; AND
- Documentation is provided that the diagnosis has been confirmed by one of the following:
 - A dried blood spot test demonstrating deficient lysosomal acid lipase activity; OR
 - Molecular genetic test shows mutations in the lipase A, lysosomal acid type (LIPA) gene;

OR

Patient is **4 years of age and older**;

- Patient has a diagnosis of LAL-D disorder; AND
- Documentation is provided that the diagnosis has been confirmed by one of the following:
 - A dried blood spot test demonstrating deficient lysosomal acid lipase activity; OR
 - Molecular genetic test shows mutations in the LIPA gene;

AND

Documentation is provided that Patient has a baseline alanine aminotransferase (ALT) level greater than or equal to 1.5 times the upper limit of normal.

Continuation Requests: (Clinical documentation required for all requests)

Provider has reviewed the attached “Criteria for Continuation” and attests the member meets ALL required PA Continuation criteria.

Patient had an adequate response or significant improvement while on this medication.

If not, please provide clinical rationale for continuing this medication: _____

ACKNOWLEDGEMENT

Request By (Signature Required): _____ **Date:** ____ / ____ / ____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Wolman’s Disease Drug PA

Drug Name(s):

KANUMA

SEBELIPASE ALFA

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.
 - If the member meets all these criteria, they may be approved by the Plan for the requested drug.
 - Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:

N/A

Prescriber Restrictions:

Endocrinologist or related specialist

Coverage Duration:

Initial Approval will be for 6 months

Continuation will be approved for 12 months

FDA Indications:

Kanuma

- Wolman’s Disease

Off-Label Uses:

N/A

Age Restrictions:

N/A

Other Clinical Consideration:

N/A

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/CS/B877BF/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/214120/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=931545&contentSetId=100&title=Sebelipase+Alfa&servicesTitle=Sebelipase+Alfa&brandName=Kanuma&UserMdxSearchTerm=Kanuma&=null#