SENTARA COMMUNITY PLAN
(MEDICAID)

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-305-2331**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

Drug Requested: Kanuma® (sebelipase alfa) **solution for IV Infusion (J2840) (Medical)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

- ❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Recommended Dosing:

- **Infants, children, adolescents, adult dosing:** 1 mg/kg every other week; may increase to maximum of 3 mg/kg every other week in members with suboptimal response
- **Infant with rapidly progressive disease (within the first 6 months of life):** 1 mg/kg/dose once weekly; may increase to 3 mg/kg/dose once weekly if response not optimal; if response remains not optimal may further increase to maximum of 5 mg/kg/dose once weekly

Quantity Limit: 340 billable units every 14 days

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CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied. **(Trials will be verified using pharmacy claims and/or submitted chart notes.)**

Initial Authorization: 6 months.

- ❑ Member is 1 month of age or older and has a diagnosis of Lysosomal Acid Lipase (LAL) deficiency
- ❑ Documented baseline values for one or more of the following have been obtained:
  - ❑ Weight-for-age z-scores for patients exhibiting growth failure
  - ❑ Low-density lipoprotein cholesterol (LDL-c)
  - ❑ High-density lipoprotein cholesterol (HDL-c)
  - ❑ Non-HDL-c
  - ❑ Triglycerides
  - ❑ Aspartate aminotransferase (AST) and/or alanine aminotransferase (ALT)
- ❑ Diagnosis of lysosomal acid lipase (LAL) deficiency has been confirmed by either biallelic pathogenic variants in LIPA or deficient LAL enzyme activity in peripheral blood leukocytes, fibroblasts, or dried blood spots

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member continues to meet the relevant criteria identified in the initial criteria
- ❑ Member has an absence of unacceptable toxicity from the drug
- ❑ Member is being continuously monitored for a beneficial response to therapy

Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy – PropriumRx**

For urgent reviews: Practitioner should call Sentara Health Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****

***Approved by Pharmacy and Therapeutics Committee**: 5/19/2022
REVISED/UPDATED/REFORMATTED: ~~5/13/2022; 6/3/2022; 6/17/2022;~~ **6/9/2026**