CareSource

PHARMACY POLICY STATEMENT **Marketplace**	
DRUG NAME	Kanuma (sebelipase alfa)
BILLING CODE	J2840
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Outpatient/Office
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— up to 3 mg/kg once weekly
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Kanuma (sebelipase alfa) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

LYSOSOMAL ACID LIPASE (LAL) DEFICIENCY

For **initial** authorization:

1. Member has lab confirmed diagnosis of LAL deficiency; AND
2. Medication must be prescribed by endocrinologist, cardiologist, or hepatologist or other or other specialist in the area of the member's disease; AND
3. Member is > 8 months but < 4 years of age with at least **one** of the following documented clinical manifestations of LALD:
   a) Dyslipidemia;
   b) Elevated transaminases (ALT ≥1.5x ULN);
   c) Impaired growth;
   d) Suspected malabsorption;
   e) Other clinical manifestation of LALD; OR
4. Member is ≥ 4 years of age with at least **one** of the following documented clinical manifestations of LALD:
   a) Evidence of advanced liver disease;
   b) Histologically confirmed disease recurrence in members with past liver or hematopoietic transplant;
   c) Persistent dyslipidemia;
   d) Suspected malabsorption;
   e) Other clinical manifestation of LALD.
5. **Dosage allowed:** 1 mg/kg administered once weekly as an IV infusion. For members with rapidly progressive LAL deficiency presenting within the first 6 months of life and who do not achieve an optimal clinical response, increase to 3 mg/kg once weekly.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Kanuma (sebelipase alfa) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
04/11/2018	New policy for Kanuma created.

References:

1. Kanuma [package inset]. New Haven, CT: Alexion Pharmaceuticals Inc.; December, 2015.
2. linicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). Identifier NCT02112994. Safety and Efficacy Study of Sebelipase Alfa in Patients With Lysosomal Acid Lipase Deficiency. February 14, 2018. Available at: https://clinicaltrials.gov/ct2/show/NCT02112994?term=sebelipase+alfa&recrs=e&rank=1.
3. Hoffman EP, et al. Lysosomal acid lipase deficiency. In: ed. Adam MP, et al. GeneReviews [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2018. 2015 Jul 30 [Updated 2016 Sep 1].
4. Desai NK, et al. Lysosomal acid lipase deficiency. In: ed. De Groot LJ, et al. Endotext [Internet]. South Dartmouth (MA): MDText.com, Inc.; 2000-. [Updated 2016 Jun 22].

Effective date: 09/21/2018
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