Medical Policy:

Kanuma™ (sebelipase) alfa intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.313	February 15, 2024	March 2019

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Kanuma, a human lysosomal acid lipase (LAL), indicated for the treatment of patients with a diagnosis of LAL deficiency. It is produced in the egg white of genetically engineered chickens via recombinant DNA technology. LAL catalyzes the breakdown of cholesteryl esters to free cholesterol and fatty acids, and the breakdown of triglycerides to glycerol and free fatty acids.

Length of Authorization

12 months

Dosing Limits [Medical Benefit]

Each dose must not exceed 5 mg/kg administered intravenously no more frequently than once per week. (560 billable units once weekly)

Guideline

1. **Lysosomal Acid Lipase Deficiency.** Approve for 1 year if the patient meets the following criteria (A and

B):

A. The diagnosis is established by one of the following (i or ii):
   i. Patient has a laboratory test demonstrating deficient lysosomal acid lipase activity in leukocytes, fibroblasts, or liver tissue; **OR**
   ii. Patient has a molecular genetic test demonstrating lysosomal acid lipase gene mutation; **AND**
B. Kanuma is prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders.

Applicable Procedure Codes

Code	Description
J2840	Injection, sebelipase alfa, 1 mg

Applicable NDCs

Code	Description
25682-0007-01	Kanuma 20mg/10mL Solution

ICD-10 Diagnoses

Code	Description
E75.5	Other lipid storage disorders

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	2/15/2024	Annual Review: Updated dosing limits, no criteria changes
EmblemHealth & ConnectiCare	04/07/2023	Transfer from CCUM template to Co-Branded Medical Template Retired MG.MM.PH.154
EmblemHealth & ConnectiCare	04/06/2022	Annual Revision: Lysosomal Acid Lipase Deficiency: The dosing limit was increased from 3 mg/kg to 5 mg/kg due to revisions in the prescribing information.
EmblemHealth & ConnectiCare	04/07/2021	Annual Revision: no criteria changes

References

1. Kanuma™ intravenous infusion [prescribing information]. Cheshire, CT: Alexion; November 2021.