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5.30.040

Section:	Prescription Drugs	**Effective Date:**	April 1, 2026
Subsection:	Endocrine and Metabolic Drugs	**Original Policy Date:**	December 30, 2015
Subject:	Kanuma	**Page:**	1 of 4

Last Review Date: March 6, 2026

Kanuma

Description

Kanuma (sebelipase alfa)

Background
Kanuma (sebelipase alfa) is used to treat Lysosomal Acid Lipase (LAL) deficiency. LAL deficiency is a disorder characterized by a genetic defect resulting in a marked decrease or loss in activity of the lysosomal acid lipase enzyme. This enzyme normally causes the breakdown of lipid particles including LDL cholesterol (LDL-c). Deficient LAL enzyme activity results in progressive complications due to the lysosomal accumulation of fat molecules in multiple organs, including the liver, spleen, intestine, and the walls of blood vessels. The resulting lipid accumulation in the liver may lead to increased liver fat content and progression of liver disease, including fibrosis and cirrhosis. Accumulation of lipid in the intestinal wall leads to malabsorption and growth failure. In parallel, dyslipidemia due to impaired degradation of lysosomal lipid is common with elevated LDL-c and triglycerides and low HDL-cholesterol (HDL-c). Kanuma is administered via intravenous infusions once weekly or once every other week (1).

Regulatory Status
FDA-approved indication: Kanuma is a hydrolytic lysosomal cholesteryl ester and triacylglycerol-specific enzyme indicated for the treatment of patients with a diagnosis of Lysosomal Acid Lipase (LAL) deficiency (1).

Kanuma contains a boxed warning for hypersensitivity reactions, including anaphylaxis. If a severe hypersensitivity reaction occurs, discontinue Kanuma and immediately initiate appropriate medical treatment, including use of epinephrine (1).

Safety and effectiveness of Kanuma have been established in pediatric patients aged 1 month and older (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Kanuma may be considered **medically necessary** if the conditions indicated below are met.

Kanuma may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 1 month of age and older

Diagnosis

Patient must have the following:

Lysosomal Acid Lipase (LAL) deficiency

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre – PA Allowance

None

Prior – Approval Limit

Duration 2 years

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary
Kanuma is indicated for patients with a diagnosis of Lysosomal Acid Lipase (LAL) deficiency. LAL deficiency is a disorder characterized by a genetic defect resulting in a marked decrease or loss in activity of the lysosomal acid lipase enzyme. This enzyme normally causes the breakdown of lipid particles including LDL cholesterol. Kanuma is administered via intravenous infusions once weekly or once every other week. Kanuma has a boxed warning for hypersensitivity reactions. Safety and effectiveness of Kanuma have been established in pediatric patients aged 1 month and older (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Kanuma while maintaining optimal therapeutic outcomes.

References
1. Kanuma [package insert]. New Haven, CT: Alexion Pharmaceuticals Inc.; July 2024.

Policy History

Date	Action
December 2015	Addition to PA
March 2016	Annual review Policy number changed from 5.08.40 to 5.30.40
June 2016	Annual review
September 2016	Annual editorial review
December 2017	Annual review
December 2018	Annual review
December 2019	Annual editorial review. Changed approval duration from lifetime to 2 years
December 2020	Annual review
June 2021	Annual review
June 2022	Annual review and reference update
June 2023	Annual review. Changed policy number to 5.30.040
March 2024	Annual review
March 2025	Annual editorial review and reference update
March 2026	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 6, 2026 and is effective on April 1, 2026.