

Kanuma® (sebelipase alfa) Injection

When requesting Kanuma® (sebelipase alfa) injection, the individual requiring treatment must be diagnosed with an FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved Indication

Kanuma (sebelipase alfa) is indicated for the treatment of individuals with lysosomal acid lipase (LAL) deficiency.

Coverage Guidelines

Lysosomal Acid Lipase Deficiency

The individual must meet **all** of the following criteria for approval:

- Diagnosis is confirmed by one of the following:
 - o Laboratory test demonstrating deficient lysosomal acid lipase activity in leukocytes, fibroblasts, or liver tissue; OR
 - o Molecular genetic test demonstrating lysosomal acid lipase gene mutation
- 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.

Approval duration: 12 months

Dosing Recommendations

Approve up to 3 mg/kg administered intravenously no more frequently than once per week.

References

1. Kanuma™ injection [prescribing information]. Cheshire, CT: Alexion Pharmaceuticals; December 2015.
2. Reiner Z, Guardamagna O, Nair D, et al. Lysosomal acid lipase deficiency – an under-recognized cause of dyslipidaemia and liver dysfunction. *Atherosclerosis*. 2014;235:21-30.
3. Erwin AL. The role of sebelipase alfa in the treatment of lysosomal acid lipase deficiency. *Ther Adv Gastroenterol*. 2017;10:553-562.