

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 is indicated for the treatment of patients with a diagnosis of Lysosomal Acid Lipase (LAL) deficiency.

Approved Off-label Compendial use(s)

None

Coverage Guidelines

The individual has a diagnosis of lysosomal acid lipase (LAL) deficiency confirmed by enzyme assay demonstrating a deficiency of lysosomal acid lipase enzyme activity or by genetic testing.

Dosing Recommendations

The recommended dosage is 1 mg/kg via intravenous infusion once every other week.

For individuals with rapidly progressive LAL deficiency presenting within the first 6 months of life:

The recommended starting dosage is 1 mg/kg via intravenous infusion once weekly. For individuals who do not achieve an optimal clinical response, increase to 3 mg/kg once weekly.

Approval duration (initial and renewal): 12 months

References

1. Kanuma prescribing information. New Haven, CT; Alexion Pharmaceuticals Inc. November 2015.
2. Reiner Z, Guardamagna O, Nair D, et al. Lysosomal acid lipase deficiency – An under-recognized cause of dyslipidemia and liver dysfunction. *Atherosclerosis*. 235 (2014):21-30.
3. National Organization for Rare Disorders: Wolman Disease. Available at: <https://rarediseases.org/rare-diseases/wolman-disease/>. Accessed on January 19, 2018.