

<b>Policy Name:</b>	<b>Kanuma (sebelipase alfa)</b>	<b>Policy #:</b>	<b>2446P</b>
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## Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Kanuma (sebelipase alfa).

## Statement of the Policy

Health Alliance Medical Plans and Health Alliance Northwest will approve the use of Kanuma (sebelipase alfa) under the Specialty Medical benefit when the following criteria have been met.

## Criteria

### 1. Coverage Criteria

- 1.1 Documented diagnosis of Wolman's Disease (Lysosomal acid lipase (LAL) deficiency) or Cholesteryl Ester Storage Disease (CESD)
  - Diagnosis must be confirmed by genetic testing showing gene defect in LIPA gene
- 1.2 Prescribed by an endocrinologist (hormone doctor) or geneticist (gene specialist)

### 2. Approval Period

- 2.1 12 months

## CPT Codes

96360 – 96361	Intravenous infusion, hydration
96365 – 96368	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug)
96379	Unlisted therapeutic, prophylactic, or diagnostic intravenous or intra-arterial injection or infusion
82657 – 82658	Enzyme activity in blood cells, cultured cells, or tissue, not elsewhere specified; nonradioactive substrate, each specimen radioactive substrate, each specimen
84460	Transferase; alanine amino (ALT) (SGPT)

## HCPCS Codes

J2840	Injection, sebelipase alfa, 1mg (Kanuma)
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## References

1. Kanuma (sebelipase alfa) [prescribing information]. Boston, MA: Alexion Pharmaceuticals; November 2021.
2. Burton BK, Feillet F, Furuya KN, et al. Sebelipase alfa in children and adults with lysosomal acid lipase deficiency: Final results of the ARISE study. *J Hepatol* 2022; 76:577.
3. Frampton JE. Sebelipase Alfa: A Review in Lysosomal Acid Lipase Deficiency. *Am J Cardiovasc Drugs* 2016 Dec;16(6):461-468.
4. Pastores GM and Hughes DA. Lysosomal Acid Lipase Deficiency: Therapeutic Options. *Drug Des Devel Ther* 2020 Feb 11;14:591-601.

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#### DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.