Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs

Kanuma® (sebelipase alfa)

Effective: March 10, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988
☒ Tufts Health Plan Commercial products; Fax 617-673-0988
CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939
☐ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956
*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956
☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956
☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration Approved Indications

Kanuma (sebelipase) 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.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Kanuma for Members, when **ALL** of the following criteria are met:

1. Documented diagnosis of Lysosomal Acid Lipase deficiency confirmed by one (1) of the following:
    a. Enzyme assay demonstrating a deficiency of lysosomal acid lipase enzyme activity
    b. Genetic testing

AND

2. The prescribing physician is a physician with expertise in the treatment of Lysosomal Acid Lipase deficiency

Limitations

None

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J2840	Injection, sebelipase alfa, 1 mg

References:

1. Burton BK, Balwani M, Feillet F et al. A phase 3 trial of sebelipase alfa in lysosomal acid lipase deficiency. *N Engl J Med*. 2015; 373:1010-20.

2. Burton BK, Deegan PB, Enns GM et al. Clinical features of lysosomal acid lipase deficiency. *J Pediatr Gastroenterol Nut*. 2015; Dec;61 (6):619-25
3. Hoffman EP, Barr ML, Giovanni MA, Murray MF. Lysosomal acid lipase deficiency. *GeneReviews*®. 2015 Jul 30. URL: ncbi.nlm.nih.gov/books/NBK305870/?report=printable. Available from Internet. Accessed 2016 April 18.
4. Jones S, Plantaz D, Vara R et al. Impact of sebelipase alfa on survival and liver function in infants with rapidly progressive lysosomal acid lipase deficiency. *Journal of Hepatology*. 2015; 62: S263- S864. Abstract 2. URL: ilc-congress.eu/abstract-book/index.html#p=634. Available from Internet. Accessed 2016 April 18.
5. Jones SA, Valayannopoulos V, Schneider E, et al. Impact of sebelipase alfa on survival and liver function in infants with rapidly progressive lysosomal acid lipase deficiency. Poster presented at SSIEM 2015. Lyon, France. 2015 September 1-4.
6. Kanuma (sebelipase afla) [prescribing Information]. Chesire, CT: Alexion Pharmaceuticals Inc.; July 2024.
7. Porto AF. Lysosomal acid lipase deficiency: diagnosis and treatment of Wolman and Cholesteryl Ester Storage Diseases. *Pediatr Endocrinol Rev*. 2014 Sep;12 Suppl 1:125-32.
8. Reiner Z, Guardamagna O, Nair D. Lysosomal acid lipase deficiency – an under-recognized cause of dyslipidemia and liver dysfunction. *Atherosclerosis*. 2014 Jul;235(1):21-30.

Approval And Revision History

May 17, 2023: Reviewed by the Medical Policy Approval Committee (MPAC)

June 13, 2023: Reviewed by Pharmacy and Therapeutics Committee (P&T)

Subsequent endorsement date(s) and changes made:

- Originally approved September 13, 2022 by P&T and September 21, 2022 by MPAC committees effective January 1, 2023
- Administrative update: April 2023 added Medical Benefit Drugs to title, updated MATogether and RITogether fax numbers to 617-673-0939
- May 17, 2023: Annual review, no change, effective July 1, 2023
- August 2023: Administrative update to rebrand Tufts Health Unify to Tufts Health One Care for 2024
- April 9, 2024: Removed Member has alanine aminotransferase level (ALT) ≥ 1.5 times the upper limit of normal (based on the age- and gender-specific normal ranges) on two consecutive ALT measurements obtained at least one week apart. Minor wording updates (eff 5/1/24).
- March 11, 2025: No changes. Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template (eff 3/11/25).
- March 10, 2026: No changes

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.