

PHARMACY POLICY STATEMENT

Marketplace

DRUG NAME
BILLING CODE

Kanuma (sebelipase alfa)

For reauthorization :

1. Chart notes must document a positive clinical response to treatment such as improved lipid profile (LDL-c, triglycerides), liver biomarkers (ALT, AST), liver volume, or growth/weight z-scores (if pediatric).

If all the above requirements are met , the medication will be approved for an additional 12 months.

CareSource considers Kanuma (sebelipase alfa) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off -Label policy.

DATE	ACTION/DESCRIPTION
04/11/2018	New policy for Kanuma created.
01/10/2022	Transferred to new template. Updated references. Corrected max dose from 3 mg/kg to 5 mg/kg; added ped/adult dosing section which was missing. Changed prescribed by to by or in consultation with; also removed general specialist, added geneticist. Amended age minimum from 8 months to 1 month. Added tests for diagnostic confirmation. Removed all criteria that listed manifestations from a specific clinical trial and was divided by age; replaced with general list of manifestations. Specified renewal criteria.