

Pharmacy Policy

Kanuma™

Policy Number: 9.311

Version Number: 2.0

Version Effective Date: 9/1/2021

Product Applicability <input type="checkbox"/> All Plan+ Products	
Well Sense Health Plan <input type="checkbox"/> New Hampshire Medicaid	Boston Medical Center HealthNet Plan <input checked="" type="checkbox"/> MassHealth ACO <input checked="" type="checkbox"/> MassHealth MCO <input type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct <input type="checkbox"/> Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- Kanuma™ (sebelipase alfa)

The Plan may authorize coverage of the above product(s) for members meeting the following criteria:

Covered Use	All FDA approved indication unless otherwise excluded.
Required Medical Information	1. Diagnosis of Lysosomal Acid Lipase deficiency confirmed by enzyme assay (i.e. Lysosomal Acid Lipase Analysis) or genetic testing; AND 2. Dose does not exceed 1 mg/kg every other week
Age	1 month of age or older

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

Restrictions	
Prescriber Restriction	Prescribed by or in collaboration with a specialist in genetics and metabolism
Coverage Duration	Initial: 6 months Reauthorization: 12 months
Other criteria	Reauthorization: <ol style="list-style-type: none"> 1. Must continue to meet initial criteria; AND 2. Provider attests member has experienced improvement in clinical signs and symptoms from baseline without treatment related adverse events

Clinical Background Information and References

1. Product Information. KANUMA™. Alexion Pharmaceuticals Inc. Cheshire, CT 06410. Dec 2015.
3. Porto AF. Lysosomal acid lipase deficiency: diagnosis and treatment of Wolman and Cholesteryl Ester Storage Diseases. Pediatric endocrinology reviews: PER. 2014 Sep;12:125-32.
4. Sebelipase alfa: Drug Information. UptoDate. Lexicomp, Inc.; accessed March 27, 2019. <http://www.uptodate.com>
5. Reynolds T. Cholesteryl ester storage disease: a rare and possibly treatable cause of premature vascular disease and cirrhosis. Journal of clinical pathology. 2013 Sep 2:jclinpath-2012.
2. Genetics Home Reference. Wolman Disease. October 2007. Available at: <http://ghr.nlm.nih.gov/condition=wolmandisease> Accessed June 26, 2015.

Applicable Coding:

Code	Medication
J2840	Injection, sebelipase alfa, 1 mg

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date	Approved by
12/1/2020	Retired Policy 9.067. Created separated policy per each applicable line of business. Addition of age restriction and documentation of diagnosis confirmed by enzyme assay or genetic testing..	1/1/2021	P&T Committee
5/13/2021	P& T Annual Review: No changes	9/1/2021	P&T Committee

Next Review Date

5/2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.