

**Kanuma (sebelipase alfa)
Effective 09/01/2021**

Plan	<input checked="" type="checkbox"/> MassHealth <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX)		
Specialty Limitations	N/A		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

Kanuma (sebelipase alfa) is a recombinant enzyme that binds to cell surface receptors via glycans and is indicated for lysosomal acid lipase deficiency.

Coverage Guidelines

Authorization may be granted for members who are currently receiving treatment with Kanuma excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

OR

Authorization of 12 months may be granted for members when **all** the following criteria are met, and documentation is provided:

1. Member has a diagnosis of LAL deficiency as confirmed by enzyme assay demonstrating a deficiency of lysosomal acid lipase enzyme activity or by genetic testing; AND
2. 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.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for lysosomal acid lipase (LAL) deficiency who are responding to therapy (e.g., improvement, stabilization, or slowing of disease progression for weight-for-age z-score if exhibiting growth failure, low-density lipoprotein [LDL], high-density lipoprotein [HDL], triglycerides, or alanine aminotransferase [ALT]).



Limitations

1. Initial approvals and reauthorizations will be granted for 12 months

References

1. Kanuma (sebelipase alfa) [prescribing information]. Cheshire, CT: Alexion Pharmaceuticals; December 2015.

Review History

01/20/2021—Reviewed P&T, changed from CVS template to custom template; overview included.
Effective 09/01/2021.

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