

Pharmacy Policy

Myalept

Policy Number: 9.307

Version Number: 1

Version Effective Date: 1/1/2021

Product Applicability <input type="checkbox"/> All Plan+ Products	
<p>Well Sense Health Plan</p> <input type="checkbox"/> New Hampshire Medicaid	<p>Boston Medical Center HealthNet Plan</p> <input checked="" type="checkbox"/> MassHealth - MCO <input checked="" type="checkbox"/> MassHealth - ACO <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:

- Myalept (metreleptin)

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	None
Required Medical Information	<ol style="list-style-type: none"> 1. Medical records documenting a low fasting leptin level within the last 30 days; AND 2. Diagnosis of congenital or acquired generalized lipodystrophy due to a leptin deficiency; AND 3. Diagnosis of diabetes mellitus or hypertriglyceridemia (> 500 mg/dL); AND 4. A failed trial of lifestyle modifications (e.g., low fat diet, increased exercise) in conjunction with at least two standard therapies for each metabolic disturbance (e.g., metformin,

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	insulin, and thiazolidinediones for diabetes; statins and fibrates for hypertriglyceridemia)
Age Restriction	None
Prescriber Restriction	Prescribed by an endocrinologist
Coverage Duration	12 months
Other criteria	Reauthorization criteria: 1. Therapy has been well tolerated; AND 2. There has been a decrease in hemoglobin A1c, triglyceride levels, and/or fasting glucose levels

Clinical Background Information and References

1. Myalept (metreleptin) [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Co; September 2015.
2. Chan JL, Lutz K, Cochran E, et al. Clinical effects of long-term metreleptin treatment in patients with lipodystrophy. *Endocr Pract.* 2011;17(6):92-932.
3. Zadeh SE, Lungu AO, Cochran EK, et al. The liver diseases of lipodystrophy: the long-term effect of leptin treatment. *J Hepatol.* 2013;59(1):131-137.
4. Mantzoros C. Lipodystrophic syndromes. www.uptodate.com. Accessed 12 December 2016.

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

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date	Approved by
12/1/2020	9.052 Myalept Policy retired, new policy created	1/1/2021	P&T Committee

Next Review Date

2021

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

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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.

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