Pharmacy Medical Necessity Guidelines: Myalept® (metreleptin)

Effective: June 12, 2018

Prior Authorization Required: √ Type of Review – Care Management
Not Covered: Type of Review – Clinical Review: √
Pharmacy (RX) or Medical (MED) Benefit: RX Department to Review: RXUM

This Pharmacy Medical Necessity Guideline applies to the following:

**Tufts Health Plan Commercial Plans**
- Tufts Health Plan Commercial Plans – large group plans
- Tufts Health Plan Commercial Plans – small group and individual plans

**Tufts Health Public Plans**
- Tufts Health Direct – Health Connector
- Tufts Health Together – A MassHealth Plan
- Tufts Health RITogether – A Rite Care + Rhody Health Partners Plan

**Tufts Health Freedom Plan products**
- Tufts Health Freedom Plan - large group plans
- Tufts Health Freedom Plan - small group plans

Fax Numbers:
RXUM: 617.673.0988

**Note:** For Tufts Health Plan Medicare Preferred Members, please refer to the Tufts Medicare Preferred Prior Authorization Criteria. Background, applicable product and disclaimer information can be found on the last page.

**OVERVIEW**

**FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS**

Myalept (metreleptin) is indicated as an adjunct to diet as replacement therapy to treat the complications of leptin deficiency in patients with congenital or acquired generalized lipodystrophy.

The safety and effectiveness of Myalept (metreleptin) for the treatment of complications of partial lipodystrophy have not been established.

The safety and effectiveness of Myalept (metreleptin) for the treatment of liver disease, including nonalcoholic steatohepatitis, have not been established.

Myalept (metreleptin) is not indicated for use in patients with human immunodeficiency virus-related lipodystrophy.

Myalept (metreleptin) is not indicated for use in patients with metabolic disease, without concurrent evidence of generalized lipodystrophy.

**COVERAGE GUIDELINES**

The plan may authorize coverage of Myalept (metreleptin) for Members, when the following criteria are met:
1. Member has a diagnosis of congenital or acquired generalized lipodystrophy due to a leptin deficiency
   **AND**
2. Conventional treatments for metabolic disturbances have failed (e.g., lifestyle modification, antidiabetic agents, statins)
   **AND**
3. Documentation Myalept (metreleptin) is being used as an adjunct to diet modification
   **AND**
4. The prescribing physician is an endocrinologist
   **AND**
5. Documentation the Member has at least one of the following conditions:
   a) Diabetes Mellitus
   b) Hypertriglyceridemia
   c) Insulin Resistance

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LIMITATIONS
1. The plan will not provide coverage of Myalept (metreleptin) for:
   a) Treatment of complications of partial lipodystrophy.
   b) Treatment of liver disease, including nonalcoholic steatohepatitis.
   c) Treatment of human immunodeficiency virus-related lipodystrophy.
   d) Treatment of metabolic disease, including diabetes mellitus and hypertriglyceridemia, without concurrent evidence of generalized lipodystrophy.
   e) Treatment of general obesity not associated with congenital leptin deficiency.
2. Initial authorization will be limited to 12 months. Subsequent authorization may be given in 12-month intervals based on submission of current progress notes from the physician documenting clinical efficacy of Myalept (metreleptin) and continued use as an adjunct to diet modification.

CODES
None

REFERENCES

APPROVAL HISTORY
September 9, 2014: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
- August 11, 2015: No changes
- January 1, 2016: Administrative change to rebranded template.
- July 12, 2016: No changes
- July 11, 2017: No changes
- June 12, 2018: No changes

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION
Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with a Member’s benefit document and in coordination with the Member’s physician(s). The plan makes coverage decisions on a case-by-case basis considering the individual Member’s health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be 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 the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member’s
benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLink℠ Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

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