Gateway Health℠ It's Wholecare.

Updated: 09/2021
PARP Approved: 10/2021

Prior Authorization Criteria

Myalept (metreleptin)

All requests for Myalept (metreleptin) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Coverage may be provided with a diagnosis of congenital or acquired generalized lipodystrophy associated with leptin deficiency and the following criteria is met:

- Must be prescribed by or in consultation with an endocrinologist.
- Member must have leptin deficiency
- Member must have documentation of ONE of the following:
    - Diagnosis of uncontrolled diabetes mellitus or insulin resistance with persistent hyperglycemia (HGbA1C greater than or equal to 6.5%) despite treatment with BOTH of the following:
        - Dietary intervention
        - Optimized insulin therapy at maximized tolerated doses.
    - Diagnosis of uncontrolled hypertriglyceridemia (TG> 200 mg/dL) despite treatment with BOTH of the following:
        - Dietary intervention
        - Optimized therapy with at least two triglyceride-lowering agents from different classes (e.g. fibrates, statins) at maximally tolerated doses.
- Medication must be used as an adjunct to diet modification.
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- **Initial Duration of Approval:** 12 months
- **Reauthorization criteria**
    - Evidence of positive clinical response and/or stabilization of laboratory parameters provided in initial authorization (i.e. fasting triglyceride concentrations, and/or HbA1c).
    - **Reauthorization Duration of Approval:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

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MYALEPT (METRELEPTIN)
PRIOR AUTHORIZATION FORM – PAGE 1 of 2

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	Provider NPI:
Provider Specialty:	Office Contact:
State license #:	Office NPI:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:	
Gateway ID:	Member weight:	Height:

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Directions:	Quantity:	Refills:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:	

Billing Information

This medication will be billed: ☐ at a pharmacy **OR** ☐ medically, JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis:	ICD Code:

Does the member have leptin deficiency? ☐ Yes, please provide value: _____ ☐ No

Does the member have diabetes mellitus or insulin resistance with persistent hyperglycemia (HbA1c ≥ 6.5%)? ☐ Yes ☐ No

- Has the member tried and failed any the following for management of the disease?
  - Dietary intervention ☐ Yes ☐ No
  - Optimized Insulin Therapy at maximized tolerated doses ☐ Yes ☐ No

Please provide HGbA1c: _____

Does the member have a diagnosis of hypertriglyceridemia (TG> 200 mg/dL)? ☐ Yes ☐ No

- Has the member tried and failed any of the following for the management of the disease?
  - Dietary intervention ☐ Yes ☐ No
  - Optimized therapy with at least two triglyceride-lowering agents from different classes (e.g. fibrates, statins) at maximally tolerated doses. ☐ Yes ☐ No

Please provide triglyceride value:

Will the medication be used as an adjunct to diet modification? ☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

***** Continued on next page *****

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MYALEPT (METRELEPTIN)
PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 2 OF 2

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MEMBER INFORMATION

Member Name:	DOB:	
Gateway ID:	Member weight:	Height:

REAUTHORIZATION

Has the member experienced improvement in the underlying condition with treatment? ☐ Yes ☐ No
Which of the following have improved?
☐ Fasting triglyceride – Previous value: _____ Recent value:_____
☐ HbA1c – Previous value: _____ Recent value: _____

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date