HIGHMARK WHOLECARE

Updated: 08/2024
PARP Approved: 9/2024

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.

HIGHMARK WHOLECARE

Updated: 08/2024
PARP Approved: 9/2024

MYALEPT (METRELEPTIN) PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Wholecare Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (800) 392-1147 Mon – Fri 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:	
Member 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 (HbA1c ≥ 6.5%)? ☐ Yes, HgA1c: _____ ☐ No

Does the member have hypertriglyceridemia (TG> 200 mg/dL)? ☐ Yes, TG level: _____ ☐ No

What has been tried? Check all that apply and list medications below.

- ☐ Dietary intervention ☐ Yes ☐ No
- ☐ Optimized insulin therapy at maximized tolerated doses
- ☐ Two triglyceride-lowering agents from different classes at max tolerated doses (e.g. fibrates, statins)

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)

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