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:

- Member must have leptin deficiency (less than 12.0 ng/mL in females and less than 8.0 ng/mL in males).
- 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 prescribed by or in association with an endocrinologist.
- Medication must be used as an adjunct to diet modification.
- Member must not be using the medication as treatment for the following:
    - HIV-related lipodystrophy.
    - Liver disease, including nonalcoholic steatohepatitis (NASH).
    - General obesity not associated with congenital leptin deficiency.
    - Complications of partial lipodystrophy.
- 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:** 4 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.

It's Wholecare.

Updated: 07/2020
PARP Approved: 08/2020

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[SM] 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:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

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

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
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

Will the medication be used in any of the following situations?
- HIV-related lipodystrophy ☐ Yes ☐ No
- Treatment of liver disease, including nonalcoholic steatohepatitis (NASH) ☐ Yes ☐ No
- General obesity not associated with congenital leptin deficiency ☐ Yes ☐ No
- Complications of partial lipodystrophy ☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY

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

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MYALEPT (METRELEPTIN)
PRIOR AUTHORIZATION FORM (CONTINUED)– PAGE 2 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[SM] 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

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