

Pharmacy Prior Authorization Form

Fax completed form to: 877.974.4411 toll free, or 616.942.8206

This form applies to: **Commercial (Traditional)** **Commercial (Individual/Optimized)**

Medicaid

This request is: **Urgent** (life threatening) **Non-Urgent** (standard review)

Urgent means the standard review time may seriously jeopardize the life or health of the patient or the patient's ability to regain maximum function.

Myalept[®] (metreleptin)

Member

Last Name: _____ First Name: _____
 ID #: _____ DOB: _____ Gender: _____
 Primary Care Physician: _____
 Requesting Provider: _____ Prov. Phone: _____ Prov. Fax: _____
 Provider Address: _____
 Provider NPI: _____ Contact Name: _____
 Provider Signature: _____ Date: _____

Product Information

New request Continuation request

Drug product: Myalept 5 mg/5 mL vial **Start date** (or date of next dose): _____
Date of last dose (if applicable): _____
Dosing frequency: _____

Drug cost information

The wholesale acquisition cost for each 5 mg vial of Myalept is \$3,298. The annual cost of treatment with this drug will vary based on the weight and gender of the patient, but may exceed \$1,187,200 yearly.

Precertification Requirements

Before this drug is covered, the patient must meet all of the following requirements:

1. Must have acquired or congenital generalized lipodystrophy resulting in leptin deficiency complications
 - Laboratory leptin assay results (i.e. serum leptin levels less than the 7th percentile of normal values reported by the 3rd National Health and Nutrition Examination survey (less than 7.0 ng/mL in females and less than 3.0 ng/mL in males) confirming leptin deficiency must be provided
2. Must have one of the following metabolic abnormalities:
 - Type 2 Diabetes mellitus
 - Triglyceride level more than 200 mg/dL
 - Hyperinsulinemia (defined by fasting serum insulin greater than 30 microunits/mL)
3. Must not have:
 - HIV
 - Infectious liver disease
 - Acquired lipodystrophy with hematologic abnormalities
4. Must not exceed maximum weight based daily dosing per FDA approved label

Yearly prior authorization is required.

Note: Authorization for indications, dosing, or a route of administration not approved by the Food and Drug Administration (FDA) or recognized in CMS-accepted compendia (e.g. DrugDex, AHFS, U.S. Pharmacopeia, and also Clinical Pharmacology for oncology indications only) require supporting evidence for coverage. Please provide two published peer-reviewed literature articles supporting the appropriateness of the drug, the dosing of the drug, or the route of administration to be used for the identified indication.

New request
Priority Health Precertification Documentation

A. Does the patient have laboratory confirmed leptin deficiency?

- Yes (*Fax a copy of the laboratory assay to Priority Health.*)
- No
- Other – the patient’s condition is: _____
Rationale for use: _____

B. What condition is this drug being requested for?

- Acquired generalized lipodystrophy
- Congenital generalized lipodystrophy
- Other – the patient’s condition is: _____

C. Which of the following conditions, if any, does the patient have?

- Diabetes mellitus
- Triglyceride level more than 200 mg/dL [The patient’s TG level was _____ mg/dL on _____ (date).]
- None of the above

D. Which of the of following conditions, if any, does the patient have?

- HIV
- Infectious liver disease
- Acquired lipodystrophy with hematologic abnormalities
- None of the above

E. What is the patient’s baseline weight?

Additional information

Note: Myalept is only covered when reconstituted using bacteriostatic water.