

## 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<sup>®</sup> (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 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.