

Metreleptin (Myalept®)

Place of Service

Office Administration
Self-Administration

HCPCS: J3590

NDC: 66780-310-01

Condition listed in policy (see criteria for details)

- [Leptin deficiency associated with congenital or acquired generalized lipodystrophy](#)

AHFS therapeutic class: leptin

Mechanism of action: recombinant human leptin analog

(1) Special Instructions and pertinent Information

This drug is managed under the outpatient Pharmacy Benefit for self-administration. Please contact the member's Pharmacy Benefit for information on how to obtain this drug.

To submit a request to the Medical Benefit, please submit clinical information for prior authorization review and include medical rationale why the patient cannot self-administer this drug in the home.

For plans with self-injectables only covered under the Medical Benefit, please submit clinical information for prior authorization review.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for metreleptin (Myalept®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Leptin deficiency associated with congenital or acquired generalized lipodystrophy

1. Meets either of the following:

- a. Diagnosis of leptin deficiency associated with congenital or acquired generalized lipodystrophy, and one of the following metabolic abnormalities or conditions:
 - i. Diabetes mellitus (HbA1c \geq of 7% or FPG \geq 126 mg/dL), OR
 - ii. Presence of hypertriglyceridemia (TG \geq 250 mg/dL), OR
 - iii. History of pancreatitis associated with hypertriglyceridemia, OR
 - iv. Increased fasting insulin ($>$ 25 mIU/L), OR
 - v. Non-alcoholic steatohepatitis in non-obese individual, OR
 - vi. Early onset cardiomyopathy, OR
 - vii. Polycystic ovary syndrome (PCOS)

OR

- b. Diagnosis of partial lipodystrophy AND Patient has all of the following:
 - i. low leptin level of $<$ 4ng/ml, and
 - ii. HbA1c $>$ 8% or triglycerides $>$ 500 mg/dL

AND

2. Provider attests not being used for the following off-label indications: HIV-related lipodystrophy, general obesity not associated with congenital leptin deficiency

Covered dose

Up to 1 vial per day

Coverage period

Indefinitely

ICD-10:

E88.1

(3) The following condition(s) DO NOT require Prior Authorization/Preservice**All requests for metreleptin (Myalept®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.****(4) This Medication is NOT medically necessary for the following condition(s)**Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.Please refer to the Provider Manual and User Guide for more information.**(5) Additional Information**How supplied: 11.3 mg (single-vial) delivers 5 mg per mL of metreleptin when reconstituted with 2.2 mL of BWFI or WFI.

The recommended Myalept daily dosages in mg/kg of body weight are:

Body Weight	Starting Dose	Dosing Increments	Max Daily Dose
≤ 40 kg	0.06 mg/kg/day	↑ or ↓ by 0.02 mg/kg	0.13 mg/kg
Males > 40 kg	2.5 mg/day	↑ or ↓ by 1.25 mg to 2.5 mg/day	10 mg/day
Females > 40 kg	5 mg/day	↑ or ↓ by 1.25 mg to 2.5 mg/day	10 mg/day

(6) References

- AHFS®. Available by subscription at <http://www.lexi.com>
- Brown RJ, Araujo-Vilar D, et al. The diagnosis and management of lipodystrophy syndromes: a multi-society practice guideline. J Clin Endocrinol Metab 2016; 101: 4500-4511.
- DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
- Myalept® (metreleptin) [Prescribing Information]. Dublin, Ireland: Amryt Pharmaceuticals DAC; 2/2022.

(7) Policy Update

Date of initial review: 3Q2022

Date of next review: 3Q2023

Changes from previous policy version:

- New policy

*BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee*