



UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2021 P 1132-9
Program	Prior Authorization/Notification
Medication	Myalept® (metreleptin)
P&T Approval Date	5/2014, 5/2015, 5/2016, 5/2017, 5/2018, 5/2019, 5/2020, 5/2021
Effective Date	8/1/2021; Oxford only: N/A

**1. Background:**

Myalept (metreleptin) is indicated as an adjunct to diet as replacement therapy to treat the complications of leptin deficiency in patients with congenital or acquired generalized lipodystrophy. Due to the risks associated with the development of anti-metreleptin antibodies that neutralize endogenous leptin and/or lymphoma, Myalept is only available through the Myalept Risk Evaluation and Mitigation Strategy (REMS) restricted program.

**2. Coverage Criteria:**

**A. Initial Authorization**

**1. Myalept** will be approved based on **both** of the following criteria:

- a. Diagnosis of congenital or acquired generalized lipodystrophy associated with leptin deficiency

**-AND-**

- b. Myalept is being used as an adjunct to diet modification

**Authorization will be issued for 12 months.**

**B. Reauthorization**

**1. Myalept** will be approved based on **both** of the following criteria:

- a. Documentation of positive clinical response to Myalept therapy

**-AND-**

- b. Myalept is being used as an adjunct to diet modification

**Authorization will be issued for 12 months.**

**3. Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

**4. Reference:**

1. Myalept [package insert]. Cambridge, MA: Aegerion Pharmaceuticals; September 2020.

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<b>Change Control</b>	
5/2014	New program.
5/2014	Annual review with no changes to coverage criteria. Updated references
5/2016	Annual review. No changes to coverage criteria. Updated reference.
5/2017	Annual review with no changes to coverage criteria.
5/2018	Annual review with no changes to coverage criteria.
12/2018	Administrative change to add statement regarding use of automated processes.
5/2019	Annual review. No changes to coverage criteria.
5/2020	Annual review. Added information related to REMS program & corrected trademark info
5/2021	Annual review. No changes to coverage criteria. Updated reference.