UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1132-13
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, 5/2022, 5/2023, 5/2024, 5/2025
Effective Date	8/1/2025

1. Background:

Myalept (metreleptin) is a leptin analog indicated as an adjunct to diet as replacement therapy to treat the complications of leptin deficiency in patients with congenital or acquired generalized lipodystrophy.

Limitations of Use:
The safety and effectiveness of Myalept for the treatment of complications of partial lipodystrophy or for the treatment of liver disease, including nonalcoholic steatohepatitis (NASH), have not been established. Myaept is not indicated for use in patients with HIV-related lipodystrophy or patients with metabolic disease, without concurrent evidence of 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]:

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.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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]. Cary, NC: Chiesi USA, Inc.; March 2024.

Program	Prior Authorization/Notification – Myalept® (metreleptin)
Change Control	
5/2014	New program.
5/2015	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.
5/2022	Annual review. Updated reference.
5/2023	Annual review with no changes to coverage criteria. Added state mandate footnote.
5/2024	Annual review with no changes to coverage criteria.
5/2025	Annual review with no changes to coverage criteria. Updated background and reference.