UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2032-14
Program	Prior Authorization/Medical Necessity
Medication	Myalept® (metreleptin)
P&T Approval Date	5/2014, 7/2014, 8/2014, 7/2015, 6/2016, 5/2017, 5/2018, 5/2019, 5/2020, 5/2021, 5/2022, 6/2023, 6/2024
Effective Date	9/1/2024

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

Myalept is available only through a restricted distribution program under a Risk Evaluation and Mitigation Strategy (REMS), called the Myalept REMS program, because of the risks associated with the development of anti-metreleptin antibodies that neutralize endogenous leptin and the risk of lymphoma.

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Myalept** will be approved based on **all** 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

   -AND-

   c. Prescribed by an endocrinologist

   -AND-

d. Patient has at least **one** of the following:

(1) Diabetes mellitus or insulin resistance with persistent hyperglycemia (HgbA1C > 7.0) despite **both** of the following:

(a) Dietary intervention
(b) Optimized insulin therapy at maximum tolerated doses

-OR-

(2) Persistent hypertriglyceridemia (TG > 250) despite **both** of the following:

(a) Dietary intervention
(b) Optimized therapy with at least **two** triglyceride-lowering agents from different classes (e.g., fibrates, statins) at maximum tolerated doses

Authorization will be issued for 12 months

B. Reauthorization

1. **Myalept** will be approved based on **all** 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

-AND-

c. Prescribed by an endocrinologist

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. References:

1. Myalept [package insert]. Amryt Pharmaceuticals, Inc. Cambridge, MA. February 2022.
2. Handelsman Y, Oral EA, Bloomgarden ZT, et al. The clinical approach to the detection of lipodystrophy – an AACE consensus statement. Endocrine Practice 2013;19(1):107-116.

3. Garg A. Acquired and inherited lipodystrophies. N Engl J Med 2004;350:1220-1234.
4. Garg A. Lipodystrophies: genetic and acquired body fat disorders. J Clin Endocrinol and Metab 2011;96(11):3313-3325.
5. Chan JL, Lutz K, Cochran E, et al. Clinical effects of long-term metreleptin treatment in patients with lipodystrophy. Endocr Pract. 2011;17(6):922-932.

Program	Prior Authorization/Medical Necessity – Myalept™ (metreleptin)
Change Control	
5/2014	New program.
7/2014	Added criterion requiring that patient continues to have insulin resistance and/or hyperglycemia or elevated triglyceride levels despite optimized standard pharmacotherapy and dietary interventions.
8/2014	Added reference values for HgbA1C and triglycerides. Clarified that optimized therapy refers to maximum tolerated doses. Modified to require insulin therapy for diabetes mellitus or insulin resistance and to require two lipid-lowering agents from different classes for hypertriglyceridemia.
7/2015	Revisions to background. Additional documentation language around the criteria. Updated references.
6/2016	Annual Review. Added prescriber requirement for reauthorization. Updated background and references.
5/2017	Annual review. Removed requirement for submission of medical records (A.1.a). Updated background.
5/2018	Annual review. 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. No changes to coverage criteria.
5/2021	Annual review. No changes to coverage criteria.
5/2022	Annual review. Revised documentation language in initial authorization coverage criteria. Added state mandate language to coverage criteria. Updated references.
6/2023	Annual review with no changes to coverage criteria.
6/2024	Annual review with no changes to coverage criteria. Updated background.