UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Myalept

Program	Prior Authorization
Medication	Myalept (metreleptin for injection)
Markets in Scope	Arizona, Hawaii, Nevada, Florida-CHIP, Maryland, New Jersey, New York, New York EPP, Ohio, Pennsylvania, Rhode Island, California
Issue Date	5/2016
Pharmacy and Therapeutics Approval Date	5/2019
Effective Date	7/2019

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.[1]

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

Myalept has a black boxed warning for risk of anti-metreleptin antibodies with neutralizing activity and risk of lymphoma. Please see full prescribing information for additional details.

2. Coverage Criteria:

A. <u>Initial Authorization</u>

1. **Myalept** will be approved based on **<u>all</u>** of the following criteria:

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

   -AND-

   b. Used as an adjunct to diet modification

   -AND-

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c. Prescribed by an endocrinologist

-AND-

d. Documentation demonstrates that 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 mg/dL) 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. Used as an adjunct to diet modification

-AND-

c. Prescribed by an endocrinologist

Authorization will be issued for 12 months.

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3. References

1. Myalept [package insert]. Aegerion Pharmaceuticals, Inc. Cambridge, MA. September 2015.
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 –Myalept (metreleptin)
Change Control	
Date	Change
5/2016	Updated policy to new template
6/2016	Annual Review. Added prescriber requirement for reauthorization. Updated background and references.
5/2017	Removed requirement for submission of medical records. Updated background.
5/2018	Annual review. No changes to criteria.
5/2019	Annual review. No changes to criteria.

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