Premier Health Plan

# POLICY AND PROCEDURE



**POLICY TITLE:** ***Myalept (metreleptin)***
**DEPARTMENT:** **Clinical Pharmacy Services- Utilization Management**
**ORIGINAL DATE:** ***April 2014 (as adopted from UPMC Health Plan)***

**Last P & T Committee Approval Date:** *February 2018*

**Product Applicability:** *mark all applicable products below:*

| | |
|---|---|
| **COMMERCIAL** | [ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x ] All |
| **OTHER** | [ x ] Self-funded/ASO |

## PURPOSE

The purpose of this policy is to define the prior authorization process for Myalept (metreleptin).

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.

Limitations of use:

- The safety and effectiveness of metreleptin for the treatment of complications of partial lipodystrophy have not been established.
- The safety and effectiveness of metreleptin for the treatment of liver disease, including nonalcoholic steatohepatitis (NASH), have not been established.
- Metreleptin is not indicated for use in patients with HIV-related lipodystrophy

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## DEFINITIONS

**Leptin** – a hormone secreted by adipocytes in quantities associated with fat cell mass. Leptin exerts its effects via binding to leptin receptors located in the central nervous system and several peripheral organs. Through interactions with these receptors, leptin plays a role in regulation of energy homeostasis and neuroendocrine function.

**Lipodystrophy** – an acquired or congenital disorder characterized by selective loss of subcutaneous adipose tissue from the face, arms and legs. Affected patients are predisposed to insulin resistance, dyslipidemia and hepatic steatosis.

## POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, <Brand (generic)>, is subject to the prior authorization process.

## PROCEDURE

**Initial Authorization Criteria:**

*Must meet all of the criteria listed below:*

- Must be prescribed by an endocrinologist
- Must have a diagnosis of congenital or acquired generalized lipodystrophy. Chart documentation of a clinical work-up to rule out other diagnoses and clinical rationale for the diagnosis and exclusion of other diagnoses must be provided.
- Must not have HIV-related lipodystrophy
- Must have a serum leptin level of < 4 ng/mL in females and < 3 ng/mL in males. Documentation of laboratory result must be submitted.
- Must have severe insulin resistance resulting in diabetes mellitus and/or severe hypertriglyceridemia:
    - Must have severe insulin resistance resulting in diabetes mellitus not adequately controlled with other therapies
    - Must have a hemoglobin A1c ≥ 7% or fasting plasma glucose ≥ 126 mg/dL

  - Must have an adequate trial and failure of physician-directed exercise and diet modifications as directed by a dietician/nutritionist. Chart documentation is required.
  - Must have an adequate trial of diabetic pharmacotherapy, such as metformin and insulin. Chart documentation showing that the member was not able to achieve adequate blood glucose control with optimized medication regimen is required.
- Must have severe hypertriglyceridemia not adequately controlled with other therapies
  - Must have a triglyceride level ≥ 500 mg/dL
  - Must have an adequate trial and failure of physician-directed exercise and diet modifications as directed by a dietician/nutritionist. Chart documentation is required.
  - Must have an adequate trial of lipid-lowering pharmacotherapy, such as fibrates, fish oil and statins. Chart documentation showing that the member was not able to achieve adequate triglyceride control with optimized medication regimen is required.

**Reauthorization Criteria:**

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation from the prescriber showing that the member has benefited from metreleptin therapy, as evidenced by having decreased hemoglobin A1c, fasting plasma glucose, and/or triglyceride levels from baseline.

**Limitations:**

| **Length of Authorization (if above criteria met)** | |
|---|---|
| Initial Authorization | Up to 6 months |
| Reauthorization | Up to 1 year |
| **Quantity Level Limit** | |
| Myalept | 30 vials per 30 days |

If the established criteria are not met, the request is referred to a Medical Director for review.

## REFERENCES

1. Myalept [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Company: February 2014
2. 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
3. Handelsman Y, Oral AO, Bloomgarden ZT, et al. The clinical approach to the detection of lipodystrophy – an AACE Consensus Statement. *Endocr Pract* 2013;19(1):107-116
4. Garg A. Lipodystrophies: genetic and acquired body fat disorders. *J Clin Endocrinol Metab* 2011;96:3313-3325
5. Garg A. Acquired and inherited lipodystrophies. *N Engl J Med* 2004;350:1220-3
6. U.S. Food and Drug Administration Center for Drug Evaluation and Research, (2013). *The Endocrinologic and Metabolic Drugs Advisory Committee Meeting: Myalept (metreleptin for injection.* Briefing Document. Washington, DC.
7. Moon H, Dalamaga M, Kim S, et al. Leptin's role in lipodystrphic and nonlipodystrophic insulin-resistant and diabetic individuals. *Endocrine Reviews* 2013;34:377-412
8. Oral AO, Simha V, Ruiz E, et al. Leptin-replacement therapy for lipodystrophy. *N Engl J Med* 2002;346:570-8

## RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

## REVIEW HISTORY

| DESCRIPTION OF REVIEW / REVISION | DATE APPROVED |
|---|---|
| *Annual review* | *02/17, 02/18* |
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