

## Pharmacy Policy Bulletin

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**Title:** Metreleptin (Myalept®)

**Policy #:** Rx.01.157

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***Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, gender or quantity restrictions. Individual member benefits must be verified.***

***This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.***

***Members are advised to use participating pharmacies in order to receive the highest level of benefits.***

### ▶ Intent:

The intent of this policy is to communicate the medical necessity criteria for metreleptin (Myalept®) as provided under the member's pharmacy benefit.

### ▶ Description:

**Metreleptin** is a recombinant human leptin analog that binds to and activates the human leptin receptor (ObR), which belongs to the class I cytokine family of receptors that signals through the JAK/STAT transduction pathway. Activation of the leptin receptor by metreleptin mimics native leptin, which is responsible for signaling the CNS with the status of energy stores in the body.

**Metreleptin (Myalept®)** is indicated as replacement therapy to treat the complications of leptin deficiency, in addition to diet, in patients with congenital or acquired generalized lipodystrophy.

### ▶ Policy:

Metreleptin (Myalept®) is approved when BOTH of the following inclusion criteria are met:

1. Diagnosis of congenital or acquired generalized lipodystrophy (excluding other forms of lipodystrophy)
2. Prescribed as adjunct to diet as replacement therapy

### ▶ Black Box Warning:

Anti-metreleptin antibodies with neutralizing activity have been identified in patients treated with metreleptin. The consequences of these neutralizing antibodies are not well characterized but could include inhibition of endogenous leptin action and/or loss of metreleptin efficacy. Severe infection and/or worsening metabolic control have been reported. Test for anti-metreleptin antibodies with neutralizing activity in patients who develop severe infections or show signs suspicious for loss of

metreleptin efficacy during treatment.

T-cell lymphoma has been reported in patients with acquired generalized lipodystrophy, both treated and not treated with metreleptin. Carefully consider the benefits and risks of treatment with metreleptin in patients with significant hematologic abnormalities and/or acquired generalized lipodystrophy.

Because of these risks associated with the development of anti-metreleptin antibodies that neutralize endogenous leptin and/or metreleptin and the risk for lymphoma, metreleptin is available only through a restricted risk evaluation and mitigation strategy (REMS) program.

**Guidelines:**

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

**BENEFIT APPLICATION**


Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

**References:**

Metreleptin. Micromedex Solutions [database on the Internet]. Available at: [www.micromedexsolutions.com](http://www.micromedexsolutions.com). Accessed November 7, 2016.

Myalept (metreleptin) [prescribing information]. Cambridge, MA. Aegerion Pharmaceuticas, Inc. September 2015. Available at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=c986f93b-855d-4ef0-b620-5d41a0513e48&type=display>. Accessed November 7, 2016.

**Applicable Drugs:**

 Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Myalept	metreleptin

**Cross References:**

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<b>Policy Version Number:</b>	3.00
<b>P&amp;T Approval Date:</b>	October 13, 2016
<b>Policy Effective Date:</b>	December 01, 2016
<b>Next Required Review Date:</b>	October 13, 2017

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