



Commercial/Healthcare Exchange PA Criteria

Effective: April 30th, 2020

Prior Authorization: Myalept (metreleptin)

Products Affected: Myalept (metreleptin) subcutaneous solution

Medication Description: 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. 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.

Covered Uses: An adjunct to diet as replacement therapy to treat the complications of leptin deficiency in patients with congenital or acquired generalized lipodystrophy.

Exclusion Criteria:

1. Patients with general obesity not associated with congenital leptin deficiency
2. Treatment of complications of partial lipodystrophy
3. Treatment of liver disease, including nonalcoholic steatohepatitis (NASH)
4. Patients with HIV-related lipodystrophy
5. Patients with metabolic disease, including diabetes mellitus and hypertriglyceridemia, without concurrent evidence of congenital or acquired generalized lipodystrophy

Required Medical Information:

1. Diagnosis
2. Medical History

Age Restrictions: N/A

Prescriber Restrictions: Prescribed by, or in consultation with, an endocrinologist.

Coverage Duration: 12 months

Other Criteria:

- A. Patient has a diagnosis of congenital or acquired generalized lipodystrophy associated with leptin deficiency; **AND**
- B. Patient will be using Myalept as an adjunct to replacement therapy; **AND**
- C. Patient has at least one complication of lipodystrophy:
 - a. Diabetes mellitus
 - b. Insulin resistance
 - c. Persistent hypertriglyceridemia; **AND**
- D. Patient has had a trial and failure with conventional treatments for metabolic disturbances (e.g., lifestyle modification, antidiabetic agents, statins).

Last Rev. April 2020



Confidential Information

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References:

1. Myalept [package insert]. Aegerion Pharmaceuticals, Inc. Cambridge, MA. September 2015.
2. Facts & Comparisons online. Accessed April 30,2020
3. Metreleptin. Micromedex Solutions [database on the Internet]. Available at:www.micromedexsolutions.com. Accessed April 30, 2020

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	4/30/2020

Last Rev. April 2020



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