Myalept (metreleptin)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Myalept (metreleptin) subcutaneous injection	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for Myalept (metreleptin) may be approved when the following criteria are met:

I. Documentation is provided that individual has a diagnosis of congenital or acquired generalized lipodystrophy;

AND

II. Individual is using as an adjunct to diet as replacement therapy for complications associated with leptin deficiency (including but not limited to type 2 diabetes mellitus, hypertriglyceridemia, and hyperinsulinemia).

Continuation requests for Myalept may be approved if the following criterion is met:

I. Documentation is provided that there is clinically significant improvement or stabilization in clinical signs and symptoms of the disease (such as reduction in hemoglobin A1c, reduction in fasting glucose, or reduction in fasting triglycerides).

Requests for Myalept (metreleptin) may **not** be approved for any of the following:

I. Individual is using for the treatment of complications of partial lipodystrophy; **OR**
II. Individual is using for the treatment of liver disease, including nonalcoholic steatohepatitis (NASH); **OR**
III. Individual is using for the treatment of HIV-related lipodystrophy; **OR**
IV. Individual is using for treatment in patients with general obesity or metabolic disease, including diabetes mellitus and hypertriglyceridemia, without concurrent evidence of congenital or acquired generalized lipodystrophy; **OR**
V. Individual is using for cosmetic reasons in the absence of metabolic complications associated with leptin deficiency; **OR**
VI. When the above criteria are not met and for all other indications.

Note:
Myalept (metreleptin) has black box warnings for the development of anti-metreleptin antibodies with neutralizing activity and risk of lymphoma. Anti-metreleptin antibodies with neutralizing activity can lead to severe infection and/or worsening metabolic control. Individuals who develop severe infections or show signs suspicious for loss of Myalept efficacy should be tested for anti-metreleptin antibodies with neutralizing activity. T-cell lymphoma has been reported in patients with acquired generalized lipodystrophy, both treated and not treated with Myalept. The FDA has required the manufacturer to develop a comprehensive risk management program that includes the enrollment of prescribers in the Myalept REMS Program. Additional information and forms for individuals, prescribers, and pharmacists may be found on the manufacturer's website: http://www.myaleptrems.com.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: November 30, 2023.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.