

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

\*FHK- Florida Healthy Kids

## Myalept (metreleptin)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Myalept (metreleptin) subcutaneous injection

### APPROVAL CRITERIA

Requests for Myalept (metreleptin) may be approved if the following criteria are met:

- I. 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 (such as but not limited to type 2 diabetes mellitus, hypertriglyceridemia, and hyperinsulinemia)

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

**Note:** Myalept (metreleptin) has a black box warning for the development of anti-metreleptin antibodies with neutralizing activity which can lead to severe infection and/or worsening metabolic control. 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

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New Program Date 02/15/2018

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

CRX-ALL-0369-19

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enrollment of physicians 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>.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

**Key References:**

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: September 7, 2018.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.

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