



**STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES**



**Office of Pharmacy Service
Prior Authorization Criteria**

**MYALEPT[®] (metreleptin)
[Prior Authorization Request Form](#)**

Myalept[®] 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.

Criteria for Approval

- 1) Myalept will ONLY be authorized for FDA-approved indications; **AND**
- 2) Patient must be diagnosed with a leptin deficiency (documentation must be provided); **AND**
- 3) Patient must be diagnosed with congenital or acquired generalized lipodystrophy; **AND**
- 4) Members with diabetes mellitus or insulin resistance must have tried and failed two previous antidiabetic therapies; **AND**
- 5) Members with hypertriglyceridemia must have tried and failed therapy with a fibrate (with or without a statin) or be unable to take fibrates and must be receiving a low-carbohydrate diet.

Criteria for Denial

- 1) Prior authorization will be denied for patients with a metabolic disease (e.g. diabetes mellitus, hypertriglyceridemia, insulin resistance) in the absence of a concurrent diagnosis of congenital or acquired generalized lipodystrophy; **OR**
- 2) Diagnosis of HIV-related lipodystrophy; **OR**
- 3) Evidence of liver-disease; **OR**
- 4) Presence of anti-metroleptin antibodies

Criteria for Continuation of Coverage

- 1) Claims history must indicate reasonable compliance; **AND**
- 2) Patient responding to treatment (documentation is required); **AND**
- 3) Patient tolerating treatment; **AND**
- 4) Patient does not have anti-metreleptin antibodies; **AND**
- 1) Patient has a clinically significant improvement in HbA1c, triglyceride levels, and/or fasting glucose levels.

References

- 1) Myalept package insert revised 8/2015
- 2) Lexi-Comp Clinical Application 09/18/2015