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-metrileptin 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

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Approved by the DUR Board 09-23-2015