ALASKA MEDICAID
Prior Authorization Criteria

Myalept™ (metreleptin)

FDA INDICATIONS AND USAGE[1]

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.

APPROVAL CRITERIA[1,2,3]

1. Patient is 18 years of age or older **AND**;
2. Prescribed by or in consultation with an endocrinologist or cardiologist **AND**;
3. Patient has a diagnosis of either congenital generalized lipodystrophy (CGL) or acquired generalized lipodystrophy (AGL) **AND**;
4. The patient also has at least one of the following additional diagnosis:
    a. diabetes mellitus **OR**;
    b. hypertriglyceridemia (≥200 mg/dL) **OR**;
    c. high fasting insulin (≥30µU/mL) **AND**;
5. Baseline labs for HbA1C, triglycerides, and fasting insulin have been obtained prior to beginning therapy **AND**;
6. Is being used as an adjunct to diet modification **AND**;
7. Physician must be enrolled in the Myalept Risk Evaluation and Mitigation Strategy (REMS) Program.

DENIAL CRITERIA [1,3]

1. Failure to meet approval criteria **OR**;
2. Patient has HIV-related lipodystrophy **OR**;
3. Patient has partial lipodystrophy **OR**;
4. Patient has liver disease, including non-alcoholic steatohepatitis (NASH) **OR**;
5. Patient has general obesity not associated with congenital leptin deficiency.

CAUTIONS[1]

- Monitor for anti-metreleptin antibodies with neutralizing activity
- A dose adjustment, including possible large reductions, of insulin or insulin secretagogue may be necessary. Closely monitor blood glucose in patients on concomitant insulin or insulin secretagogue therapy.
- Autoimmune disorder progression has been observed in patients treated with Myalept™. Carefully consider benefits and risks of Myalept™ treatment in patients with autoimmune disease.
- Carefully consider benefits and risks of treatment with Myalept™ in patients with significant hematologic abnormalities and/or acquired generalized lipodystrophy.

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to 6 months if the prescriber documents the patient has had a positive clinical response and continued as an adjunct to dietary modifications.

QUANTITY LIMIT

- Maximum dose 10mg/day (up to 1 vial per day)

REFERENCES / FOOTNOTES:

1. Myalept™ [package insert]. Aegerion Pharmaceuticals, Inc. Cambridge, MA. September 2021.
2. Handelsman Y, Oral EA, Bloomgarden Z. The Clinical Approach To The Detection of Lipodystrophy – An AACE Consensus Statement, Endocr Pract. 2013;19(No.1):107-116.
3. Chan JL, Lutz K, Cochran E, et al. Clinical effects of long-term metreleptin treatment in patients with lipodystrophy. Endocr Pract. 2011;17(6):922-932.