

# **Myalept (metreleptin)**

## **Coverage Criteria:**

Reserved for patients:

- 1. With complications of leptin deficiency in patients with congenital or acquired generalized lipodystropy, in combination with diet changes;
- 2. When prescribed by a provider specializing in genetics and metabolism;
- 3. The patient and/or guardian has attested that they will adhere to the treatment plan; and
- 4. When prescribed according to the FDA-approved starting regimen of 0.06 mg/kg daily for patients 40 kg or less, 2.5 mg/day for males over 40kg and 5 mg/day for females over 40 kg and up to a maximum of 10mg/day for all patients.

## **Required Medical Information:**

Current body weight is required.

### **Coverage Duration:**

Initial authorizations will be for 6 months.

Reauthorizations will be provided with documented reductions in fasting glucose, glycosylated hemoglobin, or triglycerides and continued adherence to the prescribed diet.

### **Renewal Criteria:**

Annual reauthorizations will require medical chart documentation that the patient has been seen within the past 12 months, continued adherence to dietary restrictions and improved markers of disease. These include but may not be limited to reductions in fasting glucose, glycosylated hemoglobin, or triglycerides.