Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	June 24, 2020

MYALEPT® (metreleptin)

LENGTH OF AUTHORIZATION: 12 MONTHS

REVIEW CRITERIA:

- Patient has leptin deficiency.
- Patient has a diagnosis of congenital or acquired generalized lipodystrophy.
- Adjunct to diet as replacement therapy for complications associated with leptin deficiency (e.g. type 2 diabetes mellitus, hypertriglyceridemia, or hyperinsulinemia).
- Not indicated for the treatment of complications of partial lipodystrophy.
- Not indicated for the treatment of liver disease including nonalcoholic steatohepatitis.
- Not indicated for the use of HIV related lipodystrophy.
- Not indicated for the use in patients with metabolic disease, without concurrent evidence of generalized lipodystrophy.

CONTINUATION OF THERAPY

- Patient met initial review requirements.
- Clinical response to therapy submitted (supporting documentation required).
- Dosage and administration does not exceed FDA approved maximum for the patient's indication.
- Supporting documentation required if dose requested exceeds FDA approved maximum.

DOSING AND ADMINISTRATION:

The recommended subcutaneous daily dosages are:

- Body weight 40 kg or less: starting dose 0.06 mg/kg/day, increase or decrease by 0.02 mg/kg to a maximum daily dose of 0.13 mg/kg.
- Males greater than 40 kg body weight: starting dose 2.5 mg/day, increase or decrease by 1.25 mg to 2.5 mg/day to a maximum dose of 10 mg/day.
- Females greater than 40 kg body weight: starting dose 5 mg/day, increase or decrease by 1.25 mg to 2.5 mg/day to a maximum dose of 10 mg/day.