Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	June 24, 2020 April 12, 2024

MYALEPT® (metreleptin)

LENGTH OF AUTHORIZATION: 12 MONTHS

REVIEW CRITERIA:

- Patient must have a documented diagnosis of leptin deficiency; supporting clinical labs are required.
- 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:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as: 11.3mg metreleptin per vial.