Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	April 30, 2024

Imcivree® (setmelanotide)

LENGTH OF AUTHORIZATION:

Proopiomelanocortin (POMC), Proprotein convertase subtilisin/kexin type 1 (PCSK 1), or Leptin receptor (LEPR) deficiency – 16 weeks

Bardet-Biedl syndrome (BBS) – 1 year

REVIEW CRITERIA:

- Patient must be ≥ 6 years of age; **AND**
- Medication is prescribed by or in consultation with an endocrinologist or expert in rare genetic disorders of obesity; **AND**

Proopiomelanocortin (POMC), Proprotein convertase subtilisin/kexin type 1 (PCSK 1), or Leptin receptor (LEPR) deficiency

- Patient must have a diagnosis of monogenic or syndromic obesity as defined by:
  - BMI ≥ 30 kg/m^2 for adults; **OR**
  - Bodyweight ≥ 95th percentile for age on growth chart assessment in pediatric patients (< 18 years of age); **AND**
- Documentation obesity is due to POMC, PCSK 1, or LEPR deficiency, confirmed by genetic testing; **AND**
- Genetic testing demonstrates that variants in POMC, PCSK1, or LEPR genes are pathogenic, likely pathogenic, or of uncertain significance.

Bardet-Biedl syndrome (BBS)

- Patient must have a diagnosis of monogenic or syndromic obesity as defined by:
  - BMI ≥ 30 kg/m^2 for adults; **OR**
  - Bodyweight ≥ 97th percentile for age on growth chart assessment in pediatric patients (< 18 years of age); **AND**
- Documentation obesity is due to BBS

CONTINUATION OF THERAPY

- Patient met initial review criteria; **AND**
- Documentation of positive clinical response (e.g., weight loss of 5% of baseline body weight or 5% of baseline BMI); **AND**
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as 10 mg/mL solution for injection in a 1 mL multiple-dose vial.