

## Imcivree (setmelanotide, SC)

### Diagnoses Considered for Coverage:

- Chronic weight management due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency
- Chronic weight management due to Bardet-Biedl Syndrome

### Coverage Criteria:

#### 1. For chronic weight management due to POMC, PCSK1, or LEPR deficiency:

##### Initial Authorization

- Patient is 6 years of age or older, and
- Dose does not exceed 3 mg per day, and
- Patient's obesity is due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency, **and**
- Deficiency is confirmed by genetic testing demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS), **and**
- Patient has obesity defined as one of the following:
  - Adult patient has body mass index (BMI) of  $\geq 30$  kg/m<sup>2</sup>,
  - OR**
  - Pediatric patient's weight is  $\geq 95$ th percentile using growth chart assessments.

**Coverage Duration:** 16 weeks

##### Reauthorization

- Patient demonstrates at least 5% weight loss from baseline or 5% of baseline BMI for patients with continued growth potential, **and**
- Dose does not exceed 3 mg per day.

**Coverage Duration:** one year

#### 2. For chronic weight management due to Bardet-Biedl Syndrome:

##### Initial Authorization

- Patient is 6 years of age or older, and
- Dose does not exceed 3 mg per day, and
- Provider attestation of a diagnosis of Bardet-Biedl Syndrome, and
- Patient has obesity defined as one of the following:
  - Adult patient has body mass index (BMI) of  $\geq 30$  kg/m<sup>2</sup>,
  - OR**
  - Pediatric patient's weight is  $\geq 97$ th percentile using growth chart assessments.

**Coverage Duration:** 6 months

##### Reauthorization

- Patient demonstrates at least 5% weight loss from baseline or 5% of baseline BMI for patients with continued growth potential, **and**
- Dose does not exceed 3 mg per day.

**Coverage Duration:** one year

**Coverage Duration:** *See coverage criteria*

Effective Date: 11/29/2023GF