**Prior Authorization Criteria**

**ImcivreeTM(setmelanotide) PA CRITERIA:**

IMCIVREE™ binds and activates melanocortin 4 (MC4) receptors, reestablishing the impaired MC4 receptor pathway indicated for chronic weight management in adult and pediatric patients 6 years of age and older with obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency confirmed by genetic testing demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance(VUS) or Bardot-Biedl syndrome (BBS).

**Prescriber is or is in consultation with an endocrinologist, a geneticist, or a physician who specializes in metabolic disorders.**

**Initial Authorization:**

1. **Approval duration: 16 weeks for POMC, PCSK1 or LEPR deficiency**
2. **Approval duration: 52 weeks for BBS**

☐ Yes ☐ No Patient must be 6 years of age or older;

***AND***

☐ Yes ☐ No Patient has a diagnosis of obesity, defined as :

* ≥ 95th percentile using growth chart assessments for participants with continued growth potential

**OR**

* BMI of ≥ 30 kg/m2

***AND***

☐ Yes ☐ No Documentation that obesity is due to diagnosis of Bardet-Biedl Syndrome (BBS) confirmed by presence of four primary features associated with BBS **OR** three primary features **plus** two secondary features:

* Primary features associated with BBS:
  + Rod-cone dystrophy
  + Polydactyly
  + Obesity
  + Learning disabilities
  + Hypogonadism in males
  + Renal abnormalities
* Secondary features associated with BBS:
  + Speech disorder/delay
  + Strabismus/cataracts/astigmatism
  + Brachydactyly/syndactyly
  + Developmental delay
  + Polyuria/polydipsia (nephrogenic diabetes insipidus)
  + Ataxia/poor coordination/imbalance
  + Mild spasticity (especially lower limbs)
  + Diabetes mellitus
  + Dental crowding/hypodontia/small roots/high arched palate
  + Left ventricular hypertrophy/congenital heart disease
  + Hepatic fibrosis

**OR**

☐ Yes ☐ No Documentation that obesity is due to a homozygous or presumed compound heterozygous variant in at least one of the following genes, confirmed by genetic testing:

* Proopiomelanocortin (POMC)
* Proprotein convertase subtilisin/kexin type 1 (PCSK1)
* Leptin receptor (LEPR)

**AND**

☐ Yes ☐ No Documentation of genetic testing demonstrating that the variants in POMC, PCSK1, or LEPR genes are interpreted as pathogenic or likely pathogenic.

**Reauthorization criteria: Approval duration: 52 weeks**

☐ Yes ☐ No Continues to meet criteria defined for initial approval;

***AND***

☐ Yes ☐ No Patient is responding positively to therapy as evidenced by one of the following (a, b, or c):

1. Initial re-authorization for POMC, PCSK1, or LEPR deficiency: After 16 weeks of treatment, reduction of at least 5% of baseline body weight or 5 % of baseline BMI;
2. Initial re-authorization for BBS: After 1 year of treatment, reduction of at least 5% of baseline body weight or 5% of baseline BMI;
3. Subsequent re-authorizations for all indications: Maintenance of ≥ 5% reduction in weight or BMI compared with baseline

***AND***

☐ Yes ☐ No If request is for dose increase, new dose does not exceed 3mg per day.

**NOTE:** Imcivree (setmelanotide) is intended to be a lifelong therapy. Patients will eventually reach a weight-loss plateau, but Imcivree (setmelanotide) will still be required in those cases to maintain the weight loss.

***Denial Criteria (Any of the Following):***

* Therapy will be denied if all approval criteria are not met
* Documented history of moderate to severe renal impairment or end stage renal disease
* Prior gastric bypass surgery resulting in > 10% weight loss that was maintained
* Documentation of genetic testing demonstrating that the variants in POMC, PCSK1, or LEPR genes are interpreted as benign or likely benign
* Participant demonstrates non-compliance to therapy regimen

**Dosage and Administration**

|  |  |  |
| --- | --- | --- |
| **Indication** | **Dosing Regimen** | **Maximum Dose** |
| Obesity due to POMC, PCSK1, or LEPR deficiency or due to BBS | ≥ 12 years and older: 2 mg SC once daily for 2 weeks; if tolerated, titrate up to 3 mg SC once daily  Age 6 to <12 years: 1 mg SC once daily for 2 weeks; if tolerated, titrate up to 3 mg SC once daily | 3 mg/day |

**Product Availability**

Vial: 10 mg/mL (1 mL multi-dose)