Prior Authorization Criteria

MISSISSIPPI DIVISION OF MEDICAID

Imcivree™(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:

a) **Approval duration: 16 weeks for POMC, PCSK1 or LEPR deficiency**
b) **Approval duration: 52 weeks for BBS**

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

AND

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

☐ 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/m^2

AND

☐ Yes ☐ No Documentation obesity is due to POMC, PCSK 1, or LEPR deficiency, confirmed by genetic testing;

AND

☐ Yes ☐ No Genetic testing demonstrates that variants in POMC, PCSK1, or LEPR genes are pathogenic, likely pathogenic, or of uncertain significance (VUS)

Bardet-Biedl syndrome (BBS)

☐ Yes ☐ No 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

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):

a) 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;
b) Initial re-authorization for BBS: After 1 year of treatment, reduction of at least 5% of baseline body weight or 5% of baseline BMI;
c) 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
- 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)