Prior Authorization Review Panel

Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 02/01/2023**
Policy Number: PA.CP.PHAR.491	**Effective Date: 01/2018** **Revision Date: 01/2023**
Policy Name: Setmelanotide (Imcivree)	

Type of Submission – Check all that apply:

- ✓ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL** - *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

1Q 2023 annual review: no significant changes; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:**

Clinical Policy: Setmelanotide (Imcivree)

Reference Number: PA.CP.PHAR.491
Effective Date: 11/2022
Last Review Date: 01/2022

Coding Implications
Revision Log

Description
Setmelanotide (Imcivree™) is melanocortin-4 receptor pathway activator.

FDA Approved Indication(s)
Imcivree is indicated for chronic weight management in adult and pediatric patients 6 years of age and older with monogenic or syndrome 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)
- Bardet-Biedl syndrome (BBS)

Limitation(s) of use: Imcivree is not indicated for the treatment of patients with the following conditions as Imcivree would not be expected to be effective:

- Obesity due to suspected POMC, PCSK1, or LEPR deficiency with POMC, PCSK1, or LEPR variants classified as benign or likely benign
- Other types of obesity not related to POMC, PCSK1 or LEPR deficiency, or BBS, including obesity associated with other genetic syndromes and general (polygenic) obesity

Policy/Criteria
It is the policy of PA Health & Wellness that Imcivree is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Genetic Obesity Disorders (must meet all)**:**

1. Diagnosis of obesity due to POMC deficiency, PCSK1 deficiency, LEPR deficiency, or BBS (*see Appendix D*);
2. Prescribed by or in consultation with an endocrinologist or expert in rare genetic disorders of obesity;
3. Member meets one of the following (a or b):
   a. Age ≥ 6 and < 18 years with one of the following weight percentiles for age on growth chart assessment (*see Appendix D*) (i or ii):
      i. POMC, PCSK1, or LEPR deficiency: ≥ 95th percentile;
      ii. BBS:≥ 97th percentile;
   b. Age ≥ 18 years of age and body mass index (BMI) ≥ 30 kg/m^2;
4. One of the following (a or b):
   a. Genetic testing confirms that variants in the following genes are interpreted as pathogenic, likely pathogenic, or of uncertain significance (i, ii, or iii):
      i. POMC;
      ii. PCSK1;
      iii. LEPR;
   b. Diagnosis of BBS is confirmed clinically per Beales criteria or genetic testing

(*see Appendix D*);

5. Documentation of baseline weight (in past 60 days) in kilograms;
6. Documentation of creatinine clearance ≥ 15 mL/min/1.73 m^2;
7. If member has had prior gastric bypass surgery, member meets one of the following (a or b):
   a. Member has not had > 10% weight loss from baseline pre-operative weight;
   b. Member has regained weight after an initial response to surgery;
8. Member has documentation of counseling regarding lifestyle changes and behavioral modification (e.g., healthy diet and increased physical activity);
9. Dose does not exceed the following (a and b):
   a. First 2 weeks (i or ii):
      i. Age ≥ 6 and < 12 years: 1 mg per day;
      ii. Age ≥ 12 years: 2 mg per day;
   b. Maintenance: 3 mg per day.

Approval duration:
POMC, PCSK1, or LEPR deficiency – 4 months
BBS – 12 months

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

A. Genetic Obesity Disorders (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member 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 12-16 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;
3. If request is for a dose increase, new dose does not exceed 3 mg per day.

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies; or
   Approval duration: 6 months;
   or
2. Refer to PA.CP.PMN.53

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

BBS: Bardet-Biedl syndrome
BMI: body mass index
FDA: Food and Drug Administration
LEPR: leptin receptor
PCSK1: proprotein convertase subtilisin/kexin type 1
POMC: pro-opiomelanocortin

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

None reported

Appendix D: General Information

- Body mass index calculator: https://globalrph.com/medcalcs/body-mass-index-bmi/
- CDC Clinical Growth Charts from 3rd to 97th percentiles:
  - 2 to 20 years: Boys Stature-for-age and Weight-for-age percentiles https://www.cdc.gov/growthcharts/data/set2clinical/cj41c071.pdf
  - 2 to 20 years: Girls Stature-for-age and Weight-for-age percentiles https://www.cdc.gov/growthcharts/data/set2clinical/cj41c072.pdf
- A clinical diagnosis of BBS is confirmed using Beales criteria. There must be presence of at least 4 primary features, OR 3 primary and 2 secondary features:
  - Primary features: rod-cone dystrophy, polydactyly, obesity, learning disabilities, hypogonadism in males, renal anomalies
  - Secondary features: 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

IV. 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	3mg/day

V. Product Availability

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

VI. References

1. Imcivree Prescribing Information. Boston, MA: Rhythm Pharmaceuticals, Inc.; June 2022. Available at:

https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/213793s001lbl.pdf. Accessed November 11, 2022.
2. Styne DM, Arslanian SA, Conner EL, et al. Pediatric Obesity: Assessment, Treatment, and Prevention: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2017; 102: 709–757.
3. Clement K, van den Akker E, Argente J, et al. Efficacy and safety of setmelanotide, an MC4R agonist, in individuals with severe obesity due to LEPR or POMN deficiency: single-arm, open-label, multicenter, phase 3 trials. Lancet Diabetes Endocrinol. 2020; 8: 960-70. DOI: 10.1016/S2213-8587(20)30364-8.
4. Haws RM, Gordon G, Han JC, et al. The efficacy and safety of setmelanotide in individuals with Bardet-Biedl syndrome or Alström syndrome: Phase 3 trial design. Contemporary Clinical Trials Communications. 2021; 22: 100780.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3490; C9399	Injection, setmelanotide, 1 mg

Reviews, Revisions, and Approvals	Date	Approval Date
Policy created	10/2022	
1Q 2023 annual review: no significant changes; references reviewed and updated.	01/2023	