setmelanotide (Imcivree®)	**Place of Service** **Self-Administration** *(May be covered under the pharmacy benefit)* **HCPCS**: **J3490** **NDC:** 72829-0010-01: 10 mg/mL (multiple-dose vial)

Condition listed in policy (*see criteria for details*)

- Chronic weight management due to POMC, PCSK1, or LEPR deficiency
- Chronic weight management in patients with obesity due to Bardet-Biedl Syndrome

AHFS therapeutic class: Hyperpigmentation agents, systemic

Mechanism of action: Melanocortin 4 (MC4) receptor agonist

(1) Special Instructions and pertinent Information

This drug is managed under the outpatient Pharmacy Benefit for self-administration. Please contact the member's Pharmacy Benefit for information on how to obtain this drug.

To submit a request to the Medical Benefit, please submit clinical information for prior authorization review and include medical rationale why the patient cannot self-administer this drug in the home.

For plans with self-injectables under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for setmelanotide (Imcivree®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Chronic weight management in patients with obesity due to POMC, PCSK1, or LEPR deficiency

1. Patient is 6 years of age or older, **AND**
2. Being used for chronic weight management in patients with obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency, **AND**
3. Patient has obesity defined as one of the following:
   a. Adult patient has body mass index (BMI) ≥30 kg/m^2, or
   b. Pediatric patient's weight is ≥95th percentile using growth chart assessments,

   AND
4. 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)

Covered Dose
Up to 3 mg (0.3 mL) SC once daily

Coverage Period
Initial authorization: 4 months

Reauthorization: Indefinite, based on response to treatment defined as ≥5% of baseline body weight, or 5% of baseline BMI for patients with continued growth potential

ICD-10:
E66.8

Chronic weight management in patients with obesity due to Bardet-Biedl Syndrome

1. Provider attestation of a diagnosis of Bardet-Biedl Syndrome, **AND**
2. Patient is 6 years of age or older, **AND**
3. Patient has obesity defined as one of the following:
    a. Adult patient has body mass index (BMI) ≥30 kg/m^2, or
    b. Pediatric patient's weight is ≥97th percentile using growth chart assessments

Covered Dose
Up to 3 mg (0.3 mL) SC once daily

Coverage Period
Initial authorization: 6 months
Reauthorization: Indefinite, based on response to treatment defined as ≥5% of baseline body weight, or 5% of baseline BMI for patients with continued growth potential

ICD-10:
Q87.89

(3) The following condition(s) DO NOT require Prior Authorization/Preservice
All requests for setmelanotide (Imcivree®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)
Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information
How supplied:
- 10 mg/mL multiple-dose vial

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Imcivree® (setmelanotide) [Prescribing information]. Boston, MA: Rhythm Pharmaceuticals, Inc. 2020.

(7) Policy Update
Date of last revision: 1Q2022 (Jan)
Date of next review: 1Q2022 (Mar)
Changes from previous policy version:
- No clinical change to policy following revision.