

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

Imcivree is managed under the Outpatient Pharmacy Benefit. If the patient has a prescription drug benefit, please contact Blue Shield Pharmacy Services to obtain a prior authorization.

To submit a request to the medical benefit, please submit clinical information for prior authorization review via fax, including medical rationale why the patient cannot self-administer Imcivree in the home.

(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/m², or
 - b. Pediatric patient's weight is $\geq 95^{\text{th}}$ 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 $\geq 5\%$ 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/m², or
 - b. Pediatric patient's weight is $\geq 97^{\text{th}}$ 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 $\geq 5\%$ 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.; 6/2022.

(7) Policy Update

Date of last revision: 3Q2022

Date of next review: 4Q2022

Changes from previous policy version:

- New indication in Section (2): Added coverage for chronic weight management in patients with obesity due to Bardet-Biedl Syndrome.

Rationale: In June 2022, FDA approved Imcivree for chronic weight management in adult and pediatric patients 6 years of age and older with monogenic or syndromic obesity due to BBS.

Commercial

setmelanotide (Imcivree®)

Effective: 08/31/2022

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*BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee*