Pharmacy Medical Necessity Guidelines: Imcivree™ (setmelanotide)

Effective: May 1, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Imcivree (setmelanotide) is a melanocortin 4 (MC4) receptor agonist indicated for chronic weight management in adult and pediatric patients 2 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.
- Bardet-Biedl syndrome (BBS)

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, including obesity associated with other genetic syndromes and general (polygenic) obesity.

COVERAGE GUIDELINES

The plan may authorize coverage of Imcivree (setmelanotide) for Members when the following criteria are met:

Initial Authorization Criteria

1. Documented diagnosis of obesity due to **ONE** (1) of the following:
    a. Genetically determined or suspected deficiency of proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) based on an interpretation of the genetic variants as pathogenic, likely pathogenic, or of uncertain significance
    b. Bardet-Biedl syndrome (BBS)

AND

2. Documentation the patient is obese, defined as **ONE** (1) of the following:
    a. For patients 18 years of age or older, a baseline body mass index of at least 30 kg/m2
    b. For pediatric patients 6 years through 17 years of age:
        i. POMC, PCSK1, and LEPR deficiencies: ≥95th percentile using growth chart assessments
        ii. BBS: ≥97th percentile using growth chart assessments
    c. For pediatric patients 2 years of age to less than 6 years of age, baseline body mass index of ≥97th percentile for age and sex and body weight ≥20 kg

AND

3. Prescribed by an endocrinologist, a geneticist, or a physician who specializes in metabolic disorders

AND

4. The patient is 2 years of age and older

AND

5. Documentation of baseline body weight and body mass index

Reauthorization Criteria

1. Documented diagnosis of obesity due to **ONE** (1) of the following:
    a. Genetically determined or suspected deficiency of proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) based on an interpretation of the genetic variants as pathogenic, likely pathogenic, or of uncertain

significance

b. Bardet-Biedl syndrome (BBS)

AND

2. Prescribed by an endocrinologist, a geneticist, or a physician who specializes in metabolic disorders

AND

3. The patient is 2 years of age and older

AND

4. Documentation the patient has experienced a therapeutic response as defined by at least **ONE** (1) of the following:
    a. Loss of at least 5% body weight from baseline
    b. Loss of at least 5% body mass index if continued growth potential

LIMITATIONS

- Initial approval by the plan will be limited to four (4) months. Reauthorization will be provided in 12-month intervals.
- Members new to the plan stable on Imcivree (setmelanotide) should be reviewed against Reauthorization Criteria.

CODES

None

REFERENCES

1. Clément 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 POMC deficiency: single-arm, open-label, multicentre, phase 3 trials. Lancet Diabetes Endocrinol. 2020;8(12):960-970.
2. Imcivree (setmelanotide) [package insert]. Boston, MA: Rhythm Pharmaceuticals, Inc.;March 2025.

APPROVAL HISTORY

September 13, 2022: Reviewed by Pharmacy & Therapeutics Committee

- June 13, 2023: Expanded provider specialty requirements, added requirements to demonstrate the patient is obese based on the requested diagnosis and age, and clarified diagnosis requirements (effective September 1, 2023).
- March 12, 2024: No changes
- January 14, 2025: No changes (eff 1/14/25)
- January 13, 2026: Updated overview and coverage criteria to include expanded indication for pediatric patients 2 years of age to less than 6 years of age. Updated prescriber requirements for initial and reauthorization criteria to remove consultation with a specialist. (eff 5/1/26).

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of

benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services