Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: Imcivree™ (setmelanotide)

Effective: September 1, 2023

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

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 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.

Imcivree (setmelanotide) is not indicated for the treatment of patients with the following conditions as Imcivree (setmelanotide) 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).

Clinical Guideline Coverage Criteria

The plan may authorization coverage of Imcivree for Members when all of the following criteria are met:

Initial Therapy

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. Bradet-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/m^2
    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

AND

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

AND

4. The patient is 6 years of age

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. Bradet-Biedl syndrome (BBS)

AND

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

AND

3. The patient is 6 years of age

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

1. Initial approval by the plan will be limited to 4 months. Reauthorization will be provided in 12-month intervals.
2. Members new to the plan stable on Imcivree should be reviewed against Reauthorization Criteria.
3. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.

Codes

None

References

1. Imcivree (setmelanotide) [package insert]. Boston, MA: Rhythm Pharmaceuticals, Inc.; November 2020.

Approval And Revision History

September 13, 2022: Reviewed by the 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).

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.