MEDICAL MUTUAL®

Drug Policy

Policy:	**20210101**	**Initial Effective Date:** **02/25/2022** **Annual Review Date:** **01/18/2024** **Last Revised Date:** **01/18/2024**
Code(s):	**HCPCS J3490**	
SUBJECT:	**Imcivree (setmelanotide)**	

☒Subject to Site of Care

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

Initial and renewal requests for the medication(s) listed in this policy are subject to site of care management. When billed under the medical benefit, administration of the medication will be restricted to a non-hospital facility-based location (i.e., home infusion provider, provider's office, free-standing ambulatory infusion center) unless the member meets the site of care exception criteria. To view the exception criteria and a list of medications subject to site of care management please click here.

OVERVIEW

Imcivree 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 (VUS) OR 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.

POLICY STATEMENT

This policy involves the use of Imcivree. Prior authorization is recommended for pharmacy and medical benefit coverage of Imcivree. Approval is recommended for those who meet the conditions of coverage in the **Criteria, Dosing (medical benefit requests only), Initial/Extended Approval, Duration of Therapy**, and **Labs/Diagnostics** for the diagnosis provided. **Waste Management** applies for all covered conditions that are administered by a healthcare professional. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria and Waste Management section. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Imcivree as well as the monitoring required for AEs and long-term efficacy, initial approval requires Imcivree be prescribed by or in consultation

with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

The site of care medical necessity criteria applies to initial therapy and reauthorizations under the medical benefit only.

***Note: Medications for the treatment of weight loss are specifically excluded as a covered benefit for many plans, regardless of underlying medical condition; therefore, use of Imcivree is generally not covered and not eligible for reimbursement. Please confirm eligibility, covered benefits and exclusions to determine coverage for this drug.**

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Imcivree is recommended in those who meet the following criteria:

1. **Chronic Weight Management, initial therapy**
   Criteria. *Patient must meet the following criteria*
   - **A.** The patient is 6 years of age or older; AND
   - **B.** The patient has been diagnosed with monogenic or syndromic obesity as per ONE of the following:
     - **a.** BMI ≥ 30 kg/m^2 for adults; OR
     - **b.** BMI ≥ 95th percentile using growth chart assessments for pediatric patients for obesity due to POMC, PCSK1, or LEPR deficiencies; OR
     - **c.** BMI ≥ 97th percentile using growth chart assessments for pediatric patients for obesity due to BBS; AND
   - **C.** The patient meets ONE of the following (a OR b):
     - **a.** The patient has a clinical diagnosis of Bardet-Biedl syndrome (BBS), as evidenced by meeting one of the following [documentation required]
       - **i.** The patient has at least FOUR (4) of the following primary features of BBS: red-cone dystrophy, polydactyly, obesity, learning disability, renal anomalies, or male hypogonadism; OR
       - **ii.** The patient has at least THREE (3) primary features of BBS (listed in Cai above) AND has at least TWO (2) of the following secondary features of BBS: speech disorder/delay, strabismus/cataracts/astigmatism, brachydachtyly/syndactyly, developmental delay, polyuria/polydipsia (nephrogenic diabetes insipidus), ataxia/poor coordination/imbalance, mild spasticity, diabetes mellitus, dental crowding/hypodontia/small roots/high arched palate, left ventricular hypertrophy/congenital heart disease, or hepatic fibrosis; OR
     - **b.** The patient meets ALL of the following:
       - **i.** Obesity is due to a deficiency of one of the following, as confirmed by genetic testing [documentation required]:
         1. Proopiomelanocortin (POMC)
         2. Proprotein convertase subtilisin/kexin type 1 (PCSK1)
         3. Leptin receptor (LEPR); AND
       - **ii.** Genetic testing demonstrates that variants in POMC, PCSK1, or LEPR genes are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS) [documentation required]; AND

D. Imcivree is prescribed by or in consultation with an endocrinologist, a geneticist, or an expert in rare genetic disorders of obesity

2. Chronic Weight Management, continuation of therapy

Criteria. *Patient must meet the following criteria*

A. Imcivree is prescribed by or in consultation with an endocrinologist, a geneticist, or an expert in rare genetic disorders of obesity; AND

B. The patient has used Imcivree for a minimum of 12 weeks for obesity due to POMC, PCSK1, or LEPR deficiency, or a minimum of 1 year for obesity due to BBS; AND

C. The patient has lost at least 5% of baseline body weight (or at least 5% of baseline BMI for patients with continued growth potential) within the first 12-16 weeks of therapy using Imcivree if obesity is due to POMC, PCSK1, or LEPR deficiency, or within the first 1 year of therapy using Imcivree if obesity is due to BBS [documentation required]; AND

D. The patient meets one of the following:

- **a.** The patient has a clinical diagnosis of Bardet-Biedl syndrome (BBS), as evidenced by meeting one of the following [documentation required]:
  - **i.** The patient has at least FOUR (4) of the following primary features of BBS: red-cone dystrophy, polydactyly, obesity, learning disability, renal anomalies, or male hypogonadism; OR
  - **ii.** The patient has at least THREE (3) primary features of BBS (listed in Dai above) AND has at least TWO (2) of the following secondary features of BBS: speech disorder/delay, strabismus/cataracts/astigmatism, brachydachtyly/syndactyly, developmental delay, polyuria/polydipsia (nephrogenic diabetes insipidus), ataxia/poor coordination/imbalance, mild spasticity, diabetes mellitus, dental crowding/hypodontia/small roots/high arched palate, left ventricular hypertrophy/congenital heart disease, or hepatic fibrosis; OR
- **b.** The patient meets all of the following:
  - **i.** The patient's obesity is due to a deficiency of one of the following, as confirmed by genetic testing [documentation required]:
    1. Proopiomelanocortin (POMC)
    2. Proprotein convertase subtilisin/kexin type 1 (PCSK1)
    3. Leptin receptor (LEPR); AND
  - **ii.** Genetic testing demonstrates that variants in POMC, PCSK1, or LEPR genes are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS) [documentation required]

Dosing in Imcivree.

Dosing must meet the following: ***(medical benefit only)***

Patients 12 years of age or older:

- Starting dose: 2 mg injected subcutaneously once daily for 2 weeks
- If the 2 mg dose is tolerated, increase the dose to 3 mg once daily. If the 3 mg dose is not tolerated, maintain administration of 2 mg once daily.

Patients 6-12 years of age:

- Starting dose: 1 mg injected subcutaneously once daily for 2 weeks
- If the 1 mg dose is tolerated, increase the dose to 2 mg once daily. If the 2 mg dose is not tolerated, reduce to 1 mg once daily.
- If the 2 mg dose is tolerated and additional weight loss is desired, the dose may be increased to 3 mg once daily

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year for obesity due to BBS; 4 months for all others
B) *Extended Approval:* 1 year

Waste Management for All Indications.

Imcivree is available as a 10 mg/mL solution in a 1-mL multiple-dose vial

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CONDITIONS NOT RECOMMENDED FOR APPROVAL

Imcivree has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **POMC, PCKS1, or LEPR Variants Classified as Benign or Likely Benign.**

2. **Obesity NOT Related to POMC, PCSK1, or LEPR Deficiency or BBS, Including Obesity Associated with Other Genetic Syndromes and General (Polygenic) Obesity.**

3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Imcivree [prescribing information]. Boston, MA: Rhythm Pharmaceuticals, Inc.; November 2023.
2. Setmelanotide. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 8 December 2023. Accessed on 12 January 2024.

Prior approval is required for HCPCS Codes J3490

†When *unclassified drugs* (J3490) determined to be Imcivree

Edits and Denials:

Prior approval: Prior approval is required for Imcivree **(HCPCS Codes J3490)**. Requests for prior approval will be authorized by a nurse reviewer if submitted documentation meets criteria outlined within the Corporate Medical Policy.

Requests for prior approval will be forwarded to a qualified physician reviewer if submitted documentation does not meet criteria outlined within Corporate Medical Policy.

TOPPS: Claims received with **HCPCS Codes J3490** will pend with **Remark Code M3M or M4M** and will be adjudicated in accordance with the Corporate Medical Policy.

Liability: A participating provider will be required to write off charges denied as not medically necessary.

HCPCS Code(s):	
J3490	Unclassified drugs