Mass General Brigham
Health Plan

Imcivree (setmelanotide)
Effective 09/01/2025

Plan	☐ MassHealth UPPL ☒ Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview

Imcivree (setmelanotide) is a melanocortin 4 (MC4) receptor agonist indicated to reduce excess body weight and maintain weight reduction long term in adults and pediatric patients 2 years of age and older with syndromic or monogenic obesity due to:

- Bardet-Biedl syndrome (BBS)
- proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency.

Coverage Guidelines

Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted for members when ALL the following criteria are met:

1. The member meets **ONE** of the following:
    a. For adult members, BMI of ≥30 kg/m^2
    b. For pediatric members 2 through 17 years of age:
        i. POMC, PCSK1, and LEPR deficiencies: ≥95th percentile using growth chart assessment
        ii. BBS: ≥ 97th percentile using growth chart assessment
2. Obesity is due to ONE of the following:
    a. Homozygous or presumed homozygous variant in at least one of the following genes (genetic test must be submitted):
        i. POMC
        ii. PCSK1
        iii. LEPR
    b. Bardet-Biedl syndrome (BBS)
3. **If obesity due to variant in POMC, PCSK1 or LEPR:** Genetic testing demonstrating that the variants in POMC, PSCK1, or LEPR genes are interpreted as pathogenic, likely pathogenic, or VUS*
4. Prescriber is an endocrinologist or in consultation with an endocrinologist
5. Member meets **ONE** of the following:
    a. For adult members, baseline body weight

b. For pediatric members, baseline BMI

6. Documentation of appropriate dosing (not to exceed 3 mg per day)
7. Member is 2 years of age or older

*Member does not meet criteria of variants in POMC, PSCK1, or LEPR, genes are interpreted as benign or likely benign

Continuation of Therapy

Requests for reauthorization will be approved when the following criteria are met:

1. ONE of the following:
    a. For adult members, at least a 5% reduction in baseline body weight or maintenance in reduction of at least 5% in baseline body weight
    b. For pediatric members, at least a 5% reduction in baseline BMI or maintenance in reduction of at least 5% in baseline BMI in members with continued growth potential
2. Member is adherent to medication

Limitations

1. Initial approvals will be granted for 4 months.
2. Reauthorizations will be granted for 6 months.
3. The following quantity limits apply:

Drug Name and Dosage Form	Quantity Limit
Imcivree 10mg/mL subcutaneous injection	10 mL per 30 days

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) [prescribing information]. Boston, MA: Rhythm Pharmaceuticals, Inc; March 2025.

Review History

05/19/2021 – Created and Reviewed for May P&T. Effective 07/01/2021.
09/21/2022 - Reviewed and Updated for Sept P&T; added age limit for pediatrics; separated out CommExch vs. MH criteria. Effective 01/01/2023.
06/11/2025 – Reviewed and Updated at June P&T. Updated language for members who are new to the Plan. Updated criteria to include supplemental indication of BBS and reduce approvable age from 6 years to 2 years. Effective 09/01/2025.