Mass General Brigham
Health Plan

Imcivree (setmelanotide)
Effective 01/01/2023

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 and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview
Imcivree (setmelanotide) is an MC4 receptor agonist that reduces hunger and promotes weight loss through decreased caloric intake and increased energy expenditure in patients with obesity due to 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 who are currently receiving treatment with Imcivree, 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, and documentation is provided:

1. The member meets **ONE** of the following:
    a. For adult members, BMI of ≥30 kg/m2
    b. For pediatric members at least 6 years of age with ≥95th percentile using growth chart assessment
2. Obesity is due to a homozygous or presumed homozygous variant in at least one of the following genes (genetic test must be submitted):
    a. POMC
    b. PCSK1
    c. LEPR
3. 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 ≥ 6 years of age

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

Continuation of Therapy

Reauthorization may be granted when one of the following is met and documentation is provided:

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:

Imcivree 10mg/mL subcutaneous injection	10mL per 30 days

References

1. Imcivree [package insert]. Boston, MA: Rhythm Pharmaceuticals, Inc; November 2020.
2. 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.

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.