New Hampshire Medicaid Fee-for-Service Program
Imcivree™ (setmelanotide) Criteria

Approval Date: October 1, 2025

Indications

Brand Name (Generic Name)	Indications
Imcivree™ (setmelanotide)	• Indicated for chronic weight management in adult and pediatric patients ≥ 2 years of age with monogenic or syndromic obesity due to: – Pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency as determined by an FDA-approved test demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS) – Bardet-Biedl syndrome (BBS)

Medications

Brand Names	Generic Names	Dosage
Imcivree™	setmelanotide	10 mg/mL

Criteria for Approval

1. Patient must be ≥ 2 years of age; **AND**
2. Baseline BMI must be 30 kg/m^2 or more **or** 95th percentile or higher on pediatric growth chart; **AND**
3. Patient has proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency, as confirmed by a genetic test; **AND**
   - Genetic variants are interpreted as pathogenic, likely pathogenic, or of uncertain significance; **OR**
4. Patient has Bardet-Biedl Syndrome (BBS) as evidenced by three or more of the following:
   - Intellectual impairment
   - Renal anomalies
   - Polydactyly
   - Retinal degeneration
   - Genital anomalies
5. Prescribed by or in consultation with an endocrinologist or geneticist.

Criteria for Renewal

1. First approval will be for four months; **AND**
2. After four months of therapy, patient must have lost at least 5% of the baseline body weight (or 5% or more of baseline BMI in those with continued growth potential); **AND**
3. The patient has not experienced treatment-limiting adverse reactions (e.g., gastrointestinal intolerability below labeled dosing for age, sexual adverse effects, depression, or suicidal ideation).

Criteria for Denial

Prior approval will be denied if the approval criteria are not met.

References

Available upon request.

Revision History

Reviewed by	Reason for Review	Date Approved
DUR Board	New	09/23/2025
Commissioner Designee	Approval	10/01/2025