Effective Date: 06/01/2021
Reviewed: 03/2021, 02/2022, 8/2022, 5/2023, 5/2024, 5/2025 Scope: Medicaid

Imcivree (setmelanotide)

POLICY

I. CRITERIA FOR APPROVAL

An authorization of 6 months may be granted when all the following criteria are met:

- Patient is 6 years or older; AND
- Prescribed by or in consultation with an endocrinologist, a geneticist, or a physician who specializes in metabolic disorders; AND
- Patient has not undergone prior bariatric surgery resulting in >10% weight loss that was maintained; AND
- Patient has a CrCl ≥30mL/min; AND

Bardet-Biedl syndrome

- Patient has a documented diagnosis of Bardet-Biedl syndrome; AND
- Patient has documented diagnosis of obesity, defined as:
  - ≥ 16 years of age: BMI of ≥ 30kg/m^2
  - 6-15 years of age: ≥ 97th percentile using growth chart assessments.

Proopiomelanocortin (POMC), Proprotein convertase subtilisin/kexin type 1 (PCSK1), Leptin receptor (LEPR) deficiency

- Patient has documented diagnosis of obesity, defined as:
  - Adult patients: BMI of ≥30kg/m^2
  - Pediatric patients: ≥ 95th percentile using growth chart assessments; AND
- Obesity is due to a homozygous or compound heterozygous variants in at least one of the following genes, confirmed by genetic testing:
  - Proopiomelanocortin (POMC)
  - Proprotein convertase subtilisin/kexin type 1 (PCSK1)
  - Leptin receptor (LEPR); AND
- Documentation of genetic testing is provided and confirms that variants of POMC, PCSK1, or LEPR genes are interpreted as pathogenic, likely pathogenic, or of uncertain significance

II. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for all members who are tolerating treatment and have documentation of a positive clinical response, as evidenced by:

A. 5% reduction in baseline body weight; OR
B. 5% reduction in baseline BMI for patients with continued growth potential

III. QUANTITY LIMIT

- 10 vials (10mg/mL) per 30 days

IV. COVERAGE DURATION

- Initial: 6 months
- Continuation: 6 months

V. REFERENCES

1. Imcivree subcutaneous injection [prescribing information]. Boston, MA: Rhythm; March 2025. Accessed June 2025.