

Effective Date: 06/01/2021
Reviewed: 03/2021, 02/2022, 8/2022, 5/2023, 5/2024, 5/2025, 7/2026
Scope: Medicaid

Imcivree (setmelanotide)

POLICY

I. CRITERIA FOR APPROVAL

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

- 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 ≥ 30 mL/min; AND

Acquired Hypothalamic Obesity (HO)

- Member is 4 years of age or older; AND
- Member has a documented diagnosis of acquired HO defined as BOTH of the following:
 - Member has experienced a traumatic or disease-related (e.g., oncological) injury to the hypothalamus documented by MRI or CT scan; AND
 - Member has had a rapid, clinically significant increase in BMI (more than or equal to 5% BMI increase in adults or 1.0 BMI standard deviation increase in pediatric members) that began within the first 12 months after the onset of hypothalamic damage; AND
- Member does NOT have a diagnosis of Prader-Willi Syndrome (PWS) or Rapid-onset obesity with hypoventilation, hypothalamic, autonomic dysregulation, neuroendocrine tumor syndrome (ROHHADNET); AND
- Member has documented diagnosis of obesity, defined as:
 - Adult patients: BMI of ≥ 30 kg/m²
 - Pediatric patients: $\geq 95^{\text{th}}$ percentile using growth chart assessments.

Bardet-Biedl syndrome (BBS)

- Member is 2 years of age or older; AND
- Member has a documented diagnosis of Bardet-Biedl syndrome defined by one of the following:
 - Member has 4 primary features of the Beales criteria; OR
 - Member has 3 primary and 2 secondary features of the Beales criteria; OR
 - Member has had genetic testing confirming a variant in both alleles of one of the core genes associated with BBS (e.g., BBS1, BBS2, ARL6) and 1 primary feature of the Beales criteria; AND
- Member has documented diagnosis of obesity, defined as:
 - Adult patients: BMI of ≥ 30 kg/m²
 - Pediatric patients: $\geq 95^{\text{th}}$ percentile using growth chart assessments.

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

- Member is 2 years of age or older; AND
- Member has documented diagnosis of obesity, defined as:
 - Adult patients: BMI of $\geq 30\text{kg/m}^2$
 - Pediatric patients: $\geq 95^{\text{th}}$ percentile using growth chart assessments; AND
- Documentation that 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 less than 18 years of age

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 2026.

Appendix:

Beales Criteria:

- Primary Features:
 - Rod-cone dystrophy
 - Polydactyly
 - Obesity
 - Learning Disability
 - Hypogonadism in males
 - Renal abnormalities

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- Secondary features:
 - Speech disorder/delay
 - Strabismus/ cataracts/ astigmatism
 - Brachydactyly/syndactyly
 - Developmental delay
 - Polyuria/polydipsia (nephrogenic diabetes insipidus)
 - Ataxia/ poor coordination/imbalance
 - Mild spasticity (especially lower limbs)
 - Diabetes mellitus
 - Dental crowding/hypodontia/small roots/high arched palate
 - Left ventricular hypertrophy/congenital heart disease
 - Hepatic fibrosis