AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Imcivree	Page:	1 of 4
Effective Date:	5/22/2025	Last Review Date:	01/23/2025
Applies to:	☒ Maryland ☒ Illinois ☒ Penn CHIP ☒ Florida Healthy Kids ☐ Kentucky PRMD		

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Imcivree under the patient's prescription drug benefit.

Description:

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Imcivree is 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:

A. Bardet-Biedl syndrome (BBS)
B. 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)

Limitations of Use:
Imcivree is not indicated for the treatment of patients with the following conditions as Imcivree would not be expected to be effective:

A. Obesity due to suspected POMC, PCSK1, or LEPR deficiency with *POMC*, *PCSK1*, or *LEPR* variants classified as benign or likely benign
B. Other types of obesity not related to POMC, PCSK1, or LEPR deficiency or BBS, including obesity associated with other genetic syndromes and general (polygenic) obesity

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Imcivree

Policy/Guideline:

Documentation:
Submission of the following information is necessary to initiate the prior authorization review:

A. Obesity Due to POMC, PCSK1 or LEPR deficiency
    1. Initial Requests:

i. Genetic test results documenting homozygous or compound heterozygous variants in *POMC*, *PCSK1*, or *LEPR* genes
ii. Medical record (e.g., chart notes) and growth chart (in members less than 18 years of age) documentation of pretreatment Body Mass Index (BMI) and weight

2. Continuation Requests (where applicable): Medical record (e.g., chart notes) and growth chart (if continued growth potential) documentation of current Body Mass Index (BMI) and current weight

B. Obesity due to Bardet-Biedl Syndrome
1. Initial Requests:
i. Chart notes or medical record documentation supporting clinical diagnosis
ii. Medical record (e.g., chart notes) and growth chart (in members less than 18 years of age) documentation of pretreatment Body Mass Index (BMI) and weight
2. Continuation Requests (where applicable): Medical record (e.g., chart notes) and growth chart documentation of current Body Mass Index (BMI) and current weight

Criteria for Initial Approval:

A. Obesity Due To POMC, PCSK1, or LEPR Deficiency
Authorization of 6 months may be granted to reduce excess body weight and maintain weight reduction long term for members with obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency when ALL the following criteria are met:
1. Diagnosis is confirmed by genetic testing demonstrating homozygous or compound heterozygous variants in *POMC*, *PCSK1*, or *LEPR* genes
2. *POMC, PCSK1*, or *LEPR* gene variants are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS)
3. The member is 2 years of age or older
4. The member has obesity defined as ONE of the following:
i. BMI greater than or equal to 30 kg/m^2 in members 18 years of age or older
ii. BMI greater than or equal to 95^{th} percentile for age on growth chart assessment in members less than 18 years of age

B. Obesity Due To Bardet-Biedl Syndrome
Authorization of 12 months may be granted to reduce excess body weight and maintain weight reduction long term for members with obesity due to Bardet-Biedl syndrome (BBS) when ALL the following criteria are met:
1. The member has a clinical diagnosis of BBS as per Beales criteria (member has 4 primary features OR 3 primary and 2 secondary features) (see Appendix)
2. The member is 2 years of age or older
3. The member has obesity defined as ONE of the following:

i. BMI greater than or equal to 30 kg/m^2 in members 18 years of age or older
ii. BMI greater than or equal to 95th percentile for age on growth chart assessment in members less than 18 years of age

Continuation of Therapy:

A. Obesity Due To POMC, PCSK1, or LEPR Deficiency
Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when one of the following is met:
1. The member has received less than 12 months of therapy and ONE of the following is met:
   i. Member has lost at least 5% of baseline body weight
   ii. Member has continued growth potential and has had a reduction in Body Mass Index (BMI) of at least 5% from baseline
2. Member has received 12 months of therapy or more and has achieved or sustained clinically meaningful weight loss

B. Obesity Due To Bardet-Biedl Syndrome
1. Authorization of up to 12 months may be granted for continued treatment in members requesting reauthorization when the member has received less than 12 months of therapy
2. Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when the member has received 12 months of therapy or more and ONE of the following is met:
   i. Member has lost at least 5% of baseline body weight
   ii. Member is less than 18 years of age and has had a reduction in Body Mass Index (BMI) of at least 5% from baseline

Appendix:

Beales Diagnostic Criteria
A. Primary features
   1. Rod-cone dystrophy
   2. Polydactyly
   3. Obesity
   4. Learning disability
   5. Hypogonadism in males
   6. Renal abnormalities
B. Secondary features
   1. Speech disorder/delay
   2. Strabismus/cataracts/astigmatism
   3. Brachydactyly/syndactyly
   4. Developmental delay
   5. Polyuria/polydipsia (nephrogenic diabetes insipidus)

6. Ataxia/poor coordination/imbalance
7. Mild spasticity (especially lower limbs)
8. Diabetes mellitus
9. Dental crowding/hypodontia/small roots/high arched palate
10. Left ventricular hypertrophy/congenital heart disease
11. Hepatic fibrosis

Approval Duration and Quantity Restrictions:

Approval:

- Initial approval for Obesity due to POMC, PCSK1, or LEPR Deficiency: 6 months
- Initial approval for Obesity due to Bardet-Biedl Syndrome: 12 months
- Renewal approval: 12 months

Quantity Level Limit: 10 vials per 30 days

References:

1. Imcivree [package insert]. Boston, MA: Rhythm Pharmaceuticals, Inc.; December 2024.
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. doi:10.1016/S2213-8587(20)30364-8
3. Beales P, Elcioglu N, Woolf AS, et al. New criteria for improved diagnosis of Bardet-Biedl syndrome: results of a population survey. J Med Genet. 1999;36(6):437-446.
4. Argente J, Verge CF, Okorie U, et al. Setmelanotide in patients aged 2-5 years with rare MC4R pathway-associated obesity (VENTURE): a 1 year, open-label, multicenter, phase 3 trial. Lancet Diabetes Nedocrinol. 2025;13:29-37.