



AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name: Imcivree Page: 1 of 4

Effective Date: 8/1/2024 Last Review Date: 7/2024

Applies to:	<input type="checkbox"/> Illinois	<input type="checkbox"/> Florida	<input type="checkbox"/> Florida Kids
	<input type="checkbox"/> New Jersey	<input checked="" type="checkbox"/> Maryland	<input type="checkbox"/> Michigan
	<input type="checkbox"/> Pennsylvania Kids	<input type="checkbox"/> Virginia	<input type="checkbox"/> Arizona
	<input type="checkbox"/> 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 for chronic weight management in adult and pediatric patients 6 years of age and older with monogenic or syndromic obesity due to:

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

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:



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**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 for treatment of chronic weight management in members with obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency when all of 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 6 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<sup>2</sup> in members 18 years of age or older
  - ii. BMI greater than or equal to 95<sup>th</sup> 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 for treatment of chronic weight management in members with obesity due to Bardet-Biedl syndrome (BBS) when all of the following criteria are met:



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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 6 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<sup>2</sup> in members 18 years of age or older
  - ii. BMI greater than or equal to 95<sup>th</sup> 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



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## 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: 6 months
- Renewal approval: 12 months

### References:

1. Imcivree [package insert]. Boston, MA: Rhythm Pharmaceuticals, Inc; June 2022.
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.