HIGHMARK WHOLECARE

Updated: 08/2025
PARP Approved: 08/2025

Prior Authorization Criteria

Imcivree (setmelanotide)

All requests for Imcivree (setmelanotide) require prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

- Must be prescribed by or in consultation with a geneticist, endocrinologist, or metabolic specialist.
- Prescriber must attest to ALL of the following:
  - A full body skin examination was performed prior to initiation of therapy and will be periodically performed during treatment to monitor pre-existing and new skin pigmentary lesions
  - The member does not have end stage renal disease [estimated glomerular filtration rate (eGFR) <15mL/min/1.73m^2]
- Requests for obesity due to suspected POMC, PCSK1, or LEPR variants classified as benign or likely benign, obesity associated with other genetic syndromes, or general obesity will not be approved.

Coverage may be provided with a diagnosis of chronic weight management for obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency and the following criteria is met:

- Documentation of member's baseline weight and body mass index (BMI)
  - For members 2-17 years of age BMI must be ≥95th percentile using growth chart assessments.
  - For members 18 and older BMI must be ≥30 kg/m^2
- Diagnosis was confirmed by genetic testing demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance.
- **Initial Duration of Approval:** 12 months
- **Reauthorization criteria**
  - Documentation the member has lost at least 5% of baseline body weight or 5% of baseline BMI if the member has continued growth potential.
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of chronic weight management for obesity due to Bardet-Biedl Syndrome and the following criteria is met:

- Chart documentation that the diagnosis was confirmed by one of the following:
  - Genetic testing
  - Presence of obesity and at least 3 other major or 2 major and 2 minor clinical manifestations
    - Major

        - Polydactyl
        - Ocular manifestations
        - Kidney disease
        - Genitourinary abnormalities
        - Cognitive impairment
        - Hypogonadism
    - Minor
        - Neurological abnormalities
        - Olfactory dysfunction
        - Oral/dental abnormalities
        - Cardiovascular and other thoraco-abdominal abnormalities
        - Gastrointestinal and/or liver abnormalities
        - Endocrine or other metabolic abnormalities
- Documentation of member's baseline weight and body mass index (BMI)
    - For members 2-17 years of age BMI must be ≥97th percentile using growth chart assessments.
    - For members 18 and older BMI must be ≥30 kg/m^2
- **Initial Duration of Approval:** 12 months
- **Reauthorization criteria**
    - Documentation the member has lost at least 5% of baseline body weight or 5% of baseline BMI if the member is less than 18 years.
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case-by-case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

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IMCIVREE (SETMELANOTIDE) PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Wholecare Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (800) 392-1147 Mon – Fri 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	Provider NPI:
Provider Specialty:	Office Contact:
State license #:	Office NPI:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Directions:	Quantity:	Refills:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:	

Billing Information

This medication will be billed: ☐ at a pharmacy **OR** ☐ medically, JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis:	ICD Code:

Please attest to the following (mark all that apply):

Please attest to the following (mark all that apply):

☐ A full body skin examination was performed prior to initiation of therapy and will be periodically performed during treatment to monitor pre-existing and new skin pigmentary lesions

☐ The member does not have end stage renal disease [(estimated glomerular filtration rate (eGFR) <15mL/min/1.73m^2]

Please provide the following:
Baseline body weight: _____ Date taken:_____
Baseline body mass index (BMI) _____ Date taken: _____

Was the diagnosis confirmed by a genetic test: (Please submit documentation)? ☐ Yes ☐ No

For Bardet-Biedl Syndrome please mark all the following symptoms that apply below:

☐ Polydactyl
☐ Ocular manifestations
☐ Kidney disease
☐ Cognitive impairment
☐ Hypogonadism
☐ Neurological abnormalities
☐ Olfactory dysfunction
☐ Oral/dental abnormalities
☐ Cardiovascular and other thoraco-abdominal abnormalities
☐ Gastrointestinal and/or liver abnormalities
☐ Endocrine or other metabolic abnormalities

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IMCIVREE (SETMELANOTIDE)
PRIOR AUTHORIZATION FORM (CONTINUED)– PAGE 2 of 2

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MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

MEDICAL HISTORY (Complete for ALL requests)
CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

Has the member experienced a significant improvement with treatment? ☐ Yes ☐ No
Please describe:_____

For obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR)
Has the member lost at least 5% of baseline body weight or 5% of baseline BMI if the member has continued growth potential since starting the requested medication? (Please submit documentation) ☐ Yes ☐ No

For Bardet-Biedl Syndrome
Has the member lost at least 5% of baseline body weight or 5% of baseline BMI if the member is less than 18 years old? (Please submit documentation) ☐ Yes ☐ No

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date