



Updated: 09/2025  
DMMA Approved: 09/2025

**Request for Prior Authorization for Imcivree (setmelanotide)**

Website Form – [www.highmarkhealthoptions.com](http://www.highmarkhealthoptions.com)

Submit request via: Fax - 1-855-476-4158

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

**Imcivree (setmelanotide) Prior Authorization Criteria:**

- 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<sup>2</sup>)]
- 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  $\geq 95$ th percentile using growth chart assessments.
  - For members 18 and older BMI must be  $\geq 30$  kg/m<sup>2</sup>
- 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:** 4 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  $\geq 97$ th percentile using growth chart assessments.
  - For members 18 and older BMI must be  $\geq 30$  kg/m<sup>2</sup>
- **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 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  $\geq 97$ th percentile using growth chart assessments.
  - For members 18 and older BMI must be  $\geq 30$  kg/m<sup>2</sup>
- **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.

Drugs are authorized in generic form unless the branded product is on the preferred drug list or the prescriber has indicated in writing that the branded product is medically necessary. If only the branded product is on the preferred drug list, the generic form will be considered non-preferred and shall not require the prescriber to indicate in writing that the branded product 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 Health Options Pharmacy Services. **FAX:** (855) 476-4158  
If needed, you may call to speak to a Pharmacy Services Representative.  
**PHONE:** (844) 325-6251 Monday through Friday 8:00am to 7:00pm

**PROVIDER INFORMATION**

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
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? <input type="checkbox"/> Yes <input type="checkbox"/> No	Date Medication Initiated:
Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? <input type="checkbox"/> Yes <input type="checkbox"/> No	

**Billing Information**

This medication will be billed:  at a pharmacy **OR**  
 medically (if medically please provide a 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: \_\_\_\_\_

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 moderate, severe, or end stage renal disease [(estimated glomerular filtration rate (eGFR) <15mL/min/1.73m<sup>2</sup>)]

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



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**IMCIVREE (SETMELANOTIDE)  
PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 2 OF 2**

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX: (855) 476-4158**  
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE: (844) 325-6251 Mon – Fri 8 am to 7 pm**

**MEMBER INFORMATION**

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

**MEDICAL HISTORY (Complete for ALL requests)**

For Bardet Biedl Syndrome please mark all that apply:

- |  |   |
|--|---|
| <input type="checkbox"/> Polydactyl            | <input type="checkbox"/> Neurological abnormalities                               |
| <input type="checkbox"/> Ocular manifestations | <input type="checkbox"/> Olfactory dysfunction                                    |
| <input type="checkbox"/> Kidney disease        | <input type="checkbox"/> Oral/dental abnormalities                                |
| <input type="checkbox"/> Cognitive impairment  | <input type="checkbox"/> Cardiovascular and other thoraco-abdominal abnormalities |
| <input type="checkbox"/> Hypogonadism          | <input type="checkbox"/> Gastrointestinal and/or liver abnormalities              |
|  | <input type="checkbox"/> Endocrine or other metabolic abnormalities               |

**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**

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