**STANDARD COMMERCIAL DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

**SETMELANOTIDE**

| Generic | Brand | HICL | GCN | Medi-Span | Exception/Other |
|---|---|---|---|---|---|
| SETMELANOTIDE ACETATE | IMCIVREE | 47002 | | GPI-10 (6125386010) | |

**GUIDELINES FOR USE**

**INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)**

1. Is the request for chronic weight management in obesity, and does the patient meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - The patient's obesity is due to **ONE** of the following deficiencies:
     - Pro-opiomelanocortin (POMC)
     - Proprotein convertase subtilisin/kexin type 1 (PCSK1)
     - Leptin receptor (LEPR)
   - Confirmed genetic testing demonstrates variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS)

   If yes, **approve for 16 weeks by HICL or GPI-10 with a quantity limit of #0.3 mL per day.**

   If no, continue to #2.

2. Is the request for chronic weight management in obesity, and does the patient meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - The patient's obesity is due to Bardet-Biedl syndrome (BBS)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.3 mL per day.**
   If no, do not approve.
   **DENIAL TEXT:** See the initial denial text at the end of the guideline.

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## SETMELANOTIDE

### INITIAL CRITERIA (CONTINUED)

**INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **SETMELANOTIDE (Imcivree)** requires the following rule(s) be met for approval:

A. The request is for chronic weight management
B. You are 6 years of age or older
C. You have a diagnosis of obesity (a condition where you have higher than normal body fat) that is caused by ONE of the following:
    1. Bardet-Biedl syndrome (BBS: a genetic disorder)
    2. A deficiency in ONE of the following:
        a. Pro-opiomelanocortin (POMC: type of gene)
        b. Proprotein convertase subtilisin/kexin type 1 (PCSK1: type of gene)
        c. Leptin receptor (LEPR: type of gene)
D. **If your obesity is caused by a POMC, PCSK1, or LEPR deficiency, approval also requires:**
    1. Confirmed genetic testing shows variants (changes) in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic (causing disease), likely pathogenic, or of uncertain significance (VUS)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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# SETMELANOTIDE

## RENEWAL CRITERIA

1. Is the request for chronic weight management in obesity caused by a deficiency in pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR), and the patient meets **ONE** of the following criteria?
   - The patient is 18 years of age or older AND has lost at least 5% of baseline body weight
   - The patient is 6 to 17 years of age AND has lost at least 5% of baseline body mass index (BMI)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #0.3 mL per day.**
   If no, continue to #2.

2. Is the request for chronic weight management in obesity caused by Bardet-Biedl syndrome, and the patient meets **ONE** of the following criteria?
   - The patient is 18 years of age or older AND has lost at least 5% of baseline body weight
   - The patient is 6 to 17 years of age AND has lost at least 5% of baseline body mass index (BMI)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.3 mL per day.**
   If no, do not approve.

   **RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **SETMELANOTIDE (Imcivree)** requires the following rule(s) be met for approval:
   A. You have a diagnosis of obesity (a condition where you have higher than normal body fat) that is caused by ONE of the following:
      1. Bardet-Biedl syndrome (BBS: a genetic disorder)
      2. A deficiency in ONE of the following:
         a. Pro-opiomelanocortin (POMC: type of gene)
         b. Proprotein convertase subtilisin/kexin type 1 (PCSK1: type of gene)
         c. Leptin receptor (LEPR: type of gene)

   B. You meet ONE of the following:
      1. You are 18 years of age or older AND have lost at least 5% of your baseline body weight
      2. You are 6 to 17 years of age AND have lost at least 5% of your baseline body mass index (BMI: a tool for evaluating body fat)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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## SETMELANOTIDE

### RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Imcivree.

### REFERENCES


- Imcivree [Prescribing Information]. Boston, MA: Rhythm Pharmaceuticals, Inc.; June 2022.


| Library | Commercial | NSA |
|---|---|---|
| Yes | Yes | No |

Part D Effective: N/A
Commercial Effective: 08/01/23
Created: 02/21
Client Approval: 06/23
P&T Approval: 01/21