# Imcivree (setmelanotide)

**Effective 07/01/2021**

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<th>Program Type</th>
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<td>This medication has been designated specialty and must be filled at a contracted specialty pharmacy.</td>
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<tr>
<td>All Plans</td>
<td>Phone: 866-814-5506</td>
<td>Fax: 866-249-6155</td>
<td>All Plans</td>
</tr>
<tr>
<td>MassHealth</td>
<td>Phone: 877-433-7643</td>
<td>Fax: 866-255-7569</td>
<td>MassHealth</td>
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<tr>
<td>Commercial</td>
<td>Phone: 855-582-2022</td>
<td>Fax: 855-245-2134</td>
<td>Exchange</td>
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| Exceptions | N/A |

**Overview**

Imcivree (setmelanotide) is an MC4 receptor agonist that reduces hunger and promotes weight loss through decreased caloric intake and increased energy expenditure in patients with obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency.

**Coverage Guidelines**

Authorization may be granted for members new to AllWays Health Partners who are currently receiving treatment with Imcivree, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

**OR**

Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:

1. The member meets **ONE** of the following:
   a. For adult members, BMI of ≥30 kg/m²
   b. For pediatric members, ≥95th percentile using growth chart assessment
2. Obesity is due to a homozygous or presumed homozygous variant in at least one of the following genes (genetic test must be submitted):
   a. POMC
   b. PCSK1
   c. LEPR
3. Genetic testing demonstrating that the variants in POMC, PSCK1, or LEPR genes are interpreted as pathogenic, likely pathogenic, or VUS*
4. Prescriber is an endocrinologist or in consultation with an endocrinologist
5. Member meets **ONE** of the following:

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AllWays Health Partners includes AllWays Health Partners, Inc. and AllWays Health Partners Insurance Company
a. For adult members, baseline body weight
b. For pediatric members, baseline BMI

6. Documentation of appropriate dosing (not to exceed 3 mg per day)
7. Member is ≥ 6 years of age

*Member does not meet criteria of variants in POMC, PSCK1, or LEPR, genes are interpreted as benign or likely benign

**Continuation of Therapy**

Reauthorization may be granted when one of the following is met and documentation is provided:

1. **ONE** of the following:
   a. For adult members, at least a 5% reduction in baseline body weight or maintenance in reduction of at least 5% in baseline body weight
   b. For pediatric members, at least a 5% reduction in baseline BMI or maintenance in reduction of at least 5% in baseline BMI in members with continued growth potential

2. Member is adherent to medication

**Limitations**

1. Initial approvals will be granted for 4 months.
2. Reauthorizations will be granted for 6 months.
3. The following quantity limits apply:

| Imcivree 10mg/mL subcutaneous injection | 10mL per 30 days |

**References**


**Review History**

05/19/2021 – Created and Reviewed for May P&T. Effective 07/01/2021.

**Disclaimer**

AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.