

**Imcivree (setmelanotide)  
Effective 07/01/2021**

<b>Plan</b>	<input checked="" type="checkbox"/> MassHealth <input type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		
<b>Specialty Limitations</b>	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
<b>Contact Information</b>	<b>Specialty Medications</b>		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	<b>Non-Specialty Medications</b>		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	<b>Medical Specialty Medications (NLX)</b>		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
<b>Exceptions</b>	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 the plan 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  $\geq 30$  kg/m<sup>2</sup>
  - b. For pediatric members at least 6 years of age with  $\geq 95$ th 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, PCSK1, 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:
  - 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  $\geq 6$  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
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### **References**

1. Imcivree [package insert]. Boston, MA: Rhythm Pharmaceuticals, Inc; November 2020.
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.

### **Review History**

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

09/21/2022 - Reviewed and Updated for Sept P&T; added age limit for pediatrics; separated out Comm/Exch vs. MH criteria

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