

**Louisiana Medicaid
Setmelanotide (Imcivree®)**

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for setmelanotide (Imcivree®).

Additional Point-of-Sale edits may apply.

*This agent may have a **Black Box Warning**, and/or may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety Regulations. Please refer to individual prescribing information for details.*

Approval Criteria

- The recipient is 6 years of age or older on the date of the request; **AND**
- **ONE** of the following is required:
 - The recipient has a diagnosis of obesity due to Bardet-Biedl syndrome (BBS); **OR**
 - The recipient has **ALL** of the following:
 - The recipient has obesity due to a deficiency of **ONE** of the following: (confirmed by genetic testing)
 - Pro-opiomelanocortin (POMC); **OR**
 - Proprotein convertase subtilisin/kexin type 1 (PCSK1); **OR**
 - Leptin receptor (LEPR); **AND**
 - The genetic variant is interpreted as pathogenic, likely pathogenic, or of uncertain significance; **AND**
- **ONE** of the following is required:
 - The recipient is 18 years of age or older and has a BMI ≥ 30 kg/m²; **OR**
 - The recipient is less than 18 years of age with obesity due to POMC, PCSK1, or LEPR deficiencies and has a BMI $\geq 95^{\text{th}}$ percentile using growth chart assessments; **OR**
 - The recipient is less than 18 years of age with obesity due to BBS and has a BMI $\geq 97^{\text{th}}$ percentile using growth chart assessments; **AND**
- This requested medication is being prescribed by, or the request states that this medication is being prescribed in consultation with, an endocrinologist or geneticist; **AND**
- By submitting the authorization request, the prescriber attests to the following:
 - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, prior treatment requirements and required storage and handling procedures; **AND**
 - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**

- The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Duration of initial approval:

- **4 months – for obesity due to POMC, PCSK1, or LEPR deficiencies**
- **12 months – for obesity due to BBS**

Reauthorization Criteria

- The recipient continues to meet initial approval criteria: **AND**
- **ONE** of the following is required:
 - The recipient has lost at least 5% of baseline body weight; **OR**
 - The recipient is less than 18 years of age and has lost at least 5% of baseline BMI.

Duration of reauthorization approval: 12 months

Reference

Imcivree (setmelanotide) [package insert]. Boston, MA: Rhythm Pharmaceuticals, Inc; June 2022.
<https://rhythm-vault-digital-publishing-production.s3.amazonaws.com/IMCIVREEPrescribingInformation.pdf>

Revision / Date	Implementation Date
Policy created / July 2023	January 2024