

IMCIVREE (setmelanotide)

Pre - PA Allowance

None

Prior-Approval Requirements

Age 6 years of age or older

Diagnosis

Patient must have **ONE** of the following:

- 1. POMC, PCSK1, or LEPR deficiency as determined by an FDA-approved test
 - a. Variants in POMC, PCSK1, or LEPR genes are pathogenic, likely pathogenic, **OR** of uncertain significance (VUS)
- 2. Bardet-Biedl syndrome (BBS)

AND ALL of the following:

- 1. Patient has the following:
 - a. Age 18+: Body mass index (BMI) \ge 30 kg/m²
 - b. Age 6-17: Body mass index (BMI) $\ge 95^{\text{th}}$ percentile for their age
- 2. Prescriber agrees to monitor patient's BMI
- 3. Prescriber agrees to monitor for depression and suicidal ideation
- 4. NO dual therapy with another Prior Authorization (PA) medication for weight loss (see Appendix 1)

Prior - Approval Limits

Quantity 30 vials per 90 days

DurationPOMC, PCSK1, or LEPR deficiency6 monthsBBS12 months

Prior – Approval Renewal Requirements

Age 6 years of age or older

Diagnosis

Patient must have **ONE** of the following:

1. POMC, PCSK1, or LEPR deficiency as determined by an FDA-approved test



Federal Employee Program.

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2. Bardet-Biedl syndrome (BBS)

AND ALL of the following:

- 1. Patient has the following:
 - a. Age 18+, must have **ONE** of the following:
 - i. Body mass index (BMI) is <30 kg/m²
 - Patient has lost ≥ 5% of body mass index (BMI) from baseline
 - b. Age 6-17, must have **ONE** of the following:
 - i. Body mass index (BMI) is < 95th percentile for their age
 - Patient has lost ≥ 5% of body mass index (BMI) from baseline
- 2. Prescriber agrees to monitor patient's BMI
- 3. Prescriber agrees to monitor for depression and suicidal ideation
- 4. **NO** dual therapy with another Prior Authorization (PA) medication for weight loss (see Appendix 1)

Prior - Approval Renewal Limits

Quantity 30 vials per 90 days

Duration POMC, PCSK1, LEPR deficiency, or BBS 12 months

Appendix 1 - List of PA Weight Loss Medications

Generic Name	Brand Name
benzphetamine	N/A
carboxymethylcellulose- cellulose-citric acid	Plenity
diethylpropion	N/A
liraglutide	Saxenda
naltrexone/bupropion	Contrave
orlistat	Xenical
phendimetrazine	N/A
phentermine	Adipxex-P/Lomaira
phentermine/topiramate ER	Qsymia
semaglutide	Wegovy
setmelanotide	Imcivree
tirzepatide	Zepbound



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