UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2026 P 2419-1
Program	Prior Authorization/Medical Necessity
Medication	Imcivree® (setmelanotide)
P&T Approval Date	5/2026
Effective Date	9/1/2026

1. Background:

Imcivree is a melanocortin 4 (MC4) receptor agonist indicated to reduce excess body weight and maintain weight reduction long term in adults and pediatric patients 2 years of age and older with syndromic or monogenic obesity due to Bardet-Biedl syndrome (BBS) and pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency as determined by an FDA-approved test demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS).

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Imcivree** will be approved based on **all** of the following criteria:

   a. **One** of the following:

      (1) Diagnosis of obesity is due to POMC, PCSK1, or LEPR gene deficiency confirmed with genetic testing interpreted as pathogenic, likely pathogenic, or of uncertain significance

      -OR-

      (2) Diagnosis of Bardet-Biedl syndrome

      -AND-

   b. **One** of the following:

      (1) Adult patient with BMI ≥ 30 kg/m^2

      -OR-

      (2) Pediatric patient with weight >95th percentile for age on growth chart assessment

      -AND-

   c. Patient is currently enrolled in or has history of a weight loss management program

Authorization will be issued for 6 months.

B. Reauthorization

1. **Imcivree** will be approved based on **one** of the following criteria:

   a. If on therapy for less than 12 months, documentation of a positive clinical response to Imcivree therapy defined as weight loss ≥5% of baseline weight

   -OR-

   b. If on therapy for ≥12 months, documentation of a positive clinical response to Imcivree therapy defined as ≥10% weight loss from baseline

   Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. **Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. **References:**

1. Imcivree [package insert]. Boston, MA: Rhythm Pharmaceuticals, Inc; March 2025.

Program	Prior Authorization/Medical Necessity - Imcivree
Change Control	
Date	Change
5/2026	Imcivree moved out of program number 1114 to separate criteria.