UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2026 P 1524-1
Program	Prior Authorization/Notification
Medication	Imcivree® (setmelanotide)
P&T Approval Date	7/2026
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 4 years and older with acquired hypothalamic obesity (HO) and 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 **one** of the following criteria:

   a. 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-

   b. Diagnosis of Bardet-Biedl syndrome

   -OR-

   c. Diagnosis of acquired hypothalamic obesity

   Authorization will be issued for 12 months.

B. Reauthorization

1. **Imcivree** will be approved based on the following criterion:

   a. Documentation of positive clinical response to therapy.

   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; April 2026.

Program	Prior Authorization/Notification - Imcivree
Change Control	
Date	Change
7/2026	New Notification program