CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Ohio Medicaid

DRUG NAME	Imcivree (setmelanotide)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Imcivree, approved by the FDA in 2020, is indicated for chronic weight management in patients with certain types of monogenic obesity confirmed by genetic testing. This group of disorders is incredibly rare. These patients have extreme hunger (hyperphagia) and may become morbidly obese as early as infancy. They may also have endocrine complications. Imcivree is an analog of endogenous melanocortin peptide α-MSH (alpha-melanocyte stimulating hormone) that acts as an agonist at the melanocortin-4 receptor (MC4R), intended to partially or completely restore signaling at the MC4 receptors in the brain, which are involved in regulation of hunger, satiety, and energy expenditure.

Imcivree (setmelanotide) will be considered for coverage when the following criteria are met:

Weight Management in Rare Genetic Obesity Disorders

For **initial** authorization:

1. Member is at least 6 years of age; AND
2. Medication must be prescribed by or in consultation with an endocrinologist or medical geneticist; AND
3. Member has a documented diagnosis of obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency confirmed by genetic testing (results must be attached to request); AND
4. Genetic testing demonstrates the variants in POMC, PCSK1, or LEPR genes are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS); AND
5. Documentation of baseline weight and body mass index (BMI); AND
6. Adult: Member has BMI of 30 or greater, or
   Pediatric: Member's weight is 95th percentile or greater for age on growth chart; AND
7. Member does NOT have any of the following:
   a) Variants in POMC, PCSK1, or LEPR classified as benign or likely benign
   b) Any other type of obesity not related to POMC, PCSK1 or LEPR deficiency, including obesity associated with other genetic syndromes and general (polygenic) obesity
   c) Prior gastric bypass surgery resulting in greater than 10% weight loss durably maintained.
8. **Dosage allowed/Quantity limit:**
   Starting dose for 6-11 years of age: 1 mg subQ once daily
   Starting dose for 12+ years of age: 2 mg subQ once daily
   Maximum maintenance dose (if tolerated): 3 mg subQ once daily.
   See package insert for dose adjustment frequency and titration details.

If all the above requirements are met, the medication will be approved for 16 weeks.

For **reauthorization**:

1. 1st renewal: Chart notes must show one of the following:
   a) At least 5% reduction of baseline body weight OR
   b) At least 5% reduction from baseline BMI for patients with continued growth potential.
2. Subsequent renewals: Chart notes must show at least 10% weight loss from baseline has been achieved and maintained.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Imcivree (setmelanotide) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
09/24/2021	New policy created for Imcivree.

References:

1. Imcivree. (prescribing information). Rhythm Pharmaceuticals, Inc.; 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. doi:10.1016/S2213-8587(20)30364-8

Effective date: 04/01/2022
Revised date: 09/24/2021