Setmelanotide (Imcivree)

Coverage Criteria:

1. Prescribed by an endocrinologist or genetic specialist; and,
2. Patient has been diagnosed with Bardet-Biedl syndrome, or at least one of the following pathogenic genetic deficiencies, confirmed with genetic testing, and documented in the medical record:
    a. Proopiomelanocortin (POMC); or
    b. Proprotein convertase subtilisin/kexin type I (PCSK1); or
    c. Leptin receptor (LEPR); and,
3. Patient has a body mass index (BMI) ≥ 30 kg/m2 (for patients at least 18 years of age) OR, obesity with weight > 97th percentile for age on growth chart assessment (for patients 17 years of age and younger); and,
4. Documentation of adequate liver and renal function has been submitted. Adequate hepatic function is as defined as ALT, AST, alkaline phosphatase, serum bilirubin < 2 times the upper limit of normal for age range. Adequate renal function is defined as a creatinine clearance > 30 mL/min; and,
5. Documented patient weight; and,
6. Imcivree is being prescribed up to the FDA-approved dosing regimen.

Coverage Duration:
Initial authorizations will be approved for 3 months.
Re-authorizations will be for 6 months.

Renewal Criteria:

1. Patient has been seen within the past 14 months by the specialist; and,
2. Confirmation patient has lost and maintained at least 5% of baseline body weight or 5% of baseline BMI for those patients with continued growth potential.

Definitions
Baseline weight or BMI: patient body weight or BMI at time of starting treatment with Imcivree

P&T Date: 4/5/2021
Effective Date: 7/1/2021, Updated 10/1/2022, 2/1/2024