

Clinical Oversight Review Board (CORB) Criteria for Prescribing/ Criteria-Based Consultation (CBC) Criteria for Coverage

Setmelanotide (Imcivree)

Notes:

- Must be ordered from outside specialty pharmacy

Non-Formulary **setmelanotide (Imrivree)** requires a clinical review. Appropriateness of therapy will be based on the following criteria:

Initiation (new start) criteria and criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously:

Non-formulary **setmelanotide (Imcivree)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Prescribed by a pediatric endocrinology or bariatrics provider
-AND-
- Age 6 years or older
-AND-
- Obesity due to Proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency confirmed by genetic testing demonstrating variants in *POMC*, *PCSK1*, or *LEPR* genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS). If VUS must be deemed highly suspicious by a medical geneticist
-OR-
- Bardet-Biedl syndrome with documented disease-causing mutation confirmed by genetic testing or highly suspected based on review and evaluation by a medical geneticist
-AND-
- Patient has been reviewed by the Kaiser Permanente Interregional Consultative Physician Panel, with recommendation to use medication

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Continued use criteria:

Non-formulary **setmelanotide (Imcivree)** will continue to be covered on the prescription drug benefit when the following criteria are met:

For POMC, PCSK1, or LEPR deficiency:

- Patient's updated weight and BMI are recently documented; AND
- Patient has lost at least 5% of baseline body weight or 5% baseline BMI for patients less than 18 years of age with the past 16 weeks from initiation (reviewed once); OR maintains at least 5% loss thereafter (reviewed every 12 months)

For Bardet-Beidl Syndrome:

- Patient's updated weight and BMI are recently documented; AND
- Patient has lost at least 5% of baseline body weight or 5% baseline BMI for patients less than 18 years of age with the past 12 months from initiation (reviewed once); OR maintains at least 5% loss thereafter (reviewed every 12 months)