

POLICY NAME	Imcivree (setmelanotide)	POLICY #	3050P
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Criteria

Coverage Criteria

- ☐ **1.1** Diagnosis of obesity (defined as body mass index (BMI) ≥ 30 in adults or as BMI ≥ 95 th percentile using growth chart assessments) related to one of the following:
 - Bardet-Biedl syndrome
 - Proopiomelanocortin (POMC), Proprotein convertase subtilisin/kexin type 1 (PCSK1) or Leptin receptor (LEPR) deficiency as determined by genetic testing o Documentation of genetic testing demonstrating that the variants in POMC, PCSK1, or LEPR genes are interpreted as pathogenic, likely pathogenic, or of uncertain significance
- ☐ **1.2** Member is 6 years or older
- ☐ **1.3** Review for coverage is completed by a pharmacist and medical director

Exclusion Criteria – Any of the following prevents coverage

- ☐ **2.1** Creatinine Clearance (CrCl) < 30 ml/min
 - Measure of kidney function
- ☐ **2.2** Prior gastric bypass surgery resulting in $>10\%$ weight loss that was maintained
- ☐ **2.3** Other types of obesity or obesity due to suspected POMC, PCSK1, or LEPR deficiency with POMC, PCSK1, or LEPR variants classified as benign or likely benign