| Effective Date: 06/01/2021 |
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| Reviewed: 03/2021, 02/2022<br>Scope: Medicaid |

# Imcivree (setmelanotide)

## POLICY

### I. CRITERIA FOR APPROVAL

An authorization of 6 months may be granted when all the following criteria are met:

A. Patient is 6 years or older; AND
B. Patient has documented diagnosis of obesity, defined as:
    a. Adult patients: BMI of $\geq$30kg/m$^2$
    b. Pediatric patients: $\geq$ 95$^{th}$ percentile using growth chart assessments; AND
C. Obesity is due to a homozygous or compound heterozygous variants in at least one of the following genes, confirmed by genetic testing:
    a. Proopiomelanocortin (POMC)
    b. Proprotein convertase subtilisin/kexin type 1 (PCSK1)
    c. Leptin receptor (LEPR); AND
D. Documentation of genetic testing is provided and confirms that variants of POMC, PCSK1, or LEPR genes are interpreted as pathogenic, likely pathogenic, or of uncertain significance; AND
E. Patient has a CrCl $\geq$30mL/min; AND
F. Patient has not undergone prior bariatric surgery resulting in >10% weight loss that was maintained

### II. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for all members who are tolerating treatment and have documentation of a positive clinical response, as evidenced by:

A. 5% reduction in baseline body weight; OR
B. 5% reduction in baseline BMI for patients with continued growth potential

### III. QUANTITY LIMIT

- 10 vials (10mg/mL) per 30 days

### IV. COVERAGE DURATION

- Initial: 6 months
- Continuation: 6 months