Pharmacy Drug Policy & Procedure

Policy Name:	Imcivree (setmelanotide)	Policy #:	3050P

Purpose of the Policy

The purpose of this policy is to establish the coverage of Imcivree.

Statement of the Policy

Health Alliance Medical Plans will approve the use of Imcivree under the Pharmacy benefit when the following criteria have been met.

Criteria

1. Coverage Criteria

1.1 Diagnosis of obesity (defined as body mass index (BMI) ≥ 30 in adults or as BMI ≥ 95th 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
  - 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

2. Exclusion Criteria

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

3. Approval Period

3.1 Initial: 12 months

3.2 Subsequent Approvals: 12 months with documentation of improved or stable disease

CPT Codes

HCPCS Codes

References

1. Imcivree (setmelanotide) [prescribing information]. Boston, MA; Rhythm Pharmaceuticals Inc; November 2023.
2. Acosta A, Streett S, Kroh MD, et al. AGA: POWER — Practice Guide on Obesity and Weight Management, Education, and Resources. Am Gastroentero Assoc. 24 Feb 2017; 15 (5); 631-649.
3. Wharton S, Lau DCW, Vallis M, et al. Obesity in adults: a clinical practice guideline. CMAJ. 2020;192(31):E875-E891.
4. Hampl SE, Hassink SG, Skinner AC, et al. Clinical Practice Guideline for the Evaluation and Treatment of Children and Adolescents With Obesity. Pediatrics. 2023 Feb 1;151(2):e2022060640.

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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.