Drug Quantity Management – Per Days
Metabolic Disorders – Imcivree

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Product Identifier(s)

Effective 1/1/23 to 2/6/23: 108633

Effective 2/7/23: 92632

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

National Formulary Medical Necessity

Drugs Affected

- Imcivree™ (setmelanotide subcutaneous injection)

This Drug Quantity Management program has been developed to manage potential dose escalation with Imcivree. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below.

Drug Quantity Limits

Product	Strength and Form	Maximum Quantity per 30 Days
Imcivree™ (setmelanotide subcutaneous injection)	10 mg/1 mL vial	6 vials (6 mL)*

* This provides a sufficient quantity for a 30-day supply at a 2 mg/day dose.

Cigna covers quantities as medically necessary when the following criteria are met:
All approvals are provided for 1 year in duration.

1. If the individual requires a maintenance dose of 3 mg once daily, approve up to nine vials (9 mL) per 30 days.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

Overview
Imcivree, a melanocortin 4 receptor agonist, is indicated for chronic weight management in patients ≥ 6 years of age with **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.[1]

Dosing
Patient ≥ 12 years of age:
- The starting dose is 2 mg (0.2 mL) injected subcutaneously once daily (QD) for 2 weeks. Monitor patients for gastrointestinal (GI) adverse reactions.
- If the starting dose is not tolerated, reduce to 1 mg (0.1 mL) QD. If the 1 mg dose is tolerated and additional weight loss is desired, titrate to 2 mg (0.2 mL) QD.
- If the 2 mg daily dose is tolerated, increase the dose to 3 mg (0.3 mL) QD. If the 3 mg dose is not tolerated, maintain administration of 2 mg (0.2 mL) QD.

Patient 6 to < 12 years of age:
- The starting dose is 1 mg (0.1 mL) injected subcutaneously QD for 2 weeks. Monitor patients for GI adverse reactions.
- If the starting dose is not tolerated, reduce to 0.5 mg (0.05 mL) QD dose. If the 0.5 mg dose is tolerated and additional weight loss is desired, titrate to 1 mg (0.1 mL) once daily.
- If the 1 mg dose is tolerated, increase the dose to 2 mg (0.2 mL) QD.
- If the 2 mg QD dose is not tolerated, reduce to 1 mg (0.1 mL) QD. If the 2 mg dose is tolerated and additional weight loss is desired, the dose may be increased to 3 mg (0.3 mL) QD.

Availability
Imcivree is available as 10 mg/1 mL multi-dose vials.[1]

References

1. Imcivree [prescribing information]. Boston, MA: Rhythm Pharmaceuticals, Inc., November 2020.

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	**Criteria:** The criterion regarding 3 mg daily dosing was clarified to reword "if the patient is increasing their daily dose from 2 mg to 3 mg" to "if the patient requires a maintenance dose of 3 mg once daily".	03/09/2022