

DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Metabolic Disorders – Imcivree Drug Quantity Management Policy – Per Days

- Imcivree® (setmelanotide subcutaneous injection – Rhythm)

REVIEW DATE: 01/30/2023

OVERVIEW

Imcivree, a melanocortin 4 receptor agonist, is indicated for chronic weight management in patients ≥ 6 years of age with obesity due to:¹

- **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.
- **Bardet-Biedl Syndrome.**

Dosing

Patient ≥ 12 years of age:

- The starting dose is 2 mg (0.2 mL) injected subcutaneously (SC) 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 for at least 1 week, increase the dose to 2 mg (0.2 mL) QD.
- If the 2 mg dose is tolerated for 2 weeks, 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) SC 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. If the 0.5 mg dose is tolerated for at least 1 week, increase the dose to 1 mg (0.1 mL) once daily.
- If the 1 mg dose is tolerated for at least 2 weeks, 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, 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

POLICY STATEMENT

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. All approvals are provided for 1 year in duration.

Automation: None.

Drug Quantity Limits

Product	Strength and Form	Retail	Home Delivery
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		Maximum Quantity per 30 Days	Maximum Quantity per 90 Days
Imcivree® (setmelanotide subcutaneous injection)	10 mg/1 mL vial	6 vials (6 mL)*	18 vials (18 mL)*

*This provides a sufficient quantity for a 2 mg/day dose for 30 days at retail or 90 days at home delivery.

CRITERIA

1. If the patient requires a maintenance dose of 3 mg once daily, approve the requested quantity, not to exceed 9 vials (9 mL) per 30 days at retail or 27 vials (27 mL) per 90 days at home delivery.

REFERENCES

1. Imcivree® subcutaneous injection [prescribing information]. Boston, MA: Rhythm; June 2022.