DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Metabolic Disorders – Imcivree Drug Quantity Management Policy – Per Days
- Imcivree® (setmelanotide subcutaneous injection – Rhythm)

REVIEW DATE: 02/07/2024

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. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Imcivree, a melanocortin 4 receptor agonist, is indicated for chronic weight management in patients ≥ 6 years of age with monogenic or syndromic 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.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per 30 Days	Home Delivery 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.

Metabolic Disorders – Imcivree Drug Quantity Management Policy – Per Days product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

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; November 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery.	01/30/2023
Annual Revision	No criteria changes.	02/07/2024