# DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

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

**REVIEW DATE:** 02/05/2025

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***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 ≥ 2 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.
- The recommended maintenance dosage is 3 mg (0.3 mL) injected SC 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) QD.
- 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.
- The recommended maintenance dosage is 3 mg (0.3 mL) injected SC QD.

Patients 2 to < 6 years of age:
- The starting dose is 0.5 mg (0.05 mL) SC QD for 2 weeks. Monitor patients for GI adverse reactions.
- If the starting dose is not tolerated, discontinue the product.
- If the 0.5 mg dose is tolerated for at least 2 weeks, increase the dose based on body weight as presented in Table 1.

**Table 1: Recommended Maintenance Dosage Based on Baseline Body Weight in Patients 2 to < 6 years of age.[1]**

| Patient Weight/Treatment Week | Daily Dose | Volume to be Injected |
|---|---|---|
| 15 kg to < 20 kg | | |
| Week 1 and onward | 0.5 mg QD | 0.05 mL QD |
| 20 kg to < 30 kg | | |
| Week 1-2 | 0.5 mg QD | 0.05 mL QD |
| Week 3 and onward | 1 mg QD | 0.1 mL QD |
| 30 kg to < 40 kg | | |
| Week 1-2 | 0.5 mg QD | 0.05 mL QD |
| Week 3-4 | 1 mg QD | 0.1 mL QD |
| Week 5 and onward | 1.5 mg QD | 0.15 mL QD |
| ≥ 40 kg | | |
| Weeks 1-2 | 0.5 mg QD | 0.05 mL QD |
| Weeks 3-4 | 1 mg QD | 0.1 mL QD |
| Weeks 5-6 | 1.5 mg QD | 0.15 mL QD |
| Weeks 7 and onward | 2 mg QD | 0.2 mL QD |

QD – Once daily.

## 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 | 9 mL (9 vials)* | 27 mL (27 vials)* |

* This provides a sufficient quantity for a 3 mg once daily 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.** No overrides recommended.

## REFERENCES

1. Imcivree® subcutaneous injection [prescribing information]. Boston, MA: Rhythm; December 2024.

## 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 |
| Annual Revision | **Imcivree 10 mg/1 mL vials:** Quantity limits were changed to 9 mL (9 vials) per 28 days at retail and 27 mL (27 vials) per 84 days at home delivery. Previously, the limits were 6 mL (6 vials) per 28 days at retail and 18 mL (18 vials) per 84 days at home delivery. Override criteria were removed. No overrides apply to the updated quantity limits. | 02/05/2025 |