



DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Multiple Sclerosis – Ponvory Drug Quantity Management Policy – Per Days

- Ponvory® (ponesimod tablets – Janssen)

REVIEW DATE: 05/02/2025

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 WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. 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

Ponvory, a sphingosine 1-phosphate receptor modulator, is indicated for the treatment of patients with relapsing forms of **multiple sclerosis**, including clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease in adults.¹

Dosing

The recommended maintenance dose of Ponvory is 20 mg once daily (QD) after initial titration is complete (maintenance dosing starts on Day 15).¹

For treatment initiation, a starter pack must be used.¹ Ponvory is initiated with a 14-day titration starting with 2 mg QD with increasing doses (Table 1).

Table 1. Ponvory Initial Dose Titration.¹

Titration Day(s)	Dose
1 and 2	2 mg
3 and 4	3 mg
5 and 6	4 mg
7	5 mg
8	6 mg
9	7 mg
10	8 mg
11	9 mg
12, 13, and 14	10 mg

Interruption during treatment, especially during titration is not recommended.¹ However, if dose titration is interrupted, missed dose instructions must be followed as outlined below:

- If fewer than 4 consecutive doses are missed:
 - **During titration:** resume treatment with the first missed titration dose and resume the titration schedule at that dose and titration day.
 - **During maintenance:** resume treatment with the maintenance dosage.
- If 4 or more consecutive doses are missed during titration or maintenance:
 - Treatment should be reinitiated with Day 1 of the titration regimen (new starter pack).

Availability

Ponvory is available as a 20 mg tablet in bottles of 30 tablets.¹ Ponvory is also available as a 14-day starter pack to accommodate the initial titration schedule containing 14 tablets in the following strengths: 2 x 2 mg tablets; 2 x 3 mg tablets; 2 x 4 mg tablets; 1 each of 5 mg, 6 mg, 7 mg, 8 mg, 9 mg tablets; 3 x 10 mg tablets.

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Ponvory. 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 the duration noted below. "One-time" overrides are provided for 30 days in duration.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per Days	Home Delivery Maximum Quantity per Days
Ponvory® (ponesimod tablets)	20 mg tablets	30 tablets per 30 days	90 tablets per 90 days
	Starter pack: 14 tablets (2 x 2 mg, 2 x 3 mg, 2 x 4 mg, 1 x 5 mg, 1 x 6 mg)	14 tablets (1 starter pack) per 365 days	

	mg, 1 x 7 mg, 1 x 8 mg, 1 x 9 mg, and 3 x 10 mg)	
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EXCEPTIONS TO THE QUANTITY LIMITS LISTED ABOVE ARE COVERED AS MEDICALLY NECESSARY WHEN THE FOLLOWING CRITERIA ARE MET. ANY OTHER EXCEPTION IS CONSIDERED NOT MEDICALLY NECESSARY.

CRITERIA

Ponvory 20 mg

No overrides recommended.

Ponvory Starter Pack

1. If the patient has missed four or more consecutive doses of Ponvory, approve a one-time override for one additional Starter Pack (14 tablets) at retail or home delivery.

REFERENCES

1. Ponvory® tablets [prescribing information]. Titusville, NJ: Janssen; June 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery. No criteria changes.	05/18/2023
Annual Revision	No criteria changes.	05/15/2024
Annual Revision	Policy Statement was updated to clarify that "one-time" overrides are provided for 30 days in duration.	05/02/2025

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