Cigna National Formulary Coverage Policy

Drug Quantity Management – Per Days
Multiple Sclerosis – Ponvory™ (ponesimod tablets)

Table of Contents

Product Identifier(s)

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

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.

Drug Quantity Limits

Product	Strength and Form	Maximum Quantity per Day
Ponvory® (ponesimod tablets)	20 mg	30 tablets per 30 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, 1 x 7 mg, 1 x 8 mg, 1 x 9 mg, and 3 x 10 mg)	14 tablets (1 starter pack) per 365 days

Cigna covers quantities as medically necessary when the following criteria are met:

Ponvory Starter Pack
1. If the individual has missed <u>four or more</u> consecutive doses of Ponvory, approve a one-time override for one Starter Pack (14 tablets).

Ponvory 20 mg
No overrides recommended.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

Overview
Ponvory, a sphingosine 1-phosphate receptor modulator, is indicated for the treatment of patients with relapsing forms of **multiple sclerosis**, to include 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.

References

1. Ponvory™ tablets [prescribing information]. Titusville, NJ: Janssen; April 2021.

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	Policy name was updated to "Per Days" (previously Per Rx) to reflect how the policy was intended to be operationalized. Per Rx limits for Ponvory 20 mg tablets (30 tablets per Rx) and the starter pack (14 tablets per Rx) were removed from the policy (previously no overrides). Per Days limits were already in the policy. **Ponvory Starter Pack**: Override criteria were revised to approve a one-time override for patients who have missed four or more consecutive doses of Ponvory. Previously, criteria were written to allow a one-time override for patients who had missed four or more consecutive doses "during titration or maintenance dosing" and for whom "treatment is being reinitiated with Day 1 of the titration regimen".	05/18/2022