DRUG QUANTITY MANAGEMENT POLICY - PER DAYS

POLICY: Multiple Sclerosis – Ponvory Drug Quantity Management Policy – Per Days
Ponvory[™] (ponesimod tablets – Janssen)

REVIEW DATE: 05/18/2022

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. Follyory Initial Dose Titration.		
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	

Table 1. Ponvory Initial Dose Titration.¹

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 <u>fewer than 4</u> 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: 2×2 mg tablets; 2×3 mg tablets; 2×4 mg tablets; 1 each of 5 mg, 6 mg, 7 mg, 8 mg, 9 mg tablets; 3×10 mg tablets.

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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.

Automation: None.

Drug Quantity Limits

Product	Strength and Form	Maximum Quantity per Day
Ponvory®	20 mg	30 tablets per 30 days
(ponesimod tablets)	Starter pack: 14 tablets (2 x 2 mg, 2 x 3 mg, 2 x 4 mg, 1 x 5	14 tablets (1 starter pack) per 365
	mg, 1 x 6 mg, 1 x 7 mg, 1 x 8 mg, 1 x 9 mg, and 3 x 10 mg)	days

CRITERIA

Ponvory Starter Pack

1. If the patient 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.

REFERENCES

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