

**PONVORY
(ponesimod)**

Pre - PA Allowance

None

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Relapsing Multiple Sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease

AND ALL of the following:

1. Baseline evaluations of **ALL** of the following have been done or will be done prior to starting therapy with Ponvory:
 - a. Complete blood count (CBC), including lymphocyte count
 - b. Electrocardiogram (ECG)
 - c. Liver function tests (LFTs)
2. Heart rate \geq 50 bpm
3. Patients with sinus bradycardia (heart rate <55 bpm), first- or second-degree (Mobitz type I) AV block, or a history of myocardial infarction or heart failure occurring more than 6 months prior to treatment initiation and in stable condition **ONLY**: will be observed for 4 hours after the first dose for signs and symptoms of bradycardia with hourly pulse and blood pressure measurements and an ECG prior to dosing and at the end of the observation period
4. Patients with a history of uveitis and/or diabetes **ONLY**: will have an ophthalmic evaluation of the fundus, including the macula, prior to initiation of therapy
5. Female patients of reproductive potential **ONLY**: will be advised to use effective contraception during treatment with Ponvory and for 1 week after the last dose
6. **NO** history (within the last 6 months) of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure
7. **NO** presence of Mobitz Type II 2nd degree or 3rd degree AV block, sick sinus syndrome, or sino-atrial block, unless patient has a pacemaker



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8. **NO** significant QTc prolongation (QTcF >450 msec in males, >470 msec in females)
9. **NO** severe untreated sleep apnea
10. **NO** concurrent use with other MS disease modifying agents
11. **NOT** given concurrently with live vaccines
12. Patient **MUST** have tried **TWO** of the preferred MS medications (see Appendix 1) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

Prior - Approval Limits

Quantity 1 fourteen-day starter pack (14 tablet titration pack)
AND
90 tablets per 90 days

Duration 12 months

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Relapsing Multiple Sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease

AND ALL of the following:

1. Heart rate \geq 50 bpm
2. Female patients of reproductive potential **ONLY**: will be advised to use effective contraception during treatment with Ponvory and for 1 week after the last dose
3. **NO** history (within the last 6 months) of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure.
4. **NO** presence of Mobitz Type II 2nd degree or 3rd degree AV block, sick sinus syndrome, or sino-atrial block, unless patient has a pacemaker
5. **NO** significant QTc prolongation (QTcF >450 msec in males, >470 msec in females)
6. **NO** severe untreated sleep apnea

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7. **NO** concurrent use with other MS disease modifying agents
8. **NOT** given concurrently with live vaccines
9. Patient **MUST** have tried **TWO** of the preferred MS medications (see Appendix 1) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

Prior - Approval *Renewal* Limits

Quantity 90 tablets per 90 days

Duration 12 months

Appendix 1 - List of Preferred Multiple Sclerosis (MS) Medications

Medication Name	Route of Administration
Aubagio	Oral**
dimethyl fumarate (generic Tecfidera)	Oral**
fingolimod (generic Gilenya)	Oral**
Mayzent	Oral**
Zeposia	Oral**

** indicates separate criteria will need to be met

Medication Name	Route of Administration
Avonex	Injectable
Betaseron	Injectable
glatiramer acetate (generic Copaxone)	Injectable
Glatopa	Injectable
Plegridy	Injectable
Rebif	Injectable