



Once you have decided to prescribe PONVORY[™],
Get your patients started in 2 simple steps with Janssen CarePath

1

**Fill out the Prescription
Enrollment Form (PEF)**

Fax your completed form to
Janssen CarePath at 833-200-6306.

2

**Confirm assessments
are completed**

Janssen CarePath can help make it simple for you to help your patients.

Janssen CarePath is your one source for access, affordability, and treatment support for your patients.

Janssen CarePath helps verify insurance coverage for your patients, provides reimbursement information, helps find financial assistance options for eligible patients, and provides ongoing support to help patients start and stay on PONVORY[™] which you prescribed.

Start and Stay on Treatment with Support from Janssen CarePath

For patients using commercial or private health insurance

Get Started

Janssen CarePath Trial Offer for PONVORY™

Free 14-day Starter Pack and 30-day maintenance supply for eligible patients

The Trial Offer helps patients become familiar with PONVORY™. At the end of the program, you and your patient decide whether to continue treatment. To be eligible, a patient must have been prescribed PONVORY™ and be 18 years of age or older. One (1) use is allowed per lifetime.

This trial program is open to patients who have commercial insurance, government coverage, or no insurance coverage. However, there is no guarantee of continuous accessibility after the program ends. Terms expire at the end of each calendar year and may change.

Before Starting Treatment

In-Home Pretest Program

Eligible patients with commercial insurance can receive **in-home pretesting at no cost** for recommended blood tests (Complete Blood Count including lymphocyte count, Liver Function Tests, Varicella Zoster Virus antibody serology), electrocardiogram (ECG), and ophthalmic evaluation (of the fundus, including the macula) before starting treatment with PONVORY™.

The In-Home Pretest Program is only for pretests needed before the first time your patient starts treatment with PONVORY™.

Not valid for patients with Medicare, Medicaid, or other government-funded programs for medical insurance coverage. The ophthalmic evaluation is only available in select areas.

Terms expire at the end of each calendar year and may change. Not valid for residents of MA, MI, MN, or RI. There is no income requirement. See full program requirements at JanssenCarePath.com.

Janssen CarePath Pretest Rebate Program

Eligible patients can save on out-of-pocket costs for required pretests and/or first dose monitoring when starting treatment with PONVORY™.

Patients can review full program requirements at JanssenCarePath.com/Ponvory-Pretest.

Not valid for patients using Medicare, Medicaid, or other government-funded programs to pay for their pretests or first dose monitoring.

Stay Supported

Janssen CarePath Savings Program

Eligible patients pay \$0 per prescription fill with an \$18,000 maximum program benefit per calendar year.

Not valid for patients using Medicare, Medicaid, or other government-funded programs to pay for their Janssen medication. Terms expire at the end of each calendar year and may change. See program requirements at Ponvory.com.
[JanssenCarePath Savings.com](http://JanssenCarePath.com/Savings.com).

Janssen Link for PONVORY™

When commercial insurance coverage is delayed (>5 business days) or denied, eligible patients will receive PONVORY™ **at no cost** until they receive insurance coverage approval or for up to 24 months from program enrollment, whichever comes first.

Patients using any state or federal government-funded healthcare program, such as Medicare, Medicaid, TRICARE, Department of Defense, or Veterans Administration, are not eligible. Program terms may change. See program requirements at JanssenCarePath.com/Ponvory/Janssen-Link.

Here for the MS Journey

The Wellness Companion Program* by Janssen CarePath provides patients with one-on-one education to help them get started and continue treatment with PONVORY™. The Wellness Companion can connect patients with resources to partner with their healthcare professional during their treatment journey with relapsing multiple sclerosis (MS).

Enrolled patients will be contacted by a dedicated Wellness Companion for support during the treatment onboarding process.

*The Wellness Companion Program is limited to education for patients about their Janssen therapy, its administration, and/or their disease. It is intended to supplement a patient's understanding of their therapy. It does not provide medical advice, health coaching or improved wellness as a result of engaging with the program, replace a treatment plan from the patient's doctor or nurse, provide case management services, or serve as a reason to prescribe.

Step 1: Fill Out Prescription Enrollment Form

Complete one easy form to:

- Request a benefits investigation
- Enroll your eligible patients in the Trial Offer for PONVORY[™]
- Enroll your eligible patients in Janssen Link for PONVORY[™]
- Request pretest scheduling support*
- Enroll in Prior Authorization Form Assistance and Status Monitoring



← Your one signature allows this form to serve as the prescription

Fax your completed form to
Janssen CarePath at 833-200-6306.

Your patient only needs to provide one signature to enroll in the full range of Janssen Patient Support Programs, including:

- Wellness Companion Program to receive support throughout the treatment onboarding process
- Benefits investigation completed by Janssen CarePath

*Coordination support includes a benefits investigation for required pretests and scheduling support for appointments with the providers identified by you and your patient.



Easy Tips for Using This Form

- Download an electronic version of the Prescription Enrollment Form
- Pre-populate the required information as appropriate (eg, your office information)
- Save the pre-populated form to your desktop to use with new patients!

[View Enrollment Form](#)



If your patient is not in the office with you, they can visit MyJanssenCarePath.com/PatientAuth to electronically sign the Patient Authorization form.

Step 2: Confirm assessments are completed

[View Pretest Attestation Form](#)

Before initiation of treatment with PONVORY[™], assess the following based on individual patient needs

- Complete blood count
- Cardiac evaluation
- Liver function tests
- Ophthalmic evaluation
- Current or prior medications with immune system effects
- Vaccinations

Once the assessments are completed, you or an authorized representative can confirm your patient is ready to start treatment with PONVORY by:

1. Calling Janssen CarePath (877-227-3728)
2. Completing the Pretest Attestation Form



Fax your completed form to Janssen CarePath at 833-200-6306

Completing this step allows your patient to receive their shipment of PONVORY[™] from Janssen CarePath



If assessments are completed through the In-Home Pretest Program, test results will be faxed directly to the prescriber along with the Pretest Attestation Form to be completed



If assessments are completed at the time of prescribing, **you can provide this confirmation in Step 1**, on the Prescription Enrollment Form, instead of the Pretest Attestation Form.

If you are using your patient's preferred specialty pharmacy, please remember that the Trial Offer for PONVORY[™] and Janssen Link for PONVORY[™] programs are only available through Janssen CarePath, and you can get your patients started by completing Step 1, filling out the Prescription Enrollment Form.

INDICATION

PONVORY™ is a sphingosine 1-phosphate receptor modulator indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

PONVORY™ is contraindicated in patients who:

- In the last 6 months experienced myocardial infarction, unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure requiring hospitalization, or Class III or IV heart failure.
- Have presence of Mobitz Type II second-degree, third-degree atrioventricular (AV) block, or sick sinus syndrome, or sino-atrial block, unless patient has a functioning pacemaker.

WARNINGS AND PRECAUTIONS

Risk of Infections

PONVORY™ causes a dose-dependent reduction in peripheral lymphocyte count to 30–40% of baseline values because of reversible sequestration of lymphocytes in lymphoid tissues. PONVORY™ may increase the susceptibility to infections. Life-threatening and rare fatal infections have been reported in association with other sphingosine 1-phosphate (S1P) receptor modulators. Before initiating treatment with PONVORY™, results from a recent complete blood count including lymphocyte count should be reviewed.

Herpes Viral Infections

Cases of herpes viral infection have been reported in the development program of PONVORY™; herpes simplex encephalitis and varicella zoster meningitis have been reported with other S1P receptor modulators. Patients without a healthcare professional confirmed history of varicella (chickenpox) or without documentation of a full course of vaccination should be tested for antibodies to VZV prior to initiating PONVORY™.

Cryptococcal Infections

Cases of fatal cryptococcal meningitis (CM) and disseminated cryptococcal infections have been reported with other S1P receptor modulators. Physicians should be vigilant for clinical symptoms or signs of CM. Patients with symptoms or signs consistent with a cryptococcal infection should undergo prompt diagnostic evaluation and treatment. PONVORY™ treatment should be suspended until a cryptococcal infection has been excluded. If CM is diagnosed, appropriate treatment should be initiated.

Progressive Multifocal Leukoencephalopathy (PML)

PML has been reported in patients treated with a S1P receptor modulator and other multiple sclerosis (MS) therapies and has been associated with some risk factors (e.g., immunocompromised patients, polytherapy with immunosuppressants). Physicians should be vigilant for clinical symptoms or magnetic resonance imaging (MRI) findings that may be suggestive of PML. MRI findings may be apparent before clinical signs or symptoms. If PML is suspected, treatment with PONVORY™ should be suspended until PML has been excluded.

If PML is confirmed, treatment with PONVORY™ should be discontinued.

Prior and Concomitant Treatment with Anti-neoplastic, Immune-Modulating, or Immunosuppressive Therapies

Anti-neoplastic, immune-modulating, or immunosuppressive therapies (including corticosteroids) should be co-administered with caution because of the risk of additive immune system effects.

Vaccinations

Patients without a confirmed history of chickenpox or without documentation of a full course of vaccination against VZV should be tested for antibodies to VZV before initiating PONVORY™ treatment. A full course of vaccination for antibody-negative patients with varicella vaccine is recommended prior to commencing treatment with PONVORY™, following which initiation of treatment should be postponed for 4 weeks to allow the full effect of vaccination to occur.

No clinical data are available on the efficacy and safety of vaccinations in patients taking PONVORY™. Vaccinations may be less effective if administered during PONVORY™ treatment. If live *attenuated* vaccines are required, administer at least 1 month prior to initiation of PONVORY™. Avoid the use of live *attenuated* vaccines during and for 1 to 2 weeks after treatment of PONVORY™.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Bradycardia and Atrioventricular Conduction Delays

Since initiation of PONVORY™ treatment results in a transient decrease in heart rate and atrioventricular (AV) conduction delays, an up-titration scheme must be used to reach the maintenance dosage of PONVORY™ (20 mg).

Reduction in Heart Rate

Initiation of PONVORY™ may result in a transient decrease in heart rate. After the first titration dose of PONVORY™, the decrease in heart rate typically begins within an hour and reaches its nadir within 2–4 hours. The heart rate typically recovers to baseline levels 4–5 hours after administration.

Atrioventricular Conduction Delays

Initiation of PONVORY™ treatment has been associated with transient atrioventricular conduction delays that follow a similar temporal pattern as the observed decrease in heart rate during dose titration. If treatment with PONVORY™ is considered, advice from a cardiologist should be sought for individuals:

- With significant QT prolongation (QTc greater than 500 msec).
- With atrial flutter/fibrillation or arrhythmia treated with Class Ia or Class III anti-arrhythmic drugs.
- With unstable ischemic heart disease, cardiac decompensated failure occurring more than 6 months prior to treatment initiation, history of cardiac arrest, cerebrovascular disease (TIA, stroke occurring more than 6 months prior to treatment initiation), or uncontrolled hypertension.
- With a history of Mobitz Type II second degree AV block or higher-grade AV block, sick-sinus syndrome, or sino-atrial heart block.

Obtain an ECG in all patients to determine whether preexisting conduction abnormalities are present. For patients taking other drugs that decrease heart rate, treatment with PONVORY™ should generally not be initiated without consultation from a cardiologist because of the potential effect on heart rate. In all patients, a dose titration is recommended for initiation of PONVORY™ treatment to help reduce cardiac effects.

Respiratory Effects

Dose dependent reductions in forced expiratory volume over 1 second (FEV₁) and reductions in diffusion lung capacity for carbon monoxide (DL_{CO}) were observed in PONVORY™-treated patients mostly occurring in the first month after treatment initiation. Spirometric evaluation of respiratory function should be performed during therapy with PONVORY™ if clinically indicated.

Liver Injury

Elevations of transaminases may occur in PONVORY™-treated patients. Obtain transaminase and bilirubin levels, if not recently available (i.e., within last 6 months) before initiation of PONVORY™ therapy.

Patients who develop symptoms suggestive of hepatic dysfunction, such as unexplained nausea, vomiting, abdominal pain, fatigue, anorexia, rash with eosinophilia, or jaundice and/or dark urine during treatment, should have hepatic enzymes checked. PONVORY™ should be discontinued if significant liver injury is confirmed.

No dosage adjustment is necessary in patients with mild hepatic impairment (Child-Pugh class A). PONVORY™ is not recommended in patients with moderate or severe hepatic impairment (Child-Pugh class B and C, respectively).

Increased Blood Pressure

PONVORY™-treated patients had an average increase of 2.9 mmHg in systolic blood pressure and 2.8 mmHg in diastolic blood pressure. Blood pressure should be monitored during treatment with PONVORY™ and managed appropriately.

Cutaneous Malignancies

Cases of basal cell carcinoma and other skin malignancies have been reported in patients treated with SIP receptor modulators, including PONVORY™. Periodic skin examination is recommended for all patients, particularly those with risk factors for skin cancer. Providers and patients are advised to monitor for suspicious skin lesions. If a suspicious skin lesion is observed, it should be promptly evaluated. As usual for patients with increased risk for skin cancer, exposure to sunlight and ultraviolet light should be limited by wearing protective clothing and using a sunscreen with a high protection factor. Concomitant phototherapy with UV-B radiation or PUVA-phototherapy is not recommended in patients taking PONVORY™.

Fetal Risk

Based on animal studies, PONVORY™ may cause fetal harm. Because it takes approximately 1 week to eliminate PONVORY™ from the body, women of childbearing potential should use effective contraception to avoid pregnancy during and for 1 week after stopping PONVORY™ treatment.

Macular Edema

SIP receptor modulators, including PONVORY™, have been associated with an increased risk of macular edema. An ophthalmic evaluation of the fundus, including the macula, is recommended in all patients before starting treatment and again at any time if a patient reports any change in vision while on PONVORY™ therapy. Continuation of therapy in patients with macular edema has not been evaluated.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Macular Edema in Patients with a History of Uveitis or Diabetes Mellitus

Patients with a history of uveitis and patients with diabetes mellitus are at increased risk of macular edema during therapy with SIP receptor modulators, including PONVORY™. Therefore, these patients should have regular follow-up examinations of the fundus, including the macula, during treatment with PONVORY™.

Posterior Reversible Encephalopathy Syndrome

Rare cases of posterior reversible encephalopathy syndrome (PRES) have been reported in patients receiving a sphingosine 1-phosphate (SIP) receptor modulator. Such events have not been reported for PONVORY™-treated patients in the development program. However, should a PONVORY™-treated patient develop any unexpected neurological or psychiatric symptoms/signs (e.g., cognitive deficits, behavioral changes, cortical visual disturbances, or any other neurological cortical symptoms/signs), any symptom/sign suggestive of an increase of intracranial pressure, or accelerated neurological deterioration, the physician should promptly schedule a complete physical and neurological examination and should consider an MRI. Symptoms of PRES are usually reversible but may evolve into ischemic stroke or cerebral hemorrhage. Delay in diagnosis and treatment may lead to permanent neurological sequelae. If PRES is suspected, PONVORY™ should be discontinued.

Unintended Additive Immunosuppressive Effects from Prior Treatment with Immunosuppressive or Immune-Modulating Therapies

When switching from drugs with prolonged immune effects, the half-life and mode of action of these drugs must be considered in order to avoid unintended additive effects on the immune system while at the same time minimizing risk of disease reactivation, when initiating PONVORY™. Initiating treatment with PONVORY™ after treatment with alemtuzumab is not recommended.

Severe Increase in Disability After Stopping PONVORY™

Severe exacerbation of disease, including disease rebound, has been rarely reported after discontinuation of a SIP receptor modulator. The possibility of severe exacerbation of disease should be considered after stopping PONVORY™ treatment. Patients should be observed for a severe increase in disability upon PONVORY™ discontinuation and appropriate treatment should be instituted, as required.

Immune System Effects After Stopping PONVORY™

After stopping PONVORY™ therapy, ponesimod remains in the blood for up to 1 week.

Starting other therapies during this interval will result in concomitant exposure to ponesimod. Lymphocyte counts returned to the normal range in 90% of patients within 1 week of stopping therapy, however, residual pharmacodynamics effects, such as lowering effects on peripheral lymphocyte count, may persist for 1 to 2 weeks after the last dose. Use of immunosuppressants within this period may lead to an additive effect on the immune system, and therefore caution should be applied 1 to 2 weeks after the last dose of PONVORY™.

OVERDOSAGE

In patients with overdosage of PONVORY™, especially upon initiation/re-initiation of treatment, it is important to observe for signs and symptoms of bradycardia as well as AV conduction blocks, which may include overnight monitoring. Regular measurements of pulse rate and blood pressure are required, and ECGs should be performed.

There is no specific antidote to ponesimod. Neither dialysis nor plasma exchange would result in meaningful removal of ponesimod from the body. The decrease in heart rate induced by PONVORY™ can be reversed by atropine.

In the event of overdose, PONVORY™ should be discontinued, and general supportive treatment given until clinical toxicity has been diminished or resolved. It is advisable to contact a poison control center to obtain the latest recommendations for the management of an overdose.

ADVERSE REACTIONS

Most common adverse reactions (incidence at least 10%) are upper respiratory tract infection, hepatic transaminase elevation, and hypertension.

Please see full [Prescribing Information and Medication Guide](#) for PONVORY™.

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Call a Janssen CarePath Care Coordinator at 877-CarePath (877-227-3728)

Monday-Friday, 8AM-8PM ET

Sign up or log in to the Provider Portal at JanssenCarePathPortal.com

Visit JanssenCarePath.com/hcp/ponvory

 **Ponvory™**
(ponesimod) tablets