Janssen CarePath UPDATE 03.24

Enrollment and Prescription Form Fax Cover Sheet

Opsynvi® macitentan/tadalafil 10 mg/40 mg tablets

Fax the following to Janssen CarePath at 866-279-0669:

1. OPSYNVI® Enrollment and Prescription Form, including the Janssen Patient Support Program Patient Authorization (all patients)
2. Please provide copies of all medical and prescription insurance cards (front and back)
3. If needed, please attach list of concomitant medications
4. If needed, please attach list of known drug allergies

Macitentan-Containing Products REMS Requirements (female patients only)

1. Prescribers must be certified in Macitentan-Containing Products REMS
2. All female patients must be enrolled in Macitentan-Containing Products REMS by their prescriber by completing the Macitentan-Containing Products REMS Patient Enrollment Form with the prescriber. Please visit MacitentanREMS.com for additional information

Macitentan-Containing Products REMS Phone: 888-572-2934
Macitentan-Containing Products REMS Fax: 833-681-0003

Requirements for OPSYNVI® Voucher Program

Please provide all of the patient's concomitant medications in **Section 3**: Diagnosis & Prescription Information. Include PAH medications and all medications for other co-morbidities. If you prefer, you can fax the medication list.

Patient Authorization Requirements (all patients)

Patients to complete and sign the Patient Support Program Patient Authorization (pages 3 and 4). Please fax the completed and signed Patient Authorization with the OPSYNVI® Enrollment and Prescription Form. If necessary, a patient can submit a digital version of the Patient Authorization at PAHconsent.com

Date: _____

Fax number: **866-279-0669**

From: _____

Facility name: _____

Facility contact: _____

Completed OPSYNVI® Enrollment and Prescription Form enclosed.

Number of pages (including cover): _____

Specialty Pharmacy preference: ☐ Accredo Health Group, Inc. ☐ CenterWell ☐ CVS/specialty ☐ Kaiser Permanente

Please note: The Specialty Pharmacy preference above will be validated through the standard benefit verification process. Other factors, like payer mandates, will ultimately determine where the enrollment is sent.

Comments: _____

_____

_____

Contact Janssen CarePath at 866-228-3546.

Please see the full Prescribing Information, including BOXED WARNING, and Medication Guide for OPSYNVI®. Provide the Medication Guide to your patients and encourage discussion.

Clear Form Print Form

OPSYNVI® (macitentan and tadalafil) Enrollment and Prescription Form

The information you provide will be used by Actelion Pharmaceuticals US, Inc., a Janssen Pharmaceutical Company, our affiliates, or our service providers to fulfill your requests. Our **Privacy Policy** further governs the use of the information you provide. By completing and submitting this form, you indicate that you read, understand, and agree to these terms.

1 Patient Information (please print)

*(REQUIRED) First name | MI | *(REQUIRED) Last name

*(REQUIRED) Birth date (MM/DD/YYYY) | *(REQUIRED) Gender ☐ Male ☐ Female | Preferred Language ☐ English ☐ Spanish ☐ Other

*(REQUIRED) Address | *(REQUIRED) City | *(REQUIRED) State | *(REQUIRED) ZIP

Email address | *(REQUIRED) Phone # ☐Home ☐Cell ☐Work | Alternate Phone # ☐Home ☐Cell ☐Work | ☐ AM ☐ PM Best time to call

Ok to leave message with: ☐Caregiver ☐Legally authorized representative (if needed, provide contact information below)

Full name | Phone # | Email address

Primary Insurance | Group # | BIN # | PCN

2 Prescriber Information (please print)

*(REQUIRED) First name | *(REQUIRED) Last name

*(REQUIRED) Prescriber NPI | State License No. | Office/Clinic/Institution name | Group NPI (if applicable) | Specialty

*(REQUIRED) Address | *(REQUIRED) City | *(REQUIRED) State | *(REQUIRED) ZIP

Office contact name | *(REQUIRED) Office contact phone # | Office contact email address | Fax #

3 Diagnosis & Prescription Information (please print)

***(REQUIRED) Please check only one box in this section.**

The following ICD-10 codes do not suggest approval, coverage, or reimbursement for specific uses or indications.

ICD-10 I27.0 Primary pulmonary hypertension:

- ☐ Idiopathic PAH
- ☐ Heritable PAH

ICD-10 I27.21 Secondary PAH associated with:

- ☐ Connective tissue disease
- ☐ Drugs/toxins induced
- ☐ Congenital heart disease
- ☐ HIV

☐ **Other:** Complete **only** if no ICD-10 code checked

OPSYNVI® (macitentan and tadalafil):

for patients transitioning from PDE5i monotherapy or PDE5i and ERA therapy in combination or maintenance dose for patients who are treatment-naïve to any PAH-specific therapy or transitioning from ERA monotherapy

☐ **Take (1) OPSYNVI® 10/40 mg tablet orally once daily as directed** - NDC 66215-814-30

*(REQUIRED) Quantity | *(REQUIRED) Refills

OPSYNVI® (macitentan and tadalafil):

for patients who are treatment-naïve to any PAH-specific therapy or transitioning from ERA monotherapy (See Prescribing information for Dosing recommendation 2.1)

☐ _____

*(REQUIRED) Quantity | *(REQUIRED) Refills

Concomitant Medications: Please check only one box in each section and if needed, attach separate list of concomitant drugs and known drug allergies.

- ☐ No other medications
- ☐ List all other medications _____

Drug Allergies:

Please check only one box.

- ☐ No known drug allergies
- ☐ List all known drug allergies _____

4 OPSYNVI® Voucher Program – Dispensing pharmacy may contact you for additional information

A free trial offer is available for eligible patients to help them become familiar with OPSYNVI®. At the conclusion of the program, you and your patient decide whether to continue treatment. Subject to one (1) use per lifetime for the patient's first trial of OPSYNVI®. See full program requirements at **JanssenCarePath.com.**

***Please check only one box in this section.**

☐ **Dispense OPSYNVI® Voucher Program** (for patients who are treatment-naïve to any PAH-specific therapy or transitioning from ERA monotherapy)

Dose: Take (1) OPSYNVI® 10/20 mg tablet by mouth once daily as directed
Dispense: 30-day supply **Refills:** 0
Dose: Take (1) OPSYNVI® 10/40 mg tablet by mouth once daily as directed
Dispense: 30-day supply **Refills:** 0

☐ **Dispense OPSYNVI® Voucher Program** (for patients transitioning from PDE5i monotherapy or PDE5i and ERA therapy in combination)

Dose: Take (1) OPSYNVI® 10/40 mg tablet by mouth once daily as directed
Dispense: 30-day supply **Refills:** 0

5 Shipping† (*REQUIRED)

Ship to: ☐ Patient home (same as section 1) ☐ Prescriber office (same as section 2) ☐ Other (if needed, provide shipping information below) **Preferred day/time:** _____

Name | Company (if applicable)

Address

City | State | ZIP | Phone #

†As allowable by law.

6 Prescriber Signature – Prescription and Statement of Medical Necessity (*REQUIRED)

I have made the determination, based on my independent clinical judgment, that the medication ordered is medically necessary for the patient for the intended use. I am personally supervising the care of this patient. I authorize Actelion Pharmaceuticals US, Inc., a Janssen Pharmaceutical Company, its affiliates, agents, and contractors to act on my behalf for the limited purposes of transmitting this prescription to the appropriate pharmacy designated by the patient utilizing their benefit plan. This authorization includes permitting Janssen to communicate to payers on my behalf to confirm this patient's health plan eligibility and benefits. **PRESCRIBER SIGNATURE REQUIRED TO VALIDATE PRESCRIPTIONS. Prescriber attests this is his/her legal signature (NO STAMPS). Prescriptions must be faxed.**

SIGN HERE _____ Dispense as Written **OR** _____ Substitution Allowed **Date** _____

The prescriber is to comply with his/her state-specific prescription requirements such as e-prescribing, state-specific prescription form, fax language, etc. Non-compliance with state-specific requirements could result in outreach to the prescriber.

Please see the full Prescribing Information, including BOXED WARNING, and Medication Guide for OPSYNVI®.
Provide the Medication Guide to your patients and encourage discussion.

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7 Janssen Patient Support Program Patient Authorization

Patients should **(1)** read the Patient Authorization, **(2)** check the desired permission boxes, and **(3)** return the form to Janssen Patient Support Program.

Options to complete and return the form:

- Download a copy, print, check the desired boxes, and sign. The completed form may be faxed to 866-279-0669 or mailed to Janssen CarePath, 6931 Arlington Road, Suite 400, Bethesda, MD 20814
- Patients may also read, sign, and submit a digital version of this form at **PAHconsent.com**

Patient name: _____ **Email address:** _____

I give permission for each of my "Healthcare Providers" (eg, my physicians, pharmacists, specialty pharmacies, other healthcare providers, and their staff) and "Insurers" (eg, my health insurance plans) to share my Protected Health Information as described on this Form.

My "Protected Health Information" includes any and all information related to my medical condition, treatment, prescriptions, and health insurance coverage.

The following person(s) or class of person(s) are given permission to receive and use my Protected Health Information (collectively "Janssen"):

- Johnson & Johnson Health Care Systems Inc., its affiliated companies, agents, and representatives
- Providers of other sources of funding, including foundations and co-pay assistance providers
- Service providers for the patient support programs, including subcontractors or healthcare providers helping Janssen run the programs
- Service providers maintaining, transmitting, de-identifying, aggregating, or analyzing data from Janssen patient support programs

Also, I give permission to Janssen to receive, use, and share my Protected Health Information in order to:

- see if I qualify for, sign me up for, contact me about, and provide services relating to Janssen patient support programs, including in-home services
- manage the Janssen patient support programs
- give me educational and adherence materials, information, and resources related to my Janssen medication in connection with Janssen patient support programs
- communicate with my Healthcare Providers regarding access to, reimbursement for and fulfillment of my Janssen medication, and to tell my Healthcare Provider that I am participating in Janssen patient support programs
- verify, assist with, and coordinate my coverage for my Janssen medication with my Insurers and Healthcare Providers
- coordinate prescription or treatment location and associated scheduling
- conduct analysis to help Janssen evaluate, create, and improve its products, services, and customer support for patients prescribed Janssen medications
- share and give access to information created by the Janssen patient support programs that may be useful for my care

I understand that my Protected Health Information may be shared by Janssen for the uses written in this Form to:

- My Insurers
- My Healthcare Providers
- Any of the persons given permission to receive and use my Protected Health Information as mentioned above
- Any individual I give permission as an additional contact

continued next page

Clear Form Print Form

7 Janssen Patient Support Program Patient Authorization (cont'd)

Janssen and the other data recipients listed on this Form may share information about me as permitted on this Form or if any information that specifically identifies me is removed. I understand that Janssen will use reasonable efforts to keep my information private but once my Protected Health Information is disclosed as allowed on this Form, it may no longer be protected by federal privacy laws.

I understand that I am not required to sign this Form. My choice about whether to sign will not change how my Healthcare Providers or Insurers treat me. If I do not sign this Form, or cancel or remove my permission later, I understand I will not be able to participate or receive assistance from Janssen's patient support programs.

I understand that pharmacies that dispense and ship my medication and service providers for the patient support programs may be paid by Janssen for their services and data. This may include payment for sharing Protected Health Information and other data in connection with these programs, as allowed on this Form.

This Form will remain in effect 10 years from the date of signature, except where state law requires a shorter time, or until I am no longer participating in any Janssen patient support programs. Information collected before that date may continue to be used for the purposes set forth in this Form.

I understand that I may cancel the permissions given by this Form at any time by letting Janssen know in writing at: Janssen CarePath, 6931 Arlington Road, Suite 400, Bethesda, MD 20814

I can also cancel my permission by letting my Healthcare Providers and Insurers know in writing that I do not want them to share any information with Janssen.

I further understand that if I cancel my permission it will not affect how Janssen uses and shares my Protected Health Information received by Janssen prior to my cancellation.

I understand I may request a copy of this Form.

Permission for communications outside of Janssen patient support programs:

☐ Yes, I would like to receive communications relating to my Janssen medication.

☐ Yes, I would like to receive communications relating to other Janssen products and services.

For privacy rights and choices specific to California residents, please see Janssen's California **privacy notice**

Permission for text communications:

☐ Yes, I would like to receive text messages. By selecting this option, I agree to receive text messages as allowed by this form to the cell phone number provided below. Message and data rates may apply. Message frequency varies. I understand I am not required to provide my permission to receive text messages to participate in the Janssen patient support programs or to receive any other communications I have selected.

Cell phone number: _____

Patient sign here: _____ **Date:** _____

If patient cannot sign, patient's legally authorized representative must sign below:

By: _____ **Print name:** _____ **Date:** _____

(Signature of person legally authorized to sign for patient)

Describe relationship to patient and authority to make medical decisions for patient:

_____

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