UPDATE 05.25

J&J withMe

Enrollment and Prescription Form Fax Cover Sheet

Opsynvi® macitentan/tadalafil 10 mg/40 mg tablets

Fax the following to J&J withMe at 866-279-0669:

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

Requirements for Voucher Program

Please provide all of the patient's concomitant medicines in **Section 5**: Diagnosis & Prescription Information. Include PAH medicines and all medicines for other comorbidities. If you prefer, you can fax the medicine list.

Patient Authorization Requirements

Patients to complete and sign all pages of the attached Patient Support Program Patient Authorization Form. 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** or by scanning the QR code.

Data rates may apply.

Fax the completed and signed Enrollment and Prescription Form to J&J withMe at 866-279-0669. You can also request benefits investigations on the Provider Portal at PATHwatch.net.

Once a decision has been made to prescribe OPSYNVI® and your patient has signed the Patient Authorization form

J&J withMe is a suite of access, affordability, and treatment support for your patients

Access Support to help navigate payer processes by verifying insurance coverage and providing reimbursement information.

Affordability Support to help your patients start and stay on the OPSYNVI® you prescribe by providing affordability options that may be available.

Treatment Support, including PAH Companion withMe, to help your patients get informed and stay on prescribed OPSYNVI®.

If you have questions, call a J&J withMe Care Coordinator at 866-228-3546, Monday–Friday, 8:00 AM–8:00 PM ET. Multilingual phone support available. Visit JNJwithMe.com.

cp-512528v1

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 J&J withMe at 866-228-3546.

The patient support and resources provided by J&J withMe and PAH Companion withMe are not intended to provide medical advice, replace a treatment plan from the patient's doctor or nurse, provide case management services, or serve as a reason to prescribe a J&J medicine.

Information about your patient's insurance coverage, cost support options, and treatment support is given by service providers for J&J withMe. The information you get does not require you or your patient to use any Johnson & Johnson product. Because the information we give you comes from outside sources, J&J withMe cannot promise the information will be complete.

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

UPDATE 05.25

J&J withMe

Enrollment and Prescription Form

Opsynvi® macitentan/tadalafil 10 mg/40 mg tablets

The information you provide will be used by Johnson & Johnson Health Care Systems Inc., our affiliates, and our service providers for your patient's enrollment and participation in J&J withMe. Our **Privacy Policy** further governs the use of the information you provide.

Fields marked with an (*) are required.

cp-512528v1

1. Patient Information (please print)

*First Name _____ MI _____ *Last Name _____

*Sex at Birth ☐ Male ☐ Female *Birth Date (MM/DD/YYYY) _____ Preferred Language ☐ English ☐ Spanish ☐ Other _____

*Address _____

*City _____ *State _____ *ZIP _____

Email Address _____

*Primary Phone # _____ ☐ Home ☐ Cell ☐ Work Alternate Phone # _____ ☐ Home ☐ Cell ☐ Work ☐ AM ☐ PM Best time to call

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

Full Name _____ Phone # _____ Email Address _____

Primary Insurance _____ Group # _____ BIN # _____ PCN _____

2. Prescriber Information (please print)

Prescriber's First Name _____ Prescriber's Last Name _____ Specialty _____

*Prescriber NPI _____ State License # _____

Office/Clinic/Institution Name _____ Group NPI (if applicable) _____

Address _____

City _____ State _____ ZIP _____

Office Contact Name _____ Office Contact Phone # _____

Office Contact Email Address _____ Fax # _____

3. Shipping

***Ship to** (As allowable by law): ☐ Patient home (same as section 1) ☐ Prescriber office (same as section 2) ☐ Other (if needed, provide shipping information below)

*Address _____

*City _____ *State _____ *ZIP _____

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

OPSYNVI® (macitentan and tadalafil) Enrollment and Prescription Form

The information you provide will be used by Johnson & Johnson Health Care Systems Inc., our affiliates, and our service providers for your patient's enrollment and participation in J&J withMe. Our **Privacy Policy** further governs the use of the information you provide.

Fields marked with an (*) are required.

cp-512528v1

4. Patient and Prescriber Information (please print)

*Patient First Name _____ MI ____ *Patient Last Name _____ *Birth Date (MM/DD/YYYY) _____

*Prescriber First Name_____ *Prescriber Last Name _____ *Office Contact Phone #_____

*Address _____ *City_____ *State _____ *ZIP _____

5. 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
- ☐ Congenital heart disease
- ☐ Drugs/toxins induced
- ☐ HIV

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

All doses will be dispensed in original packaging per Prescribing Information

Treatment-Naïve or Transitioning from ERA Monotherapy

☐ OPSYNVI® (macitentan and tadalafil)
First, take (1) OPSYNVI® 10/20 mg tablet orally once daily as directed – NDC 66215-812-30

_____ 0 Refills
*(Quantity) (Refills)

If tolerated, up-titrate to (1) OPSYNVI® 10/40 mg tablet orally once daily as directed – NDC 66215-814-30

_____ _____
*(Quantity) *(Refills)

Transitioning from PDE5i Monotherapy or PDE5i and ERA Therapy in Combination or Maintenance Dose

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

_____ _____
*(Quantity) *(Refills)

Alternate Dosing Instructions

☐ OPSYNVI® (macitentan and tadalafil)

_____

_____ _____
*(Quantity) *(Refills)

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

- ☐ No other medicines
- ☐ List all other medicines _____

Drug Allergies: Please check only one box.

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

6. Voucher Programs – Dispensing pharmacy may contact you for additional information

Free trial offer programs are available for OPSUMIT® and OPSYNVI® to help eligible patients become familiar with the medicine you choose to prescribe. At the conclusion of the trial offer program, you and your patient decide whether to continue treatment. Subject to one (1) use per lifetime for the patient's first trial of OPSUMIT® and OPSYNVI®. See program requirements at **JNJwithMe.com/Opsumit-Voucher** and **JNJwithMe.com/Opsynvi-Voucher**.

Choose Initial Treatment Path

Choose this option if you want to evaluate
OPSUMIT® before transitioning to OPSYNVI®

Opsumit

Start with OPSUMIT® (macitentan)

Checking this box constitutes a prescription for OPSUMIT®

☐ **Dose:** 10 mg tablet once daily
Dispense: 1-month supply
Refills: 0

Opsynvi

Transition to OPSYNVI® (macitentan and tadalafil)

For patients who are treatment-naïve or transitioning from ERA monotherapy

☐ First take:
Dose: 10/20 mg tablet by mouth once daily as directed
Dispense: 30-day supply
Refills: 0

If tolerated, up titrate to:
Dose: 10/40 mg tablet by mouth once daily as directed
Dispense: 30-day supply
Refills: 0

OR

For patients transitioning from PDE5i monotherapy or PDE5i and ERA therapy in combination

☐ **Dose:** 10/40 mg tablet by mouth once daily as directed
Dispense: 30-day supply
Refills: 0

Choose this option if you want to evaluate
OPSYNVI® only

Opsynvi

OPSYNVI® (macitentan and tadalafil)

For patients who are treatment-naïve or transitioning from ERA monotherapy

☐ First take:
Dose: 10/20 mg tablet by mouth once daily as directed
Dispense: 30-day supply
Refills: 0

If tolerated, up titrate to:
Dose: 10/40 mg tablet by mouth once daily as directed
Dispense: 30-day supply
Refills: 0

OR

For patients transitioning from PDE5i monotherapy or PDE5i and ERA therapy in combination

☐ **Dose:** 10/40 mg tablet by mouth once daily as directed
Dispense: 30-day supply
Refills: 0

If selecting a trial offer option, complete the prescription details in Section 5 and specify the maintenance dose.

7. Prescriber Signature – Prescription and Statement of Medical Necessity

I have made the determination, based on my independent clinical judgment, that the medicine(s) ordered is/are medically necessary for the patient for the intended use. I am personally supervising the care of this patient. I authorize Johnson & Johnson Health Care Systems Inc., 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 J&J 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 _____ **OR** _____ **Date** _____
Dispense as Written Substitution Allowed

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 read full Prescribing Information, including BOXED WARNING for OPSUMIT® and OPSYNVI®, and Medication Guides for OPSUMIT® and OPSYNVI®. Provide the appropriate Medication Guide to your patients and encourage discussion.

Johnson & Johnson

Patient support program patient authorization form

Why should I sign this Form?

This Form gives your Healthcare Providers permission to use and share your medical information with the patient support programs offered by Johnson & Johnson.

Section 1 What health information am I sharing and with whom?

I give permission for my Healthcare Providers and Insurers (eg, my health insurance plans) to share my Protected Health Information, as described on this Form.

My Protected Health Information includes information related to: my medical condition, treatment, prescriptions, and health insurance coverage

My Healthcare Providers may include: physicians, pharmacists, specialty pharmacies, other healthcare providers, and staff members at my healthcare providers' offices

I give permission to these people or groups to receive and use my Protected Health Information (collectively "J&J"):

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

My Protected Health Information may be shared by J&J with these people and groups: my Insurers, my Healthcare Providers, any other people given permission to receive and use my Protected Health Information (as mentioned above), anyone I give permission to as an additional contact, and service providers who review data from J&J's patient support programs

J&J and the other groups on this Form may share information about me in 2 ways: as permitted on this Form, and if any information that identifies me is removed from what has been shared

Section 2 How can giving permission help with patient support programs and access?

I give permission to J&J to receive, use, and share my Protected Health Information to:

- See if I qualify for, sign me up for, contact me about, and provide services relating to J&J's patient support programs. This includes in-home services
- Manage J&J's patient support programs
- Give me resources and information related to my J&J medicine in connection with J&J's patient support programs. This includes educational and adherence materials
- Communicate with my Healthcare Providers about access, reimbursement, and fulfillment for my J&J medicine
- Inform my Healthcare Provider that I am enrolled in J&J's patient support programs
- Help verify and coordinate coverage for J&J medicines with my Insurers and Healthcare Providers
- Help with prescription or treatment location and associated scheduling
- Conduct analysis to help J&J evaluate, create, and improve their patient support services and products for patients prescribed J&J medicines
- Share information from J&J's patient support programs that may be useful for my care

Section 3 What should I understand before signing this Form?

I understand that:

- J&J 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 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 in or receive assistance from J&J's patient support programs
- The following groups may be paid by J&J for their services and data, including Protected Health Information:
  - Pharmacies that dispense and ship my medicine
  - Service providers for J&J's patient support programs
- This Form will remain in effect 10 years from the date I signed below, except if:
  - State law requires a shorter time, or
  - I am no longer in any patient support program from J&J
- Information collected before that date may continue to be used for the purposes noted in this Form
  - I may cancel the permissions given by this Form at any time by letting J&J know in writing at: J&J withMe, 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 J&J
  - If I cancel my permission, it will not affect how J&J uses and shares my Protected Health Information received by J&J before my cancellation
  - I may request a copy of this Form

Section 4 Fill in Personal Information & Sign Patient Authorization Form

Patient name (print) _____ **DOB *(mm/dd/yyyy)*** _____

Email Address _____ **Phone Number** _____

Patient Address _____

City _____ **State** _____ **ZIP Code** _____

Patient signature _____ **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:

_____

See page 3 for helpful resources and instructions for completing and returning this Form. ▼

Please visit **JNJwithMe.com** for information about J&J's patient support programs

Data rates may apply.

Helpful resources you can sign up for (optional)

Permission for communications outside of J&J's patient support programs:

- ☐ Yes, I would like to receive communications about my J&J medicine
- ☐ Yes, I would like to receive communications about other products and services from J&J

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 J&J's patient support programs or to receive any other communications I have selected. Cell phone number: _____

For privacy rights and choices specific to California, Colorado, Connecticut, Utah, Virginia, and Washington residents, please see J&J's US Supplemental Privacy Notice available at ***InnovativeMedicine.JNJ.com/us/privacy-policy#supplemental***

How to Complete and Return the Patient Authorization Form

Sign and return pages 1 and 2 of this Form to: (If optional resources are selected, complete and return page 3)

- Fax to: 866-279-0669
- J&J withMe
  6931 Arlington Road, Suite 400
  Bethesda, MD 20814

Or, eSign a digital Form:

- In your healthcare provider's office
- At **PAHconsent.com** or scan this QR code

Data rates may apply.