OPSUMIT® (macitentan) Prescription and Statement of Medical Necessity (PSMN)

Once you've completed this form, please see below for documentation requirements for ALL patients:

[Female patients only]
Complete the OPSUMIT® REMS Patient Enrollment and Consent Form.*

*Please visit OPSUMITREMS.com to download the form.

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

1) [ALL patients] This OPSUMIT® PSMN Form
2) [Female patients only] OPSUMIT® REMS Patient Enrollment and Consent Form

Fax a copy of all insurance cards (front and back). Ensure drug benefit card/information is included.

Requirements to expedite OPSUMIT® Voucher Program shipping *(see section 4)*:

1) Complete all ★REQUIRED fields in this form
2) Fax this form, along with the REMS form [female patients only], to Janssen CarePath before 1 PM, eastern time

If requirements above are met, and forms are received Mon-Fri, OPSUMIT® may ship as soon as the same business day.

1 Patient Information (please print)

★(REQUIRED) **First name** | ★(REQUIRED) **Last name** | ★(REQUIRED) **Birth date** | ☐ Male ☐ Female ★(REQUIRED) **Gender**

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

★(REQUIRED) **Primary phone #** | Best time to call | Alternate phone # | Specialty pharmacy preference

Legal guardian name | Legal guardian phone #

2 Prescriber Information (please print)

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

★(REQUIRED) **Prescriber NPI** | Practice | Specialty

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

Office contact phone # | Fax #

3 Diagnosis & Prescription (please print)

★(REQUIRED) **The following ICD-10 codes do not suggest approval, coverage, or reimbursement for specific uses or indications. (Please check only one box below.)**

☐ ICD-10 I27.0 Primary pulmonary hypertension
☐ ICD-10 I27.21 Secondary pulmonary arterial hypertension
☐ Other _____

★(REQUIRED) **OPSUMIT® (macitentan) dosing: 10 mg tablet(s) NDC66215-501-30** | **Time(s) daily** | **Quantity** | **Refills** | **Instructions for use**

4 OPSUMIT® Voucher Program: Prescription and Shipping Information

☐ **Dispense OPSUMIT® Voucher Program**

The OPSUMIT® Voucher Program is a 30-day supply of OPSUMIT® free of charge for eligible patients.

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

Dispensing pharmacy may contact you for additional information

★(REQUIRED Only if "Dispense OPSUMIT® Voucher Program" is selected)
Ship to: ☐ Patient home (same as above) ☐ Prescriber office (same as above) ☐ Other

Preferred day/time

Name | Company (if applicable)

Address

City | State | ZIP | Phone #

★(REQUIRED) **Please check only one box below.**
☐ No other medications
☐ List all other medications below

Other medications (including herbal supplements)

★(REQUIRED) **Please check only one box below.**
☐ No known drug allergies
☐ List all known drug allergies below

All known allergies

5 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. **PHYSICIAN SIGNATURE REQUIRED TO VALIDATE PRESCRIPTIONS. Physician attests this is his/her legal signature (NO STAMPS). Prescriptions must be faxed.**

Physician signature _____ Dispense as Written | **Physician signature** _____ Substitution Allowed | **Date** _____

Please Complete Additional Fields on the Following Page ▶

6 Janssen CarePath Patient Authorization

★(REQUIRED Only if patient consents to enroll in Janssen CarePath)

By signing this Authorization, I agree that I want Janssen CarePath support, including prescription/enrollment assistance and evaluation for financial assistance, and authorize Janssen CarePath to use and/or share my information ("Authorization").

I authorize my healthcare providers, pharmacies, health plans, or payers ("my healthcare organizations") to share personal and health information about me related to my Janssen PAH therapies ("my information") with Actelion Pharmaceuticals US, Inc., a Janssen Pharmaceutical Company, its affiliates, agents, and contractors. I understand that once my information is shared with Janssen, my information may be protected by certain state privacy laws but not by federal health privacy laws, and may be redisclosed by Janssen. Janssen agrees to protect my information and to use and share it only for the reasons listed below. I understand that my pharmacy may receive compensation in connection with sharing my information with Janssen as allowed under this Authorization.

I authorize my healthcare organizations to share my information with Janssen, in order for Janssen to: (1) contact me or my healthcare organizations, or others I have identified, about my disease or treatment; (2) confirm my health plan eligibility and benefits, identify other payers for my therapy, or determine whether I may be eligible for assistance programs; (3) enroll me in Janssen PAH therapies-related programs and provide therapy access support services; (4) perform analyses or improve or develop products, services, programs, or treatment related to my disease; (5) provide me by any means of communication, including by e-mail, mail, or telephone (including voicemail), with information to educate or inform me about Janssen PAH therapies and ways to help me maintain my prescribed treatment; and (6) use and disclose my information for safety reasons or as required by law. I understand that if I do not sign this form, I will still be eligible for health plan benefits and my treatment and payment for my treatment by my healthcare providers and pharmacy will not be affected, but I will not have access to the Janssen services and support described above.

This Authorization will expire 10 years from the date signed below unless a shorter period is required by the law of my state of residence. I may discuss the scope of my Authorization at any time by calling 866-875-0277 and may cancel it by writing a letter saying I cancel my Authorization, and mailing it to Actelion Pharmaceuticals US, Inc., a Janssen Pharmaceutical Company: PO Box 826, South San Francisco, CA 94083. My cancellation will not be effective until after Janssen receives it and my healthcare organizations are notified of it by Janssen, and it will not apply to prior actions taken by Janssen and my healthcare organizations based on this Authorization. I have a right to request and receive a copy of this Authorization in the same ways described above for cancellation.

Patient name (please print)

Patient or parent/guardian/representative signature **Date**

If this form is signed by someone who is not the patient listed, describe the signer's legal authority to act for the patient:

janssen