Opsumit® REMS Patient Enrollment and Consent Form

Complete this form for ALL patients.

For immediate patient enrollment, please go to OpsumitREMS.com, or call *Actelion Pathways*® at 1-866-228-3546, or fax this completed form to 1-866-279-0669.

Contact *Actelion Pathways* at 1-866-228-3546 for questions.

EO2201512

1 Patient Information (please print)

First name | Middle initial | Last name | ☐ Male ☐ Female Gender

Birth date | Primary language | Email address

Primary phone # | Alternate phone # | Best time to call

Address | City | State | ZIP

Legal guardian | Relationship | Phone #

Emergency contact | Relationship | Phone #

2 Female Patient Agreement

For All Females: I acknowledge that I understand that Opsumit is only available through a restricted distribution program under an FDA-required Risk Evaluation and Mitigation Strategy (REMS). I acknowledge that I have received and read the *Guide for Female Patients*.

For Females Who Can Get Pregnant: I acknowledge that I have been counseled on the risks of Opsumit, including the risk of serious birth defects. I have read the *Guide for Female Patients*. I understand that I will be contacted by Actelion and/or its agents and contractors to receive counseling and education on the Opsumit REMS and the risk of serious birth defects, the need to use reliable contraception during Opsumit treatment and for 1 month after stopping Opsumit treatment, the importance of not becoming pregnant, and to ensure that I have completed pregnancy testing: before I start Opsumit, monthly before each refill, and for 1 month after stopping Opsumit. I agree to be counseled each month by the certified pharmacy on the need to use reliable contraception during Opsumit treatment and for 1 month after stopping Opsumit. I understand that I must immediately contact my healthcare provider if I miss a menstrual period or suspect that I am pregnant; and that I may be contacted by Actelion and/or its agents and contractors to obtain information about my pregnancy, if I become pregnant.

For Pre-pubertal Females: I acknowledge that I have been counseled on the risks of Opsumit, including the risk of serious birth defects. I understand that I must immediately contact my healthcare provider if I get my menstrual period.

For Post-menopausal Females: I acknowledge that I have been counseled on the risks of Opsumit, including the risk of serious birth defects.

For Females with other medical reasons for permanent, irreversible infertility: I acknowledge that I have been counseled on the risks of Opsumit, including the risk of serious birth defects.

★ (REQUIRED FOR ALL FEMALES) Patient or Parent/Guardian Signature | Date

3 Prescriber Information (please print)

First name | Middle initial | Last name

Address | City

State | ZIP | Phone # | Opsumit Prescriber ID

Fax # | NPI # | Office contact and email address

4 Prescriber Authorization: If your patient is FEMALE, check correct female patient category (please see definitions of these terms on the following page):

REQUIRED (Check one category)

☐ **Female of Reproductive Potential**

→ If this patient is a Female of Reproductive Potential (which includes females who have undergone tubal sterilization), has a negative pregnancy test been completed prior to prescribing Opsumit?

☐ Yes ☐ No

Female of Non-Reproductive Potential

☐ **Pre-pubertal Female**

☐ **Post-menopausal Female**

☐ **Female with other medical reasons for permanent, irreversible infertility**

I certify that the above therapy ordered is medically necessary and agree to follow the "Prescriber Requirements" indicated on the second page of this form. Further, I hereby authorize Actelion and/or its designated representative(s), to act on my behalf for the limited purposes of providing this prescription to the certified specialty pharmacy for patient treatment purposes.

★ (REQUIRED FOR ALL PRESCRIBERS) Prescriber Signature | Date

Definitions of Reproductive Potential Status

Females of Reproductive Potential

- Females of reproductive potential include girls who have entered puberty and all females who have a uterus and have not passed through menopause (as defined below)
- For the purposes of this REMS, puberty includes those girls who are at least Tanner Stage 3 and have not yet had a menses (premenarchal)
- For the purposes of this REMS, females who have undergone tubal sterilization are classified as females of reproductive potential

Females of Non-Reproductive Potential

- Pre-pubertal Females: Females who are at Tanner Stages 1 and 2 are not considered to be of reproductive potential
- Post-menopausal Females: Females who have passed through menopause. Menopause is defined as 12 months of spontaneous amenorrhea (not amenorrhea induced by a medical condition or medical therapy) or post-surgical from bilateral oophorectomy
- Females with other medical reasons for permanent, irreversible infertility

Prescriber Requirements

For All Females

- I acknowledge that I have counseled the patient (and parent/guardian when appropriate) that Opsumit is only available through a restricted distribution program under an FDA-required REMS
- I will evaluate the patient and agree to document any change or misclassification in reproductive potential status by submitting a *Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form* or contacting *Actelion Pathways*® at 1-866-228-3546 within 10 business days of becoming aware of the change

For Females of Reproductive Potential

- I acknowledge that I have counseled the patient (and parent/guardian when appropriate) on the risks of Opsumit, including the risk of serious birth defects, and that I have reviewed the *Guide for Female Patients* with the patient (and parent/guardian when appropriate)
- I will order and review pregnancy tests prior to initiation of Opsumit treatment, monthly during treatment, and for 1 month after stopping treatment in accordance with the Opsumit REMS

For Pre-pubertal Females

- I acknowledge that I have counseled the patient and parent/guardian on the risks of Opsumit, including the risk of serious birth defects, and that I have reviewed the *Guide for Female Patients* with the patient and parent/guardian
- I will evaluate the patient's reproductive potential status, verify reproductive potential status annually for Pre-pubertal Females who are at least 8 years of age and older, and agree to report any change or misclassification in reproductive potential status on a *Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form* or contact *Actelion Pathways* at 1-866-228-3546 within 10 business days of becoming aware of the change

5 Fax this form to 1-866-279-0669

Please visit www.OpsumitREMS.com or call 1-866-ACTELION (1-866-228-3546) for immediate patient enrollment, or for more information about the Opsumit REMS.

Janssen CarePath

OPSUMIT® Prescription and Statement of Medical Necessity (PSMN)

Opsumit macitentan tablets 10 mg

Once you've completed this form, please see below for documentation requirements for ALL patients: Patients to complete and sign section 6 (pages 2 and 3) or submit a digital version of the Janssen Patient Support Program Patient Authorization at PAHconsent.com.

[Female patients only]
Must 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
3) Please provide copies of all medical and prescription insurance cards (front and back)

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 1:00 PM, Eastern time
If requirements above are met, and forms are received Mon–Fri, OPSUMIT® may ship as soon as the same business day.

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) | ☐ Male ☐ Female ★(REQUIRED) Gender

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

★(REQUIRED) Primary phone # | Cell phone # or ☐ check if same as primary | Best time to call | Specialty pharmacy preference | ☐ English ☐ Spanish Preferred Language

Email address | Legally authorized representative name | Phone #

2 Prescriber Information (please print)

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

★(REQUIRED) Prescriber NPI | Site name | Specialty

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

Office contact name | Office contact phone # | Office contact email address | Fax #

3 Diagnosis & Prescription Information (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
☐ Idiopathic PAH
☐ Heritable PAH

ICD-10 I27.21 Secondary PAH associated with:
☐ Connective tissue disease
☐ Congenital heart disease
☐ Drugs/toxins induced
☐ HIV

☐ Other:

OPSUMIT® (macitentan) 10 mg tablet(s)
NDC 66215-501-30

★(REQUIRED) Time(s) daily | ★(REQUIRED) Quantity | ★(REQUIRED) Refills | ★(REQUIRED) Instructions for use

4 OPSUMIT® Voucher Program

☐ **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 #

Concomitant Medications
★(REQUIRED) **Please check only one box below.**
☐ No other medications ☐ List all other medications below
Other medications (including herbal supplements)

Drug Allergies
★(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. **PRESCRIBER SIGNATURE REQUIRED TO VALIDATE PRESCRIPTIONS. Prescriber attests this is his/her legal signature (NO STAMPS). Prescriptions must be faxed.**

Prescriber signature _____ (Dispense as Written) **Prescriber signature** _____ (Substitution Allowed) **Date** _____

Please see the full Prescribing Information, including Boxed Warning for embryo-fetal toxicity, and Medication Guide for OPSUMIT®. Provide the Medication Guide to your patients and encourage discussion.

Clear Form Print Form

6 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:

A. 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, PO Box 826, South San Francisco, CA 94083.

B. 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.

My "Protected Health Information" includes but is not limited to the following 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 include foundations and co-pay assistance providers
- Service providers supporting or analyzing data from Janssen patient support programs

Specifically, 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, and contact me about Janssen patient support programs
- 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 confirm to my Healthcare Provider that support has been provided by the 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

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

I understand that my Protected Health Information will not be used or shared by Janssen for any other use without my permission. Janssen may share information about me where legally allowed or if any information that specifically identifies me is removed. I understand that Janssen will make every effort to keep my information private. Further, I understand that if my information is accidentally shared, federal privacy laws do not require that the person/party receiving it not share the information further and that such information provided to a third party may no longer be protected by federal privacy laws. I understand that my pharmacy may receive compensation in connection with sharing my information with Janssen as allowed under this Authorization.

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.

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, PO Box 826, South San Francisco, CA 94083

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:

_____

Clear Form Print Form