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

Complete this form for ALL patients.
Please visit OpsumitREMS.com to access the Opsumit REMS Patient Enrollment and Consent Form for female patients.
Fax this completed form, the Opsumit REMS Patient Enrollment and Consent Form, and copies of all insurance cards (front and back) to 1-866-279-0669. Contact *Actelion Pathways*® at 1-866-228-3546 for questions.

1 Patient Information (please print)

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

Address _____ City _____ State _____ ZIP _____

★ (REQUIRED) Primary phone # _____ Alternate phone # _____ Best time to call _____

Specialty pharmacy preference _____

2 Prescriber Information (please print)

★ (REQUIRED) First name _____ ★ (REQUIRED) Last name _____

Practice name _____ Specialty _____

Address _____ City _____ State _____ ZIP _____

Phone # _____ Fax # _____

★ (REQUIRED) Prescriber NPI _____

3 Diagnosis (please print)

★ **(REQUIRED) ICD-10 I27.0 Primary Pulmonary Hypertension**

- ☐ Idiopathic PAH
- ☐ Heritable PAH

★ **(REQUIRED) ICD-10 I27.21 Secondary Pulmonary Arterial Hypertension**

- ☐ Connective tissue disease
- ☐ Congenital heart disease with repaired shunts
- ☐ Other _____

Is patient diagnosed with pulmonary arterial hypertension (PAH, World Health Organization (WHO) Group I), defined as mean pulmonary arterial pressure ≥25 mmHg, pulmonary arterial wedge pressure ≤15 mmHg, and pulmonary vascular resistance >3 Wood units? ☐ Yes ☐ No

Functional class _____

Is request submitted by, or under the recommendation of, a pulmonologist or cardiologist? ☐ Yes ☐ No

Right heart catheterization (RHC)

Mean pulmonary artery pressure (mPAP) _____ mmHg

Pulmonary arterial wedge pressure (PAWP) _____ mmHg

Pulmonary vascular resistance (PVR) _____ mmHg

Acute vasoreactivity testing (Check one box, if completed)

- ☐ Patient responded
- ☐ Patient did not respond

Date of test _____

Additional test results

Echocardiography (See enclosed test results) _____ Date _____

6-minute walk distance (6MWD) _____ Date _____

6-minute walk distance (6MWD) _____ Date _____

★ 4 (REQUIRED) Prescription and Shipping Information (please print)

OPSUMIT® (macitentan) dosing: 10 mg tablet(s) NDC66215-501-30

_____ Time(s) daily Quantity: _____ Refills: _____

Instructions for use: _____

☐ Ship OPSUMIT Voucher Program, a 30-day supply of OPSUMIT, free of charge for eligible patients: 10 mg tablet once daily Dispense: 1-month supply

☐ Ship Bridge* to patient if patient is eligible and has signed Actelion Pathways Services Authorization in Section 6 (next page)

Ship to: ☐ Patient home ☐ Prescriber office ☐ Other

Address _____

City _____ State _____ ZIP _____

*Bridge: An *Actelion Pathways* program providing temporary drug to eligible patients prescribed Actelion products while patient's insurance plan completes coverage decision.

★ 5 (REQUIRED) Statement of Medical Necessity

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., its affiliates, agents, and contractors (collectively, "Actelion") 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 Actelion 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's signature _____ Date _____

Please Complete Additional Fields on the Following Page ▶

★ _____

(REQUIRED) Patient name

6 *Actelion Pathways*® Services 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 Actelion therapies ("my information") with Actelion Pharmaceuticals US, Inc., its affiliates, agents, and contractors (collectively, "Actelion"). I understand that once my information is shared with Actelion, my information may be protected by certain state privacy laws but not by federal health privacy laws, and may be redisclosed by Actelion. Actelion 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 Actelion as allowed under this Authorization. I authorize my healthcare organizations to share my information with Actelion, in order for Actelion 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 Actelion 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 Actelion 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 Actelion services and support described above. This Authorization will expire in 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 1-866-875-0277 and may cancel it by writing a letter saying I cancel my Authorization, and mailing it to Actelion Pharmaceuticals US, Inc.: PO Box 826, South San Francisco, CA 94083. My cancellation will not be effective until after Actelion receives it and my healthcare organizations are notified of it by Actelion, and it will not apply to prior actions taken by Actelion 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 or Parent/Guardian Signature | Date

7 Current and Past Treatments (please print)

☐ Is patient already taking OPSUMIT® (macitentan)?

_____

Past treatments

_____

Reason for discontinuation

_____

Past treatments

_____

Reason for discontinuation

_____ _____

Current treatment(s) | Current specialty pharmacy/pharmacies

8 Fax Requirements

Once you've completed this form:

1) Complete the Opsumit REMS Patient Enrollment and Consent Form for all Female patients

2) Fax this Opsumit PSMN Form and the Opsumit REMS Patient Enrollment and Consent Form to Actelion Pathways at **1-866-279-0669**

3) Be sure to include copies of all insurance cards (front and back)

4) If applicable, submit Prior Authorization (PA) Form to patient's health insurance plan