TRACLEER® (bosentan) Prescription and Statement of Medical Necessity (PSMN)

Complete this form for ALL patients.

Fax the following to 1-866-279-0669:

- This TRACLEER® Prescription and Medical Necessity form
- Prior Authorization (PA) form, signed and dated
- Copies of all insurance cards (front and back)

Contact Janssen CarePath at 1-866-228-3546 for questions.

For Patient Enrollment into the REMS program, please go to www.BosentanREMSProgram.com.

For questions, please call the Bosentan REMS Program at 1-866-359-2612.

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

Legal guardian name | Legal guardian phone #

2 Prescriber Information (please print)

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

★(REQUIRED) **Practice Name** | ★(REQUIRED) **Address**

★(REQUIRED) **City** | ★(REQUIRED) **State** | ★(REQUIRED) **ZIP** | Office contact phone # | Email address

★(REQUIRED) **Prescriber NPI** | Prescriber Tax ID

Certified pharmacy preference (If left blank, this referral will be sent to the appropriate certified pharmacy based on the patient's existing benefits.)

3 Diagnostic Testing (please print)

Is the patient diagnosed with pulmonary arterial hypertension (PAH, World Health Organization [WHO, Group 1]), defined as mean pulmonary arterial pressure ≥25 mmHg, pulmonary arterial wedge pressure ≤15 mmHg, and pulmonary vascular resistance >3 Wood units? ☐ Yes ☐ No

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) _____ **Wood units**

Acute vasoreactivity testing (CHECK ONE BOX)

☐ Patient responded

☐ Patient did not respond

Date of test

Additional test results

WHO functional class

Echocardiography (See enclosed test results) | Date

6-minute walk distance (6MWD) | Date

6-minute walk distance (6MWD) | Date

4 Current and Past Treatments (please print)

Past treatment | Reason for discontinuation

Past treatment | Reason for discontinuation

Current treatment(s) | Current specialty pharmacies

Please Complete Additional Fields on the Following Page ▶

5 Prescription and Shipping Information (please print)

★**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 _____

★**Pulmonary arterial hypertension (PAH) classification**

☐ Idiopathic PAH

☐ Heritable PAH

☐ Connective tissue disorder

☐ Congenital heart disease

☐ Other _____

_____

★**TRACLEER®** (bosentan) dosing: 62.5 and 125 mg tablets
Directions for use and dispensing instructions: Complete A or B below

A. ☐ Sig: Take 62.5 mg tablet by mouth twice daily × 4 weeks, then increase to the maintenance dose of 125 mg tablet by mouth twice daily.

Disp: TRACLEER® 62.5 mg tablets (66215-101-06) (60 tablets). No refills.
TRACLEER® 125 mg tablets (66215-102-06) (60 tablets). Refill × 11.

OR

B. ☐ Sig: _____

_____

Disp: TRACLEER® 62.5 mg tablets (66215-101-06)_____(Qty) tablets Refill x _____.

TRACLEER® 125 mg tablets (66215-102-06)_____(Qty) tablets Refill x _____.

TRACLEER® (bosentan) Pediatric Dosing: 32 mg tablets (66215-103-56)
Directions for use and dispensing instructions: Complete the below

Sig: _____

_____

Dose: _____ (mg per dose) Disp: _____ day supply Refill x _____

★**Ship to:**

☐ Patient home

☐ Prescriber office

☐ Other—Please specify address if different than patient home or prescriber office.

_____

_____

_____
Address

_____
City

_____
State Zip

6 Statement of Medical Necessity

★I have made the determination, based on my independent clinical judgment, that the medication ordered on the front 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) **Date**

_____ _____
Physician signature (substitution allowed) **Date**

The physician is to comply with their state-specific prescription requirements, such as e-prescribing, state-specific prescription form, fax language, etc. Noncompliance with state-specific requirements could result in outreach to the prescriber.

7 Insurance Information (please print)

☐ Insurance card and/or prescription card attached

_____ _____
Primary insurance Subscriber name

_____ _____
Name of insured Policy #

_____ _____
Group # Phone #

_____ _____
Secondary insurance Subscriber name

_____ _____
Name of insured Policy #

_____ _____
Group # Phone #

8 Janssen CarePath Patient Authorization

★(REQUIRED Only if patient consents to Janssen CarePath services)

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 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., 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