Janssen CarePath

TRACLEER® Prescription and Statement of Medical Necessity (PSMN)

Tracleer BOSENTAN 62.5 mg/125 mg Tablets 32 mg Tablets for Oral Suspension

Complete this form for ALL patients. Patients to complete and sign section 8 (pages 3 and 4) or submit a digital version of the Janssen Patient Support Program Patient Authorization at PAHconsent.com.

Fax the following to 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)

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

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

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

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**

Email address

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

Legally authorized representative name | Relationship | Phone #

2 Prescriber Information (please print)

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

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

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

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

★ (REQUIRED) **Prescriber NPI** | State license # | 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 Prescription and Shipping 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 ☐ ICD-10 I27.21 Secondary pulmonary arterial hypertension ☐ Other _____

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

- ☐ Idiopathic PAH
- ☐ Heritable PAH
- ☐ Connective tissue disorder
- ☐ Congenital heart disease
- ☐ Other _____

★ (REQUIRED) **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 x 4 weeks, then increase to the maintenance dose of 125 mg tablet by mouth twice daily.

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

OR

B. ☐ Sig: _____

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

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

TRACLEER® (bosentan) Pediatric Dosing: 32 mg tablets (NDC 66215-232-56)

Directions for use and dispensing instructions: Complete the fields below

Sig: _____

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

★ (REQUIRED) **Ship to:**

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

Address

City

State ZIP

4 Statement of Medical Necessity

★ (REQUIRED) 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. **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) | **Date**

Prescriber signature (substitution allowed) | **Date**

The prescriber 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.

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

Please Complete Additional Fields on the Following Pages ▶

Janssen CarePath

Tracleer BOSENTAN 62.5 mg/125 mg Tablets 32 mg Tablets for Oral Suspension

5 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

6 Current and Past Treatments (please print)

_____ _____
Past treatment Reason for discontinuation

_____ _____
Past treatment Reason for discontinuation

_____ _____
Current treatment(s) Current specialty pharmacies

7 Insurance Information (please print)

Please provide copies of all medical and prescription insurance cards (front and back).

☐ 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 #

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

8 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

8 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:

_____

janssen