UPDATE 12.25

J&J withMe

Enrollment and Prescription Form Fax Cover Sheet

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

Complete this form for ALL patients. In order for J&J withMe to complete this benefits investigation, your patient must complete and sign the attached Johnson & Johnson Patient Support Program Patient Authorization Form or submit a digital version of the Patient Authorization Form online at PAHconsent.com.

Fax the following to J&J withMe at 866-279-0669:

1. This TRACLEER® Enrollment and Prescription Form
2. Patient Authorization Form, signed and dated
3. Copies of all insurance cards (front and back)

Contact J&J withMe at 866-228-3546 for questions.

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

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

cp-501384v2

Date: _____

Fax number: **866-279-0669**

From: _____

Facility name: _____

Facility contact: _____

Completed TRACLEER® Enrollment and Prescription Form enclosed.

Number of pages (including cover): _____

Specialty Pharmacy preference: _____

Please note: The Specialty Pharmacy preference above will be validated through the standard benefit verification process. Other factors, like payer mandates, will ultimately determine where the enrollment is sent.

Comments: _____

_____

_____

Contact J&J withMe at 866-228-3546.

The patient support and resources provided by J&J withMe are not intended to provide medical advice, replace a treatment plan from the patient's doctor or nurse, provide case management services, or serve as a reason to prescribe a J&J medicine.

Please read full Prescribing Information, including BOXED WARNING, and Medication Guide for TRACLEER®. Provide the Medication Guide to your patients and encourage discussion.

J&J withMe UPDATE 12.25

TRACLEER® Enrollment and Prescription Form

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

The information you provide will be used by Johnson & Johnson Health Care Systems Inc., our affiliates, or our service providers to fulfill your requests. Our **Privacy Policy** further governs the use of the information you provide.

Fields marked with an (*) are required.

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1. Patient Information (please print)

*First Name _____ MI _____ *Last Name _____

*Sex at Birth ☐ Male ☐ Female *Birth Date (MM/DD/YYYY) _____

*Address _____ *City _____ *State _____ *ZIP _____

Email Address _____

*Primary Phone # _____ Cell Phone # or ☐ Check if same as primary _____

Best time to call _____ Preferred Language ☐ English ☐ Spanish

Legally authorized representative name (if applicable) _____ Relationship _____ Phone # _____

2. Prescriber Information (please print)

*Prescriber's First Name _____ *Prescriber's Last Name _____ Specialty _____

*Site Name _____ *Address _____

*City _____ *State _____ *ZIP _____

Office Contact Name _____ Office Contact Phone # _____

Office Contact Email Address _____ Fax # _____

*Prescriber NPI _____ State License # _____ Prescriber Tax ID _____

3. 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 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® 62.5 mg tablets (NDC 66215-101-06) _____ (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 _____

***Ship to:** ☐ Patient home ☐ Prescriber office ☐ Other—Please specify address if different than patient home or prescriber office.

Address _____ City _____ State _____ ZIP _____

4. Prescriber Signature—Prescription and Statement of Medical Necessity

*I have made the determination, based on my independent clinical judgment, that the medicine ordered is medically necessary for the patient for the intended use. I am personally supervising the care of this patient. I authorize Johnson & Johnson Health Care Systems Inc., 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 J&J 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.**

SIGN HERE _____ OR _____ Date _____

Dispense as Written Substitution Allowed

The prescriber is to comply with his/her state-specific prescription requirements such as e-prescribing, state-specific prescription form, fax language, etc. Non-compliance with state-specific requirements could result in outreach to the prescriber.

Please read full Prescribing Information, including BOXED WARNING, and Medication Guide for TRACLEER®. Provide the Medication Guide to your patients and encourage discussion.

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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 read full Prescribing Information, including BOXED WARNING, and Medication Guide for TRACLEER®. Provide the Medication Guide to your patients and encourage discussion.

Johnson & Johnson

Patient support program patient authorization form

Why should I sign this Form?

This Form gives your Healthcare Providers permission to use and share your medical information with the patient support programs offered by Johnson & Johnson.

Section 1 What health information am I sharing and with whom?

I give permission for my Healthcare Providers and Insurers (eg, my health insurance plans) to share my Protected Health Information, as described on this Form.

My Protected Health Information includes information related to: my medical condition, treatment, prescriptions, and health insurance coverage

My Healthcare Providers may include: physicians, pharmacists, specialty pharmacies, other healthcare providers, and staff members at my healthcare providers' offices

I give permission to these people or groups to receive and use my Protected Health Information (collectively "J&J"):

- Johnson & Johnson Health Care Systems Inc., its affiliated companies, agents, and representatives
- Providers of other sources of funding. This includes foundations and co-pay assistance providers
- Service providers for the patient support programs. This includes subcontractors or healthcare providers helping J&J run the programs
- Service providers maintaining, transmitting, de-identifying, aggregating, or analyzing data from J&J's support programs

My Protected Health Information may be shared by J&J with these people and groups: my Insurers, my Healthcare Providers, any other people given permission to receive and use my Protected Health Information (as mentioned above), anyone I give permission to as an additional contact, and service providers who review data from J&J's patient support programs

J&J and the other groups on this Form may share information about me in 2 ways: as permitted on this Form, and if any information that identifies me is removed from what has been shared

Section 2 How can giving permission help with patient support programs and access?

I give permission to J&J to receive, use, and share my Protected Health Information to:

- See if I qualify for, sign me up for, contact me about, and provide services relating to J&J's patient support programs. This includes in-home services
- Manage J&J's patient support programs
- Give me resources and information related to my J&J medicine in connection with J&J's patient support programs. This includes educational and adherence materials
- Communicate with my Healthcare Providers about access, reimbursement, and fulfillment for my J&J medicine
- Inform my Healthcare Provider that I am enrolled in J&J's patient support programs
- Help verify and coordinate coverage for J&J medicines with my Insurers and Healthcare Providers
- Help with prescription or treatment location and associated scheduling
- Conduct analysis to help J&J evaluate, create, and improve their patient support services and products for patients prescribed J&J medicines
- Share information from J&J's patient support programs that may be useful for my care

Section 3 What should I understand before signing this Form?

I understand that:

- J&J will use reasonable efforts to keep my information private. But, once my Protected Health Information is disclosed as allowed on this Form, it may no longer be protected by federal privacy laws
- 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 in or receive assistance from J&J's patient support programs
- The following groups may be paid by J&J for their services and data, including Protected Health Information:
  - Pharmacies that dispense and ship my medicine
  - Service providers for J&J's patient support programs
- This Form will remain in effect 10 years from the date I signed below, except if:
  - State law requires a shorter time, or
  - I am no longer in any patient support program from J&J
- Information collected before that date may continue to be used for the purposes noted in this Form
  - I may cancel the permissions given by this Form at any time by letting J&J know in writing at: J&J withMe, 6931 Arlington Road, Suite 400, Bethesda, MD 20814
  - 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 J&J
  - If I cancel my permission, it will not affect how J&J uses and shares my Protected Health Information received by J&J before my cancellation
  - I may request a copy of this Form

Section 4 Fill in Personal Information & Sign Patient Authorization Form

Patient name (print) _____ **DOB *(mm/dd/yyyy)*** _____

Email Address _____ **Phone Number** _____

Patient Address _____

City _____ **State** _____ **ZIP Code** _____

Patient signature _____ **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:

_____

See page 5 for helpful resources and instructions for completing and returning this Form. ▼

Please visit **JNJwithMe.com** for information about J&J's patient support programs

Data rates may apply.

Helpful resources you can sign up for (optional)

Permission for communications outside of J&J's patient support programs:

- ☐ Yes, I would like to receive communications about my J&J medicine
- ☐ Yes, I would like to receive communications about other products and services from J&J

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 J&J's patient support programs or to receive any other communications I have selected. Cell phone number: _____

For privacy rights and choices specific to California, Colorado, Connecticut, Utah, Virginia, and Washington residents, please see J&J's US Supplemental Privacy Notice available at ***InnovativeMedicine.JNJ.com/us/privacy-policy#supplemental***

How to Complete and Return the Patient Authorization Form

Sign and return pages 3 and 4 of this Form to: (If optional resources are selected, complete and return page 5)

Fax to: 866-279-0669

J&J withMe
6931 Arlington Road, Suite 400
Bethesda, MD 20814

Or, eSign a digital Form:

In your healthcare provider's office

At **PAHconsent.com** or scan this QR code

Data rates may apply.

