TRACLEER® Patient Enrollment and Consent Form

Complete this form for ALL patients.

Fax this completed 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.

ET3201604

1 Patient Information (please print)

First name	MI	Last name	Gender
FirstName		Last1478851499401	☒ Male ☐ Female

Birth date	Primary language	Email address
2001-03-03	English	See Attached [2]

Primary phone #	Alternate phone #	Best time to call
478-851-5058		Any time (9am - 9pm)

Address	City	State	ZIP
address1478851504693	city1478851504901	MA	14788

Legal guardian	Relationship	Phone #

Emergency contact	Relationship	Phone #
contactName1478851506024	6557656877898	478-851-5063

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

2 *Actelion Pathways* Services Authorization

I authorize my healthcare providers, pharmacies, health plans, or payers ("my health care 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 health care 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 health care organizations are notified of it by Actelion, and it will not apply to prior actions taken by Actelion and my health care 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.

★ _____ See [3]

(REQUIRED FOR ALL PATIENTS) Patient or Parent/Guardian Signature — Date

3 Patient Agreement

For All Patients: I acknowledge that I understand that Tracleer is only available through a restricted distribution program under an FDA-required Risk Evaluation and Mitigation Strategy (REMS). I acknowledge that I have been counseled on the risks of Tracleer, including the risk of liver damage and serious birth defects. I have read the *Tracleer Medication Guide* and the *Tracleer REMS Guide for Patients*. I understand that I will be contacted by Actelion, its agents, and/or a healthcare provider to receive counseling on the risks of Tracleer treatment, to ensure that I am completing the required liver function tests before I start Tracleer and monthly before each refill. I agree to be counseled each month by the pharmacy on the need for the monthly liver testing.

For Females Who Can Get Pregnant: I understand that I will be contacted by Actelion and/or its agents and contractors to receive counseling on the risk of serious birth defects, the need to use reliable contraception during Tracleer treatment and for one month after stopping Tracleer treatment, the importance of not becoming pregnant, and to ensure that I have completed pregnancy testing before I start Tracleer, monthly before each refill, and for one month after stopping Tracleer. I agree to be counseled each month by the certified pharmacy on the need to use reliable contraception during Tracleer treatment and for one month after stopping Tracleer. 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 received and read the *Tracleer Medication Guide* and that 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 received and read the *Tracleer Medication Guide*.

For Females with other medical reasons for permanent, irreversible infertility: I acknowledge that I have received and read the *Tracleer Medication Guide*.

★ _____ _____

(REQUIRED) Patient or Parent/Guardian Signature — Date

4 Prescriber Information

First name	Middle initial
Lindsay	

Last name
Goldman

Address
192 South St

City	State	ZIP
Boston	MA	02111

Phone #	Fax
617-555-5555	

NPI #	Tracleer Prescriber ID
6895439888	

Office contact and email address
office@zapprx.com

5 Diagnosis, Prescription, and Shipping Information

(Check ONLY ONE Box for the Diagnosis Related to Tracleer Treatment)

Pulmonary Arterial Hypertension (PAH)

☐ Idiopathic PAH ☐ Heritable PAH ☐ Connective Tissue Disorder ☐ Congenital Heart Disease

☑ Other 572.3 Portal Hypertension

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
Tracleer 125 mg tablets (66215-102-06) _____ (Qty) tablets

Ship to: ☑ Patient home ☐ Prescriber office ☐ Other

Address _____

City _____ State _____ ZIP _____

6 Prescriber Authorization

For this patient, have you reviewed their liver function tests? ☑ Yes ☐ No

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

REQUIRED (Check one box)

Female of Reproductive Potential

If this patient is a Female of Reproductive Potential, has a negative pregnancy test been completed prior to prescribing Tracleer?

☐ 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.

★ _____ [1]

(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)

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 form bilateral oophorectomy
- Females with other medical reasons for permanent, irreversible infertility

Prescriber Requirements

For All Patients

- I acknowledge that I have counseled the patient (and parent/guardian when appropriate) that Tracleer® is only available through a restricted distribution program under an FDA-required REMS
- I acknowledge that I have counseled the patient (and parent/guardian when appropriate) on the risks of Tracleer, including the risk of liver damage and serious birth defects, and that I have reviewed the *Tracleer Medication Guide* and the *Tracleer REMS Guide for Patients* with the patient (and parent/guardian when appropriate)
- I will order and review liver function tests (ALT/AST/bilirubin) prior to initiation of treatment and monthly during treatment

For Females of Reproductive Potential

- I will order and review pregnancy tests prior to initiation of Tracleer treatment, monthly during treatment, and for 1 month after stopping treatment in accordance with the Tracleer REMS Program
- I will evaluate the patient and agree to document any change or misclassification in reproductive potential status by submitting a *Tracleer REMS Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form* within 10 business days of becoming aware of the change

For Pre-pubertal Females

- 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 *Tracleer REMS Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form* within 10 business days of becoming aware of the change

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

Please visit www.TracleerREMS.com or call 1-866-ACTELION (1-866-228-3546) for more information about the Tracleer REMS Program.

Patient Name: FirstName Last1478851499401 **Accredo**
Patient DOB: 03/03/2001 **Tracleer**
Physician Name: Lindsay Goldman

[1] 12/14/2016

[2] FirstNameLast1478851499401@zapprx.com

[3] 12/14/2016

Physician Signature **Date**
12/14/2016