# Letairis Patient Enrollment and Consent Form

Enroll patient in *LabSync*®: ☐ Yes ☑ No

**Fax this form and all patient insurance information, including drug benefit cards (front and back), to: 1-888-882-4035**

## 1 Specialty Pharmacy

Select a preferred Certified Pharmacy:

- ☑ Accredo
- ☐ Aetna Specialty Pharmacy
- ☐ CIGNA Tel-Drug
- ☐ CuraScript
- ☐ CVS Caremark
- ☐ Exactus Pharmacy Solutions
- ☐ Kaiser Specialty Pharmacy
- ☐ OptumRx
- ☐ *Right*Source Specialty Pharmacy
- ☐ Walgreens Specialty Pharmacy

## 2 Patient Information (PLEASE PRINT)

| First Name: | Middle Initial: | Last Name: |
|---|---|---|
| FirstName | | Last1478851499401 |

| Address: | City: | State: | ZIP: |
|---|---|---|---|
| address1478851504693 | See [3] | MA | 14788 |

| Birthdate: | Gender: | Preferred Time to Contact: | Phone: | Alternate Phone: | E-mail: |
|---|---|---|---|---|---|
| 2001-03-03 | ☑ M ☐ F | ☐ Day ☐ Evening | 478-851-5058 | | See Attached [4] |

| Alternate Contact Name: | Phone: | Relationship: |
|---|---|---|
| See Attached [1] | 482-932-2415 | SELF |

## 3 Written Permission to Share Information

I allow my healthcare providers and health plans to share personal and medical information about me with Gilead and its agents and contractors ("Gilead"). I allow Gilead to use and share this information to: 1) communicate with me, my healthcare providers and health plans about my medical care; 2) provide support services, including providing Letairis® (ambrisentan) to me and planning laboratory testing for me; 3) learn how well Letairis, the Letairis REMS, or LEAP program is working; and 4) contact me so that I may receive educational materials about Letairis, the Letairis REMS, or the LEAP program.

I understand that I may choose not to take part in *LabSync*, but I may still take part in Letairis support services. Once my health information has been shared with Gilead, federal privacy laws may no longer protect it.

This means that Gilead can give it to others, such as the Food and Drug Administration (FDA), to learn if the Letairis REMS Program is being run properly as required by law. I understand that my pharmacy may receive payment in connection for disclosing my health information to Gilead for the purposes allowed under this authorization. I may also cancel my permission at any time by writing a letter to Gilead and faxing to 1-888-882-4035 or by calling 1-866-664-5327. If I cancel, Gilead will stop using or sharing my information for the reasons listed above, except as required by law to end my participation in the Letairis REMS Program. If I am a female and not enrolled in the Letairis REMS Program, I will no longer be able to receive Letairis. If I do not sign this form, I understand my eligibility for health plan benefits and treatment by my doctor will not change. I am allowed a copy of this signed agreement. My written permission ends 10 years from the date I signed it.

| REQUIRED FOR ALL PATIENTS | Patient or Parent/Guardian Signature: | Date: 12/28/2016 |
|---|---|---|

## 4 Female Patient Agreement

**For All Females:** I acknowledge that I have been counseled that Letairis is only available through a restricted distribution program under an FDA-required Risk Evaluation and Mitigation Strategy (REMS).

**For Females Who Can Get Pregnant:** I acknowledge that I have been counseled on the risks of Letairis, including the risk of serious birth defects. I have read the *Letairis Medication Guide* and the *Letairis REMS Program Guide for Females Who Can Get Pregnant*. I understand that I will be contacted by Gilead and/or its agents and contractors to receive counseling on the risk of serious birth defects and the importance of not becoming pregnant, ensure that I have completed pregnancy testing before I start Letairis, monthly before each refill, and for 1 month after stopping Letairis, and obtain information about my pregnancy, if I become pregnant.

**For Pre-Pubertal Females:** I acknowledge that I have been counseled on the risks of Letairis, including the risk of serious birth defects, and that I have read the *Letairis Medication Guide*. Parent or guardian must sign below.

| REQUIRED FOR ALL FEMALE PATIENTS | Patient or Parent/Guardian Signature: | Date: |
|---|---|---|

## 5 Prescriber Information (PLEASE PRINT)

| First Name: | Last Name: | State License #: |
|---|---|---|
| Lindsay | Goldman | 666-7654-999 |

| Address: | City: | State: | ZIP: |
|---|---|---|---|
| 192 South St | Boston | MA | 02111 |

| Phone: | Fax: | NPI #: |
|---|---|---|
| 617-555-5555 | | 6895439888 |

| Office Contact (First and Last Name): | E-mail: |
|---|---|
| | office@zapprx.com |

## 6 Prescription

| Letairis: | | Refills: | Instructions: | Ship to: | Name: |
|---|---|---|---|---|---|
| ☑ 5 mg tablets (30 tablets)<br>☑ 10 mg tablets (30 tablets) | ☑ PO<br>☑ QD | 11 | See Attached [2] | ☑ Patient Home (address listed above)<br>☐ Prescriber Office (address listed above)<br>☐ Other (please indicate below) | |

| Address: | City: | State: | ZIP: | Phone: |
|---|---|---|---|---|
| | | | | |

## 7 Statement of Medical Necessity

**Diagnosis: Pulmonary Arterial Hypertension** (This is for insurance purposes only, not to suggest approved uses or indications. Please select one category below.)

- ☐ Familial (ICD 416.0)
- ☐ Idiopathic (ICD 416.0)
- ☐ Scleroderma (ICD 710.1)
- ☐ HIV (ICD 042 _____)
- ☐ Lupus (ICD 710.0)
- ☑ Portal Hypertension (ICD 572.3)
- ☐ Congenital Heart Defects (ICD 745._____)
- ☐ Other: _____ (ICD_____)

## 8 Prescriber Authorization

**For female patients, please indicate the patient's current reproductive status below. Only 1 box should be checked. (Pease see definitions of these terms on the following page)**

**Female of Reproductive Potential**

Has a negative pregnancy test been confirmed prior to prescribing Letairis? ☐ Yes ☐ No

OR

**Female of Non-Reproductive Potential (choose one below)**

- ☐ Pre-Pubertal Female
- ☐ Post-Menopausal Female
- ☐ Other medical reasons for permanent, irreversible infertility

I certify that for female patients, I have provided the appropriate counseling and Letairis REMS materials, and I will continue to fulfill my obligations under the Letairis REMS Program as outlined on page 2 of this form.

By signing, I certify that the above therapy is medically necessary.

| REQUIRED FOR ALL PRESCRIBERS | Prescriber Signature: X | Date: 12/28/2016 |
|---|---|---|

## 8 Prescriber Authorization (continued)

**Definitions:**

**Females of Reproductive Potential**

- Females of Reproductive Potential include girls who have entered puberty and all women who have a uterus and have not passed through Menopause (as defined below).
- For the purposes of 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 (as defined below)
- Other medical reasons for permanent, irreversible infertility

**Menopause**

Menopause is defined as 12 months of spontaneous amenorrhea (not amenorrhea induced by a medical condition or medical therapy) or postsurgical from bilateral oophorectomy.

**Prescriber Obligations Under the Letairis REMS Program**

**For All Females**

- I acknowledge that I have counseled the patient (and parent/guardian when appropriate) that Letairis is only available through a restricted distribution program under an FDA-required REMS.
- I will evaluate the patient and agree to document any change in reproductive potential status by submitting a *Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form* within 10 business days of becoming aware of the change.

**For Females of Reproductive Potential**

- I acknowledge that I have counseled the patient (and parent/guardian when appropriate) on the risks of Letairis, including the risk of serious birth defects, and that I have reviewed the *Letairis Medication Guide* and the *Letairis REMS Program Guide for Females Who Can Get Pregnant* with the patient (and parent/guardian when appropriate).
- I will order and review pregnancy tests prior to initiation of Letairis treatment, monthly during treatment, and for 1 month after stopping treatment in accordance with the Letairis REMS Program.

**For Pre-Pubertal Females**

- I acknowledge that I have counseled the patient and parent/guardian on the risks of Letairis, including the risk of serious birth defects, and that I have reviewed the *Letairis Medication Guide* with the patient and parent/guardian.
- 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 in reproductive potential status on a *Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form* within 10 business days of becoming aware of the change.

## 9 Fax this enrollment form and all patient insurance information, including drug benefit cards (front and back), to 1-888-882-4035.

Please visit **www.letairisrems.com** or call **1-866-664-5327** for more information about the Letairis REMS Program.

Please see accompanying patient Medication Guide and full Prescribing Information, including **BOXED WARNING**.

This form is part of an FDA-approved REMS.

CLEAR PRINT

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

**[1] contactName1478851506024**

**[2] Initiate treatment at  once per day, with or without tadalafil 20 mg once daily. At 4-week intervals, either the dose of Letairis or tadalafil can be increased, as needed and tolerated, to Letairis 5 mg once per day or tadalafil 40 mg.**

**[3] city1478851504901**

**[4] FirstNameLast1478851499401@zapprx.com**

**Physician Signature** **Date**
**12/28/2016**