

# LETAIRIS Education and Access Program (LEAP) and LabSync Patient Enrollment and Consent Form

Initial Enrollment  Re-enrollment  Benefits Investigation Only **Enroll Patient in LabSync:  Yes  No**

Select a preferred specialty pharmacy:

- Accredo  Aetna Specialty Pharmacy  CVS Caremark  CIGNA Tel-Drug  CuraScript  Fairview Specialty Pharmacy  
 Kaiser Specialty Pharmacy (CA residents only)  PrecisionRx Specialty Solutions  Walgreens Specialty Pharmacy  WellCare Specialty Pharmacy

## Patient Information (PLEASE PRINT)

First Name: \_\_\_\_\_ Middle Initial: \_\_\_\_\_ Last Name: \_\_\_\_\_

Address: \_\_\_\_\_ City: \_\_\_\_\_ State: \_\_\_\_\_ ZIP: \_\_\_\_\_

Birthdate: \_\_\_\_ / \_\_\_\_ / \_\_\_\_ Gender:  M  F Preferred Time to Contact:  Day  Evening

Preferred Phone: (\_\_\_\_) \_\_\_\_\_ Alternate Phone: (\_\_\_\_) \_\_\_\_\_ E-mail: \_\_\_\_\_

Alternate Contact Name: \_\_\_\_\_ Phone: (\_\_\_\_) \_\_\_\_\_ Relationship: \_\_\_\_\_

**FAX ALL PATIENT INSURANCE INFORMATION, INCLUDING DRUG BENEFIT CARDS, TO: 1-888-882-4035.**

I authorize my healthcare providers and health plans to disclose personal and medical information about me to Gilead and its agents and contractors ("Gilead") and I authorize Gilead to use and disclose this information to: 1) establish my benefit eligibility, including benefit eligibility for laboratory services; 2) communicate with my healthcare providers and health plans about my medical care; 3) provide support services, including facilitating the provision of Letairis® (ambrisentan) to me and facilitating laboratory testing on my behalf; and 4) evaluate the safety and overall effectiveness of Gilead's education program, the LEAP and LabSync programs, as well as the safety and efficacy of LETAIRIS. I agree that using the contact information I provide, Gilead may get in touch with me for reasons related to the LEAP and LabSync programs and may leave messages for me that disclose that I take LETAIRIS. Additionally, I understand that I may choose not to participate in LabSync, but I am still eligible to participate in LEAP.

I understand that once my health information has been disclosed to Gilead, privacy laws may no longer restrict its use or disclosure; however, Gilead agrees to protect my information by using and disclosing it only for the purposes described above or as required by law. I further understand I may refuse to sign this authorization and that if I refuse, my eligibility for health plan benefits and treatment by my doctor will not change, but I will not have access to the LETAIRIS support services described herein. I may also cancel this authorization in the future by notifying Gilead in writing and submitting it by fax to 1-888-882-4035 or by calling 1-866-664-LEAP (5327). If I cancel, Gilead will cease using or disclosing my information for the purposes listed above, except as required by law or as necessary for the orderly termination of my participation in LEAP. I am entitled to a copy of this signed authorization, which expires 10 years from the date it is signed by me.

**Patient/Guardian Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

By signing below, I acknowledge that I have read the patient Medication Guide and patient education brochure and that I have been informed about the risks of LETAIRIS, including the risks of liver injury, serious birth defects, low red blood cell count, and low sperm count. I acknowledge that I will be contacted by Gilead and/or its agents and contractors to receive counseling on the risks of LETAIRIS treatment, to ensure that I am completing the required liver function tests and pregnancy tests (for women who are able to become pregnant) and, if I am a woman who becomes pregnant, to obtain information about my pregnancy.

**Patient/Guardian Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

## Prescriber Information (PLEASE PRINT) Office Contact and E-mail Address: \_\_\_\_\_

First Name: \_\_\_\_\_ Last Name: \_\_\_\_\_ State License #: \_\_\_\_\_

Address: \_\_\_\_\_ City: \_\_\_\_\_ State: \_\_\_\_\_ ZIP: \_\_\_\_\_

Phone: (\_\_\_\_) \_\_\_\_\_ Fax: (\_\_\_\_) \_\_\_\_\_ NPI #: \_\_\_\_\_ DEA #: \_\_\_\_\_

**Prescription: LETAIRIS:**  5 mg tablets (30 tablets) Refills: \_\_\_\_\_  10 mg tablets (30 tablets) Refills: \_\_\_\_\_

Instructions: \_\_\_\_\_

Ship to:  Patient Home (address listed above)  Prescriber Office (address listed above)  Other: (please indicate below)

Name: \_\_\_\_\_ Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ ZIP: \_\_\_\_\_ Phone: (\_\_\_\_) \_\_\_\_\_

**For all patients, please indicate whether pre-LETAIRIS liver function test has been completed:**  Yes  No

**For female patients only, please indicate whether this patient is of childbearing potential:**  Yes  No

**(Please note that female patients who have had a tubal sterilization are considered to be of childbearing potential.)**

**- If yes, has a negative pre-LETAIRIS pregnancy test been confirmed?**  Yes  No

## Statement of Medical Necessity (This is for insurance purposes only, not to suggest approved uses or indications.)

Diagnosis: Pulmonary Arterial Hypertension (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 \_\_\_\_\_)

I certify that I am prescribing LETAIRIS for a medically appropriate use in the treatment of pulmonary arterial hypertension, as described in the LETAIRIS full prescribing information. I have reviewed the Medication Guide and patient education brochure with the patient and have counseled them on the risks of LETAIRIS, including hepatotoxicity, teratogenicity, decreases in hemoglobin concentration and hematocrit, and the potential risk of reduced male fertility. I commit to ordering and reviewing liver function, pregnancy (if this patient is a female of childbearing potential), and hemoglobin tests in accordance with the LETAIRIS full prescribing information. I authorize LabSync to order laboratory tests and receive laboratory results on my behalf for patients enrolled in LEAP and LabSync.

**Prescriber Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

# LETAIRIS Education and Access Program (LEAP) Instructions

LEAP is a program to help prescribers and patients learn about the risks of Letairis® (ambrisentan), including the serious risks of liver injury and birth defects. Because of the risk of liver injury, and in an effort to make the chance of fetal exposure to LETAIRIS as small as possible, LETAIRIS may only be prescribed through the LEAP program.

**Please complete the following steps prior to faxing the patient enrollment form.**

**Step 1:** Check the box that indicates if this patient is a new enrollment, re-enrollment, or benefits investigation only

**Step 2:** Check “Yes” or “No” to indicate whether patient will participate in LabSync

**Step 3:** Check the box that indicates the patient’s preferred specialty pharmacy

**Step 4:** Complete Patient Information section, including the best method for LEAP to contact your patient

**Step 5:** Obtain patient signature. Two signatures are required for HIPAA release and to confirm that the patient has read the LETAIRIS patient Medication Guide and has been informed of the risks of LETAIRIS

**Step 6:** Obtain second patient signature

**Step 7:** Complete Prescriber Information section, including office contact for additional questions regarding this application

**Step 8:** Complete Prescription section

**Step 9:** Prescriber must sign the form

**Step 10:** Fax completed form and copies of all relevant insurance information to **LEAP** at **1-888-882-4035**

Please visit [www.letairis.com](http://www.letairis.com) or [www.gilead.com](http://www.gilead.com) or call **1-866-664-LEAP (5327)** for more information.

Please see accompanying patient Medication Guide and full prescribing information, including **boxed WARNINGS**.

