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** or **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**.

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