LEAP LETAIRIS Education and Access Program (LEAP)

LEAP Prescriber Enrollment and Agreement Form

To be enrolled into the LETAIRIS Education and Access Program, complete and fax the front of this form. **FAX:** 1-888-882-4035

Prescriber Information

First Name: _____ Middle Initial: _____ Last Name: _____ Suffix: _____

Specialty: _____ Name of Facility: _____ Office Contact: _____

Address: _____ City: _____ State: _____ ZIP: _____

E-mail: _____ Phone: (____) _____ Fax: (____) _____

State License No.: _____ NPI No.: _____ DEA No.: _____

Prescriber Agreement

By signing below, you signify your understanding of the risks of Letairis® (ambrisentan) treatment and your obligation as a LETAIRIS prescriber to educate your patients about these risks, counsel them on risk reduction, monitor them appropriately, and report adverse events to LEAP. Specifically, you attest to the following:

- I have read the full prescribing information for LETAIRIS.
- I agree to enroll in LEAP all patients prescribed LETAIRIS and re-enroll patients annually by completing the patient re-enrollment form.
- I will review the Medication Guide and Patient Enrollment Guide with each patient prior to prescribing LETAIRIS, and will discuss the risks of LETAIRIS, including the risk of teratogenicity, decreases in hemoglobin concentration and hematocrit, and the potential risk of reduced male fertility.
- I will determine if a woman is of childbearing potential* before enrolling her in LEAP. For women of childbearing potential I will order and review pregnancy tests prior to initiating treatment with LETAIRIS, and monthly during treatment in accordance with the LETAIRIS full prescribing information.
- For women of childbearing potential: I will educate and counsel them to use highly reliable contraception during LETAIRIS treatment and for one month after stopping treatment. If the patient has had a tubal sterilization or chooses to use a Copper T 380A IUD or LNg 20 IUS for pregnancy prevention, no additional contraception is needed. Women who do not choose one of these methods should always use two acceptable forms of contraception—one hormone method and one barrier method, or two barrier methods where one method is the male condom.
  - Acceptable hormone methods include: progesterone injectables, progesterone implants, combination oral contraceptives, transdermal patch, and vaginal ring.
  - Acceptable barrier methods include: diaphragm (with spermicide), cervical cap (with spermicide), and the male condom.
  - Partner's vasectomy must be used along with a hormone method or a barrier method.
  - All women of childbearing potential should undergo contraceptive counseling, with either the prescriber or another designated healthcare practitioner trained in contraceptive counseling.
  - Educate and counsel women of childbearing potential* on the use of emergency contraception in the event of unprotected sex or known or suspected contraceptive failure.
- I will counsel patients who fail to comply with the program requirements.
- I will notify LEAP of any adverse events, including death, or if any patient becomes pregnant during LETAIRIS treatment.

REQUIRED

Prescriber Signature: _____ Date: _____

Please visit **www.letairisrems.com** or call **1-866-664-LEAP (5327)** for more information about the LETAIRIS REMS program.

*See reverse side for definition of a woman of childbearing potential.

GILEAD

Letairis® ambrisentan
5 mg and 10 mg Tablets

The prescriber must determine if a woman is of childbearing potential before enrolling her in LEAP.

- Women of childbearing potential must use highly reliable contraception during LETAIRIS treatment and for one month after stopping treatment.
  - If the patient has a tubal sterilization or chooses to use a Copper T 380A IUD or LNg 20 IUS for pregnancy prevention, no additional contraception is needed.
  - Women who do not choose one of these methods should always use two acceptable forms of contraception—one hormone method and one barrier method, or two barrier methods where one method is the male condom.
  - All women of childbearing potential should undergo contraceptive counseling, with either the prescriber or another designated healthcare practitioner trained in contraceptive counseling.
  - Educate and counsel women of childbearing potential on the use of emergency contraception in the event of unprotected sex or known or suspected contraceptive failure.

Acceptable Contraceptive Methods

Methods to Use by Themselves	Combination Methods	
	Hormone Methods Choose one and use with a barrier method	**Barrier Methods** Choose two OR choose one and use with a hormone method
Intrauterine devices (IUDs) • Copper T 380A IUD • LNg 20 IUS (progesterone IUD) **Tubal sterilization**	**Estrogen and progesterone** • Oral contraceptives • Transdermal patch • Vaginal ring **Progesterone only** • Injection • Implant	• Diaphragm with spermicide OR cervical cap with spermicide • Male condom (with or without spermicide)
	Partner's vasectomy must be used along with a hormone method or a barrier method.	

Definition of a Woman of Childbearing Potential

A woman of childbearing potential is a non-menopausal female who has not had a hysterectomy, bilateral oophorectomy, or medically documented ovarian failure. This includes pubertal females who have not yet had a menses (premenarchal, Tanner Stage 3), perimenopausal women who have had a spontaneous menses in the last 12 months, and women who have had a tubal sterilization.

Pre-pubertal females (Tanner Stages 1 and 2) are not considered to be of childbearing potential. These patients should be carefully monitored for changes in childbearing potential status during LETAIRIS treatment. Notify LEAP if the patient's childbearing potential status changes.

Definition of Menopause

Menopause can be assumed to have occurred in a woman when there is either:

- Appropriate medical documentation of prior complete bilateral oophorectomy (i.e., surgical removal of the ovaries, resulting in "surgical menopause" and occurring at the age at which the procedure was performed), OR
- Permanent cessation of previously occurring menses as a result of ovarian failure with documentation of hormonal deficiency by a certified healthcare provider (i.e., "spontaneous menopause," which occurs in the United States at a mean age of 51.5 years).
  - Hormonal deficiency should be properly documented in the case of suspected spontaneous menopause as follows:
    - If age ≥54 years and with the absence of normal menses: Serum follicle stimulating hormone (FSH) level elevated to within the post-menopausal range based on the laboratory reference range where the hormonal assay is performed;
    - If age <54 years and with the absence of normal menses: Negative serum or urine human chorionic gonadotropin (hCG) with concurrently elevated serum FSH level in the post-menopausal range, depressed estradiol (E2) level in the post-menopausal range, and absent serum progesterone level, based on the laboratory reference ranges where the hormonal assays are performed.

This form is part of an FDA approved REMS.
There is no need to fax this side of the form.

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

Letairis® ambrisentan
5 mg and 10 mg Tablets

GILEAD