

Complete Patient and Physician information (PLEASE PRINT)

STEP 1	Member Name:	Physician Name:
	Address:	Address:
	Member ID:	Phone #:
	Member DOB:	Fax #:
		Tax ID or NPI #:

If Applicable: Pharmacy Name: _____
 Pharmacy Phone: _____

Complete the Clinical Assessment:

STEP 2	Diagnosis	<input type="checkbox"/> Pulmonary Arterial Hypertension <input type="checkbox"/> WHO Group I <input type="checkbox"/> Functional Class II to III symptoms	<input type="checkbox"/> Other (please state): _____ _____ _____
	Physician Specialty	<input type="checkbox"/> Pulmonology <input type="checkbox"/> Cardiology	<input type="checkbox"/> Other (please state): _____ _____ _____
	Supporting Documentation	Diagnosis: ICD-9/10 Code #/ Description / J Code (required): Please attach a copy of the prescription or provide ALL of the information below: Letairis [®] (ambrisentan) Strength _____ Sig _____ Qty _____ Refills _____	
<p><i>*Please attach all relevant medical records and test results*</i></p> <p>We will not process incomplete forms.</p> <p>If we do not receive the completed form & all relevant medical records & test results within 10 calendar days of this request, it will be denied.</p>			

STEP 3 I certify that the above is correct and accurate to the best of my knowledge and that the form is complete. (please sign and date)

 Prescriber Signature Date

STEP 4 Fax completed form to the Rocky Mountain Health Plans Pharmacy Help Desk:
970-248-5034

Name of Person filling out form: _____

Pharmacy Technician initials _____ Date Initiated _____

RMHP Formulary Coverage Policy

THIS INFORMATION IS NOT ALL-INCLUSIVE AND IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY

Letairis® (ambrisentan)

CLASSIFICATION

- Pulmonary Antihypertensive
- Endothelin receptor antagonist

DESCRIPTION

- Letairis® is indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group I) to improve exercise ability and delay clinical worsening. Efficacy trials included predominately patients with NYHA Functional Class II-III symptoms and etiologies of idiopathic or heritable PAH (64%) or PAH associated with connective tissue diseases (32%). *Note: Patients with congenital heart disease were excluded from ambrisentan trials.*
- In two 12-week, randomized, double-blind, placebo-controlled, multicenter trials (ARIES-1 and ARIES-2, oral ambrisentan, given daily at doses of 2.5 to 10 milligrams, resulted in significant improvement in 6-minute walk distance compared to placebo in patients (n=394) with PAH (WHO Group I).
- In an uncontrolled, open-label study, treatment with Letairis® was tolerated in patients with PAH (n=36) who had previously discontinued therapy with other endothelin receptor antagonists (i.e. bosentan or an investigational drug) due to aminotransferase elevations of more than 3 times the upper limit of normal. At a median follow-up of 13 months at which time 50% of the study patients were at a 10 mg/day dose, there were no cases of study discontinuation due to aminotransferase elevations.
- An integrated analysis of the ARIES-1, ARIES-2, or ARIES-E (the long-term extension study) studies (n=383) showed maintenance of improvements in exercise capacity, dyspnea, and WHO functional class with the 5mg and 10mg doses over 2 years. Long-term use was also associated with a low risk of clinical worsening and death.
- Ambrisentan is an endothelin receptor antagonist with selectivity for the endothelin-1 (ET-1) receptor subtype-A (ET-A), thus blocks the vasoconstriction and cell proliferation effects of ET-A in the vascular smooth muscle and endothelium. This allows blood vessels to relax and reduces the right atrial pressure in patients with PAH.
- Letairis® is only available through a special restricted distribution program called the Letairis education and Access Program (LEAP) due to the *black box warning* for risk of birth defects. Prescribers and pharmacies must be registered in order to prescribe and distribute Letairis®.
- Females of child-bearing potential are required to have a negative pregnancy test and must use two reliable methods of contraception. Urine or serum pregnancy tests should be obtained monthly. Contraception must be continued during and for one month following discontinuation of Letairis®.
- Improvement in signs and symptoms of pulmonary arterial hypertension (dyspnea or fatigue, chest pain, or near syncope), exercise capacity, WHO functional classification, and a decrease in the rate of clinical worsening are indicative of efficacy.
- Due to the complicated nature and severity of PAH as a disease state as well as the high cost of the agents used for PAH, patients should be managed by a pulmonary specialist. Consideration will be given to cardiology specialist.

FORMULARY COVERAGE

Prior authorization:	Required
Good Health Formulary:	Tier 4
Commercial Formulary:	Tier 4
Medicare Part D coverage:	Tier 5

COVERAGE CRITERIA

Letairis (ambrisentan) meets the definition of **medical necessity** for the following:

- Pulmonary arterial hypertension (PAH) (WHO Group I) to improve exercise ability and delay clinical worsening.
 - NYHA Functional Class II-III symptoms

Letairis (ambrisentan) is considered **experimental** for the following:

- Ambrisentan will not be covered for any indication that is not FDA approved or Compendia supported.

Required Provider Specialty:

- Approval is limited to Pulmonary and Cardiology specialists.

DOSAGE/ADMINISTRATION:

Adult Dosing (safety and efficacy has not been determined for children):

- Pulmonary Arterial Hypertension:
 - Initiate with 5 mg orally once daily with or without food.
 - May be increased to 10 mg daily if 5 mg dose is tolerated.
- Not recommended in patients with moderate to severe hepatic impairment.
- No dose adjustment needed in patients with mild to moderate renal impairment.

PRECAUTIONS:

- **Black Box Warning:** Contraindicated in pregnancy
- Women should always use two acceptable forms of contraception, a barrier method and a hormonal method. If tubal sterilization or use of Copper T 380A IUD or LNG 20 IUS, no additional contraception is needed.
- If clinically significant anemia, there is risk of further decrease in hemoglobin and hematocrit; therefore, use not recommended.
- Fluid retention (with or without weight gain) has been reported and may require discontinuation of therapy and medical management.
- Monitor hemoglobin and hematocrit due to reported decreases; consider discontinuation if occurs.
- Use in preexisting moderate or severe hepatic impairment is not recommended.
- Signs of pulmonary edema may occur; discontinue use if associated with pulmonary veno-occlusive disease.
- Reduction in sperm count may occur.

Billing/Coding information

CPT Coding:

J8499	Prescription drug, oral, non-chemotherapeutic, Not Otherwise Specified
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HCPCS Coding:

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ICD-9 Diagnoses Codes That Support Medical Necessity:

416.0	Primary pulmonary hypertension

COST

- AWP (November 2011):
 - Letairis 5mg tablets (30): \$6,835.20
 - Letairis 10mg tablets (30): \$6,835.20

COMMITTEE APPROVAL:

- September 2007

GUIDELINE UPDATE INFORMATION:

September 2007	Prior Authorization Form created
November 2011	Coverage Policy created

REFERENCES:

- DRUGDEX®, accessed 11/29/2011
- Product Information: Letairis® (ambrisentan) oral. Gilead Sciences, Inc., Foster City, CA, 2011.