ROCKY MOUNTAIN HEALTH PLANS®
We understand Colorado. We understand you.

UNIFORM PHARMACY PRIOR AUTHORIZATION REQUEST FORM

CONTAINS CONFIDENTIAL PATIENT INFORMATION

Complete this form in its entirety and send to Rocky Mountain Health Plans at 858-357-2538

☐ **Initial Request** ☐ **Renewal** ☐ **Appeal/Redetermination**[1]

☐ **Urgent**[2] ☐ **Non-Urgent**

Requested Drug Name: Letairis® (ambrisentan) – Medicare Part D

Patient Information:	**Prescribing Provider Information:**
Patient Name:	Prescriber Name:
Member/Subscriber Number:	Prescriber Fax:
Policy/Group Number:	Prescriber Phone:
Patient Date of Birth (MM/DD/YYYY):	Prescriber Pager:
Patient Address:	Prescriber Address:
Patient Phone:	Prescriber Office Contact:
Patient Email Address:	Prescriber NPI:
	Prescriber DEA:
Prescription Date:	Prescriber Tax ID:
	Specialty/Facility Name (If applicable):
	Prescriber Email Address:

Prior Authorization Request for Drug Benefit

Patient Diagnosis and ICD Diagnostic Code(s):

Drug(s) Requested (with J-Code, if applicable):

Strength/Route/Frequency:

Unit/Volume of Named Drug(s):

Start Date and Length of Therapy:

Location of Treatment: (e.g. provider office, facility, home health, etc.) including name, Type 2 NPI (if applicable), address and tax ID:

Clinical Criteria for Approval, Including other Pertinent Information to Support the Request, other Medications Tried, Their Name(s), Duration, and Patient Response:

Letairis® (ambrisentan)

Diagnosis (documentation supportive of diagnosis is required for approval)

☐ Pulmonary Arterial Hypertension (WHO Group I)
☐ Functional Class II to III symptoms
☐ Other (please state):_____

Physician Specialty

☐ Pulmonology
☐ Cardiology
☐ Other (please state):_____

☐ For use in clinical trial? (If yes, provide trial name and registration number):			
Drug Name (Brand Name and Scientific Name)/Strength:			
Dose:	Route:	Frequency:	
Quantity:	Number of Refills:		
Product will be delivered to: ☐ Patient's Home ☐Physician Office		Other:	
Prescriber or Authorized Signature:		Date:	
Dispensing Pharmacy Name and Phone Number:			
☐ **Approved** ☐ **Denied**			
If denied, provide reason for denial, and include other potential alternative medications, if applicable, that are found in the formulary of the carrier:			

1. Appeal/redetermination requests can be made for this medication within 60 calendar days from the date on the faxed/written denial notice you received at the time of the original request.

2. A request for prior authorization that if determined in the time allowed for non-urgent requests could seriously jeopardize the life or health of the covered person or the ability of the covered person to regain maximum function, or subject the person to severe pain that cannot be adequately managed without the drug benefit contained in the prior authorization request.

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 any FDA approved indication, not otherwise excluded from Part D, including 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:**
    - Embryo-fetal toxicity: Do not administer ambrisentan to a pregnant female because it may cause fetal harm. Ambrisentan is very likely to produce serious birth defects if used by pregnant females, as this effect has been seen consistently when it is administered to animals.
    - Exclude pregnancy before the initiation of treatment with ambrisentan. Females of reproductive potential must use acceptable methods of contraception during treatment with ambrisentan and for one month after treatment. Obtain monthly pregnancy tests during treatment and 1 month after discontinuation of treatment.
    - Because of the risks of embryo-fetal toxicity, females can only receive ambrisentan through a restricted program called the Letairis®REMS program

    - 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.
- Contraindications:
    - Idiopathic pulmonary fibrosis (IPF), including IPF patients with pulmonary hypertension.
    - Pregnancy (Category X all trimesters)
- Precautions:
    - 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.
    - Hepatic transaminase elevations, hepatotoxicity, and hepatic failure have been reported. Discontinue use if liver dysfunction is confirmed.
    - 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

COST

- AWP (November 2011):
    - Letairis 5mg tablets (30): $6,835.20
    - Letairis 10mg tablets (30): $6,835.20
- AWP (January 2014):
    - Letairis 5mg tablets (30): $ 8,271.90
    - Letairis 10mg tablets (30): $ 8,271.90

COMMITTEE APPROVAL:

- September 2007

GUIDELINE UPDATE INFORMATION:

September 2007	Prior Authorization Form created
November 2011	Coverage Policy created
May 2014	Coverage Policy updated

REFERENCES:

- DRUGDEX®, accessed 11/29/2011, 5/17/2014
- Product Information: Letairis® (ambrisentan) oral. Gilead Sciences, Inc., Foster City, CA, 2011.