Prior Authorization Approval Criteria
Letairis (ambrisentan)

Generic name: Ambrisentan
Brand name: Letairis
Medication class: Endothelin receptor antagonist
FDA-approved uses: Treatment of symptomatic patients (WHO Group I)

Criteria for approval (bullet points below are all inclusive unless otherwise noted):
- Clinically diagnosed with pulmonary arterial hypertension WHO Group 1 that was confirmed by right heart catheterization or echocardiogram with NYHA functional class II-IV symptoms.
- Prescribed by a pulmonologist, a cardiologist, or a physician specializing in pulmonary arterial hypertension.
- Patient must be at least 18 years of age
- Patient is not using tobacco products.
- The patient has had a vasoreactivity test unless the provider indicates that the patient has a contraindication to the test or indicates clinical inappropriateness to the vasoreactivity test.
- Must have tried and failed or has a contraindication to the use of a calcium channel blocker if they have a positive vasoreactivity test.
- Women of child bearing age must have a negative pregnancy test and must be using two reliable methods of contraception unless the patient has had a tubal sterilization or a Copper T 380A IUD or LNG 20 IUD inserted.
- Aminotransferases must be less than 3 x the ULN at baseline.
- Prescribers must enroll in the Letairis REMS Program and comply with the Letairis REMS Program requirements to prescribe Letairis.
- All female patients must enroll in the Letairis REMS Program to receive Letairis.
- Must have tried and failed or contraindication to the use of sildenafil.

Criteria for continuation of therapy:
- Patient’s therapy has been re-evaluated within the last 12 months, unless a re-evaluation is not clinically appropriate for the patient’s condition at this time.
- Patient is tolerating treatment and there continues to be a medical need for the medication.
- Patient has disease stabilization or improvement in disease (as defined by standard parameters for the patient’s condition).
- Women of child bearing age must have monthly pregnancy tests with negative results.
- Aminotransferases must remain less than 3 x the ULN and patient must have no clinical symptoms or liver injury (nausea, vomiting, fever, abdominal pain, jaundice, or unusual lethargy or fatigue).
- Bilirubin must be less than 2 x the ULN.

Caution:

The criteria listed above applies to Fallon Health Plan and its subsidiaries.
- Not recommended in patients with moderate or severe hepatic impairment

**Monitoring:**
- Measure hemoglobin at initiation, at 1 month, and periodically thereafter
- Monitor liver transaminases monthly
- Exclude pregnancy prior to initiating treatment, monthly during treatment, and for 1 month after discontinuation of treatment.
- Improvement in exercise capacity, WHO functional class, and dyspnea are indicative of efficacy.

**Contraindication:**
- Women who are pregnant
- Idiopathic pulmonary fibrosis (IPF), including those with pulmonary hypertension

**Approval Duration:**
- Initial 1 year
- Renewal 1 year

**Benefit Type:**
- Pharmacy

FCHP Pharmacy and Therapeutics Committee approval: ____________________________

Adopted: 12/12/07
Revised: 02/01/13, 3/12/14, 4/21/14, 12/14/16