



## Prior Authorization Approval Criteria

### *Letairis (ambrisentan)*

**Generic name:** ambrisentan

**Brand name:** Letairis

**Medication class:** Selective endothelin type A receptor antagonist

**FDA approved uses:** Treatment of symptomatic patients (WHO class II or III) with pulmonary hypertension (PAH)

**Available dosage forms:** 5 mg and 10 mg tablet

**Usual dose:** 5mg once daily may; be increased to 10 mg once daily if 5 mg is tolerated.

**Duration of therapy:** Indefinite

**Approximate monthly cost** (based on AWP 2007): \$4,728.00

**Criteria for use:** (bullet points below are all inclusive unless otherwise noted)

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
- Clinically diagnosed pulmonary arterial hypertension WHO group 1
- WHO Class II or III.
- 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.
- Patients, prescribers, and pharmacies must be enrolled in LEAP (Letairis Education and Access Program) at 1-800-664-5327 in order to obtain the medication

**Criteria for continuation of therapy:**

- Improved exercise capacity.
- Delay in clinical worsening.
- 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.

**Cautions:**

- 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.

**Contraindications:**

- Women who are pregnant.

**Not approved if:**

- Patient has any contraindications to the use of ambrisentan.
- Patient does not meet the above stated criteria for approval.

**Special considerations:**

**Drugs for Pulmonary Arterial Hypertension (Medical Letter, 2007)**

<b>Drug</b>	<b>Route</b>	<b>Dosage</b>	<b>Cost<sup>1</sup></b>
Ambrisentan – <i>Letairis</i> <sup>2</sup>	oral	5-10 mg once/d	\$4,728.00
Bosentan – <i>Tracleer</i> <sup>2</sup>	oral	62.5 mg bid (for 4 wks) then 125 mg bid <sup>4</sup>	4,657.50 <sup>3</sup>
Sildenafil – <i>Revatio</i>	oral	20-80 mg tid	1,063.45
Epoprostenol – <i>Flolan</i> <sup>2</sup>	continuous IV infusion	20-40 ng/kg/min <sup>5</sup>	2,762.73 <sup>6</sup>
Treprostinil – <i>Remodulin</i> <sup>2</sup>	continuous SC IV infusion	40-160 ng/kg/min <sup>7</sup>	8,134.56 <sup>6</sup>
Iloprost – <i>Ventavis</i> <sup>2</sup>	inhalation	2.5-5 mcg/inhalation, 6-9 times a day	7,678.80

1. Cost of 30 days' treatment at the lowest dosage for the drug alone according to Wolters Kluwer Health (May 31, 2007), or AWP listings in *Red Book 2007*, and the October 2007 *Update*. Ancillary costs will substantially increase the cost of non-oral drugs. Assistance in purchasing these drugs is available from the manufacturers.
2. Available only through specialty pharmacies such as Accredo Therapeutics (1-866-344-4874) or Curascript (1-866-474-8326).
3. Price for 30 days' maintenance treatment.
4. Tablets should be taken in the morning and evening with or without food.
5. Initial dosage recommended is 2 ng/kg/min with subsequent increases of 2 ng/kg/min as tolerated. Dosage requirements tend to increase over time. Average dosage after 6 months is about 20-40 ng/kg/min.
6. For a 70-kg patient.
7. Initial dosage recommended is 1.25 ng/kg/min, or half if poorly tolerated, with subsequent increases of <1.25 ng/kg/min weekly for the first 4 weeks, then <2 ng/kg/min weekly thereafter. Average dosage after 9 months is about 60 ng/kg/min.

P&T Approval: \_\_\_\_\_ Date: \_\_\_\_\_  
Adopted: 12/12/07