

The following policy is for medication that falls under the Medicare Part D benefit only.

**Prior Authorization Group:** LETAIRIS Policy

**Drug(s):** LETAIRIS (ambrisentan)

**Covered Uses:** Diagnosis of primary pulmonary hypertension or pulmonary hypertension secondary to any of the following conditions: Collagen vascular disease, Portal hypertension, HIV infection, Drugs/toxins (i.e. anorexiant). All criteria in "other criteria" section must be met for coverage.

**Required Medical Information:** Documentation should include verification of primary pulmonary hypertension by right sided catheterization, New York Heart Association (NYHA) Class status, 6-minute walk test, acute vasoreactivity test results, treatment rationale, previous therapies, time frames and plan for administration, blood pressure, oxygen saturation, liver function tests, kidney function (i.e. serum creatinine, creatinine clearance, etc.), hemoglobin, pregnancy test monthly for females of child bearing age, and medical history.

**Age Restrictions:** Restricted to 18 years and older.

**Prescriber Restrictions:** Ordered by or consult with pulmonologist or cardiologist.

**Other Criteria:** Coverage will be considered if all of the following criteria are met:

1. WHO Group 1 with WHO class II or III symptoms.
2. PAP pressures not adequately controlled using an oral vasodilator (e.g. CCB) at maximal doses OR the member was not vasodilator sensitive as determined by a epoprostenol, adenosine, or inhaled nitric oxide challenge.

Extension of therapy is dependent upon documentation of clinical response including but not limited to: improvement in exercise capacity (6-minute walk test) versus baseline, improvement in NYHA class versus baseline, lack of deterioration.

**Exclusion Criteria:** Coverage will not be provided if any of the following are true:

- Use in pregnancy, Chronic Obstructive Pulmonary Disease (COPD), severe asthma, Congestive Heart Failure (CHF), lung resection, ischemic vascular disease, history of significant liver disease.
- More than 1 tablet per day,
- Diagnosis of digital ulcers or erectile dysfunction,
- Combination therapy with other PAH agents such as Flolan, Tracleer, Remodulin, Revatio, Ventavis, ketoconazole or omeprazole.
- Use in World Health Organization (WHO) group II (left heart disease including left-sided atrial or ventricular heart disease and left-sided valvular heart disease),
- WHO group III (pulmonary hypertension associated with lung diseases and/or hypoxemia including chronic obstructive pulmonary disease, interstitial lung disease, sleep-disordered breathing, alveolar hypoventilation disorders, chronic exposure to high altitudes, developmental abnormalities),

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- WHO group IV [pulmonary hypertension due to chronic thrombotic and/or embolic disease including thromboembolic obstruction of proximal or distal pulmonary arteries and non-thrombotic pulmonary embolism (e.g. tumor, parasites, foreign material)],
- WHO group V [including sarcoidosis, histiocytosisX, lymphangiomatosis, compression of pulmonary vessels (adenopathy, tumor, fibrosing mediastinitis)].
- Coverage is not provided for doses exceeding package labeling.

**Coverage Duration:** Initial authorization will be limited to 3 months. Extended authorizations will be limited to 6 months.