

Market Applicability															
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

Letairis (ambrisentan)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Letairis (ambrisentan) 5mg, 10mg	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Letairis (ambrisentan) may be approved if the following criteria are met:

- I. Individual has a catheterization-proven diagnosis² of pulmonary arterial hypertension (PAH) [World Health Organization (WHO) Group 1]³; **AND**
- II. Individual has WHO functional class II-IV⁴ symptoms.

Letairis (ambrisentan) may **not** be approved for the following:

- I. Individual has a diagnosis of idiopathic pulmonary fibrosis (IPF); **OR**
- II. Individual has a diagnosis of moderate (Child-Pugh Class B) or severe (Child-Pugh Class C) hepatic impairment; **OR**
- III. Individual is on dialysis or has a diagnosis of severe renal impairment (creatinine clearance less than 20 mL/min); **OR**
- IV. In combination with other endothelin receptor antagonist (ERA) agents, such as but not limited to Opsumit (macitentan) or Tracleer (bosentan); **OR**
- V. Individual is initiating therapy and has a diagnosis of clinically significant/severe anemia.

Notes:

1. Letairis (ambrisentan) has a black box warning for embryo-fetal toxicity. Letairis is very likely to produce serious birth defects if used by pregnant women, as this effect has been seen consistently when it is administered to animals. Pregnancy must therefore be excluded before the initiation of treatment and prevented during treatment with acceptable methods of contraception. Monthly pregnancy tests should be obtained

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This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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during treatment and 1 month post-treatment. Because of the risks of birth defects, Letairis is available for females only through a special restricted distribution program under a Risk Evaluation and Mitigation Strategy (REMS). As a component of the Letairis REMS, prescribers, individuals, and pharmacies must enroll in the program.

2. Diagnostic criteria:

- A. PAH: Right heart catheterization which shows a mean pulmonary artery pressure (mPAP) greater than 25 mm Hg; a pulmonary capillary wedge pressure (PCWP), left atrial pressure, or left ventricular end-diastolic pressure (LVEDP) less than or equal to 15 mm Hg; and a pulmonary vascular resistance (PVR) greater than 3 Wood units (ACCF/AHA 2009).
- B. CTEPH: Pulmonary angiography via right-heart catheterization which shows a mPAP greater than 25 mm Hg caused by thromboemboli in the pulmonary arterial system (ACCF/AHA 2009, Kim et al. 2013).

3. WHO Pulmonary Hypertension (PH) Group Classification (ACCF/AHA 2009, Simonneau et al. 2013):

- A. Group 1: Pulmonary arterial hypertension (PAH)
- B. Group 2: PH due to left heart disease
- C. Group 3: PH due to lung diseases and/or hypoxia
- D. Group 4: Chronic thromboembolic PH (CTEPH)
- E. Group 5: Miscellaneous/PH with unclear multifactorial mechanisms

4. WHO functional classification of PH (CHEST 2014):

- A. Class I: No limitation of physical activity. Ordinary physical activity does not cause undue dyspnea or fatigue, chest pain, or near syncope.
- B. Class II: Slight limitation of physical activity. Comfortable at rest but ordinary physical activity causes undue dyspnea or fatigue, chest pain, or near syncope.
- C. Class III: Marked limitation of physical activity. Comfortable at rest but less than ordinary activity causes undue dyspnea or fatigue, chest pain, or near syncope.
- D. Class IV: Inability to carry out any physical activity without symptoms. Dyspnea and/or fatigue may be present at rest and discomfort is increased by any physical activity.

State Specific Mandates

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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	NA

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State name N/A	Date effective N/A	Mandate details (including specific bill if applicable) N/A
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Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2017. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed January 30, 2017.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2017; Updated periodically.

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