

**Letairis (ambrisentan)
Ambrisentan (generic)
Effective 09/01/2023**

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange		Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit			<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.			
Contact Information	Medical Benefit	Phone: 833-895-2611	Fax: 888-656-6671	
	Pharmacy Benefit	Phone: 800-711-4555	Fax: 844-403-1029	
Exceptions	N/A			

Overview

FDA-Approved Indications

Ambrisentan is indicated for the treatment of pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1):

1. To improve exercise ability and delay clinical worsening
2. In combination with tadalafil to reduce the risks of disease progression and hospitalization for worsening PAH, and to improve exercise ability.

Coverage Guidelines

Authorization may be granted for members new to General Brigham Health Plan who are currently receiving treatment with the requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Pulmonary Arterial Hypertension (PAH)

Authorization may be granted for treatment of PAH when ALL of the following criteria are met:

1. Member has PAH defined as WHO Group 1 class of pulmonary hypertension (Refer to Appendix)
2. PAH was confirmed by ONE of the following:
 - a. PAH was confirmed by right heart catheterization with all of the following pretreatment results:
 - i. mPAP > 20 mmHg
 - ii. PCWP ≤ 15 mmHg
 - iii. PVR ≥ 3 Wood units
 - b. For infants less than one year of age, PAH was confirmed by Doppler echocardiogram if right heart catheterization cannot be performed

Continuation of Therapy

Authorization of 12 months may be granted for members with a covered indication who are currently receiving the requested medication and who are experiencing benefit from therapy as evidenced by disease stability or disease improvement.

Limitations

1. Initial approvals and reauthorizations will be granted for 12 months.

Appendix: WHO Classification of Pulmonary Hypertension

1. PAH

- 1.1 Idiopathic (PAH)
- 1.2 Heritable PAH
- 1.3 Drug- and toxin-induced PAH
- 1.4 PAH associated with:
 - 1.4.1 Connective tissue diseases
 - 1.4.2 HIV infection
 - 1.4.3 Portal hypertension
 - 1.4.4 Congenital heart diseases
 - 1.4.5 Schistosomiasis
- 1.5 PAH long-term responders to calcium channel blockers
- 1.6 PAH with overt features of venous/capillaries (PVOD/PCH) involvement
- 1.7 Persistent PH of the newborn syndrome

2. PH due to left heart disease

- 2.1 PH due to heart failure with preserved LVEF
- 2.1 PH due to heart failure with reduced LVEF
- 2.2 Valvular heart disease
- 2.3 Congenital/acquired cardiovascular conditions leading to post-capillary PH

3. PH due to lung diseases and/or hypoxia

- 3.1 Obstructive lung disease
- 3.2 Restrictive lung disease
- 3.3 Other lung disease with mixed restrictive/obstructive pattern
- 3.4 Hypoxia without lung disease
- 3.5 Developmental lung disorders

4. PH due to pulmonary artery obstruction

- 4.1 Chronic thromboembolic PH
- 4.2 Other pulmonary artery obstructions
 - 4.2.1 Sarcoma (high or intermediate grade) or angiosarcoma
 - 4.2.2 Other malignant tumors
 - Renal carcinoma
 - Uterine carcinoma
 - Germ cell tumours of the testis
 - Other tumours
 - 4.2.3 Non-malignant tumours
 - Uterine leiomyoma
 - 4.2.4 Arteritis without connective tissue disease
 - 4.2.5 Congenital pulmonary artery stenosis
 - 4.2.6 Parasites
 - Hydatidosis



5. PH with unclear and/or multifactorial mechanisms

- 5.1 Hematologic disorders: Chronic hemolytic anemia, myeloproliferative disorders
- 5.2 Systemic and metabolic disorders: Pulmonary Langerhans cell histiocytosis, Gaucher disease, glycogen storage disease, neurofibromatosis, sarcoidosis
- 5.3 Others: chronic renal failure with or without hemodialysis, fibrosing mediastinitis
- 5.4 Complex congenital heart disease

References

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10. Abman, SH, Hansmann G, Archer SL, et al. Pediatric pulmonary hypertension: guidelines from the American Heart Association and American Thoracic Society. *Circulation*. 2015;132(21):2037-99.
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12. Galie, N., McLaughlin, VV, Rubin, LJ, Simonneau, G. An overview of the 6th World Symposium on Pulmonary Hypertension. *Eur Respir J* 2019; 53: 1802148; DOI: 10.1183/13993003.02148-2018. Published 24 January 2019
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Review History

07/12/2023 – Reviewed at July P&T; Switched from CVS Standard to custom criteria; Effective 9/1/23

