PRIOR AUTHORIZATION CRITERIA

BRAND NAME	**LETAIRIS**
(generic)	**(ambrisentan)**
Status: CVS Caremark Criteria	***MDC***
Type: Initial Prior Authorization	***Ref # 640-A***

FDA-APPROVED INDICATION[1]

Letairis is indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1)

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

Studies establishing effectiveness included predominantly patients with WHO Functional Class II to III symptoms and etiologies of idiopathic or heritable PAH (60%) or PAH associated with connective tissue diseases (34%).

CRITERIA FOR APPROVAL

1	Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1)? [If no, no further questions.]	Yes	No
2	Has pulmonary arterial hypertension (PAH) been confirmed by right heart catheterization? [If no, no further questions.]	Yes	No
3	Has the patient previously received the prescribed drug for pulmonary arterial hypertension (PAH)? [If yes, no further questions.]	Yes	No
4	Does the patient meet all of the following criteria: 1) Pretreatment mean pulmonary arterial pressure greater than or equal to 25 mmHg, and 2) Pretreatment pulmonary capillary wedge pressure less than or equal to 15 mmHg, and 3) Pretreatment pulmonary vascular resistance greater than 3 Wood units?	Yes	No

Guidelines for Approval			
Duration of Approval		**12 months**	
Set 1: PAH, renewal		**Set 2:** PAH, initial	
Yes to question(s)	**No to question(s)**	**Yes to question(s)**	**No to question(s)**
1	None	1	3
2		2	
3		4	

Internal Use Only – Mapping Instructions		
	Yes	**No**
1	Go to 2	Deny
2	Go to 3	Deny
3	Approve, 12 months	Go to 4
4	Approve, 12 months	Deny

RATIONALE

These criteria meet the Medicare Part D definition of a medically accepted indication. This definition includes uses which are approved by the FDA or supported by a citation included, or approved for inclusion, in one of the Medicare approved compendia.

The intent of the criteria is to ensure that patients follow selection elements noted in labeling and/or practice guidelines in order to decrease the potential for inappropriate utilization.

REFERENCES

1. Letairis [package insert]. Foster City, CA: Gilead Sciences, Inc.; October 2015.
2. McLaughlin VV, Archer SL, Badesch DB, et al. ACCF/AHA 2009 expert consensus document on pulmonary hypertension a report of the American College of Cardiology Foundation Task Force on Expert Consensus Documents and the American Heart Association developed in collaboration with the American College of Chest Physicians; American Thoracic Society, Inc.; and the Pulmonary Hypertension Association. *J Am Coll Cardiol*. 2009;53(17):1573-1619.
3. Badesch DB, Champion HC, Gomez-Sanchez MA, et al. Diagnosis and assessment of pulmonary arterial hypertension. *J Am Coll Cardiol.* 2009;54:S55-S66.
4. Taichman DB, Ornelas J, Chung L, et al. Pharmacologic therapy for pulmonary arterial hypertension in adults. CHEST guideline and expert panel report. *Chest*. 2014;46(2):449-475.

DOCUMENT HISTORY

Written by:	Specialty Clinical Development (AK) 06/2007
Revised:	Specialty Clinical Development (MG) 04/2008; (AC) 03/2009, (KH) 05/2010, (KH) 03/2011 Split into 2 versions per CMS guidance, (KH) 03/2011 (Boxed Warning revised to remove LFT monitoring), KR 04/2011, KR 10/2011, DK 09/2012 (CMS), 09/2013; HY 09/2014 (CMS), JP 08/2015 (CMS); KF 04/2015, 06/2016 (CMS), KF 09/2016 (CMS revision); ST 04/2016, 03/2017 (CMS 2017), 07/2017 (CMS)
Reviewed:	CDPR (WLF) 06/2007, 04/2008, 05/2009, (WLF/DL) 05/2010, (KP) 03/2011, 05/2011, 05/2012; (LCB) 05/2013, DNC 06/2014; KRU 05/2015; AN 09/2016; DNC 04/2016; LMS 03/2017
External Review:	06/2007, 07/2008, 06/2009, 07/2010, 06/2011, 06/2012, 06/2013, 07/2014, 06/2015, 06/2016