Opsumit (macitentan)

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

Medications	Quantity Limit
Opsumit (macitentan) tablets	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for Opsumit (macitentan) may be approved if the following criteria are met:

I. Individual has pulmonary arterial hypertension (PAH) [World Health Organization (WHO) Group 1][2]; **AND**
II. Individual has the diagnosis of PAH confirmed by a right-heart catheterization showing all of the following (Hoeper, 2013; Ivy, 2013; Abman, 2015):
    A. Mean pulmonary artery pressure (mPAP) greater than or equal to 25 mm Hg at rest;
    B. Pulmonary capillary wedge pressure (PCWP), mean pulmonary artery wedge pressure (PAWP), left atrial pressure, or left ventricular end-diastolic pressure (LVEDP) less than or equal to 15 mm Hg;
    C. Pulmonary vascular resistance (PVR) greater than 3 Wood units; **AND**
III. Individual has WHO functional class II-IV[3] symptoms.

Continuation requests for Opsumit (macitentan) may be approved if the following criterion is met:

I. There is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to improvement in walk distance, dyspnea and/or functional class).

Opsumit (macitentan) may not be approved for the following:

I. Individual is initiating therapy and has a diagnosis of clinically significant anemia **OR**
II. In combination with other endothelin receptor antagonist (ERA) agents, such as but not limited to Letairis (ambrisentan) or Tracleer (bosentan).

Notes:

1. Opsumit (macitentan) has a black box warning for embryo-fetal toxicity. Opsumit is very likely to produce serious birth defects if used by pregnant women, as this effect has been seen consistently when they are administered to animals. Pregnancy must be excluded before the initiation of treatment and prevented during treatment and for one month after treatment with acceptable methods of contraception. Monthly pregnancy tests should be obtained during treatment and one month post-treatment. Because of the risks of birth defects, Opsumit is available for females only through a special restricted distribution program under a Risk Evaluation and Mitigation Strategy (REMS).

2. WHO Pulmonary Hypertension (PH) Group Classification (ACCF/AHA 2009):
   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

3. WHO functional classification of PH (CHEST 2019):
   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
   E. and/or fatigue may be present at rest and discomfort is increased by any physical activity.

Key References:

1. 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):2037-2099.
2. Badesch BD, Abman SH, Simonneau G, et al. Medical therapy for pulmonary arterial hypertension: updated ACCP evidence-based clinical practice guidelines. *Chest*. 2007; 131(6):1917-1928.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: January 3, 2021.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Hoeper MM, Bogaard HJ, Condliffe R, et al. Definitions and Diagnosis of Pulmonary Hypertension. *J Am Coll Cardiol*. 2013; 62(suppl 25):D42- D50. Available at: http://www.onlinejacc.org/content/62/25_Supplement/D42. Accessed: January 6, 2021.
6. Ivy DD, Abman SH, Barst RJ, et al. Pediatric Pulmonary Hypertension. *J Am Coll Cardiol*. 2013; 62(suppl 25):D117-D126. Available from: http://www.onlinejacc.org/content/62/25_Supplement/D117. Accessed: January 6, 2021.
7. Klinger JR, Elliott CG, Levine DJ, et. al. Therapy for Pulmonary Arterial Hypertension in Adults: Update of the CHEST Guideline and Expert Panel Report. *CHEST*. 2019; 155(3): 565-586.
8. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.

9. 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. *J Am Coll Cardiol*. 2009; 53:1573-1619. Available at: http://circ.ahajournals.org/content/119/16/2250.full.pdf+html. Accessed: January 6, 2021.
10. Simonneau G, Montani D, Celermajer DS, et al. Haemodynamic definitions and updated clinical classification of pulmonary hypertension. *Eur Respir J*. 2019; 53(1).

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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