| Market Applicability/Effective Date | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Market** | **FL & FHK** | **FL MMA** | **FL LTC** | **GA** | **KS** | **KY** | **LA** | **MD** | **NJ** | **NV** | **NY** | **TN** | **TX** | **WA** |
| **Applicable** | X | NA | NA | X | NA | X | X | X | X | X | X | NA | NA | X |

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# Opsumit (macitentan)

| Override(s) | Approval Duration |
|---|---|
| Prior Authorization<br>Quantity Limit | 1 year |

| Medications | Quantity Limit |
|---|---|
| Opsumit (macitentan) 10 mg | May be subject to quantity limit |

## APPROVAL CRITERIA

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

I. Individual has a catheterization-proven diagnosis[2] of pulmonary arterial hypertension (PAH) [World Health Organization (WHO) Group 1][3]; **AND**
II. Individual has WHO functional class II-IV[4] symptoms.

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. Pregnancy should be excluded prior to start of treatment, monthly during treatment, and 1 month after stopping treatment in females of reproductive potential. Opsumit should not be administered to pregnant females due to the potential of causing fetal harm. Pregnancy should be prevented using acceptable means of contraception during treatment and for one month after therapy discontinued. Opsumit will be available for all females, regardless of reproductive potential, through a restricted risk evaluation and mitigation strategy (REMS) program. As a component of the Opsumit REMS, prescribers, individuals, and pharmacies must enroll in the program.

2. Diagnostic criteria:

| Market Applicability/Effective Date | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Market** | **FL & FHK** | **FL MMA** | **FL LTC** | **GA** | **KS** | **KY** | **LA** | **MD** | **NJ** | **NV** | **NY** | **TN** | **TX** | **WA** |
| **Applicable** | X | NA | NA | X | NA | X | X | X | X | X | X | NA | NA | X |

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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 | | |
|---|---|---|
| State name | Date effective | Mandate details (including specific bill if applicable) |
| N/A | N/A | N/A |

**Key References**:

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

| Market Applicability/Effective Date | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Market** | **FL & FHK** | **FL MMA** | **FL LTC** | **GA** | **KS** | **KY** | **LA** | **MD** | **NJ** | **NV** | **NY** | **TN** | **TX** | **WA** |
| **Applicable** | X | NA | NA | X | NA | X | X | X | X | X | X | NA | NA | X |

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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.



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.