

**Commercial/Healthcare Exchange PA Criteria**  
**Effective: 5/11/2018**

**Prior Authorization:** Opsumit (macitentan)

**Products Affected:** Opsumit (macitentan) oral tablets

**Medication Description:**

Endothelin-1 (ET) can cause inflammation, hypertrophy, vasoconstriction, fibrosis, and proliferation when it binds to ET-A and ET-B receptors. Macitentan is a dual endothelin ET(A) and ET(B) receptor antagonist with a high affinity for and long occupancy period of ET receptors in pulmonary arterial smooth muscle cells.

**Covered Uses:** Treatment of pulmonary arterial hypertension (PAH, WHO Group I) to reduce the risks of disease progression and hospitalization for PAH.

**Exclusion Criteria:** Pregnancy

**Required Medical Information:**

1. Diagnosis
2. World Health Organization (WHO) functional class
3. Previous therapies tried and failed

**Age Restrictions:** 18 years of age and older

**Prescriber Restrictions:** Prescribed by, or in consultation with, a pulmonologist or a cardiologist

**Coverage Duration:** 12 months

**Other Criteria:**

**Pulmonary Arterial Hypertension.** Approve if the patient meets the following criteria:

- A. Patient has clinically diagnosed primary or secondary PAH (defined as a mean pulmonary arterial pressure >25mm Hg at rest or >30mm Hg during exercise, with a normal pulmonary capillary wedge pressure); **AND**
- B. Patient has had a trial and failure, intolerance, or contraindication to a generic endothelin receptor antagonist, ambrisentan or bosentan.

**References:**

1. Product Information: OPSUMIT(R) oral tablets, macitentan oral tablets. Actelion Pharmaceuticals US, Inc. (per FDA), South San Francisco, CA, 2015.
2. Macitentan. IBM Micromedex® [database online]. Greenwood Village, CO. Truven Health Analytics. Available at: <https://www.micromedexsolutions.com>. Updated March 20, 2020. Accessed June 18, 2020.

Policy Revision history:

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	05/11/2018
2	Annual Review	No Changes; CCI adopted EH policy and template	All	01/14/2020
3	Revision	Coverage duration updated to 12 months Removal of other criteria: Patient must not be using tobacco products Removal of other criteria: Removal of NYHA functional class symptoms	All	7/1/2020