

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Macitentan (Opsumit)

Notes:

- Quantity Limits: No
- Macitentan is teratogenic and should not be used in pregnant females
- Macitentan is available through a restricted risk evaluation and mitigation strategy (REMS) program

Initiation (new start) criteria: Non-formulary **macitentan (Opsumit)** will be covered on the prescription drug benefit when the following criteria are met:

- Prescriber is a Pulmonologist or Cardiologist
- Diagnosis of pulmonary arterial hypertension World Health Organization [WHO] Group I with WHO New York Heart Association Functional Class II, III or IV
- Any of the following:
 1. Documented treatment failure, intolerance or contraindication to both bosentan **-AND-** ambrisentan
 2. Diagnosis of moderate (Child-Pugh Class B) to severe (Child-Pugh Class C) hepatic impairment
 3. Liver transaminases more than 3 times the upper limit of normal