Commercial PA Criteria

Effective: June 28, 2024

Prior Authorization: Opsynvi (macitentan/tadalafil)

Products Affected: Opsynvi (macitentan/tadalafil) oral tablets

Medication Description: Opsynvi is a combination of macitentan, an endothelin receptor antagonist (ERA), and tadalafil, a phosphodiesterase 5 (PDE5) inhibitor, indicated for the treatment of pulmonary arterial hypertension in adult patients of WHO functional class II to III.

Covered Uses: Pulmonary arterial hypertension in adult patients of WHO functional class II to III

Exclusion Criteria:

1. **Concurrent use with Guanylate Cyclase Stimulators** - Coadministration of GC stimulators such as riociguat with OPSYNVI is contraindicated. Tadalafil may potentiate the hypotensive effects of GC stimulators.
2. **Pregnancy** - OPSYNVI may cause fetal harm when administered to a pregnant woman. OPSYNVI is contraindicated in females who are pregnant. Macitentan was consistently shown to have teratogenic effects when administered to animals.
3. **Concurrent use with organic Nitrates** - OPSYNVI is contraindicated in patients who are using any form of organic nitrate, either regularly or intermittently. Do not use nitrates within 48 hours of the last dose of OPSYNVI. Tadalafil potentiates the hypotensive effect of nitrates

Required Medical Information:

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

Prescriber Restriction: The medication is prescribed by or in consultation with a cardiologist or a pulmonologist.

Age Restriction: 18 years of age and older

Coverage Duration: 12 months

Other Criteria:

Initial Approval Criteria

1. **Pulmonary Arterial Hypertension (PAH) [World Health Organization {WHO} Group 1].**
   Approve for 1 year if the patient meets ALL of the following (A, B, **AND** C).
   A. Patient has a diagnosis of World Health Organization (WHO) Group 1 pulmonary arterial hypertension (PAH); **AND**
   B. Patient meets BOTH of the following (i **AND** ii):
      i. Patient has had a right heart catheterization; **AND**

ii. Results of the right heart catheterization confirm the diagnosis of WHO Group 1 PAH; **AND**

C. The medication is prescribed by or in consultation with a cardiologist or a pulmonologist.

Renewal Criteria

1. **Pulmonary Arterial Hypertension (PAH) [World Health Organization {WHO} Group 1].**

Approve for 1 year if the patient meets ALL of the following (A, B, **AND** C).

A. Patient has a diagnosis of World Health Organization (WHO) Group 1 pulmonary arterial hypertension (PAH); **AND**

B. Patient meets BOTH of the following (i **AND** ii):

i. Patient has had a right heart catheterization; **AND**

Note: This refers to prior to starting therapy with a medication for WHO Group 1 PAH

ii. Results of the right heart catheterization confirm the diagnosis of WHO Group 1 PAH; **AND**

C. The medication is prescribed by or in consultation with a cardiologist or a pulmonologist.

References:

1. Opsynvi® tablets [prescribing information]. Titusville, NJ: Actelion/Janssen; March 2024.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	06/28/2024