HAP CareSource™

PHARMACY POLICY STATEMENT
HAP CareSource™ Marketplace

DRUG NAME	Opsynvi (macitentan and tadalafil)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Opsynvi is a combination of macitentan, an endothelin receptor antagonist (ERA), and tadalafil, a phosphodiesterase 5 (PDE5) inhibitor, indicated for chronic treatment of pulmonary arterial hypertension (PAH, WHO Group I) in adult patients of WHO functional class (FC) II-III.
PAH is a rare but serious condition characterized by elevated pulmonary arterial resistance. Symptoms develop slowly over time and can include shortness of breath, fatigue, and chest pain. WHO group 1 encompasses a variety of different types of PAH including idiopathic, heritable and drug induced.
In a phase 3 trial, Opsynvi reduced pulmonary vascular resistance (PVR) when compared to monotherapy with macitentan and tadalafil at 16 weeks.

Opsynvi (macitentan and tadalafil) will be considered for coverage when the following criteria are met:

Pulmonary Arterial Hypertension [WHO Group I]

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a cardiologist or pulmonologist; AND
3. Member must have a diagnosis of WHO Group 1 PAH confirmed by right heart catheterization; AND
4. Member has functional class II or III (see appendix); AND
5. Member must have documentation of **ONE** of the following:
   a) Patient had an acute response to vasodilator testing AND has tried a calcium channel blocker (CCB) for at least 3 months;
   b) Patient did not have a response to vasodilator testing;
   c) Patient cannot undergo vasodilator testing;
   d) Patient cannot take CCB therapy; AND
6. Member has tried and failed a phosphodiesterase type 5 inhibitor (ex. sildenafil, tadalafil) AND an endothelin receptor antagonist (ex. ambrisentan, bosentan, macitentan) concomitantly; AND
7. Provider attests that member is **NOT** pregnant.
8. **Dosage allowed/Quantity limit:** Quantity limit: 30 tablets per 30 days.
   a) For patients who are treatment-naïve to any PAH specific therapy or transitioning from ERA monotherapy: administer one 10 mg/20 mg tablet taken orally once daily for one week. If tolerated, titrate to one 10 mg/40 mg tablet taken orally once daily as the maintenance dose.
   b) For patients transitioning from PDE5 inhibitor monotherapy or PDE5 inhibitor and ERA therapy in combination: one 10 mg/40 mg tablet taken orally once daily.

If all the above requirements are met, the medication will be approved for 6 months.

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For **reauthorization**:

1. Chart notes must show improvement or stabilized signs and symptoms of disease (such as decrease in symptoms or functional class, increase in 6MWD (6-minute walk distance) or reduction in PVR).

If all the above requirements are met, the medication will be approved for an additional 12 months.

HAP CareSource considers Opsynvi (macitentan and tadalafil) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
04/10/2024	New policy for Opsynvi created.
07/02/2024	Added trial of phosphodiesterase type 5 inhibitor AND an endothelin receptor antagonist concomitantly.

Appendix:

World Health Organization Functional Assessment Classification	
Class I	Patients with PAH but without resulting limitation of physical activity. Ordinary physical activity does not cause undue dyspnea, fatigue, chest pain or near syncope.
Class II	Patients with PAH resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity increases dyspnea, fatigue, chest pain, or near syncope.
Class III	Patients with PAH resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity increases dyspnea, fatigue, chest pain, or near syncope.
Class IV	Patients with PAH unable to carry out any physical activity without symptoms. These patients may have signs of right-heart failure. Dyspnea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

References:

1. Opsynvi [prescribing information]. Actelion Pharmaceuticals US, Inc.; 2024.
2. Maron BA. Revised Definition of Pulmonary Hypertension and Approach to Management: A Clinical Primer. *J Am Heart Assoc.* 2023;12(8):e029024. doi:10.1161/JAHA.122.02902
3. Humbert M, Kovacs G, Hoeper MM, et al. 2022 ESC/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension. *Eur Respir J.* 2023;61(1):2200879. Published 2023 Jan 6. doi:10.1183/13993003.00879-2022
4. Coons, J.C., Pogue, K., Kolodziej, A.R. et al. Pulmonary Arterial Hypertension: a Pharmacotherapeutic Update. *Curr Cardiol Rep.* 2019; 21(141)
5. Klinger JR, Elliott CG, Levine DJ, et al. Therapy for Pulmonary Arterial Hypertension in Adults: Update of the CHEST Guideline and Expert Panel Report [published correction appears in Chest. 2021 Jan;159(1):457]. *Chest.* 2019;155(3):565-586. doi:10.1016/j.chest.2018.11.030

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