

**OPSYNVI
(macitentan and tadalafil)**

Pre - PA Allowance

None

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Pulmonary Arterial Hypertension (PAH) - **WHO Group I**
 - a. NYHA functional **class II or III**

AND NONE of the following:

1. Concurrent therapy with any nitrates (in any form)
2. Concurrent therapy with another phosphodiesterase 5 (PDE5) inhibitor
3. Concurrent therapy with guanylate cyclase (GC) stimulators
4. Concurrent therapy with alpha blockers
5. Severe hepatic impairment (Child-Pugh Class C)
6. Severe renal impairment (creatinine clearance <30 mL/min)

AND ALL of the following:

1. Absence of clinically significant anemia
2. Prescribed by or recommended by a cardiologist or pulmonologist
3. Prescriber agrees to monitor for pulmonary edema and discontinue if confirmed
4. Prescriber agrees to counsel and evaluate the patient for sudden loss of vision or hearing associated with this medication
5. Females of reproductive potential **only**: patient should have pregnancy excluded before the start of treatment with Opsynvi and patient should be advised to use effective contraception during treatment and for one month after the last dose

Prior - Approval Limits

Quantity 90 tablets per 90 days

Duration 2 years

**OPSYNVI
(macitentan and tadalafil)**

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Pulmonary Arterial Hypertension (PAH) - **WHO Group I**

AND NONE of the following:

- a. Concurrent therapy with any nitrates (in any form)
- b. Concurrent therapy with another phosphodiesterase 5 (PDE5) inhibitor
- c. Concurrent therapy with guanylate cyclase (GC) stimulators
- d. Concurrent therapy with alpha blockers
- e. Severe hepatic impairment (Child-Pugh Class C)
- f. Severe renal impairment (creatinine clearance <30mL/min)

AND ALL of the following:

1. Symptoms have improved or stabilized
2. Prescriber agrees to monitor for pulmonary edema and discontinue if confirmed
3. Prescriber agrees to counsel and evaluate the patient for sudden loss of vision or hearing associated with this medication
4. Females of reproductive potential **only**: patient should be advised to use effective contraception during treatment with Opsynvi and for one month after the last dose

Prior - Approval *Renewal* Limits

Same as above