

OPSUMIT (macitentan)

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 ALL of the following:

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

Prior - Approval Limits

Quantity 90 tablets per 90 days

Duration 2 years

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 ALL of the following:

1. Symptoms have improved or stabilized



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- 2. Females of reproductive potential **only**: patient should be advised to use effective contraception during treatment with Opsumit and for one month after the last dose
- 3. Prescriber agrees to monitor for pulmonary edema and discontinue if confirmed

Prior - Approval Renewal Limits

Same as above