

ALASKA MEDICAID
Prior Authorization Criteria

**Opsumit™
(macitentan)**

FDA INDICATIONS AND USAGE¹

Opsumit™ is an endothelin receptor antagonist (ERA) indicated for the treatment of pulmonary arterial hypertension (PAH, WHO Group I) to reduce the risks of disease progression and hospitalization for PAH

APPROVAL CRITERIA^{1,2}

1. Prescribed by or in consultation with a cardiologist or pulmonologist; **AND**
2. The diagnosis of pulmonary arterial hypertension (PAH, WHO Group I) as confirmed by right heart catheterization; **AND**
3. The patient is currently symptomatic.
4. The patient has tried and failed after 60 days or is currently taking a PDE5 inhibitor (e.g. tadalafil) **AND**
5. Provider certifies patient is not pregnant or will not become pregnant while receiving Opsumit™ treatment.
6. Baseline liver function tests (LFT) required.

DENIAL CRITERIA¹

1. Failure to meet approval criteria; **OR**
2. Baseline LFT indicate moderate to severe hepatic impairment

CAUTIONS¹

- Opsumit™ is contraindicated in pregnancy.
- Monitor for pulmonary edema in patients with PVOD (pulmonary veno-occlusive disease)
- Monitor LFTs throughout treatment as clinically indicated
- Avoid co-administration with strong CYP3A4 inhibitors (e.g. ritonavir) or moderate dual CYP3A4/CYP2C9 inhibitors (e.g. amiodarone)

DURATION OF APPROVAL

Opsumit™ Criteria
Version: 1
Original: 12/27/2022
Approval: 01/20/2023
Effective: 03/01/2023

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- Initial Approval: 6 months
- Reauthorization 12 months with chart notes indicating the patient has shown a positive clinical response to treatment.

QUANTITY LIMIT¹

- #30 10mg tablets per 30 days

REFERENCES / FOOTNOTES:

1. Opsumit™ [prescribing information]. South San Francisco, CA: Actelion Pharmaceuticals US, Inc. Revised 04/2019
2. Klinger JR, Elliott CG, Levine DJ, et al. Therapy for pulmonary arterial hypertension in adults. Update of the CHEST guideline and Expert Panel Report. CHEST. 2019;155(3):565-586
3. Hopkins, W., and Rubin, L.(2022). Treatment of pulmonary arterial hypertension (group 1) in adults: Pulmonary hypertension-specific therapy. In J. Mandel(Ed.), *UpToDate*. Retrieved Dec 28, 2022 from <https://www.uptodate.com/contents/treatment-of-pulmonary-arterial-hypertension-group-1-in-adults-pulmonary-hypertension-specific-therapy#!>