



Opsynvi in India

The CDSCO named-patient coordination pathway — indicative 2026

IMMUNOLOGY · PULMONARY ARTERIAL HYPERTENSION

The clinical situation

Opsynvi (macitentan/tadalafil fixed-dose combination) is an oral single-tablet combination of an endothelin receptor antagonist and a PDE5 inhibitor, FDA-approved for the chronic treatment of pulmonary arterial hypertension (PAH, WHO Group 1) in adults with WHO functional class II-III. Manufactured by Johnson & Johnson. Dosing is one tablet (10 mg/40 mg) once daily. Pre-treatment workup covers right-heart catheterisation confirmation, LFTs, CBC, haemoglobin, pregnancy testing (ERA REMS-equivalent), and review of contraindicated concomitant medications per FDA labelling.

The pathway, 5 steps

- 1 Consultation & clinical rationale.** Your PH specialist documents WHO Group 1 PAH diagnosis by right-heart catheterisation, WHO functional class, and Opsynvi rationale.
- 2 Baseline workup.** LFTs, CBC, haemoglobin, pregnancy testing and counselling (ERA class), contraindicated-medication review per FDA labelling.
- 3 CDSCO named-patient application.** Physician or hospital pharmacy files clinical rationale, patient reference, and chain-of-custody commitment.
- 4 US-side sourcing & logistics.** Reserve Meds coordinates product through our US-licensed DSCSA-compliant specialty wholesale partner with controlled-ambient shipment.
- 5 Arrival & first dose.** Dispensing pharmacy releases the first 30-day supply; monthly refill cadence and LFT/pregnancy monitoring established.

Indicative economics

Reference US cash-pay range: USD 13,000–16,000 per month of Opsynvi (drug-only reference; Reserve Meds provides a transparent delivered quote at intake).

Indicative first-dose timing

7–14 days from a complete CDSCO application to first dispensation, once cohort intake opens. Indicative — not guaranteed.

Reserve Meds's role

Sourcing. US-licensed specialty wholesale partner, DSCSA chain-of-custody from Johnson & Johnson authorised distribution.

Documentation. Physician kit tailored to CDSCO review, with right-heart-catheter confirmation and ERA-class pregnancy-precaution annex.

Logistics. Controlled-ambient internationally tracked shipment. **Concierge case lead.** Named point of contact for family and physician through monthly refills. **We are a coordinator** — not the prescriber, not the dispensing pharmacy. All clinical decisions remain with your treating physician.

COMPOSITE EXAMPLE · PRE-LAUNCH WAITLIST

Join the Opsynvi × India first-cohort waitlist. *Our concierge reaches out as we open intake.*

reservemed.com/access-guides/opsynvi-india.html



SCAN TO JOIN

Reserve Meds · US-based concierge for cross-border specialty medicine. We are a coordinator; we are not the prescriber and not the dispensing pharmacy. All clinical decisions remain with the treating physician. Not medical advice.

Reserve Meds is in pre-launch. Service availability is limited to our first cohort; all timelines published are indicative, not guarantees. Composite case examples only.

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