



Empaveli in India

The CDSCO named-patient coordination pathway — indicative 2026

RARE DISEASE · PNH (C3 INHIBITION)

The clinical situation

Empaveli (pegcetacoplan) is an FDA-approved PEGylated complement C3 inhibitor indicated for paroxysmal nocturnal hemoglobinuria (PNH) in adults, particularly those with inadequate response to C5 inhibitors. Manufactured by Apellis. Administered as twice-weekly subcutaneous infusion via portable pump; meningococcal, pneumococcal, and H. influenzae vaccination required. Requires 2–8°C cold-chain storage.

The pathway, 5 steps

- 1 Consultation & clinical rationale.** Your treating hematologist confirms PNH diagnosis, reviews prior C5-inhibitor response, and documents clinical rationale; required vaccinations administered.
- 2 Infusion training site confirmed.** An Indian tertiary centre or hematology clinic accepts the case for subcutaneous pump training and monitoring.
- 3 CDSCO named-patient application.** Clinical rationale, patient reference, product details, and cold-chain plan filed with the Central Drugs Standard Control Organisation.
- 4 US-side sourcing & logistics.** Reserve Meds coordinates product through our US-licensed DSCSA-compliant specialty wholesale partner on validated 2–8°C cold-chain.
- 5 Arrival & administration.** The centre receives the dose under temperature-monitored handling; patient trained on twice-weekly subcutaneous pump use.

Indicative economics

Reference US cash-pay range: USD 50,000–60,000 per month. Cold-chain logistics, CDSCO documentation, and concierge coordination are incremental. Full transparent quote at intake.

Indicative first-dose timing

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

Reserve Meds's role

Sourcing. US-licensed specialty wholesale partner, DSCSA chain-of-custody. **Documentation.** Regulatory package for your physician and CDSCO review. **Logistics.** Cold-chain, temperature-monitored shipment coordination. **Concierge case lead.** Named point of contact for family and physician through the full process. **We are a coordinator** — not the prescriber, not the dispensing pharmacy. All clinical decisions remain with your treating hematologist.

COMPOSITE EXAMPLE · PRE-LAUNCH WAITLIST

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

reservemed.com/access-guides/empaveli-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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