

## Empaveli

Saudi Arabia · access guide

# How to access Empaveli from Saudi Arabia, the named-patient import pathway, 2026

By Reserve Meds · Clinical & regulatory team · Last reviewed 2026-04-23

An Saudi Arabian patient with paroxysmal nocturnal hemoglobinuria (PNH), particularly one who remains anaemic or transfusion-dependent despite prior C5-inhibitor therapy, may be evaluated by their treating haematologist for Empaveli (pegcetacoplan). Empaveli is FDA-approved in the United States and developed by Apellis Pharmaceuticals (partnered with Sobi outside the US). It is a PEGylated C3 complement inhibitor, acting upstream of C5, which allows it to address both intravascular and extravascular haemolysis in PNH. Empaveli is rarely locally registered outside the US and EU, and for Saudi Arabian patients the named-patient import pathway via SFDA is the legitimate route.

This guide explains the pathway, what documentation your physician needs, typical costs and timing, and where Reserve Meds fits in.

## The clinical situation

Empaveli is administered as a twice-weekly subcutaneous infusion using an infusion pump (commercial mini-pump, delivered over 30 minutes). Because Empaveli inhibits C3 rather than C5, it carries the same class-level warning about encapsulated-organism infections; vaccination (meningococcus, pneumococcus, H. influenzae type B) ahead of therapy is a gating step. Your treating haematologist confirms PNH diagnosis (flow cytometry), prior therapy history, vaccination completion, and the monitoring plan per FDA labeling.

## Is Empaveli legally importable into Saudi Arabia?

Yes, through the SFDA / Drugs Controller General of Saudi Arabia (DCGI) personal-use and hospital-sponsored named-patient import frameworks. The route permits a registered medical practitioner to request import of a medicine not locally registered when the medicine is approved by a recognised reference authority (FDA qualifies), no clinically equivalent registered option fits, and chain of custody is documented.

For ultra-rare PNH therapy, Saudi Arabian tertiary haematology centres in Mumbai, Delhi, Bangalore, Chennai, Hyderabad, and Kolkata are experienced with named-patient imports, and diaspora-supported care is a common pattern.

## How the pathway works, step by step

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1. **Consultation with your treating haematologist.** PNH flow cytometry confirmation, prior therapy history, and clinical rationale.
2. **Pre-treatment vaccination.** Meningococcal, pneumococcal, and Hib vaccinations per labeling, typically at least 2 weeks before first dose or with appropriate prophylaxis.
3. **SFDA application.** The physician or hospital files the personal-use / named-patient application.
4. **US-side sourcing.** Reserve Meds coordinates with our US-licensed specialty wholesale partner for Empaveli and the infusion pump / administration supplies.
5. **Cold-chain shipment.** Empaveli ships at 2-8°C with continuous temperature monitoring and chain-of-custody documentation end to end.
6. **Arrival, training, and ongoing twice-weekly infusion.** The haematology unit or home-care partner supports training on the infusion pump; ongoing administration is typically at home after training.

## What documentation your physician needs

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Your physician will typically need to provide:

- Clinical rationale letter confirming PNH, diagnostic evidence (flow cytometry), prior therapies, and Empaveli as the indicated treatment
- Verification of their Saudi Arabian medical registration (NMC)
- Patient identifier and address for the import record
- Vaccination documentation
- Planned twice-weekly infusion schedule and training plan

Reserve Meds provides a physician documentation kit that bundles the templates Saudi Arabian customs and SFDA reviewers expect to see for complement inhibitors, plus the infusion-pump training note.

## Costs and timing

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Empaveli's US cash-pay drug-only reference price is a high-cost ultra-rare-disease therapy; annualised cost is commonly quoted in a broad indicative range of USD 450,000+ and total course depends on duration of therapy. International cold-chain logistics, customs clearance, SFDA documentation handling, and concierge coordination add incremental cost. Reserve Meds issues a full transparent quote at the start of intake. Indicative range.

Indicative timing for first dose after cohort intake opens is 21-35 days from the moment a complete application is submitted and customs processing begins, plus vaccination lead time. Ongoing supplies ship on a rolling basis.

*Fulfillment availability is limited to our first cohort, and all timelines published on this site are indicative. If your clinical situation is time-sensitive, tell us at intake. We triage accordingly.*

A culturally-aware note: PNH is an ultra-rare condition with long treatment horizons and high cost; Saudi Arabian diaspora families frequently co-fund care across generations and cities. Our concierge case lead is set up to include every designated family member on coordination and document flow.

## Reserve Meds's role

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Reserve Meds is a US-based concierge coordinator for cross-border specialty medicine. For Empaveli specifically, we provide:

- **Sourcing.** Through our US-licensed specialty wholesale partner, operating under DSCSA chain-of-custody.
- **Documentation.** Regulatory package for your physician and for SFDA / customs review.
- **Logistics.** Cold-chain, temperature-monitored, internationally tracked shipment of drug and infusion-pump supplies.
- **Concierge case lead.** A named point of contact.

**What we do not do:** we are not the prescriber, we do not practise medicine, and we are not the dispensing pharmacy. All clinical decisions remain with your treating haematologist.

## Frequently asked

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**Is this legal in Saudi Arabia?** Yes, when executed through the SFDA personal-use / named-patient framework with appropriate documentation.

**Why Empaveli rather than a C5 inhibitor?** Empaveli inhibits C3 upstream, addressing both intravascular and extravascular haemolysis. For patients who remain anaemic on C5 inhibition, this upstream mechanism can be clinically relevant. Your haematologist will decide.

**Can the family abroad pay directly?** Yes. Diaspora-supported invoicing is common for ultra-rare-disease care.

**Will insurance cover this?** Cash-pay is the default. Some Saudi Arabian insurers and diaspora policies consider ultra-rare-disease named-patient imports on escalated review; we supply documentation for your submission but do not process insurance claims directly.

### *Reserve Meds's role*

US-based concierge coordinator for cross-border specialty medicine. We are not the prescriber, not the dispensing pharmacy, and not the manufacturer. All clinical decisions remain with your treating physician.

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### Reserve Meds

*reserved for you.*

Composite case examples. This document is for general information only and does not constitute medical advice. Please consult your treating physician.

Reserve Meds is in pre-launch. Published timelines and cost ranges are indicative, not guarantees.  
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