



Ultomiris in India

The CDSCO named-patient coordination pathway — indicative 2026

HEMATOLOGY / COMPLEMENT · PNH, AHUS, GMG, NMOSD

The clinical situation

Ultomiris (ravulizumab-cwvz) is a long-acting terminal complement C5 inhibitor, FDA-approved for paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS), generalised myasthenia gravis (gMG), and NMOSD. Manufactured by Alexion (AstraZeneca Rare Disease), it succeeds Soliris with every-eight-week maintenance (versus biweekly), delivered IV with weight-based loading. It carries a US boxed warning regarding meningococcal infections, which is why meningococcal vaccination (or antibiotic prophylaxis) is a gating step. Internationally, equivalent manufacturer risk-minimisation measures apply.

The pathway, 5 steps

- 1 Consultation & clinical rationale.** Your physician confirms indication (flow cytometry for PNH; clinical/ADAMTS13 for aHUS; AChR-antibody for gMG; AQP4-IgG for NMOSD) and documents any prior Soliris exposure.
- 2 Meningococcal vaccination & risk minimisation.** Vaccination at least 2 weeks before first dose, or antibiotic prophylaxis per FDA labeling.
- 3 CDSCO named-patient application.** Physician or hospital pharmacy files dossier: rationale, patient reference, vaccination documentation, induction & every-8-week dosing plan.
- 4 US-side sourcing & logistics.** Reserve Meds coordinates product through our US-licensed specialty wholesale partner, aligned with the manufacturer's controlled-distribution model.
- 5 Arrival, induction & maintenance.** Cold-chain (2–8°C) delivery; infusion facility administers induction, then every-8-week maintenance.

Indicative economics

Reference US cash-pay range: USD 400,000–500,000 annualised at US list for PNH/aHUS (Reserve Meds provides a transparent delivered quote at intake).

Indicative first-dose timing

7–14 days from a complete CDSCO application to first dispensation; vaccination lead time may extend this. 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, including the meningococcal-infection risk-minimisation block. **Logistics.** Cold-chain (2–8°C) shipment with continuous temperature monitoring and importer-of-record handling. **Concierge case lead.** Named point of contact for family and care team. **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 Ultomiris × India first-cohort waitlist. *Our concierge reaches out as we open intake.*

reservemed.com/access-guides/ultomiris-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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