Soliris access in India

A patient-first guide to accessing Soliris (eculizumab) for paroxysmal nocturnal hemoglobinuria, atypical hemolytic uremic syndrome, generalized myasthenia gravis, and neuromyelitis optica spectrum disorder in India, through the CDSCO Rule 36 named-patient framework and certified infusion centers.

Quick orientation

Soliris is a humanized monoclonal antibody that blocks terminal complement activation by binding the C5 protein, indicated for paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS), generalized myasthenia gravis (gMG) in AChR-antibody-positive adults, and aquaporin-4 antibody-positive neuromyelitis optica spectrum disorder (NMOSD). India's CDSCO has registered eculizumab, but day-to-day commercial availability across the country is uneven and is frequently a friction point for patients seeking continuity of supply. The Rule 36 named-patient route under the Drugs and Cosmetics Rules 1945 is the operational pathway for Indian patients filling supply gaps or accessing the broader indication set. The REMS-style meningococcal vaccination requirement is documented as a hard prerequisite. Reserve Meds coordinates the US-side sourcing, cold-chain logistics, and the documentation kit. Reserved for you.

Why patients in India need Soliris via NPP

Soliris reaches Indian patients through named-patient channels for a defined set of reasons. First, while CDSCO has registered eculizumab, commercial availability is concentrated at one or two tertiary centers in major cities and is inconsistent outside metropolitan catchment areas. Patients with PNH or aHUS resident in tier 2 or tier 3 cities sometimes cannot access continuous every-two-weeks supply through their local pharmacy network even though the drug is technically registered.

Second, the indication breadth matters. In India eculizumab registration historically focused on PNH and aHUS; patients diagnosed with gMG (AChR-antibody-positive) or NMOSD (AQP4-antibody-positive) may face an off-label-in-country situation even though the FDA-approved indication is on-label internationally. Reserve Meds operates against the FDA-approved label set across all four indications.

Third, cost. Even where Soliris is available, the absence of a public payer that funds orphan biologics for non-citizens or for adult-onset autoimmune indications in many parts of the country forces cash-pay procurement. Private insurers handle Soliris case-by-case rather than as a standard benefit, and CGHS reimbursement for non-formulary life-saving medicines runs through an Expert Committee process. For families across PNH, aHUS, gMG, and NMOSD diagnoses, the indefinite indefinite-duration therapy commitment (Soliris is not curative) creates a continuity-of-supply problem that named-patient coordination addresses.

The Soliris-versus-Ultomiris discussion is a frequent parallel inquiry. Ultomiris (ravulizumab), the longer-acting C5 inhibitor from the same manufacturer, is dosed every eight weeks rather than every two weeks. Where Ultomiris is locally registered and accessible, many treating clinicians

transition. Soliris remains in use where Ultomiris is not yet registered, not yet reimbursed, or where the treating clinician has clinical reasons to continue eculizumab specifically.

The CDSCO named-patient pathway for Soliris

The legal foundation for personal import of medicines into India for supply-gap or off-label indication scenarios is Rule 36 of the Drugs and Cosmetics Rules 1945. Rule 36 permits import of small quantities of a drug for the exclusive personal use of a named patient. Form 12A is the application; Form 12B is the permit issued by the office of the Drugs Controller General of India (DCGI) at FDA Bhawan in New Delhi, or by designated CDSCO Port Offices. The quantity of any single drug imported shall not exceed one hundred average doses per application.

For Soliris, the application packages: the treating hematologist, nephrologist, neurologist, or ophthalmologist prescription with the National Medical Commission (NMC) registration number; the indication-specific diagnosis confirmation (flow cytometry confirming PNH clone size; ADAMTS13 and complement testing for aHUS; AChR antibody titer for gMG; AQP4 antibody for NMOSD); the dosing plan referencing the FDA label by indication and patient body weight; a chain-of-custody plan from the US specialty pharmacy or distributor to the infusion facility in India; and the dispensing facility's drug licence (hospital pharmacy or licensed specialty infusion suite).

The meningococcal vaccination prerequisite is documented as a discrete element of the file. The Soliris REMS (Risk Evaluation and Mitigation Strategy) requires patients to receive meningococcal vaccination against serogroups A, C, W, Y, and B at least two weeks before the first dose, with revaccination per ACIP guidance. While the REMS framework is US regulatory infrastructure and does not transfer into India, Reserve Meds documents the patient's vaccination status as part of intake. The treating Indian physician confirms the vaccination record aligns with the US prescribing standard before the first dose; local Indian guidance is followed for the on-the-ground administration. The clinical justification angle for Soliris is indication-specific: prior-line failure documentation (for gMG, prior immunosuppressive therapy outcomes; for NMOSD, prior immunotherapy and attack history; for PNH and aHUS, the hemolysis or thrombotic microangiopathy markers), and the rationale for terminal complement blockade specifically.

CDSCO published guidance indicates that Form 12B permits issue on a priority basis, typically within one to two days for routine applications where the documentation is complete. The practical two to four week window from physician decision to dispensed medicine covers upstream documentation assembly and downstream international logistics. The indefinite-duration nature of the therapy means the case file lives across years; Reserve Meds maintains the case-file continuity across the every-two-weeks maintenance cycle.

Where Soliris gets dispensed in India

The infusion-suite requirement subsets the dispensing map to hospitals with cold-chain biologic infusion capability. The institutions that handle named-patient and compassionate imports as established workflow, and that maintain the hematology, nephrology, neurology, and ophthalmology infusion infrastructure relevant to Soliris across its four indications, include All India Institute of Medical Sciences (AIIMS), New Delhi (designated Centre of Excellence under the National Policy for Rare Diseases); Tata Memorial Centre, Mumbai; Christian Medical College (CMC), Vellore (long-standing hematology, nephrology, and neurology programmes); Apollo Hospitals (Chennai, Delhi, Bangalore, Hyderabad); Fortis Healthcare (Fortis Memorial Research

Institute Gurgaon, Mumbai, Bangalore); Medanta in Gurgaon; Kokilaben Dhirubhai Ambani Hospital in Mumbai; MGM Healthcare in Chennai; and Manipal Hospitals in Bangalore.

The infusion site, not the patient's home, is the delivery endpoint for every Soliris dose. The vial requires 2 to 8 C refrigerated storage in the original carton protected from light; the diluted solution carries stability of up to 24 hours under refrigeration or room temperature per the FDA label. For an Indian patient with PNH or aHUS resident outside a major metropolitan area, the every-two-weeks maintenance cadence requires travel to the dispensing center or a coordinated infusion at a closer hospital where the dispensing center can hand off the vial under documented cold-chain conditions. Reserve Meds matches the dispensing facility to the patient's geographic context across the chronic-therapy lifecycle.

Real cost picture for Soliris in India

Soliris is one of the most expensive long-running biologics in the world. Published US pricing references put the annual wholesale acquisition cost in the range of USD 500,000 to USD 700,000 for PNH dosing in an average-weight adult, with aHUS, gMG, and NMOSD maintenance dosing landing at the higher end because of the larger 1,200 mg maintenance dose. Vial-level WAC is commonly cited at approximately USD 7,000 per 300 mg vial. At the USD/INR rate in the 94 to 95 range in May 2026, the annual drug cost converts to approximately INR 4.7 to 6.7 crore depending on indication and dosing.

International logistics add a defined surcharge in the USD 400 to 1,500 per shipment range depending on cold-chain configuration and routing (refrigerated air freight in validated 2 to 8 C shippers). Regulatory documentation handling, customs handling, hospital infusion-suite fees, and the Reserve Meds concierge coordination fee are separate, transparently itemised lines. The US biosimilar landscape since 2024 to 2025 (EPYSQLI / eculizumab-aagh, Bkemv) has introduced approximately 30% domestic price pressure on Soliris WAC; for Indian named-patient cases, the brand-versus-biosimilar question depends on the treating clinician's preference, the patient's prior treatment history, and the family's procurement preference. Reserve Meds quotes both lines on request.

Indian private insurer behavior varies. Star Health, HDFC ERGO, ICICI Lombard, and Niva Bupa each handle Soliris on a case-by-case basis; reimbursement is most common where the patient has a documented PNH or aHUS diagnosis and the plan recognises the indication. CGHS provides for life-saving medicines not in the standard formulary to be considered case-by-case by an Expert Committee under Special DG (DGHS) for central government employees and pensioners. The National Policy for Rare Diseases 2021 ceiling under Rashtriya Arogya Nidhi (INR 50 lakh per patient) is relevant for some cohorts but does not cover lifetime therapy. Cash-pay remains the default operating posture. Union Budget 2026-27 expanded the customs duty exemption list for life-saving and rare-disease drugs; HSN code applicability for any specific Soliris shipment is confirmed at the documentation stage.

Typical timeline for Soliris

Rule 36 documentation runs the standard one to two days at CDSCO for routine applications with complete paperwork. The practical two to four week window from physician decision to first dispensed dose covers upstream documentation assembly (diagnosis confirmation, meningococcal vaccination, prescription, dispensing facility licence, chain-of-custody plan) and downstream cold-chain logistics (refrigerated air freight in validated 2 to 8 C shippers, customs clearance, infusion-site receipt). The meningococcal vaccination must be completed at least two

weeks before the first Soliris dose; this constraint sometimes sets the timeline rather than the regulatory or logistics windows. The induction schedule then runs four weekly doses, a transition dose at week five, and maintenance every two weeks indefinitely. The chronic-therapy nature of the case means the timeline is not a one-off; it is a recurring every-two-weeks cadence that Reserve Meds maintains across years.

What your physician needs to provide

The clinical justification letter for a Soliris case is signed by a treating specialist appropriate to the indication, holding an active NMC registration number with state council registration where required. For PNH, the letter is typically from a hematologist; for aHUS, a nephrologist or hematologist; for gMG, a neurologist; for NMOSD, a neurologist or neuro-ophthalmologist. The letter addresses the indication-specific diagnosis with ICD-10 coding (D59.5 for PNH; D59.3 for HUS / aHUS; G70.0 for gMG; G36.0 for NMOSD), the diagnostic confirmation (flow cytometry confirming GPI-deficient clones for PNH; ADAMTS13 activity and complement testing for aHUS; AChR antibody titer for gMG; AQP4 antibody for NMOSD), prior therapies attempted with outcomes, the meningococcal vaccination record, and the clinical case for terminal complement blockade.

The dosing reference is the FDA label by indication. For adult PNH: 600 mg IV every 7 days for the first 4 weeks (4 doses), 900 mg IV in week 5, then 900 mg IV every 14 days as ongoing maintenance. For adult aHUS at or above 40 kg: 900 mg IV every 7 days for the first 4 weeks, 1,200 mg IV at week 5, then 1,200 mg IV every 14 days; pediatric aHUS is fully weight-banded across multiple body-weight tiers per the package insert. For adult gMG and adult NMOSD: 900 mg IV weekly for 4 weeks, 1,200 mg at week 5, then 1,200 mg every 14 days. Soliris is intended for chronic indefinite use across all four indications; treatment is not curative, and discontinuation in PNH and aHUS carries a documented risk of severe hemolysis or thrombotic microangiopathy rebound that requires monitoring per the FDA label's warnings.

The dominant safety concern is serious meningococcal infection due to terminal complement blockade. Meningococcal infections have been reported in both vaccinated and unvaccinated patients. Other warnings include other types of serious infections (encapsulated organisms), infusion reactions, and rebound risk on discontinuation in PNH and aHUS. The monitoring plan covers indication-specific labs: LDH and reticulocyte count in PNH; platelet count, serum creatinine, and LDH in aHUS; clinical symptom monitoring in gMG and NMOSD; and infection vigilance across all indications. Adverse event reporting through the Pharmacovigilance Programme of India (PvPI) applies and is referenced in the documentation kit; the reporting obligation itself stays with the prescribing physician.

Common questions about Soliris in India

Will Star Health, HDFC ERGO, ICICI Lombard, or Niva Bupa cover Soliris? Each plan handles Soliris on a case-by-case basis. Reimbursement is most common where the patient has a documented PNH or aHUS diagnosis and the plan recognises the indication. gMG and NMOSD coverage is more variable. Reserve Meds provides documentation that lets a payer evaluate; the claim itself is filed by the patient or family. Cash-pay is the default operating posture.

Will CGHS or the National Policy for Rare Diseases ceiling cover this? CGHS provides for life-saving medicines not in the standard formulary to be considered case-by-case by an Expert Committee under Special DG (DGHS), for central government employees and pensioners. The Rashtriya Arogya Nidhi ceiling under NPRD 2021 (INR 50 lakh per patient) is relevant for some

cohorts but does not cover lifetime indefinite-duration therapy. Check eligibility before assuming coverage.

Can I receive Soliris infusion in my home city? The dispensing facility must hold a valid drug licence and the procedural capability for cold-chain biologic infusion. AIIMS, Tata Memorial, CMC Vellore, Apollo, Fortis, Medanta, Kokilaben, MGM, and Manipal handle Soliris infusions across the four indications. For patients resident outside the major metropolitan areas, the dispensing center can sometimes hand off the vial to a closer hospital under documented cold-chain conditions; Reserve Meds matches the infrastructure to the patient's geographic context.

Why Soliris versus Ultomiris? Ultomiris (ravulizumab), the longer-acting C5 inhibitor from the same manufacturer, is dosed every 8 weeks rather than every 2 weeks. Where Ultomiris is locally registered and accessible, many treating clinicians transition. Soliris remains in use where Ultomiris is not yet registered or reimbursed, or where the treating clinician has clinical reasons to continue eculizumab. The decision rests with the treating specialist. For patients evaluating both, Reserve Meds can quote both lines.

Is the meningococcal vaccination really required? Yes. Terminal complement blockade dramatically increases susceptibility to encapsulated organisms, particularly Neisseria meningitidis. Vaccination against serogroups A, C, W, Y, and B must be completed at least two weeks before the first dose, with revaccination per ACIP guidance. Reserve Meds documents the vaccination status as part of intake; the treating Indian physician confirms the record before first dose. The Soliris REMS framework is US infrastructure, but the underlying vaccination prerequisite is clinically universal.

What about biosimilar eculizumab? The US biosimilar landscape since 2024 to 2025 includes EPYSQLI (eculizumab-aagh) and Bkemv at roughly a 30% discount to Soliris WAC. For Indian named-patient cases, the brand-versus-biosimilar question depends on the treating clinician's preference, the patient's prior treatment history, and the family's procurement preference. Reserve Meds quotes either line on request.

Where Reserve Meds fits in Soliris cases

Reserve Meds is a US-based concierge coordinator. For a Soliris inquiry from an Indian family, the working unit is US-side sourcing through Alexion's distribution channel or validated specialty pharmacy, refrigerated air freight in validated 2 to 8 C shippers, customs and chain-of-custody documentation, India-side coordination with the treating specialist on the every-two-weeks maintenance schedule and the meningococcal vaccination prerequisite, and a single named coordinator who carries the case across years of recurring doses. The clinical decisions remain with the treating specialist (hematologist, nephrologist, neurologist, or neuro-ophthalmologist depending on indication). The regulatory authority remains CDSCO. The infusion remains with the dispensing facility's infusion team.

What Reserve Meds carries: identification of an infusion-capable dispensing facility matching the patient's geographic context, preparation of the Rule 36 documentation kit including the meningococcal vaccination record and the FDA-label-aligned dosing plan, coordination of refrigerated logistics dose-by-dose, single-coordinator continuity across the multi-year maintenance arc, and the PvPI reference for the prescribing physician's reporting obligation. Where the treating clinician is evaluating an Ultomiris transition or a biosimilar switch, Reserve Meds quotes the alternative line on request. Reserved for you.

Next step

If you or a family member is on Soliris and facing a supply-continuity gap, or has been newly diagnosed with PNH, aHUS, gMG, or NMOSD and is considering terminal complement blockade, the first step is a coordinated intake that confirms eligibility, identifies the appropriate infusion facility, and produces a transparent firm quote across the induction and maintenance phases. The waitlist request prefills the relevant context so the coordinator who reaches out is already oriented to your case.

Reserved for you.

About Soliris

PNH, aHUS, gMG, NMOSD
Manufacturer: Alexion (AstraZeneca)
Modality: Anti-C5 monoclonal antibody IV infusion
Full drug page →

About India

South Asia
Authority: CDSCO / DCGI
Pathway: Rule 36 (Form 12A / 12B); Compassionate Use
Full country page →

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PNH
aHUS
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Review & oversight. Content on this page is reviewed by Reserve Meds's clinical and regulatory team. A US-licensed pharmacist reviews every prescription before dispensing. Regulatory posture is informational, not legal advice; case-specific questions route to retained outside counsel. Review methodology ›
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