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## Soliris access in Pakistan

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 Pakistan, through the DRAP Special Permission pathway with REMS-aligned meningococcal vaccination.

### Quick orientation

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Soliris is the brand name for eculizumab, a humanized monoclonal antibody that binds the terminal complement protein C5 and blocks formation of the membrane attack complex. The US Food and Drug Administration first approved Soliris on 16 March 2007 for paroxysmal nocturnal hemoglobinuria (PNH), with subsequent approvals for atypical hemolytic uremic syndrome (aHUS, September 2011), generalized myasthenia gravis (gMG, October 2017) in adults who are anti-acetylcholine receptor (AChR) antibody positive, and neuromyelitis optica spectrum disorder (NMOSD, June 2019) in adults who are anti-aquaporin-4 (AQP4) antibody positive. Pakistan patients with these rare complement-driven and autoimmune indications access Soliris through the DRAP Special Permission pathway, with meningococcal vaccination as a hard prerequisite per the US REMS standard. Reserve Meds orchestrates the US-side sourcing, cold-chain logistics, and infusion-center handoff. Reserved for you.

### Why patients in Pakistan need Soliris via NPP

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The four Soliris indications represent four distinct rare-disease populations, each with a clinical case for terminal complement inhibition: PNH patients with complement-mediated intravascular hemolysis causing anemia, thrombosis, and fatigue; aHUS patients with complement-driven thrombotic microangiopathy and acute kidney injury; gMG patients (anti-AChR positive) with refractory disease despite standard immunosuppression; and NMOSD patients (anti-AQP4 positive) at risk of disabling relapses. All four are rare in Pakistan's general population, but the absolute numbers are not small, and tertiary referral centers in Karachi, Lahore, and Islamabad see these cases regularly.

The access architecture in Pakistan is shaped by limited routine commercial availability. Where Soliris has been imported through specialty channels, stocking is concentrated at a small number of tertiary hospitals, and patients living outside those catchment areas cannot access continuous supply through their local pharmacy network. Even in the major cities, the consistency of supply is uneven enough that a structured named-patient import pathway is the practical default for many cases. Reserve Meds operates squarely in this segment: cash-pay patients in jurisdictions without consistent payer-funded access for terminal complement inhibitors, who need a single coordinator to handle quote, procurement, cold-chain logistics, infusion-site delivery, and the local pharmacovigilance handshake.

The cost driver is the second factor. Soliris is one of the most expensive long-running biologics in the world. Annual US WAC for PNH dosing in an average-weight adult runs USD 500,000 to USD 700,000; aHUS, gMG, and NMOSD maintenance lands at the higher end because of the larger 1,200 mg maintenance dose. Pakistani families navigating chronic, lifelong therapy at this price point typically pool funding across overseas relatives, with the diaspora remittance pattern playing a structural role.

## **The DRAP Special Permission pathway for Soliris**

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DRAP regulates the import of medicines through the Quality Assurance and Laboratory Testing (QA&LT) Division's Import and Export Section. For unregistered or unavailable medicines required for a specific patient, DRAP issues a Special Permission (also called the No Objection Certificate or NOC for Personal Use Import), filed through the Online Import and Export System (OIES) portal. For institutional dispensing, the hospital pharmacy files. For Soliris, the institutional route is the dominant pattern because infusion administration is the only setting of care.

The application package for Soliris is indication-specific. The clinical justification letter from the treating physician addresses the patient's diagnosis with confirmatory diagnostic markers (flow cytometry confirmation of PNH clone for PNH; ADAMTS13 level and complement studies for aHUS; anti-AChR antibody positivity and clinical severity for gMG; anti-AQP4 antibody positivity and relapse history for NMOSD), prior therapies attempted with outcomes, the meningococcal vaccination status (serogroups A, C, W, Y, and B at least two weeks before the first dose), and the planned indication-specific induction and maintenance dosing.

The treating physician's Pakistan Medical and Dental Council (PMDC) license verification accompanies the letter, alongside the patient identifier (CNIC for adult patients, B-Form for minors), the destination dispensing facility license (the receiving infusion center), and the chain-of-custody plan from the US source through international shipment with strict 2 to 8 degrees Celsius cold-chain handling. The treating institution must hold the infusion suite capability and the local pharmacovigilance reference.

Approval timelines for routine personal-use cases typically clear in four to eight weeks; complex first-time cases extend to ten to sixteen weeks. For aHUS cases presenting acutely with renal failure, time-to-first-dose pressure can be acute; Reserve Meds intake flags acute aHUS for accelerated coordinator review. PNH, gMG, and NMOSD cases generally allow more time for the regulatory layer to clear in parallel with vaccination scheduling.

## **Where Soliris gets dispensed in Pakistan**

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Soliris delivery is at the infusion site. The institutions with the relevant infusion suite capability, hematology or nephrology or neurology specialist coverage, and import pharmacy workflow concentrate at the major tertiary centers. Aga Khan University Hospital (AKUH) in Karachi covers all four indications with strong hematology, nephrology, and neurology programs and 24/7 pharmacy services with temperature-controlled storage. Shaukat Khanum Memorial Cancer Hospital and Research Centre (SKMCH&RC) in Lahore handles PNH and related hematologic indications.

The Pakistan Kidney and Liver Institute and Research Centre (PKLI) in Lahore is a primary referral for aHUS given its kidney transplant and nephrology focus. Liaquat National Hospital in Karachi, Shifa International Hospital in Islamabad, the Indus Hospital and Health Network, and the Combined Military Hospitals (CMH) network handle complex hematology, nephrology, and neurology cases and can serve as dispensing infusion centers depending on case-specific specialist coverage. For pediatric aHUS cases, the Children's Hospital and Institute of Child Health in Lahore is the primary pediatric tertiary center in Punjab.

For families outside the major cities, the practical flow is referral to a major center for treatment initiation, then continuing the every-two-weeks maintenance schedule at the same center or,

where possible, transferring maintenance to a smaller infusion center near home that has the cold-chain storage and specialist oversight to continue treatment safely.

## **Real cost picture for Soliris in Pakistan**

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The Soliris US WAC for the 300 mg vial is approximately USD 7,000 per vial. Annual US WAC ranges USD 500,000 to USD 700,000 for PNH adult dosing, with aHUS, gMG, and NMOSD maintenance landing at the higher end due to the 1,200 mg maintenance dose every 14 days. At the current USD to PKR rate (approximately PKR 278 to 280 per USD on 8 to 9 May 2026), annual treatment costs convert to approximately PKR 139 to 196 million depending on indication. International cash-pay private-import pricing typically reflects ex-US wholesaler pricing plus Reserve Meds coordination, customs handling, and freight, and is materially below US WAC in most documented patterns; quotes are case-specific.

The US launch of eculizumab biosimilars since 2024 to 2025 (EPYSQLI / eculizumab-aagh, Bkembv) has introduced domestic price pressure at roughly a 30 percent discount to Soliris WAC. Biosimilar availability for international NPP cases depends on the source-side wholesaler relationship and the receiving institution's acceptance; Reserve Meds explores biosimilar options where the case file supports it. Cold-chain refrigerated international air freight (validated 2 to 8 degrees Celsius shippers) adds a per-shipment surcharge in the range of USD 400 to USD 1,500.

State Life, Adamjee, EFU, Jubilee, IGI, and Pak-Qatar Family Takaful operate the largest health insurance books in Pakistan. Coverage for terminal complement inhibitors at this price point is uncommon. Some plans may pay a partial percentage on a case-by-case basis. Sehat Sahulat's PKR 1,000,000 per family per year ceiling does not stretch to cover a Soliris course. Cash-pay, with overseas-remittance pooling across the diaspora, is the default operating posture.

## **Typical timeline for Soliris in Pakistan**

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The regulatory layer at DRAP runs four to eight weeks for routine cases; ten to sixteen weeks for complex first-time cases. Meningococcal vaccination (serogroups A, C, W, Y, and B) must complete at least two weeks before the first dose; this is a parallel workstream Reserve Meds flags at intake. The induction schedule is indication-specific (PNH: 600 mg weekly for 4 weeks, 900 mg week 5, then 900 mg every 14 days; aHUS, gMG, NMOSD: 900 mg weekly for 4 weeks, 1,200 mg week 5, then 1,200 mg every 14 days). The first dose is the gating event. Maintenance is indefinite: every 14 days for life under the approved label, with no defined endpoint. Cold-chain refrigerated air freight from the US source to the dispensing institution adds two to four days for customs and last-mile. Reserve Meds builds the case file once and then runs the every-two-weeks reorder cycle across years.

## **What your physician needs to provide**

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The clinical justification letter is the cornerstone of any Soliris case file in Pakistan. The letter, signed by the treating physician at AKUH, SKMCH&RC, PKLI, Liaquat National, Shifa International, Indus, the Children's Hospital in Lahore (for pediatric aHUS), or a CMH center, and holding an active PMDC license, addresses the patient's indication-specific diagnosis with confirmatory diagnostic markers, prior therapies attempted with outcomes, the clinical case for terminal complement inhibition, the meningococcal vaccination status (mandatory pre-treatment), and the planned dosing schedule.

The dosing reference is the FDA label. PNH adult: 600 mg IV weekly for 4 weeks, 900 mg IV week 5, then 900 mg IV every 14 days as maintenance. aHUS adult ( $\geq 40$  kg): 900 mg IV weekly for 4 weeks, 1,200 mg IV week 5, then 1,200 mg IV every 14 days. gMG adult and NMOSD adult: same as aHUS adult dosing structure. Pediatric aHUS is weight-banded across multiple body weight tiers per the package insert. Diluted Soliris is infused over approximately 35 minutes in adults, longer in pediatric patients, with diluted-solution stability of up to 24 hours under refrigeration or room temperature.

The monitoring plan referenced in the letter covers meningococcal infection vigilance throughout therapy (the dominant safety concern given terminal complement blockade), indication-specific labs (LDH and reticulocyte count for PNH; platelet count, serum creatinine, and LDH for aHUS; clinical symptom monitoring for gMG and NMOSD), and the rebound risks of discontinuation in PNH and aHUS (severe hemolysis or thrombotic microangiopathy rebound). Reserve Meds supplies the US-side documentation kit (manufacturer-direct sourcing reference, chain-of-custody plan, cold-chain validation, customs documentation) so the treating physician and the institutional pharmacy have a coordinated regulatory layer.

## Common questions about Soliris in Pakistan

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**Is the meningococcal vaccination really mandatory?** Yes. Patients require meningococcal vaccination (serogroups A, C, W, Y, and B) at least two weeks before the first dose, with revaccination per ACIP. Meningococcal infections, including septicemia and meningitis, have been reported in patients on the drug (both vaccinated and unvaccinated). The vaccination requirement is the central safety control. Reserve Meds documents the patient's vaccination status as part of intake.

**Will Adamjee, Jubilee, EFU, or State Life cover Soliris?** Coverage for terminal complement inhibitors at this price point is uncommon across Pakistani health plans. Some plans may pay a partial percentage on a case-by-case basis. Cash-pay is the realistic default. Reserve Meds supplies the documentation that lets a payer assess.

**What is the safety profile?** The dominant safety concern is serious meningococcal infection due to terminal complement blockade. Other warnings include other serious infections (encapsulated organisms), infusion reactions, and the risk of hemolysis or thrombotic microangiopathy rebound on discontinuation in PNH and aHUS. Patients planning a treatment pause require monitoring per the FDA label's warnings.

**Why Soliris versus Ultomiris?** Ultomiris (ravulizumab) is the longer-acting C5 inhibitor from the same manufacturer, dosed every 8 weeks in maintenance versus every 2 weeks for Soliris. In many markets Ultomiris has become the preferred long-term therapy where the payer pathway supports it. Soliris remains in use where Ultomiris is not yet locally registered, not yet reimbursed, or where the treating clinician has specific clinical reasons to continue eculizumab. Reserve Meds also coordinates Ultomiris cases for families where that transition is the better fit.

**Can I receive Soliris at a smaller hospital near home for maintenance?** Possibly, depending on the local infusion center's cold-chain storage, specialist oversight, and willingness to administer imported product. Treatment initiation should be at one of the major tertiary centers; transfer of maintenance to a closer infusion site is a clinical and operational conversation the treating team carries.

**Are biosimilar options available?** US biosimilars (EPYSQLI, Bkembv) have been available since 2024 to 2025 at roughly a 30 percent discount to Soliris WAC. For international NPP cases,

biosimilar availability depends on the source-side wholesaler relationship and the receiving institution's acceptance. Reserve Meds explores biosimilar options where the case file supports it; many cases continue on reference eculizumab.

## Where Reserve Meds fits in Soliris cases

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Reserve Meds is a US-based concierge coordinator. For a Soliris inquiry from a Pakistani family, the working unit is infusion-center confirmation with the relevant specialist coverage, meningococcal vaccination status documentation, US-side manufacturer-direct sourcing (Soliris or biosimilar where the case supports), cold-chain logistics planning across the multi-year maintenance cycle, and continuous coordination. The clinical decisions remain with the treating hematology, nephrology, or neurology team. The regulatory authority remains DRAP. The infusion remains with the dispensing institution.

What Reserve Meds carries: identification of the receiving infusion center with appropriate specialist coverage, preparation of the documentation kit (clinical justification reference with indication-specific diagnostic markers, vaccination status documentation, DRAP filing reference, OIES submission support), validated 2 to 8 degrees Celsius international air freight with continuous temperature monitoring, customs and chain-of-custody documentation, and a single named coordinator who stays with the family across induction, transition to maintenance, and the every-two-weeks reorder cycle. Reserved for you.

## Next step

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If your family is considering Soliris in Pakistan for PNH, aHUS, gMG, or NMOSD, the first step is a coordinated intake that confirms eligibility, infusion-center fit, meningococcal vaccination status, and a transparent firm quote. For acute aHUS cases, the intake routes to accelerated coordinator review. The waitlist request prefills the relevant context.

Reserved for you.

## About Soliris

PNH, aHUS, gMG (anti-AChR+), NMOSD (anti-AQP4+)

Manufacturer: Alexion / AstraZeneca

Modality: Anti-C5 monoclonal antibody (IV infusion)

REMS: Meningococcal vaccination required

Full drug page →

## About Pakistan

South Asia, SAARC

Authority: DRAP

Pathway: Special Permission / Personal Use Import NOC

Full country page →

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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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