Alhemo access in Pakistan

How patients in Pakistan reach Alhemo (concizumab-mtci) for hemophilia A or B with inhibitors through the DRAP Special Permission Personal Use Import pathway.

Quick orientation

Alhemo is the brand name for concizumab-mtci, a humanized IgG4 monoclonal antibody targeting tissue factor pathway inhibitor (TFPI). It is supplied as a prefilled subcutaneous pen for once-daily injection, indicated by the U.S. FDA (December 20, 2024) for routine prophylaxis in patients aged 12 and older with hemophilia A or B with factor VIII or IX inhibitors, with a later FDA expansion to non-inhibitor hemophilia A or B. In Pakistan, concizumab has no DRAP marketing authorization. Patients with hemophilia and inhibitors are a rare-within-rare population, concentrated at AKUH, Indus Hospital, and the few hematology programs supported by the Hemophilia Patients Welfare Society of Pakistan, where conventional bypass agents and standard factor products are the operating reality. Families pursuing concizumab prophylaxis reach the molecule through the Drug Regulatory Authority of Pakistan's Special Permission for Personal Use Import. Reserve Meds is the U.S.-side coordinator for that import. The treating hematologist remains the prescriber. The dispensing hospital pharmacy remains the dispensing setting. Reserved for you.

Why hemophilia families in Pakistan need Alhemo via NPP

Three structural reasons converge on the DRAP Special Permission pathway for Alhemo. First, concizumab is not registered with DRAP, so no Pakistani pharmacy can stock or fill it through normal commercial channels. Second, the indicated population (hemophilia A or B with inhibitors aged 12 and older) is exceptionally small in Pakistan and concentrated at a handful of tertiary hematology programs, mostly in Karachi and Lahore. The country's clinical default for inhibitor patients has historically been recombinant factor VIIa or activated prothrombin complex concentrate on demand, with emicizumab where available for hemophilia A only. Concizumab offers a different proposition: once-daily subcutaneous prophylaxis for both hemophilia A and hemophilia B with inhibitors, which is a meaningful regimen change rather than a marginal step. Third, the practical reality is that the Hemophilia Patients Welfare Society of Pakistan and the major hematology centers handle a long-standing gap between what the global hemophilia armamentarium offers and what local procurement can deliver. Named-patient imports are how that gap is bridged for individual patients with the means or family network to fund advanced therapy.

Patients across Karachi, Lahore, Islamabad, and the smaller cities all route through the same DRAP framework. The operational difference is whether the patient is treated at one of the major hematology programs with in-house import pharmacy capacity, or partners with a DRAP-licensed importer that handles the regulatory and cold-chain interface on behalf of the treating clinic.

The DRAP Special Permission pathway for Alhemo

The Drug Regulatory Authority of Pakistan issues Special Permission for Personal Use Import of unregistered medicines through its Quality Assurance and Laboratory Testing Division, with

applications filed on the Online Import and Export System (OIES) portal. For an Alhemo case, the file is built in the patient's name with the CNIC (or B-Form for patients under 18) as identifier, against a PMDC-licensed treating hematologist, with a clinical justification letter that establishes the case for the unregistered biologic.

The application package includes the clinical justification letter from the treating hematologist with hemophilia A or B diagnosis, factor VIII or IX deficiency level, inhibitor titer in Bethesda Units with the testing laboratory and date, the patient's bleeding history (annualized bleeding rate where measured, joint involvement, recent serious bleeds), prior prophylaxis or on-demand therapy attempted with outcomes, and the rationale for concizumab prophylaxis. It includes PMDC license verification for the prescriber. It includes product details (brand Alhemo, INN concizumab-mtci, manufacturer Novo Nordisk A/S based in Bagsvaerd, Denmark, country of origin, presentation as prefilled pens at 60 mg, 150 mg, or 300 mg strengths, requested quantity, batch and expiry where available). It includes the destination dispensing facility license. And it includes the cold-chain plan covering 2 to 8 degrees Celsius transit, validated insulated packaging, temperature loggers, and the FBR Customs clearance at Karachi or Lahore airport.

For Alhemo specifically, two file features deserve attention. The clinical letter should address the thrombosis-risk profile explicitly, because the explorer7 and explorer8 trials reported three serious thromboembolic events that prompted a clinical-hold pause, a maintenance-dose reduction from 0.25 mg/kg to 0.20 mg/kg, and explicit risk-mitigation guidance on concurrent bypass-agent dosing. DRAP reviewers expect to see the prescriber's documented assessment of thrombosis risk factors (active cancer, severe atherosclerosis, recent thromboembolic events) and the breakthrough-bleed plan that specifies lowest approved dose of any procoagulant. Second, the file should reference the loading-dose schedule (1 mg/kg subcutaneous on Day 1) and the 4-week plasma-concentration measurement that drives uptitration to 0.25 mg/kg or downtitration to 0.15 mg/kg, so the requested quantity tracks an individualized regimen rather than a uniform supply order.

Routine cases at established hematology centers typically clear in four to eight weeks from a complete submission. The cold-chain requirement does not extend regulatory review but does extend logistics on the back end. Complex cases involving documentation queries on inhibitor confirmation, first-time DRAP filers, or PMDC license issues can extend to ten to sixteen weeks.

Where Alhemo gets dispensed in Pakistan

For Alhemo, the relevant institutions are the centers with established hematology programs, cold-chain pharmacy infrastructure for 2 to 8 degrees Celsius biologics, and DRAP-experienced import operations. Aga Khan University Hospital (AKUH) in Karachi has the Department of Oncology with eighteen full-time faculty across medical, pediatric, radiation, and palliative oncology, bone marrow transplant capability, and a 24/7 temperature-controlled pharmacy operation that is among the most comprehensive in Pakistan. The Indus Hospital and Health Network has strong hematology capability across Karachi, Lahore, and Hyderabad. Shaukat Khanum Memorial Cancer Hospital and Research Centre in Lahore handles named-patient imports as a matter of practice and has the cold-chain infrastructure to receive 2 to 8 degrees Celsius biologics. Liaquat National Hospital in Karachi adds a further private tertiary hematology option. Shifa International Hospital in Islamabad operates an established import pharmacy workflow for federal-capital-region patients. The Children's Hospital and Institute of Child Health in Lahore handles pediatric hematology cases (relevant for adolescents aged 12 and older within the Alhemo label).

Because concizumab is a cold-chain biologic (2 to 8 degrees Celsius), the dispensing-facility list is narrower than for ambient products. Pen storage, in-use post-first-use stability (up to 4 weeks at room temperature below 30 degrees Celsius or refrigerated), and training on subcutaneous self-injection are all part of the dispensing institution's workflow. Patients outside the major metros typically have their case routed through one of the centers above, with last-mile travel handled separately by the patient.

Real cost picture for Alhemo in Pakistan

Per Drugs.com and specialty pricing references, Alhemo U.S. list pricing is approximately USD 10,088 per 60 mg / 1.5 mL pen, USD 25,209 per 150 mg / 1.5 mL pen, and USD 50,411 per 300 mg / 3 mL pen. Annual cost depends on patient weight because dosing is weight-based. For a typical adult patient at 70 kg on the 0.2 mg/kg maintenance dose, daily consumption is roughly 14 mg, or approximately 420 mg per month before loading-dose effects, which lands annualized cost well above USD 500,000 per patient at list pricing, consistent with rare-disease prophylaxis pricing benchmarks for bypass and substitution biologics.

For a Pakistan DRAP case, the cost stack has three line items. The drug cost reflects the U.S. list price for the pens dispensed against the named-patient case, in the order of USD 30,000 to USD 50,000 per month of supply for a typical adult, with adolescent patients at lower body weight running proportionally lower. International logistics for a 2 to 8 degrees Celsius biologic run in the USD 600 to USD 1,500 range per shipment, reflecting validated insulated packaging, temperature loggers, expedited air freight, and bonded transit through Karachi or Lahore airport. Reserve Meds adds a transparent coordination fee per quote, shown separately rather than embedded in the drug price.

Currency context matters in Pakistan. The PKR is in the 278 to 280 range to the USD as of May 2026, with April 2026 CPI inflation at 10.9 percent. Reserve Meds quotes in USD and accepts wire transfers from any USD-accessible source. The Pakistani diaspora funding pattern is important here. Pakistan received roughly USD 4.4 billion in remittances from Saudi Arabia, USD 3.1 billion from the UAE, and USD 2.7 billion from the UK in recent reporting periods. For a chronic prophylactic biologic like Alhemo, where the case is not a one-time event but an indefinite monthly cost, multi-country funding coordination is the operating norm. Adamjee, Jubilee, EFU, IGI, and State Life typically do not cover named-patient imports of unregistered specialty biologics; some plans reimburse partially after delivery. Sehat Sahulat does not stretch to a six-figure annual prophylaxis course. Cash-pay is the default operating posture.

Typical timeline for Alhemo in Pakistan

For a hemophilia patient with a treating hematologist at an established tertiary center, the typical end-to-end window is six to ten weeks from first inquiry to first dose at home. Reserve Meds intake and documentation kit delivery to the prescriber typically runs 24 to 48 hours. DRAP filing through the hospital's import pharmacy or a DRAP-licensed importer typically adds three to seven business days of preparation, then four to eight weeks of DRAP review for routine cases. U.S. sourcing and international shipping of the cold-chain pens run in parallel with regulatory review and add four to seven days from approval (including the cold-chain handling premium of two to three days versus ambient), plus an additional two to four days for FBR Customs clearance at Karachi or Lahore airport with cold-chain priority handling. Because Alhemo is once-daily dosing with no buffer for prolonged customs delays, Reserve Meds plans monthly reorders to overlap rather than back-to-back. Reorders run faster because the operational rails are in place; the second and third DRAP cycle for the same patient typically runs four to six weeks end-to-end.

What your physician needs to provide

The treating hematologist's clinical justification letter is the cornerstone of the DRAP file. For an Alhemo case the letter should include the hemophilia A or B diagnosis with factor VIII or IX baseline level, the inhibitor titer in Bethesda Units with testing laboratory and date (and any history of immune tolerance induction), the patient's bleeding history with annualized bleeding rate where measured and joint involvement, prior prophylaxis or on-demand therapy attempted with outcomes, the rationale for concizumab prophylaxis, the requested regimen (loading dose 1 mg/kg subcutaneous Day 1, maintenance 0.2 mg/kg once daily from Day 2, plasma concentration check at approximately 4 weeks with uptitration to 0.25 mg/kg if below 200 ng/mL or downtitration to 0.15 mg/kg if above 4,000 ng/mL), the requested treatment duration (typically 6 or 12 months with renewal expected), and the monitoring plan covering plasma concentration, thrombosis signs and symptoms, anti-drug antibody assessment if response declines, and the breakthrough-bleed plan specifying lowest approved dose of any concurrent procoagulant.

The letter should explicitly state that the prescriber has assessed thrombosis risk factors (active cancer, severe atherosclerosis, recent thromboembolic events) and that the patient is suitable for concizumab prophylaxis given the explorer7 and explorer8 safety findings. The prescriber's PMDC license must be active for the full requested duration. Adverse-event reporting flows through the prescriber to the DRAP Pharmacovigilance Centre throughout the treatment course.

Common questions about Alhemo in Pakistan

Will Adamjee, Jubilee, EFU, or State Life cover this? Coverage for named-patient imports of unregistered biologics is uncommon across Pakistani health plans. Some plans reimburse partially on a case-by-case basis after delivery. Reserve Meds supplies the documentation the insurer needs to assess. The claim is yours or your hospital's to file. Cash-pay is the default posture.

Will the cold chain hold through Karachi or Lahore customs? Validated 2 to 8 degrees Celsius packaging with active temperature loggers is standard. Reserve Meds plans logistics around 96-hour cold-chain validity and coordinates with the dispensing pharmacy's import desk for priority clearance. Heat-excursion risk during Karachi or Lahore summer windows is the principal operational concern and is mitigated through expedited transit and validated insulation.

Our family pools funds across Pakistan, the Gulf, and the UK. How does Reserve Meds handle that? The Pakistani diaspora funding pattern is well-established and Reserve Meds works with it routinely. We quote in USD, accept wire transfers from any USD-accessible source, and coordinate timing across multiple senders. For a chronic monthly biologic like Alhemo, multi-country funding coordination is the operating norm.

Why concizumab versus emicizumab? This is a clinical question for the treating hematologist. Emicizumab is dosed less frequently (weekly to monthly subcutaneously) but is approved only for hemophilia A. Concizumab is daily but covers both hemophilia A and hemophilia B with inhibitors with one product. Reserve Meds does not advise on the selection.

What about thrombosis risk? This is the central safety consideration for concizumab and is the prescriber's responsibility to assess. The label specifies risk mitigation including the lowest approved dose of any concurrent procoagulant for breakthrough bleeds. Reserve Meds does not provide clinical guidance on thrombosis monitoring.

Is Alhemo a controlled substance? No. Concizumab is a biologic and is not on any DEA schedule. The standard DRAP Special Permission pathway applies.

Where Reserve Meds fits in Alhemo cases

Reserve Meds is the U.S.-side concierge coordinator. For an Alhemo case in Pakistan, Reserve Meds confirms eligibility and case fit within 24 to 48 hours of intake, sends the documentation kit to your hematologist, coordinates U.S. specialty pharmacy sourcing through Novo Nordisk's authorized channel, manages the validated 2 to 8 degrees Celsius international logistics with active temperature logging through Karachi or Lahore customs, and assigns a single named Concierge Patient Coordinator with Urdu- and English-language support who stays with the patient across monthly reorders. Reserve Meds does not file the DRAP application, that sits with the hospital's import pharmacy or the DRAP-licensed importer, does not prescribe, and does not advise on the concizumab-versus-emicizumab choice or on thrombosis risk assessment. The clinical authority remains with the PMDC-licensed hematologist. The regulatory authority remains with DRAP. The dispensing remains with the licensed Pakistani pharmacy.

Next step

If you are exploring Alhemo prophylaxis for hemophilia A or B with inhibitors, the waitlist is the entry point. Reserve Meds responds within 24 to 48 hours with a documentation kit for your hematologist and an indicative cost range. The firm quote follows after the prescriber confirms the dose, the inhibitor titer, and the treatment duration.

Reserved for you.