Alhemo access in Saudi Arabia

How Saudi families with hemophilia A or B with inhibitors reach Alhemo (concizumab) prophylaxis through the SFDA Personal Importation Program.

Quick orientation

Alhemo is the brand name for concizumab-mtci, a once-daily subcutaneous monoclonal antibody that targets tissue factor pathway inhibitor (TFPI) to restore thrombin generation in patients whose intrinsic coagulation cascade is broken by hemophilia. The U.S. FDA first approved Alhemo on December 20, 2024 for hemophilia A or B with inhibitors in patients 12 and older, and subsequently expanded the label to include hemophilia A or B without inhibitors. In Saudi Arabia, Alhemo has no SFDA marketing authorization. Saudi families with a treating hematologist at KFSH&RC, KAMC, MNGHA, or HMG who need prophylactic bleed prevention reach Alhemo through the SFDA Personal Importation Program (PIP). Reserve Meds is the U.S.-side coordinator; the treating hematologist owns the prescription and the inhibitor management plan. Reserved for you.

Why hemophilia patients in Saudi Arabia need Alhemo via NPP

Three structural reasons drive Saudi inhibitor-population access through PIP. First, Alhemo is not on the SFDA national drug registration list. The molecule cannot be filled at a Saudi pharmacy through normal commercial channels regardless of the prescriber's seniority. Second, the indicated population, hemophilia A or B with inhibitors aged 12 and older, is a rare-within-rare cohort in the Kingdom, concentrated in a small number of hematology centers of excellence. The clinical case for once-daily subcutaneous prophylaxis over older bypass agents (recombinant factor VIIa, activated prothrombin complex concentrate) often originates from international treating hematologists or from KSA hematologists familiar with the explorer7 and explorer8 data, and the named-patient pathway is the only lawful procurement mechanism. Third, for hemophilia B with inhibitors specifically, emicizumab (Hemlibra) is not indicated, which leaves concizumab as one of the first prophylactic options rather than a secondary choice. Even where Hemlibra is locally accessible for hemophilia A, hemophilia B inhibitor patients have no equivalent local prophylaxis option.

The patient experience in the Kingdom matters here. A 14-year-old with hemophilia B and inhibitors on rotating recombinant factor VIIa infusions for breakthrough bleeds, with a treating hematologist at KFSH&RC who reviewed the explorer8 publication, is exactly the case PIP was designed to handle.

The SFDA Personal Importation Program (PIP) for Alhemo

SFDA's Personal Importation Program allows a KSA-licensed hematologist to request import of a specific medicine for a specific named patient when the medicine is approved by a recognized reference authority (FDA, EMA, MHRA, PMDA, Health Canada all apply to Alhemo) and a locally registered alternative is not clinically suitable. For Alhemo, the clinical-justification angle has three documentable pillars: factor VIII or factor IX deficiency confirmation with the inhibitor titer history, the bleeding history that establishes prophylaxis necessity, and the rationale for once-

daily concizumab over the current bypass-agent regimen or, for hemophilia A inhibitor patients, over emicizumab.

The PIP application contains a clinical justification letter from the treating hematologist addressing diagnosis with ICD-10 coding (D66 for hemophilia A, D67 for hemophilia B, with the inhibitor specifier), the inhibitor titer measured in Bethesda units with the trend over time, the patient's bleeding history including annualized bleeding rate, the prior bypass-agent or substitution-therapy regimen and why it is not adequately controlling bleeds or is operationally limiting, and the requested concizumab dose. It includes Saudi Commission for Health Specialties (SCFHS) license verification for the prescriber in hematology or pediatric hematology. It includes the patient identifier in SFDA's required format. It includes product details (brand Alhemo, INN concizumab-mtci, manufacturer Novo Nordisk A/S, country of origin, the specific pen strength or strengths requested, requested quantity, lot, and expiry). It includes the dispensing facility license confirming refrigerated biologic handling capacity. And it includes the chain-of-custody plan with cold-chain validation (2 to 8 degrees Celsius continuous monitoring, no-freeze handling).

Two PIP-file features matter for Alhemo. First, the clinical letter should describe the planned breakthrough-bleed regimen explicitly, because the FDA label specifies using the lowest approved dose of any concurrent procoagulant given the thrombosis-risk signal from the explorer7 and explorer8 trials. The PIP reviewer expects to see a coherent acute-bleed plan alongside the prophylaxis plan. Second, the letter should reference the 4-week plasma-concentration check that drives dose individualization (target between 200 and 4,000 ng/mL), because the requested supply for the first 30 days is at the starting maintenance dose, with the possibility of uptitration to 0.25 mg/kg or downtitration to 0.15 mg/kg afterwards. Anticipating this in the file avoids a second filing for the dose adjustment.

Approval timelines for routine hemophilia cases at established centers typically run 10 to 21 business days. First-time concizumab cases at the Kingdom level may run longer because the molecule is new to SFDA's named-patient case file; 4 to 8 weeks is reasonable to plan for.

Where Alhemo gets dispensed in Saudi Arabia

For Alhemo, the relevant institutional subset is centers with established hemophilia or inhibitor-management programs and refrigerated biologic handling capacity. King Faisal Specialist Hospital and Research Centre (KFSH&RC) in Riyadh, Jeddah, and Madinah is the principal referral setting for hemophilia in the Kingdom, with bleeding-disorder specialists, factor laboratory infrastructure, and in-house import pharmacy operations that handle named-patient biologics routinely. King Abdulaziz Medical City (KAMC) and the broader MNGHA network in Riyadh and Jeddah have established adult and pediatric hematology programs. King Saud University Medical City handles academic hematology referrals. Dr. Sulaiman Al Habib Medical Group (HMG) operates hematology services across its multiple Riyadh and Jeddah facilities. Saudi German Health and Dr. Soliman Fakeeh Hospital in Jeddah round out the established private referral set.

Because Alhemo is a refrigerated biologic with 2 to 8 degrees Celsius cold-chain requirements and the patient self-administers daily at home, the institutional capability that matters is refrigerated dispensing and patient pen-training infrastructure. The patient takes pens home from the dispensing facility and stores them in their own household refrigerator. Smaller hospitals route through one of the established centers or through an SFDA-licensed specialty importer in Riyadh or Jeddah.

Real cost picture for Alhemo in Saudi Arabia

Per Drugs.com and specialty pricing references, U.S. list pricing for Alhemo 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 at 0.2 mg/kg maintenance daily. For a typical 70 kg adult patient consuming approximately 14 mg daily (420 mg per month), the annualized cost at U.S. list lands well above USD 500,000 per patient per year, which is consistent with rare-disease prophylaxis pricing benchmarks.

For a Saudi PIP case, the cost stack has three line items. The drug cost reflects the pen mix dispensed against the named-patient case, typically in the USD 35,000 to USD 50,000 range per 30 days at U.S. list pricing for a maintenance-dose adult patient (approximately SAR 131,000 to SAR 188,000 at the SAR 3.75 to USD 1.00 peg). International logistics for a 2 to 8 degrees Celsius cold-chain biologic run in the USD 800 to USD 2,500 range per shipment (approximately SAR 3,000 to SAR 9,400), reflecting validated insulated packaging with temperature loggers and end-to-end refrigerated chain-of-custody. Reserve Meds adds a transparent coordination fee per quote, shown separately rather than embedded in the drug price.

Bupa Arabia, Tawuniya, and MedGulf Arabia handle named-patient hemophilia biologics case-by-case. Pre-authorization with the clinical justification letter is the typical first step. Some plans engage with rare-bleeding-disorder prophylaxis at meaningful coverage levels; others do not. Cash-pay is the default operating posture, with reimbursement pursued after delivery where the plan permits.

Typical timeline for Alhemo in Saudi Arabia

For a hemophilia inhibitor patient with a treating hematologist at an established tertiary center, the typical end-to-end window is 6 to 9 weeks from first inquiry to first dose, longer than for an ambient oral product because of the cold-chain logistics layer and the novelty of concizumab at SFDA level. Reserve Meds intake and documentation kit delivery to the prescriber typically runs 24 to 48 hours. PIP filing preparation runs 5 to 10 business days because the inhibitor titer history, prior-line documentation, and breakthrough-bleed plan all need to be assembled. SFDA review runs 10 to 21 business days for routine cases, 4 to 8 weeks for first-time concizumab cases at the institution. Cold-chain U.S. sourcing, validated packaging, and international refrigerated shipping add 4 to 7 days from approval, with the cold-chain leg specifically slower than ambient because of the 2 to 8 degrees Celsius handling requirement at every transit point. Reorders run faster, typically 4 to 6 weeks end-to-end, because the operational rails are in place.

What your physician needs to provide

The treating hematologist's clinical justification letter is the cornerstone. For an Alhemo case the letter should include the hemophilia diagnosis with subtype (A or B) and severity, the inhibitor titer history with Bethesda values and the time course, the patient's annualized bleeding rate over the prior 12 months, the current bypass-agent or substitution-therapy regimen with outcomes, the rationale for switching to once-daily concizumab prophylaxis with reference to the explorer7 and explorer8 trials and the FDA label, the dosing plan (1 mg/kg subcutaneous loading dose Day 1, 0.2 mg/kg subcutaneous daily maintenance starting Day 2, with the planned 4-week plasma-concentration check and titration logic), the breakthrough-bleed plan specifying the lowest approved dose of the concurrent procoagulant agent, and the monitoring plan covering thrombosis signs and symptoms, anti-drug antibody surveillance, and ongoing factor activity.

The letter should explicitly acknowledge the thrombosis risk that prompted the explorer7 clinical hold and the resulting dose adjustment from 0.25 to 0.20 mg/kg maintenance, and document that the patient has been assessed for thrombosis risk factors (active cancer, severe atherosclerosis, recent thromboembolic events). Adverse-event reporting through the SFDA National Pharmacovigilance Center is the prescriber's responsibility throughout the treatment course. The prescriber's SCFHS license must be active for the full requested duration.

Common questions about Alhemo in Saudi Arabia

Will Bupa Arabia or Tawuniya cover this? Each plan handles named-patient hemophilia biologics case-by-case. Pre-authorization with the clinical justification letter is the typical first step. Some plans engage with rare-bleeding-disorder prophylaxis at meaningful coverage; others do not. Cash-pay is the default posture.

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. For hemophilia B with inhibitors specifically, emicizumab is not indicated, which makes concizumab one of the first prophylactic options.

Can I store the pens at home? Yes. Per the FDA label, unopened pens are stored at 2 to 8 degrees Celsius in the original carton, protected from light. Once in use, a pen can be kept at room temperature below 30 degrees Celsius or refrigerated, for up to 4 weeks before discarding. Pens must not be frozen. Reserve Meds delivers pens that are fully within the validated cold chain; home storage is the patient's responsibility from that point.

What about the thrombosis warning? The explorer7 trial reported three serious thromboembolic events, including a renal infarction, which prompted a clinical-hold pause and a dose reduction from 0.25 to 0.20 mg/kg maintenance. The treating hematologist assesses thrombosis risk factors before initiation and monitors throughout therapy. The breakthrough-bleed plan uses the lowest approved dose of any concurrent procoagulant to manage acute bleeds without stacking pro-coagulant load. This is a clinical management question; Reserve Meds does not advise on it.

Is the 4-week plasma concentration check available in the Kingdom? Yes. KFSH&RC and other major centers have the laboratory infrastructure to draw and assay the plasma concentration. The treating hematologist coordinates the draw against the dosing schedule.

Is Alhemo a controlled substance? No. Concizumab is a biologic and is not DEA-scheduled. The standard PIP pathway applies.

Where Reserve Meds fits in Alhemo cases

Reserve Meds is the U.S.-side concierge coordinator. For an Alhemo case in Saudi Arabia, Reserve Meds confirms eligibility and case fit within 24 to 48 hours, sends the documentation kit to your treating hematologist, coordinates U.S. specialty pharmacy sourcing through Novo Nordisk's authorized cold-chain channel, manages the validated 2 to 8 degrees Celsius international logistics with temperature loggers and continuous chain-of-custody, and assigns a single named Concierge Patient Coordinator with Arabic-language support who stays with the patient and family across reorders. Reserve Meds does not file the PIP application, does not prescribe, and does not advise on the concizumab-versus-emicizumab clinical choice. The clinical

authority remains with the SCFHS-licensed hematologist. The regulatory authority remains with SFDA. The dispensing remains with the licensed Saudi hospital pharmacy.

Next step

If you or your family member has hemophilia A or B with inhibitors and the treating hematologist has discussed concizumab prophylaxis, 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 and supply schedule.

Reserved for you.