Altuviiio

Saudi Arabia · access guide

Altuviiio (efanesoctocog alfa) for a Saudi family: what the pathway looks like in 2026

By Reserve Meds clinical & regulatory team. Last reviewed 2026-05-20.

A Saudi family of a boy newly diagnosed with severe haemophilia A, or a Saudi adult patient looking at the move from a twice-weekly extended-half-life factor VIII regimen to once-weekly Altuviiio, walks into this decision with the benefit of one of the strongest haemophilia infrastructures in the region. King Faisal Specialist Hospital and Research Centre in Riyadh and Jeddah has run a comprehensive haemophilia programme for decades. King Abdulaziz Medical City, King Fahad Specialist Hospital Dammam, King Fahad Medical City Riyadh, and King Faisal Hospital Riyadh round out a deep network. The Saudi Food and Drug Authority framework is mature for haematology biologics. There is still a regulatory question about how Altuviiio specifically moves into the country in 2026, a financial question that is multi-decade and weight-based, and the family question that recurs in MENA haemophilia care because the disease often appears in a relative before this patient.

This page is meant to be the first honest read you get on Altuviiio in Saudi Arabia, written by the team that would coordinate around your case if you decided you wanted operational support on the workup, the import, the haemophilia treatment centre liaison, the home-infusion training, or the long-term cost picture.

We will be specific about what Altuviiio is, what makes it different from prior factor VIII products, what the switch conversation looks like, what the regulatory pathway looks like in 2026, what it costs in SAR and US dollars, where the infusion can be initiated and where home self-infusion takes over, and what life looks like for a Saudi family settling into a once-weekly lifelong routine.

What Altuviiio actually is, and why once weekly matters

Haemophilia A is an X-linked recessive bleeding disorder caused by pathogenic variants in the F8 gene encoding coagulation factor VIII (FVIII). FVIII is a co-factor in the intrinsic clotting cascade. Severe-phenotype patients have less than 1% normal FVIII activity and bleed spontaneously into joints and muscles without identifiable trauma; the bleeding is what drives the long-arc complications of chronic synovitis, target joints, and progressive haemophilic arthropathy.

For five decades the treatment has been factor VIII replacement therapy: intravenous infusion of FVIII, either from human plasma (historically) or from recombinant cell culture (since the early 1990s). Standard-half-life recombinant FVIII concentrates have a circulating half-life of approximately 12 hours, which puts prophylaxis on an every-2-3-day schedule. First-generation extended-half-life FVIII products (Eloctate / Elocta, Adynovate, Esperoct, Jivi) extended the half-life to around 19 hours and pushed prophylaxis to twice weekly. None of those products broke through the half-life ceiling set by endogenous von Willebrand factor (VWF), which binds circulating FVIII and protects it from clearance.

Altuviiio breaks through that ceiling. The molecule carries its own VWF binding partner intramolecularly via the D'D3 domain of VWF fused into the construct, plus an IgG1 Fc fragment for FcRn-mediated recycling, plus two XTEN polymer chains that slow renal clearance. The result is a half-life of approximately 47 hours in adults, three to four times the half-life of prior FVIII products. Once-weekly dosing at 50 IU/kg produces sustained FVIII activity around 15% of normal across the dosing interval, with peak activity reaching the normal range early in the dosing interval. Prior extended-half-life products ran at roughly 5-10% trough; the Altuviiio profile is closer to non-haemophilia physiological FVIII for more of the dosing interval than any prior product.

This is the reason your haematologist is talking to you about Altuviiio.

The pre-treatment workup that decides eligibility

Most Saudi patients arriving for an Altuviiio conversation are already inside the haematology system, with diagnosis and prior treatment history on file from KFSHRC Riyadh, KFSHRC Jeddah, KAMC Riyadh, KFMC Riyadh, KFSH Dammam, or one of the regional teaching hospitals.

The relevant workup pieces:

First, confirmed diagnosis of haemophilia A with severity classification. FVIII activity assay, F8 gene sequencing, severity grading severe / moderate / mild. KFSHRC's molecular genetics laboratory has F8 sequencing capability in-Kingdom and has characterised much of the Saudi haemophilia A mutation spectrum.

Second, treatment history review. Prior FVIII product, prophylaxis schedule, recent annualised bleeding rate, FVIII trough levels, prior Hemlibra exposure if any. The switch decision flows from this history.

Third, inhibitor status. Bethesda assay for FVIII inhibitor titre. Patients with active high-titre inhibitors are not the appropriate population for Altuviiio; bypassing agents or immune tolerance induction protocols apply, and Hemlibra is the alternative for inhibitor patients.

Fourth, joint health assessment. Haemophilia Joint Health Score, target-joint imaging, physiotherapy review.

Fifth, baseline pharmacokinetic study, optional. Some Saudi centres run a baseline PK on the first dose to fine-tune dosing for the individual patient.

A clinical rationale letter from the treating haematologist documents the diagnosis, the prior treatment history, the rationale for the switch, and the planned monitoring schedule.

The Saudi regulatory pathway in 2026

The Saudi Food and Drug Authority (SFDA) handles medicinal product registration. Altuviiio is a relatively new product in MENA (FDA approval February 2023, EMA September 2023) and [VERIFY: current SFDA registration status of Altuviiio 2026]. Where formal SFDA registration is in place, standard prescription applies and procurement runs through NUPCO (the National Unified Procurement Company) for public-sector cases or through the hospital's authorised distributor for private-sector cases. Where formal registration is in process, the named-patient mechanism filed by the hospital's import pharmacy is the operational route. The Sanofi and Sobi commercial presence in the Saudi market means the supply chain is functional for legitimate prescriptions.

For public-sector Saudi national patients, the procurement loop typically runs through NUPCO via the treating hospital. For private-sector cases, procurement is direct through the authorised distributor. Reserve Meds plays the documentation and logistics coordination role; the actual procurement and dispensing remains with the treating hospital pharmacy.

The realistic Saudi haemophilia A infrastructure: - **King Faisal Specialist Hospital and Research Centre (KFSHRC), Riyadh and Jeddah.** The deepest comprehensive haemophilia programme in the Kingdom. Adult and paediatric haematology, coagulation laboratory with FVIII activity and Bethesda assay in-house, F8 sequencing, home-infusion programme infrastructure, multidisciplinary surveillance. - **King Abdulaziz Medical City (KAMC), Riyadh.** Adult and paediatric haematology with comprehensive haemophilia experience under the National Guard Health Affairs system. - **King Fahad Specialist Hospital, Dammam.** Eastern Province haematology centre. - **King Fahad Medical City (KFMC), Riyadh.** Paediatric haematology depth. - **King Faisal Hospital, Riyadh.** Adult haematology and inhibitor management. - **Saudi German Hospital network** and **Dr Sulaiman Al Habib Medical Group** for private-sector adult haematology in major cities.

For paediatric patients in the southern regions, paediatric haematology services in Asir, Jazan, and Najran refer to KFMC Riyadh or to KFSHRC for the higher-complexity decisions including switch evaluations.

The cost conversation, in the form a Saudi family needs

Altuviiio is among the most expensive haematology agents on the market, and because it is weight-based and lifelong, the multi-decade financial picture is what matters more than any single dose price.

The 2026 indicative annual list price is roughly USD 800,000 to USD 1,200,000 per year for an adult on standard 50 IU/kg weekly prophylaxis, or approximately SAR 3.00 million to SAR 4.50 million per year. A paediatric patient at lower weight runs at a proportionally lower absolute cost (per-kg cost is the same). Over a multi-decade lifelong therapy course for a severe-phenotype patient diagnosed in infancy, the cumulative drug cost at list can reach USD 30 million to USD 50 million.

Real-world cost is typically lower because of NUPCO procurement contracts, payer arrangements, and the public-system funding pathways that apply to Saudi national patients. The cash-pay sticker number is what private-sector and expatriate families need to see at intake.

When we issue a quote, we separate every line: drug per infusion (50 IU/kg, weight-adjusted), home-infusion programme set-up, infusion supplies, monitoring labs (FVIII trough, Bethesda assay, joint imaging), our coordination fee. Nothing is bundled. We do not put a markup on the manufacturer's drug price.

For Saudi nationals treated at KFSHRC, KAMC, KFMC, KFSH Dammam, or other Ministry of Health and government-system facilities, much of the cost may be underwritten through the public health funding pathway. Your treating consultant and the hospital's pharmacy department will confirm what is covered and how. For expatriate residents and for private-sector Saudi patients, the cost picture is typically a mix of insurance coverage (Bupa Arabia, Tawuniya, MedGulf, AXA, and others handle rare-disease prior authorisation case by case) and family-pay.

For Saudi national patients on the Ministry of Health treatment-abroad pathway who may need cross-border evaluation for a switch decision or for a gene therapy consult, the application runs through the treating consultant and the MoH treatment-abroad office; we can support documentation at no charge.

The once-weekly infusion reality

Altuviiio is administered as an intravenous bolus over several minutes; reconstituted from lyophilised powder with provided diluent at the time of infusion. No titration period, no routine pre-medication. The first one or two infusions are typically performed at the haemophilia treatment centre with nursing supervision and infusion training for the patient or for a family member. After that, home self-infusion is the operational norm for stable patients.

For a Saudi family, the practical implication of once-weekly versus every-2-3-day or twice-weekly is a meaningful drop in calendar burden. School attendance, university attendance, work attendance, Hajj and Umrah for patients of suitable age and clinical stability, summer family travel, all become operationally easier. The disease is still present and still requires the weekly discipline, but the rhythm is less invasive than older regimens.

For families with a newly diagnosed boy who has never been on FVIII therapy before (a previously untreated patient, PUP), the early phase requires closer haemophilia treatment centre supervision and more frequent inhibitor surveillance during the first 50 exposure days, when inhibitor risk is highest. The home-infusion transition typically waits until the early surveillance window is clear.

Monitoring on therapy

The surveillance schedule on long-term Altuviiio: annualised bleeding rate tracking via patient diary, periodic FVIII trough activity, periodic Bethesda assay for inhibitor (particularly during the first 50 exposure days for PUPs), annual joint health assessment with HJHS and imaging, physiotherapy and orthopaedic input on a schedule set by the treating team, hepatitis vaccination status and liver function (legacy surveillance from the plasma-derived era), genetic counselling for family planning at the appropriate life stage. KFSHRC, KAMC, KFMC, KFSH Dammam, and the major teaching hospitals have the multidisciplinary infrastructure to run the full surveillance schedule in-Kingdom.

When Altuviiio is not the right answer, or not the only answer

For patients with active high-titre FVIII inhibitors, Altuviiio is not the appropriate product. Hemlibra (emicizumab) is often the right answer for these patients: a bispecific antibody given by subcutaneous injection that works regardless of inhibitor status. The choice between FVIII replacement and Hemlibra is a clinical conversation between you and your haematologist, depending on inhibitor status, bleeding phenotype, perioperative needs, and patient preference. Reserve Meds will not push you away from the Hemlibra conversation.

For patients exploring gene therapy, Roctavian is the FDA- and EMA-approved AAV gene therapy for adult severe haemophilia A; real-world uptake has been slower than initially projected because of variable durability, the lack of redo options after the initial dose, hepatic safety considerations, and acquisition cost. Gene therapy and Altuviiio are not mutually exclusive in the long arc of a patient's treatment plan.

For patients with non-A haemophilia (haemophilia B), Altuviiio is not indicated; recombinant factor IX products and Hemgenix gene therapy are the equivalent options.

For severe-phenotype patients during the early diagnostic phase with active joint or muscle bleeding, immediate bleed control is the priority and prophylaxis decisions follow once the acute phase is stabilised; the haemophilia treatment centre's protocol drives this.

What Reserve Meds does for a Saudi family

Reserve Meds is a US-based concierge coordinator for cross-border and complex specialty medicine. For a Saudi family or adult patient pursuing Altuviiio, our scope is the regulatory documentation packet, the SFDA filing in collaboration with your treating hospital's import pharmacy (where applicable), the sourcing logistics from Sanofi's authorised distribution through DSCSA-compliant chain of custody, cold-chain shipment to the qualified Saudi centre or home-infusion programme, and named case-lead coordination from intake through the establishment of a stable weekly infusion routine. For public-sector Saudi national patients where NUPCO procurement is the operational route, our role is documentation and coordination rather than direct procurement.

Reserve Meds is not your prescriber. We do not practise medicine. We do not manufacture Altuviiio. We do not own or operate the haemophilia treatment centre or the home-infusion programme. We are not your insurer. Clinical decisions stay with your treating haematologist and the haemophilia treatment centre team; we are the operational layer.

We work cash-pay (where applicable). Our coordination fee is disclosed in writing. We will not start work without a signed engagement.

A note for families weighing this

For Muslim families thinking through the religious-ethical dimension, Altuviiio is recombinant, produced in CHO cell culture, not derived from animal tissue or human plasma. For families with longer memories of the plasma-derived factor concentrate era in the 1980s and 1990s, when HIV and HCV transmission risk was real, the recombinant nature of modern FVIII products including Altuviiio is itself a meaningful reassurance. Islamic bioethics consensus on life- and function-preserving therapies that prevent disabling joint disease is broadly permissive across Sunni schools, which is the dominant register in the Saudi context.

For families who already have an affected relative, the carrier-testing conversation for the mother, for adult sisters of patients, and for the extended maternal family is an important separate thread, and the haematology and genetic counselling team at your treating centre will offer the appropriate referrals.

What to do if you want to start

The first concrete step is a call with our case-lead so we can confirm where the patient is in the diagnostic and treatment-history picture, and whether the right next move is the switch evaluation, the SFDA pathway documentation, the home-infusion programme set-up, or a combination.

If your child has just been diagnosed at KFSHRC, KAMC, KFMC, or another centre and the haematologist is starting the prophylaxis conversation, reach out anyway: we will help you understand the product landscape (Altuviiio, prior-generation FVIII products, Hemlibra) and the regulatory pathway before the first prescription is written.

Most families reach us first on WhatsApp, which is the medium we hold open during Saudi business hours (Sunday-Thursday) and on weekends for active cases.

Start your case on the portal, or open a WhatsApp conversation with the case-lead and we will take it from there.

Reserve Meds's role

US-based concierge coordinator for cross-border specialty medicine. We are not the prescriber, not the dispensing pharmacy, and not the manufacturer. All clinical decisions remain with your treating physician.

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