Altuviiio

United Arab Emirates · access guide

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

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

A UAE family of a boy newly diagnosed with severe haemophilia A, or a UAE 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 more than a single product question. There is a clinical question about which prior treatment has been used and what the inhibitor-status picture is. There is a regulatory question about how Altuviiio moves into the country. There is a financial question that is multi-decade and weight-based, not month-to-month. And there is a family question, often a familiar one in MENA families, because haemophilia A has appeared in a relative before this patient. This page is meant to be the first honest read you get on Altuviiio in the UAE, written by the team that would coordinate around your case if you decided you wanted operational support on the workup, the import, the qualified 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 the UAE in 2026, what it costs in AED and US dollars, where the infusion can be initiated and where home self-infusion takes over, and what life looks like for a family settling into a once-weekly lifelong infusion 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. Patients with severe haemophilia A have less than 1% normal FVIII activity and bleed spontaneously into joints and muscles without identifiable trauma; the bleeding is what causes the characteristic complications, chronic synovitis, target joints, progressive haemophilic arthropathy.

The treatment for the last fifty years 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 means severe-phenotype patients on prophylaxis required infusion every 2 to 3 days. First-generation extended-half-life FVIII products (Eloctate / Elocta, Adynovate, Esperoct, Jivi), most of which became available between 2014 and 2018, 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; VWF itself has a half-life of approximately 12 to 15 hours, and FVIII is dragged along with it.

Altuviiio breaks through that ceiling. The molecule is a recombinant FVIII fused to an IgG1 Fc fragment, fused to the D'D3 domain of VWF (so that the FVIII carries its own VWF binding partner intramolecularly rather than relying on endogenous VWF in circulation), with two XTEN polymer chains that add hydrodynamic volume and 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, which is enough to prevent most spontaneous bleeds but is well below normal activity. The Altuviiio profile is closer to non-haemophilia physiological FVIII for more of the dosing interval than any prior product.

We mention this first because it is the reason your haematologist is talking to you about Altuviiio. The drug class is not new; the molecule is what is new.

The pre-treatment workup that decides eligibility

Many UAE patients arriving at Reserve Meds for an Altuviiio question already have most of the diagnostic workup on file from SKMC, Tawam Hospital, Mediclinic City Hospital, American Hospital Dubai, or Cleveland Clinic Abu Dhabi. The starting point for the Altuviiio conversation is the patient's prior treatment record.

The relevant workup pieces:

First, confirmed diagnosis of haemophilia A with severity classification. FVIII activity assay and F8 gene sequencing (specific pathogenic variant identification, relevant to inhibitor risk and family carrier counselling). Severity grading severe / moderate / mild. Most UAE patients arrive with this already complete.

Second, treatment history review. What FVIII product was the patient on? What was the prophylaxis schedule (every 2-3 days, twice weekly)? What was the recent annualised bleeding rate (ABR)? What were the FVIII trough levels? Was the patient on Hemlibra (the bispecific antibody alternative to FVIII replacement, given by subcutaneous injection)? The transition decision flows from this history. Patients with high ABR despite adherence on prior products, patients with target joints continuing to bleed, patients with a strong preference for a less frequent schedule, are all candidates for the Altuviiio conversation.

Third, inhibitor status. The Bethesda assay measures anti-FVIII inhibitor titre. Patients with active high-titre inhibitors are not the appropriate population for Altuviiio; bypassing agents (FEIBA, recombinant factor VIIa) or immune tolerance induction protocols apply, and Hemlibra is a strong alternative for inhibitor patients. Inhibitor screening is part of routine haemophilia surveillance and most UAE patients will have a recent result on file.

Fourth, joint health assessment. Haemophilia Joint Health Score (HJHS), MRI or ultrasound of target joints, physiotherapy review. The baseline for the long-term surveillance schedule.

Fifth, baseline pharmacokinetic study, optional. Some centres perform a PK study on the first Altuviiio dose to confirm the half-life response and fine-tune dosing.

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

The UAE regulatory pathway: how it actually works in 2026

The Emirates Drug Establishment, which absorbed 44 of the Ministry of Health and Prevention's regulatory functions by early 2026, is the federal authority that the treating hospital files through. Altuviiio is a relatively new product in MENA (FDA approval February 2023, EMA approval September 2023) and [VERIFY: current EDE registration status of Altuviiio 2026]; where formal registration is in place, standard prescription and import procurement applies, and where not, the named-patient mechanism is filed via ede.gov.ae by the hospital's import pharmacy on the treating physician's behalf. The Department of Health Abu Dhabi or the Dubai Health Authority adds the emirate-level layer depending on where the patient is treated.

In our experience coordinating haemophilia A cases for UAE families, EDE coordination on a complete, well-documented file runs three to six weeks from filing to approval. The active Sanofi and Sobi commercial presence in the region means the product supply chain is operationally functional even where formal local registration is still being secured.

The realistic UAE infrastructure for haemophilia A: - **Sheikh Khalifa Medical City (SKMC), Abu Dhabi.** Adult and paediatric haematology with comprehensive haemophilia experience; longstanding cohort. - **Tawam Hospital, Al Ain.** Paediatric haematology service with deep experience in chronic FVIII replacement; the natural infusion home for many Al Ain and broader Abu Dhabi paediatric haemophilia patients. - **Sheikh Shakhbout Medical City (SSMC), Abu Dhabi.** Adult haematology with FVIII replacement and inhibitor management experience. - **Cleveland Clinic Abu Dhabi.** Adult haematology programme with home-infusion programme support. - **American Hospital Dubai.** Adult and paediatric haematology, home-infusion programme infrastructure. - **Mediclinic City Hospital, Dubai.** Haematology depth. - **King's College Hospital London Dubai.** Adult haematology referral options.

For new paediatric diagnoses, the typical path is SKMC, Tawam, or the Dubai-side paediatric service running the workup and initiating prophylaxis. For adults on a switch decision, any of the adult haematology services can manage the transition. Home self-infusion training is the operational end-state for stable patients regardless of the initiating centre.

The cost conversation, in the form a UAE 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 AED 2.94 million to AED 4.41 million per year. A 25 kg child runs at roughly a third of an adult cost in absolute terms because the dose scales with weight (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 than this list-price math because of payer rebates, hospital procurement contracts, rare-disease funding pathways, and manufacturer patient-access programmes. But the cash-pay sticker number is what 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. We charge a transparent coordination fee for the case-management work, disclosed in writing before any funds move.

Insurance coverage of Altuviiio in the UAE is evolving. Daman has approved cases for certain employer plans and Thiqa-covered Emirati nationals on the rare-disease prior-authorisation pathway, with case-by-case assessment. Private insurers vary. The Daman rare-disease pathway has been workable historically for haemophilia patients. We supply your insurer with the documentation packet at no charge; we do not process the claim or guarantee coverage.

For Emirati nationals being treated at SKMC, Tawam, or SSMC under the public system, much of the cost may be underwritten through Thiqa and the government health funding pathways. Your treating consultant will confirm whether and how. For expatriate residents, the cost picture is typically a mix of insurance coverage, employer support where applicable, and family-pay.

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.

The practical implications of once-weekly home infusion are real. Compared to a twice-weekly extended-half-life regimen or every-2-3-day standard-half-life regimen, the calendar burden drops significantly. School attendance, work attendance, family travel, summer trips, Hajj or Umrah where clinically appropriate, all become operationally easier. The disease is still present and still requires the weekly discipline, but the rhythm is less invasive.

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.

For adults on a switch from a prior product, the transition is typically faster because the patient is already trained on home infusion and the surveillance schedule is established.

Monitoring on therapy

The surveillance schedule on long-term Altuviiio is built around bleed prevention and joint preservation: - Annualised bleeding rate (ABR) tracking via patient diary. - FVIII trough activity at intervals to confirm the dosing interval is right for the individual patient. - Bethesda assay (anti-FVIII inhibitor) periodically, particularly for previously untreated patients during the first 50 exposure days. - Annual joint health assessment: Haemophilia Joint Health Score, joint imaging as clinically indicated. - Physiotherapy and orthopaedic input on a schedule set by the treating team. - Hepatitis vaccination status and liver function monitoring (legacy surveillance from the plasma-derived era; clinically less relevant for patients only ever exposed to recombinant products but still part of standard haemophilia care). - Genetic counselling for family planning at the appropriate life stage.

SKMC, Tawam, SSMC, Cleveland Clinic Abu Dhabi, and the Dubai-side comprehensive haematology services have the multidisciplinary infrastructure to run the full surveillance schedule in-emirate.

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 mimics FVIII's co-factor function and works regardless of inhibitor status. The choice between FVIII replacement (whether Altuviiio or a prior-generation product) and Hemlibra is a clinical conversation that depends on inhibitor status, bleeding phenotype, perioperative needs, patient preference, and your haematologist's read of the case. Reserve Meds will not push you away from the Hemlibra conversation; if your haematologist's recommendation is Hemlibra, we can coordinate that pathway instead.

For patients exploring gene therapy, Roctavian (valoctocogene roxaparvovec) 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 of FVIII expression, the lack of redo options after the initial dose, hepatic safety considerations, and high acquisition cost. The Pfizer / Sangamo gene therapy programme is at a different development stage. Gene therapy and Altuviiio are not mutually exclusive in the long arc of a patient's treatment plan; some patients move from FVIII replacement to gene therapy and may move back to FVIII replacement if expression wanes. This is a conversation to have with the treating haematologist, not on a concierge page.

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

For severe-phenotype patients during the early diagnostic phase with active joint bleeding 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, and what we do not do

Reserve Meds is a US-based concierge coordinator for cross-border and complex specialty medicine. For a UAE family or adult patient pursuing Altuviiio, our scope is the regulatory documentation packet, the EDE filing in collaboration with your treating hospital's import pharmacy, the sourcing logistics from Sanofi's authorised distribution through DSCSA-compliant chain of custody, cold-chain shipment to the qualified UAE centre or home-infusion programme (2-8 degrees Celsius with permitted room-temperature excursion), and named case-lead coordination from intake through the establishment of a stable weekly infusion routine. We continue to coordinate refills, documentation, and any cross-border travel for second opinions or for switch-product evaluation where it applies.

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

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 the modern FVIII products including Altuviiio is itself a meaningful reassurance. The Islamic bioethics consensus on life- and function-preserving therapies that prevent disabling joint disease is broadly permissive across Sunni and Shia schools. Families typically consult with their religious advisors before committing; we will not pressure that conversation.

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 a separate but important thread, and your haematology and genetic counselling team 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 EDE filing, the home-infusion programme set-up, or a combination.

If your child has just been diagnosed 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 UAE business hours 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.

Reserve Meds

reserved for you.

Composite case examples. This document is for general information only and does not constitute medical advice. Please consult your treating physician.
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