Altuviiio access in India

How families with severe hemophilia A in India pursue Altuviiio (efanesoctocog alfa), the once-weekly factor VIII replacement that extends protection beyond the limits of standard half-life products.

Last reviewed 2026-05-12 by Reserve Meds clinical & regulatory team. This page combines the India country regulatory module with the Altuviiio drug module to describe the path families actually walk.

Quick orientation

Altuviiio (efanesoctocog alfa) is a once-weekly recombinant factor VIII replacement therapy approved by the US Food and Drug Administration in February 2023 for adults and children with hemophilia A, for routine prophylaxis, on-demand treatment, and perioperative management. The product is marketed in the United States approximately by Sanofi in partnership with Sobi. It is the first factor VIII therapy to break the von Willebrand factor ceiling that limited dosing intervals for prior extended half-life products, and clinical data show sustained near-normal factor VIII levels through most of the week with once-weekly dosing. For an Indian family weighing this option, the access question is structural rather than clinical. Reserved for you.

Why this drug is hard to source in India

India has a substantial hemophilia patient population estimated in tens of thousands of severe and moderate cases, and the Hemophilia Federation (India) coordinates patient advocacy and care access through more than 90 chapters. Yet for Altuviiio specifically, the access wall is real. The molecule is novel, the manufacturer's commercial launch sequence has prioritised the United States and selected reference markets, and an Indian marketing authorisation through CDSCO has not been a near-term filing as of this review date. Recombinant standard half-life factor VIII products are available in India through public-sector programs and private pharmacies; extended half-life products with an Indian registration include certain pegylated and Fc-fusion molecules through specialty importers. Altuviiio sits outside that locally registered set. For severe hemophilia A patients who have failed to achieve adequate prophylaxis on standard half-life products, or who experience breakthrough bleeding even on extended half-life regimens, the once-weekly dosing of efanesoctocog alfa is the clinical differentiator that justifies the import pathway.

The CDSCO personal-import pathway under Rule 36

The legal foundation for personal import of an unregistered medicine into India is Rule 36 of the Drugs and Cosmetics Rules 1945. Rule 36 permits import of a small quantity of a drug whose import would otherwise be prohibited under Section 10 of the Drugs and Cosmetics Act 1940, for the exclusive personal use of a named patient. The mechanism is documented and accessible. Form 12A is the application for a permit to import. Form 12B is the permit itself, issued by the office of the Drugs Controller General of India at FDA Bhawan in New Delhi or by designated CDSCO Port Offices. The application is accompanied by a prescription from a Registered Medical Practitioner showing the practitioner's NMC registration number and the quantity required for treatment. The quantity of any single drug imported under one application shall not exceed one hundred average doses.

For Altuviiio, the routine application set is sufficient where the treating hematologist documents the clinical justification, weight-based dosing, prior factor product history, and the planned prophylaxis schedule. The dispensing facility is the hospital pharmacy where the patient is followed, or a CDSCO-licensed specialty importer in Mumbai, Delhi, or Bangalore acting on behalf of the patient's institution. The Form 12B permit issues on the CDSCO documented priority timeline, typically within one to two days for routine applications with complete documentation. End-to-end timing from physician decision to dispensed product is typically two to four weeks, with the bulk of the elapsed time in documentation assembly and international logistics rather than the regulator's stamp.

Real costs in INR and USD

The US wholesale acquisition cost for Altuviiio is set by international units. List pricing is approximately USD 0.75 to 0.95 per IU, which puts a typical adult prophylaxis weekly dose of 50 IU/kg for a 70 kg patient at approximately USD 2,600 to 3,400 per weekly dose. Annualised, severe hemophilia A prophylaxis on Altuviiio sits in a USD 135,000 to 175,000 per year range for a 70 kg adult, before logistics, documentation handling, and the Reserve Meds concierge fee. In INR at the prevailing 94 to 95 range, that translates to approximately INR 1.27 crore to 1.66 crore per year.

An Indian-made generic of efanesoctocog alfa does not exist as of this review date. The molecule is under patent protection, and biosimilar pathways for novel recombinant factor products have a long lead time. Indian-made standard half-life recombinant factor VIII is available at materially lower cost through several domestic manufacturers, and the National Health Mission underwrites factor for severe hemophilia patients in many states through district hospital and medical college supply chains. Families pursuing Altuviiio specifically are doing so because the dosing interval and trough level profile differ from anything currently registered locally. Indian Union Budget 2026-27 expanded the customs duty

exemption list for rare-disease and life-saving drugs; the specific HSN code and exemption status of an Altuviiio shipment is confirmed at the documentation stage.

Timing, what to expect

From physician decision to dispensed product, a routine Altuviiio import case runs two to four weeks. The Form 12B permit issues on the CDSCO documented one to two business day priority timeline once the application is complete. Documentation assembly, including the clinical justification letter, prescription, NMC registration verification, dispensing facility drug licence, and the chain-of-custody plan, typically takes three to five business days. US-side sourcing and cold-chain shipment is the long pole at one to two weeks depending on lane and customs handling at the port of entry. For ongoing prophylaxis, Reserve Meds aligns refill cycles to a six to eight week reorder rhythm so the family is not waiting at the end of each supply.

What your physician needs

The clinical justification letter for an Altuviiio Form 12A submission documents the patient's diagnosis (severe hemophilia A with factor VIII activity below 1%), the weight-based dose and planned dosing interval, the history of prior factor products tried and the rationale for transition to efanesoctocog alfa, and the planned monitoring schedule including inhibitor surveillance. The treating hematologist's NMC registration number and state council registration, where required, appears on the prescription. The dispensing facility's drug licence number is part of the submission package. The chain-of-custody plan from the US manufacturer or distributor to the dispensing pharmacy in India is documented. Cold-chain handling is required throughout; efanesoctocog alfa is stored refrigerated at 2 to 8 degrees Celsius with limited room-temperature stability.

Customs clearance and IOR

Customs at the port of entry (Delhi, Mumbai, Bangalore, Chennai, or Hyderabad airports for most specialty shipments) reviews the Form 12B permit, the commercial documentation, the airway bill, the cold-chain monitoring records, and the importer's drug licence. The Importer of Record on an Altuviiio shipment is the licensed dispensing facility or specialty importer holding the wholesale drug licence under the Drugs and Cosmetics Rules. Reserve Meds does not act as the IOR. We align with the licensed importer named on the Form 12B permit so the consignment clears without discrepancy. Cold-chain temperature excursions during transit are documented through the carrier's monitor; any out-of-range event is flagged at clearance and may require manufacturer disposition before dispensing.

Pharmacovigilance

India operates the Pharmacovigilance Programme of India (PvPI) coordinated by the Indian Pharmacopoeia Commission. Treating physicians are expected to report adverse events through PvPI for any imported product. For Altuviiio specifically, the post-marketing safety profile from US use is being collected through the manufacturer's pharmacovigilance system, and serious adverse events are reportable to both PvPI and the manufacturer. Inhibitor development to factor VIII is the principal long-term safety question for any factor product, and the prescribing physician's monitoring schedule is documented in the Form 12A clinical justification letter. Reserve Meds includes the PvPI reference in the physician documentation kit; the reporting obligation itself stays with the prescribing physician.

Where Reserve Meds fits

Reserve Meds is a US-based concierge coordinator. We do not replace the treating hematologist, CDSCO, the hospital pharmacy, or the licensed importer. For an Altuviiio case, our work is US-side sourcing of the originator product through authorised distribution, documentation orchestration so the Form 12A package is complete the first time, cold-chain logistics coordination from US warehouse to Indian port to dispensing pharmacy, and a single named coordinator who carries the case through the multi-week first cycle and into the ongoing refill rhythm.

Next step

If a treating hematologist in India is weighing Altuviiio for a patient with severe hemophilia A, the waitlist is the first step. We respond within 24 to 48 hours with an eligibility confirmation and a documentation kit for the physician.

Reserved for you.

Related

- Altuviiio clinical resource
- India country page
- CDSCO personal-import pathway

Sources

1. FDA approval, Altuviiio (efanesoctocog alfa), Sanofi/Sobi, BLA approval February 2023 for hemophilia A.

2. CDSCO, Procedure for Permission to Import Small Quantities of Drugs for Personal Use (Form 12A / Form 12B under Rule 36, Drugs and Cosmetics Rules 1945).
3. National Medical Commission, Indian Medical Register and registration verification framework.

Common questions Indian families ask

Will Star Health, HDFC ERGO, ICICI Lombard, or Niva Bupa cover this? Each Indian private insurer assesses named-patient imports case by case. None of the major private insurers reimburse a Rule 36 personal import as a standard line item. Some have reimbursed full or partial drug cost where the underlying medicine is on the formulary and the named-patient route operated as a stocking workaround. Reserve Meds supplies the documentation that lets your insurer evaluate. The claim itself is filed by the patient or the hospital. Cash-pay remains the default posture for Reserve Meds patient cases.

Will my CGHS or ESIC entitlement cover this? CGHS (Central Government Health Scheme) provides for life-saving and anti-cancer medicines not in the standard formulary to be considered case by case by an Expert Committee under the Special DG (DGHS) where the prescribing specialist documents the requirement. Drugs not approved by the DCGI for use in India face a stricter Expert Committee review. ESIC's formulary is narrower. Neither scheme is structured for routine personal-import reimbursement; check eligibility with your CGHS Wellness Centre or the ESIC dispensary before assuming coverage.

Will my AIIMS, Tata Memorial, Apollo, Fortis, Medanta, Kokilaben, MGM, CMC Vellore, or Manipal physician's letter be sufficient? Yes. A Registered Medical Practitioner with a valid National Medical Commission registration number can support a Form 12A application. Physicians at AIIMS, Tata Memorial Centre, government medical colleges, and state-run tertiary hospitals routinely do so. Private-sector specialists at Apollo, Fortis, Medanta, Kokilaben Dhirubhai Ambani Hospital, MGM Healthcare, CMC Vellore, and Manipal Hospitals also have signing authority subject to their institutional drug licence.

What if my treating institution does not have an import pharmacy desk? The practical route is to work with one of the named tertiary centres that handles compassionate and named-patient imports as established workflow, or with a CDSCO-licensed specialty importer in Mumbai, Delhi, or Bangalore that handles the documentation and chain-of-custody on behalf of smaller hospitals or independent specialists. Reserve Meds aligns with the importer named on the Form 12B permit.

Can I receive the drug at home, or do I need a hospital? The dispensing facility must hold a valid drug licence under the Drugs and Cosmetics Rules. For oral medicines, a hospital outpatient pharmacy or a licensed import pharmacy is the dispensing point. For infusion

products, the medicine ships to the infusion centre where the patient will receive it. Direct-to-home delivery outside a licensed dispensing facility is not the model.

What about pediatric patients? The Rule 36 framework applies the same way for pediatric patients. The clinical justification letter typically includes weight-adjusted dosing and pediatric-specific monitoring. AIIMS, Tata Memorial, Apollo, Kokilaben, and CMC Vellore handle pediatric named-patient imports routinely. Where the indication is approved in adults only, the off-label use is the physician's clinical judgement and is documented as such in the Form 12A letter.

Does FCRA affect a patient case? The Foreign Contribution (Regulation) Act 2010 (FCRA), as proposed to be amended by the Foreign Contribution (Regulation) Amendment Bill 2026, regulates foreign donations to Indian organisations and individuals. For a patient family paying for the medicine themselves, FCRA is generally not engaged. Where a foreign foundation or diaspora group is funding a treatment, FCRA registration of the recipient organisation and the donation route can become relevant; the structure should be reviewed with counsel before funds move. Reserve Meds does not provide FCRA legal advice; we flag the question so it reaches the right adviser early.

What is the role of the Indian Pharmacopoeia Commission? The Indian Pharmacopoeia Commission coordinates the Pharmacovigilance Programme of India (PvPI) and publishes the Indian Pharmacopoeia, the legal compendium of pharmaceutical standards in India. For imported originator products under Rule 36, the PvPI reporting framework applies to adverse event surveillance, and the prescribing physician is the reporting party. The Indian Pharmacopoeia is the reference standard against which Indian-manufactured products are tested; imported originator products carry their reference-country pharmacopoeial standards (typically USP for FDA-approved products).

How does this compare with access in the UAE or Saudi Arabia? India's Rule 36 framework with the published Form 12B priority timeline (one to two business days for routine documentation) is often faster than the SFDA Personal Importation Program in Saudi Arabia (typically 10 to 21 business days routine) and broadly comparable to the UAE Emirates Drug Establishment pathway. India's offsetting friction is the customs and logistics layer rather than the regulator's stamp. India's tertiary specialty hospital depth substantially exceeds any single peer country in the South Asia and GCC region, which usually offsets the longer end-to-end cycle for complex cases.

What documentation does my family need to assemble before contacting Reserve Meds? The minimum useful package is the treating physician's name and registration number, the patient's diagnosis and current treatment summary, recent relevant investigations (imaging, biopsy, molecular pathology, blood work as applicable), and a contact pathway to the dispensing facility you intend to use. With that package, Reserve Meds can complete eligibility within 24 to 48 hours and route the documentation kit to your physician.

How Indian families coordinate across cities and countries

For Indian families, the coordination problem is often distributed across multiple cities and sometimes multiple countries. A grandmother in Hyderabad, an oncologist at Tata Memorial in Mumbai, an adult child in Bangalore managing logistics, and a son in Dubai or London paying the invoice is a common configuration. The Reserve Meds single named coordinator model is built for exactly this pattern. One coordinator carries the case file, one chain of correspondence captures the decisions and documents, and one set of contact records reaches every family member who needs visibility into the case, regardless of how many cities the family touches or how many time zones the case spans. The Reserve Meds patient portal at portal.reservemeds.com holds the document set and the case timeline; the coordinator handles the email, phone, and WhatsApp follow-through that the case needs at each step.

For smaller cities where the local hospital does not maintain an import pharmacy desk, the practical route is to work with a CDSCO-licensed specialty importer in Mumbai, Delhi, Bangalore, Chennai, or Hyderabad. The importer carries the CDSCO relationship, the customs broker relationship, and the chain-of-custody documentation. Reserve Meds aligns with the importer on US-side sourcing and with the treating physician on clinical documentation. The patient sees one face throughout, which is the named coordinator.

The patient experience, step by step

From the family side, the sequence looks like this. Your physician decides this drug is the right next step. That is a clinical decision and stays with them. Your physician or the hospital pharmacy team reaches out to Reserve Meds, or the patient submits a request through the Reserve Meds portal and Reserve Meds connects with the physician. Reserve Meds confirms eligibility within 24 to 48 hours and sends a documentation kit to your physician, including the Form 12A reference, the clinical justification letter template, and the chain-of-custody plan. Your physician completes the documentation, attaches the prescription with their NMC registration number, and the application goes to CDSCO through the appropriate port office or the DCGI New Delhi office, or via the hospital's licensed importer. The Form 12B permit issues on the documented priority timeline. While the permit issues, Reserve Meds aligns US-side sourcing and the shipment plan with the dispensing pharmacy. The shipment moves cold-chain or ambient as appropriate. Customs at the destination port reviews the permit and clears the consignment. The dispensing pharmacy receives, logs, and stores the medicine according to its drug licence requirements. Your physician initiates therapy. Adverse event reporting through PvPI continues for the duration of therapy.

Review and oversight. Content on this page is reviewed by the Reserve Meds 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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