

# Wainua access in the Kingdom of Saudi Arabia

How families in the Kingdom pursue Wainua (eplontersen), AstraZeneca's ligand-conjugated antisense oligonucleotide targeting transthyretin (TTR) mRNA, through the SFDA Personal Importation Program.

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

## Quick orientation

Wainua (eplontersen) is the GalNAc-conjugated antisense oligonucleotide for hereditary transthyretin-mediated amyloidosis with polyneuropathy. It received FDA approval in December 2023 and is co-commercialized in the US under the Wainua brand by Ionis Pharmaceuticals and AstraZeneca; the underlying brand attribution in your home jurisdiction may use either name. For Saudi Arabia patients with confirmed hATTR-PN whose treating physician has recommended eplontersen, this page describes the SFDA Personal Importation Program pathway. The user-supplied spelling 'Wainzua' is noted here; the FDA-approved spelling is Wainua.

## Why this drug is hard to source in Saudi Arabia

Hereditary transthyretin amyloidosis is a rare autosomal dominant disease, and the KSA patient population, while increasingly identified through expanding genomic and cardiology amyloid programs, remains small. Wainua is a 2023-approved therapy, and SFDA registration uptake is at an early stage. The therapy class also includes patisiran (Onpattro), vutrisiran (Amvuttra), and inotersen (Tegsedi), each at different stages of regional availability. The access gap is structural: a small patient population, a recent approval, and a competitive therapy class together mean a patient identified through KSA's amyloid programs often needs patient-specific import. The PIP route is the lawful path.

## **The SFDA Patient Import Permit (PIP) pathway applied to Wainua**

The Saudi Food and Drug Authority's Personal Importation Program is the federal pathway that allows an SCFHS-licensed physician to import a specific medicine for a specific named patient when the medicine is approved by a recognized reference authority (typically the US FDA, EMA, MHRA, PMDA Japan, or Health Canada) and a clinically equivalent locally registered alternative is not suitable. Wainua (eplontersen) holds FDA approval since 2023 for polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR-PN) in adults, which places it squarely within the framework's scope.

The application is filed through the dispensing institution's import pharmacy (or, where the institution does not hold internal import-pharmacy capability, through an SFDA-licensed specialty importer in Riyadh or Jeddah). The standard package contains the clinical justification letter from the treating physician, the SCFHS license verification, the anonymized patient identifier, the full product details for Wainua including 45 mg per 0.8 mL subcutaneous auto-injector, once monthly, with cold-chain handling at 2 to 8 degrees Celsius documented in the file, the destination dispensing facility license, and the chain-of-custody plan from the US point of release through international transit to the receiving Saudi pharmacy. The SFDA portal at [sfda.gov.sa](https://sfda.gov.sa) handles regulatory transactions, and named-patient activity increasingly routes through the agency's Ghad digital platform.

## **Where Wainua gets dispensed in the Kingdom**

The major Saudi institutions that handle named-patient imports as established workflow include King Faisal Specialist Hospital and Research Centre (KFSH&RC) with operations in Riyadh, Jeddah, and Madinah; King Abdulaziz Medical City (KAMC) and the Ministry of National Guard Health Affairs network; King Saud University Medical City and the academic medical centers; King Khalid University Hospital; Dr. Sulaiman Al Habib Medical Group (HMG) across multiple Riyadh, Jeddah, and Eastern Province facilities; the Saudi German Hospital network; Dr. Soliman Fakeeh Hospital in Jeddah; and Dallah Hospital in Riyadh. Smaller hospitals typically route their named-patient cases through one of these centers or through an SFDA-licensed specialty importer. For a Wainua case, the dispensing facility is selected on the basis of where the treating physician practices and where the patient receives ongoing care; Reserve Meds does not select the dispensing facility on the family's behalf.

## **Real costs in SAR and USD**

The US wholesale acquisition cost for Wainua is approximately USD 38,000 to USD 40,000 per 45 mg auto-injector. Monthly dosing produces a monthly drug cost of approximately

USD 38,000 to USD 40,000 (roughly SAR 142,000 to SAR 150,000). Cold-chain logistics for a refrigerated biologic add approximately SAR 3,000 to SAR 5,600 per shipment. The treatment is chronic, the cost structure is high, and ongoing payer engagement is central. Bupa Arabia and Tawuniya rare-disease benefits handle hATTR therapies case by case.

Reserve Meds quotes an indicative range based on the initial intake and then a transparent firm quote with each line item shown separately. The Reserve Meds concierge fee is published on a tiered schedule and is shown as a separate line. Nothing is bundled. Nothing is hidden.

## **Timing, what to expect**

The SFDA Personal Importation Program processes routine cases (recognized reference-authority drug, well-documented indication, established institution) in approximately 10 to 20 business days. Complex cases (novel mechanism, off-label use within the FDA label scope, ultra-rare patient population, first-time importer) can extend to 6 to 8 weeks. SFDA does not publish guaranteed turnaround times, so case-by-case planning is the norm. In parallel with the SFDA review, Reserve Meds aligns the US-side sourcing, the packaging and cold-chain validation, and the shipment plan, so the drug is ready to move on the day approval comes through. The patient experience runs through ten well-defined steps from initial physician decision through reorder coordination; the full ten-step sequence is documented in the Saudi Arabia country module and in our patient-facing operations brief.

## **What your physician needs to provide**

The treating physician's clinical justification letter typically documents the confirmed hATTR-PN diagnosis (TTR gene mutation report attached, since the indication is genotype-defined; neurology evaluation with peripheral neuropathy scoring; cardiac evaluation including echocardiogram, cardiac MRI or PYP scan where indicated; baseline serum TTR), prior therapy if any, the rationale for antisense oligonucleotide therapy versus siRNA (patisiran, vutrisiran) or stabilizer (tafamidis) approaches, and the proposed once-monthly dosing. The SCFHS registration in neurology, cardiology, or internal medicine with rare-disease practice scope accompanies the letter. Mandatory baseline vitamin A status documentation (since TTR suppression reduces serum vitamin A) and the planned vitamin A supplementation are included.

The dispensing facility's SFDA-licensed pharmacy completes the submission and accepts the chain-of-custody documentation. The institutional license is what authorizes the dispensing pharmacy to receive the imported drug, so the physician's individual SCFHS license is necessary but not sufficient on its own. Post-import pharmacovigilance commitment to report adverse events through the SFDA National Pharmacovigilance

Center is part of the application and runs through the full course of therapy, not just the initial dose.

## **Vision 2030 and the specialty-access environment**

Saudi Vision 2030's Health Sector Transformation Program (HSTP) is the operating frame for healthcare reform in the Kingdom. HSTP is restructuring the Ministry of Health from a provider-and-regulator into a regulator and strategist, with clinical delivery devolving into regional Health Clusters and Centers of Excellence. The program names tertiary cancer care, rare-disease care, organ transplantation, genomics, and digital health as priority verticals, all of which are heavy users of specialty drugs not registered locally. The practical effect on the PIP framework is twofold. HSTP is expanding the universe of specialty drugs that get formal SFDA registration, which closes some access gaps. At the same time, HSTP is increasing diagnostic capacity in rare disease and oncology genomics, which surfaces new patients who need drugs that are FDA-approved but not yet registered in the Kingdom. The named-patient framework remains essential for the foreseeable future. Saudization (the Nitaqat workforce-nationalization program) does not change the PIP framework, but confirming the prescriber's SCFHS license status before filing is good practice in any case where the treating physician is in a renewal window.

## **Pharmacovigilance and cold-chain considerations**

Wainua carries warnings for reduced serum vitamin A (TTR is the principal carrier of retinol) and ophthalmologic complications related to vitamin A deficiency. The SFDA pharmacovigilance commitment includes baseline and periodic vitamin A monitoring, the documented vitamin A supplementation regimen, ophthalmologic referral for any visual symptom, and any serious adverse event reporting. Cold-chain at 2 to 8 degrees Celsius is required.

Reserve Meds' physician documentation kit includes the SFDA adverse-event reporting reference so the treating physician has the framework on hand from day one. Reserve Meds does not file adverse-event reports; that responsibility sits with the SCFHS-licensed treating physician. The dispensing facility carries the chain-of-custody and storage obligations through the dispensing event, and off-label transfer of the imported supply to another patient is not permitted under the PIP framework.

## **Common questions about Wainua in the Kingdom**

**Will Bupa Arabia, Tawuniya, or MedGulf cover this?** Each insurer handles named-patient imports case by case under the Council of Cooperative Health Insurance (CCHI) framework. Some plans reimburse fully when the medicine appears on the insurer's formulary even

where the local hospital pharmacy does not stock it. Others reimburse a percentage. Many require pre-authorization with the clinical justification letter attached. Reserve Meds supplies the documentation that lets the insurer assess the case; the claim is yours or your hospital's to file. Cash-pay is the default operating posture for cross-border access, with reimbursement sought after delivery where your plan permits.

**Will my Ministry of Health-employed physician's letter be sufficient if SFDA flags the case?** Yes. KSA-licensed physicians at Ministry of Health hospitals, KFSH&RC, KAMC, MNGHA, KSUMC, and other public-sector institutions have full signing authority on PIP applications under their SCFHS license. The clinical justification letter is the cornerstone of the package. Private-sector physicians at HMG, Saudi German, Fakeeh, Dallah, and similar institutions also have signing authority under their institutional license.

**Can I receive the drug at home, or do I need a hospital?** The dispensing facility must be a locally licensed pharmacy. For oral medicines, a hospital outpatient pharmacy or specialized SFDA-licensed import pharmacy dispenses to the patient. For infusion or injection products, the medicine ships to the infusion center where you will receive it. Direct-to-home delivery without a licensed dispensing facility in the chain is not the operating model.

**What about pediatric patients?** The PIP framework applies to pediatric patients the same way it applies to adults. The clinical justification letter typically includes weight-based dosing, pediatric-specific monitoring, and where relevant the involvement of the pediatric specialty center. KFSH&RC, KAMC, and the major HMG facilities have established pediatric specialty programs that handle named-patient imports routinely.

**How does Saudization (Nitaqat) affect my case?** Saudization is the workforce-nationalization program that shapes hospital staffing composition. It does not change the PIP framework. It can occasionally affect timing if a non-Saudi treating physician's license is in renewal at the moment the PIP file is being prepared. Confirming the prescriber's SCFHS license status before filing is good practice.

**Is Wainua a controlled substance?** No. Wainua is not a US DEA scheduled substance. The Saudi narcotics-section approvals do not apply. The chain-of-custody documentation, the dispensing facility's pharmaceutical establishment license, and the SFDA pharmacovigilance commitment do apply.

## **Where Reserve Meds fits in Wainua cases**

Reserve Meds is a US-based concierge coordinator. We do not replace your treating physician, the SFDA, the dispensing pharmacy, or the institutional import-pharmacy team. For a Wainua case in the Kingdom, our work is to orchestrate the US-side sourcing, prepare the regulatory documentation kit your physician needs, coordinate international logistics with cold-chain validation where required, and assign a single named coordinator who stays

with the case through reorders. The clinical decisions remain with the treating physician. The regulatory authority remains SFDA. The dispensing remains with the licensed Saudi pharmacy. Reserve Meds is the connective tissue between the US supply side and those three Saudi pillars. Reserved for you.

## Next step

If a treating physician in the Kingdom is weighing Wainua for a patient, 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

- Wainua clinical resource
- Wainua in the United Arab Emirates
- Wainua in Qatar
- Wainua in Kuwait
- Kingdom of Saudi Arabia country page

## Sources

1. FDA approval, Wainua (eplontersen), approximately Ionis Pharmaceuticals and AstraZeneca (Wainua is co-commercialized; the brand is marketed as Wainua in the United States), initial FDA approval 2023.
2. Saudi Food and Drug Authority (SFDA), Personal Importation Program framework, <https://www.sfda.gov.sa/en>, and the Ghad digital regulatory platform at <https://ghad.sfda.gov.sa/>.
3. Saudi Vision 2030, Health Sector Transformation Program, <https://www.vision2030.gov.sa/en/explore/programs/health-sector-transformation-program>.
4. Saudi Commission for Health Specialties (SCFHS), <https://scfhs.org.sa/en>, for treating-physician licensing and the institutional pharmacy framework.

**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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