## Wainua

Saudi Arabia · access guide

# How to access Wainua from Saudi Arabia, the named-patient import pathway, 2026

*By Reserve Meds · Clinical & regulatory team · Last reviewed 2026-04-23*

A Saudi Arabia patient diagnosed with hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy may receive a prescription for Wainua (eplontersen) from their treating neurologist, often in coordination with a multidisciplinary amyloid service in Abu Dhabi, Dubai, or Sharjah. Wainua is FDA-approved for this indication and is developed by Ionis and Sobi. It is a newer-generation ligand-conjugated antisense oligonucleotide (ASO) designed to improve on the earlier ASO generation. Wainua is not routinely stocked through Saudi Arabia domestic supply chain for this indication, so access typically runs through the named-patient import pathway.

This guide explains the legal pathway, the documentation your neurologist prepares, typical timing, indicative cost posture, and where Reserve Meds fits in.

## The clinical situation

Wainua is a subcutaneous ligand-conjugated antisense oligonucleotide that silences hepatic TTR production. It is self-administered (or caregiver-administered) monthly by subcutaneous auto-injector after in-clinic training, a meaningful step up in convenience relative to weekly injections, and without the REMS-level platelet monitoring programme of the earlier ASO generation. Routine labs still matter (vitamin A supplementation, periodic platelet and renal panels), but the monitoring cadence is closer to other monthly specialty injectables. Eligibility requires genetic confirmation of a pathogenic TTR variant, symptomatic polyneuropathy, and a cardiac workup to characterise any ATTR-CM overlap. Your neurologist will establish baseline NIS+7, polyneuropathy disability score, and baseline labs.

## Is Wainua legally importable into Saudi Arabia?

Yes, through the Saudi Food and Drug Authority (SFDA) named-patient import framework, with parallel authority operated by the Department of Health (DoH) in Abu Dhabi and the Dubai Health Authority (DHA) in Dubai depending on where the prescribing facility sits.

The named-patient mechanism permits a Saudi Arabia-licensed physician to import a medicine not locally registered when (a) it is approved by a recognised reference authority such as the US FDA, (b) no clinically equivalent locally available alternative suits the specific patient, (c) the physician accepts clinical responsibility, and (d) chain of custody is documented end-to-end.

## How the pathway works, step by step

1. **Consultation with your treating neurologist.** TTR genetic report, neuropathy scoring, and a clinical rationale letter.
2. **Baseline assessment.** NIS+7, polyneuropathy disability score, cardiac workup (ECG, echocardiogram, NT-proBNP), platelet / renal / liver panels, vitamin A level.
3. **SFDA named-patient application.** The physician or hospital pharmacy files clinical rationale, monitoring plan, patient reference, and chain-of-custody commitment.
4. **US-side sourcing.** Reserve Meds coordinates with our US-licensed specialty wholesale partner to secure Wainua from authorised distribution under DSCSA.
5. **Cold-chain shipment.** Wainua requires refrigerated handling; shipment follows validated cold-chain protocols with temperature logging.
6. **Arrival, dispensing, and auto-injector training.** The hospital pharmacy releases product; the neurology clinic provides self-injection training and sets the monthly schedule.

## What documentation your physician needs

- Clinical rationale letter confirming hATTR polyneuropathy and Wainua as the indicated therapy
- Verification of Saudi Arabia medical license
- TTR genetic test result
- Baseline NIS+7 and polyneuropathy disability score
- Cardiac assessment for ATTR-CM overlap
- Baseline platelet count, renal function, liver panel, vitamin A level
- Planned dosing schedule (monthly SC auto-injector) and vitamin A supplementation plan

Reserve Meds provides a physician documentation kit bundling the templates SFDA reviewers expect for rare-disease neurology named-patient imports.

## Costs and timing

Wainua for hATTR polyneuropathy is a substantial rare-disease therapy. Reference US cash-pay for a full annual course (monthly subcutaneous auto-injector) typically sits in the high six-figure USD range. Reserve Meds operates on a drug-only reference basis and provides a transparent, itemised delivered quote, covering product, cold-chain logistics, SFDA documentation handling, customs clearance, and concierge coordination, at the start of intake. Figures are indicative, not a binding quote until intake is complete.

Indicative timing for first dispense after cohort intake opens is 7-14 days from the moment a complete SFDA application is submitted. Monthly refill cadence is established with the hospital pharmacy thereafter.

*Fulfillment availability is limited to our first cohort, and all timelines published on this site are indicative. If your clinical situation is time-sensitive, tell us at intake. We triage accordingly.*

## Reserve Meds's role

- **Sourcing.** Through our US-licensed specialty wholesale partner under DSCSA chain-of-custody.
- **Documentation.** Regulatory package for your physician and SFDA / DoH / DHA review.
- **Logistics.** Validated cold-chain shipment to your prescribing hospital pharmacy.
- **Concierge case lead.** A named point of contact coordinating long-term monthly refills.

**What we do not do:** We are not the prescriber. We do not practise medicine. We are not the dispensing pharmacy. All clinical decisions remain with your treating neurologist.

## Frequently asked

**Is this legal in Saudi Arabia?** Yes, when executed through the SFDA / DoH / DHA named-patient framework with appropriate documentation. See our trust and compliance page.

**How is Wainua different from Tegsedi?** Both are subcutaneous ASOs that silence hepatic TTR, but Wainua is ligand-conjugated, dosed monthly via auto-injector, and carries a cleaner monitoring profile than the weekly-dosed Tegsedi, which operates under a REMS programme for thrombocytopenia and glomerulonephritis. Many clinicians and families prefer Wainua's monthly cadence when both options are available.

**How is Wainua different from Amvuttra?** Both are monthly-to-quarterly subcutaneous therapies for hATTR polyneuropathy, but they act via different mechanisms, Wainua is an antisense oligonucleotide; Amvuttra is an siRNA. Your neurologist will select based on the clinical picture and product availability.

**Will insurance cover this?** Cash-pay is the default. Some Saudi Arabia private insurers consider rare-disease imports case by case; we supply documentation for your submission but do not process insurance claims directly.


### *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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