Amvuttra

Saudi Arabia · access guide

How to access Amvuttra for hereditary TTR amyloidosis from Saudi Arabia: 2026 pathway via Saudi neurology, cardiology, and pharmacy supply

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

Saudi Arabia operates one of the deepest specialty-medicine and rare-disease ecosystems in the Gulf. King Faisal Specialist Hospital and Research Centre (KFSHRC) in Riyadh runs a substantial cardiology amyloid programme with cardiac amyloid imaging and a multidisciplinary review pathway; the KFSHRC Jeddah branch carries the same model on the western coast. King Abdulaziz Medical City (KAMC) Riyadh and Jeddah, Prince Sultan Cardiac Centre (PSCC) Riyadh, King Fahd Medical City (KFMC) Riyadh, King Fahd Specialist Hospital Dammam, IMC Jeddah, and the Dr Sulaiman Al-Habib Medical Group all carry the neurology and cardiology services needed to diagnose and manage hereditary transthyretin-mediated amyloidosis (hATTR) in adults. Amvuttra (vutrisiran) is Alnylam Pharmaceuticals' GalNAc-conjugated small interfering RNA (siRNA) therapy for hATTR with polyneuropathy and, since the March 2025 label expansion, for ATTR cardiomyopathy in both hereditary and wild-type forms. For a Saudi-resident adult with confirmed TTR amyloidosis, the operational question is which TTR-targeted agent fits, where the prescribing amyloid clinic conversation happens, how the quarterly subcutaneous injection routine works, how the genetic-testing and family-screening dimensions are handled, and how the MoH and CCHI coverage conversation runs at the rare-disease price point.

This page explains the 2026 pathway for a Saudi-resident patient: who qualifies, where the prescribing neurologist and cardiologist conversation happens, how Amvuttra is dispensed and stored, what the quarterly dosing schedule looks like, what the realistic out-of-pocket exposure band is in SAR at the rare-disease price point, the mandatory vitamin A supplementation that goes with the siRNA mechanism, and how the multi-year treatment course fits into a Saudi patient's life.

Why Amvuttra, and why now

Amvuttra is vutrisiran, a 21-nucleotide double-stranded small interfering RNA conjugated to N-acetylgalactosamine (GalNAc). The GalNAc ligand is recognised by the asialoglycoprotein receptor on hepatocytes, which gives Amvuttra hepatic selectivity. Inside the hepatocyte the siRNA is loaded into the RNA-induced silencing complex (RISC) and cleaves TTR mRNA, sustained over months. Serum transthyretin falls by typically more than 80 percent, which over time slows or partially reverses peripheral nerve and cardiac amyloid deposition.

FDA approved June 2022 for hATTR-PN (HELIOS-A trial); FDA expanded to ATTR-CM March 2025 (HELIOS-B trial). The MENA registration runway for the hATTR-PN indication has been longer than for the March 2025 ATTR-CM expansion; the SFDA label status for the cardiomyopathy indication should be `[VERIFY: ...]` at intake for any ATTR-CM case.

For a Saudi patient with progressive sensorimotor polyneuropathy attributed to a confirmed TTR mutation, or with ATTR cardiomyopathy confirmed by 99m-Tc-PYP scintigraphy and AL exclusion, Amvuttra is the operational pathway to a disease-modifying therapy that is administered four times per year. The quarterly cadence is a meaningful operational simplification compared with Onpattro (patisiran IV every 3 weeks), Tegsedi (inotersen SC weekly), and Wainua (eplontersen SC monthly).

What Amvuttra is, in plain language

Amvuttra is a subcutaneous injection given once every 3 months. No infusion centre, no inpatient stay, no IV access. The dose is 25 mg as a single prefilled syringe. Administration is at the prescribing amyloid clinic or, after training, at home.

Standard adult dose: 25 mg SC every 3 months. Injection sites: abdomen, thigh, or upper outer arm; rotate between quarterly doses.

Storage: 2 to 8 degrees Celsius. Before injection, room temperature for 30 minutes. Do not freeze; do not shake.

Treatment is indefinite, for as long as Amvuttra provides clinical benefit and is tolerated. Response assessed by serum TTR reduction (>80 percent target engagement), neurology scoring (mNIS+7, Norfolk QoL-DN) for hATTR-PN, and cardiology scoring (NT-proBNP, 6-minute walk, echo strain) for ATTR-CM.

Mandatory vitamin A supplementation accompanies Amvuttra. The siRNA mechanism reduces hepatic retinol binding protein 4 along with TTR, which reduces vitamin A transport. All patients take oral vitamin A at the recommended daily allowance (approximately 2,500 to 3,000 IU/day for adults) for the duration of treatment. This is mandatory and lifelong.

Eligibility at a Saudi amyloid clinic

1. **Confirmed TTR amyloidosis**. For polyneuropathy: TTR gene sequencing confirming a pathogenic variant, plus clinical features of progressive sensorimotor and/or autonomic neuropathy, plus where indicated tissue biopsy with Congo red staining and amyloid typing. For cardiomyopathy: TTR sequencing (for hereditary form) or non-biopsy diagnosis using 99m-Tc-PYP scintigraphy with grade 2 or 3 myocardial uptake, plus exclusion of AL amyloidosis. Equivocal cases proceed to endomyocardial biopsy with amyloid typing. 2. **AL amyloidosis exclusion**. Serum free light chains, serum and urine immunofixation electrophoresis. Required because Amvuttra targets TTR mRNA only. 3. **Genetic counselling** for confirmed hereditary forms. First-degree relatives should be offered TTR sequencing and clinical surveillance. 4. **Baseline neurology assessment** (for hATTR-PN cases): mNIS+7, Norfolk QoL-DN, 10-metre walk test, modified Body Mass Index, autonomic testing where indicated. 5. **Baseline cardiology assessment** (for ATTR-CM cases or hATTR-PN with cardiac involvement): NT-proBNP, troponin, echocardiogram with strain imaging, cardiac MRI where available, 99m-Tc-PYP scintigraphy. 6. **Treatment-naive vs switching status**. Switching from Onpattro (patisiran), Tegsedi (inotersen), Wainua (eplontersen), tafamidis (Vyndaqel/Vyndamax), or acoramidis (Attruby). Switch managed by the treating amyloid clinic. 7. **Vitamin A baseline and supplementation plan**. Baseline serum vitamin A, ophthalmology referral if symptoms or risk factors. Supplementation at RDA started at or before first dose, lifelong. 8. **Pregnancy planning** for women of childbearing potential. Effective contraception during treatment. 9. **Renal and hepatic function review**. Standard baseline labs.

A Saudi patient should arrive at the amyloid clinic with available diagnostic documentation: prior neurology or cardiology workup, nerve conduction studies, echo and cardiac imaging reports, any prior amyloid biopsy, family history (multi-generational sensorimotor neuropathy or unexplained cardiomyopathy), and current medications.

The Saudi prescribing and supply picture, plainly

Amvuttra availability in Saudi Arabia depends on SFDA registration status at the point of prescription and indication. Alnylam's MENA commercial footprint runs through specialty distributor partners. The pathway is:

1. **Prescribing neurologist with amyloidosis experience and/or cardiologist with amyloidosis experience**. Dual-specialty drug. The Saudi centres with established amyloid programmes include KFSHRC Riyadh (deep cardiology amyloid centre with PYP scintigraphy and multidisciplinary amyloid clinic), KFSHRC Jeddah, KAMC Riyadh and Jeddah, Prince Sultan Cardiac Centre Riyadh, KFMC Riyadh, King Fahd Specialist Hospital Dammam, IMC Jeddah, and the Dr Sulaiman Al-Habib Medical Group network. Public-sector amyloid pathways for Saudi nationals run through KFSHRC, KAMC, and KFMC. 2. **Genetic testing infrastructure**. KFSHRC, KAMC, and KFMC run in-house molecular labs that handle TTR sequencing directly. Turnaround is typically 4 to 8 weeks. Smaller centres send samples to KFSHRC or to Centogene/Invitae partners. 3. **Cardiac amyloid imaging**. 99m-Tc-PYP scintigraphy is available at KFSHRC, KAMC, Prince Sultan Cardiac Centre, KFMC, and the major Saudi tertiary nuclear medicine centres. Cardiac MRI is widely available across Saudi tertiary centres. 4. **Pharmacy dispensing**. Specialty pharmacy at the prescribing tertiary centre, cold-chain refrigeration. Quarterly cadence makes stocking straightforward. Named-patient pathway available for documented physician-initiated prescriptions referencing FDA or EMA approved indications where SFDA registration has not yet caught up. 5. **MoH and CCHI coverage**. For Saudi nationals: MoH rare-disease orphan-therapy programmes typically cover Amvuttra on a documented case-by-case basis through KFSHRC, KAMC, or KFMC. The Council of Cooperative Health Insurance (CCHI) frames the commercial-insurance landscape; major commercial insurers (Tawuniya, Bupa Arabia, MedGulf, AXA Cooperative) handle commercial cover with documented medical necessity and prior-authorisation. 6. **Self-injection training**. Single supervised session at the prescribing amyloid clinic, or an Alnylam patient-support nurse educator visit. Many Saudi patients prefer the quarterly clinic visit to home self-administration; the cadence is forgiving and the clinic visit doubles as clinical follow-up. 7. **Ongoing monitoring**. Amyloid clinic follow-up at 6 months and 12 months, then annually for stable patients. Serum TTR level at intervals. Vitamin A serum level and ophthalmology assessment if deficiency symptoms develop.

The 2026 pathway, step by step

Week 0 to 4: Diagnostic confirmation. Documentation pack with the treating amyloid clinic. TTR sequencing (if not already done), AL exclusion labs, baseline neurology or cardiology scoring, baseline PYP scintigraphy or other cardiac imaging as appropriate. Family history documentation.

Week 4 to 8: MoH or CCHI coverage conversation in parallel with the diagnostic workup. For Saudi nationals: MoH rare-disease orphan-therapy pathway through KFSHRC, KAMC, or KFMC case-management. For commercial-insurance patients: pre-authorisation with documented medical necessity.

Week 8 to 12: First dose dispensing and administration at the prescribing amyloid clinic. Vitamin A supplementation started. Self-injection training if home administration is preferred.

Month 3: Second quarterly dose. Reserve Meds coordinates supply logistics for cold-chain delivery if the patient is self-administering at home.

Month 6 to 12: Response assessment at the amyloid clinic. Serum TTR reduction confirmed. Neurology scoring or cardiology scoring compared to baseline. Vitamin A serum level reviewed.

Month 12 onwards: Maintenance quarterly dosing. Annual amyloid clinic review. Family-screening conversation continues over time.

Cost expectation in SAR

US list price (WAC) for Amvuttra is approximately USD 463,500 per year (USD 116,000 per quarterly dose). MENA pricing varies. Saudi-channel cash-pay retail commonly sits in the range of USD 350,000 to 480,000 per year for rare-disease orphan therapy.

At 2026 indicative cross rates, the SAR-equivalent annual cost band is approximately SAR 1,310,000 to 1,800,000 at cash-pay retail. For Saudi nationals, MoH rare-disease orphan-therapy coverage typically covers Amvuttra on a case-by-case basis through the major tertiary centres; the financial pre-authorisation conversation needs to start before the first dispensing. CCHI-regulated commercial covers vary; the prescribing amyloid clinic's case-management team is the gating step.

For non-Saudi residents whose employer plan or commercial cover does not extend to rare-disease orphan therapy, the cash-pay exposure is the full annual band. Reserve Meds surfaces this reality early. Cross-border named-patient supply adds modest overhead.

What to monitor

Vitamin A deficiency. The siRNA mechanism reduces vitamin A transport. Oral vitamin A supplementation at RDA (approximately 2,500 to 3,000 IU/day for adults) for the duration of treatment is mandatory. Deficiency manifests slowly as night vision difficulty, dry eyes, or in extreme cases corneal changes. Ophthalmology assessment with serum vitamin A measurement for any ocular symptoms during treatment.

Injection-site reactions (redness, swelling, mild pain) are common and typically resolve with site rotation.

Limb pain and arthralgia reported in pivotal trials at modestly higher rates than placebo. Most cases mild to moderate.

Falls reported, particularly in patients with autonomic involvement from polyneuropathy. Fall prevention counselling is standard amyloid clinic follow-up.

Pregnancy. No human data. Animal data suggest teratogenicity from vitamin A depletion. Effective contraception during treatment required for women of childbearing potential.

No specific cardiac, hepatic, or renal toxicity from the siRNA mechanism. Favourable adverse-event profile compared with antisense oligonucleotide alternatives.

Religious, ethical, and family-logistics framing

Amvuttra is a synthetic chemical: a chemically modified short double-stranded RNA conjugated to a sugar ligand (GalNAc). No human or animal source material, no donor element, no foreign cells, no viral vector. Halal-compatible and kosher-compatible by general consensus on synthetic RNA therapeutics. The classical analogy is to other synthetic injectable drugs rather than to vaccines or biologics. Written halal-certification documentation of the specific commercial product can be requested through Alnylam at intake if the family requires it.

The quarterly cadence is a major operational and family-logistics advantage. Travel, work, multi-generational family commitments, Hajj and Umrah, Ramadan, and the rhythm of Saudi life accommodate a four-times-a-year clinic visit far more easily than weekly or monthly self-injection. The case-management conversation often hinges on this practical reality.

The genetic dimension is the more sensitive cultural conversation. Hereditary TTR amyloidosis is autosomal dominant with variable penetrance. A confirmed case in a Saudi family carries implications for first-degree relatives who may be presymptomatic. The page does not push specific family-disclosure decisions; the treating amyloid clinic's genetic counselling service is the right home for that conversation. Reserve Meds supports coordinating sibling and adult-child genetic testing where the family decides to pursue it. Saudi populations carry multiple TTR variants; the variant influences phenotype and family-screening priorities.

Vitamin A supplementation deserves a separate practical note. Patients who would not realistically take a daily oral supplement for years should discuss this frankly with the amyloid clinic at initiation. The supplementation is mandatory and lifelong; treatment without it is not the right course.

When Amvuttra is not the right call

For a Saudi patient whose amyloidosis is AL rather than TTR, Amvuttra has no role. AL amyloidosis is treated under haematology care.

For a patient with confirmed TTR amyloidosis whose phenotype is milder cardiomyopathy without progressive polyneuropathy, where the operational simplicity of an oral once-daily therapy outweighs deeper TTR suppression, tafamidis (Vyndaqel for hATTR-PN, Vyndamax for ATTR-CM) or acoramidis (Attruby for ATTR-CM) is the appropriate alternative.

For a patient who cannot or will not comply with mandatory vitamin A supplementation, Amvuttra is not the appropriate choice; tafamidis or acoramidis are operationally simpler and do not carry the vitamin A obligation.

For a pregnant patient or a woman planning pregnancy in the near term, Amvuttra is contraindicated until the pregnancy and lactation course is complete; the amyloid clinic manages discontinuation and re-initiation timing.

For a patient on Onpattro, Tegsedi, or Wainua who is doing well, the switch decision is individualised; Amvuttra's quarterly cadence is the operational draw, but the clinical evidence for switching versus staying on the current agent is patient-specific.

Reserve Meds does not push a default. The page above describes the Amvuttra pathway because Amvuttra is the therapy the patient has asked about.

What Reserve Meds does on this case

We are a US-based concierge coordinator. We are not the prescriber and not the dispensing pharmacy. On a Saudi Amvuttra case we build the documentation pack with the treating amyloid clinic, confirm SFDA registration status for the specific indication (hATTR-PN or ATTR-CM), run the MoH or CCHI pre-authorisation conversation alongside the clinical pre-authorisation conversation, coordinate the cold-chain supply logistics for ongoing quarterly dispensing, support family-screening genetic-counselling coordination where the family chooses to pursue it, organise self-injection training if the patient prefers home administration, and stay with the case through the first year of dosing with handoff to the local amyloid clinic for ongoing surveillance. Clinical decisions remain with your treating neurologist and cardiologist.

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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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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