

Amvuttra

Pakistan · access guide

Amvuttra access in Pakistan: the DRAP named-patient pathway

Last reviewed 2026-05-16 by Reserve Meds clinical and regulatory team.

Quick orientation

Amvuttra (vutrisiran) is a subcutaneous siRNA targeting transthyretin developed by Alnylam Pharmaceuticals. It is approved by the US FDA for hereditary transthyretin-mediated amyloidosis (hATTR) polyneuropathy, wild-type or hereditary ATTR cardiomyopathy (HELIOS-B). The standard regimen is 25 mg subcutaneous every 3 months. Amvuttra is available in the global pharmaceutical supply chain in 25 mg per 0.5 mL prefilled syringe. The drug may or may not be locally registered in Pakistan, and even when registered, a Pakistan family asking for Amvuttra is often asking for a precise version of it (specific indication, specific presentation, specific schedule) that the local market has not caught up to. Reserve Meds coordinates the US-side sourcing, the validated cold-chain logistics, and the documentation packet your physician needs.

Why Pakistan patients need Amvuttra through the named-patient pathway

The Drug Regulatory Authority of Pakistan (DRAP), established under the DRAP Act 2012 and operating alongside the Drugs Act 1976, administers personal-import permissions for unregistered medicines. A treating physician licensed by the Pakistan Medical Commission applies for the import permission through DRAP when the medicine is approved by a recognised reference regulator (US FDA, EMA, MHRA, PMDA, or Health Canada) and a clinically equivalent locally registered alternative is not available.

Several patterns drive these cases: indication lag against the FDA label; specialty biologic and oncology cases where DRAP-registered local stock is constrained; payer denials by private insurers; and Pakistani families using cross-border supply for the precise FDA-labeled originator product or for indications the local route has not caught up to. For Amvuttra specifically, the named-patient pathway exists to handle exactly the situations the local registered route cannot: a newer FDA indication that has not yet propagated to Pakistan labeling, a presentation or strength the local agent does not reliably carry, a payer denial that is uneconomic to appeal, or a biomarker-defined regimen where the prescriber's clinical judgement runs ahead of the local label's molecular language. In each pattern, the named-patient pathway is the mechanism that connects a Pakistan-licensed physician's clinical decision with US-sourced, FDA-labeled Amvuttra for a specific patient.

Amvuttra (FDA June 2022 for hATTR polyneuropathy) and the cardiomyopathy expansion via HELIOS-B reshaped the ATTR amyloidosis landscape in 2025. Local registration of the originator vutrisiran lags the data, and many patients pursue cross-border supply for the FDA-labeled subcutaneous every-three-months regimen rather than the alternatives.

The DRAP named-patient pathway for Amvuttra

A complete application typically includes a clinical justification letter from the treating physician (diagnosis, severity or stage, prior therapies, biomarker results where relevant, why Amvuttra is appropriate, why the locally available alternative is not suitable for this case); the treating physician's Pakistan license verification (issued by Pakistan Medical Commission (PMC)); an anonymised patient identifier where the regulator submission allows; full product details (brand name Amvuttra, generic vutrisiran, manufacturer Alnylam Pharmaceuticals, strength 25 mg per 0.5 mL prefilled syringe, quantity requested calibrated to the planned cycles or treatment duration); the destination dispensing facility name, license number, and pharmacy in charge; and a chain-of-custody plan describing how the medicine will move from the US manufacturer through the importer to the dispensing pharmacy, including cold-chain handling at 2 to 8 degrees Celsius from the US manufacturer through to the dispensing pharmacy.

For Amvuttra, the clinical justification typically rests on documentation of TTR gene sequencing for hereditary form; cardiac PYP scan, technetium scan, biopsy with mass spec typing for ATTR where applicable, line of therapy and prior treatments, and a clear statement of why this medicine is the appropriate next step in this patient's care.

Approval timelines for routine cases are typically 15 to 30 business days from a complete filing. Complex cases (rare indication, paediatric application, larger multi-cycle quantities, gene therapy or cell therapy logistics, first-import scrutiny on a presentation new to the local route) can extend to 5 to 8 weeks. The DRAP retains discretion on timing, and we do not promise specific durations.

Where Amvuttra gets dispensed in Pakistan

A small group of Pakistan institutions handle named-patient imports as established workflow, with in-house import pharmacy infrastructure and physicians experienced with the application set. Tertiary and major private hospitals that fit this profile include Shaukat Khanum Memorial Cancer Hospital and Research Centre in Lahore (cancer referral), Aga Khan University Hospital in Karachi (JCI-accredited tertiary referral), Liaquat National Hospital in Karachi, Hashmanis Hospital, South City Hospital, The Indus Hospital network, Doctors Hospital Lahore, Hameed Latif Hospital, Pakistan Kidney and Liver Institute in Lahore, Shifa International Hospital in Islamabad, Maroof International Hospital, and Quaid-e-Azam International Hospital.

For physicians at smaller hospitals without internal import infrastructure, the common pattern is to route through a Karachi, Lahore, and Islamabad-based specialty importer that holds a pharmaceutical establishment license and files the DRAP application on the prescribing physician's behalf. The medicine then moves into the prescribing hospital's pharmacy under chain-of-custody documentation, where the patient receives the first dose under physician supervision; subsequent doses self-administered at home after injection training.

Real cost picture for Amvuttra in Pakistan

US WAC for Amvuttra is approximately USD 119,000 per dose (every 3 months), which translates to approximately USD 476,000 per year. The Pakistani rupee floats with material volatility; a working reference rate of approximately 280 PKR to 1 USD applies for illustrative conversion, but live quotes track current FX, so the annual reference range converts accordingly when expressed in PKR at US WAC equivalents.

International validated cold-chain logistics typically run USD 500 to USD 1,700 (varies materially with PKR volatility) per shipment depending on destination city, urgency, and pack size. Pakistan customs and DRAP permit fees are nominal relative to drug cost. Reserve Meds' concierge fee is itemised separately on every firm quote.

On the insurance side, each Pakistan insurer assesses named-patient imports case by case. Local payer cover is administered through Adamjee Health, EFU Life, Jubilee Life, IGI General, State Life, TPL Life, Salaam Takaful Pakistan, and Sehat Sahulat Programme for eligible families. We do not promise coverage from any insurer. The US manufacturer copay programmes and patient assistance programs do not extend internationally; cross-border patients pay cash or rely on local payer coverage where it applies.

Clinical evidence behind Amvuttra

Amvuttra's pivotal HELIOS-A (hATTR polyneuropathy) demonstrated improvement in mNIS+7 versus external placebo from APOLLO. HELIOS-B (ATTR cardiomyopathy) reshaped the ATTR cardiomyopathy treatment landscape in 2025, broadening the patient population beyond polyneuropathy.

Typical timeline for Amvuttra in Pakistan

DRAP routine processing is typically 15 to 30 business days from a complete filing. For Amvuttra specifically, cold-chain shipment adds 2 to 3 days versus an ambient small molecule because validated thermal packaging, continuous temperature monitoring, and customs clearance scheduled to avoid extreme-heat exposure are non-negotiable. End-to-end, most cases complete within 3 to 6 weeks from first complete documentation to dispensing or first dose. For longer treatment courses, we coordinate cycle-by-cycle or quarterly resupply so the patient never approaches an empty pharmacy shelf.

What your physician needs to provide

For a Pakistan-licensed physician prescribing Amvuttra through the DRAP pathway, the clinical justification letter is the cornerstone of the application. The letter typically documents the patient's diagnosis with relevant staging or severity language for the indication, the prior therapy history, the rationale for Amvuttra as the appropriate next step, and the precise FDA-labeled regimen (dose, route, frequency, expected duration). For Amvuttra specifically, the FDA-approved regimen is 25 mg subcutaneous every 3 months.

For Amvuttra, the relevant molecular or laboratory documentation includes TTR gene sequencing for hereditary form; cardiac PYP scan, technetium scan, biopsy with mass spec typing for ATTR. The letter references the test results that establish the patient's eligibility for the FDA-labeled indication. The treating physician's Pakistan license number, the dispensing facility license number, and the pharmacy in charge complete the package. Monitoring requirements relevant to Amvuttra (baseline labs, imaging cadence, adverse-event surveillance) are stated in the letter and operationalised by the prescribing physician's team.

Monitoring for Amvuttra: Baseline vitamin A (siRNA-mediated TTR reduction lowers retinol-binding protein and serum vitamin A; supplementation 2,500 IU daily standard), serial neurologic assessment (mNIS+7, Norfolk QOL), cardiac biomarkers and echocardiogram for cardiomyopathy patients, and ongoing FAP staging where applicable. **Adverse-event profile:** Limb pain, arthralgia, dyspnoea, decreased serum vitamin A, injection-site reactions. Daily vitamin A supplementation with the recommended dose is part of the standard regimen.

Common questions about Amvuttra in Pakistan

Will my insurer cover this? Each Pakistan insurer (Adamjee Health, EFU Life, Jubilee Life, IGI General, State Life, TPL Life, Salaam Takaful Pakistan, and Sehat Sahulat Programme for eligible families) assesses named-patient imports case by case. We supply the documentation set that allows your insurer to assess the case; the claim itself sits with you or your hospital.

Is Amvuttra already locally registered in Pakistan? Local registration status can shift over time; Amvuttra may already be on the Pakistan register for some indications but not others, or the registered presentation may not match what the prescriber needs. The DRAP pathway exists precisely to bridge these gaps and is the cleanest legal route when the local supply chain does not match the prescription.

What about competitors? Alternatives in the same therapeutic class include patisiran (Onpattro IV siRNA), inotersen (Tegsedi antisense), tafamidis (Vyndaqel/Vyndamax), eplintersen (Wainua), acoramidis (Attruby). Choice depends on the patient's full profile, prior therapy, biomarker status, and the prescriber's judgment. Reserve Meds coordinates whichever medicine the physician has prescribed.

How does the cold chain work? This medicine requires cold-chain handling at 2 to 8 degrees Celsius from manufacture through to dispensing. Reserve Meds uses validated thermal packaging with continuous temperature logging. Customs clearance is scheduled to avoid prolonged tarmac exposure. The cold chain is broken only at the dispensing pharmacy.

Will my US manufacturer assistance program help? US patient assistance programs (PAP), copay cards, and bridge programs from Merck, Pfizer, AstraZeneca, Lilly, Roche, Genentech, Novartis, AbbVie, Janssen, Gilead, Biogen, BMS, and other manufacturers are generally restricted to US residents with US prescriptions filled at US pharmacies. Cross-border patients pay cash or use local payer cover.

What if treatment is multi-year? For long-running treatment, we coordinate cycle-by-cycle or quarterly resupply through the same DRAP pathway, with each shipment authorised against the same physician documentation set updated for the current cycle. Patients never need to navigate the supply chain themselves.

Where is the medicine actually administered? After the first physician-supervised dose, most patients self-administer at home using the prefilled syringe or autoinjector pen after a brief injection-technique training. Home refrigeration is required; we provide a patient onboarding kit.

What if my physician is at a smaller clinic that does not import directly? The standard pattern is to route through a Karachi, Lahore, and Islamabad-based specialty importer that holds a pharmaceutical establishment license. The importer files the DRAP application on behalf of the prescribing physician, takes delivery of the medicine, and transfers it under chain-of-custody to the prescribing facility's pharmacy.

Operational notes for the DRAP workflow

Operationally, the DRAP personal-import permission is filed by the treating physician through DRAP via the Federal Drug Inspector channel. Common reasons for delay are FX availability and import-clearance timing, incomplete documentation of the unmet need, or chain-of-custody plans that do not specify continuous temperature logging. Karachi and Lahore have the most developed specialty-import infrastructure and the highest concentration of tertiary referral centres comfortable with the workflow.

Where Reserve Meds fits in Amvuttra cases

Reserve Meds is a US-based concierge coordinator. We do not replace your prescribing physician, we do not replace the DRAP, and we do not replace your dispensing pharmacy. For Amvuttra specifically, we orchestrate the US-side sourcing through a DSCSA-compliant specialty channel, build the documentation packet your physician submits, coordinate validated cold-chain logistics with appropriate temperature monitoring into Pakistan, plan cycle-by-cycle resupply across longer treatment courses, and assign a single named coordinator through the case. Standard NPP coordination under our cold-chain biologic playbook applies.

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.

Reserve Meds is in pre-launch. Published timelines and cost ranges are indicative, not guarantees.

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