Agamree access in Pakistan

How families in Pakistan reach Agamree (vamorolone) for Duchenne muscular dystrophy through the DRAP Special Permission Personal Use Import pathway.

Quick orientation

Agamree is the brand name for vamorolone, a first-in-class dissociative steroidal anti-inflammatory drug for Duchenne muscular dystrophy (DMD), approved by the U.S. FDA on October 26, 2023 for patients aged 2 and older. In Pakistan, vamorolone has no DRAP marketing authorization. Pakistan's high rate of consanguineous marriage produces a sizable DMD population concentrated in pediatric neurology programs at the Children's Hospital and Institute of Child Health in Lahore, Aga Khan University Hospital in Karachi, and a small set of additional tertiary centers. Families who want their son on vamorolone, often switching from prednisone or deflazacort to reduce growth, bone, and behavior side effects, reach Agamree through the Drug Regulatory Authority of Pakistan's Special Permission for Personal Use Import, filed by the hospital's import pharmacy or a DRAP-licensed specialty importer. Reserve Meds is the U.S.-side coordinator for that import. The pediatric neuromuscular specialist remains the prescriber. The dispensing hospital pharmacy remains the dispensing setting. Reserved for you.

Why DMD families in Pakistan need Agamree via NPP

Three structural reasons converge on the DRAP Special Permission pathway for Agamree. First, vamorolone is not registered with DRAP. The product has no Pakistani marketing authorization, which means no retail or hospital pharmacy can fill the prescription through normal commercial channels regardless of how senior the prescribing pediatric neurologist is. Second, Pakistan has a meaningful and arguably under-counted DMD population. The country's first-cousin marriage rate is among the highest in the world, and recessive and X-linked muscular dystrophies are over-represented relative to global averages. The clinical community at the major pediatric centers sees enough DMD that named-patient imports for newer DMD therapies are a recognized workflow rather than a novelty. Third, vamorolone's clinical positioning is specifically as a corticosteroid alternative with a better profile on linear growth, bone density, and behavior than prednisone or deflazacort. Families with a son already on a standard corticosteroid who are seeing growth stunting or behavioral side effects often initiate the conversation with the treating physician precisely because of this profile, and the clinical decision to switch precedes the regulatory mechanism.

Families in Lahore, Karachi, Islamabad, and the smaller cities all flow through the same DRAP framework. The operational difference is whether the family is treated at one of the major tertiary centers with in-house import pharmacy capacity, or partners with a Karachi- or Lahore-based DRAP-licensed importer that handles the regulatory and customs interface on behalf of the treating clinic.

The DRAP Special Permission pathway for Agamree

The Drug Regulatory Authority of Pakistan was established in 2012 under the DRAP Act and reports to the Federal Ministry of National Health Services, Regulations and Coordination. For

medicines not on the national drug registration list, DRAP's Quality Assurance and Laboratory Testing (QA and LT) Division issues a Special Permission for Personal Use Import, also referred to as the No Objection Certificate (NOC) for Personal Use Import. Applications are filed through DRAP's Online Import and Export System (OIES) portal. For an Agamree case, the application is filed in the patient's name (using the B-Form pediatric identifier rather than the adult CNIC), against a PMDC-licensed treating physician, with a clinical justification letter that establishes the case for the unregistered medicine.

The application package includes the clinical justification letter from the treating pediatric neurologist or neuromuscular specialist; PMDC license verification for the prescriber in the appropriate pediatric neurology subspecialty; the B-Form for the child as patient identifier; product details (brand name Agamree, INN vamorolone, manufacturer Santhera Pharmaceuticals with Catalyst Pharmaceuticals as U.S. license holder, country of origin, strength 40 mg/mL, presentation 100 mL bottle, requested quantity, batch and expiry where available); the destination dispensing facility license (the hospital pharmacy license at AKUH, Children's Hospital Lahore, Indus, or wherever the case will dispense); a manufacturer or authorized distributor letter confirming the product is genuine and sourced through the legitimate U.S. specialty channel; and a chain-of-custody plan covering U.S. release through international air freight, FBR Customs clearance at Karachi or Lahore airport, and delivery to the dispensing pharmacy.

For Agamree specifically, two file features deserve attention. The clinical letter should reference the VISION-DMD (VBP15-004) phase 2b trial and the FDA approval as the evidence base, and should state that vamorolone is dosed continuously rather than cyclically, which is relevant for the requested-quantity calculation. The letter should also reference the corticosteroid-class tapering requirement on discontinuation, because DRAP reviewers expect a treatment plan that anticipates the full course, not just initiation. Pakistan's pharmacovigilance posture is sharpening over time, and DRAP increasingly looks for a coherent monitoring plan in the file.

Routine pediatric DMD cases at established institutions typically clear in four to eight weeks from a complete submission. Complex cases involving first-time filers, smaller hospitals routing through a DRAP-licensed importer, or documentation queries can extend to ten to sixteen weeks. Reserve Meds plans on the longer end of the routine range and treats faster turnaround as upside.

Where Agamree gets dispensed in Pakistan

For Agamree, the relevant institutions are the centers with established pediatric neurology and neuromuscular DMD programs and the institutional pharmacy infrastructure to receive imported medicines. The Children's Hospital and Institute of Child Health in Lahore is Pakistan's major pediatric tertiary center, with pediatric oncology, hematology, neurology, and rare disease capability, and handles named-patient imports for children routinely. Aga Khan University Hospital (AKUH) in Karachi has the Department of Oncology with eighteen full-time faculty across medical, pediatric, radiation, and palliative oncology, a pharmacy network operating 24/7 with temperature-controlled storage, and an established pediatric neurology service that handles named-patient imports as part of its tertiary workflow. The Indus Hospital and Health Network has pediatric capability across its Karachi, Lahore, and Hyderabad collection centers. Shifa International Hospital in Islamabad operates an established import pharmacy workflow for federal-capital-region patients. Shaukat Khanum Memorial Cancer Hospital and Research Centre in Lahore handles named-patient imports as a matter of practice and can serve as a dispensing facility where the family's case is being coordinated through Lahore. Liaquat National Hospital in

Karachi adds a further private tertiary option. The Combined Military Hospitals (CMH) network handles military family pediatric cases and accepts civilian referrals.

Because Agamree is a room-temperature oral suspension and does not require cold-chain refrigeration, the dispensing-facility list is wider than for the typical biologic. The relevant institutional capability is pediatric neuromuscular care and DRAP-experienced import pharmacy operation, not -80°C storage. Families in Peshawar, Quetta, Multan, Faisalabad, and other smaller cities typically have their case routed through one of the major centers above, with last-mile travel handled separately by the family.

Real cost picture for Agamree in Pakistan

The U.S. wholesale acquisition cost (WAC) for Agamree 40 mg/mL is approximately USD 9,500 per 100 mL bottle per Catalyst Pharmaceuticals' February 2024 WAC filing with the North Dakota Insurance Department. Because dosing is weight-based at 6 mg/kg per day, the annual U.S. acquisition cost for a typical pediatric DMD weight profile runs in the USD 400,000 to USD 500,000 range, with one widely cited figure of approximately USD 481,000 per year. A typical 30-day supply ranges between one and three bottles depending on the child's weight.

For a Pakistan DRAP case, the cost stack has three line items. The drug cost reflects the U.S. WAC for the bottles dispensed against the named-patient case, in the order of USD 9,500 to USD 28,500 per month of supply depending on weight. International logistics for an ambient-temperature oral product run in the USD 250 to USD 600 range per shipment, substantially lower than for cold-chain biologics because there is no -80°C handling, no liquid-nitrogen dry shipper, and no validated insulated packaging requirement beyond standard pharmaceutical packaging with heat-excursion logging through Karachi or Lahore customs. Reserve Meds adds a transparent coordination fee per quote, shown separately rather than embedded in the drug price.

Currency context matters more in Pakistan than in some peer markets. The PKR is in the 278 to 280 range to the USD as of May 2026, with April 2026 CPI inflation at 10.9 percent and a history of meaningful volatility. Reserve Meds quotes in USD and accepts wire transfers from any USD-accessible source. The Pakistani diaspora pattern is a defining feature of how families fund this care. Pakistan received roughly USD 4.4 billion in remittances from Saudi Arabia, USD 3.1 billion from the UAE, and USD 2.7 billion from the UK in recent reporting periods, with material contributions from the United States and Canada as well. Many DMD families coordinate funding across one or more relatives abroad, often consolidating funds in USD before the wire. Adamjee, Jubilee, EFU, IGI, and State Life typically do not cover named-patient imports of unregistered specialty drugs; some plans reimburse partially after delivery. Sehat Sahulat's Rs. 1,000,000 per family per year ceiling does not stretch to cover U.S.-sourced specialty therapy at this price tier. Cash-pay is the default operating posture.

Typical timeline for Agamree in Pakistan

For a pediatric DMD family with a treating neuromuscular specialist at an established tertiary center, the typical end-to-end window is six to ten weeks from first inquiry to first dose at home. Reserve Meds intake and documentation kit delivery to the prescriber typically runs 24 to 48 hours. DRAP filing through the hospital's import pharmacy or a DRAP-licensed importer typically adds three to seven business days of preparation, then four to eight weeks of DRAP review for routine cases. U.S. sourcing and international shipping of the ambient-temperature bottles run in parallel with regulatory review and add three to seven days from approval, plus an additional two

to four days for FBR Customs clearance at Karachi or Lahore airport. Because vamorolone ships ambient, there is no cold-chain add. Complex cases (smaller hospitals, first-time DRAP filers, documentation queries, or PMDC license issues) extend to ten to sixteen weeks. Reorders run faster because the operational rails are in place; the second and third DRAP cycle for the same family typically runs four to six weeks end-to-end.

What your physician needs to provide

The treating pediatric neuromuscular specialist's clinical justification letter is the cornerstone of the DRAP file. For an Agamree case the letter should include the DMD diagnosis with ICD-10 G71.01 and the molecular confirmation (dystrophin gene mutation analysis where available), the patient's age and current weight, the corticosteroid history including specific agent, dose, duration, and observed side effects (growth velocity, bone density findings where measured, behavioral observations), the rationale for switching to vamorolone with reference to the VISION-DMD trial and the FDA label, the requested dose (6 mg/kg orally once daily with food, with a stated maximum daily dose of 300 mg for patients at or above 50 kg), the requested treatment duration (typically a 6- or 12-month authorization with renewal expected), and the monitoring plan covering adrenal suppression, growth, bone health, blood pressure, serum potassium, and vaccination status.

The letter should explicitly state that the prescriber is responsible for adverse-event reporting through the DRAP Pharmacovigilance Centre throughout the treatment course. The prescriber's PMDC license must be active for the full requested duration. For a family transitioning from prednisone or deflazacort, the letter should include the planned tapering schedule for the prior corticosteroid and the planned vamorolone initiation timing, which DRAP reviewers expect to see as a coherent clinical plan rather than two disconnected events.

Common questions about Agamree in Pakistan

Will Adamjee, Jubilee, EFU, or State Life cover this? Coverage for named-patient imports of unregistered drugs is uncommon across Pakistani health plans. Jubilee General's Personal HealthCare and Adamjee Health Insurance cover in-hospital chemotherapy and radiotherapy in their formularies, but specialty imports of FDA-approved-but-not-locally-registered drugs are typically outside formulary. Some plans pay a partial percentage on a case-by-case basis. Reserve Meds supplies the documentation the insurer needs to assess. The claim is yours to file. Cash-pay is the default posture.

Can my child receive Agamree at home, or only at the hospital? The dispensing facility must be a locally licensed pharmacy. For Agamree, which is an oral suspension self-administered at home, the hospital outpatient pharmacy or DRAP-licensed import pharmacy dispenses the bottle to the family, who then administers daily at home with the calibrated oral dosing syringe. The hospital pharmacy remains the regulatory dispensing point.

Our family pools funds across Pakistan, the Gulf, and the UK. How does Reserve Meds handle that? The Pakistani diaspora funding pattern is well-established and Reserve Meds works with it routinely. We quote in USD, accept wire transfers from any USD-accessible source, and coordinate timing across multiple senders. The pricing transparency on this page lets the family plan funding before contacting us, which matters when timing across relatives in Saudi Arabia, the UAE, the UK, the U.S., or Canada is part of the workflow.

What if my son's weight changes during therapy? Weight-based dosing recalculates every three to six months as your son grows. Reserve Meds tracks the cadence through the assigned

Concierge Patient Coordinator so the next DRAP reorder accounts for the updated dose and the right bottle count is shipped.

Is Agamree safer than prednisone? This is a clinical question for the treating neuromuscular specialist. The VISION-DMD trial showed fewer effects on linear growth, bone turnover, and behavior compared with prednisone. Vamorolone still carries corticosteroid-class risks including adrenal suppression and the need for taper on discontinuation. Reserve Meds does not advise on the prednisone-versus-vamorolone choice.

Is Agamree a controlled substance? No. Vamorolone is not DEA-scheduled. The standard DRAP Special Permission pathway applies, not the controlled-substance route through the Anti-Narcotics Force.

Where Reserve Meds fits in Agamree cases

Reserve Meds is the U.S.-side concierge coordinator. For an Agamree case in Pakistan, Reserve Meds confirms eligibility and case fit within 24 to 48 hours of intake, sends the documentation kit to your pediatric neuromuscular specialist, coordinates U.S. specialty pharmacy sourcing through Catalyst Pathways' authorized channel, manages the ambient-temperature international logistics with heat-excursion logging through Karachi or Lahore customs, and assigns a single named Concierge Patient Coordinator with Urdu- and English-language support who stays with the family across reorders. Reserve Meds does not file the DRAP application, that sits with the hospital's import pharmacy or the DRAP-licensed importer, does not prescribe, and does not advise on the clinical switch decision. The clinical authority remains with the PMDC-licensed pediatric neuromuscular specialist. The regulatory authority remains with DRAP. The dispensing remains with the licensed Pakistani pharmacy.

Next step

If you are exploring Agamree for a son on prednisone or deflazacort, or initiating corticosteroid therapy for the first time, the waitlist is the entry point. Reserve Meds responds within 24 to 48 hours with a documentation kit for your pediatric neuromuscular specialist and an indicative cost range. The firm quote follows after the prescriber confirms the dose and treatment duration.

Reserved for you.