Evrysdi

Pakistan · access guide

Evrysdi access in Pakistan: the DRAP named-patient pathway

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

Quick orientation

Patients in Pakistan access Evrysdi (risdiplam) for spinal muscular atrophy across age bands through the DRAP named-patient mechanism, a federal mechanism that allows a PMDC-licensed physician to import the FDA-labelled product for a specific named patient. This page details the documentation, approval timeline, and real cost in PKR.

Why Pakistani patients need Evrysdi through the named-patient pathway

Pakistan operates a developed pharmaceutical regulatory environment, and Evrysdi may be on the local register, may be in commercial review, or may be entirely absent depending on the stage of Genentech/Roche's regional rollout. Several patterns drive cross-border requests. First, indication lag: newer indications, particularly the August 2020 FDA approval timeline, often reach local registration 12 to 36 months later. Second, biomarker-defined eligibility: genetic confirmation of biallelic SMN1 deletion or pathogenic variant (the molecular cause of SMA), with SMN2 copy number informing prognosis can be the diagnostic gate, and where the relevant testing infrastructure is still maturing locally, families coordinate the workup before or in parallel with sourcing. Third, payer coverage: Adamjee Insurance, EFU Health, Jubilee, IGI, State Life, TPL, Salaam Takaful, and the Sehat Sahulat Program for eligible beneficiaries each assess specialty therapies case by case, and step-therapy criteria can fail even where the drug is registered. Fourth, stocking gaps: the local agent may not carry every presentation or dose strength reliably, and named-patient import is the operational mechanism that bridges to the exact label the prescriber has written. In each pattern, the named-patient pathway is the legal mechanism that connects a Pakistani-licensed physician's clinical decision with US-sourced, FDA-labelled product for a specific identified patient.

The DRAP named-patient pathway for Evrysdi

The Drug Regulatory Authority of Pakistan (DRAP) administers personal-use imports under the DRAP Act 2012 read with the Drugs Act 1976. The Special Permission or NOC for Personal Use Import is filed via the DRAP OIES portal at dra.gov.pk and routes through the DRAP Division of Pharmacy Services. The framework permits hospitals and licensed pharmaceutical establishments to import a specific medicine for a specific patient when the medicine is approved by a recognised reference authority (typically the US FDA, EMA, MHRA, PMDA Japan, or Health Canada) and either a clinically equivalent locally registered alternative is not suitable, or the patient's clinical profile does not match the locally approved label.

A complete application for Evrysdi typically includes a clinical justification letter from the treating physician documenting the patient's diagnosis (spinal muscular atrophy (SMA) of all types), severity assessment, prior systemic therapy history, any relevant biomarker results (genetic confirmation of biallelic SMN1 deletion or pathogenic variant (the molecular cause of SMA), with SMN2 copy number informing prognosis), and a clinical rationale for selecting Evrysdi over locally available alternatives. The Pakistani physician's licensure with the Pakistan Medical Commission (PMC) and the relevant provincial healthcare regulators (Sindh Healthcare Commission, Punjab Healthcare Commission, etc.) is verified through the application. The packet also specifies the dispensing facility name and license number, the pharmacy in charge of the facility, full product details (brand name, generic name, manufacturer, strength, dosage form, pack size, quantity, intended treatment duration), and a chain-of-custody plan describing how the medicine will move from the US manufacturer through the importer to the dispensing pharmacy.

For Evrysdi specifically, the clinical justification typically frames the case around the oral daily home-based dosing is the key operational advantage versus Spinraza (intrathecal q4m) and Zolgensma (one-time IV); paediatric neurology referral and SMN1/SMN2 genetic confirmation anchor the workup. Approval timelines are typically 15 to 30 business days for routine cases; FX timing and bank documentation often govern wire scheduling more than DRAP itself. The DRAP retains discretion on timing, and we do not promise specific durations.

Where Evrysdi gets dispensed in Pakistan

A focused group of Pakistan institutions handle named-patient specialty-medicine imports as established workflow, with in-house import pharmacy capabilities and physicians experienced with the application set. For Evrysdi specifically, the dispensing facility must accommodate the administration profile: outpatient paediatric neurology or neuromuscular clinic; oral liquid administered at home by the parent or caregiver; quarterly motor function assessment (CHOP-INTEND, HFMSE, RULM as age-appropriate). Tertiary centres that meet this profile include Shaukat Khanum Memorial Cancer Hospital and Research Centre (SKMCH&RC) in Lahore and Peshawar, Aga Khan University Hospital (AKUH) in Karachi, Liaquat National Hospital in Karachi, Indus Hospital in Karachi, Doctors Hospital Lahore, Hameed Latif Hospital, Shifa International Hospital in Islamabad, and Quaid-e-Azam International Hospital.

For physicians at smaller hospitals without internal import infrastructure, the common pattern is to route through a licensed pharmaceutical establishment that holds the import licence and files the DRAP application on the prescribing physician's behalf. The medicine then moves under chain-of-custody documentation into the prescribing hospital's outpatient pharmacy for administration.

Real cost picture for Evrysdi in Pakistan

US WAC for Evrysdi is approximately USD 28,300 per 60 mg bottle, which translates to an annual WAC in the range of USD 100,000 to USD 340,000 per year (weight-banded; maxes at the adult dose) for the standard regimen at the labelled dose. The Pakistani rupee has been volatile against the US dollar; 1 USD is approximately 280 PKR as of May 2026 (flagged as indicative; we quote USD primary, and the State Bank of Pakistan outward remittance allowance for medical purposes is a practical sequencing constraint families plan around). On that basis, the drug cost alone is materially significant before logistics, the DRAP permit fees (which are nominal relative to drug cost), the destination dispensing hospital's administration fees, and Reserve Meds' concierge fee (which is itemised separately on every firm quote).

International cold-chain or ambient logistics into Pakistan typically runs in the low to mid four-figure USD range depending on origin, urgency, and packaging requirements. On the insurance side, Adamjee Insurance, EFU Health, Jubilee, IGI, State Life, TPL, Salaam Takaful, and the Sehat Sahulat Program for eligible beneficiaries each assess named-patient imports case by case. Some reimburse fully when the medicine is on their formulary even if not stocked, some reimburse a percentage subject to copay, and many require pre-authorisation with documented step-therapy failure. We do not promise coverage from any payer. US manufacturer patient assistance programmes do not extend internationally; cross-border patients pay cash or rely on local payer coverage where available.

Clinical evidence and where Evrysdi sits in the treatment landscape

FIREFISH (infantile-onset SMA type 1), SUNFISH (later-onset SMA types 2 and 3), JEWELFISH (previously treated patients), and RAINBOWFISH (presymptomatic newborns) collectively demonstrated motor function improvement and survival benefit across SMA phenotypes. The drug acts as SMN2 splicing modifier (oral), and the dosing schedule is weight-banded oral daily liquid: 0.20 mg/kg for infants under 2 months titrated to 0.25 mg/kg at 2 months and above, with a maximum daily dose of 5 mg in patients over 20 kg.

Within the treatment landscape, Evrysdi sits alongside nusinersen (Spinraza) intrathecal antisense oligonucleotide, onasemnogene abeparvovec (Zolgensma) AAV9 gene therapy for patients under 2 years; risdiplam is the only oral disease-modifying SMA therapy. The choice between targeted therapies in this space depends on the patient's full clinical profile, prior therapy exposure, biomarker status, comorbidities, and the prescriber's judgment. Reserve Meds coordinates whichever therapy the physician has selected; we do not steer prescribing.

Safety surveillance for Evrysdi centres on diarrhoea, rash, fever, pneumonia, and constipation in younger patients; teratogenicity warnings for adult patients of reproductive potential (effective contraception required). The dispensing facility and the prescribing physician retain clinical responsibility for monitoring and adverse-event management; Reserve Meds does not provide medical care.

Typical timeline for Evrysdi in Pakistan

DRAP routine processing is typically 15 to 30 business days for routine cases; FX timing and bank documentation often govern wire scheduling more than DRAP itself from a complete filing. End-to-end, most cases complete within 4 to 8 weeks from first complete documentation, with first-of-kind cases and complex biomarker-dependent workups potentially extending further. Where the administration setting is outpatient paediatric neurology or neuromuscular clinic, hospital scheduling and infusion-chair availability are additional sequencing factors that families plan around. We do not promise specific durations; the DRAP retains discretion on timing, and shipping windows depend on lane and packaging.

What your Pakistani physician needs to provide

For a Pakistani-licensed specialist prescribing Evrysdi through the DRAP pathway, the clinical justification letter is the cornerstone of the application. The letter typically documents the patient's diagnosis (spinal muscular atrophy (SMA) of all types), the relevant biomarker work (genetic confirmation of biallelic SMN1 deletion or pathogenic variant (the molecular cause of SMA), with SMN2 copy number informing prognosis), prior systemic therapy history, the FDA-approved indication being invoked, and the clinical rationale for Evrysdi as the appropriate next step.

The letter also specifies the exact dosing plan per the FDA-approved label: weight-banded oral daily liquid: 0.20 mg/kg for infants under 2 months titrated to 0.25 mg/kg at 2 months and above, with a maximum daily dose of 5 mg in patients over 20 kg. The monitoring plan references diarrhoea, rash, fever, pneumonia, and constipation in younger patients; teratogenicity warnings for adult patients of reproductive potential (effective contraception required). The treating physician's licence number with the Pakistan Medical Commission (PMC) and the relevant provincial healthcare regulators (Sindh Healthcare Commission, Punjab Healthcare Commission, etc.), the dispensing facility license number, and the pharmacy in charge of dispensing complete the package. Where biomarker testing requires reference-lab coordination, the physician documents the assay used and the report; Reserve Meds can route this through a US-side reference laboratory where the regional pathway is unavailable.

Common questions about Evrysdi in Pakistan

Will Adamjee Insurance or other major Pakistani insurers cover Evrysdi? Each insurer assesses named-patient imports case by case. Some reimburse fully when Evrysdi is on their formulary even if not currently stocked; others assess based on step-therapy criteria and biomarker documentation. We supply the documentation set that allows your insurer to assess the case; the claim itself sits with you, your physician, or your hospital. We do not promise coverage from any payer.

Is Evrysdi registered locally in Pakistan? Local registration status changes as Genentech/Roche pursues regional rollout; even where the drug is registered, the specific indication, presentation, or dosing strength your prescriber has written may not align with what is currently stocked. The DRAP named-patient pathway exists precisely to bridge these gaps for individually identified patients.

What about competitor therapies? The treatment landscape includes nusinersen (Spinraza) intrathecal antisense oligonucleotide, onasemnogene abeparvovec (Zolgensma) AAV9 gene therapy for patients under 2 years; risdiplam is the only oral disease-modifying SMA therapy. The choice depends on the patient's full clinical profile and prescriber judgment. Reserve Meds coordinates whichever medicine the physician has prescribed; we do not steer prescribing decisions and we do not have a financial relationship with any specific manufacturer.

How is the cold chain or storage managed? Evrysdi ships in validated thermal packaging with continuous temperature logging through the lane. The cold-chain handoff or temperature-controlled handoff ends at the dispensing pharmacy; home storage instructions, where the patient takes the medicine home for self-administration, are part of the patient onboarding kit.

Do US manufacturer patient assistance programmes (such as Genentech/Roche co-pay or PAP programmes) extend to Pakistan patients? No. US-resident patient assistance programmes are limited to US-resident patients with US prescription coverage by programme design. Cross-border patients pay cash for the drug and the coordination fee, with local payer reimbursement assessed separately.

Can the case be resupplied year over year if the patient responds? Yes. Reserve Meds maintains the case file and re-files DRAP permits at the relevant intervals (or coordinates with the dispensing hospital's pharmacy if they hold the permit). Patients on long-term therapy typically settle into a quarterly or biannual resupply cadence after the first cycle.

What is the administration setting? Outpatient paediatric neurology or neuromuscular clinic; oral liquid administered at home by the parent or caregiver; quarterly motor function assessment (chop-intend, hfmse, rulm as age-appropriate).

My physician is at a smaller hospital without an internal import pharmacy. Can the case still proceed? Yes. The common pattern is to route through a Dubai, Riyadh, Mumbai, Cairo, Karachi, or other regional licensed pharmaceutical establishment that holds the import licence and files the DRAP application on the prescribing physician's behalf. The medicine moves into the prescribing hospital's outpatient pharmacy under chain-of-custody documentation.

Where Reserve Meds fits in Evrysdi cases

Reserve Meds is a US-based concierge coordinator. We do not replace your Pakistani specialist, we do not replace the DRAP, and we do not replace your dispensing pharmacy. For Evrysdi specifically, we orchestrate the US-side sourcing through a DSCSA-compliant specialty channel, build the documentation packet your physician submits, coordinate logistics into Pakistan, and assign a single named coordinator through the case. The pharmacist-of-record review, prescription validation, biomarker confirmation, and physician sign-off are the recurring operational fundamentals for this drug.

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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