Revuforj access in Pakistan via the DRAP named-patient pathway

How patients in Pakistan obtain Revuforj (revumenib) for relapsed or refractory acute leukemia with a KMT2A translocation or susceptible NPM1 mutation, through the Drug Regulatory Authority of Pakistan Special Permission / Personal Use Import pathway.

Last reviewed 2026-05-12 by Reserve Meds clinical and regulatory team.

1. Quick orientation

Revuforj is the brand name for revumenib, a first-in-class oral small-molecule menin inhibitor that disrupts the menin to KMT2A protein interaction driving leukemogenesis in genetically defined subsets of acute leukemia. The US Food and Drug Administration granted accelerated approval on November 15, 2024 for relapsed or refractory acute leukemia with a KMT2A translocation in adult and pediatric patients 1 year of age and older. In October 2025, the FDA expanded the label to include relapsed or refractory acute myeloid leukemia with a susceptible NPM1 mutation in patients 1 year and older. In Pakistan, families with a child or adult facing relapsed KMT2A-rearranged or NPM1-mutated acute leukemia face a setting with very few targeted options. The Drug Regulatory Authority of Pakistan (DRAP) Special Permission / Personal Use Import pathway, filed through the Online Import and Export System (OIES) portal, is the lawful route once a Pakistan Medical and Dental Council (PMDC) licensed hematologist or pediatric oncologist has decided this is the right next step. Reserve Meds is the US-side coordinator that aligns the sourcing, the documentation kit, and the international logistics. Reserved for you.

2. Why patients in Pakistan need Revuforj via NPP

KMT2A-rearranged acute leukemia accounts for a small minority of adult AML and a larger fraction of infant and pediatric ALL. The absolute patient count in any individual market is small, which discourages local stocking and slows the regulatory case for a manufacturer to register country by country. There is no public record of DRAP registration of Revuforj at the time of this review. Pakistan's pediatric and adult hematology services are concentrated at a few specialty centers, but the gap between FDA availability and on-shelf availability in Pakistan remains real for first-in-class targeted oncology agents.

Three features make Revuforj a high-fit NPP candidate for Pakistani families. First, the drug is first-in-class with no approved competitor in the menin-inhibitor class. Second, the pediatric eligibility at age 1 year and older is unusual for a novel targeted oncology therapy, which means infant and pediatric KMT2A-rearranged leukemia cases at Shaukat Khanum Memorial Cancer Hospital and Research Centre (SKMCH&RC) pediatric oncology, AKUH pediatric hematology and oncology, Indus Hospital pediatrics, and the Children's Hospital and Institute of Child Health in Lahore can reach Revuforj on the same regulatory basis as adults. Third, the molecular rationale is specific: KMT2A-rearranged or NPM1-mutated leukemias depend on the menin-KMT2A interaction, and disrupting that interaction is mechanistically targeted at the disease driver. Standard relapsed or refractory regimens (intensive reinduction chemotherapy, venetoclax-based regimens for AML, FLT3 inhibitors for FLT3-mutated AML, blinatumomab and inotuzumab for B-ALL) are not selected for KMT2A biology. The named-patient pathway is the recognized regulatory route.

3. The DRAP Special Permission pathway for Revuforj

DRAP regulates the import of medicines through the Quality Assurance and Laboratory Testing (QA&LT) Division's Import and Export Section. For unregistered medicines required by a specific patient, DRAP issues a Special Permission, 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). Patient-level personal-use applications can be filed by the patient or applicant directly on the portal; institutional applications are filed by the hospital pharmacy.

For Revuforj specifically, the application package contains:

- **Clinical justification letter** from the treating hematologist or pediatric oncologist, addressing acute leukemia diagnosis (AML or ALL with subtype), molecular confirmation of a KMT2A translocation or a susceptible NPM1 mutation (with the cytogenetics or molecular pathology report attached), prior-line therapies attempted with outcomes, the rationale for menin inhibition, the planned weight-based dosing, and any consolidation plan (for example allogeneic hematopoietic stem cell transplant after response).
- **PMDC licensure verification** for the treating physician in hematology, medical oncology, or pediatric hematology-oncology.
- **Patient identifier:** CNIC for adult patients; B-Form for minors. Pediatric cases require weight-band documentation for the body-surface-area-based dosing.
- **Product details** including brand name (Revuforj), international nonproprietary name (revumenib), manufacturer (Syndax Pharmaceuticals, Inc., Waltham, Massachusetts), country of origin (USA), strength (110 mg or 160 mg film-coated tablets), pack size, requested quantity for the multi-month initial sourcing window, lot, and expiry.
- **Destination dispensing facility license** showing the receiving hospital pharmacy is licensed to dispense oral oncology agents.
- **Manufacturer or authorized distributor letter** confirming the product is genuine and was sourced through Syndax's authorized US specialty pharmacy partner under DSCSA serialization.
- **Chain-of-custody plan** from the US specialty pharmacy through international air freight to the receiving Pakistani facility, including the freight forwarder, customs broker for FBR clearance at the Karachi seaport or Lahore airport, and importer of record. Because Revuforj is a solid oral dosage form with room-temperature stability, no cold-chain leg is required, which simplifies routing materially compared to biologic NPP cases.

Routine personal-use cases typically clear in four to eight weeks from a complete submission. Cases involving novel first-in-class targeted oncology agents can extend to ten to sixteen weeks. Reserve Meds plans on the longer end and treats any faster turnaround as upside.

4. Where Revuforj gets dispensed in Pakistan

Revuforj is room-temperature stable, oral, and continuous twice daily, so the dispensing footprint is broader than for biologics. The capability set that does matter is differentiation-syndrome surveillance during the first 28 days, ECG monitoring at baseline and weekly then monthly for QT prolongation, electrolyte correction infrastructure, and CYP3A4 interaction awareness for the common pattern of azole antifungal co-prescription in this patient population. Pediatric AML and ALL cases route most naturally to Shaukat Khanum Memorial Cancer Hospital and Research Centre (SKMCH&RC) in Lahore, the Children's Hospital and Institute of Child Health in Lahore, AKUH pediatric oncology in Karachi, and Indus Hospital pediatrics in Karachi. Adult AML cases route to AKUH adult oncology, SKMCH&RC, Liaquat National Hospital in Karachi, the Combined Military Hospitals (CMH) network at Rawalpindi and Lahore, and Shifa International Hospital in Islamabad.

Smaller-city patients in Peshawar, Multan, Faisalabad, or Quetta typically travel to a major center for treatment initiation, then continue oral therapy closer to home with periodic follow-up at the original tertiary center. Reserve Meds plans logistics to a major-city dispensing facility and works with the family on the in-country last-mile.

5. Real cost picture for Revuforj in Pakistan

Three line items make up the patient-facing cost of a Revuforj case sourced from the United States into Pakistan.

Drug acquisition. Syndax-disclosed US wholesale acquisition cost (WAC) is approximately USD 39,500 per month. On an annualized basis the order-of-magnitude reference is approximately USD 474,000 per patient per year at WAC, before any insurer rebates or manufacturer assistance. Reserve Meds quotes in USD as the primary currency because the Pakistani Rupee has been volatile. At the current USD to PKR range of approximately 278 to 280 as of May 2026, the monthly drug-only cost lands around PKR 11 million at the WAC reference, with annualized PKR equivalents above PKR 132 million at continuous twice-daily dosing.

International logistics surcharge. Because Revuforj is room-temperature stable, validated cold-chain shipping is not required, which reduces the logistics line meaningfully compared to biologic NPP cases. Standard international air courier with declared-value insurance, continuous tracking, customs documentation, and importer-of-record handling typically adds USD 400 to USD 800 per shipment. Multi-month consolidation reduces per-shipment cost on an ongoing basis. FBR customs clearance at the Karachi seaport or Lahore airport adds friction that experienced specialty importers manage routinely.

Coordination, documentation, and concierge fee. Reserve Meds quotes the concierge fee transparently on every case, with the rate disclosed on the firm quote rather than buried in a bundled total. The fee covers documentation kit preparation, US sourcing, international logistics, customs paperwork, and a single named coordinator from intake through reorders.

Cytogenetic and molecular pathology confirmation (KMT2A FISH, NPM1 mutation testing), ECG monitoring, electrolyte correction infrastructure, and physician oversight are billed by the receiving Pakistani institution and are not part of the Reserve Meds quote. Local insurer behavior on named-patient imports is conservative: Adamjee, Jubilee, EFU, and State Life typically do not reimburse imported unregistered specialty drugs.

6. Typical timeline for Revuforj in Pakistan

From the date the clinical justification letter is signed and the OIES file is submitted, routine DRAP review for Revuforj typically runs four to eight weeks. Cases involving novel first-in-class targeted oncology agents can extend toward ten to sixteen weeks while internal pharmacy committees onboard a new oral oncology product. Because Revuforj is room-temperature stable and oral, international transit and FBR customs clearance are streamlined relative to biologic NPP cases. After the initial supply lands, the twice-daily continuous dosing pattern sets the rhythm: Reserve Meds plans multi-month reorder windows to align with the AUGMENT-101 trial's median duration of complete remission of 6.4 months in the KMT2Ar cohort, which gives a rough planning anchor for forward supply commitments.

7. What your physician needs to provide

The clinical justification letter is the cornerstone of the DRAP submission. For a Revuforj Personal Use Import application, the letter typically covers the following.

- **Diagnosis and molecular profile.** Acute leukemia type (AML or ALL), with cytogenetic and molecular confirmation of a KMT2A translocation or a susceptible NPM1 mutation, and the underlying pathology report attached.
- **Prior therapy.** Lines of therapy attempted (induction, consolidation, salvage), best responses, and date of relapse or refractoriness.
- **Mechanism rationale.** Why menin inhibition is appropriate for this patient at this point in the course, in line with the FDA-labeled indication.
- **Dosing plan.** For patients weighing 40 kg or more, 270 mg orally twice daily. For patients weighing less than 40 kg, 160 mg/m² orally twice daily. When co-administered with a strong CYP3A4 inhibitor (commonly an azole

antifungal such as posaconazole or voriconazole used for invasive fungal prophylaxis in acute leukemia), the dose is reduced to 160 mg twice daily for patients 40 kg or more, and 95 mg/m² twice daily for patients under 40 kg. Tablets taken approximately 12 hours apart with or without food.

- **Monitoring plan.** Differentiation syndrome surveillance during the first 28 days with corticosteroid readiness; ECG monitoring at baseline, weekly for the first month, and at least monthly thereafter; electrolyte correction (potassium, magnesium); CBC and chemistry monitoring.
- **Consolidation plan.** Any planned allogeneic hematopoietic stem cell transplant in eligible responders.
- **Adverse-event reporting commitment.** The treating physician's commitment to report adverse events through the DRAP Pharmacovigilance Centre, signed under the PMDC license.

8. Common questions about Revuforj in Pakistan

Will Adamjee, Jubilee, EFU, or State Life cover Revuforj? Coverage for named-patient imports of unregistered drugs is uncommon across Pakistani health plans. Some plans pay a partial percentage on a case-by-case basis. Reserve Meds supplies the documentation an insurer would need to assess a claim; the claim itself is yours or your hospital's to file. The realistic default is cash-pay.

How does Sehat Sahulat interact with a Revuforj case? The Sehat Sahulat Program's annual ceiling of Rs. 1,000,000 per family typically does not stretch to cover US-sourced specialty oncology agents at this price level. Patients can still use Sehat Sahulat for hospitalization, supportive oncology care, and consolidation transplant where empaneled, while Revuforj is procured separately on a cash-pay basis.

What about pediatric patients? Revuforj is FDA-approved for adult and pediatric patients 1 year of age and older. The framework applies the same way for pediatric patients. The clinical justification letter includes weight-band dosing or body-surface-area dosing and pediatric-specific monitoring. SKMCH&RC pediatric oncology, AKUH pediatric oncology, Indus Hospital pediatrics, and the Children's Hospital and Institute of Child Health in Lahore handle named-patient imports for children routinely. The B-Form is used in place of the CNIC for the patient identifier.

What is the safety profile? The FDA label carries a boxed warning for differentiation syndrome, which can be fatal. Other notable risks include QT-interval prolongation, embryo-fetal toxicity, and myelosuppression. In the AUGMENT-101 KMT2Ar cohort, grade 3 or higher febrile neutropenia occurred in 37.2 percent, differentiation syndrome in 16.0 percent, and QTc prolongation in 13.8 percent of treated patients.

Is there an alternative? There is no approved competitor in the menin-inhibitor class. Standard relapsed or refractory regimens are mechanistically different and are not selected for KMT2A biology. The choice is a treating-physician decision and Reserve Meds does not select therapy.

Our family pools funds across Pakistan and overseas. How does Reserve Meds handle that? Pakistan's diaspora pattern is well-established. Reserve Meds quotes in USD, accepts wire transfers from any USD-accessible source, and works with families coordinating funds across multiple countries before treatment can start.

9. Where Reserve Meds fits in Revuforj cases

Reserve Meds has no prior Pakistan Revuforj case experience as of the review date. Standard NPP coordination applies, with particular attention to four operational realities: molecular-confirmation documentation in the case file (KMT2A FISH or NPM1 mutation report) before procurement is initiated; CYP3A4 interaction awareness on the destination team (the azole antifungal co-prescription pattern is common in acute leukemia and triggers a label-defined dose reduction); pediatric weight-band documentation where applicable; and multi-month reorder cadence planned at case acceptance because continuous twice-daily dosing rewards forward planning. The clinical decisions remain with the PMDC-licensed treating physician. The regulatory authority remains DRAP. The dispensing remains with the licensed Pakistani facility. Reserve Meds is the connective tissue between the US specialty pharmacy and those three Pakistani pillars, with a single named coordinator who stays with the case through reorders.

10. Next step

If you have a relapsed or refractory KMT2A-rearranged or NPM1-mutated acute leukemia patient in your family and a treating physician in Pakistan ready to write the clinical justification letter, the next step is to add your case to the waitlist so Reserve Meds can confirm eligibility within 24 to 48 hours and send the documentation kit to your physician and hospital pharmacy.

Reserved for you.

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