Revuforj access in the UAE: the MOHAP and EDE named-patient pathway

How UAE patients with relapsed or refractory KMT2A-rearranged or NPM1-mutated acute leukemia, adult or pediatric, legally obtain Revuforj (revumenib) from US-source supply when the medicine is not yet registered locally.

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

Quick orientation

Revuforj (revumenib) is the first-in-class oral menin inhibitor approved by the US FDA in November 2024 for relapsed or refractory acute leukemia with a KMT2A translocation (KMT2Ar) 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 of age and older. Revuforj is the only approved therapy in its mechanistic class. There is no SFDA, MOHAP, or CDSCO registration of Revuforj at the time of this review. UAE adult and pediatric hematology patients reach the medicine through the unregistered-medicine import permit administered by the Ministry of Health and Prevention (MOHAP) and, from 29 December 2025, through the Emirates Drug Establishment (EDE) portal. Reserve Meds handles the US-side specialty sourcing and the documentation kit your hematologist needs.

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Why UAE patients need Revuforj via the named-patient pathway

The UAE federal regulatory environment is one of the most developed in the Gulf, with MOHAP holding the national drug register and the EDE assuming 44 core services from December 2025. Even with this maturity, UAE hematology patients face structural access gaps that converge on Revuforj specifically. The drug is not on the UAE federal register at all; Revuforj is approved by the FDA in the United States only as of this review. There is no clinically equivalent local substitute, because Revuforj is first-in-class and no other menin inhibitor is approved. There is no generic.

Three features make Revuforj a high-fit NPP candidate for the UAE pediatric and adult hematology population. KMT2A-rearranged acute leukemia is rare; it accounts for a small minority of adult AML and a slightly larger fraction of infant and pediatric ALL. The absolute patient count in any individual ex-US market is small, which slows the regulatory ROI calculation for the manufacturer to register country by country. Revuforj is first-in-class, and there is no therapeutically equivalent local substitute that a UAE hematologist can prescribe instead. The pediatric eligibility (age 1 year and older from first approval) is unusual for a novel targeted oncology therapy, which expands the pool of legitimate cross-border requests to include the infant and pediatric KMT2Ar leukemia population historically underserved by adult-first oncology launches. The result is a single-source, no-substitute, pediatric-eligible, ex-US-unregistered drug for a high-mortality indication. That profile is the textbook compassionate-use case the UAE legal framework contemplates.

The MOHAP and EDE named-patient pathway for Revuforj

The federal pathway for a UAE-licensed physician to obtain a medicine that is not registered locally is the unregistered-medicine import permit. Historically administered by MOHAP and from 29 December 2025 administered through the EDE portal at ede.gov.ae under Federal Decree-Law No. 38 of 2024, the framework allows hospitals and licensed pharmaceutical establishments to import a specific medicine for a specific patient when the medicine is approved by a recognised reference authority (US FDA, EMA, MHRA, PMDA Japan, Health Canada) and a clinically equivalent locally registered alternative is not suitable. Compassionate-use provisions cover patients with a serious illness or life-threatening condition outside of

clinical trials when no alternative treatment options are available, and relapsed or refractory acute leukemia with a defined molecular driver fits squarely within that scope.

A complete Revuforj application typically includes:

- A clinical justification letter from the treating hematologist or pediatric hematologist (diagnosis of acute leukemia, with molecular confirmation of KMT2A translocation or susceptible NPM1 mutation from a qualified cytogenetics or molecular lab report, history of prior therapies and the documented relapse or refractory status, and the rationale for menin inhibition in a single-source first-in-class context)
- The treating physician's UAE medical license verification (MOHAP, DHA, DOH, or Sharjah Health Authority, matched to the dispensing facility's emirate)
- A patient identifier (anonymised reference is preferred where the EDE submission allows), and for pediatric patients, the weight and body surface area underlying the dosing calculation
- Full product details: Revuforj (revumenib), Syndax Pharmaceuticals, Inc., film-coated tablets in 110 mg or 160 mg strengths, with the quantity reflecting twice-daily continuous dosing across the planned supply window
- The destination dispensing facility, typically a hospital outpatient pharmacy at a center with hematology service capability, with the pharmaceutical establishment license number and the pharmacy in charge
- A chain-of-custody plan describing how Revuforj will move from the US specialty pharmacy (SyndAccess-coordinated network) through the importer to the dispensing pharmacy under DSCSA serialization, ambient temperature transit, and full manufacturer-serialized lot traceability

For Revuforj, the clinical justification letter benefits from documentation specific to a first-in-class oral menin inhibitor: confirmed KMT2A translocation or NPM1 mutation report from a qualified molecular pathology lab, the proposed dosing plan based on patient weight (270 mg twice daily for patients 40 kg and over; 160 mg/m² twice daily for patients under 40 kg, with the CYP3A4-adjusted dose where applicable for patients on azole antifungal prophylaxis), and the planned differentiation-syndrome surveillance and ECG monitoring schedule. Approval timelines for routine UAE cases are typically 5 to 15 business days. First-time imports of a novel-mechanism oral oncology agent may extend to 4 to 6 weeks.

Where Revuforj gets dispensed in the UAE

Revuforj is a room-temperature oral tablet, dosed twice daily on a continuous basis. International logistics are materially simpler than for biologics and cell therapies: there is no cold chain, no temperature excursion risk in transit, and no compounding step at the destination. The clinical complexity sits at the hematology center where the patient is followed. The UAE institutions with hematology and pediatric hematology services that routinely handle named-patient imports include Cleveland Clinic Abu Dhabi (the M42 group's 364-bed multispecialty hospital with adult hematology and pharmacy services accredited by the American Society of Health-System Pharmacists), Sheikh Khalifa Medical City in Abu Dhabi (the SEHA network's 586-bed JCI-accredited tertiary center managed by the Cleveland Clinic, with pediatric subspecialty services that handle named-patient imports for pediatric cases routinely), and Tawam Hospital in Al Ain (the SEHA network's national oncology referral center with hematology and pediatric oncology developed in collaboration with the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center).

American Hospital Dubai (Mayo Clinic Care Network member with pediatric oncology services), Mediclinic City Hospital, and the larger NMC Healthcare sites with hematology can also dispense Revuforj through in-house import pharmacy. For pediatric cases in particular, SKMC's pediatric service and Tawam's pediatric oncology program are the centers most experienced with weight-band dosing and pediatric named-patient documentation. Smaller hospitals without import infrastructure route through a Dubai or Abu Dhabi specialty importer.

Real cost picture for Revuforj in the UAE

The UAE dirham is pegged to the US dollar at approximately 3.67 AED to 1 USD. Per Syndax public disclosures in state pricing transparency filings (Colorado and Vermont), the US wholesale acquisition cost for Revuforj is approximately USD 39,500 per month, which annualizes to approximately USD 474,000 per patient per year at WAC (approximately AED 1.74 million per year) at the adult dose of 270 mg twice daily. Pediatric weight-band dosing scales the cost down by patient size. WAC excludes rebates, discounts, and net-price adjustments and does not reflect actual transacted prices.

International logistics for an oral room-temperature oncology tablet typically runs USD 400 to 900 (approximately AED 1,500 to 3,300) per shipment, depending on the destination emirate and urgency window. There is no cold-chain surcharge. UAE customs and EDE permit fees are nominal relative to the drug cost. Reserve Meds itemises the US-side specialty pharmacy procurement, the international logistics, and the concierge coordination fee separately on every firm quote. Daman National Health Insurance (operator of Thiqa), GIG Gulf, Sukoon Insurance, ADNIC, Orient Insurance, and Al Buhaira National Insurance handle named-patient imports case by case. We do not promise coverage.

Typical timeline for Revuforj in the UAE

For a routine UAE Revuforj case, the EDE permit window is typically 5 to 15 business days from a complete filing. Because Revuforj is an oral tablet at room temperature with no cold-chain dependency, the international transit window is shorter than for cold-chain biologics; standard international air courier with declared-value insurance is the typical mode. First-time imports of a novel-mechanism oral oncology agent at a given UAE hematology center can add 2 to 3 weeks for institutional pharmacy onboarding. Because dosing is continuous twice-daily until disease progression or unacceptable toxicity, Reserve Meds plans multi-month supply windows at the case-acceptance stage rather than month-by-month resourcing.

What your physician needs to provide

The clinical justification letter is the cornerstone of the EDE application. For Revuforj, the strongest letters consistently include: a confirmed diagnosis of acute leukemia (AML or ALL) with molecular pathology confirmation of either a KMT2A translocation or a susceptible NPM1 mutation, with the molecular report attached; documentation of prior therapy and the relapse or refractory status that establishes second-line or beyond eligibility; the patient's age and weight (and body surface area for pediatric patients under 40 kg); the proposed dosing plan (270 mg twice daily for patients 40 kg and over, or 160 mg/m² twice daily for patients under 40 kg, with the CYP3A4-adjusted dose noted where the patient is on a strong CYP3A4 inhibitor such as posaconazole or voriconazole for invasive fungal prophylaxis); the planned monitoring plan including differentiation-syndrome surveillance during the first 28 days, weekly ECG monitoring for the first month, and CBC and chemistry monitoring; and the prescribing hematologist's UAE license verification matched to the emirate of the dispensing facility.

The treating hematologist retains the clinical decision and the pharmacovigilance reporting obligation under UAE Good Vigilance Practice. Reserve Meds supplies the documentation template from the US side; we do not write the clinical letter and do not direct dosing.

Common questions about Revuforj in the UAE

Will Daman, Thiqa, GIG Gulf, Sukoon, ADNIC, or Orient cover Revuforj?

Each insurer assesses named-patient imports case by case. Some reimburse in full when the medicine is on their formulary even if not stocked, some reimburse a percentage subject to copay, and several require pre-authorisation. Thiqa, the government-funded programme for UAE nationals administered by Daman, has the broadest specialty coverage in Abu Dhabi. We do not promise coverage from any insurer. We supply the documentation set that allows your insurer to assess; the claim sits with you or your hospital.

Does the pathway work for pediatric patients?

Yes. Revuforj is FDA-approved in patients 1 year of age and older, and the UAE named-patient framework applies the same way for pediatric patients. The clinical justification letter typically includes weight-adjusted dosing (160 mg/m² twice daily for patients under 40 kg) and pediatric-specific monitoring. SKMC's pediatric service, the Tawam pediatric oncology program, and the pediatric services at American Hospital Dubai and Cleveland Clinic Abu Dhabi handle named-patient imports for pediatric cases routinely.

What is the safety profile we should be aware of?

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. Differentiation-syndrome surveillance is mandatory during the first 28 days; ECG monitoring runs weekly for the first month and at least monthly thereafter, with electrolyte correction to mitigate QT prolongation.

Will a DOH-licensed or DHA-licensed hematologist's letter be sufficient?

Yes. Any UAE-licensed hematologist or pediatric hematologist practicing in good standing in the emirate of the dispensing facility has signing authority on the clinical justification letter. Joint-privilege physicians who hold licenses in multiple emirates can file in any emirate where they are credentialed.

Is there a competitor or alternative?

There is no approved competitor in the menin-inhibitor class as of this review. Other menin inhibitors are in clinical development but not approved. Outside the menin-inhibitor class, standard relapsed or refractory acute-leukemia options (intensive reinduction chemotherapy, venetoclax-based regimens for AML, FLT3 inhibitors for FLT3-mutated AML, blinatumomab and inotuzumab for B-ALL) operate via different mechanisms and are not selected for KMT2A or NPM1 biology specifically. The decision is the treating hematologist's clinical call.

What is the typical course duration?

Dosing is continuous, twice daily, until disease progression or unacceptable toxicity. There is no fixed end point. In the AUGMENT-101 trial, median duration of complete remission (with or without full hematologic recovery) was 6.4 months in the KMT2Ar cohort, and many responders subsequently proceeded to allogeneic hematopoietic stem cell transplant. Multi-month continuous supply planning is the working assumption.

Where Reserve Meds fits in Revuforj cases

Reserve Meds is a US-based concierge coordinator. We do not replace your hematologist, do not replace the EDE or any emirate-level authority, and do not replace the dispensing hospital pharmacy. What we do is orchestrate the US-side specialty pharmacy sourcing through the Syndax-authorized SyndAccess network under DSCSA serialization with full pedigree, the international logistics under standard ambient air courier with declared-value insurance, and the documentation kit your hematologist needs for the EDE application. Because dosing is continuous twice daily on an open-ended schedule, we plan multi-month supply windows at intake. Revuforj is included in the Matrix Deepening v1 sprint as a high-priority cell precisely because the drug profile fits the brand's operating model: rare disease, novel first-in-class oncology mechanism, pediatric-eligible, ex-US-unregistered, single-source manufacturer, oral room-temperature handling.

Next step

If a UAE patient (adult or pediatric, age 1 year or older) has relapsed or refractory acute leukemia with a confirmed KMT2A translocation or susceptible NPM1 mutation, and the treating hematologist is considering Revuforj, add the case to the waitlist. We will respond within 24 to 48 hours with a documentation kit for your hematologist and an indicative cost range.

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