Idhifa access in Pakistan: the DRAP Special Permission pathway

How patients in Pakistan access Idhifa (enasidenib) for IDH2-mutated relapsed or refractory acute myeloid leukemia.

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

1. Quick orientation

Idhifa is the brand name for enasidenib, an orally bioavailable selective inhibitor of mutant isocitrate dehydrogenase-2 (IDH2) that allows leukemic blasts to resume normal differentiation rather than killing them outright. The US Food and Drug Administration granted regular approval to Idhifa on August 1, 2017 for adult patients with relapsed or refractory acute myeloid leukemia (AML) carrying an IDH2 mutation confirmed by an FDA-approved companion diagnostic. Bristol Myers Squibb is the US marketing authorisation holder following the 2019 Celgene acquisition; Servier holds ex-US development and commercial rights through its 2020 acquisition of the Agios oncology business. There is no current DRAP registration for Idhifa in Pakistan, no EMA centralised authorisation following Celgene's 2020 withdrawal, and no UK MHRA national authorisation. Pakistani patients whose treating hematologist has confirmed IDH2-mutated relapsed or refractory AML reach Idhifa through the Drug Regulatory Authority of Pakistan (DRAP) Special Permission / Personal Use Import No Objection Certificate. Reserved for you.

2. Why Pakistan patients need Idhifa via the named-patient pathway

Three patterns of access gap apply across Pakistan: a drug is on the DRAP register but the patient's hospital pharmacy does not have it on hand; a drug is registered for a different indication that the local distributor does not import in the required form; or a drug is FDA-approved but not registered in Pakistan because the patient population is small relative to the registration cost. Idhifa sits in the third pattern, with the harder structural reality that the EMA marketing authorisation application was withdrawn in early 2020, UK MHRA has issued no separate authorisation, and registration in the Middle East, India, and most of Asia is either absent or limited. There is no local stock to dispense from a Pakistani hospital pharmacy.

Three structural reasons drive Idhifa to the named-patient channel for Pakistani patients. First, the indication is biomarker-driven. Patients reach Idhifa only after IDH2 mutation testing confirms eligibility, which means the prescribing hematologist already knows the patient cannot use a substitute IDH1 inhibitor, BCL-2 inhibitor, or hypomethylating agent in place of enasidenib. Substitution is not a clinical option once the IDH2 mutation is identified. Second, the cumulative ex-US patient population is small. IDH2 mutations occur in roughly 8 to 19 percent of AML cases depending on cohort, and only a subset are in the relapsed or refractory setting. The annual Pakistani patient count is in the dozens at most, which is below the threshold at which any commercial entity will pursue local registration. Third, Pakistan's specialty pharmaceutical market is cash-pay dominant for advanced therapies. Private health insurance covers a small share of the population, and even policyholders frequently find that named-patient imports sit outside formulary coverage. Families routinely fund specialty care through pooled household resources, including overseas remittances from relatives in Saudi Arabia, the UAE, the UK, the US, and Canada.

3. The DRAP Special Permission pathway for Idhifa

DRAP regulates the import of medicines through the Quality Assurance and Laboratory Testing (QA&LT) Division's Import and Export Section, with Drug Registration Board oversight for new product registration matters. For unregistered medicines required by a specific patient, DRAP issues a Special Permission, also known as the Personal Use Import No Objection Certificate (NOC). This is the pathway a Pakistani hematologist uses when an FDA-approved oncology medicine is not registered in Pakistan. The framework covers Personal Use Import by an individual patient on physician prescription

and Special Permission for Import of Unregistered Therapeutic Goods by hospitals or institutions. Applications are filed through DRAP's Online Import and Export System (OIES) electronic portal.

A complete DRAP application for Idhifa includes the clinical justification letter from the treating hematologist (diagnosis of relapsed or refractory AML, IDH2 mutation status, prior therapies attempted, reason this specific drug is required); the treating physician's PMDC license verification with specialist registration in hematology or medical oncology; the patient identifier (CNIC for adults, B-Form for minors, passport for foreign nationals receiving treatment in Pakistan); full product details (Idhifa, enasidenib, Bristol Myers Squibb, 50 mg or 100 mg tablets in bottles of 30, requested quantity covering the minimum six-month treatment trial the label specifies); the destination dispensing facility license (hospital pharmacy license for institutional dispensing); the manufacturer or authorised distributor letter confirming the product is genuine and was sourced through the legitimate supply chain; and a chain-of-custody plan from the US source through international shipment to the dispensing facility.

The clinical justification angle for Idhifa turns on biomarker confirmation and prior-line failure. The treating hematologist documents the patient's IDH2 mutation status with explicit reference to the testing platform (the Abbott RealTime IDH2 Assay or an equivalent CLIA-certified IDH2 next-generation sequencing panel), the laboratory, and the date of the result, and confirms relapsed or refractory disease status with the prior treatment history that establishes ineligibility for the front-line setting. The letter states the planned dosing regimen (100 mg orally once daily, continuous until disease progression or unacceptable toxicity, with a minimum six-month treatment trial to allow time for the differentiation mechanism to produce clinical response). Routine DRAP personal-use cases typically clear in four to eight weeks from a complete submission; complex first-import oncology cases involving novel mechanisms can extend to ten to sixteen weeks. Reserve Meds plans on the longer end of the routine range and treats faster turnaround as upside.

4. Where Idhifa gets dispensed in Pakistan

Idhifa is a small-molecule oral tablet supplied in 50 mg and 100 mg strengths in bottles of 30 tablets, stored at controlled room temperature (20 to 25 degrees Celsius) with excursions permitted between 15 and 30 degrees Celsius. There is no refrigeration, no reconstitution, no infusion infrastructure required, and no temperature monitoring equipment in transit. The dispensing requirement is therefore a DRAP-licensed hospital outpatient pharmacy or specialty import pharmacy aligned with a hematology service capable of differentiation-syndrome surveillance, complete blood count and bilirubin monitoring, and QT-interval review for concomitant medications.

Pakistani institutions with adult hematology services that handle named-patient oncology imports as routine workflow include Aga Khan University Hospital (AKUH) in Karachi, whose Department of Oncology has eighteen full-time faculty across medical, pediatric, radiation, and palliative oncology with bone marrow transplant capability and a 24/7 pharmacy network with temperature-controlled storage; Shaukat Khanum Memorial Cancer Hospital and Research Centre (SKMCH&RC) in Lahore, Pakistan's flagship cancer hospital with established direct-import relationships with multinational manufacturers; Indus Hospital and Health Network in Karachi with strong hematology and oncology capability; Liaquat National Hospital in Karachi; Pakistan Kidney and Liver Institute (PKLI) in Lahore for bone marrow transplant integration; Combined Military Hospitals (CMH) in Rawalpindi and Lahore for military and civilian referrals; and Shifa International Hospital in Islamabad. For families whose treating hematologist is at a smaller hospital, the practical route is to partner with an AKUH, SKMCH&RC, or Indus Hospital as the dispensing facility while the treating physician retains clinical oversight, or to use a DRAP-licensed specialty importer based in Karachi or Lahore.

5. Real cost picture for Idhifa in Pakistan

The Pakistani Rupee has been volatile across the last several years. As of May 2026 the USD to PKR rate is in the 278 to 280 range, with annual CPI inflation rising to 10.9 percent in April 2026, well above the State Bank of Pakistan's 5 to 7 percent target range. Reserve Meds quotes in USD and accepts wire transfers from any USD-accessible source. Families with overseas relatives often consolidate funds in USD before disbursing. Three line items frame the cost.

First, drug cost. The manufacturer-published list price on the BMS pricing information site is approximately USD 36,034 per 30-day supply at either the 50 mg or 100 mg once-daily dose, equivalent to roughly PKR 10.05 million per 30-day pack

at the May 2026 exchange rate. A 12-month course at full label dose corresponds to roughly USD 420,000 to USD 440,000 at US WAC before any rebates. BMS Access Support US patient services and copay assistance programs do not extend to international named-patient cases.

Second, international logistics. Idhifa is room-temperature stable in standard ambient packaging with no temperature monitoring equipment, no insulated shipper, no gel packs, and no excursion-limited transit window. International logistics for an ambient shipment to Karachi or Lahore typically runs USD 400 to USD 1,000.

Third, regulatory and coordination. DRAP documentation handling fees, FBR Customs clearance, and Reserve Meds' concierge fee are itemised separately. On the insurance side, Adamjee Insurance, Jubilee General Insurance (Personal HealthCare plan), EFU Health, State Life Insurance Corporation, IGI, and Pak-Qatar Family Takaful handle in-hospital chemotherapy and radiotherapy in their formularies, but specialty imports of FDA-approved-but-not-locally-registered drugs are typically outside formulary. The realistic operating default is cash-pay for the indefinite-duration treatment trial.

6. Typical timeline for Idhifa in Pakistan

The DRAP timeline for routine Personal Use Import cases runs four to eight weeks from a complete submission; complex first-import oncology cases can extend to ten to sixteen weeks. Idhifa is an ambient oral tablet, so cold-chain transit time does not apply, which removes two to three days from a comparable cold-chain timeline. End-to-end, a typical Idhifa case in Pakistan runs as follows: 24 to 48 hours from intake to eligibility confirmation by Reserve Meds; three to seven days for the treating hematologist and the dispensing hospital's import pharmacy to assemble the application with IDH2 mutation documentation; four to eight weeks for DRAP review through the OIES portal (longer for first-time differentiation-modulator imports into the institution); three to five days for US sourcing through BMS-aligned specialty distribution under DSCSA-compliant chain-of-custody; two to four days for FBR Customs clearance at Karachi seaport or Lahore or Islamabad airport under the DRAP NOC; and final receipt and release at the dispensing pharmacy. Because Idhifa is dosed continuously until progression with a minimum six-month treatment trial, Reserve Meds plans repeat-shipment cadence and refill checkpoints at the case-acceptance stage rather than treating each 30-day bottle as a one-off.

7. What your physician needs to provide

The clinical justification letter is the cornerstone of the DRAP application. The treating Pakistani hematologist documents the diagnosis of acute myeloid leukemia with ICD-10 coding; states the IDH2 mutation status with explicit reference to the testing platform (Abbott RealTime IDH2 Assay or equivalent CLIA-certified NGS panel), the laboratory, the date, and confirmation that the mutation is on the FDA-approved Idhifa label; confirms relapsed or refractory disease status with the prior treatment history; documents the clinical rationale that no IDH1 inhibitor, BCL-2 inhibitor, or hypomethylating agent is an interchangeable substitute once the IDH2 mutation is identified; states the planned dosing regimen (100 mg orally once daily, taken at approximately the same time every day, with or without food, continuous until disease progression or unacceptable toxicity, minimum six-month treatment trial per the label); and describes the monitoring plan with particular emphasis on the boxed warning for differentiation syndrome.

The monitoring stack includes vigilance for differentiation syndrome at every visit (fever, dyspnea, hypoxia, pulmonary infiltrates, pleural or pericardial effusion, rapid weight gain, peripheral oedema, renal dysfunction) with vigilance highest in the first three months and corticosteroids and hemodynamic monitoring initiated for any confirmed case; complete blood count and chemistries including bilirubin at baseline and at least monthly; QT-interval monitoring given the label-noted concomitant medication considerations; leukocytosis management with hydroxyurea when needed without dose interruption; and dose reduction to 50 mg once daily for Grade 3 or 4 hyperbilirubinemia not attributable to differentiation syndrome.

The letter is co-filed with the physician's PMDC license verification, the institutional pharmacy license, the requested pack count covering the minimum six-month trial with refill plan, and the chain-of-custody plan for the ambient shipment to the dispensing site. Post-import, the treating physician and dispensing pharmacy commit to adverse-event reporting through the DRAP Pharmacovigilance Centre for the full course of therapy.

8. Common questions about Idhifa in Pakistan

Will Adamjee, Jubilee, EFU, or State Life cover Idhifa? 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. We supply the documentation the insurer needs to assess the claim; the claim itself is yours or your hospital's to file. The realistic default is cash-pay.

How does Sehat Sahulat interact with named-patient Idhifa imports? The Sehat Sahulat Program's Rs. 1,000,000 per family per year ceiling typically does not stretch to cover the cost of US-sourced specialty oncology therapies at the Idhifa price point, and the program is generally structured around in-network empaneled hospital treatment rather than imported drug procurement. Patients can still use Sehat Sahulat for hospitalisation and supportive care while Idhifa is procured separately on a cash-pay basis.

Will my PMDC-licensed hematologist's letter be sufficient if DRAP queries the case? Yes. PMDC-licensed hematologists and medical oncologists at AKUH, SKMCH&RC, Indus Hospital, Liaquat National, PKLI, CMH, and Shifa International all have signing authority on Personal Use Import applications. The clinical justification letter is the cornerstone; DRAP may request additional clarification on the prior-line failure history or the differentiation-syndrome monitoring plan and the treating physician answers those queries directly.

What is the safety profile? Idhifa carries a boxed warning for differentiation syndrome, which can be fatal if not recognised and treated. Symptoms include fever, dyspnea, hypoxia, pulmonary infiltrates, pleural or pericardial effusion, rapid weight gain, peripheral oedema, and renal dysfunction. Other common adverse reactions include nausea, vomiting, decreased appetite, hyperbilirubinemia (indirect), and elevated transaminases. There is no REMS program for Idhifa; the boxed warning is managed through prescriber education and the label monitoring schedule.

Why this drug versus a venetoclax-based regimen? Reserve Meds does not endorse one regimen over another. Selection between Idhifa and other options rests with the treating hematologist based on prior therapy, performance status, mutation profile, and patient preference. For IDH2-mutated relapsed or refractory AML, enasidenib is the only FDA-approved IDH2-selective inhibitor. Ivosidenib (Tibsovo) targets IDH1 and is not interchangeable.

What is the typical course duration? Continuous daily dosing until disease progression or intolerance. The label specifies a minimum six-month trial before declaring lack of response, given that the mechanism is differentiation rather than cytoreduction and responses are typically delayed (median time to first response approximately 1.9 months, median time to best response approximately 3.7 months in the AG221-C-001 trial).

9. Where Reserve Meds fits in Idhifa cases

Reserve Meds is a US-based concierge coordinator. We do not replace your treating hematologist, DRAP, the dispensing hospital pharmacy or specialty importer, or your insurer. What we do for an Idhifa case is verify eligibility within 24 to 48 hours; supply your physician's team with a documentation kit referencing the FDA prescribing information, the 100 mg once-daily continuous dosing schedule, the IDH2 biomarker framing, the differentiation-syndrome monitoring stack, and the minimum six-month treatment trial; align US-side sourcing through BMS-aligned specialty distribution under DSCSA-compliant chain-of-custody; coordinate ambient shipment with a qualified specialty 3PL; and provide a single named Patient Concierge Coordinator across the multi-month treatment trial and any refill shipments. Because Idhifa is room-temperature stable, biomarker-driven, and has a clearly absent local registration story across the SAARC region, the case complexity sits in regulatory documentation and clinical continuity rather than in physical logistics. No prior Reserve Meds case experience predates this page; standard NPP coordination applies.

10. Next step

If your Pakistani hematologist has confirmed IDH2-mutated relapsed or refractory AML and recommends Idhifa, start the request and we will reach out within 24 to 48 hours.

Reserved for you.

Review & oversight. Content on this page is reviewed by Reserve Meds's clinical and regulatory team. A US-licensed pharmacist reviews every prescription before dispensing. Regulatory posture is informational, not legal advice; case-specific questions route to retained outside counsel. Review methodology ›

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