Idhifa access in India: the CDSCO Rule 36 named-patient pathway

How patients in India access Idhifa (enasidenib) for IDH2-mutated relapsed or refractory acute myeloid leukemia when the medicine is not locally registered.

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

1. Quick orientation

Idhifa is the brand name for enasidenib, an oral once-daily small-molecule inhibitor of mutant isocitrate dehydrogenase-2 (IDH2). The US Food and Drug Administration granted regular approval on 1 August 2017 for adults with relapsed or refractory acute myeloid leukemia (AML) carrying a confirmed IDH2 mutation, as detected by an FDA-approved companion diagnostic. In India, Idhifa is not registered with the Central Drugs Standard Control Organization (CDSCO). Patients with biopsy-confirmed IDH2-mutated relapsed or refractory AML reach the medicine through Rule 36 of the Drugs and Cosmetics Rules 1945, administered by the office of the Drugs Controller General of India (DCGI), using Form 12A to apply for a Form 12B permit. The pathway is documented, accessible, and well used at India's tertiary specialty centres. Reserved for you.

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

India has the deepest tertiary specialty hospital network of any Reserve Meds priority country and supplies a significant share of the world's generic medicines. Yet for a specific group of US-sourced specialty drugs, families in India still hit an access wall. Three patterns of access gap repeat: registered but not stocked, registered for a different indication, or not registered locally at all. Idhifa is firmly in the third pattern.

Servier holds the ex-US commercial rights for enasidenib after acquiring Agios's oncology business for USD 1.8 billion in May 2020. The European Medicines Agency application was withdrawn by Celgene in early 2020, after EMA review identified unresolved questions following the assessment cycle. Servier has not refiled centrally as of the most recent public disclosures, and CDSCO has no current registration of Idhifa. There is no local stock to dispense from a domestic pharmacy. The cumulative Indian patient population for IDH2-mutated relapsed or refractory AML in any one year is in the dozens rather than the hundreds, which sits below the threshold at which a commercial entity typically pursues local registration.

The clinical case for the Rule 36 pathway is unusually clean for Idhifa. Enasidenib is the only FDA-approved IDH2-selective inhibitor. Ivosidenib (Tibsovo) targets IDH1 and is not interchangeable. Venetoclax-based regimens and hypomethylating agents work through different mechanisms in different clinical settings. Once the IDH2 mutation is confirmed on the Abbott RealTime IDH2 Assay companion diagnostic or an equivalent CLIA-certified IDH2 next-generation sequencing panel, substitution to a locally registered alternative is not a clinical option. That fact carries the medical-necessity narrative for the Form 12A filing.

3. The CDSCO Rule 36 named-patient pathway for Idhifa

The legal foundation for personal import of unregistered medicines into India is Rule 36 of the Drugs and Cosmetics Rules 1945. Rule 36 permits import of a small quantity of a drug, whose import would otherwise be prohibited under Section 10 of the Drugs and Cosmetics Act 1940, for the exclusive personal use of a named patient.

The mechanism is documented and accessible. Form 12A is the application for a permit, made under the second proviso to Rule 36. Form 12B is the permit itself, issued by the office of the Drugs Controller General of India (DCGI) at FDA

Bhawan, Kotla Road, New Delhi, or by designated CDSCO Port Offices. The application is accompanied by a prescription from a Registered Medical Practitioner (RMP) showing the RMP's National Medical Commission (NMC) registration number and the quantity required for treatment. The quantity of any single drug imported shall not exceed one hundred average doses per application.

For institutional Compassionate Use where the drug is not approved for marketing in India at all, the parallel pathway is the Compassionate Use application route to the DCGI by a government hospital, a registered medical practitioner, a pharmaceutical company, or the patient. This route is used when the drug is approved by a recognised reference authority such as the FDA for a life-threatening condition. Idhifa fits the criteria, and AIIMS and Tata Memorial Centre have established workflow for this route.

A complete CDSCO application for Idhifa typically includes:

- A clinical justification letter (diagnosis, IDH2 mutation status, prior therapies tried and failed, the specific reason this product is required)
- The treating hematologist's NMC registration number and state-council registration where required
- A patient identifier and supporting medical records
- Product details: Idhifa, enasidenib, Bristol Myers Squibb, 100 mg tablets, bottle of 30, quantity sufficient for the planned treatment cycle
- The dispensing facility's drug licence (hospital pharmacy, or specialty importer's wholesale licence)
- A chain-of-custody plan from the US specialty distributor to the dispensing pharmacy in India

The clinical-justification angle that matters most for Idhifa is biomarker confirmation. The treating hematologist documents the IDH2 mutation on the pathology report, states the relapse or refractory status against prior therapy (induction regimen, hypomethylating agent or venetoclax-based combination, allogeneic stem cell transplant where applicable), and explicitly notes that no IDH2-selective inhibitor is registered in India and that an IDH1 inhibitor is not substitutable for IDH2-mutated disease. CDSCO published guidance states the Form 12B permit is issued on a priority basis, typically within one to two days for routine applications where the documentation is complete. In practice, families and hospitals plan for a two to four week window from physician decision to dispensed medicine, because the bulk of the elapsed time is upstream documentation assembly and downstream international logistics rather than the regulator's stamp.

4. Where Idhifa gets dispensed in India

Idhifa is an oral oncology product. It does not require infusion infrastructure, cold-chain storage, or cell-therapy capability. The dispensing requirement is a CDSCO-licensed hospital outpatient pharmacy or a licensed specialty importer, paired with an NMC-registered hematologist supervising the case.

Indian tertiary institutions that handle named-patient hematology imports as established workflow include the All India Institute of Medical Sciences (AIIMS), New Delhi, the apex public-sector institution and a designated Centre of Excellence under the National Policy for Rare Diseases; Tata Memorial Centre, Mumbai, India's largest cancer institute and anchor of the National Cancer Grid; Apollo Hospitals at Chennai, Delhi, Bangalore, Hyderabad, and Kolkata, JCI and NABH accredited with dedicated international patient services; Fortis Memorial Research Institute in Gurgaon and other Fortis Healthcare flagship sites in Mumbai and Bangalore with strong oncology and bone marrow transplant programs; Medanta The Medicity in Gurgaon with established rare-disease activity; Kokilaben Dhirubhai Ambani Hospital in Mumbai with advanced cancer and BMT capability; Christian Medical College (CMC) Vellore, globally recognised for hematology and oncology; and Manipal Hospitals Bangalore with active hematology programs.

For physicians at smaller institutions without an import pharmacy desk, the practical route is to work with one of the centres above, or with a CDSCO-licensed specialty importer in Mumbai, Delhi, or Bangalore that handles the Form 12A filing and chain-of-custody documentation on behalf of the prescribing physician.

5. Real cost picture for Idhifa in India

Costs sit in INR with the rupee floating against the US dollar. In May 2026 the USD/INR rate is in the 94 to 95 range, with the rupee having weakened modestly against the dollar over the prior twelve months. Three line items frame the case economics.

First, drug cost. The Bristol Myers Squibb US wholesale acquisition cost for Idhifa is approximately USD 36,034 per 30-day supply at the 100 mg once-daily dose, which corresponds to roughly INR 33.9 to INR 34.2 lakh per month at the prevailing exchange rate. Drugs.com price-guide data shows 30 tablets of 50 mg branded Idhifa at roughly USD 35,000, consistent with the BMS-published figure. A 12-month course at full label dose runs to approximately USD 420,000 to USD 440,000 (INR 4.0 to INR 4.2 crore) before any rebates, copay assistance, or 340B pricing, which are US-only programmes that do not extend to international patients.

Second, international logistics. Idhifa is a small-molecule oral tablet, room-temperature stable at 20 to 25 degrees Celsius with permitted excursions between 15 and 30 degrees Celsius. International logistics for an ambient shipment to India typically runs USD 400 to USD 1,500 (approximately INR 38,000 to INR 1.4 lakh) depending on destination city and urgency window. No gel packs, no temperature loggers, no cold-chain quarantine risk.

Third, regulatory and coordination. India's Union Budget 2026-27 expanded the list of life-saving drugs and rare-disease drugs eligible for customs duty exemption, including a notable expansion in cancer medicines. GST on most life-saving medicines is 5 percent; the specific HSN code and exemption status of each Idhifa shipment is confirmed at the documentation stage. On the insurance side, Star Health and Allied Insurance, HDFC ERGO, ICICI Lombard, and Niva Bupa each assess named-patient imports case by case and none reimburses a Rule 36 personal import as a standard line item. CGHS provides for life-saving and anti-cancer medicines not in the standard formulary to be considered by an Expert Committee under the Special DG (DGHS) on a case-by-case basis, with stricter constraints on drugs not approved by DCGI. Cash-pay is the default posture; the documentation kit is structured so the patient or hospital can pursue reimbursement after the fact if the plan allows.

6. Typical timeline for Idhifa in India

CDSCO's published guidance states the Form 12B permit is issued on a priority basis, typically within one to two days for routine applications where the documentation is complete. Idhifa is an ambient small-molecule product, which removes the cold-chain transit window from the timeline. End-to-end, a typical Idhifa case in India runs as follows: 24 to 48 hours from intake to eligibility confirmation by Reserve Meds; 3 to 7 days for the treating hematologist and the hospital pharmacy or specialty importer to assemble the application and IDH2 biomarker documentation; one to two business days for routine DCGI review of a complete Form 12A; 3 to 5 days for US sourcing, release documentation, and ambient courier shipment; 1 to 2 days for customs clearance under the Form 12B permit; and final verification and dispense at the hospital pharmacy. The FDA label specifies a minimum six-month trial of Idhifa because the differentiation mechanism produces delayed responses, with median time to first response of approximately 1.9 months and median time to best response of approximately 3.7 months, so supply cadence is planned for repeat shipments from the first case.

7. What your physician needs to provide

The clinical justification letter is the cornerstone of the Form 12A application for Idhifa. The treating Indian hematologist documents the patient's diagnosis as relapsed or refractory acute myeloid leukemia; states the IDH2 mutation status with explicit reference to the testing platform (Abbott RealTime IDH2 Assay or an equivalent CLIA-certified IDH2 next-generation sequencing panel) and the date of the pathology report; itemises prior lines of therapy with response and relapse documentation; states the reason a locally registered alternative is not suitable (the only FDA-approved IDH2-selective inhibitor is Idhifa; IDH1 inhibitors are not interchangeable for IDH2-mutated disease; venetoclax-based regimens, hypomethylating agents, and intensive chemotherapy work through different mechanisms and are options in different clinical settings); states the planned dosing regimen as 100 mg orally once daily continuous, taken at approximately the same time every day, with or without food, until disease progression or unacceptable toxicity, with a minimum six-month

trial per the FDA label given the differentiation mechanism; and describes the monitoring plan, including vigilance for differentiation syndrome at every visit (the boxed warning), complete blood count and chemistries including bilirubin at baseline and at least monthly, QT interval monitoring where concomitant medication considerations apply, and management of leukocytosis with hydroxyurea without dose interruption when needed.

The letter is co-filed with the physician's NMC registration number and state-council registration where required, the dispensing facility's drug licence (hospital pharmacy or specialty importer wholesale licence), the requested pack and quantity (Idhifa 100 mg tablets, bottle of 30, typically a 30-day supply per bottle, capped at one hundred average doses per Form 12A application), and the chain-of-custody plan describing how the medicine will move from the US specialty distributor through the importer to the hospital pharmacy. Pharmacovigilance Programme of India (PvPI) reporting through the Indian Pharmacopoeia Commission applies for the duration of therapy and is the prescribing physician's obligation.

8. Common questions about Idhifa in India

Will Star Health, HDFC ERGO, ICICI Lombard, or Niva Bupa cover the cost? Each insurer assesses named-patient imports case by case. None of the major private insurers reimburse a Rule 36 personal import as a standard line item. Some have reimbursed full or partial drug cost when the underlying medicine is on their formulary and the import route was a stocking workaround. We supply the documentation that lets the insurer evaluate; the claim itself is filed by the patient or the hospital.

Will my CGHS or ESIC entitlement cover this? CGHS provides for life-saving and anti-cancer medicines not in the standard formulary to be considered by an Expert Committee under Special DG (DGHS), case by case. Drugs not approved by the DCGI for use in India face a stricter Expert Committee review. ESIC's formulary is narrower. Neither scheme is structured for routine personal-import reimbursement; check eligibility with your CGHS Wellness Centre or the ESIC dispensary before assuming coverage.

Will my NMC-registered hematologist's letter be sufficient? Yes. Any Registered Medical Practitioner with a valid NMC registration number can support a Form 12A application. Hematologists at AIIMS, Tata Memorial, Apollo, Fortis, Medanta, Kokilaben, CMC Vellore, and Manipal sign these letters as part of established institutional workflow.

Is the IDH2 mutation test available in India? Yes. Major Indian oncology pathology services run IDH2 mutation testing on CLIA-equivalent next-generation sequencing panels. Where a patient has had testing at a US, UK, or other reference laboratory, that pathology report is accepted in the Form 12A filing.

What is the safety profile I should know about? 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. The boxed warning is managed through prescriber education and the label rather than through a restricted-distribution REMS programme.

Is Idhifa a controlled substance? No. Idhifa is not on the US DEA schedule and is not a controlled substance under Indian law. Narcotics Control Bureau coordination does not apply. The standard Rule 36 Form 12A and Form 12B permit is the operative framework.

9. Where Reserve Meds fits in Idhifa cases

Reserve Meds is a US-based concierge coordinator. We do not replace your treating hematologist, the DCGI, the dispensing hospital pharmacy or licensed 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 BMS prescribing information, the IDH2 biomarker requirements, and the Form 12A application format; align the US-side sourcing through DSCSA-compliant US specialty distributors with the Indian dispensing pharmacy or specialty importer; coordinate the ambient courier shipment under chain-of-custody documentation; and provide a single named coordinator across the case, regardless of how many Indian cities the family touches. The Reserve Meds operating model maps cleanly onto Idhifa: room-temperature handling, no infusion or reconstitution, biomarker-confirmed eligibility that simplifies the medical-necessity narrative for the DCGI

filing, and a clearly absent local registration story. No prior Reserve Meds case experience predates this page; standard NPP coordination applies.

10. Next step

If your Indian 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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