Gavreto access in India

How Indian patients with RET fusion-positive non-small cell lung cancer and RET-mutant thyroid cancers pursue Gavreto (pralsetinib), a selective RET kinase inhibitor.

Last reviewed 2026-05-12 by Reserve Meds clinical & regulatory team. This page combines the India country regulatory module with the Gavreto drug module to describe the path families actually walk.

Quick orientation

Gavreto (pralsetinib) is a selective RET (rearranged during transfection) kinase inhibitor approved by the US Food and Drug Administration in September 2020 for RET fusion-positive metastatic non-small cell lung cancer, in December 2020 for RET-mutant medullary thyroid cancer in patients 12 years and older, and for RET fusion-positive thyroid cancers refractory to radioactive iodine. The product is marketed approximately by Genentech in collaboration with Blueprint Medicines. Pralsetinib has shown durable response rates in molecularly selected patients with RET-altered tumours and is a precision oncology option distinct from broader multi-kinase tyrosine kinase inhibitors. Reserved for you.

Why this drug is hard to source in India

RET fusion-positive NSCLC accounts for approximately 1 to 2% of non-small cell lung cancers, and RET-mutant medullary thyroid cancers are individually rare but clinically distinct. Indian molecular pathology capability for RET testing has grown rapidly through Tata Memorial Centre, AIIMS, Apollo, and major reference laboratories, and clinically significant RET-altered cases are increasingly identified at diagnosis or progression. The access wall for Gavreto in India is that the originator product does not have a current Indian marketing authorisation through CDSCO as of this review date, and the commercial launch sequence has prioritised the United States and select reference markets. The competing selective RET inhibitor selpercatinib (Retevmo) has similar global access dynamics. Patients identified with a RET fusion or mutation whose treating oncologist judges that selective RET targeting is the appropriate next line typically reach the import pathway for one or both of these products.

The CDSCO personal-import pathway under Rule 36

The legal foundation for personal import of an unregistered medicine 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. Form 12A is the application; Form 12B is the permit issued by the office of the Drugs Controller General of India at FDA Bhawan in New Delhi. The application is accompanied by a prescription from a Registered Medical Practitioner showing the practitioner's NMC registration number, with the quantity capped at one hundred average doses per application. For Gavreto, the clinical justification letter documents the molecular pathology confirming the RET alteration (fusion partner and method, or mutation), the tumour type and stage, the prior systemic therapy course, the rationale for selective RET inhibition, and the planned monitoring schedule.

Real costs in INR and USD

The US wholesale acquisition cost for Gavreto is approximately USD 22,000 to 24,000 per 30-day supply at the standard adult dose of 400 mg once daily. In INR at the prevailing 94 to 95 range, that translates to approximately INR 20.7 lakh to 22.7 lakh per month. An Indian-made generic of pralsetinib does not exist as of this review date; the molecule is under patent protection and a domestic generic pathway has not been initiated. Indian Union Budget 2026-27 expanded the customs duty exemption list for cancer medicines, and several oncology drugs were named for full basic customs duty exemption. The specific exemption status of a Gavreto shipment is confirmed at the documentation stage.

Timing, what to expect

From physician decision to dispensed product, a routine Gavreto import case runs two to four weeks. Documentation assembly including the molecular pathology report takes three to five business days. The Form 12B permit issues in one to two business days on the priority timeline. US-side sourcing and shipment runs one to two weeks. For ongoing supply on continuous daily dosing, Reserve Meds aligns refill cycles to a four to six week reorder rhythm.

What your physician needs

The clinical justification letter for a Gavreto Form 12A submission documents the tumour type (RET fusion-positive NSCLC, RET-mutant medullary thyroid cancer, or RET fusion-positive radioactive iodine-refractory thyroid cancer), the molecular pathology report confirming the RET alteration with the fusion partner where applicable, the stage and disease burden, the prior systemic therapy course, the rationale for selective RET inhibition

versus alternatives, the dosing plan, and the planned monitoring schedule including liver function, blood pressure, complete blood count, and pneumonitis surveillance. The treating oncologist's NMC registration number appears on the prescription.

Customs clearance and IOR

Customs at the port of entry reviews the Form 12B permit, the commercial documentation, and the importer's drug licence. The Importer of Record is the licensed dispensing facility or specialty importer holding the wholesale drug licence under the Drugs and Cosmetics Rules. Reserve Meds does not act as the IOR. Gavreto capsules ship ambient and do not require cold-chain handling.

Pharmacovigilance

India operates the Pharmacovigilance Programme of India (PvPI) coordinated by the Indian Pharmacopoeia Commission. Treating physicians report adverse events through PvPI. For pralsetinib specifically, key adverse events tracked in the US post-marketing experience include pneumonitis, hypertension, hepatotoxicity, hemorrhagic events, and tumour lysis syndrome in highly responsive patients. The prescribing oncologist's monitoring schedule is documented in the Form 12A clinical justification letter.

Where Reserve Meds fits

Reserve Meds is a US-based concierge coordinator. We do not replace the treating oncologist, CDSCO, the hospital pharmacy, or the licensed importer. For a Gavreto case, our work is US-side sourcing, documentation orchestration, logistics coordination, and a single named coordinator through the first import cycle and into the ongoing refill rhythm.

Next step

If a treating oncologist in India is weighing Gavreto for a patient with a confirmed RET alteration, the waitlist is the first step. We respond within 24 to 48 hours with an eligibility confirmation and a documentation kit for the physician.

Reserved for you.

Related

- Gavreto clinical resource
- India country page

- CDSCO personal-import pathway

Sources

1. FDA approval, Gavreto (pralsetinib), Genentech/Blueprint Medicines, NDA approval September 2020 for RET fusion-positive NSCLC and December 2020 for RET-altered thyroid cancers.
2. CDSCO, Procedure for Permission to Import Small Quantities of Drugs for Personal Use (Form 12A / Form 12B under Rule 36, Drugs and Cosmetics Rules 1945).
3. Indian Pharmacopoeia Commission, Pharmacovigilance Programme of India (PvPI) reporting framework.

Common questions Indian families ask

Will Star Health, HDFC ERGO, ICICI Lombard, or Niva Bupa cover this? Each Indian private 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 where the underlying medicine is on the formulary and the named-patient route operated as a stocking workaround. Reserve Meds supplies the documentation that lets your insurer evaluate. The claim itself is filed by the patient or the hospital. Cash-pay remains the default posture for Reserve Meds patient cases.

Will my CGHS or ESIC entitlement cover this? CGHS (Central Government Health Scheme) provides for life-saving and anti-cancer medicines not in the standard formulary to be considered case by case by an Expert Committee under the Special DG (DGHS) where the prescribing specialist documents the requirement. 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 AIIMS, Tata Memorial, Apollo, Fortis, Medanta, Kokilaben, MGM, CMC Vellore, or Manipal physician's letter be sufficient? Yes. A Registered Medical Practitioner with a valid National Medical Commission registration number can support a Form 12A application. Physicians at AIIMS, Tata Memorial Centre, government medical colleges, and state-run tertiary hospitals routinely do so. Private-sector specialists at Apollo, Fortis, Medanta, Kokilaben Dhirubhai Ambani Hospital, MGM Healthcare, CMC Vellore, and Manipal Hospitals also have signing authority subject to their institutional drug licence.

What if my treating institution does not have an import pharmacy desk? The practical route is to work with one of the named tertiary centres that handles compassionate and named-patient imports as established workflow, or with a CDSCO-licensed specialty importer in Mumbai, Delhi, or Bangalore that handles the documentation and chain-of-

custody on behalf of smaller hospitals or independent specialists. Reserve Meds aligns with the importer named on the Form 12B permit.

Can I receive the drug at home, or do I need a hospital? The dispensing facility must hold a valid drug licence under the Drugs and Cosmetics Rules. For oral medicines, a hospital outpatient pharmacy or a licensed import pharmacy is the dispensing point. For infusion products, the medicine ships to the infusion centre where the patient will receive it. Direct-to-home delivery outside a licensed dispensing facility is not the model.

What about pediatric patients? The Rule 36 framework applies the same way for pediatric patients. The clinical justification letter typically includes weight-adjusted dosing and pediatric-specific monitoring. AIIMS, Tata Memorial, Apollo, Kokilaben, and CMC Vellore handle pediatric named-patient imports routinely. Where the indication is approved in adults only, the off-label use is the physician's clinical judgement and is documented as such in the Form 12A letter.

Does FCRA affect a patient case? The Foreign Contribution (Regulation) Act 2010 (FCRA), as proposed to be amended by the Foreign Contribution (Regulation) Amendment Bill 2026, regulates foreign donations to Indian organisations and individuals. For a patient family paying for the medicine themselves, FCRA is generally not engaged. Where a foreign foundation or diaspora group is funding a treatment, FCRA registration of the recipient organisation and the donation route can become relevant; the structure should be reviewed with counsel before funds move. Reserve Meds does not provide FCRA legal advice; we flag the question so it reaches the right adviser early.

What is the role of the Indian Pharmacopoeia Commission? The Indian Pharmacopoeia Commission coordinates the Pharmacovigilance Programme of India (PvPI) and publishes the Indian Pharmacopoeia, the legal compendium of pharmaceutical standards in India. For imported originator products under Rule 36, the PvPI reporting framework applies to adverse event surveillance, and the prescribing physician is the reporting party. The Indian Pharmacopoeia is the reference standard against which Indian-manufactured products are tested; imported originator products carry their reference-country pharmacopoeial standards (typically USP for FDA-approved products).

How does this compare with access in the UAE or Saudi Arabia? India's Rule 36 framework with the published Form 12B priority timeline (one to two business days for routine documentation) is often faster than the SFDA Personal Importation Program in Saudi Arabia (typically 10 to 21 business days routine) and broadly comparable to the UAE Emirates Drug Establishment pathway. India's offsetting friction is the customs and logistics layer rather than the regulator's stamp. India's tertiary specialty hospital depth substantially exceeds any single peer country in the South Asia and GCC region, which usually offsets the longer end-to-end cycle for complex cases.

What documentation does my family need to assemble before contacting Reserve Meds? The minimum useful package is the treating physician's name and registration number, the patient's diagnosis and current treatment summary, recent relevant investigations (imaging, biopsy, molecular pathology, blood work as applicable), and a contact pathway to the dispensing facility you intend to use. With that package, Reserve Meds can complete eligibility within 24 to 48 hours and route the documentation kit to your physician.

How Indian families coordinate across cities and countries

For Indian families, the coordination problem is often distributed across multiple cities and sometimes multiple countries. A grandmother in Hyderabad, an oncologist at Tata Memorial in Mumbai, an adult child in Bangalore managing logistics, and a son in Dubai or London paying the invoice is a common configuration. The Reserve Meds single named coordinator model is built for exactly this pattern. One coordinator carries the case file, one chain of correspondence captures the decisions and documents, and one set of contact records reaches every family member who needs visibility into the case, regardless of how many cities the family touches or how many time zones the case spans. The Reserve Meds patient portal at portal.reservemeds.com holds the document set and the case timeline; the coordinator handles the email, phone, and WhatsApp follow-through that the case needs at each step.

For smaller cities where the local hospital does not maintain an import pharmacy desk, the practical route is to work with a CDSCO-licensed specialty importer in Mumbai, Delhi, Bangalore, Chennai, or Hyderabad. The importer carries the CDSCO relationship, the customs broker relationship, and the chain-of-custody documentation. Reserve Meds aligns with the importer on US-side sourcing and with the treating physician on clinical documentation. The patient sees one face throughout, which is the named coordinator.

The patient experience, step by step

From the family side, the sequence looks like this. Your physician decides this drug is the right next step. That is a clinical decision and stays with them. Your physician or the hospital pharmacy team reaches out to Reserve Meds, or the patient submits a request through the Reserve Meds portal and Reserve Meds connects with the physician. Reserve Meds confirms eligibility within 24 to 48 hours and sends a documentation kit to your physician, including the Form 12A reference, the clinical justification letter template, and the chain-of-custody plan. Your physician completes the documentation, attaches the prescription with their NMC registration number, and the application goes to CDSCO through the appropriate port office or the DCGI New Delhi office, or via the hospital's licensed importer. The Form 12B permit issues on the documented priority timeline. While

the permit issues, Reserve Meds aligns US-side sourcing and the shipment plan with the dispensing pharmacy. The shipment moves cold-chain or ambient as appropriate. Customs at the destination port reviews the permit and clears the consignment. The dispensing pharmacy receives, logs, and stores the medicine according to its drug licence requirements. Your physician initiates therapy. Adverse event reporting through PvPI continues for the duration of therapy.

Review and oversight. Content on this page is reviewed by the Reserve Meds 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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