Tagrisso access in India

How Indian patients with EGFR-mutated non-small cell lung cancer access Tagrisso (osimertinib), the third-generation EGFR tyrosine kinase inhibitor.

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

Quick orientation

Tagrisso (osimertinib) is a third-generation oral EGFR tyrosine kinase inhibitor approved by the US Food and Drug Administration originally in November 2015 for EGFR T790M-positive metastatic non-small cell lung cancer (NSCLC), with subsequent approvals expanding to first-line treatment of EGFR exon 19 deletion or L858R mutation metastatic NSCLC, adjuvant treatment after tumour resection in early-stage EGFR-mutant disease, and combinations in select settings. The product is marketed approximately by AstraZeneca. Osimertinib has central nervous system activity and has changed first-line standard of care for EGFR-mutant NSCLC. The standard dose is 80 mg once daily. Reserved for you.

Why this drug is hard to source in India (originator vs Indian-made versions)

Osimertinib is registered in India through AstraZeneca's local affiliate, and the originator brand has been available in India for several years. Beyond the originator, the access landscape in India for osimertinib is unusual. Court decisions and patent compulsory licence proceedings, combined with separate manufacturing through Indian pharmaceutical companies under varying legal interpretations, have meant that lower-priced Indian-made versions of osimertinib have circulated in the Indian market and through cross-border channels into other jurisdictions. The legal and regulatory status of each specific Indian-made version of osimertinib is case-dependent, and treating oncologists vary in their comfort prescribing non-originator versions. For Indian patients pursuing the originator AstraZeneca product specifically, either because of treating-team preference, clinical research enrollment, or a stability-of-supply consideration, the import pathway is the route to the US-sourced originator. For Indian patients prescribed an Indian-made version by their treating oncologist, the local supply chain is the route and Reserve Meds does not have a role.

The CDSCO personal-import pathway under Rule 36

Where the originator US Tagrisso product is the right answer, the legal foundation for import 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. The application is accompanied by a prescription from a Registered Medical Practitioner showing the practitioner's NMC registration number. The Form 12A justification specifically addresses why the named patient requires the US originator product rather than an Indian-registered alternative.

Real costs in INR and USD

The US wholesale acquisition cost for Tagrisso is approximately USD 18,000 to 20,000 per 30-day supply at the 80 mg dose. In INR at the prevailing 94 to 95 range, the originator US product imported into India translates to approximately INR 16.9 lakh to 19 lakh per month. The originator AstraZeneca brand in India has historically been priced meaningfully below US pricing at approximately INR 1.5 lakh to 2 lakh per month at the 80 mg dose, depending on patient assistance programs and market dynamics. Indian-made non-originator versions of osimertinib have been documented in the Indian market at substantially lower prices, with the legal and regulatory status of each version varying. The cost differential between the US originator and the Indian-registered AstraZeneca brand is the principal consideration; for most Indian patients, the India-supplied AstraZeneca product is the rational originator-quality choice. Reserve Meds operates with full price transparency.

Timing, what to expect

For a US-sourced originator Tagrisso import case, the timeline runs two to four weeks from physician decision to dispensed product. The Form 12B permit issues on the CDSCO documented one to two business day priority timeline. Documentation assembly takes three to five business days. US-side sourcing and shipment runs one to two weeks. For ongoing daily dosing, Reserve Meds aligns refill cycles to a four to six week reorder rhythm.

What your physician needs

The clinical justification letter documents the NSCLC diagnosis with stage and disease burden, the molecular pathology report confirming the EGFR sensitising mutation (exon 19 deletion, L858R, T790M after prior therapy, or other relevant variant), the treatment line and prior therapy course, the specific reason US originator product is required rather than the India-registered originator or the Indian-made alternatives, the dosing plan, and the

planned monitoring schedule including pneumonitis surveillance, cardiac function (QTc and LVEF), and other osimertinib-specific monitoring. 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. Tagrisso tablets ship ambient and do not require cold-chain handling.

Pharmacovigilance

India operates the Pharmacovigilance Programme of India (PvPI) coordinated by the Indian Pharmacopoeia Commission. For osimertinib, the principal post-marketing safety concerns are interstitial lung disease and pneumonitis, QT interval prolongation, cardiomyopathy, keratitis, and cutaneous adverse reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis. 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. For Tagrisso in India, our role is narrow. We orchestrate US-sourced originator import only where a specific reason justifies the US channel over the India-registered AstraZeneca brand. For most Indian patients with EGFR-mutated NSCLC, the locally registered AstraZeneca Tagrisso product is the rational originator-quality choice.

Next step

If there is a specific reason the US-sourced originator Tagrisso is required for a patient in India, the waitlist is the first step. We respond within 24 to 48 hours with an eligibility confirmation, and we will be candid if the case is better served by the India-registered AstraZeneca brand.

Reserved for you.

Related

- Tagrisso clinical resource
- India country page

- CDSCO personal-import pathway

Sources

1. FDA approval, Tagrisso (osimertinib), AstraZeneca, NDA approval November 2015 for EGFR T790M-positive metastatic NSCLC with subsequent expansions in first-line and adjuvant settings.
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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