

Olumiant access in India

How Indian patients with rheumatoid arthritis, severe alopecia areata, and select hospitalised COVID-19 patients access Olumiant (baricitinib), an oral JAK inhibitor.

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

Quick orientation

Olumiant (baricitinib) is an oral selective Janus kinase (JAK1 and JAK2) inhibitor. It was approved by the US Food and Drug Administration in May 2018 for adults with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies; the FDA approval expanded in June 2022 for severe alopecia areata in adults, and an emergency use authorisation followed by full approval covers hospitalised COVID-19 patients requiring supplemental oxygen, mechanical ventilation, or extracorporeal membrane oxygenation. The product is marketed approximately by Eli Lilly under licence from Incyte Corporation. The standard rheumatology dose is 2 mg once daily, with 4 mg used in alopecia areata. Reserved for you.

Why this drug is hard to source in India (originator vs generic)

Baricitinib is registered in India and Indian-made generic versions of baricitinib are available through CDSCO-approved domestic manufacturers, particularly following the surge in JAK inhibitor demand during the COVID-19 pandemic when several Indian generics entered the market under voluntary licence and compulsory licence frameworks. For most Indian patients with rheumatoid arthritis, severe alopecia areata, or eligible COVID-19 indications, a domestically manufactured baricitinib generic prescribed by their physician is the practical choice at a fraction of US originator pricing. The Reserve Meds access conversation for Olumiant in India therefore applies in narrow circumstances: international patients temporarily resident in India who have been stabilised on the originator US product, patients enrolled in multinational clinical research tied to the originator, or patients whose physician has a specific reason to prefer originator pharmacokinetic and excipient consistency.

The CDSCO personal-import pathway under Rule 36

Where the originator US 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 originator US product rather than a locally registered generic alternative.

Real costs in INR and USD

The US wholesale acquisition cost for Olumiant is approximately USD 4,800 to 5,400 per 30-day supply at the 2 mg dose, with the 4 mg dose used in alopecia areata at proportionally higher cost. In INR at the prevailing 94 to 95 range, the originator product imported from the US translates to approximately INR 4.5 lakh to 5.1 lakh per month at the 2 mg dose. By comparison, an Indian-manufactured baricitinib generic typically retails for approximately INR 1,500 to 4,500 per month at the 2 mg or 4 mg dose, depending on brand and pack size. The cost differential is dramatic and is the reason originator import is rarely the rational choice for a routine case. Reserve Meds operates with full price transparency, and the patient or family makes an informed decision with the actual delta in view.

Timing, what to expect

For an originator Olumiant 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 diagnosis (rheumatoid arthritis, severe alopecia areata, or eligible COVID-19 indication), the prior therapy course, the specific reason originator product is required rather than the Indian generic, the dosing plan, and the planned monitoring schedule including complete blood count with differential, liver function, lipid panel, infection screening (latent tuberculosis, hepatitis B and C), and thromboembolism risk assessment. The treating physician's NMC registration number appears on the prescription. The FDA label carries a boxed warning for serious infection,

mortality, malignancy, major adverse cardiovascular events, and thrombosis class effects of JAK inhibitors.

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. Olumiant 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. Treating physicians report adverse events through PvPI. For baricitinib, the JAK inhibitor class boxed warning items (serious infection, malignancy, MACE, thrombosis) frame the monitoring schedule the prescribing physician maintains.

Where Reserve Meds fits

Reserve Meds is a US-based concierge coordinator. For Olumiant in India, our role is narrow. We orchestrate originator US product import only where a specific clinical or continuity reason justifies it. For routine Indian patients, we encourage the patient and physician to use the locally available Indian generic baricitinib.

Next step

If there is a specific reason originator Olumiant 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 Indian generic.

Reserved for you.

Related

- [Olumiant clinical resource](#)
- [India country page](#)
- [CDSCO personal-import pathway](#)

Sources

1. FDA approval, Olumiant (baricitinib), Eli Lilly under licence from Incyte, NDA approval May 2018 for rheumatoid arthritis with subsequent expansions for alopecia areata (June 2022) and hospitalised COVID-19.
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, generic baricitinib quality standards under CDSCO oversight.

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.reservemed.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](#) ›

Last medically reviewed: 2026-05-12.