

## Kalydeco

India · access guide

# Kalydeco access in India: the CDSCO named-patient pathway

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

## Quick orientation

Patients in India access Kalydeco (ivacaftor) for cystic fibrosis in patients aged 1 month and older who have at least one mutation in the CFTR gene that is responsive to ivacaftor potentiation through the CDSCO named-patient pathway, a Central Drugs Standard Control Organisation-administered mechanism that allows a Indian-licensed physician at a registered facility to import the FDA-labelled product for a specific named patient. This page details the documentation, approval timeline, and real cost in INR.

## Why Indian patients need Kalydeco through the named-patient pathway

The Republic of India operates a structured pharmaceutical regulatory environment. Kalydeco (ivacaftor) is regulated through CDSCO (Central Drugs Standard Control Organisation) channels, and a Indian family asking for Kalydeco is rarely asking for a medicine that does not exist locally. They are usually asking for a precise version of it that the local market has not caught up to.

Four converging patterns drive these cases. First, indication lag. Kalydeco's newer FDA-approved indications and dosing expansions often reach local registration 12 to 36 months after the US label. A family whose treating physician has documented a clear FDA-label fit may still find that the local label has not caught up. Second, presentation gaps. The exact strength, weight-banded dose, or pen format the prescriber needs may not be stocked at the local agent even when the medicine is registered. Third, payer denial. Star Health and HDFC ERGO each assess specialty therapies case by case, and step-therapy or formulary rules often produce denials even when the drug is on the local register. Cash-pay families pursue cross-border supply rather than wait through appeals. Fourth, continuity of supply. When a US-stable patient relocates to India or visits family for an extended period, maintaining the original FDA-sourced regimen matters more than switching to a different local presentation.

In each pattern, the CDSCO named-patient pathway is the mechanism that connects a Indian-licensed physician's clinical decision with US-sourced, FDA-labeled product for a specific patient. Clinically, Kalydeco is an oral CFTR potentiator administered twice daily with fat-containing food that increases the channel-open probability of CFTR at the cell surface, applicable to selected gating, conductance, and residual-function mutations identified on a validated FDA-approved CFTR genotyping assay, and the named-patient route preserves that mechanism rather than substituting a non-equivalent local option.

## **The CDSCO named-patient pathway for Kalydeco**

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The pathway for an Indian-licensed physician to obtain a medicine that is not registered or not stocked locally is Rule 36 of the New Drugs and Clinical Trials Rules, 2019, which permits the personal import of a small quantity of an unregistered drug for the bona fide use of a named patient, supplemented by Form 12A institutional compassionate-use authorisation for hospital-administered therapies, with applications filed through the CDSCO SUGAM portal at cdscoonline.gov.in. The framework allows registered healthcare facilities to import a specific medicine for a specific patient when the medicine is approved by a recognised reference authority (typically the US FDA, EMA, MHRA, PMDA Japan, or Health Canada) and a clinically equivalent locally registered alternative is not suitable. For Kalydeco specifically, the clinical justification typically frames the case around the precise FDA-approved indication and the documented gap in the local route.

A complete application includes a clinical justification letter from the treating physician (diagnosis, severity, prior therapies, why this specific drug, why the locally stocked option is not suitable for this case), the treating physician's Indian medical license verification through the State Medical Council and the CDSCO Zonal Office, an anonymised patient identifier where the CDSCO submission allows, full product details (brand name, generic name, manufacturer, strength, dosage form, pack size, quantity requested, intended treatment duration), the destination dispensing facility name, license number, and pharmacy in charge, and a chain-of-custody plan describing how the medicine will move from the US manufacturer through the importer to the dispensing pharmacy.

For Kalydeco, the clinical justification angle typically rests on one or more of three documented elements: a pediatric or weight-banded request that fits the FDA label but not the local label, a denied biologic or specialty claim where prior step-therapy has been documented, or a continuity-of-supply request for a patient previously stabilised on the US-sourced presentation. The treating physician documents the relevant clinical criteria for the prescribed indication: severity scores, biomarker levels, prior therapy failures, and the rationale for Kalydeco versus the next-in-line local alternative.

Approval timelines for routine cases are typically 10 to 30 business days. Complex cases (rare indication, larger quantities, first import of a given pediatric or weight-banded format) can extend to 6 to 10 weeks. CDSCO retains discretion on timing, and we do not promise specific durations.

## **Where Kalydeco gets dispensed in India**

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A small group of Indian institutions handle named-patient imports as established workflow, with in-house import pharmacy infrastructure and physicians experienced with the application set. Tertiary and major private hospitals that meet this profile include Indraprastha Apollo Hospitals New Delhi pediatric pulmonology, Kokilaben Dhirubhai Ambani Hospital in Mumbai, and Christian Medical College (CMC) Vellore. Each maintains pharmacy infrastructure appropriate to the storage requirements of the imported medicine (2 to 8 degrees Celsius cold-chain for biologics, ambient storage for oral therapies, ultra-cold or specialised handling where the FDA label requires it).

For physicians at smaller hospitals without internal import infrastructure, the common pattern is to route through a specialty importer that holds a pharmaceutical establishment license and files the CDSCO application on the prescribing physician's behalf. The medicine then moves into the prescribing hospital's outpatient or specialty pharmacy under chain-of-custody documentation.

## **Real cost picture for Kalydeco in India**

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US WAC for Kalydeco runs in the range of USD 286,120 to USD 335,880 per year at the standard FDA-labelled regimen for cystic fibrosis in patients aged 1 month and older who have at least one mutation in the CFTR gene that is responsive to ivacaftor potentiation. INR is trading at approximately 83.5 INR to 1 USD, so the annual reference range converts to roughly INR 23,891,000 to INR 28,046,000 for the drug itself at US WAC equivalents.

International logistics for shipment to India typically runs USD 250 to USD 900 depending on destination city, urgency, and presentation (cold-chain biologics carry the higher end of the range; ambient oral solids the lower). The Republic of India customs and CDSCO permit fees are nominal relative to drug cost. Reserve Meds' concierge fee is itemised separately on every firm quote.

On the insurance side, Star Health and HDFC ERGO each assess named-patient imports case by case. Some reimburse fully when the medicine is on their formulary even if not stocked, some reimburse a percentage subject to copay, and many require pre-authorisation. We do not promise coverage from any insurer. US manufacturer copay cards and patient assistance programs do not extend internationally; cross-border patients pay cash or rely on local payer coverage.

## **Typical timeline for Kalydeco in India**

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CDSCO routine processing is typically 10 to 30 business days from a complete filing. International logistics adds 2 to 5 additional days depending on whether the presentation is ambient or cold-chain, the dispensing city, and customs clearance. End-to-end, most routine adult cases complete within 3 to 6 weeks from first complete documentation. Pediatric, weight-banded, or first-import cases can run slightly longer because presentation selection and first-import scrutiny can extend CDSCO review.

For temperature-sensitive products, the dispensing facility must maintain validated storage with continuous monitoring; the manufacturer's room-temperature excursion runway on the FDA label informs how we plan the Gulf, South Asia, or North Africa shipping lane, and the cold chain is broken only at the dispensing pharmacy under documented control.

When a case is on a clinical clock (a flare, a new diagnosis with an active disease, or a treatment cycle scheduled at the dispensing centre), the practical question is which step controls the timeline. In our experience the binding step is rarely the CDSCO review itself when the application is filed clean; it is usually documentation completeness on the prescriber's side or, for cold-chain biologics, the dispensing facility's storage and monitoring confirmation. The intake is where we lock the case-team contact, gather the documents in parallel, and start the US sourcing clock so that approval and product land in the same week rather than serially.

## What your physician needs to provide

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For a Indian-licensed specialist prescribing Kalydeco through the CDSCO pathway, the clinical justification letter is the cornerstone of the application. The letter typically documents the patient's confirmed diagnosis for cystic fibrosis in patients aged 1 month and older who have at least one mutation in the CFTR gene that is responsive to ivacaftor potentiation, severity assessment (scoring instrument, biomarker, imaging, or biopsy as appropriate for the indication), prior therapy history including first-line options tried, and a clinical rationale for why Kalydeco is the appropriate next step given an oral CFTR potentiator administered twice daily with fat-containing food that increases the channel-open probability of CFTR at the cell surface, applicable to selected gating, conductance, and residual-function mutations identified on a validated FDA-approved CFTR genotyping assay.

The letter also specifies the exact dosing plan per the FDA-approved label: starting dose, maintenance dose, route of administration, schedule, and intended duration of therapy. Monitoring plan should reference any baseline laboratory or imaging requirements specific to Kalydeco (full blood count, liver function, infection screen, ophthalmology assessment, or pregnancy testing where the FDA label requires it), planned follow-up intervals, and dose-modification criteria for the most common adverse events.

The treating physician's Indian license number, the dispensing facility license number, and the pharmacy in charge of dispensing complete the package. For cold-chain or specialty-handling products, the dispensing pharmacy's documented storage protocol and continuous-temperature-monitoring log are part of the chain-of-custody record we share with the importer.

## Common questions about Kalydeco in India

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**Will Star Health and HDFC ERGO cover this?** Each insurer assesses named-patient imports case by case. Some reimburse fully when Kalydeco is on their formulary even if not currently stocked, some reimburse a percentage subject to copay, and many require pre-authorization. We supply the documentation set that allows your insurer to assess the case; the claim itself sits with you or your hospital.

**Is the FDA-approved indication recognised by CDSCO?** The CDSCO named-patient pathway exists precisely to permit access when the local registration or stocking lags the FDA label. The application documents the FDA indication, the reference-authority approval, and the local gap; CDSCO review focuses on the clinical justification rather than re-litigating the FDA decision.

**My physician is licensed in one emirate / state / province and the hospital is in another. Is that fine?** Any Indian-licensed physician practicing in good standing in the jurisdiction of the dispensing facility has signing authority on the clinical justification letter. The State Medical Council and the CDSCO Zonal Office verifies the active license; the CDSCO application records both the prescribing physician and the dispensing facility.

**Can I receive Kalydeco at home?** The dispensing facility must be Indian-licensed. The hospital outpatient or specialty pharmacy releases the medicine to you after final verification, and you then administer or self-administer at home where the FDA label permits, after the dispensing pharmacy's training. The cold-chain or controlled-storage handoff ends at the dispensing pharmacy; home storage and any handling protocol are part of your patient onboarding kit.

**What about competitors or alternative therapies in the same class?** Choice of therapy depends on the patient's full phenotype, prior therapy, and the prescriber's judgment. Reserve Meds coordinates whichever medicine the physician has prescribed; we do not substitute, advise on substitution, or promote one brand over another.

## Where Reserve Meds fits in Kalydeco cases

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Reserve Meds is a US-based concierge coordinator. We do not replace your treating physician, we do not replace CDSCO, and we do not replace your dispensing pharmacy. For Kalydeco specifically, we orchestrate the US-side sourcing through a DSCSA-compliant specialty channel, build the documentation packet your physician submits, coordinate validated logistics (cold-chain with continuous temperature logging where the FDA label requires it) into India, and assign a single named coordinator through the case. Standard named-patient coordination under our specialty playbook applies. Presentation selection, dose-band confirmation, and patient onboarding for self-administration where applicable are the recurring operational fundamentals we expect for this drug.

Operationally, a typical Kalydeco case runs across four parallel tracks. The clinical track is the physician's: justification letter, dosing plan, monitoring schedule, and the next patient-facing follow-up. The regulatory track is the CDSCO application packaged by the importer; we provide the documentation template, the dispensing facility license check, and the chain-of-custody attestation. The logistics track is the US-side sourcing and the validated international shipment with continuous temperature logging and customs broker coordination. The patient-experience track is the named coordinator who keeps everyone aligned on dates, addresses dispensing-pharmacy questions, and confirms the medicine has been received and stored correctly. The four tracks are run in parallel rather than in series; that is the operational difference between a 3-week and a 9-week case.

Kalydeco requires confirmation of an FDA-responsive CFTR mutation on a validated genotyping assay before initiation; named-patient files in India document the CFTR genotype, baseline sweat chloride, baseline FEV1 where age-appropriate, liver function tests, and the ophthalmology assessment required for paediatric initiation per the FDA label. Cystic fibrosis specialty services concentrate at the paediatric pulmonology programmes referenced above.

### *Reserve Meds's role*

US-based concierge coordinator for cross-border specialty medicine. We are not the prescriber, not the dispensing pharmacy, and not the manufacturer. All clinical decisions remain with your treating physician.

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## Reserve Meds

*reserved for you.*

Composite case examples. This document is for general information only and does not constitute medical advice. Please consult your treating physician.

Reserve Meds is in pre-launch. Published timelines and cost ranges are indicative, not guarantees.

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