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

How patients in India access Alyftrek (vanzacaftor/tezacaftor/deutivacaftor) for cystic fibrosis when the medicine is not yet locally registered.

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1. Quick orientation

Alyftrek is the brand name for vanzacaftor/tezacaftor/deutivacaftor, the next-in-class oral once-daily fixed-dose triple combination cystic fibrosis transmembrane conductance regulator (CFTR) modulator from Vertex Pharmaceuticals. The US Food and Drug Administration approved Alyftrek on 20 December 2024 for patients aged 6 years and older with at least one F508del mutation or one of approximately 94 other responsive mutations in the CFTR gene, including approximately 31 additional mutations not covered by the Trikafta label. The UK MHRA approved Alyftrek in March 2025 and the European Commission granted EU marketing authorization on 1 July 2025. In India, Alyftrek is not yet registered with the Central Drugs Standard Control Organization (CDSCO). Patients with a confirmed CFTR genotype reach the medicine through Rule 36 of the Drugs and Cosmetics Rules 1945, with the office of the Drugs Controller General of India (DCGI) issuing Form 12B against a complete Form 12A application. Reserved for you.

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

India has the deepest tertiary specialty hospital network of any Reserve Meds priority country, but the Indian cystic fibrosis cohort is structurally underserved. CF is a rare, life-shortening genetic disease, and the locally registered CFTR-modulator footprint in India is narrower than the US and EU footprints. Alyftrek is not yet routinely stocked through Indian commercial channels. The Cystic Fibrosis India Forum, the Indian Cystic Fibrosis Foundation, and pediatric-pulmonology centres at AIIMS New Delhi, PGIMER Chandigarh, and Christian Medical College Vellore have publicly advocated for CFTR-modulator access for Indian patients, and the Vertex-India advocacy conversation is well documented.

Three patterns of access gap repeat. First, eligibility expansion: the Alyftrek label covers approximately 31 CFTR mutations not on the Trikafta label, so a patient with a responsive but Trikafta-ineligible mutation now has a label-supported option that is unavailable in India through commercial channels. Second, switch demand: patients established on Trikafta who would benefit from once-daily simpler dosing (paediatric families, adolescents with school routines, adults with adherence challenges) sometimes elect to pursue Alyftrek through Rule 36 where the product is not yet locally registered. Third, second-opinion and expatriate patients: Indian CF expert centres, expatriate families, and patients travelling for second-opinion care who elect to source US-origin product directly through cash-pay specialty coordination.

CFTR-modulator therapy is sole-sourced globally by Vertex. There is no non-Vertex competitor in the class, which means substitution to a domestic alternative is not a clinical option. The Form 12A medical-necessity narrative is anchored by the CFTR genotype on the patient's pathology report and the label table that confirms the responsive mutation.

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

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 for the exclusive personal use of a named patient, with the legal basis sitting under Section 10 of the Drugs and Cosmetics Act 1940.

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 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) whose National Medical Commission (NMC) registration number appears on the prescription, with 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 where the drug is approved by a recognised reference authority such as the FDA for a serious permanent disability or an unmet medical need. CFTR-modulator-eligible cystic fibrosis fits the criteria, and AIIMS, PGIMER, and CMC Vellore handle pediatric named-patient and compassionate imports as established workflow.

A complete CDSCO application for Alyftrek typically includes:

- A clinical justification letter (CF diagnosis, CFTR genotype matched to the FDA label table, prior CFTR-modulator history if any, age, weight, the specific reason this product is required)
- The treating CF specialist's NMC registration number and state-council registration where required
- Patient identifier, sweat chloride test result, and pulmonary function records
- Product details: Alyftrek, vanzacaftor/tezacaftor/deutivacaftor, Vertex Pharmaceuticals, weight-banded tablet strength per FDA label table, 28-day pack
- The dispensing facility's drug licence (hospital pharmacy with paediatric specialty experience, or specialty importer's wholesale licence)
- A chain-of-custody plan from the US Vertex-contracted specialty pharmacy through to the dispensing pharmacy in India

The clinical-justification angle that matters most for Alyftrek is CFTR genotype confirmation. The treating CF specialist documents the patient's mutation profile and matches it to the FDA label table of approximately 94 responsive mutations, explicitly noting where the mutation is on the Alyftrek label but not on the Trikafta label (the approximately 31 additional mutations). For paediatric patients aged 6 and older, the letter states weight-banded tablet strength selection from the label table. CDSCO published guidance states the Form 12B permit is issued on a priority basis, typically within one to two days for routine applications. In practice, families plan for a two to four week window from physician decision to first dispense.

4. Where Alyftrek gets dispensed in India

Alyftrek is an oral, room-temperature-stable, weigh