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

How families in India legally obtain Leqembi (lecanemab-irmb) from US-source supply for amyloid-confirmed early Alzheimer's disease through CDSCO personal importation, with cold-chain integrity and MRI surveillance built into the case plan.

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

Quick orientation

Leqembi (lecanemab-irmb) is a humanized IgG1 monoclonal antibody that binds soluble amyloid-beta protofibrils and promotes clearance of amyloid plaque. The US FDA granted accelerated approval in January 2023 and converted Leqembi to traditional approval in July 2023 for the treatment of Alzheimer's disease in patients with mild cognitive impairment or mild dementia stage of disease, with confirmed amyloid pathology established before treatment. Indian registrations for amyloid-targeting antibody therapy lag US, Japan, and EU timing, and amyloid-confirmed early-stage Alzheimer's patients with cash means routinely reach Leqembi through the Central Drugs Standard Control Organization (CDSCO) personal importation framework under Rule 36 of the Drugs and Cosmetics Rules 1945, with the Form 12A application and Form 12B permit issued by the Drugs Controller General of India (DCGI) office in New Delhi. Reserve Meds coordinates the US-side specialty sourcing through DSCSA-compliant wholesalers, the validated 2 to 8 degree Celsius cold-chain logistics, and the documentation kit your neurologist needs to file.

Reserved for you.

Why patients in India need Leqembi via the named-patient pathway

India has a deep tertiary specialty hospital network and a growing memory-disorder and cognitive-neurology clinical base across AIIMS Delhi, Apollo, Fortis, Medanta, Kokilaben, MGM, CMC Vellore, and Manipal. What India lacks for many amyloid-confirmed early-stage Alzheimer's patients is a routinely stocked anti-amyloid antibody on the hospital formulary. Three structural patterns explain the access gap: the drug may not be on the CDSCO register at all, it may be registered for a different stage or indication, or it may be in name available but not stocked in the patient's city on the day infusion therapy is meant to start. For Leqembi, the operative gap is the first. Registrations across MENA and South Asia for amyloid-directed therapy are uneven and frequently lag US and Japan timing. The personal-importation pathway under Rule 36 is the legal route.

The clinical urgency is real. Alzheimer's progresses through a narrow window in which Leqembi treatment is consistent with the approved indication, mild cognitive impairment or mild dementia with confirmed amyloid pathology. Once progression moves the patient beyond mild dementia, the label-defined window closes. Indian families with affected parents and grandparents in this window are time-sensitive, and the multi-month coordination cadence of biweekly infusion dosing rewards the kind of single-coordinator case file Reserve Meds is built around. Diaspora-funded care is a common operating reality, with an adult child in Dubai, London, or New York paying the invoice for a parent under care at a Mumbai, Delhi, or Bengaluru memory clinic. The Rule 36 framework accommodates that financial pattern when the named patient is the Indian resident.

India's dementia-care landscape adds a third pressure to the case. The estimated population living with dementia in India is in the millions and growing as the demographic curve ages, and the early-stage cohort with confirmed amyloid pathology is a small but motivated subset within that population. Amyloid PET imaging is available at the larger metro centres (AIIMS, Apollo Chennai and Delhi, Tata Memorial-adjacent diagnostic radiology services, Medanta, Kokilaben, MGM) but is not

uniformly accessible in tier-2 and tier-3 cities. CSF biomarker testing (A β 42/40 ratio, p-tau, total tau) provides an alternative route to amyloid confirmation when PET access is constrained, and is increasingly available through specialty laboratories that serve neurology centres of excellence. Both confirmation routes are accepted under the FDA label and under the Rule 36 documentation framework when the prescribing neurologist documents the result in the clinical justification letter.

The CDSCO Rule 36 named-patient pathway for Leqembi

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 the 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 for the permit. 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) showing the RMP's National Medical Commission (NMC) registration number and the quantity required for treatment. The quantity of any single drug imported is capped at one hundred average doses per application.

For institutional Compassionate Use of drugs not approved for marketing in India at all, the 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 applies when the drug is approved by a recognised reference authority (FDA, EMA, MHRA, Health Canada, PMDA) for a life-threatening condition, a serious permanent disability, or an unmet medical need. Government institutions including AIIMS New Delhi have established workflow for this pathway in cognitive-neurology cases.

For Leqembi specifically, the clinical-justification angle is precise. The strongest Form 12A applications consistently include four elements that the CDSCO reviewer looks for in an amyloid-targeting biologic: a neurologist-confirmed diagnosis of mild cognitive impairment or mild dementia due to Alzheimer's disease (not moderate or severe dementia, which falls outside the FDA-approved indication); confirmation of amyloid pathology established before initiating treatment, by amyloid PET imaging or cerebrospinal fluid biomarker testing; ApoE epsilon-4 genotyping with the result documented and the higher ARIA risk profile of homozygous ApoE4 carriers acknowledged in the monitoring plan; and a recent baseline brain MRI (within one year before initiating treatment) with documented capacity at the dispensing institution for the label-required MRI surveillance schedule (additional MRIs before the 5th, 7th, and 14th infusions). CDSCO's published guidance states Form 12B is typically issued within one to two days for routine applications where documentation is complete. Indian families and hospitals plan for a two to four week window from neurologist decision to first dose, because the bulk of elapsed time runs through upstream documentation assembly and downstream cold-chain international logistics rather than the regulator's stamp.

Where Leqembi gets dispensed in India

Leqembi is an intravenous infusion administered approximately every two weeks at the FDA-labeled 10 mg/kg dose, with a label-permitted transition to less-frequent maintenance dosing once an initial period of biweekly dosing is completed. The dispensing institution must have refrigerated 2 to 8 degree Celsius storage in the original carton, infusion-suite capacity for an approximately one-hour IV administration with observation for infusion-related reactions, and protocol access to brain MRI for the surveillance schedule. Indian institutions with established cognitive-neurology and memory-disorder programmes plus the infusion and MRI infrastructure include AIIMS New Delhi (apex public-sector institution, designated NPRD Centre of Excellence), Apollo Hospitals (Chennai flagship, Delhi, Bangalore, Hyderabad, Kolkata, with dedicated international patient services and JCI plus NABH accreditation), Fortis Healthcare (Fortis Memorial Research Institute Gurgaon and Mulund Mumbai), Medanta The Medicity Gurgaon, Kokilaben Dhirubhai Ambani Hospital Mumbai, MG