

[Skip to main content](#)

[Home](#) / [Drugs](#) / [Leqembi](#) / [In Pakistan](#)

# Leqembi access in Pakistan via the DRAP named-patient pathway

How patients in Pakistan obtain Leqembi (lecanemab-irmb) for confirmed early Alzheimer's disease, through the Drug Regulatory Authority of Pakistan Special Permission / Personal Use Import pathway.

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

## 1. Quick orientation

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Leqembi is the brand name for lecanemab-irmb, a humanized IgG1 monoclonal antibody that selectively binds soluble amyloid-beta protofibrils to clear amyloid plaque from the brain. The US Food and Drug Administration granted traditional approval on July 6, 2023 for the treatment of mild cognitive impairment or mild dementia stage of Alzheimer's disease in patients with confirmed amyloid pathology. In Pakistan, families with an amyloid-confirmed early Alzheimer's diagnosis frequently look across borders for an anti-amyloid therapy because the drug is not yet routinely stocked through local distributors. The Drug Regulatory Authority of Pakistan (DRAP) Special Permission / Personal Use Import pathway, filed through the Online Import and Export System (OIES) portal, is the lawful route once a Pakistan Medical and Dental Council (PMDC) licensed physician has decided this is the right next step. Reserve Meds is the US-side coordinator that aligns the sourcing, the cold-chain logistics, and the regulatory documentation kit your treating physician and hospital pharmacy need. Reserved for you.

## 2. Why patients in Pakistan need Leqembi via NPP

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Pakistan's specialty drug market has matured around a small number of large private-sector tertiary hospitals concentrated in Karachi, Lahore, and Islamabad. Even with that maturity, the gap between FDA-approved availability in the United States and on-shelf availability in Pakistan remains real for newer neurology therapeutics, and Leqembi sits clearly in that gap. International registration for lecanemab is patchy across MENA and South Asia, and there is no public record of DRAP registration of Leqembi at the time of this review. Where lecanemab is approved internationally, payer coverage is often the binding constraint. The UK NICE decision against NHS funding is the clearest example of registration without funding, and similar gaps appear across regional peers.

Dementia care in Pakistan has historically been managed at home with limited pharmacologic intervention beyond cholinesterase inhibitors and memantine. The arrival of disease-modifying anti-amyloid therapy in the United States changed the conversation for families who can fund cross-border care. Pakistan's amyloid-confirmed, ApoE4-genotyped, MRI-monitored patient profile is narrow but motivated, and disease progression is unforgiving. The label-eligible window of mild cognitive impairment or mild dementia is finite, which is why timing matters. ApoE4 carrier status carries particular weight in this population because homozygous APOE4 carriers have a higher incidence of amyloid-related imaging abnormalities (ARIA), and the destination-physician team needs to plan ARIA surveillance accordingly. Reserve Meds positions Leqembi as a Tier-1 access case where coordination quality, cold-chain discipline at 2 to 8 degrees Celsius across multi-leg international transit, and destination-physician readiness for the FDA-labeled MRI schedule are the value drivers that distinguish a clean cycle from an unpredictable one.

## 3. The DRAP Special Permission pathway for Leqembi

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DRAP regulates the import of medicines through the Quality Assurance and Laboratory Testing (QA&LT) Division's Import and Export Section, with Drug Registration Board oversight for new product registration matters. For unregistered medicines required by a specific patient, DRAP issues a Special Permission, also referred to as the No Objection Certificate

(NOC) for Personal Use Import. Applications are filed through DRAP's Online Import and Export System (OIES), an electronic application portal that lets applicants and DRAP communicate digitally on import and export permission matters. Patient-level personal-use applications are submitted by the patient or applicant directly on the portal; institutional applications are filed by the hospital pharmacy.

For Leqembi specifically, the application package contains:

- **Clinical justification letter** from the treating physician, addressing diagnosis with ICD-10 coding for Alzheimer's disease, documentation of staging at mild cognitive impairment or mild dementia, the amyloid-pathology confirmation method (amyloid PET imaging or cerebrospinal fluid biomarker testing), prior cognitive-enhancement therapies attempted, the rationale for an anti-amyloid monoclonal antibody, and the requested dosing schedule.
- **PMDC licensure verification** for the treating physician in neurology, geriatric medicine, or a related specialty appropriate to manage early Alzheimer's disease and ARIA surveillance.
- **ApoE4 genotype documentation.** The FDA label specifically calls for ApoE4 testing prior to initiation because homozygous carriers carry the highest ARIA risk. The DRAP file should reflect that this step has been completed at the destination institution.
- **Baseline brain MRI within one year** of initiation, with the FDA label-required protocol for additional MRIs prior to the 5th, 7th, and 14th infusions documented in the treatment plan.
- **Patient identifier:** CNIC for adult patients, with B-Form used in place of CNIC for minors and passport for foreign nationals receiving treatment in Pakistan.
- **Product details** including brand name (Leqembi), international nonproprietary name (lecanemab-irmb), manufacturer (Eisai Inc., with Biogen as US co-promotion partner), country of origin (USA), strength (200 mg per 2 mL or 500 mg per 5 mL single-dose vial), pack size, requested quantity for the initial sourcing window, lot, and expiry.
- **Destination dispensing facility license** showing the receiving infusion pharmacy is licensed to handle imported biologics with cold-chain storage.
- **Manufacturer or authorized distributor letter** confirming the product is genuine and was sourced through the legitimate US specialty supply chain under DSCSA serialization.
- **Chain-of-custody plan**