Leqembi access in Saudi Arabia via the SFDA named-patient pathway

How patients in the Kingdom of Saudi Arabia obtain Leqembi (lecanemab-irmb) for confirmed early Alzheimer's disease, through the Saudi Food and Drug Authority Personal Importation Program.

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

1. Quick orientation

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 Saudi Arabia, families with an amyloid-confirmed early Alzheimer's diagnosis often reach for Leqembi while the drug works its way through local registration and stocking pathways. The Saudi Food and Drug Authority (SFDA) Personal Importation Program (PIP) is the lawful, documented route for a patient-specific import once a Saudi Commission for Health Specialties (SCFHS) 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 needs. Reserved for you.

2. Why patients in Saudi Arabia need Leqembi via NPP

The Kingdom operates one of the most mature pharmaceutical regulatory frameworks in the Gulf Cooperation Council, and SFDA has run a well-developed named-patient framework for over a decade. Even so, the gap between FDA-approved availability in the United States and KSA market presence is real for newer specialty therapeutics, and Leqembi sits clearly in that gap. International registration for lecanemab is patchy across MENA. Where Leqembi is registered in other major markets, payer coverage is often the binding constraint, and the same pattern is visible in KSA where stocking, formulary listing, and reimbursement do not move in lockstep with regulatory listing.

The drug is amyloid-confirmed-only, ApoE4-tested-prior-to-initiation, and dosed IV every two weeks against MRI surveillance prior to the 5th, 7th, and 14th infusions. That specificity narrows the candidate population. Families in Riyadh, Jeddah, Dammam, and the Eastern Province with means and with a confirmed early-stage diagnosis are actively seeking anti-amyloid therapy because disease progression is unforgiving and the label-eligible window is finite. PIP is the structured route. The alternative is no route, which is not a route at all.

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 transit, and destination-physician readiness for ARIA monitoring are the value drivers that distinguish a clean named-patient cycle from an unpredictable one.

3. The SFDA Personal Importation Program for Leqembi

The SFDA Personal Importation Program allows a KSA-licensed physician to request import of a specific medicine for a specific named patient when the medicine is approved by a recognized reference authority (US FDA for Leqembi) and a clinically equivalent locally registered alternative is not suitable. The framework explicitly contemplates neurology and rare-disease therapies. Applications are filed through the dispensing institution's import pharmacy and reviewed by SFDA's Drug Sector. Increasingly, the agency routes named-patient activity through its Ghad digital regulatory platform.

For Leqembi specifically, the application package contains:

- **Clinical justification letter** from the treating physician, addressing diagnosis with ICD-10 coding (G30.0 or G30.9 for Alzheimer's disease, with documentation of mild cognitive impairment stage or mild dementia stage), the amyloid-pathology confirmation method (amyloid PET imaging or cerebrospinal fluid biomarker testing), prior cognitive-enhancement therapies attempted with outcomes, the rationale for an anti-amyloid monoclonal antibody, and the requested dosing schedule.
- **SCFHS licensure verification** 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 PIP 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** in the format SFDA requires, typically an anonymized internal reference linked to the national ID inside the hospital record.
- **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 SFDA-licensed to handle imported biologics with cold-chain storage.
- **Chain-of-custody plan** from the US specialty wholesaler through international transit (with validated 2 to 8 degree Celsius packaging and continuous temperature monitoring) to the receiving Saudi pharmacy, including the freight forwarder, customs broker, and importer of record.

Approval timelines for routine cases typically run 10 to 21 business days. Complex cases, which can include first-time imports of a novel mechanism such as anti-amyloid therapy at a given institution, can extend to 6 to 10 weeks. SFDA does not publish guaranteed turnaround times, so case-by-case planning is the norm.

4. Where Leqembi gets dispensed in Saudi Arabia

Leqembi requires a 2 to 8 degree Celsius cold-chain handoff, an infusion suite with one-hour IV administration capacity, MRI access for the label-required surveillance schedule, and a neurology or geriatric medicine team that can manage ARIA. That capability set narrows the realistic dispensing footprint to tertiary cen