# Leqembi access in Egypt: the EDA Personal Importation pathway

How families in Egypt legally obtain Leqembi (lecanemab-irmb) from US-source supply for amyloid-confirmed early Alzheimer's disease when the medicine is not stocked or not yet registered locally.

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

## Quick orientation

Leqembi (lecanemab-irmb) is an anti-amyloid monoclonal antibody approved by the US Food and Drug Administration in 2023 for adults with mild cognitive impairment or mild dementia stage of Alzheimer's disease, where amyloid pathology has been confirmed by PET imaging or cerebrospinal fluid biomarker testing. In Egypt, registration and stocking are not yet routine, and families of patients with confirmed early-stage Alzheimer's frequently look for a structured legal route to obtain the medicine. That route is the Personal Importation framework administered by the Egyptian Drug Authority (EDA) under Law No. 151 of 2019. An Egyptian-licensed neurologist or geriatrician submits the application through a licensed dispensing hospital for a specific patient. Reserve Meds handles the US-side sourcing, the cold-chain logistics, and the documentation kit your physician needs.

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## Why patients in Egypt need Leqembi via the named-patient pathway

Egypt operates one of the most active named-patient import workflows in the Arab world precisely because the gap between what the FDA approves and what is registered and stocked in Egypt remains wide for advanced neurology, specialty oncology, and rare disease therapies. Three structural patterns sit between an Egyptian family and Leqembi access. The drug may not yet be on the EDA register at all, because the manufacturer has not pursued local registration for a small patient population. It may be on the register but absent from hospital pharmacy shelves and from the importer's stock. Or routine clinical availability for the early-Alzheimer's indication may simply not exist in the governorate where the patient is being treated. Egypt's Universal Health Insurance rollout under Law No. 2 of 2018 is expanding public coverage in stages, but specialty imports for neurology remain dominated by cash-pay families, often coordinated with USD funds from relatives in the Gulf.

Leqembi's own profile reinforces why the named-patient pathway is the appropriate route. International registration is patchy: the European Medicines Agency granted authorisation only in April 2025 with a restriction excluding ApoE epsilon-4 homozygotes, the UK MHRA approved in August 2024 but NICE declined NHS funding, and registration across MENA jurisdictions lags US and Japan timing. The eligible population (early-stage, amyloid-confirmed, ApoE4 status established) is small, motivated, and time-sensitive. The clinical window in which Leqembi treatment remains consistent with the approved indication is limited, and disease progression is unforgiving. Families in Cairo, Alexandria, and Giza pursuing anti-amyloid therapy for a parent or spouse are typically working against time, which is what makes a documented named-patient pathway the right operating model rather than ad hoc effort.

## The EDA named-patient pathway for Leqembi

The Egyptian Drug Authority was created by Law No. 151 of 2019, issued 25 August 2019 in the Official Gazette, with executive regulations issued by Prime Minister Decision No. 777 of 2020. EDA is a public service authority affiliated to the Prime Minister and consolidates functions previously held by the National Organization for Drug Control and Research

(NODCAR), the National Organization for Research and Control of Biopharmaceuticals (NORCB), and the Ministry of Health's Central Administration of Pharmaceutical Affairs. The EDA Drug Registration Sector handles registration files, and the Egyptian Pharmacovigilance Center (EPVC) handles post-market safety.

EDA permits importation of unregistered medicines for a specific patient under defined conditions, most importantly where no equivalent registered product is available locally or where the available quantity cannot meet the patient's clinical need. This pathway is commonly referred to as Personal Importation, sometimes described in EDA correspondence as Special Access or Compassionate Use. The application is filed through the dispensing institution's import pharmacy, which is typically a private specialty hospital, a university hospital import desk, or a licensed specialty importer acting on the patient's behalf.

A complete Leqembi application typically includes:

- A clinical justification letter from the treating neurologist or geriatrician, original, stamped, on hospital letterhead, stating the diagnosis of mild cognitive impairment or mild dementia stage of Alzheimer's disease, objective confirmation of amyloid pathology by PET or CSF, ApoE4 genotype status, prior therapies, and why Leqembi is the appropriate next step
- The treating physician's Egyptian Medical Syndicate (EMS) membership number and Ministry of Health licence reference
- A recent prescription specifying brand name (Leqembi), generic name (lecanemab-irmb), strength, dosage form, and the quantity tied to the patient's weight-based 10 mg/kg biweekly regimen
- A patient identifier (national ID or passport copy)
- Product details: Eisai Inc., country of origin, FDA approval reference, shelf life, and the 2 to 8 degree Celsius storage condition
- The destination dispensing facility licence number (the infusion centre where the medicine will be administered)
- A chain-of-custody plan describing how Leqembi will move from the US specialty wholesaler through air freight to Cairo International Airport under continuous 2 to 8 degree Celsius cold chain, with documented temperature logging at every handoff

For Leqembi, the clinical justification letter carries a specific weight. The strongest applications include explicit documentation of amyloid-pathology confirmation, ApoE4 genotype (since homozygotes carry the highest amyloid-related imaging abnormality risk and the EU and UK labels restrict accordingly), a recent baseline brain MRI within one year, and a plan for the FDA-labeled MRI surveillance schedule prior to the 5th, 7th, and 14th infusions. Routine EDA personal-import authorisations for well-documented neurology and rare-disease cases are typically processed in a 3 to 6 week window once a complete package is submitted. Complex cases involving novel-mechanism biologics with cold-chain sensitivity can extend to 8 to 14 weeks. EDA reserves discretion at every step, and Reserve Meds does not promise EDA timelines.

## Where Leqembi gets dispensed in Egypt

Leqembi is an intravenous biologic that requires an infusion centre with capacity for amyloid-related imaging abnormality (ARIA) monitoring through MRI access, APOE4 genotyping coordination, and standard infusion-suite logistics. The Egyptian institutions that fit this profile and routinely handle named-patient imports include Cairo University Hospitals (Kasr Al Ainy), the oldest and largest academic hospital network in Egypt and the Middle East, with a Drug Information Center and dedicated neurology services; Ain Shams University Hospitals, the second major academic hospital network in Cairo with strong neurology and routine experience importing specialty drugs; Dar Al Fouad Hospital in 6th of October City, the private super-specialty hospital signed with the Cleveland Clinic since 1999 and JCI-accredited since 2005; As-Salam International Hospital in Cairo, one of the most advanced multispecialty hospitals in Egypt; and the Cleopatra Hospitals Group, the largest private hospital group in Egypt with over 1.2 million patients treated annually across multiple Cairo facilities.

For families outside Cairo, Giza, and Alexandria, the practical pattern is to route the case to one of these centres or through a Cairo-based licensed specialty importer, with the treating neurologist either holding privileges at the dispensing facility or co-managing the case with an Egyptian-licensed specialist at one of the named institutions.

## Real cost picture for Leqembi in Egypt

Reserve Meds quotes patients in US dollars and accepts USD wire transfers. The Egyptian pound has lost more than 70 percent of its value against the US dollar since early 2022, with the USD/EGP rate near 52 to 53 in May 2026. Quoting in USD insulates the patient from intra-case currency drift between firm quote and shipment. Eisai set the US wholesale acquisition cost (WAC) for Leqembi at approximately USD 26,500 per patient per year at launch, based on a reference body weight of 75 kg and the 10 mg/kg biweekly IV regimen, with per-vial WAC of USD 254.81 for the 200 mg vial and USD 637.02 for the 500 mg vial.

The drug cost is the first line item, not the only one. International cold-chain logistics from a US specialty wholesaler to Cairo International Airport typically run USD 600 to 1,500 per shipment, depending on volume and urgency. EDA permit fees and customs charges sit on the Egyptian side and vary by dispensing facility and licensed importer. The dispensing hospital's infusion administration fee, baseline and surveillance MRI, APOE4 genotyping, and amyloid-confirmation testing (PET or CSF) sit on the hospital's ledger. Reserve Meds itemises the US-side drug procurement, the international logistics, and the concierge coordination fee separately on every firm quote, never bundled.

On the insurance side, Bupa Egypt, AXA Egypt, MetLife Egypt, Allianz Egypt, and Misr Insurance each assess named-patient claims case by case. The Universal Health Insurance Authority (UHIA) coverage is still rolling out by governorate phase under Law No. 2 of 2018 and does not currently cover most specialty imports for most patients. Cash-pay remains the dominant posture, and many Egyptian families coordinate USD funds via relatives in the Gulf, the UK, or the US.

## Typical timeline for Leqembi in Egypt

For a routine Egyptian Leqembi case with complete documentation, the EDA personal-import window is typically 3 to 6 weeks. The biologic class extends operational logistics by 2 to 3 days beyond ambient-product shipments because of validated 2 to 8 degree Celsius packaging and continuous temperature monitoring across multi-leg international transit through Cairo International Airport. A first-time import of Leqembi at a given Egyptian infusion centre, where the institution has not previously stocked the product, can add 2 to 3 weeks for hospital pharmacy onboarding. Once the first cycle is in place, subsequent biweekly shipments follow the same chain on a planned cadence. The 14-infusion sequence in the first 6 months of therapy is a planned cadence rather than 14 one-off events.

## What your physician needs to provide

The clinical justification letter is the cornerstone of the EDA application and, for Leqembi, the strongest letters consistently include: a confirmed diagnosis of mild cognitive impairment or mild dementia stage of Alzheimer's disease per the FDA-approved indication; objective confirmation of amyloid pathology by amyloid PET imaging or cerebrospinal fluid biomarker testing, with the imaging or laboratory report in the patient file; ApoE4 genotype testing performed prior to initiation, with explicit acknowledgment where the patient is a homozygote because of higher ARIA risk; a recent baseline brain MRI within one year prior to treatment; the proposed dosing plan (10 mg/kg every two weeks, with patient weight and the corresponding 200 mg or 500 mg vial selection); the surveillance MRI plan prior to the 5th, 7th, and 14th infusions per the FDA label; and the prescribing physician's EMS membership and Ministry of Health licence verification matched to the dispensing facility.

The treating physician retains the clinical decision and the pharmacovigilance reporting obligation through the Egyptian Pharmacovigilance Center (EPVC), using either the Yellow Card form or CIOMS forms depending on the case. Reserve Meds supplies the structured documentation template, the EPVC reference contacts in the physician kit, and the chain-of-custody packet from the US side. We do not write the clinical letter, we do not direct dosing, and we do not file adverse-event reports.

## Common questions about Leqembi in Egypt

### Will Bupa Egypt, AXA Egypt, MetLife Egypt, or Allianz Egypt cover Leqembi?

Each insurer assesses named-patient imports case by case. Some plans reimburse a percentage when the drug treats a covered indication even if the specific product is not on a local formulary; many require pre-authorisation. Reserve Meds supplies the documentation set that allows your insurer to assess. The claim filing remains with you or the dispensing hospital. Cash-pay is the default posture, and many Egyptian families reimburse themselves later if coverage applies.

### Does UHIA cover Leqembi as a specialty import?

Not as a general rule. The Universal Health Insurance Authority rollout under Law No. 2 of 2018 is phased through to 2032, with Cairo, Giza, and Qalyubia in the final phase. For most named-patient specialty imports in 2026, UHIA coverage is not the funding path; cash-pay or private insurance reimbursement is.

### Is the ARIA risk specific to ApoE4 homozygotes a concern in the Egyptian patient population?

The FDA label carries a boxed warning for ARIA, including ARIA-E (edema) and ARIA-H (microhemorrhage and superficial siderosis), with the highest risk in ApoE4 homozygotes. The EU and UK labels restrict to non-homozygotes for that reason. APOE4 genotyping prior to initiation is a global standard regardless of country, and the treating neurologist manages the clinical surveillance plan including the label-required MRI schedule.

### Is there an alternative to Leqembi?

Donanemab (Kisunla, Eli Lilly) is another FDA-approved anti-amyloid monoclonal antibody for early Alzheimer's disease. Comparative selection between Leqembi and Kisunla is a clinical decision that belongs with the treating physician, not with the coordinator.

### Can Leqembi reverse Alzheimer's disease?

No. The Clarity AD confirmatory trial reported a slowing of decline on the CDR-SB scale at 18 months compared with placebo. Leqembi is not a cure and does not reverse established neurodegeneration. Families approach treatment with that expectation and the treating physician sets the goals of care.

### Our family is split between Cairo and the Gulf. Can you coordinate in both places?

Yes. Reserve Meds runs the patient-side coordination in Arabic where requested and the family-side coordination in English in parallel, with a single named coordinator running the case end to end. We support family correspondence across the UAE, Saudi Arabia, the UK, North America, and elsewhere in the Egyptian diaspora.

## Where Reserve Meds fits in Leqembi cases

Reserve Meds is a US-based concierge coordinator. We do not replace your neurologist, do not replace EDA, and do not act as an Egyptian importer of record. What we do is orchestrate the US-side specialty wholesaler sourcing under DSCSA serialization with full pedigree, prepare the cold-chain logistics under validated 2 to 8 degree Celsius packaging with continuous temperature monitoring through Cairo International Airport, and prepare the documentation kit your physician needs for the EDA Personal Importation filing. A single named concierge stays on the case from intake through the biweekly dose cadence, with Arabic-language patient-facing materials where the family requests them. Leqembi has no prior Reserve Meds case experience as of this review, so the operating posture is standard NPP coordination with particular attention to cold-chain integrity, destination-site MRI access for the label-required surveillance schedule, APOE4 documentation, and amyloid-pathology confirmation in the patient file before any procurement step.

## Next step

If a family member in Egypt has a confirmed amyloid-positive early Alzheimer's diagnosis and the treating neurologist is considering Leqembi, add the case to the waitlist. We will respond within 24 to 48 hours with a documentation kit for your physician and an indicative cost range in USD.

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*This guide is informational, not medical or legal advice. The Personal Importation framework requires a licensed Egyptian physician's clinical judgment; Reserve Meds is the coordinator, not the prescriber.*