

Leqembi

United Kingdom · access guide

Leqembi access in the United Kingdom: the Specials Licence pathway

Last reviewed 2026-05-16 by Reserve Meds clinical and regulatory team.

Quick orientation

Leqembi (lecanemab) is Eisai and Biogen's anti-amyloid beta protofibril humanised IgG1 monoclonal antibody for early Alzheimer's disease. The US FDA granted accelerated approval in January 2023 and full traditional approval in July 2023 for adults with mild cognitive impairment due to Alzheimer's disease or mild Alzheimer's dementia, confirmed by positive amyloid pathology. The MHRA granted UK marketing authorisation in August 2024. NICE issued draft guidance in late 2024 that did not recommend Leqembi for routine NHS funding, citing cost-effectiveness concerns despite the regulatory approval. The medicine is therefore licensed in the UK but not NHS-funded.

UK patients with early Alzheimer's disease whose neurologist has identified them as suitable candidates pursue private supply through UK-licensed specialty pharmacy distribution, private infusion centres, and the operational chain for the every-two-weeks IV infusion schedule. Reserve Meds coordinates US-side sourcing where required and provides operational support across the multi-month therapy.

Why UK patients pursue Leqembi privately

Approximately 944,000 people are living with dementia in the UK, with Alzheimer's disease as the most common cause. Until the arrival of the anti-amyloid antibodies the standard of care has been symptomatic treatment with cholinesterase inhibitors (donepezil, rivastigmine, galantamine) and memantine. Leqembi is the first disease-modifying therapy ever approved in the UK for early Alzheimer's disease. The CLARITY-AD registration trial showed a statistically significant 27% reduction on the Clinical Dementia Rating Sum of Boxes (CDR-SB) versus placebo over 18 months, with corresponding effects on other cognitive and functional endpoints.

The NICE not-recommended decision in late 2024 was driven by the cost-effectiveness analysis at the assessed price, with the size of the clinical effect, the cost of the medicine, the cost of the infrastructure required (amyloid PET or CSF assessment, MRI surveillance for ARIA, infusion delivery, longitudinal monitoring), and the prevalence of the eligible population all factoring in. The decision means that NHS-funded access is not available; the private supply route handles UK patients with the resources to self-fund.

The Specials Licence pathway for Leqembi in the UK

Leqembi holds UK marketing authorisation and is supplied through Eisai's UK specialty distribution chain against a private prescription from a UK consultant neurologist, geriatrician, or memory clinic physician with appropriate expertise. The Specials Licence framework is not the primary route given UK marketing authorisation; the operative supply route is a UK private prescription dispensed through a UK-licensed specialty pharmacy and administered at a private infusion centre.

The clinical infrastructure required is substantial. The eligibility workup includes amyloid pathology confirmation (amyloid PET scan or CSF amyloid beta 42/40 ratio), structural MRI to rule out exclusion criteria, APOE genotype (APOE4 homozygotes have higher ARIA risk and the FDA label flags this; UK practice and the MHRA SmPC reflect this), and the patient's cognitive baseline. The administration is 10 mg/kg IV infusion every two weeks. MRI surveillance for ARIA-E (oedema) and ARIA-H (haemorrhage) is required at specific time points throughout therapy.

Where Leqembi is delivered in the UK

The principal UK private memory clinic and infusion centre network for Leqembi includes Re:Cognition Health (a specialist private clinical research and treatment network with multiple UK sites focused on neurodegenerative disease), HCA Healthcare UK at The Wellington Hospital, Cromwell Hospital, The Princess Grace Hospital, The London Clinic, Spire Healthcare's specialist neurology services, and a growing footprint of private memory clinics in London, the South East, and major regional centres. NHS memory clinics across the country do not deliver Leqembi given the NICE position; private memory clinics and infusion centres handle the patient pathway.

Leqembi infusion is a structured outpatient service with the every-two-weeks IV infusion (each infusion approximately 60 minutes plus post-infusion observation), the MRI surveillance schedule (typically before doses 5, 7, 14, and after any new neurological symptom), and the ongoing cognitive and functional follow-up at the prescribing clinic.

Real cost picture for Leqembi in the UK

Leqembi's US WAC is approximately USD 26,500 per year at the average adult body weight; the dose is weight-banded (10 mg/kg every 2 weeks), so the precise cost depends on patient weight. At 0.79 GBP to 1 USD the US WAC equivalent converts to approximately GBP 20,900 per year for the medicine alone, before UK supply, infusion, and monitoring infrastructure costs.

The full UK private cost stack for Leqembi extends well beyond the medicine. The eligibility workup (amyloid PET scan or CSF analysis, MRI, APOE genotype, cognitive baseline) typically adds GBP 3,000 to GBP 6,000. The 26 IV infusions per year at a private infusion centre at typically GBP 400 to GBP 800 per infusion administration session add GBP 10,000 to GBP 21,000. The MRI surveillance schedule adds further cost. The clinical follow-up adds further cost. For a UK private Leqembi patient the all-in annual cost typically lands in the GBP 40,000 to GBP 60,000 range. UK private medical insurance generally does not cover Leqembi for early Alzheimer's disease at present.

Typical timeline for Leqembi in the UK

The Leqembi timeline runs as follows: Week 0 to 4 is the eligibility workup (amyloid pathology confirmation via PET or CSF, MRI, APOE genotype, cognitive baseline). Week 4 is the first IV infusion at the private infusion centre. Weeks 5 onwards is the every-two-weeks IV infusion maintenance, with MRI surveillance at the specified time points. Therapy continues until the consultant and patient decide to discontinue, typically based on disease progression beyond the early Alzheimer's window, intolerable ARIA, or other clinical reasons.

What your UK consultant needs to provide

The treating UK consultant neurologist, geriatrician, or memory clinic consultant is the prescribing physician of record. The clinical packet typically includes the diagnosis of mild cognitive impairment due to Alzheimer's disease or mild Alzheimer's dementia with cognitive screening (MMSE, MoCA, or equivalent), the amyloid pathology confirmation (amyloid PET scan or CSF amyloid beta 42/40 with phospho-tau profile), structural MRI excluding the contraindications (more than 4 microhaemorrhages, prior macrohaemorrhage, vasogenic oedema, cortical infarct), APOE genotype, anticoagulant medication review (which is a contraindication or significant risk consideration), and the proposed infusion centre.

The MHRA Yellow Card scheme is the active pharmacovigilance route for any suspected adverse drug reaction including amyloid-related imaging abnormalities (ARIA-E and ARIA-H), infusion reactions, and any clinical deterioration.

Common questions about Leqembi in the UK

Will the NHS pay for Leqembi? No. NICE issued draft guidance in late 2024 that did not recommend Leqembi for routine NHS funding. NHS England does not commission Leqembi as a result. NICE may issue a final updated position over time; the current position is no NHS funding.

What about Individual Funding Request (IFR)? NHS England Individual Funding Requests succeed only on a genuinely exceptional case basis and are not a workaround for medicines that NICE has not recommended. IFR is unlikely to be a productive route for Leqembi.

Will my private medical insurance cover Leqembi? Major UK private medical insurers generally do not cover Leqembi for early Alzheimer's disease at present. Some specialty schemes may consider case-by-case funding but cover is rare.

What is ARIA and how serious is it? Amyloid-related imaging abnormality (ARIA) describes two related radiographic findings: ARIA-E (vasogenic oedema or sulcal effusions) and ARIA-H (microhaemorrhages or superficial siderosis). ARIA is a known complication of anti-amyloid antibody therapy. Most ARIA is asymptomatic and detected on routine surveillance MRI; a minority is symptomatic, with rare cases of clinically significant deterioration. APOE4 homozygotes have materially higher ARIA risk. The MHRA SmPC and FDA label reflect these considerations.

How does Leqembi compare to Kisunla (donanemab)? Kisunla (donanemab) is Eli Lilly's anti-amyloid antibody, FDA-approved in July 2024 for the same early Alzheimer's disease indication. The MHRA reviewed Kisunla and NICE will also issue a position. The two medicines have different binding profiles (Leqembi binds soluble amyloid protofibrils; Kisunla binds pyroglutamate-modified amyloid plaque) and different dosing regimens (Leqembi every 2 weeks continuously; Kisunla every 4 weeks with potential to stop on amyloid plaque clearance). The choice between them is a clinical decision based on patient profile, infusion logistics, and the prescriber's experience.

What about patients on anticoagulant or antiplatelet therapy? Anticoagulant therapy is generally a contraindication or significant risk factor for anti-amyloid antibody therapy. Antiplatelet therapy is a relative consideration. Patients on warfarin, direct oral anticoagulants, or dual antiplatelet therapy should discuss the risk-benefit calculation with their consultant in detail.

Where Reserve Meds fits in Leqembi cases

Reserve Meds is a US-based concierge coordinator. For Leqembi the UK private supply chain through UK-licensed specialty pharmacy distribution and UK private infusion centres is the standard private route and is typically efficient. Our role is most relevant for international patients moving between markets who want a single coordinator across borders, for documentation support across the multi-month therapy and monitoring schedule, and for specific operational scenarios where US-side sourcing is preferred. For most standard UK private Leqembi cases the UK supply chain is the more straightforward route.

The Yellow Card pharmacovigilance pathway for Leqembi

The MHRA Yellow Card scheme is the UK's national pharmacovigilance reporting system. Healthcare professionals, patients, and carers can report suspected adverse drug reactions, medical device incidents, defective medicines, and counterfeit medicines through the scheme. For specialty medicines accessed through the Specials Licence pathway, Yellow Card reporting is the operational mechanism that connects the UK clinical experience back to the global pharmacovigilance dataset that the MHRA, FDA, EMA, and other regulators rely on.

For Leqembi specifically, Reserve Meds coordinates the pharmacovigilance reporting chain in three ways. First, the prescribing UK consultant or the dispensing pharmacy submits any suspected adverse reactions through the Yellow Card scheme as standard practice. Second, the manufacturer's UK pharmacovigilance contact receives the case report through the standard regulatory channel and connects the case to the global safety database. Third, where the patient's clinical follow-up continues across markets, Reserve Meds provides the documentation continuity that lets the patient's consultants and the manufacturer's safety team coordinate across borders.

The MHRA also operates the Black Triangle (inverted black triangle) safety monitoring scheme for medicines that are under additional monitoring (typically newer medicines or medicines for which additional safety data are being collected). The Yellow Card scheme works the same way for Black Triangle medicines but with heightened attention to reporting.

UK consumer protection and patient rights for Leqembi

UK patients accessing specialty medicines through private pharmacy supply have the same consumer protections that apply to any UK regulated medicine purchase. The Care Quality Commission regulates private healthcare providers in England; Healthcare Improvement Scotland, Healthcare Inspectorate Wales, and the Regulation and Quality Improvement Authority in Northern Ireland are the parallel regulators in the devolved nations. The General Pharmaceutical Council regulates pharmacy professionals and registered pharmacy premises. The General Medical Council regulates doctors. The Nursing and Midwifery Council regulates nurses, including specialist nurses involved in cell therapy and homecare administration.

For UK patients accessing Leqembi, the relevant protections include the prescribing consultant's professional duty under GMC Good Medical Practice, the dispensing pharmacist's professional standards under General Pharmaceutical Council standards, the homecare provider's regulatory framework (where applicable), and the manufacturer's UK pharmacovigilance obligations. Reserve Meds operates as a US-based coordinator and is subject to US regulatory frameworks for our US-side operations; we do not replace or substitute for UK consumer protections, which the UK clinical and pharmacy chain provides directly.

Special considerations for international UK residents and dual-citizen families

The UK is home to a substantial population of international residents, dual-citizen families, and patients who spend significant time across multiple markets. For Leqembi cross-border continuity of care across the UK, the United States, the Gulf, India, and other markets is a recurring operational pattern. Reserve Meds is structured to support this cross-market reality with a single coordinator who understands the regulatory frameworks across the relevant jurisdictions, the documentation portability across markets, and the operational connection back to the UK clinical team during periods of UK residence.

UK patients who spend time in the United States may also pursue treatment at a US authorised treatment centre when this is clinically or operationally preferable. Reserve Meds provides the US-side liaison, the documentation packet for the US treatment centre, and the operational support across the UK-US clinical handover both at the start and on return to the UK for long-term follow-up.

Where to read more about Leqembi and the UK Specials pathway

Reserve Meds publishes detailed reference material across the regulatory pathways, country specifics, and condition-specific access guides. For the regulatory framework underlying the UK route to Leqembi, the named-patient pathway overview covers the international framework and the United Kingdom country deep-dive covers the MHRA Specials Licence, NICE technology appraisal, NHS England Specialised Commissioning, and the dispensing infrastructure in detail. The MHRA's own guidance on the supply of unlicensed medicinal products (often called the MHRA Guidance Note 14) provides the formal regulatory framing for prescribers and pharmacists. The General Pharmaceutical Council's standards on the dispensing of unlicensed medicines provide the pharmacy practice framework.

For UK patient information on the NHS-funded pathway, the National Institute for Health and Care Excellence (NICE) publishes the relevant technology appraisal guidance, and NHS England Specialised Commissioning publishes the corresponding clinical commissioning policy. Patients can search the NICE website for the specific technology appraisal that applies to their medicine and indication.

Reserve Meds's role

US-based concierge coordinator for cross-border specialty medicine. We are not the prescriber, not the dispensing pharmacy, and not the manufacturer. All clinical decisions remain with your treating physician.

Reserve Meds

reserved for you.

Composite case examples. This document is for general information only and does not constitute medical advice. Please consult your treating physician.

Reserve Meds is in pre-launch. Published timelines and cost ranges are indicative, not guarantees.

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