Kisunla

United Kingdom · access guide

Kisunla access in the United Kingdom: the Specials Licence pathway

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

Quick orientation

Kisunla (donanemab) is Eli Lilly's anti-amyloid humanised IgG1 monoclonal antibody, FDA-approved in July 2024 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, and NICE has progressed Kisunla through technology appraisal. Where Leqembi received a NICE not-recommended position in late 2024, Kisunla's NICE position is being formed at the time of writing. The two medicines have similar overall positioning as the new generation of disease-modifying therapies for early Alzheimer's disease, with different binding profiles and dosing strategies.

Kisunla's distinctive feature is the limited-duration dosing strategy: the medicine targets pyroglutamate-modified amyloid plaque, and on confirmed plaque clearance (typically assessed by follow-up amyloid PET at 6, 12, and 18 months) the medicine can be stopped, potentially reducing total exposure, cost, and ARIA risk over a complete treatment course.

Why UK patients pursue Kisunla

The same reasons that drive UK patients toward Leqembi apply to Kisunla: early Alzheimer's disease has historically had no disease-modifying treatment, the anti-amyloid antibodies represent the first generation of disease-modifying therapy, and UK patients with the clinical profile and the resources to self-fund pursue private supply. Where Leqembi has the NICE not-recommended position, Kisunla's NICE outcome may differ given the limited-duration dosing strategy and its effect on the cost-effectiveness analysis.

Patients and consultants choose Kisunla over Leqembi based on the limited-duration dosing strategy (Kisunla can be stopped on confirmed amyloid plaque clearance, where Leqembi is currently continuous), the every-four-weeks IV infusion schedule (Kisunla) versus every-two-weeks (Leqembi), the specific amyloid binding profile, and the prescriber's clinical experience.

The Specials Licence pathway for Kisunla in the UK

Kisunla holds UK marketing authorisation and is supplied through Eli Lilly's UK specialty distribution chain against a private prescription from a UK consultant neurologist, geriatrician, or memory clinic consultant. The standard private route is a UK private prescription dispensed through a UK-licensed specialty pharmacy and administered at a private infusion centre. The Specials Licence framework is not the primary route given UK marketing authorisation; the supply chain operates through standard licensed channels.

Eligibility workup mirrors Leqembi: amyloid pathology confirmation (PET or CSF), structural MRI to rule out exclusions, APOE genotype (with the same higher ARIA risk for APOE4 homozygotes), and cognitive baseline. The administration is a weight-banded IV infusion every four weeks. MRI surveillance for ARIA is required at specific time points throughout therapy.

Where Kisunla is delivered in the UK

The same UK private memory clinic and infusion centre network that delivers Leqembi handles Kisunla. The principal sites include Re:Cognition Health (multi-site UK private memory clinic and clinical research network), HCA Healthcare UK private hospitals (The Wellington, Princess Grace, Harley Street Clinic), Cromwell Hospital, The London Clinic, Spire Healthcare's neurology services, and the growing private memory clinic footprint in London and major UK cities. The every-four-weeks dosing cadence requires less frequent infusion centre attendance than Leqembi's every-two-weeks schedule, which can simplify the operational pattern.

The MRI surveillance schedule for ARIA-E and ARIA-H is mandatory, typically with scans before doses 2, 3, 4, and 7, and after any new neurological symptom. The infusion centre must coordinate with the imaging provider and the prescribing consultant on the surveillance schedule.

Real cost picture for Kisunla in the UK

Kisunla's US WAC is approximately USD 32,000 per year at the dose ascending schedule, before the potential dose reduction or discontinuation on confirmed amyloid plaque clearance. At 0.79 GBP to 1 USD the US WAC equivalent converts to approximately GBP 25,300 per year for the medicine before UK supply and infrastructure costs. The limited-duration dosing strategy can materially reduce the lifetime cost of therapy if amyloid plaque clearance is confirmed early (some patients achieve clearance at 6 or 12 months and can stop the medicine).

The full UK private cost stack for Kisunla extends to the eligibility workup (amyloid PET or CSF, MRI, APOE genotype, cognitive baseline: GBP 3,000 to GBP 6,000), the 13 IV infusions per year (at typically GBP 400 to GBP 800 per administration), the MRI surveillance schedule, and the clinical follow-up. Annual all-in cost for a UK private Kisunla patient typically lands in the GBP 35,000 to GBP 50,000 range. UK private medical insurance generally does not cover Kisunla for early Alzheimer's disease at present.

Typical timeline for Kisunla in the UK

The Kisunla timeline runs as follows: Week 0 to 4 is the eligibility workup. Week 4 is the first IV infusion. Weeks 8, 12, 16 onwards is the every-four-weeks IV infusion maintenance with MRI surveillance at the specified time points. At month 6, 12, and 18 the consultant may order follow-up amyloid PET to assess plaque clearance; on confirmed clearance the medicine can be stopped. Therapy duration ranges from approximately 6 months (in patients achieving rapid clearance) to several years.

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 mirrors the Leqembi packet: early Alzheimer's disease diagnosis with cognitive screening, amyloid pathology confirmation (amyloid PET scan or CSF amyloid profile), structural MRI excluding contraindications (more than 4 microhaemorrhages, prior macrohaemorrhage, vasogenic oedema, cortical infarct), APOE genotype, anticoagulant medication review, and the proposed infusion centre.

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

Common questions about Kisunla in the UK

Will the NHS fund Kisunla? NICE technology appraisal is in progress. The NHS England commissioning position depends on the eventual NICE recommendation. The limited-duration dosing strategy may change the cost-effectiveness calculation compared with Leqembi's continuous dosing.

How does Kisunla compare to Leqembi? Both are anti-amyloid antibodies for early Alzheimer's disease. Kisunla targets pyroglutamate-modified amyloid plaque and is dosed every 4 weeks with the option to stop on confirmed plaque clearance. Leqembi targets soluble amyloid protofibrils and is dosed continuously every 2 weeks. The TRAILBLAZER-ALZ 2 trial showed Kisunla efficacy at 76 weeks; the CLARITY-AD trial showed Leqembi efficacy at 18 months. Head-to-head comparison is limited. The choice is a clinical decision.

What is the limited-duration dosing strategy? Kisunla's mechanism targets pre-existing amyloid plaque. Once plaque is cleared (assessed by follow-up amyloid PET), continuing the medicine offers limited additional benefit. The FDA label permits stopping the medicine on confirmed plaque clearance, typically assessed at 6, 12, and 18 months. The strategy can materially reduce the total treatment exposure, cost, and the cumulative ARIA risk.

What is the ARIA risk profile? ARIA risk is similar in profile to Leqembi though the specific incidence and severity vary across trial datasets. APOE4 homozygotes have higher ARIA risk. The MHRA SmPC and FDA label reflect these considerations. MRI surveillance is mandatory.

What about patients on anticoagulant or antiplatelet therapy? Anticoagulant therapy is generally a significant risk consideration for anti-amyloid antibody therapy. The risk-benefit calculation is patient-specific and rests with the consultant.

Will my UK private medical insurance cover Kisunla? Major UK private medical insurers generally do not cover Kisunla for early Alzheimer's disease at present. Cover may evolve as the disease-modifying therapy class establishes in UK practice.

Where Reserve Meds fits in Kisunla cases

Reserve Meds is a US-based concierge coordinator. For Kisunla our role is most relevant for international patients moving between markets, for documentation support across the multi-month therapy and PET-guided dosing strategy, and for specific operational scenarios where US-side sourcing is preferred. The UK private supply chain through UK-licensed specialty pharmacy and private infusion centres is the standard private route for most cases.

The Yellow Card pharmacovigilance pathway for Kisunla

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 Kisunla 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 Kisunla

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 Kisunla, 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 Kisunla 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 Kisunla 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 Kisunla, 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.

reserved for you.

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