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Interim Analysis of the United Kingdom Donanemab Controlled Access Programme: Early Patient Characteristics and Prescribing Patterns

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OBJECTIVE

- To describe the demographic and clinical characteristics of patients registered in the UK donanemab CAP during the first 12 months of programme operation
- To evaluate prescriber adherence to approved UK Summary of Product Characteristics (SmPC) prescribing criteria
- To characterise patterns of donanemab prescribing, including indication, diagnostic testing, and initial dosing

CONCLUSION

- This interim analysis of 147 patients registered in the UK donanemab CAP demonstrates high prescriber adherence to approved labelling criteria for indication, amyloid confirmation, baseline MRI, medical history screening, and anticoagulant avoidance.
- 55.8% of registrations reported an initial dose other than 700 mg. Per anecdotal reports, this likely reflects adoption of the modified dosing regimen now approved in multiple markets.
- The UK CAP questionnaire was amended in November 2025 to capture the 350 mg initial dose; further characterisation of dosing patterns is expected in future reports.
- 20.4% of registrations had unknown APOE ε4 genotype status.
- Regular evaluations of the CAP will continue.

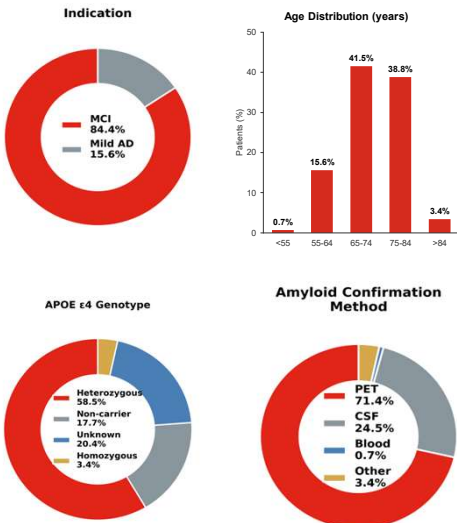
BACKGROUND

- Donanemab, an amyloid-targeting therapy for early symptomatic Alzheimer's disease, received approval in the United Kingdom (UK) in October 2024.
- As a condition of marketing authorisation, the Medicines and Healthcare Products Regulatory Agency (MHRA) required implementation of a controlled access programme (CAP) as an additional risk minimisation measure, in alignment with Good Pharmacovigilance Practice (GVP) Module XVI and UK pharmacovigilance legislation.
- The UK CAP does not restrict access to donanemab; it functions as a registration system that confirms appropriate patient characteristics and provides healthcare professionals (HCPs) with educational materials prior to treatment initiation.
- Results from CAP analyses are reported to MHRA in Periodic Safety Update Reports.
- As of the data lock for this analysis, donanemab was not reimbursed in the UK, limiting use and CAP reporting to privately funded patients.

Patient Characteristics (N=147)

- 57.8% female, 42.2% male
- Majority aged 65 to 84 years (80.3%)
- 100% confirmed amyloid pathology; 100% baseline MRI
- 0% concomitant anticoagulant use; 0% contraindicated medical history

Figure 2. Distribution of patient demographics, clinical characteristics, and diagnostic methods.



STUDY DESIGN

Programme Design

The UK CAP, designed in alignment with GVP Module XVI, launched on 27 January 2025. Registration is required prior to the first infusion of donanemab for all patients. Data for this analysis were collected from 27 January 2025 through the data lock point of 02 January 2026.

Data Collected at Registration

- Patient demographics (age, gender)
- Indication for use
- Method of amyloid pathology confirmation
- APOE ε4 genotype
- Baseline MRI status
- Relevant medical history
- Concomitant antithrombotic medication use
- Initial donanemab dose

Prescribing appropriateness was evaluated against approved UK SmPC criteria.

Prescribing Patterns

Self-Reported Prescribing HCP Specialty

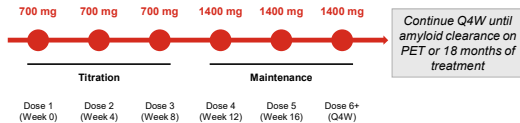
- Neurologist: 25.9% (n=38)
- Geriatrician: 2.7% (n=4)
- Old age psychiatrist: 1.4% (n=2)
- Other*: 70.1% (n=103), predominantly consultant neuroradiologist (n=98)

*Self report from HCPs selecting "Other"

Initial Dose

- 44.2% received the approved initial dose of 700 mg; 55.8% received an alternative initial dose.
- In all cases where the initial dose differed, no other prescribing criteria (aside from dose and APOE ε4 status) were unmet.
- On 10 November 2025, the CAP questionnaire was updated to include 350 mg as a selectable initial dose option.
- UK clinician feedback suggests prescribers adopted the modified dosing regimen (initial dose 350 mg) from the TRAILBLAZER-ALZ 6 study, approved multiple markets.

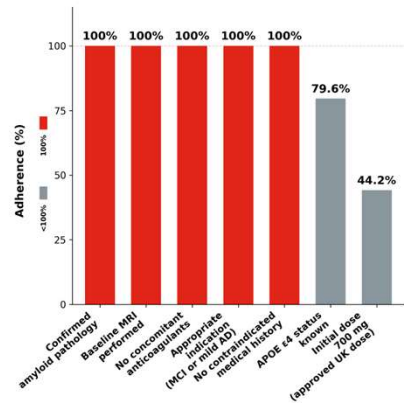
Figure 3: UK Approved Donanemab Dosing Schedule



KEY RESULT

- Complete adherence to indication, diagnostic, and safety-related prescribing criteria was observed (Figure 1).
- 55.8% of patients received an initial dose other than the approved 700 mg.
- 20.4% of registrations reported APOE ε4 genotype as unknown.

Figure 1. Adherence to approved UK SmPC prescribing criteria (N=147).



Pharmacovigilance Context

- The UK CAP is complemented by 3 non-interventional PASS approved by the MHRA:
- a safety registry to characterise ARIA,
- a secondary database study,
- and an HCP survey to assess effectiveness of risk minimisation.

Limitations

- Small sample size (N=147) with a majority from a single organization, limiting patient mix and prescriber behaviors
- Limited to privately funded patients; prescribing patterns may differ once NHS reimbursement is available
- First 12-month reporting period; more patients treated across more diverse settings may be expected in the future

References

1. Sims JR, et al. JAMA. 2023;330(6):512-527.
2. EMA. GVP Module XVI: Risk minimisation measures (Rev 3). 2024.
3. Kisunla (donanemab) UK SmPC. Eli Lilly and Company. 2024.