



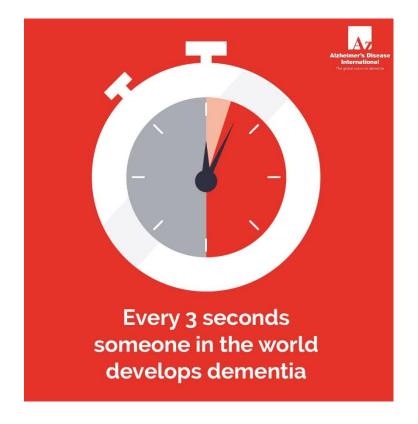
Τελευταίες εξελίξεις στη Νόσο Alzheimer. Βιοδείκτες στο αίμα Μονοκλωνικά αντισώματα κατά του β-αμυλοειδούς

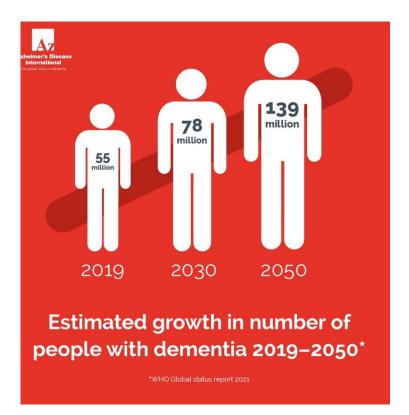
Παρασκευή Σακκά

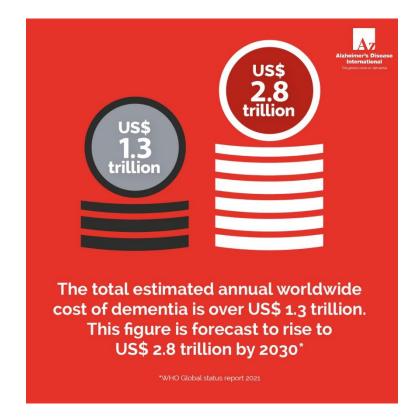
Νευρολόγος – Ψυχίατρος

Εταιρεία Alzheimer Αθηνών Εθνικό Παρατηρητήριο για την Άνοια και τη νόσο Alzheimer Ιατρείο Μνήμης Νοσοκομείου ΥΓΕΙΑ

Νοέμβριος 2025











Η άνοια σήμερα

- Η άνοια πλήττει το 5% των ανθρώπων άνω των 65 ετών
- 98% των ατόμων με άνοια είναι άνω των 65 ετών
- Με την αύξηση του προσδόκιμου επιβίωσης, μείζον ιατρικό, κοινωνικό και οικονομικό πρόβλημα για τα συστήματα ασφάλισης υγείας αλλά και την ποιότητα ζωής των νοικοκυριών!



Η άνοια στην Ελλάδα σήμερα

- •250.000 άτομα με άνοια στην Ελλάδα
- •350.000 άτομα με Ήπια Νοητική Διαταραχή
- •2 φροντιστές ανά ασθενή
- •Αφορά σε περισσότερο από 1,5 εκατομμύριο Έλληνες πολίτες
- •Το κόστος της άνοιας στην Ελλάδα ανέρχεται σε 3 δισεκατομμύρια € ετησίως!

Brain Health Determinants











Physical health

Maternal health, intrauterine environment

Genetic and epigenetic factors

Nutrition

Infections

NCDs

Health behaviours

Traumatic injuries

Healthy environments

Safe use of chemicals

Protection from radiation

Healthy and safe workplaces and agricultural practices

Air and water quality

Stable climate

Access to preserved nature and health-supportive built environments

Safety & security

Physical safety

Financial security

Humanitarian crises and emergencies

Learning & social connection

Education

Lifelong learning

Nurturing care

Social connection/ social isolation

Social networks

Access to quality services

Integrated care at all health/social care levels

Skilled workforce and Interdisciplinary teams

Access to essential medicines, diagnostics and health products

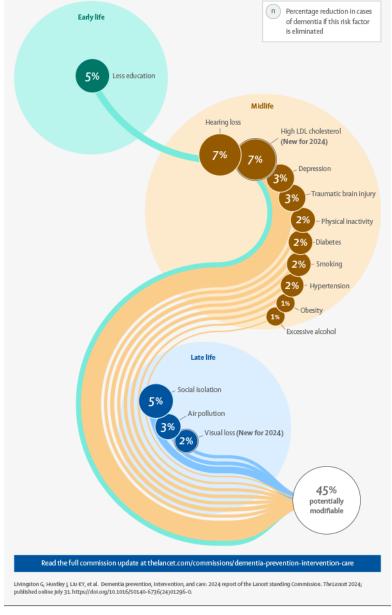
Carer support

WHO 2024

Dementia prevention, intervention, and care: 2024 report of the *Lancet* Commission

Risk factors for dementia — 2024 update

The 2024 update to the standing Lancet Commission on dementia prevention, intervention, and care adds two new risk factors (high LDL cholesterol and vision loss) and indicates that nearly half of all dementia cases worldwide could be prevented or delayed by addressing 14 modifiable risk factors.



THE LANCET

Η Ελληνική Παρεμβατική Πρωτοβουλία Αποτροπής της Εμφάνισης Νοητικής Διαταραχής και Αναπηρίας



TYPE Study Protocol PUBLISHED 18 March 2025 DOI 10 3389/fpsyt 202515L4227



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Interventional Geriatric Initiative
to Prevent Cognitive Impairment
and Disability in individuals with
subjective cognitive decline:
paving the way towards brain
health clinics in Greece

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and Constantine Lyketsos^{23†}



Brain health services: Κέντρα Υγείας Εγκεφάλου

Νέες καινοτόμες υπηρεσίες – Ιατρική Ακριβείας

4 BHMATA

- Εξατομικευμένη εκτίμηση κινδύνου
- Έγκυρη ενημέρωση σωστή επικοινωνία
- Προσωπικό πλάνο φροντίδας
- Γνωσιακή ενίσχυση νέες τεχνολογίες







European Parliament Lunch Debate "Preparing for new Alzheimer's treatments in Europe" 3 June 2025





World Alzheimer Report 2025

Reimagining life with dementia – the power of rehabilitation



Αποκατάσταση: Το εργαλείο για μια πιο ανεξάρτητη ζωή

Εξατομικευμένη προσέγγιση - οι στόχοι τίθενται από κοινού με το ίδιο το άτομο και την οικογένειά του. Οι στόχοι πρέπει να είναι SMART:

- **Specific** (Συγκεκριμένοι): Περιγράφουν σαφείς δράσεις, π.χ. «θα μπορώ να μαγειρεύω το αγαπημένο μου φαγητό».
- **Measurable** (Μετρήσιμοι): Επιτρέπουν την παρακολούθηση της προόδου, π.χ. «θα χρησιμοποιώ την εφαρμογή μετακινήσεων στο κινητό μου».
- Achievable (Εφικτοί): Είναι ρεαλιστικοί, π.χ. η βελτίωση της κινητικότητας μετά από πτώση.
- Relevant (Σχετικοί): Έχουν πραγματική σημασία για το άτομο, π.χ. να μιλά με τα παιδιά του μέσω βιντεοκλήσης.
- **Time-bound** (Χρονικά προσδιορισμένοι): Έχουν καθορισμένο χρονικό πλαίσιο επίτευξης.

The dementia rehabilitation journey

- Family, friends, neighbours
- Home carers and care home staff
- Health and care professionals



Involving one's support network

Defining one's goals

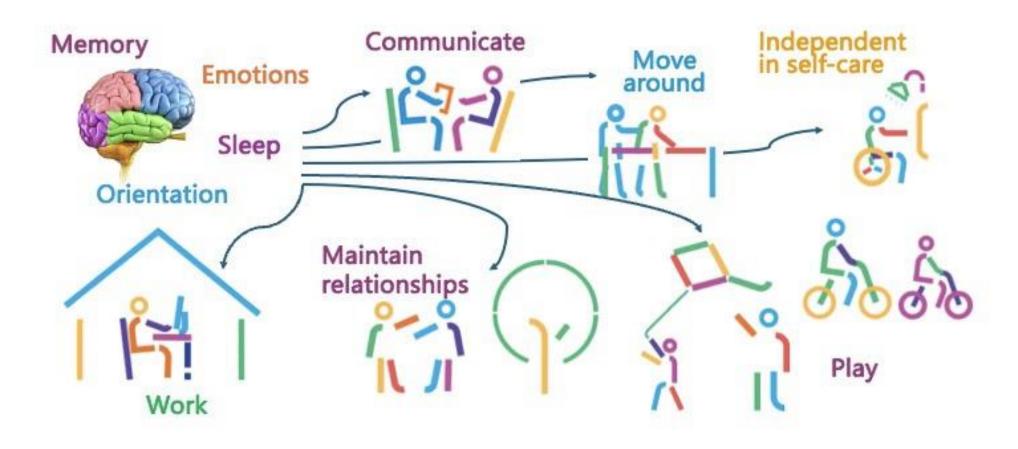
- Focus on the impact of cognitive challenges on everyday functioning
- Address range of complex needs
- Physical rehabilitation following illness or injury

Progress towards goal

Working collaboratively with rehabilitation practitioners

- Occupational therapists
- Speech and language therapists
- Physiotherapists
- Geriatricians
- · And/or others...

Rehabilitation is about "functioning"

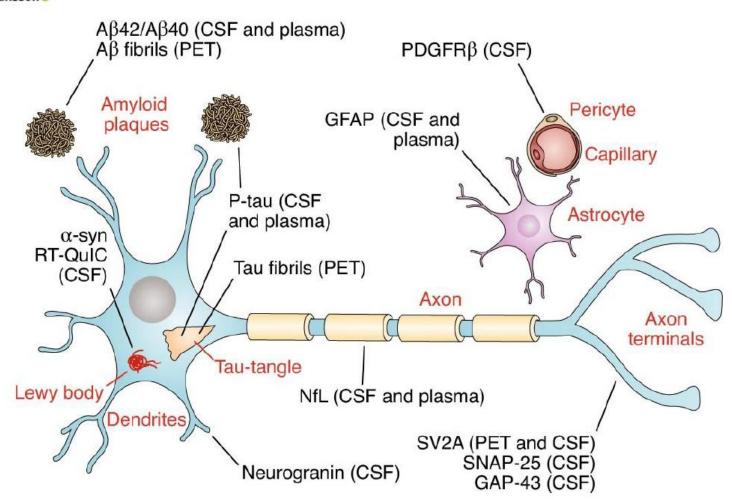






Biomarkers for neurodegenerative diseases

Oskar Hansson®1,2 ☑



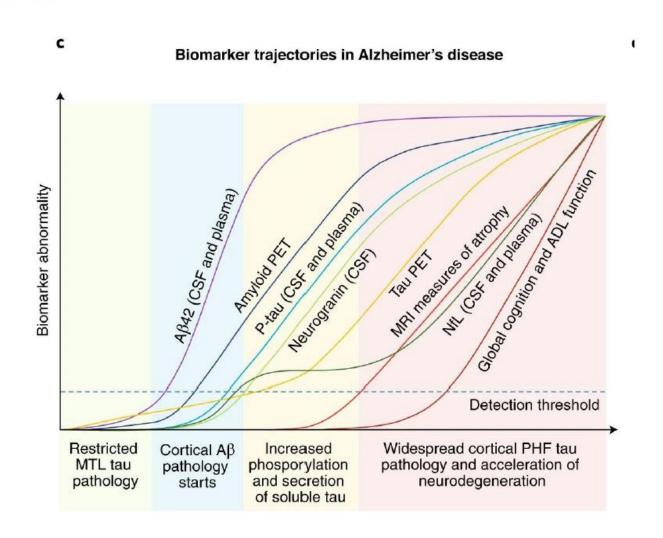




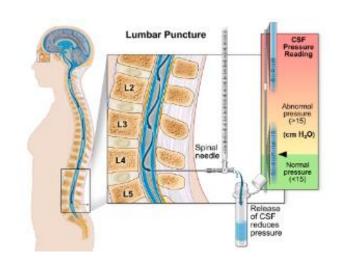


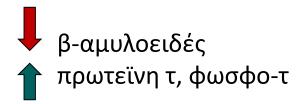
Biomarkers for neurodegenerative diseases

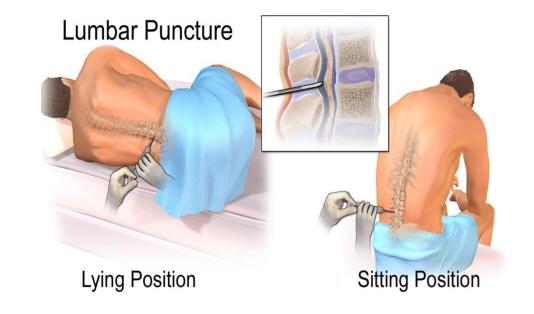




Βιοδείκτες στο Εγκεφαλονωτιαίο Υγρό: β-αμυλοειδές / πρωτεΐνη τ

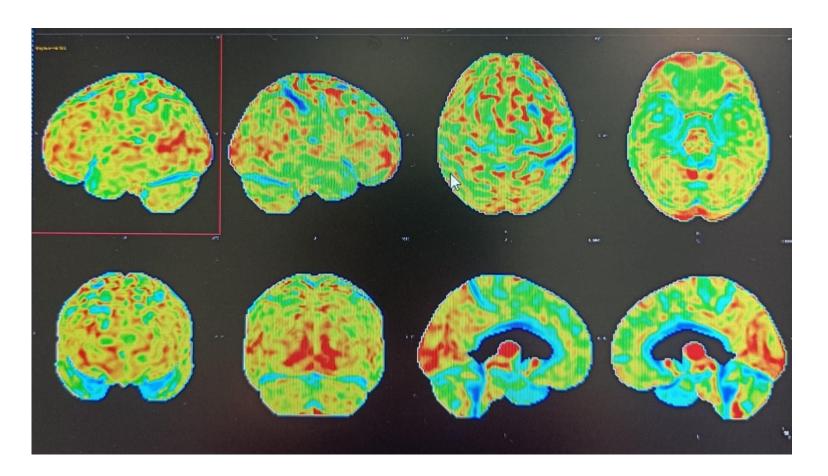






PET/CT αμυλοειδούς-Neuraceq

- Μη επεμβατική μέθοδος ανίχνευσης των αμυλοειδών πλακών στον εγκέφαλο.
- Εμφανίζει εξαιρετικά υψηλή ευαισθησία και ειδικότητα επιτρέποντας την πρώιμη και ακριβή διάγνωση.



ΤΜΗΜΑ PET-CT ΝΟΣΟΚΟΜΕΙΟΥ ΥΓΕΙΑ Received: 7 February 2024

Revised: 21 March 2024 Accepted: 4 April 2024

DOI: 10.1002/alz 13859

RESEARCH ARTICLE



Revised criteria for diagnosis and staging of Alzheimer's disease: Alzheimer's Association Workgroup

```
Clifford R. Jack Jr. J. Scott Andrews Thomas G. Beach Teresa Buracchio Teresa Buracchio
Billy Dunn<sup>5</sup> | Ana Graf<sup>6</sup> | Oskar Hansson<sup>7,8</sup> | Carole Ho<sup>9</sup> | William Jagust<sup>10</sup>
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Reisa Sperling<sup>19</sup> | Charlotte E. Teunissen<sup>20</sup> | Maria C. Carrillo<sup>18</sup>
```

TABLE 1 Categorization of fluid analyte and imaging biomarkers.

| Biomarker category | CSF or plasma analytes | Imaging | | | | | | |
|---|---|---------------------------------|--|--|--|--|--|--|
| Core Biomarkers | | | | | | | | |
| Core 1 | | | | | | | | |
| A (A β proteinopathy) | Αβ 42 | Amyloid PET | | | | | | |
| T ₁ : (phosphorylated and secreted AD tau) | p-tau217, p-tau181, p-tau231 | | | | | | | |
| Core 2 | | | | | | | | |
| T ₂ (AD tau proteinopathy) | MTBR-tau243, other phosphorylated tau forms (e.g., p-tau205), non-phosphorylated mid-region tau fragments ^a | Tau PET | | | | | | |
| Biomarkers of non-specific processes involved in AD pathophysiology | | | | | | | | |
| N (injury, dysfunction, or degeneration of neuropil) | NfL | Anatomic MRI, FDG PET | | | | | | |
| I (inflammation) Astrocytic activation | GFAP | | | | | | | |
| Biomarkers of non-AD copathology | | | | | | | | |
| V vascular brain injury | | Infarction on MRI or CT, WMH | | | | | | |
| Sα-synuclein | α Syn-SAA a | | | | | | | |

Notes: P-tau231, p-tau205, MTBR-tau243, and non-phosphorylated tau fragments are included in this table because they are discussed in the text; however, these analytes have not undergone the same level of validation testing as other Core biomarkers. Biomarkers are categorized based on four criteria. First, three broad mechanistic groupings have been identified. Second, biomarkers are subclassified based on the proteinopathy or pathophysiologic pathway that each measures (e.g., A, T₁, T₂, N etc.). Third, within the Core category we distinguish between Core 1 and Core 2 biomarkers. Fourth, imaging and fluid analyte biomarkers are listed separately within each category.

Received: 7 February 2024 | Revised: 21 March 2024 | Accepted: 4 April 2024

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RESEARCH ARTICLE

Alzheimer's & Dementia

Revised criteria for diagnosis and staging of Alzheimer's disease: Alzheimer's Association Workgroup

TABLE 2 Intended uses for imaging, CSF, and plasma biomarker assays.

| Intended use | CSF | Plasma | Imaging | |
|--|--|---|---------------------------------|--|
| Diagnosis | | | | |
| A: (Aβ proteinopathy) | _ | _ | Amyloid PET | |
| T ₁ : (phosphorylated and secreted AD tau) | - | p-tau217 | - | |
| Hybrid ratios | p-tau181/Aβ42, t-tau/Aβ42, Aβ42/40 | %p-tau217 | - | |
| Staging, prognosis, as an indicator | of biological treatment effect | | | |
| A: (Aβ proteinopathy) | = | - | Amyloid PET | |
| T ₁ : (phosphorylated and secreted AD tau) | - | p-tau217 | - | |
| Hybrid ratios | p-tau181/Aβ42, t-tau/Aβ42, Aβ42/40 | %p-tau217 | - | |
| T ₂ : (AD tau proteinopathy) | MTBR-tau243, other p-tau forms (e.g., p-tau205), non-phosphorylated mid-region tau fragments | MTBR-tau243, other p-tau forms (e.g., p-tau205) | Tau PET | |
| N (injury, dysfunction, or degeneration of neuropil) | NfL | NfL | Anatomic MRI, FDG PET | |
| I (inflammation) Astrocytic activation | GFAP | GFAP | - | |
| Identification of copathology | | | | |
| N (injury, dysfunction, or degeneration of neuropil) | NfL | NfL | Anatomic MRI, FDG PET | |
| V vascular brain injury | - | - | Infarction on MRI or CT, WMH | |
| S α-synuclein | αSyn-SAA | - | | |

Notes: Table 2 lists assays while Table 1 lists analytes; therefore, plasma and CSF are listed separately in Table 2 but listed together in Table 1. The focus in this table is on plasma p-tau217 and not p-tau231, p-tau181, or $A\beta42/40$ because p-tau217 typically outperforms these other plasma assays in head-to-head comparisons. %p-tau is the ratio p-tau217/non-phosphorylated-tau217. Combinations of Core 1 biomarkers may also be used for diagnosis. P-tau205, MTBR-tau243, and non-phosphorylated tau fragments have not undergone the same level of validation testing as has tau PET; however, they are included to support a "conceptual" staging scheme outlined in Table 5.

Received: 7 February 2024 Revised: 21 March 2024 Accepted: 4 April 2024

DOI: 10.1002/alz 13859

RESEARCH ARTICLE

Alzheimer's & Dementia*

Εγκεκριμένοι βιοδείκτες για τη νόσο Alzheimer

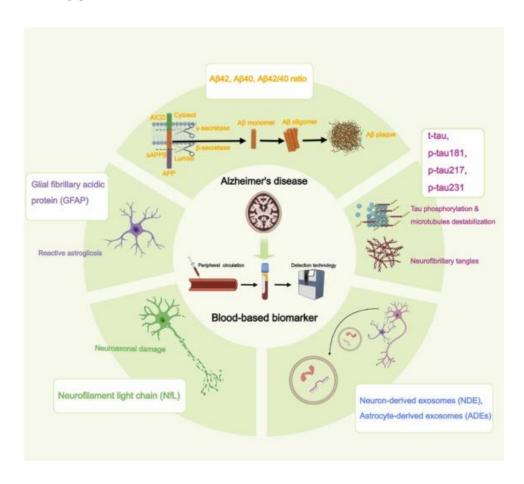
• ↑ Αβ42, ↓ptau στο εγκεφαλονωτιαίο υγρό

ENY

• Aβ42/Aβ40 ratio (CSF)

Βιοδείκτες στο αίμα

- ptau217/Ab42
- Amyloid PET
- Tau PET



Βιοδείκτες για τη νόσο Alzheimer στο πλάσμα

- Πλήθος βιοδεικτών έχουν μελετηθεί!
- Ab42/Ab40
- ptau 181, ptau231
- NFL (neurodegeneration μη ειδικό)
- GFAP (glial fibrillary acidic protein) σταδιοποίηση και παρακολούθηση
- ptau 217
- Ptau217/Ab42



Φαρμακευτική θεραπεία νόσου Alzheimer

Συμπτωματική Θεραπεία

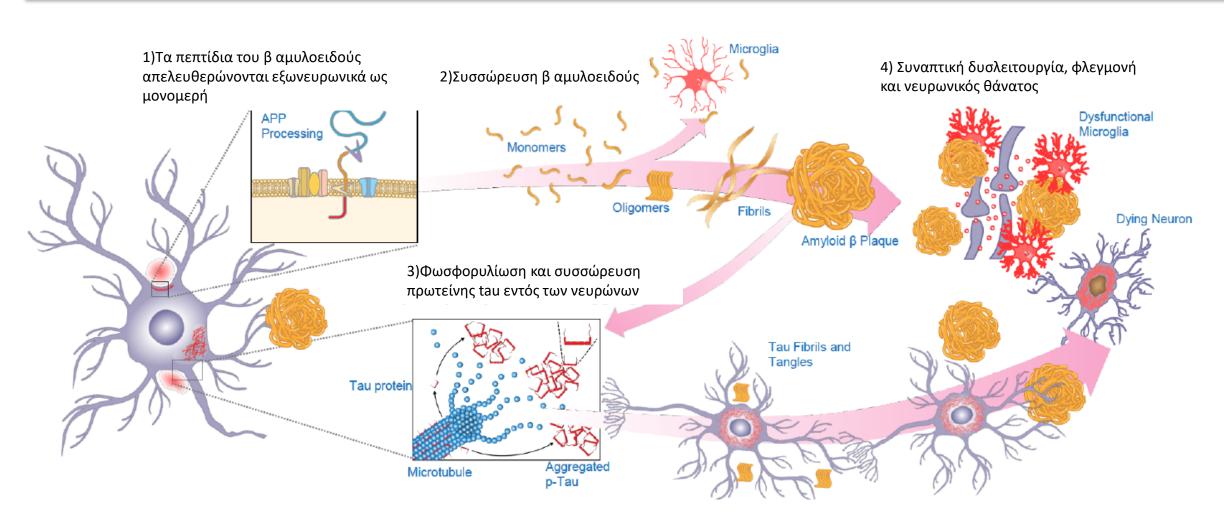
- Νοοτρόπα φάρμακα (piracetam, aniracetam, nimodipine)
- Κεντρικοί Αναστολείς Χολινεστερασών
- NMDA ανταγωνιστής (memantine)

Αιτιολογική Θεραπεία

Μονοκλωνικά αντισώματα κατά του β-αμυλοειδούς

- Aducanumab 2021
- Lecanemab 2023 ΗΠΑ 2024 Ευρώπη
- Donanemab 2024 ΗΠΑ 2025 Ευρώπη

Τα δύο σημαντικότερα παθολογοανατομικά χαρακτηριστικά της νόσου Alzheimer είναι οι αμυλοειδικές πλάκες και τα νευροϊνιδιακά συμπλέγματα



Aβ = amyloid beta; APP = amyloid precursor protein. Based on Pospich S, Raunser S. Science. 2017;358(6359):45-46. Nature. 1999 Jul 8;400(6740):173-7. doi: 10.1038/22124.

Immunization with amyloid-beta attenuates Alzheimer-disease-like pathology in the PDAPP mouse

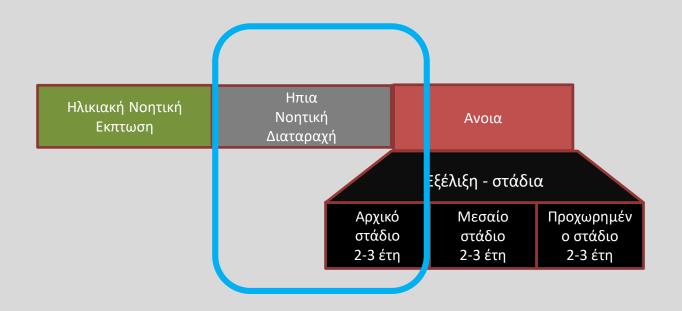
D Schenk ¹, R Barbour, W Dunn, G Gordon, H Grajeda, T Guido, K Hu, J Huang, K Johnson-Wood, K Khan, D Kholodenko, M Lee, Z Liao, I Lieberburg, R Motter, L Mutter, F Soriano, G Shopp, N Vasquez, C Vandevert, S Walker, M Wogulis, T Yednock, D Games, P Seubert

Affiliations + expand

PMID: 10408445 DOI: 10.1038/22124

Μονοκλωνικά αντισώματα κατά του Αβ

| Αντίσωμα | FDA | EMA | Δράση Εκλεκτικότητα | Μείωση αμυλοειδικού φορτίου | Επιβράδυνση ρυθμού επιδείνωσης | Θάνατοι | ARIA |
|---|---------------------------|----------------------------------|--------------------------|-----------------------------------|---|---------|---------|
| Aducanumab | Accelerated approval 2021 | Αποσύρθηκε η αίτηση 22-4-2022 | Ολιγομερή και ινίδια | 70%-80% | 22% | 3 | 20-35% |
| Lecanemab (Leqembi, Eisai/Biogen) | Έγκριση 2023 | Έγκριση 14-11-2024 | Διαλυτά πρωτοϊνίδια | 80%-93% | 26%-27% | 3 | 9-12,6% |
| Donanemab (Kisunla, Eli Lilly) | Έγκριση 2024 | Έγκριση 25-7-2025 | Εγκατεστημένες πλάκες | 87%-88% | 36%-40% 45%-60% σε MCI Ηλικία <75 ✔ φορτίο tau | 3 | 24% |



Μονοκλωνικά αντισώματα κατά του β- αμυλοειδούς







J Prev Alz Dis 2023; Published online March 27, 2023, http://dx.doi.org/10.14283/jpad.2023.30 Review

Lecanemab: Appropriate Use Recommendations

J. Cummings¹, L. Apostolova², G.D. Rabinovici³, A. Atri⁴, P. Aisen⁵, S. Greenberg⁶, S. Hendrix⁷, D. Selkoe⁸, M. Weiner⁹, R.C. Petersen¹⁰, S. Salloway¹¹, For the Alzheimer's Disease and Related Disorders Therapeutics Work Group

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The Journal of Prevention of Alzheimer's Disease 12 (2025) 100150



Contents lists available at ScienceDirect

The Journal of Prevention of Alzheimer's Disease





Special Article

Donanemab: Appropriate use recommendations

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- d Alzheimer's Treatment Research Institute, University of Southern California, San Diego, CA, USA
- ^e Departments of Neurology, Radiology, Medical and Molecular Genetics, Indiana University School of Medicine, Indianapolis, Indiana, USA
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- iPentara Corporation, Millcreek UT, USA
- Department of Neurology, Mayo Clinic, Rochester, MN, USA
- Experiments of Radiology and Biomedical Imaging, Medicine, Psychiatry and Neurology, University of California San Francisco, San Francisco, CA, USA

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- Butter Hospital and Warren Apert Medical School of Brown University, Providence KI, USA
 "Chambers-Grundy Center for Transformative Neuroscience, Department of Brain Health, Kirk Kerkorian School of Medicine, University of Nevada Las Vegas, Las Vegas, NV, USA

CLARITY AD: 2022

TRAILBLAZER- ALZ 2:2023



Επιλέξιμοι ασθενείς

- Ήπια συμπτωματική νόσο Alzheimer: Ήπια Νοητική Διαταραχή-Ήπια άνοια
- Επιβεβαιωμένη με βιοδείκτες διάγνωση νόσου Alzheimer

Ηλικία: 55-85

MMSE: 20-28

- Σταθερή δόση αντιχολινεστερασικών
- MRI εγκεφάλου εντός των τελευταίων 12 μηνών, πρέπει να περιλαμβάνει ακολουθίες FLAIR και αιμοσιδηρίνης (T2*GRE ή SWI)
- Προσδιορισμός γονότυπου ApoE συζήτηση με ασθενείς και φροντιστές
- Αξιόπιστος φροντιστής



Κριτήρια αποκλεισμού

- ΑΕΕ παροδικό ή εγκατεστημένο ισχαιμικό εντός του τελευταίου έτους
- Νευρολογικό ή ψυχιατρικό νόσημα που μπορεί να συνεισφέρει στην άνοια ή οποιαδήποτε άλλη μη Alzheimer άνοια
- Μη ελεγχόμενο ανοσολογικό νόσημα υπό θεραπεία με ανοσοφαιρίνες, μονοκλωνικά αντισώματα, βιολογικούς παράγοντες και πλασμαφαίρεση
- Κακοήθεια υπό θεραπεία
- Μη ελεγχόμενο, σοβαρό καρδιολογικό, αναπνευστικό, νεφρικό, γαστρεντερολογικό, ηπατικό νόσημα
- Μείζονες ψυχιατρικές διαταραχές ή διάγνωση χρήσης ουσιών
- Ομοζυγωτία ΑροΕ
- Διαταραχή πηκτικότητας, χρήση αντιπηκτικών (donanemab:αντιθρομβωτικά, αντιαιμοπεταλιακά, μόνο σε μονοθεραπεία)
- Απαγορεύονται οι θρομβολυτικοί παράγοντες- μηχανική θρομβόλυση
- Αδυναμία διεξαγωγής MRI

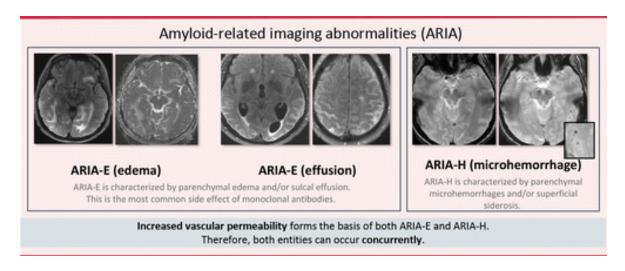
ΚΛΙΝΙΚΗ ΚΡΙΣΗ ΠΟΛΥ ΣΗΜΑΝΤΙΚΗ

Κριτήρια αποκλεισμού

MRI

- > 2 μικροαιμορραγίες
- > 1 εστία επιφανειακής αιμοσιδήρωσης
- > 2 κενοτοπιώδη έμφρακτα
- Ισχαιμικά έμφρακτα ή αιμορραγίες >1cm
- Ενδείξεις CAA-ri
- Fazekas 3
- Μείζονα ευρήματα (όγκοι, ανευρύσματα, οίδημα κ.α)

Amyloid Related Imaging Abnormalities ARIA



- Συχνότητα 4-40% στις κλινικές μελέτες -- Συχνότερα τα ARIA-E
- Κυρίως τους πρώτους 6 μήνες συχνότερα στους ΑροΕ ε4 ομοζυγώτες
- Σε συντριπτικό ποσοστό ασυμπτωματικά 2% συμπτωματικά
- Αναστρέψιμα με τη διακοπή του φαρμάκου σπάνια εμφανίζονται μετά την επαναχορήγηση
- Παρακολούθηση με MRI (T2 FLAIR , SWI)

Figure 1. MRI monitoring for lecanemab MRI if any symptoms suggestive of ARIA occur T1 T2 T3 **T4** T5 T6 **T8** T26 T14 W4 W16 W52 MRI prior MRI for MRI prior MRI within MRI prior to 5th selected to 14th 1 year prior to 7th patients infusion to initiation infusion infusion

- Donanemab: MRI πριν την 2^η ,3^η ,4^η και πιθανώς 12^η έγχυση
- Μη προγραμματισμένες MRI σε περίπτωση κλινικών συμπτωμάτων που δυνητικά μπορεί να οφείλονται σε ARIA
- Αλληλοεπικάλυψη με συμπτώματα της άνοιας!

FULL PRESCRIBING INFORMATION

WARNING: AMYLOID RELATED IMAGING ABNORMALITIES

Monoclonal antibodies directed against aggregated forms of beta amyloid, including LEQEMBI, can cause amyloid related imaging abnormalities (ARIA), characterized as ARIA with edema (ARIA-E) and ARIA with hemosiderin deposition (ARIA-H). Incidence and timing of ARIA vary among treatments. ARIA usually occurs early in treatment and is usually asymptomatic, although serious and life-threatening events rarely can occur. Serious intracerebral hemorrhages, some of which have been fatal, have been observed in patients treated with this class of medications [see Warnings and Precautions (5.1), Adverse Reactions (6.1)].

ApoE £4 Homozygotes

Patients who are apolipoprotein E ε4 (ApoE ε4) homozygotes (approximately 15% of Alzheimer's disease patients) treated with this class of medications, including LEQEMBI, have a higher incidence of ARIA, including symptomatic, serious, and severe radiographic ARIA, compared to heterozygotes and noncarriers. Testing for ApoE ε4 status should be performed prior to initiation of treatment to inform the risk of developing ARIA. Prior to testing, prescribers should discuss with patients the risk of ARIA across genotypes and the implications of genetic testing results. Prescribers should inform patients that if genotype testing is not performed they can still be treated with LEQEMBI; however, it cannot be determined if they are ApoE ε4 homozygotes and at higher risk for ARIA [see Warnings and Precautions (5.1)].

Consider the benefit of LEQEMBI for the treatment of Alzheimer's disease and potential risk of serious adverse events associated with ARIA when deciding to initiate treatment with LEQEMBI [see Warnings and Precautions (5.1) and Clinical Studies (14)].

1 INDICATIONS AND USAGE

LEQEMBI is indicated for the treatment of Alzheimer's disease. Treatment with LEQEMBI should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials.

2 DOSAGE AND ADMINISTRATION

2.1 Patient Selection

Confirm the presence of amyloid beta pathology prior to initiating treatment [see Clinical Pharmacology (12.1)].

2.2 Dosing Instructions

The recommended dosage of LEQEMBI is 10 mg/kg that must be diluted then administered as an intravenous infusion over approximately one hour, once every two weeks.

If an infusion is missed, administer the next dose as soon as possible.

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use LEQEMBI* safely and effectively. See full prescribing information for LEQEMBI*.

LEQEMBI* (lecanemab-irmb) injection, for intravenous use Initial U.S. Approval: 2023

WARNING: AMYLOID RELATED IMAGING ABNORMALITIES See full prescribing information for complete boxed warning.

Monoclonal antibodies directed against aggregated forms of beta amyloid, including LEQEMBI, can cause amyloid related imaging abnormalities (ARIA), characterized as ARIA with edema (ARIA-E) and ARIA with hemosiderin deposition (ARIA-H). ARIA is usually asymptomatic, although rarely serious and life-threatening events can occur. Serious intracerebral bemorrhage greater than 1 cm have occurred in patients treated with this class of medications. (S.1, 6, 1)

ApoE £4 Homozyrotes

Patients treated with this class of medications, including LEQEMBI, who are ApoE of homozygotes have a higher incidence of ARIA, including symptomatic and serious ARIA, compared to heterozygotes and noncarriers. Testing for ApoE of status should be performed prior to initiation of treatment to inform the risk of developing ARIA. Prior to testing, prescribers should discuss with patients the risk of ARIA across genotypes and the implications of genetic testing results. (5.1)

Consider the benefit of LEQEMBI for the treatment of Alzheimer's disease and potential risk of serious adverse events associated with ARIA when deciding to initiate treatment with LEQEMBI. (5.1, 14)

| RECENT MAJOR CHANGES | 7/2023 | Indications and Usage (1) 7/2023 | Desage and Administration (2.3) 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7/2023 | 7

- INDICATIONS AND USAGE-

LEQEMBI is indicated for the treatment of Alzheimer's disease. Treatment with LEQEMBI should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials. (1)

-- DOSAGE AND ADMINISTRATION --

 Confirm the presence of amyloid beta pathology prior to initiating treatment. (2.1)

- The recommended dosage is 10 mg/kg that must be diluted then administered as an intravenous infusion over approximately one hour, once every two weeks. (2.2)
- Obtain a recent baseline brain MRI prior to initiating treatment. (2.3, 5.1)
- Obtain an MRI prior to the 5th, 7th, and 14th influsions. If radiographically observed ARIA occurs, treatment recommendations are based on type, severity, and presence of symptoms. (2.3, 5.1)
- Dilution in 250 mL of 0.9% Sodium Chloride Injection, USP, is required prior to administration. (2.4)
- Administer as an intravenous infusion over approximately one hour via a terminal low-protein binding 0.2 micron in-line filter. (2.5)

DOSAGE FORMS AND STRENGTHS---

Injection:

- 500 mg/5 mL (100 mg/mL) solution in a single-dose vial (3)
- 200 mg/2 mL (100 mg/mL) solution in a single-dose vial (3)

-- CONTRAINDICATIONS --

LEQEMBI is contraindicated in patients with serious hypersensitivity to lecanemab-irmb or to any of the excipients of LEQEMBI. (4)

--- WARNINGS AND PRECAUTIONS --

- Amyloid Related Imaging Abnormalities (ARIA): Enhanced clinical vigilance for ARIA is recommended during the first 14 weeks of treatment with LEQEMBI. Risk of ARIA, including symptomatic ARIA, was increased in apolipoprotein E 64 homozygotes compared to heterozygotes and noncarriers. If a patient experiences symptoms suggestive of ARIA, clinical evaluation should be performed, including MRI scanning if indicated. (2.3, 5.1)
- Infusion-Related Reactions: The infusion rate may be reduced, or the infusion may be discontinued, and appropriate therapy administered as clinically indicated. Consider pre-medication at subsequent dosing with antihistamines, non-steroidal anti-inflammatory drugs, or corticosteroids. (5.3)

---- ADVERSE REACTIONS ---

Most common adverse reactions (at approximately 10% and higher incidence compared to placebo): inflasion-related reactions, amyloid related imaging abnormality-microhemorrhages, amyloid related imaging abnormalityedema/effusion, and headache. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Eisai Inc. at 1-888-274-2378 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 7/2023

FULL PRESCRIBING INFORMATION: CONTENTS*

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- 5 WARNINGS AND PRECAUTIONS
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17 PATIENT COUNSELING INFORMATION

* Sections or subsections omitted from the full prescribing information are not listed

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use KISUNLA safely and effectively. See full prescribing information for KISUNLA.

KISUNLA (donanemab-azbt) injection, for intravenous use Initial U.S. Approval: 2024

WARNING: AMYLOID RELATED IMAGING ABNORMALITIES See full prescribing information for complete boxed warning.

Monoclonal antibodies directed against aggregated forms of beta amyloid, including KISUNLA, can cause amyloid related imaging abnormalities (ARIA), as ARIA with edema (ARIA-E) and ARIA with hemosiderin deposition (ARIA-H). ARIA is usually asymptomatic, although serious and life-threatening events can rarely occur. Serious intracerebral hemorrhages >1 cm have occurred in patients treated with this class of medications. ARIA-E can cause focal neurologic deficits that can mimic ischemic stroke. (5.1, 6.1)

ApoE £4 Homozygotes

Patients treated with this class of medications, including KISUNLA, who are ApoE £4 homozygotes have a higher incidence of ARIA, including symptomatic and serious ARIA, compared to heterozygotes and noncarriers. Testing for ApoE ε4 status should be performed prior to initiation of treatment to inform the risk of developing ARIA. Prior to testing, prescribers should discuss with patients the risk of ARIA across genotypes and the implications of genetic testing results. (5.1)

Consider the benefit for the treatment of Alzheimer's disease and risk of ARIA when deciding to treat with KISUNLA. (5.1, 14)

------INDICATIONS AND USAGE ------

KISUNLA is an amyloid beta-directed antibody indicated for the treatment of Alzheimer's disease. Treatment with KISUNLA should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in the clinical trials. (1)

-----DOSAGE AND ADMINISTRATION ------

- Confirm the presence of amyloid beta pathology prior to initiating treatment. (2.1)
- The recommended dosage of KISUNLA is 700 mg administered as an intravenous infusion over approximately 30 minutes every four weeks for the first three doses, followed by 1400 mg every four weeks. (2.2)

- Consider stopping dosing with KISUNLA based on reduction of amyloid plagues to minimal levels on amyloid PET imaging. (2.2)
- Obtain a recent baseline brain MRI prior to initiating treatment. (2.3, 5.1)
- Obtain an MRI prior to the 2nd, 3rd, 4th, and 7th infusions. If radiographically observed ARIA occurs, treatment recommendations are based on type, severity, and presence of symptoms. (2.3, 5.1)
- Dilution to a final concentration of 4 mg/mL to 10 mg/mL with 0.9% Sodium Chloride Injection, is required prior to administration. (2.4)

-----DOSAGE FORMS AND STRENGTHS------Injection: 350 mg/20 mL (17.5 mg/mL) in a single-dose vial. (3)

------ CONTRAINDICATIONS ------

KISUNLA is contraindicated in patients with known serious hypersensitivity to donanemab-azbt or to any of the excipients. (4, 5.2)

------WARNINGS AND PRECAUTIONS ------

- Amyloid Related Imaging Abnormalities (ARIA): Enhanced clinical vigilance for ARIA is recommended during the first 24 weeks of treatment with KISUNLA. Risk of ARIA, including symptomatic ARIA, was increased in apolipoprotein Ε ε4 (ApoE ε4) homozygotes compared to heterozygotes and noncarriers. The risk of ARIA-E and ARIA-H is increased in KISUNLA-treated patients with pretreatment microhemorrhages and/or superficial siderosis. If a patient experiences symptoms suggestive of ARIA, clinical evaluation should be performed, including MRI scanning if indicated. (2.3, 5.1)
- Infusion-Related Reactions: The infusion rate may be reduced, or the infusion may be discontinued, and appropriate therapy initiated as clinically indicated. Consider pre-treatment with antihistamines, acetaminophen, or corticosteroids prior to subsequent dosing. (5.3)

----- ADVERSE REACTIONS ------

Most common adverse reactions (at least 10% and higher incidence compared to placebo): ARIA-E, ARIA-H microhemorrhage, ARIA-H superficial siderosis, and headache. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Eli Lilly and Company at 1-800-LillyRx (1-800-545-5979) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Προϋποθέσεις ασφαλούς και αποτελεσματικής χρήσης του LECANEMAB

- Clinician skilled in the assessment of cognition to identify individuals with mild cognitive impairment or mild dementia due to Alzheimer's disease
- MRI available for baseline assessment of cerebrovascular pathology and for monitoring of amyloid related imaging abnormalities (ARIA)
- Radiologists, neurologists, or other clinicians expert in the identification and interpretation of cerebrovascular lesions and ARIA
- Amyloid positron emission tomography or lumbar puncture capability to determine the amyloid status of treatment candidates
- Radiologists, nuclear medicine specialists, neurologists, or other specialists skilled in the interpretation of amyloid imaging or neurologist, radiologists, or other clinicians skilled in the conduct of lumbar puncture
- Apolipoprotein E genotyping resources
- Genetic expertise to counsel patients on the implications of apolipoprotein E genotyping
- Expertise in communicating with patients and care partners regarding anticipated benefits, potential harm, and requirements for administration and monitoring while on lecanemab
- Infusion settings that can be made available every two weeks to patients receiving therapy
- Knowledgeable staff at infusion sites capable of recognizing and managing infusion reactions
- Communication channels established between experts interpreting MRIs and clinicians treating patients with lecanemab
- Communication channels established between clinicians treating patients with lecanemab and the patient and care partner
- Availability of hospital resources including intensive care unit
- Expertise in the management of seizures and status epilepticus for patients with severe or serious ARIA
- Protocol with standard operating procedures for management of serious and severe ARIA

Υπηρεσίες Κέντρου Χορήγησης LECANEMAB και διαχείριση σοβαρών ανεπιθύμητων ενεργειών

- Emergency department with resources to assess suspected or known ARIA
- MRI scanners readily available for unscheduled scanning of symptomatic patients
- Knowledgeable MRI readers proficient in detection and interpretation of ARIA
- Clinicians with experience in the management of cerebral edema or ARIA
- Hospital ward for monitoring and management
- Intensive care unit availability
- Electroencephalography available to inpatients
- Neurologist with experience in management of seizures and status epilepticus

Πρακτικά ζητήματα

- Προετοιμασία συστήματος υγείας δημιουργία εξειδικευμένων κέντρων
- Εκπαίδευση κλινικών και εργαστηριακών επαγγελματιών υγείας
- Ανάπτυξη πρωτοκόλλων έγχυσης και παρακολούθησης ασθενών registries
- Συχνές νοσηλείες ταλαιπωρία ενδοφλεβίων εγχύσεων ανά 2-4 εβδομάδες, συχνές MRI
- Κόστος φαρμάκου αποζημίωση;
- Προσδιορισμός γονότυπου ΑροΕ συζήτηση με ασθενείς και φροντιστές
- ΕΜΑ: για θέματα ασφαλείας πρέπει να μη χορηγείται σε ε4/ε4
- Στο Ηνωμένο Βασίλειο η θεραπεία με lecanemab και donanemab έχει εγκριθεί αλλά το NICE πήρε θέση ότι δεν αντισταθμίζει το κόστος και δεν αποζημιώνεται!
- Στις ΗΠΑ τα μονοκλωνικά αποζημιώνονται υπό προϋποθέσεις (registries) και με συμμετοχή του ασθενούς (20%)



Ερωτήματα – Μελλοντικά βήματα

- Πρωϊμότερα ή πιο προχωρημένα στάδια;
- Ασθενείς με αγγειακές βλάβες μεικτές μορφές;
- Ηλικίες εκτός κλινικών μελετών;
- Για πόσο χρονικό διάστημα; Πότε σταματάμε;
- Αντιπηκτικά; Θρομβολυτικά;
- Αδύνατη η MRI;
- Μακροχρόνια επίδραση των ARIA στον εγκέφαλο;
- Απαραίτητες μεγαλύτερες και περισσότερες μελέτες
- Απαιτείται μεγάλη αύξηση υλικών και ανθρώπινων πόρων



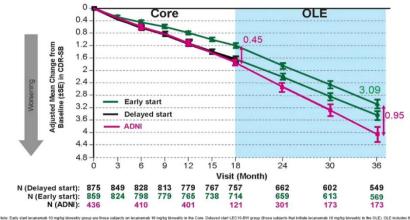
Διάρκεια θεραπείας

• Το κλινικό όφελος διατηρείται για 3 χρόνια – μελέτες ανοικτής επέκτασης lecanemab

Clarity AD OLE: CDR-SB Efficacy Through 36 Months

Lecanemab-Treated Patients Continue to Accrue Benefit Through 36 Months

- Treatment effect between lecanemab and ADNI cohort continues to expand from 18 through 36 months
- Delayed start group also shows benefit in OLE relative to ADNI cohort



- ADNI observational cohort was pre-specified and used during design of Clarity AD; represents exact population of those in Clarity AD study
- Matched ADNI participants for inclusion and exclusion criteria show similar degree of decline to placebo group out to 18 months

Note: Early start lecamemab 10 mg/ling bleveildy group are those subjects on lecamemab 10 mg/ling bleveildy in the CLE) of E includes Those subjects bank initiate lecamemab 10 mg/ling bleveildy in the OLE). Of E includes Those participants on subcotaneous and introversors formulations. Bissed on a fishing the published in the annual start arm maintains and least bank of the relative extraction and least on model as pasted on model as a fishing being bank on Applied annual change, Applied annual change, Applied annual change, a fishing annual change and a fishing annual change and a fishing annual change and a fishing annual change annual

 75% των ασθενών που συμμετείχαν στην μελέτη του donanemab πέτυχαν κάθαρση (clearance) από το αμυλοειδικό φορτίο στους 18 μήνες και 52% στον 1 χρόνο και βγήκαν από την μελέτη





New Data Presented at AAIC Demonstrates Investigational LEQEMBI® (lecanemab-irmb) 360 mg Subcutaneous Maintenance Dosing Could Offer a New Option for Ongoing Treatment of Early Alzheimer's Disease

Lecanemab subcutaneous autoinjector has the potential to become a new expanded treatment option for patients with early Alzheimer's disease, their care partners and healthcare professionals, with results showing a comparable efficacy and safety profile to the intravenous formulation

TOKYO and CAMBRIDGE, Mass., July 31, 2025 - Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") and Biogen Inc. (Nasdaq: BIIB, Headquarters: Cambridge, Massachusetts, CEO: Christopher A. Viehbacher, "Biogen") announced today that results on investigational maintenance therapy with subcutaneous autoinjector (SC-AI) of lecanemab-irmb (U.S. brand name: LEQEMBI*), an anti-amyloid beta (Aβ) protofibril* antibody for the treatment of early Alzheimer's disease (AD), were presented at the Alzheimer's Association International Conference (AAIC) 2025, held in Toronto, and virtually. Only lecanemab fights AD in two ways— targeting both protofibrils and plaque, which can impact tau accumulation downstream.

Importance of Ongoing Treatment and SC Development Program

Due to the reaccumulation of AD biomarkers and return to placebo rate of decline after therapy is stopped¹, Eisai is investigating a new lecanemab SC maintenance treatment option following 18 months of IV therapy so patients can continue to fight this progressive, relentless disease.

Clinical trials of lecanemab SC were conducted as a sub-study of the open-label extension (OLE) following the core Phase 3 Clarity AD study in individuals with early AD, to evaluate a range of doses administered by SC vial or autoinjector. Eisai has developed a SC-AI for maintenance therapy at a dose of 360 mg weekly and a 500 mg SC-AI is being developed for initiation dosing.

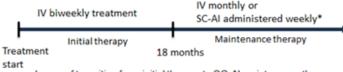


Image of transition from initial therapy to SC-Al maintenance therapy "Application for SC-Al maintenance therapy is under US FDA review.

Similar Impact on Clinical Outcomes and Biomarkers with IV and SC Dosing

The pharmacology (PK/PD), clinical (efficacy endpoints such as CDR-SB) and biomarker (amyloid PET and blood biomarkers) relationships established with extensive clinical data supported the FDA approval of IV maintenance therapy after the initial 18 months of treatment and support the investigational SC maintenance dose option.



Lilly's Kisunla (donanemab-azbt) showed growing benefit over three years in early symptomatic Alzheimer's disease

July 30, 2025

Findings from the TRAILBLAZER-ALZ 2 long-term extension study highlight Kisunla continued to demonstrate slowing of decline, with most participants having completed treatment

Data underscores the value of early intervention and supports a limited duration dosing approach with sustained long-term benefits

INDIANAPOLIS, July 30, 2025 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced results from the long-term extension (LTE) of the Phase 3 TRAILBLAZER-ALZ 2 study showing that participants treated with Kisunla (donanemab-azbt) demonstrated slowing of decline, a benefit that continued to grow over three years compared to an untreated external cohort from the Alzheimer's Disease Neuroimaging Initiative (ADNI). 1

FDA approves updated label for Lilly's Kisunla (donanemab-azbt) with new dosing in early symptomatic Alzheimer's disease



The newly recommended dosing schedule significantly lowered ARIA-E rates compared to the original dosing schedule, adding to the established safety profile of the treatment

INDIANAPOLIS, July 9, 2025 /PRNewswire/ -- Eli Lilly and Company (NYSE: <u>LLY</u>) announced today that the U.S. Food and Drug Administration (FDA) has approved a label update with a new recommended titration dosing schedule for Kisunla (donanemab-azbt), Lilly's once-monthly amyloid-targeting therapy for adults with early symptomatic Alzheimer's disease (AD), which includes people with mild cognitive impairment (MCI) as well as people in the mild dementia stage of AD, with confirmed amyloid pathology. In the TRAILBLAZER-ALZ 6 study, the modified titration schedule significantly lowered the incidence of amyloid-related imaging abnormalities with edema/effusion (ARIA-E) versus the original dosing schedule at 24 and 52 weeks, while still achieving similar levels of amyloid plague removal and P-tau217 reduction.



Contents lists available at ScienceDirect

The Journal of Prevention of Alzheimer's Disease

journal homepage: www.elsevier.com/locate/tjpad



Brief Report

The effect of modified donanemab titration on amyloid-related imaging abnormalities with edema/effusions and amyloid reduction: 18-month results from TRAILBLAZER-ALZ 6



Hong Wang ^{a,1}, Emel Serap Monkul Nery ^{a,1}, Paul Ardayfio ^a, Rashna Khanna ^a, Diana Otero Svaldi ^a, Sergey Shcherbinin ^a, Wen Xu ^a, Scott W. Andersen ^a, Paula M. Hauck ^a, Dawn A. Brooks ^a, Emily C. Collins ^a, Stephen Salloway ^b, Mark A. Mintun ^a, John R. Sims ^{a,*}

ARTICLE INFO

Keywords: Alzheimer's disease Amyloid amyloid-related imaging abnormalities (ARIA) Donanemab Titration

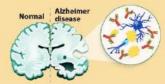
ABSTRACT

The TRAILBLAZER-ALZ 6 study (NCT05738486) evaluated the effect of different donanemab dosing regimens on amyloid-related imaging abnormalities with edema/sulcal effusions (ARIA-E). The modified titration arm met the primary outcome and significantly reduced ARIA-E frequency compared with the standard dosing while maintaining a similar pharmacodynamic effect on amyloid reduction at 24 weeks. Primary outcome and 52-week data were previously published. Completed study results at 76 weeks are reported here. ARIA-E frequencies were 15.6 % and 24.2 % in the modified titration and standard arms, respectively. ARIA-E radiographic severity was significantly lower (p = 0.015) with modified titration than with standard dosing. Additionally, symptomatic ARIA-E frequency was lower with modified titration versus standard dosing (2.8 % vs 4.8 %). The frequency of serious adverse events was comparable between the modified titration and standard dosing arms. A more gradual titration of donanemab dosing significantly reduced ARIA-E risk versus standard dosing. Clinicaltrials.gov: NCT05738486

a Eli Lilly and Company, Indianapolis, IN, USA

b Butler Hospital, and Department of Neurology and Department of Psychiatry, Warren Alpert Medical School of Brown University, Providence, RI, USA

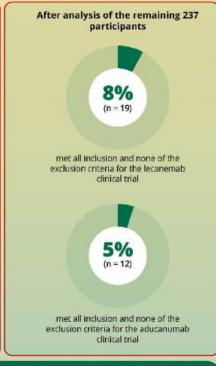
Determining Eligibility for Anti-Beta Amyloid Antibody Treatment in Adults with Mild Cognitive Impairment or Dementia



The anti-beta amyloid monoclonal antibodies (mAbs) lecanemab and aducanumab were recently approved by the FDA for use in the treatment of early symptomatic Alzheimer disease (AD)

What proportion of patients with mild cognitive impairment(MCI) or mild AD seen in a memory clinic would meet the inclusion criteria used in the clinical trials of aducanumab and lecanemab?





Only a small proportion of participants in the MCSA would be eligible for anti-amyloid mABS if the criteria used in the clinical trials of lecanemab and aducanumab were applied in routine practice

Neurology^{*}

Αριθμός πιθανών ασθενών χρηστών

RESEARCH ARTICLE

Eligibility for Anti-Amyloid Treatment in a Population-Based Study of Cognitive Aging

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Proportion of Community-Dwelling Individuals Older Than 70 Years Eligible for Lecanemab Initiation

The Gothenburg H70 Birth Cohort Study

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Neurology® 2024;102:e209402. doi:10.1212/WNL.0000000000209402

Abstract

Objectives

To determine the prevalence of individuals with Alzheimer disease (AD) eligible for treatment with the recently FDA-approved lecanemab based on data from a population-based sample of 70-year-olds and extrapolate an estimation of individuals eligible in Europe and the United States.

Methods

Participants from the Gothenburg H70 Birth Cohort Study with clinical data, CSF-amyloid beta 42, and brain MRI analysis were evaluated for eligibility to receive lecanemab treatment according to FDA-approved recommendations, noting factors requiring special consideration. Results were used to extrapolate the number of eligible individuals in Europe and the United States using public demographic data.

Results

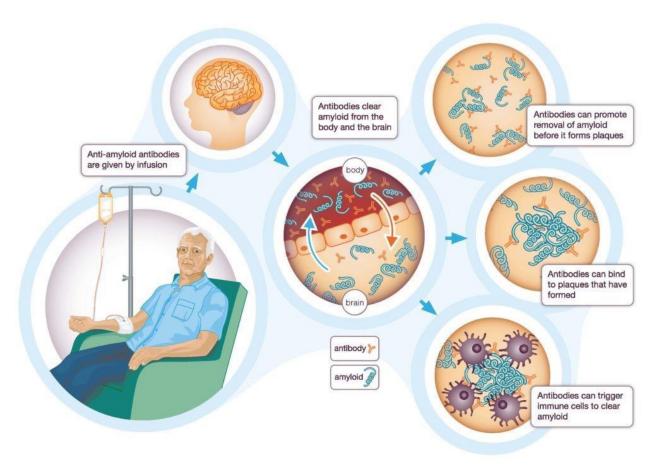
Thirty (10.3%) of 290 participants met the indication for treatment of whom 18 (6.2%) were eligible and did not present factors requiring special consideration. Our estimate that 6.2% of all 70-year-olds in the full cohort are eligible for treatment extrapolates to an approximation that around 5.9 million Europeans and 2.2 million US residents could be eligible.

Discussion

Information on proportion of individuals eligible for AD treatment with lecanemab in the general public is limited. We provide information on 70-year-olds in Sweden and extrapolate these data to Europe and the United States. This study opens for larger studies on this proportion and implementation of lecanemab treatment.



Ενημέρωση και εκπαίδευση ασθενών



https://www.alzheimersresearchuk.org/blog/behind-the-headlines-is-a-new-alzheimers-treatment-in-sight/
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Στόχοι νέων θεραπειών

- Παρέμβαση στα πρώιμα στάδια
- Αφαίρεση πλακών β-αμυλοειδούς από τον εγκέφαλο
- Επιβράδυνση της γνωστικής έκπτωσης που σχετίζεται με τη νόσο



- Η νόσος δεν είναι μόνο το αμυλοειδές
 - Η αγωγή δεν θεραπεύει τη νόσο
- Γενετικοί παράγοντες επηρεάζουν τις παρενέργειες



Είναι οι νέες φαρμακευτικές θεραπείες της νόσου Alzheimer με μονοκλονωνικά αντισώματα κατάλληλες για μένα;





Κίνδυνοι

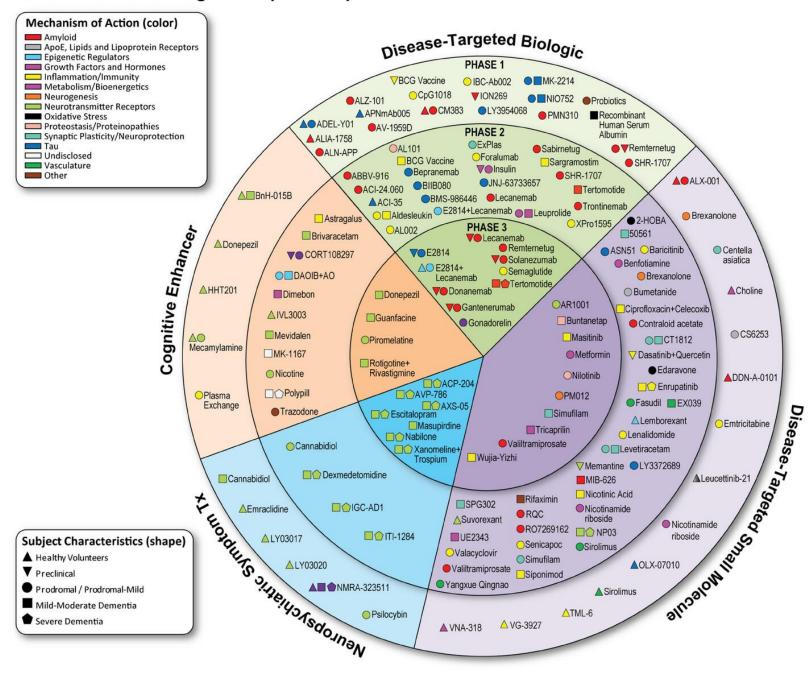
- Υψηλό επιβάρυνση δοκιμών και επισκέψεων
 - Ενδεχομένως υψηλό οικονομικό κόστος
 - Αντιδράσεις εγχύσεων
 - Οίδημα ή αιμορραγία εγκεφάλου (ARIA)



Εναλλακτικές λύσεις

- Τρέχουσα φαρμακευτική αγωγή
 - Τροποποιήσεις τρόπου ζωής
- Μελλοντικά προς έγκριση φάρμακα
 - Κλινικές δοκιμές

2025 Alzheimer's Drug Development Pipeline



ΑΔΑ: ΨΧΩ5465ΦΥΟ-ΝΤΧ

Αθήνα, 02.09.2025

Αριθ. πρωτ. Α1β/Γ.Π. οικ. 38310



ΕΛΛΗΝΙΚΗ ΔΗΜΟΚΡΑΤΙΑ ΥΠΟΥΡΓΕΙΟ ΥΓΕΙΑΣ ΓΕΝΙΚΗ ΔΙΕΥΘΥΝΣΗ ΔΙΟΙΚΗΤΙΚΩΝ ΥΠΗΡΕΣΙΩΝ ΚΑΙ ΤΕΧΝΙΚΗΣ ΥΠΟΣΤΗΡΙΞΗΣ ΔΙΕΥΘΥΝΣΗ ΑΝΘΡΩΠΙΝΟΥ ΔΥΝΑΜΙΚΟΥ ΚΑΙ ΔΙΟΙΚΗΤΙΚΗΣ ΥΠΟΣΤΗΡΙΞΗΣ ΤΜΗΜΑ ΣΥΣΤΑΣΗΣ ΚΑΙ ΣΥΓΚΡΟΤΗΣΗΣ ΣΥΛΛΟΓΙΚΩΝ ΟΡΓΑΝΩΝ

Ταχ. Δ/νση : Αριστοτέλους 17-19 Ταχ. Κώδικας : 104 33 - Αθήνα

Πληροφορίες : Μ. Βλαστάκη Τηλέφωνο : 2132161613

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ΘΕΜΑ: «Συγκρότηση και ορισμός μελών στην Ομάδα Εργασίας για τη Νόσο ALZHEIMER, του Κεντρικού Συμβουλίου Υγείας (ΚΕ.Σ.Υ.)»

ΚΟΙΝΗ ΑΠΟΦΑΣΗ

Έργο της Ομάδας Εργασίας είναι:

- 1. Ο καθορισμός όρων και προϋποθέσεων και η διαδικασία αξιολόγησης Νοσοκομειακών Δομών (Νευρολογικών Κλινικών-Ιατρεία Μνήμης) για την ασφαλή χορήγηση των Μονοκλωνικών Αντισωμάτων κατά του ALZHEIMER/β-αμυλοειδούς.
- 2. Ο καθορισμός όρων, προϋποθέσεων και ενδείξεων χορήγησης των Μονοκλωνικών Αντισωμάτων κατά του ΑLZHEIMER/β-αμυλοειδούς και η διαδικασία επιλογής των ασθενών που πληρούν τα κριτήρια λήψης, βάσει εθνικής ηλεκτρονικής βάσης καταγραφής (Registry-Μητρώο Ασθενών).

Η θητεία της Ομάδας Εργασίας είναι ενός (1) έτους.

Ο ΥΦΥΠΟΥΡΓΟΣ ΥΓΕΙΑΣ

Ο ΥΠΟΥΡΓΟΣ ΥΓΕΙΑΣ

ΜΑΡΙΟΣ ΘΕΜΙΣΤΟΚΛΕΟΥΣ

ΣΠΥΡΙΔΩΝ – ΑΔΩΝΙΣ ΓΕΩΡΓΙΑΔΗΣ

Πανευρωπαϊκό Registry - CAP

2002 - 2025



9 Κέντρα Ημερήσιας Φροντίδας



4 Κινητές Μονάδες



12.500 επισκέψεις κατ'οίκον







Υποστήριξη του Εθνικού Σχεδίου Δράσης για την Άνοια



Υλοποίηση
41 Ευρωπαϊκών
Προγραμμάτων



11.000 online παρεμβάσεις για άτομα με άνοια και φροντιστές



31.145 κλήσεις



Περισσότερες από 2.000 ενημερωτικές ομιλίες για το κοινό



17 συνέδρια για επαγγελματίες υγείας 58 καμπάνιες ευαισθητοποίησης για την άνοια













- Ενημερώνουμε
- Στηρίζουμε
- Συμβουλεύουμε

Απέναντι στην άνοια έχουμε όλοι την ίδια γραμμή





