

Today's Presenters



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Disclosure: We have all received honoraria from Eisai Inc. for participating in this symposium.

Disclaimer: All the information discussed today is for informational purposes only; it does not constitute medical advice and is not intended to be a substitute for independent professional medical judgment, advice, or treatment.

Housekeeping





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Pre-symposium Polling



Which of the following best describes your confidence using anti-amyloid mAb therapies for treatment of AD?

- A. Not planning on administering mAb therapies
- Interested in administering mAb therapies but unsure how to establish a treatment program
- C. Have begun setting up a treatment program but have not initiated administration
- D. Started administering mAb therapies but facing challenges with implementation
- E. Expert in use of mAb therapies
- F. Not affiliated with an institution that is or is planning on administering mAb therapies for AD





Which of the following best describes your confidence using anti-amyloid mAb therapies for treatment of AD?



Educational Objectives



- To offer best practices and operational strategies for establishing anti-amyloid treatment programs within integrated delivery networks
- To review consensus recommendations from clinicians and administrators who have successfully implemented antiamyloid mAbs within private practice
 - To provide practical guidance for using novel expert-developed tools to optimize implementation of anti-amyloid mAbs

mAb, monoclonal antibody.

Burden of AD/MCI Due to AD



Approximately 1 in 9 people aged 65 or older has AD^{1,2}

6.9M

Approximately
6.9 million people aged
65 and older in the US
are estimated to be living
with clinical AD, with an
additional 12.2 million
showing signs of MCI^{1,2}

13.8M

The projected number of people aged 65 and older in the US with AD is continuing to grow:

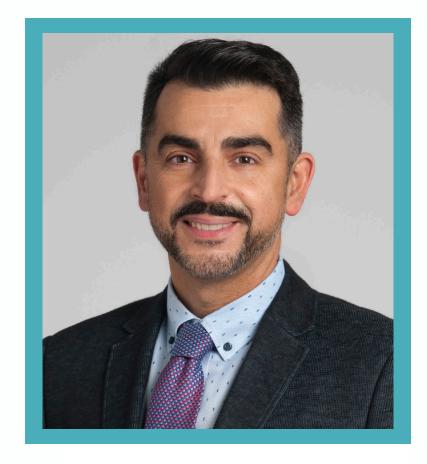
13.8 million in 2060^{1,2}

The advent of new treatment modalities (eg, mAbs) for patients with early AD and new diagnostic techniques (eg, BBMs) may require neurology practitioners across diverse practice settings to be flexible and update their care delivery

There is a need for strategies and recommendations that are **comprehensive** and **flexible** to efficiently diagnose and treat patients with early AD



Disclosures*



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- Consulting, membership on advisory committees, or teaching and speaking engagements for Biogen, Eisai, Lilly, and Novo Nordisk
- Funding support from Roche, Biogen, Eisai, Janssen, Cognition Therapeutics, EIP, and Novo Nordisk

Early AD Patient Care Pathway Project Approach





Conducted evidence scan of published literature and public information



Conducted Real-World Evidence Council (RWEC)^a with 8 AD care experts/advisors to identify key components of a pathway and identify needs/ opportunities for **integrated delivery networks**



Built AD Care Pathway based on RWEC^a insights

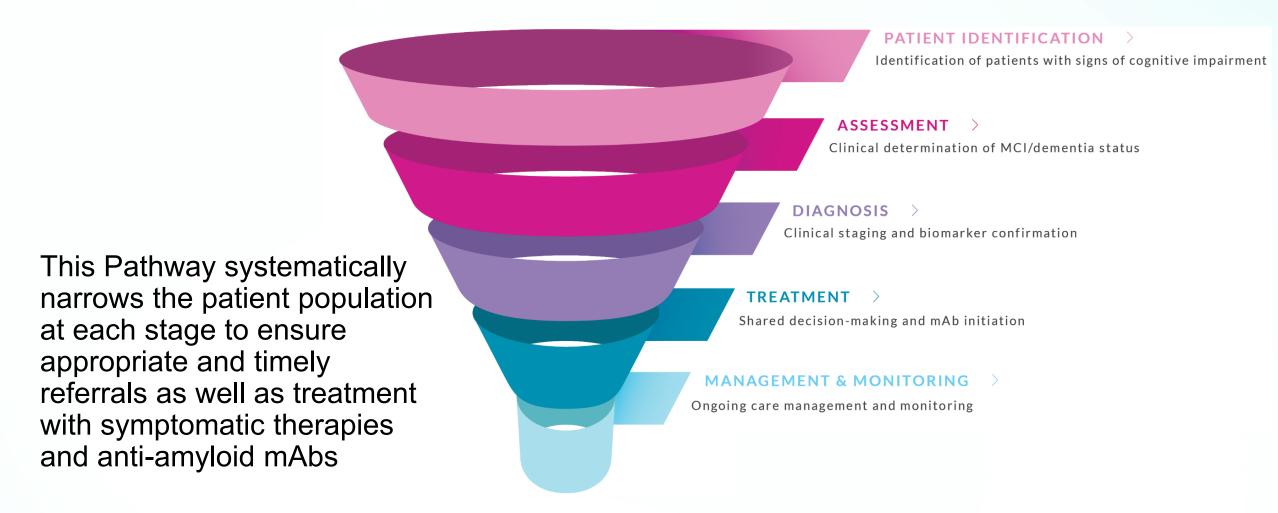


Hosting "Early Alzheimer's Disease Patient Care Pathway (Including Anti-amyloid Monoclonal Antibody Treatment): A Health System Readiness and Implementation Guide" on Premier PINC AI Platform Download the Pathway:



https://mygrcode.mobi/26a66b9b

The Early AD Patient Care Pathway Functions as a Funnel



Organization of the Patient Care Pathway

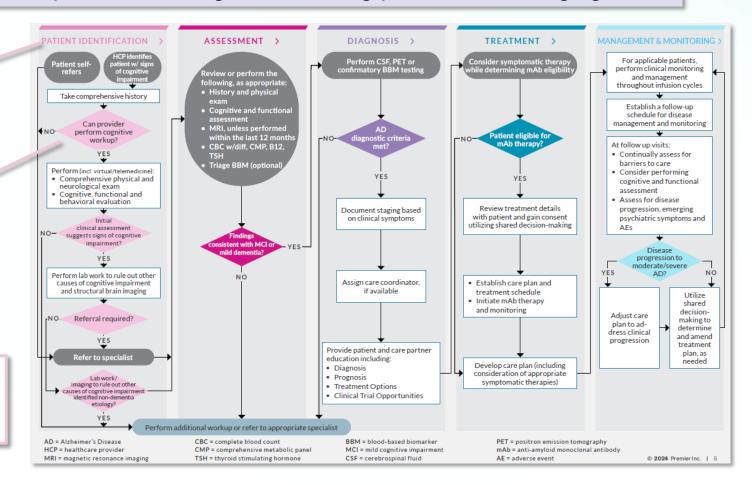
The Early AD Patient Care Pathway is a **comprehensive interactive resource** designed to guide healthcare providers through the evolving process of managing AD

Recommendations are provided at each step in the patient journey

Key decision points are clearly identified

Relevant **checklists** are provided

Needs and opportunities are outlined as examples of **best practices**



Patient Identification

Patient Intake

- Need: Manage patient influx and waiting list
- Opportunities: Leverage PCPs to perform initial testing/differential diagnosis; use APPs for new patient screenings and to provide counseling

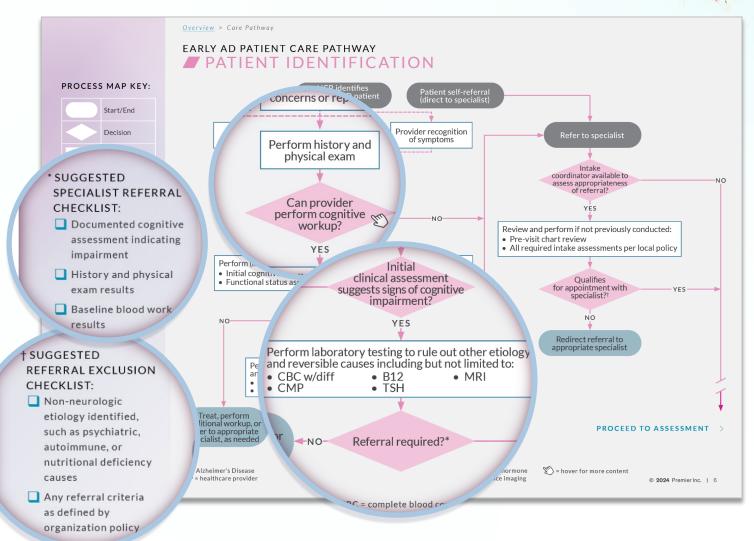
Care Coordination

- Need: Navigate patients throughout complex patient journey
- Opportunities: Implement care coordinator and/or navigator programs to assist patients and care partners



Best practice:

Refer patients only as needed



Assessment



Staffing

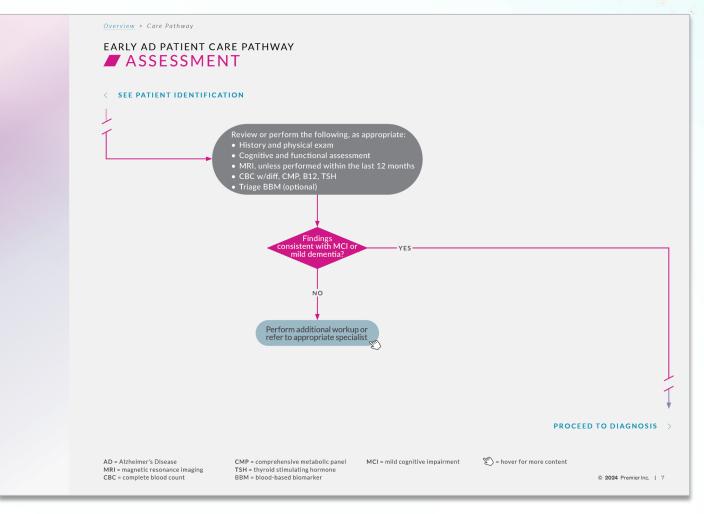
- Need: Secure adequate staffing levels for AD care
- Opportunities: Use APPs and non-provider staff; leverage technology to streamline workflows and improve efficiency

Blood-Based Biomarkers (BBMs)

- Need: Consider test performance and payer policy for mAb coverage to determine best use of available diagnostic options (triaging or confirmatory)
- Opportunities: Leverage BBMs in current capacity (eg, triaging vs triaging and confirmatory) while supporting research for further development



Best practice: Include all appropriate components before proceeding to diagnosis



Diagnosis

Patient Education

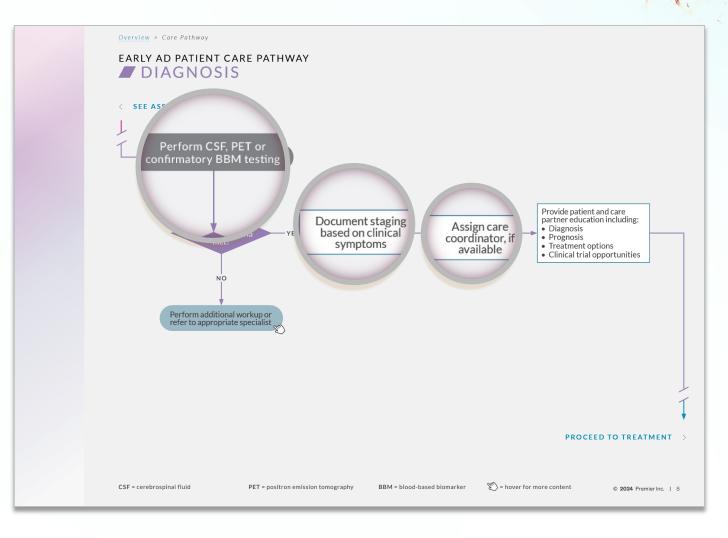
- Need: Offer educational materials related to memory issues
- Opportunities: Develop AD patient–friendly educational materials (eg, videos, infographics)

Provider Education

- **Need:** Optimize channels of communication across providers (eg, radiologists, PCPs, neurologists)
- Opportunities: Implement multidisciplinary meetings or provider consensus meetings



Best practice: Provide multiple options for patient and provider education



Treatment

Magnetic Resonance Imaging (MRI)

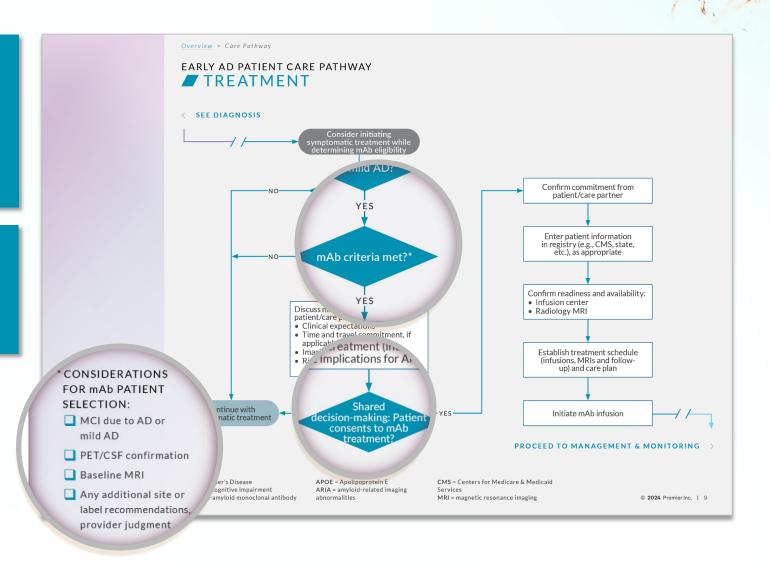
- Need: Assess AD-specific training needs for radiologists
- Opportunities: Centralize imaging services; work with imaging partners to streamline process and ensure use of trained radiologist or neuroradiologist to read MRIs

Monoclonal Antibodies (mAbs)

- Need: Simplify patient management and care coordination
- Opportunities: Centralize infusion services; work with infusion partners to streamline process



Best practice: Check considerations for mAb patient selection



AD, Alzheimer's disease.

Management and Monitoring

Economic Challenges

- Need: Identify and secure required resources for successful AD program
- Opportunities: Integrate AD program into larger neurology program; pursue available funding mechanisms (eg, grants, federal assistance)

Quality Measures

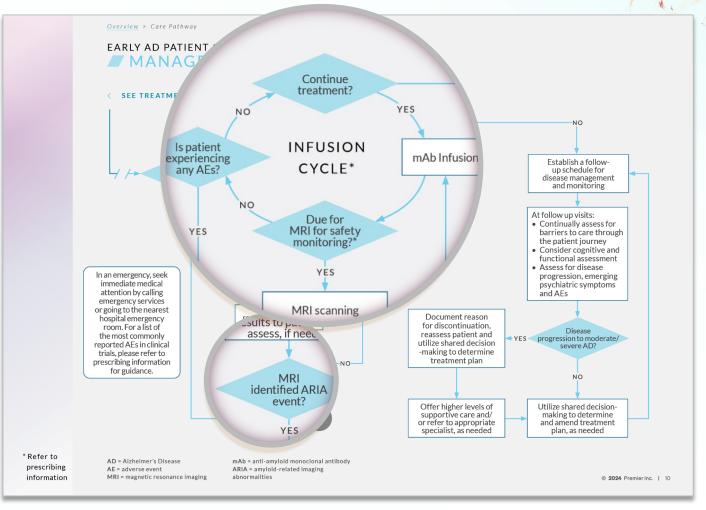
- Need: Define and implement standardized measures
- **Opportunities:** Track time from referral to first visit, diagnosis, and treatment; monitor and manage waitlist

Social Determinants of Health

- Need: Identify needs for underserved populations and patients in rural areas
- **Opportunities:** Use telemedicine or develop relationships with external imaging and infusion centers



Best practice: Optimize EHR workflows and explore AI tools to improve efficiency



Operational Strategies for Readiness and Implementation

RWEC advisors cited common operational challenges for providing high-quality care for patients with early AD. The "Early AD Patient Care Pathway: A Health System Readiness and Implementation Guide" includes strategies for addressing these challenges

Strategies in Practice

Patients are provided with a
2-sided ID card listing all
medications and an
emergency contact number
on one side and critical
information for HCPs
(eg, potential side effects of
anti-amyloid mAbs,
recommended MRI protocols,
warning regarding thrombolytic
use) on the other



Strategies in Practice

Mandatory safety MRI is integrated into the treatment plan, ensuring that the next infusion cannot proceed unless the MRI has been reviewed and approved by the clinician

Number of refills is restricted to align with the timing of the next safety MRI

Best Practice Advisory (BPA) is implemented within the EMR system to alert providers when thrombolytics are prescribed

Audience Polling



For which of these areas has your practice faced the greatest challenges?

- A. Program and business planning
- B. Technology
- C. Education and resources
- D. Access and reimbursement
- E. Care coordination





For which of these areas has your practice faced the greatest challenges?



Request Access to the Care Pathway

Step 1: Use the QR code to access the request form



https://myqrcode.mobi/26a66b9b

Step 2: Submit the online request form

PINC AI™ Request Form: Early Alzheimer's Disease Patient Care Pathway Complete this form to request access to the Early Alzheimer's Disease Patient Care Pathway (Including Anti-Amyloid Monoclonal Antibody Treatment)	
Last Name *	
Email Address * Personal email addres	ses are not permitted (gmail, yahoo, or similar).
Company/Institution *	
Title/Role *	
City *	
State *	
☐ I consent to share	my contact information with Eisai Inc.
Send me a copy of m	y responses
Submit	
	Powered by 5 smartsheet

Step 3: Receive an email with a link to download the Pathway

From: automation@app.smartsheet.com

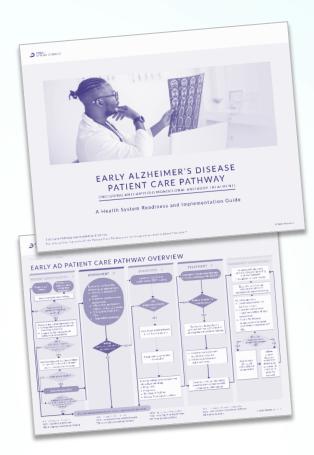
Subject: Next Steps: Premier - Early Alzheimer's Disease Patient Care Pathway (including Antiamyloid Monoclonal Antibody Treatment)

Thank you for submitting a request to access the "Early Alzheimer's Disease Patient Care Pathway (including Anti-amyloid Monoclonal Antibody Treatment): A Health System Readiness and Implementation Guide." Your request has been approved and you may now access and download the care pathway by visiting ________

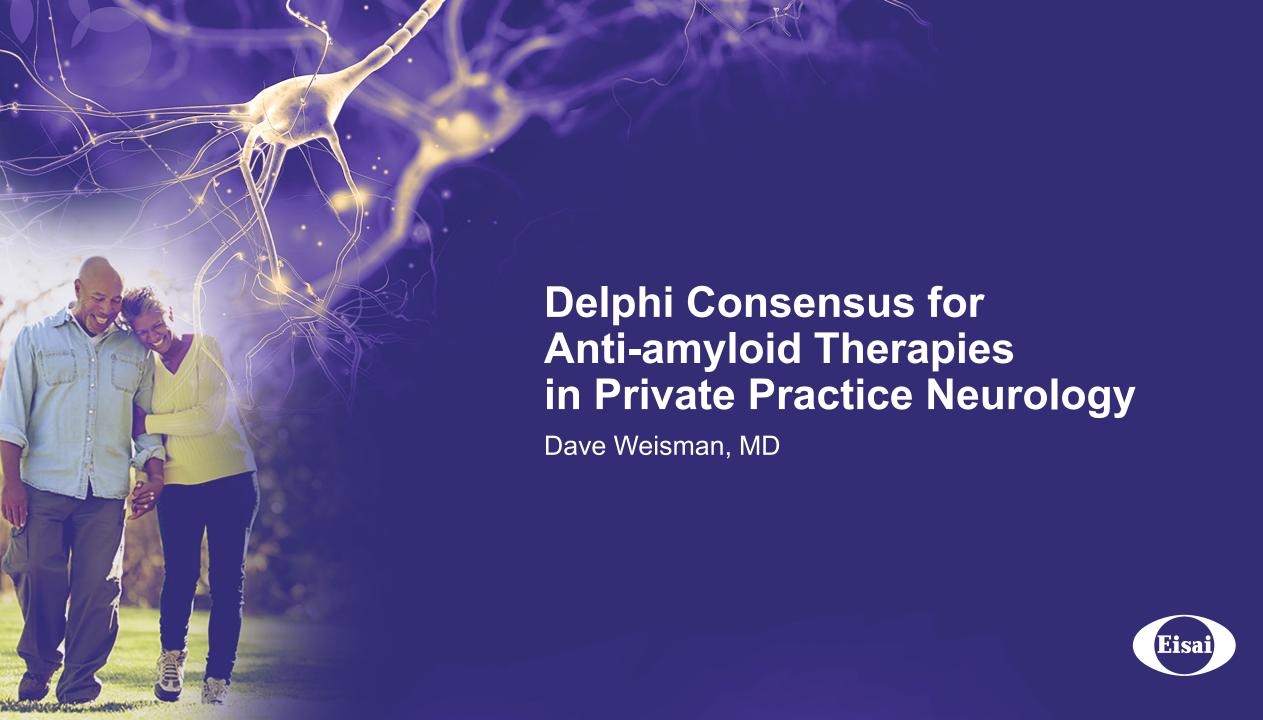
If you have questions or need help, please contact Heather_Reiter@premierinc.com

From: automation@app.smartsheet.com

Step 4: Download the Pathway



Questions: Contact heather_reiter@premierinc.com



Disclosures*



Dave Weisman, MD

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- Advisory panels for Biogen, Eisai, Novartis, Lantheus, and Maplight/VizAl
- Speaking engagements or live events for Biogen, Eisai, Lilly, and AAN
- Program steering committee member for Novartis
- FDA PCNS Advisory Committee
- Trial support from Eisai, Cognition, Acumen, Alnylam, Cerevel, Sage, Acadia, Alzheimer's Association, Lilly, Ventus, Sanofi, Roche, and Serono

Delphi Consensus for Anti-amyloid mAb Therapies in Private Practice Neurology



- ?
- What are the key consensus recommendations for initiating treatment with anti-amyloid mAbs in private practice?
- ?

How can these recommendations address barriers to initiating treatment that private practice physicians may experience?

The Delphi methodology uses an iterative review process to achieve consensus on recommendations

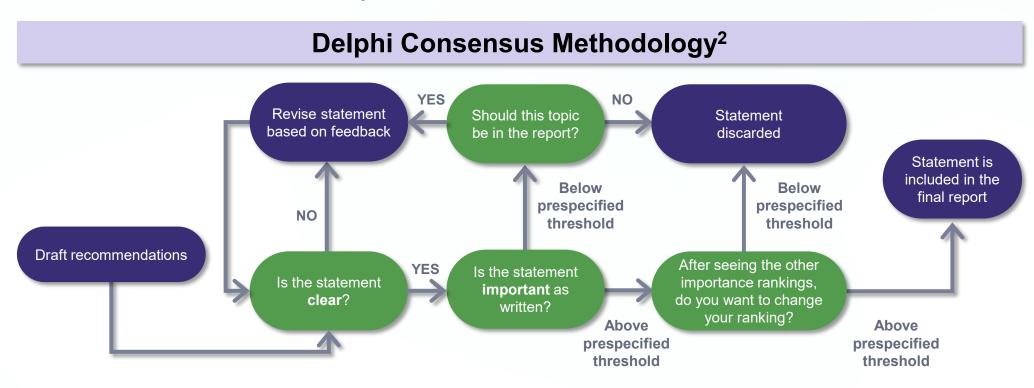
Insight Gathering & Delphi Preparation

Delphi Consensus Exercise

Dissemination of Best Practices

Delphi Consensus Methodology

- The Delphi technique is a well-established, rigorous method for gathering consensus
- Iterative process allows for panelists to reevaluate their own positions while taking into account feedback from other experts¹



^{1.} Hsu and Sandford. *Practical Assess Res Eval.* 2007;12(10). **2.** Gelblum and Weisman. Delphi Consensus on mAb Initiation in Private Practice Neurology (protocol). doi:10.17605/OSF.IO/CT28N. Accessed January 17, 2025.

from experts on a specific issue related to clinical decision-making¹

Key Topics Where Consensus Recommendations Are Needed for Private Practice Neurology



Consensus recommendations generally focused on 6 main areas where panelists faced the greatest challenges

Panelists identified novel solutions to address these challenges within private practice settings

Addressing Educational Needs

- Educational outreach and resources
- Training curriculum

Patient Identification

- Recommended screening tools
- Strategies for engaging PCPs

Assessment & Diagnosis

- Biomarker confirmation (BBMs, PET, CSF)
- Neuropsychological testing

Treatment

- · Accessing infusion resources
- Understanding recommendations for maintenance vs discontinuation

Management & Monitoring

- Recommendations for ARIA monitoring
- Guidance for other specialists (eg, neurologists, emergency physicians)

Administrative Challenges

- Development of standardized checklists and protocols
- Designating process creator/owner

Diagnostic Pathways

Treatment Pathways

Addressing Educational Needs





Physicians and other staff may have **limited experience** regarding monitoring for ARIA and appropriate risk/benefit assessments



Consider development of **formal training programs** for staff members

Patient Identification





Lack of familiarity with cognitive testing and perception of cognitive decline as "just aging" may prevent **timely referral of appropriate patients** by PCPs



Strategies to incentivize use of standardized screening tools (eg, MoCA, MMSE, BBMs) by PCPs should be implemented to avoid delays in patient identification

Assessment and Diagnosis





Private practices have **limited access to diagnostic biomarkers**, including access to trusted collaborators who are skilled in interpreting amyloid PET and identifying ARIA risk factors on MRI



Determination of treatment eligibility should be based on **comprehensive assessment** using available resources (eg, amyloid PET, CSF testing, BBMs)

Treatment





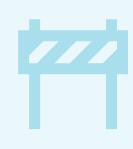
Private practices have variable access to ancillary resources, including **imaging and infusion** capabilities



Establish collaboration with other practices and infusion centers, applying learnings from administration of mAbs for multiple sclerosis

Management and Monitoring





Identification of neuroradiologists with expertise in detection of ARIA can be challenging



Novel resources to search for experienced radiologists or **standardized technologies** (eg, psychometrics) would help provide confidence in ARIA detection

Administrative Challenges





Coordination of patient care is complex, and designating a specific individual responsible for process navigation may be associated with additional costs



Existing staff can be responsible for process development and coordination, including patient coordinators, nurse navigators, infusion nurses, or denervation coordinators

Audience Polling



What resources based on these consensus recommendations would you find most helpful for your practice?

- A. Educational resources
- B. Process checklists
- C. Directory of local infusion centers/radiologists
- D. Examples of successful strategies





What resources based on these consensus recommendations would you find most helpful for your practice?



Next Steps for Delphi Consensus Recommendations





Final consensus recommendations will be published^{1,2}

Publication will include:

- Summary of consensus recommendations
- Strategies for implementing recommendations
- Example resources to aid in implementation

Insight Gathering & Delphi Preparation

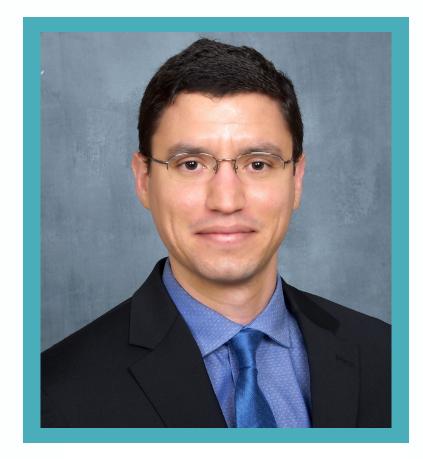
Delphi Consensus Exercise

Dissemination of Best Practices

1. Moon et al. Poster presented at: Antibodies as Drugs: Innovative Formats, Design and Engineering; February 17-20, 2025; Keystone, CO. 2. Gelblum and Weisman. Delphi Consensus on mAb Initiation in Private Practice Neurology (protocol). doi:10.17605/OSF.IO/CT28N. Accessed January 17, 2025.



Disclosures*



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- Research funding: Dr. Soria-Lopez has received clinical trial research funding from Biogen, Novartis, Eli Lilly, Aribio, Karuna/BMS, and the Alzheimer's Association. Additionally, he serves as a co-investigator on an NIH-NIA R01 grant funded by the National Institute on Aging (NIH-NIA)
- Speaking engagements: Dr. Soria-Lopez has participated in speakers' bureaus for Biogen, Eisai, and Eli Lilly, and has delivered presentations for Eisai, Arrowhead Pharmaceuticals, and the Global Learning Collaborative
- Advisory roles: Dr. Soria-Lopez has served as an advisory board member for Biogen, Eisai, Merck, and Genentech
- Travel & honoraria: Dr. Soria-Lopez has received travel and lodging support from the Alzheimer's Association for invited lectures

Practices Vary in Preparedness for Implementing Anti-amyloid mAbs



Complexity of patient coordination may place a strain on resources of smaller practices with reduced availability of support staff

Small private practice (≤5 clinicians)

- Established relationships with outside services?

Medium-sized private practice (6-15 clinicians)

- In-house ancillary services?
- Established relationships with outside services?

Large private practice (>15 clinicians)

- In-house ancillary services?
- Established relationships with outside services?

Practices without access to diagnostic techniques (ie, amyloid PET, CSF analysis), infusion capabilities, or surveillance imaging may face additional challenges

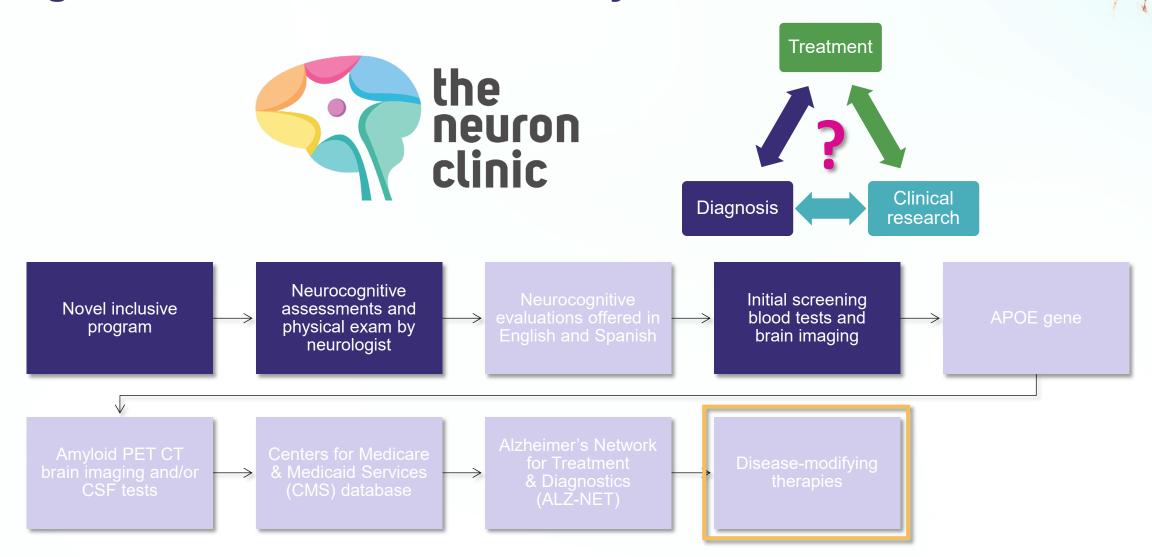
The Neuron Clinic

Patient-focused neurology medical practice serving communities in Southern California

- 25 providers across 6 clinics
- 6 years of experience administering mAb therapies for neurologic disease
- 4 years of experience administering anti-amyloid mAbs
- ~130 patients treated with anti-amyloid mAbs
- Expertise working with underserved populations (~50%)
- Seamless integration of care, treatment, and research
- Streamlined care coordination and safety monitoring



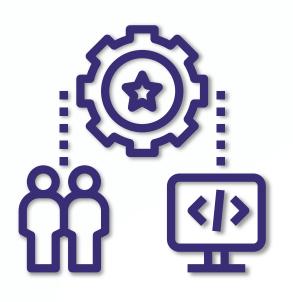
Diagnosis and Treatment Pathways at The Neuron Clinic



APOE, apolipoprotein E; CSF, cerebrospinal fluid; CT, computed tomography; PET, positron emission tomography.

Clinical and Research Teams and Infrastructure





Referral and care coordinators

Psychometrists and social workers

Nurse practitioners, general neurologists, dementia specialists

Neuropsychologists and neuroradiologists^a

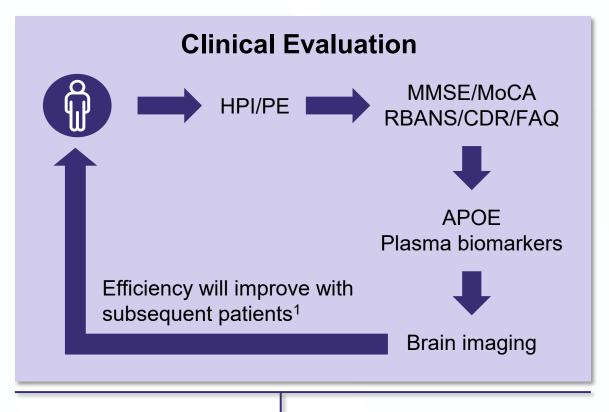
Research coordinators and data analysts

Regulatory and operational team

Clinical and research space

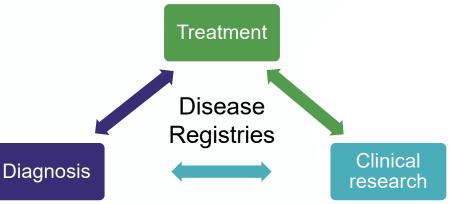
Integrating Clinical Diagnosis and Treatment Into the Current Healthcare Ecosystem: Clinical Evaluation





Why and when should you do testing?

- 1. Narrow differential diagnosis
- 2. Consider treatment options
- 3. Consider trial opportunities
- 4. Benefit/risk ratio
- 5. Caregiver involvement
- 6. Resources and support available
- 7. Cost to patient

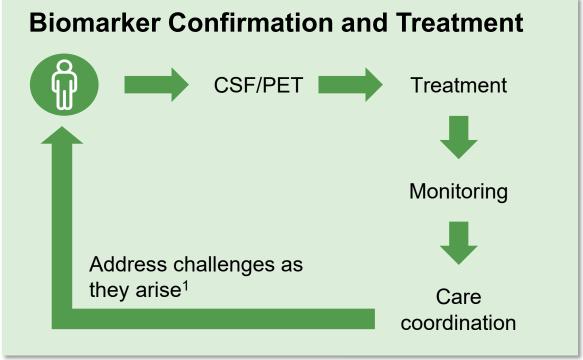


APOE, apolipoprotein E; CDR, Clinical Dementia Rating; FAQ, Functional Activities Questionnaire; HPI, history of present illness; MMSE, Mini-Mental State Exam; MoCA, Montreal Cognitive Assessment; PE, physical exam; RBANS, Repeatable Battery for Assessment of Neuropsychological Status.

1. Rosenbloom et al. CNS Drugs. 2024;38:493-505.

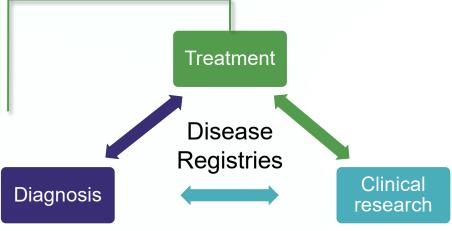
Integrating Clinical Diagnosis and Treatment Into the Current Healthcare Ecosystem: Biomarker Confirmation and Treatment





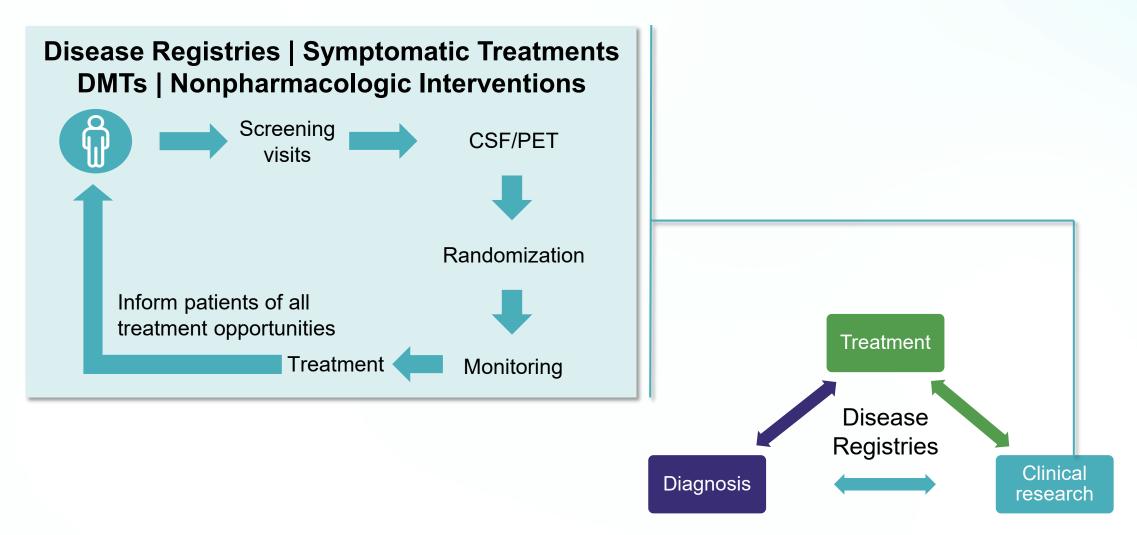
What are the challenges?

- 1. Limited disease awareness
- 2. Limited access to healthcare
- 3. Rising labor costs
- 4. Limited expertise with biomarkers
- 5. Competing clinical demands
- 6. Fragmented health systems



Integrating Clinical Diagnosis and Treatment Into the Current Healthcare Ecosystem: Clinical Research





Roadblocks Faced During Implementation of Anti-amyloid mAbs



Limited experience monitoring for ARIA



What strategies from the Early AD Patient Pathway could have been applied?

 Optimize MRI monitoring (per label guidance) by using the same machine when possible, scheduling in advance, and setting up patient reminders

What strategies from the Delphi Consensus recommendations¹ could have been applied?

- Identify trusted collaborators, including radiologists skilled in detection of ARIA, ER physicians, and vascular neurologists
- In the panelists' experience, reimbursement and cost considerations for MRI monitoring are generally not a significant barrier

Roadblocks Faced During Implementation of Anti-amyloid mAbs (cont.)



Screening processes to determine patient eligibility are complex and time consuming



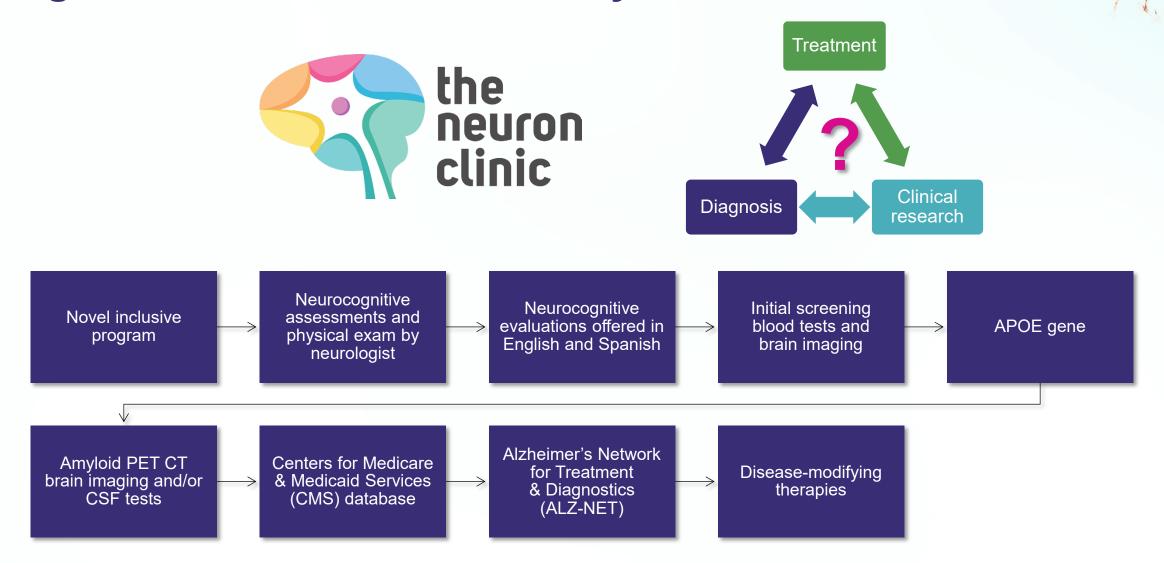
What strategies from the Early AD Patient Pathway could have been applied?

- Consider whether PCPs can conduct initial assessment
- Use APPs for new patient screenings and counseling

What strategies from the Delphi Consensus recommendations¹ could have been applied?

- Train medical staff to administer cognitive assessments
- Screen patients using BBMs

Diagnosis and Treatment Pathways at The Neuron Clinic



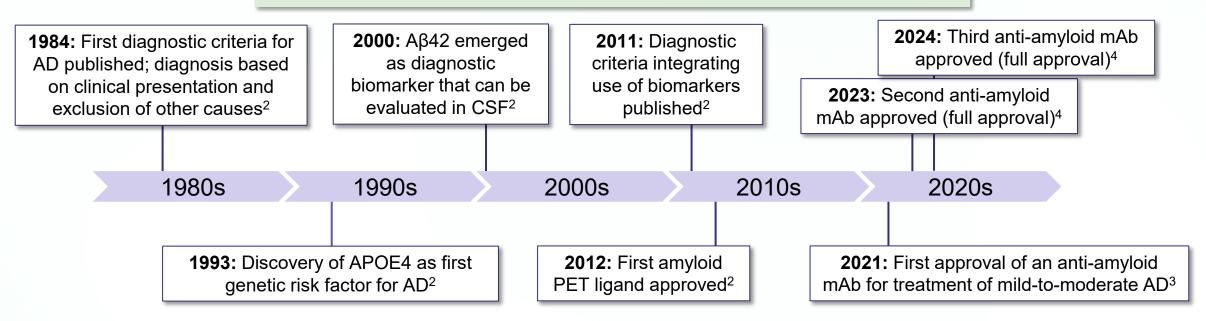
APOE, apolipoprotein E; CSF, cerebrospinal fluid; CT, computed tomography; PET, positron emission tomography.

Diagnostic and Treatment Pathways for AD Are Continuously Evolving



Pathways should be flexible and responsive to emerging technology and novel therapies¹

- Diagnosis using BBMs
- Guidance for maintenance vs discontinuation of anti-amyloid mAbs
- Technology for ARIA detection
- Novel EMR processes



Aβ, amyloid beta; AD, Alzheimer's disease; APOE, apolipoprotein E; ARIA, amyloid-related imaging abnormalities; BBM, blood-based biomarker; CSF, cerebrospinal fluid; EMR, electronic medical record; mAb, monoclonal antibody; PET, positron emission tomography.

^{1.} Moon et al. Poster presented at: Antibodies as Drugs: Innovative Formats, Design and Engineering; February 17-20, 2025; Keystone, CO. 2. Ahmed et al. Brain Res. 2021;1758:147342.

^{3.} Vogt et al. Int J Mol Sci. 2023;24:3895. 4. Geldmacher. Continuum (Minneap Minn). 2024;30:1823-1844.





Summary



- The Early AD Patient Care Pathway provides strategies for optimizing AD diagnosis and treatment within integrated delivery networks
- Delphi consensus recommendations provide guidance for implementation of anti-amyloid mAbs within private practice neurology
- Existing treatment pathways will vary across practices, requiring flexibility when identifying optimal implementation strategies
- Expert-developed resources can provide flexible guidance for neurologists establishing anti-amyloid mAb treatment programs across diverse practice settings

Accessing Expert Resources





The Early AD Patient Pathway is currently available

- Use the QR code to access the request form
- Submit the online request form
- Receive an email with a link to download the Pathway
- Download the Pathway

Questions: Contact heather_reiter@premierinc.com



Final consensus recommendations will be published^{1,2}

Publication will include:

- Summary of consensus recommendations
- Strategies for implementing recommendations
- Example resources to aid in implementation

^{1.} Moon et al. Poster presented at: Antibodies as Drugs: Innovative Formats, Design and Engineering; February 17-20, 2025; Keystone, CO. 2. Gelblum and Weisman. Delphi Consensus on mAb Initiation in Private Practice Neurology (protocol). doi:10.17605/OSF.IO/CT28N. Accessed January 17, 2025.







