Lecanemab for Early Alzheimer's Disease: Final Policy Recommendations

April 17, 2023

Policy Recommendations

Introduction

The following policy recommendations reflect the main themes and points made during the Policy Roundtable discussion at the March 17, 2023 CTAF public meeting on the use of lecanemab for the treatment of early Alzheimer's disease. At the meeting, ICER presented the findings of its revised report on these treatments and the CTAF voting council deliberated on key questions related to their comparative clinical effectiveness, potential other benefits and contextual considerations, and long-term value for money at current prices. Following the votes, ICER convened a Policy Roundtable of two patients, two clinical experts, two payers, and one representative from the pharmaceutical manufacturer to discuss how best to apply the evidence and votes to real-world practice and policy. The discussion reflected multiple perspectives and opinions, and therefore, none of the statements below should be taken as a consensus view held by all participants.

A recording of the conversation can be accessed here and a recording of the voting portion of the meeting can be accessed here. More information on Policy Roundtable participants, including conflict of interest disclosures, can be found in the appendix of this document. ICER's report on these treatments, which includes the same policy recommendations, can be found here.

The roundtable discussion was facilitated by Dr. Steven Pearson, MD, MSc, President of ICER. The main themes and recommendations from the discussion are organized by audience and summarized below.

All Stakeholders

Recommendation 1

All stakeholders have a responsibility and an important role to play in ensuring that new treatment options for patients with Alzheimer's disease are introduced in a way that addresses the impact on health inequities.

AD is underdiagnosed and undertreated in the United States, with significant racial and ethnic disparities. Black and Hispanic Americans both have a higher risk of developing AD, are more likely to have delayed or missed diagnosis, and have more advanced cognitive and functional limitations at diagnosis than their non-Hispanic White counterparts.[1] Additionally, individuals with limited English proficiency and persons with low education levels are also more likely to be underdiagnosed and diagnosed at later stages of cognitive dysfunction.[2]

As noted in the ICER report and presentation and confirmed by the vote of the CTAF panel, the evidence on balance of risks and benefits of lecanemab has significant limitations and may not be judged adequate for full regulatory approval. Even if the FDA does approve the drug under its traditional pathway as "safe and effective," CMS may judge that the evidence does not yet meet the standard for being "reasonable and necessary" and private insurers may judge that the evidence does not meet the standard for being "medically necessary."

As described in a subsequent policy recommendation below, there are several options through which payers may choose to link coverage to requirements for further evidence development, which are likely to increase the risk that access to lecanemab will skew further toward patients and clinicians already connected with academic practice, resulting in poorer access for patients with lower economic resources, including many patients from Black and Hispanic communities.

If lecanemab is covered without requirements for further evidence development, its introduction into practice will be prone to exacerbating health inequities due to several factors including the complexity in confirming eligibility for treatment, the lack of adequate tools for shared decision-making, and the potentially complicated logistics for receiving treatment and monitoring. Eligibility for treatment requires the diagnosis of MCI or mild AD, as well as confirmation of the presence of amyloid and evaluation for comorbidities that may heighten the risk of or be contraindications to treatment. Such evaluations are usually done by a dementia specialist, who is generally a neurologist or geriatrician. However, use of dementia specialists within one year of diagnosis is low, particularly amongst Black and Asian Americans [3], in part due to the shortage of such specialists.[4] Furthermore, payer coverage of the PET scans and ApoE genotype testing has been limited. Because lecanemab requires biweekly IV infusions, as well as MRIs to monitor for complications, timely access to both infusion centers and MRIs is essential. Studies have shown that barriers to timely medical care are often non-medical, such as lack of transportation, long waiting times, and lack of time off from work[5,6]; these barriers can contribute to health inequities and increase caregiver impact. Finally, while CLARITY-AD included more patients from racial and ethnic minority communities than prior clinical trials testing anti-amyloid antibodies for AD, it was not representative of the US AD population and thus conclusions about the efficacy of lecanemab in subpopulations is limited.

To address these concerns:

<u>Manufacturers should take the following actions:</u>

- **Set initial prices according to value assessments from independent analysts to preserve access and affordability of new therapies.** Fair pricing is required to fulfill the social responsibility held by manufacturers to avoid financial toxicity that falls hardest on the most underserved patients. Drug prices that are set well beyond the cost-effectiveness range can not only cause direct financial toxicity to patients, but also contribute to general health care

cost growth that pushes families out of the insurance pool and causes rationing of care that may be harmful. Although Eisai should be praised for their transparency in presenting their model by which they calculated their launch price, studies have shown that industry-sponsored cost-effectiveness analyses are more likely to report favorable results for a new treatment.[7] Thus, fair pricing should be based on independent cost-effectiveness analyses.

- **Work with communities and patient groups to develop reliable methods for recruiting diverse populations with MCI and AD for clinical trials and promote retention of such populations**. The clinical trial population for CLARITY-AD included a more diverse patient population than prior studies of anti-amyloid therapies; however, patients from racial and ethnic minority communities were still underrepresented in the trial compared with the US population, as demonstrated by ICER's sample diversity rating of "fair". This limits the conclusions that can be drawn about the efficacy and safety of lecanemab in patients from such groups.

<u>Payers should take the following actions:</u>

- If considering coverage with evidence development, select options that **balance the need for better evidence with the risks to equal access** for patients with fewer economic resources and those from communities with less connection to academic clinicians and institutions.

- Ensure that **benefit designs** developed in conjunction with employers and other plan sponsors do not create requirements for out-of-pocket spending that create major barriers to appropriate access for patients. For example, the out-of-pocket maximum for Part B services in Medicare is not capped, leading to a situation in which many patients will not be able to undertake certain treatments or will do so only with the guarantee of suffering significant financial hardship. Although many patients will carry supplemental insurance, close to six million Medicare beneficiaries do not, and millions more with Medicare Advantage have very high out-of-pocket maximums that they may not be able to afford. Oncology has been the primary example of this phenomenon, and it would be unconscionable should the advent of effective treatments for AD be accompanied by the extension of this same dysfunctional system. Lower out-of-pocket requirements obviously have broader financial repercussions on Medicare premiums and sustainability, and should be linked conceptually, and perhaps legislatively, with requirements for value-based pricing for infused agents.

- Ensure **coverage of PET scans and ApoE ε4 genotype testing** for the accurate diagnosis of AD and risk stratification for treatment with anti-amyloid antibodies, since only patients with demonstrated amyloid in the brain will be eligible for treatment and risk of ARIA may be greater in patients who are homozygous for the ApoE ε4 mutation.

- Recognize that because of a shortage of dementia specialists, in order to facilitate timely diagnosis and treatment of AD, **continuation of the COVID pandemic-era expansion of telemedicine policies** is necessary (e.g., allow for inter-state consultations, reimbursement for telehealth). However, due to the potential serious risks of treatment, expansion of tele-prescribing, rather than looser consultation-type arrangements should be the preferred option.

- Consider **wraparound programs** that could help address barriers related to social determinants of health, such as transportation, case management, benefit counseling, legal assistance, education, and respite care. Use of wraparound programs has been associated with lower rates of hospitalization and emergency department use.[8]

- Payers should follow the requirements set by the 2020 Improving HOPE for Alzheimer's Act[9] for CMS and provide outreach to providers and patients about the **comprehensive care planning benefit** for Medicare patients.

<u>Health systems should take the following actions:</u>

- **Invest resources to increase capacity for screening and diagnosis**. Improved access for screening and diagnosis across all segments of the patient population is an important goal to reduce existing disparities in dementia care. Actions to reduce disparities could include increasing access to dementia specialists in all communities through outreach clinics and telehealth; improving training, time support, and reimbursement for screening and diagnosis to be done in non-specialist settings (e.g., primary care); and supporting development of newer diagnostic testing such as blood-based biomarkers.

- **Ensure that all interventions are appropriate for culturally and linguistically diverse populations and that interventions are accessible to low literacy populations**. Such populations, due to social, economic, and cultural differences, may have different perceptions of illness and different goals of care.[10]

- **Invest in infrastructure that will increase access to dementia care and infusion centers, particularly in rural or underserved areas.** Most specialized dementia care occurs at large tertiary care centers. However, 85% of people were diagnosed with dementia by a non-specialist physician; less than one-quarter of those patients saw a dementia specialist within one year after diagnosis.[3] Additionally, 20 states are considered "deserts" for neurologists, as a result, the average wait time to see a dementia specialist is 19 months.[4] Furthermore, dementia patients who live in rural areas receive less home health care and have shorter survival than their urban counterparts.[11] Thus, geographic expansion of dementia diagnosis and treatment services is essential to decreasing health inequities. This can be done through partnerships with local physicians and medical centers, as well as telehealth.

Clinicians and clinical specialty societies should take the following actions:

- Given the shortage of dementia specialists to diagnose and manage patients with AD is likely only to grow, develop programs to **educate and assist primary care providers** in diagnosing and managing AD.

- Develop programs to **recruit and retain a diverse workforce** for the diagnosis and treatment of dementia.

Patient advocacy groups should take the following actions:

- Develop programs to help **deliver culturally sensitive information about AD** diagnosis and treatment, and in collaboration with manufacturers and researchers, **target the recruitment and retention of diverse populations** for clinical trials.

Multiple Stakeholders

Recommendation 1

Patient groups, the manufacturer, clinicians, and clinical specialty societies should accurately describe the clinical benefits of lecanemab as a slowing of decline of cognition and function and avoid over-selling the potential benefit of treatment by using terms such as "improvement" or "return of quality of life" or "game changer" in all personal statements and advertising. Furthermore, there should not be an over-emphasis on the removal of amyloid from the brain, which still has not been conclusively linked to clinical outcomes.

- Messaging from the manufacturer, clinical specialty societies, and patient groups, such as in patient-oriented websites and advertisements and provider education and detailing, should make it clear that lecanemab has not been shown to improve cognitive and functional performance. Rather, the messaging should state that lecanemab may slow the decline of cognition, function, and quality of life for patients and caregivers.

- Clinicians and their patients should engage in shared decision-making founded upon a robust, individualized discussion of the potential harms and benefits of treatment. This should include discussion about the likelihood of benefit and risk of harm based on patients' individual clinical and social situation, uncertainty about whether removal of amyloid affects clinical outcomes, uncertainty about long-term harms, lack of benefit in moderate-to-severe AD, and potential financial toxicity. Many patients will have contraindications to therapy or a combination of comorbidities that should lead to very careful consideration of the risks and potential benefits for the individual. One common scenario is the active use of anticoagulant medication; while these patients were included in the trial, the safety and

long-term outcomes of either stopping anticoagulation or taking lecanemab while anticoagulated must be weighed carefully for each individual patient.

Recommendation 2

Payers, healthcare systems, clinicians, and policymakers should work together to assure that the financial incentives associated with infusion delivery do not overly influence patient selection and prescribing.

In order to ensure equitable access to infusions of lecanemab, there will be a need for more infusion centers, particularly in rural and underserved areas. There may be financial incentives for healthcare systems and clinicians to set up infusion centers. However, because of the potential risks of treatment, careful patient selection will be critical to maximize the benefit/harm ratio for the drug. Thus, stakeholders involved in delivery of infusions should build in safeguards to ensure that lecanemab is being prescribed only to patients who fit clinical criteria consistent with those receiving treatment benefit in the clinical trials, and only by prescribers with expertise in diagnosing and managing AD and potential treatment complications.

Recommendation 3

All stakeholders would benefit from a robust yet practical evidence generation system linked to payer coverage in order to learn more about the real-world risks and benefits of lecanemab.

CMS decided to employ coverage with evidence development (CED) for anti-amyloid antibodies for AD under accelerated approval, and this decision currently extends to lecanemab while it is in the accelerated approval pathway. However, even if lecanemab is approved under a traditional FDA pathway, the balance of risks and potential benefits is narrow given questions about the longer-term durability of benefit and the real-world incidence and consequences of ARIA when the drug is used in broader populations. Whether or not the FDA requires a Risk Evaluation and Mitigation Strategy (REMS) to monitor safety, we recommend that stakeholders work together to establish a simple registry that will be able to provide rigorous data without creating access problems in diverse communities.

There are a number of options that can be employed to generate additional post-approval real-world evidence. CED typically involves observational registries to collect standardized data on efficacy and safety. However, such registries are generally voluntary and collection of registry data can be time-consuming for providers, making it less likely that some providers will be willing to participate – potentially missing patients – and may require innovative approaches to funding the additional data collection (e.g., manufacturers, NIH or PCORI, clinical specialty societies). An example of an existing registry that could be leveraged is the Alzheimer's Network for Treatment & Diagnostics (ALZ-NET, https://www.alz-net.org). The US Department of Veterans Affairs (VA) has

opted to require prescribers to participate in prospective medication use evaluation, also focused on safety. Finally, passive data collection using administrative claims or electronic health record data may also be employed; however, claims data often lack the clinical detail needed to fully assess efficacy and safety concerns. Although more patients may be captured through this strategy compared with voluntary registries, since the US does not have either a national all-payer claims database or a national electronic health record system, it would require agreement from all payers and/or health systems to share their data to a third party with analytic capabilities.

Payers

Recommendation 1

Although there is a tremendous need for disease-modifying treatment for AD, given that amyloid removal has not been conclusively linked to clinical benefit and that questions remain about the longer-term safety and effectiveness of lecanemab, it will be reasonable for payers to use prior authorization as a component of coverage of lecanemab, even if it receives full FDA approval. Prior authorization criteria for lecanemab should be based on clinical evidence and input from clinical experts and patient groups. The process for authorization should also be clear, accessible, efficient, and timely for providers.

Coverage Criteria: General

ICER has previously described general criteria for fair coverage policies that should be considered as cornerstones of any drug coverage policy: see Cornerstones of "Fair" Drug Coverage: Appropriate Cost-Sharing and Utilization Management Policies for Pharmaceuticals.

Drug-Specific Coverage Criteria: Lecanemab

The large number of patients with MCI and mild dementia due to AD, combined with the potential for side effects and the high annual price for lecanemab, will lead payers to develop prior authorization criteria and to consider other limits on utilization.

None of these limits, however, should undermine the tenets of fair access to which all patients have a fundamental right.[12] To explore the appropriate application of evidence to coverage policy, and to reflect the views of patient experts and clinicians on specific ways that payers might appropriately use coverage policy to manage resources prudently, we present the following perspectives on specific elements of cost sharing and coverage criteria for lecanemab.

Coverage Criteria

- **Age:** Age criteria are likely to follow the age range from the clinical trials for lecanemab, which encompass ages 50-90 years old. However, it is not unreasonable for payers to

consider excluding patients <65 years old from coverage. Subgroup analyses from the pivotal trial are exploratory and may be confounded by ApoE ε4 status, but there was no statistically significant benefit from treatment among patients <65 years old. In considering this age cutoff for coverage, payers should carefully weigh the evidence in light of the likelihood that patients under age 65 and their clinicians may not view the subgroup analysis as persuasive.

- **Clinical eligibility**: Because of its modest efficacy and potential for harm, payers are likely to closely adhere to clinical trial inclusion criteria. Treatment with lecanemab is indicated in patients with MCI due to AD and mild AD, with biomarker evidence of Alzheimer's disease.

    - **Diagnosis of MCI and mild dementia** should be based on cognitive and functional assessments of patients. Some assessments used in the CLARITY-AD clinical trial (e.g., Weschler Memory Scale IV-Logical Memory (subscale) II) are not commonly used in clinical practice. Thus, it is reasonable to define MCI and mild AD with more commonly used, validated scales such as the MMSE, CDR-GS, St. Louis University Mental Status (SLUMS) scale, or the Montreal Cognitive Assessment (MoCA). For example, the VA has established the following criteria: MMSE >21, SLUMS or MoCA >16, and Functional Assessment Staging Test (FAST) Stage score or 2-4.

    - **Determination of AD versus other causes of dementia**: To exclude other causes of dementia, payers are likely to require a screening MRI within the previous year that does not show evidence of acute or sub-acute hemorrhage or diffuse white matter disease. Although tests to demonstrate the presence of amyloid will be the next step in insurance coverage for most payers, some may also request that blood tests be done to exclude other causes of dementia, including tests for syphilis, thyroid disease, and vitamin B12 deficiency, and screening for depression.

      To establish amyloid presence in the brain, payers will have the choice of covering PET scans and/or CSF-based testing and should cover both to provide broad options for patients and clinicians in different practice settings.

    - **Testing for ApoE ε4**: Subgroup analysis of CLARITY-AD data suggests that there may be lower efficacy of lecanemab in ApoE ε4 homozygotes, which may represent the higher risk of ARIA in this group. Given the modest efficacy of lecanemab and potentially severe consequences of ARIA, it is not unreasonable to require testing for ApoE ε4 status prior to treatment. However, payers should be aware that some patients may be reluctant to be tested due to ethical implications of testing positive for the mutation (e.g., impact of knowledge of mutation on children). Additionally, if payers require ApoE testing, it may be more efficient to do ApoE testing prior to a

PET scan or CSF testing for amyloid, as patients who are homozygous for the mutation may not be candidates for treatment regardless of amyloid status.

- **Exclusion criteria**: Exclusion criteria in the CLARITY-AD clinical trial focused on patients who had evidence of dementia caused by etiologies other than AD and patients who may be at higher risk for complications from treatment.

    - Evidence of any medical, neurological, or mental health condition that may be a contributing or primary cause of cognitive impairment. For example, significant lesions on brain MRI that indicate another cause of dementia; untreated thyroid disease, vitamin B12 deficiency, or HIV; transient ischemic attack, stroke, or seizures; brain tumors.

    - Patients at increased risk of cerebral bleeding (e.g., evidence of cerebral micro- or macrohemorrhages, superficial siderosis, vasogenic edema, aneurysms or vascular malformations, lacunar infarcts or severe small vessel or white matter disease on screening MRI, uncontrolled bleeding disorder, platelet count <50,000 or international normalized ratio >1.5). Given the potential risk of fatal cerebral hemorrhage in patients already on anticoagulation, it is reasonable for payers to consider restricting use in this population.

    - Payers may consider exclusion of patients who carry two copies of the ApoE ε4 genotype (i.e., ApoE ε4 homozygotes). Based on a subgroup analysis of the CLARITY-AD trial, the efficacy of treatment with lecanemab may be less in ApoE ε4 homozygotes compared with ApoE ε4 heterozygotes and non-carriers. Additionally, ApoE ε4 homozygotes carry a higher risk of suffering from ARIA, particularly symptomatic ARIA. Thus, the harms of treatment for ApoE ε4 homozygous patients with MCI or mild AD may outweigh any benefit in slowing cognitive decline.

- **Duration of coverage and renewal criteria**: Initial coverage will likely be limited in some fashion in order to check periodically that the patient still meets coverage criteria, particularly that cognitive function has not declined into moderate-severe AD, a stage at which there is no current evidence that the treatment has benefit. Payers are therefore likely to institute a requirement that clinicians provide cognitive test results to demonstrate that patients remain in the MCI or mild dementia state every 6-12 months to receive ongoing coverage. For continuing coverage payers are also likely to require documentation that appropriate MRI screening for ARIA is being performed.

- **Provider restrictions**: Because of the narrow benefit/harm balance and the potential for severe side effects, initiation of lecanemab is best managed by specialists who have the expertise to accurately diagnose AD and monitor for and manage ARIA. Relevant specialties

include neurology or geriatrics. However, given the shortage of dementia specialists, particularly in rural and other underserved areas, insurance coverage for other models of care such as intra- or interstate consultation via telehealth should be established to reduce access barriers.

- **Step Therapy:** At this time there is no clinical rationale to justify requiring step therapy through other treatment options for AD. "Failure" on other options (e.g., acetylcholinesterase inhibitors, NMDA receptor antagonists) could mean that the patient progresses to moderate AD, at which point they will no longer be eligible for treatment with lecanemab. However, there is no clinical contraindication to simultaneous use of these other medications with lecanemab

Manufacturers

Recommendation 1

Manufacturers of future treatments for Alzheimer's disease should follow the example set by the manufacturer of lecanemab by sharing a transparent, explicit justification for their pricing. However, to foster affordability and good access for all patients, manufacturers should align prices with the patient-centered therapeutic value of their treatments as suggested in independent value assessments.

Upon accelerated approval of lecanemab, when announcing the pricing of the drug, Eisai presented a cost-effectiveness model to justify the launch price of $26,500 for lecanemab. This kind of transparency regarding pricing should be standard when a new drug is launched or when the price of an existing drug is changed, and all manufacturers should follow the example of what Eisai did with explaining the price for lecanemab.

However, the $26,500 price for lecanemab still falls above the value-based price range found in ICER's independent value assessment. This is likely ***in*** part due to the fact that industry-funded cost-effectiveness analyses are more likely to report favorable results for a new treatment.[7] Pricing beyond a drug's value threatens access for patients and causes financial toxicity. Aligning prices with independent assessments of the patient-centered value of treatments helps ensure that all patients who need treatment are able to access it at an affordable price.

Recommendation 2

Until longer-term data are available to address the significant uncertainties regarding the real-world risks and benefits of lecanemab, the manufacturer should provide all payers with a price similar to that negotiated with the VA that is at the lower range of value-based assessment.

Drug prices that are set well beyond the cost-effective range cause not only financial toxicity for patients and families using the treatments, but also contribute to general health care cost growth that pushes families out of the insurance pool and causes others to ration their own care in ways that can be harmful.

Manufacturers should therefore price novel treatments in accordance with the demonstrated benefits to patients. In settings of substantial uncertainty, initial pricing should err on the side of being more affordable. For example, the VA has negotiated a price for lecanemab that is below the list price and within the value-based price range suggested by the ICER's independent assessment. The manufacturer should provide other payers with the price negotiated by the VA, which would allow more patients access, generating additional data on the real-world effectiveness of novel treatments that could be used in future assessment updates. If longer-term data demonstrates a more substantial and more certain benefit/harm ratio, the manufacturer should be allowed to increase pricing in accordance with benefit.

Recommendation 3

Manufacturers should release all patient-level data in order to help patients, clinicians, researchers, and regulators to understand more about the link between amyloid reduction and cognitive outcomes.

The use of a surrogate outcome such as amyloid reduction is a common surrogate marker in clinical trials of anti-amyloid drugs, despite the fact that removal of amyloid has not been conclusively linked with clinical benefit in AD. Additionally, clinical trials typically report mean changes between groups. Aggregate measures can potentially obscure changes in individual patients that are important for assessing the magnitude of clinical benefit and for assessing the correlation between surrogate markers and clinical outcomes.

Without patient-level data, clinicians have less ability to judge the relative harms and benefits for a particular patient (since aggregate results do not necessarily apply to individual patients), and patients are then forced to make decisions about treatment using data points that may or may not apply to them. For a drug with a small potential benefit and a benefit/harm ratio that depends highly on patient characteristics, this is the opposite of patient-centered care.

Furthermore, without patient-level data, researchers and regulators are not only unable to perform independent analyses of the clinical trial results, but they are also not able to further explore the

correlation between amyloid reduction and outcomes such as cognitive decline and quality of life. These kinds of analyses are crucial to advance the understanding of the pathophysiology of AD, and to understand whether amyloid reduction is an appropriate and useful surrogate outcome for future clinical trials. Thus, researchers and other stakeholders should push manufacturers for full patient-level data sets to be released, and the FDA should require such a data release to be standard for drug approvals.

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Appendix

Appendix Tables 1 through 3 contain conflict of interest (COI) disclosures for all participants at the March 17, 2023 public meeting of CTAF.

Appendix Table 1. ICER Staff and Consultants and COI Disclosures

ICER Staff and Consultants*	
Kelsey Gosselin, MA, Program Manager, ICER	**David Rind, MD, MSc,** Chief Medical Officer, ICER
Serina Herron-Smith, BA, Associate Research Manager, ICER	**Melanie Whittington, PhD, MS,** Director of Health Economics, ICER
Yasmine Kayali, BA, Program Coordinator, ICER	**Abigail Wright, PhD, MSc**, Senior Research Lead, Evidence Synthesis, ICER
Grace Lin, MD, Medical Director for Health Technology Assessment, ICER	

*No conflicts of interest to disclose, defined as individual health care stock ownership (including anyone in the member's household) in any company with a product under study, including comparators, at the meeting in excess of $10,000 during the previous year, or any health care consultancy income from the manufacturer of the product or comparators being evaluated.

Appendix Table 2. CTAF Panel Member Participants and COI Disclosures

Participating Members of CTAF*	
Felicia Cohn, PhD, HEC-C Bioethics Director, Kaiser Permanente Orange County	**Annette Langer-Gould, MD, PhD** Regional Lead for Clinical and Translational Neuroscience, Southern California Permanente Medical Group, Kaiser Permanente
Robert Collyar Patient Advocate	**Sei Lee, MD, MAS** Professor of Medicine, University of California San Francisco
Sanket Dhruva, MD, MHS Assistant Professor of Medicine, University of California San Francisco	**Joy Melnikow, MD, MPH** Professor emeritus, University of California Davis
Rena Fox, MD Professor of Medicine, University of California San Francisco	**Elizabeth Murphy, MD, DPhil** Professor of Medicine, University of California San Francisco
Kim Gregory, MD, MPH Vice Chair OBGYN, Division Director Maternal Fetal Medicine, Cedars-Sinai	**Kathryn Phillips, PhD** Professor, University of California San Francisco
Paul Heidenrich, MD Professor of Medicine, Stanford University	**Rita Redberg, MD, MSc** Professor of Medicine, University of California San Francisco
Jeffrey Hoch, MA, PhD Professor, University of California Davis	**Tony Sowry, BA** Patient Advocate and Lead Volunteer, California, National Patient Advocate Foundation
Jeffrey Klingman, MD Chair of Neurology, Kaiser Permanente Northern California	

*No relevant conflicts of interest to disclose, defined as more than $10,000 in healthcare company stock or more than $5,000 in honoraria or consultancies during the previous year from health care manufacturers or insurers.

Appendix Table 3. Policy Roundtable Participants and COI Disclosures

Policy Roundtable Participant	Conflict of Interest
Victor Henderson, MD, MS, Professor of Epidemiology and Population Health and of Neurology, Stanford University	No conflicts to disclose.
Jason Karlawish, MD, Professor of Medicine, University of Pennsylvania	Dr. Karlawish has received manufacturer support of research in the clinical area of this meeting. Dr. Karlawish has served as a site investigator for clinical trails sponsored by Eli Lilly & Co. and Biogen Inc
Doreen Monks, RN, MSN, Patient Advocate	No conflicts to disclose.
Russ Paulsen, MA, Chief Operating Officer, UsAgainstAlzheimer's	UsAgainstAlzheimer's receives funding from companies, including less than 25% from Eisai Co.
Gail Ryan, PharmD, Director of Pharmaceutical Transformation, Point32Health	Dr. Ryan is a full-time employee of Point32Health.
Amir A. Tahami, MD, MS, Ph.D, Head of Global Value & Access, Alzheimer's Disease and Brain Health, Eisai Co.	Dr. Tahami is a full-time employee of Eisai Co., Ltd.
Susan Wojcicki, PharmD, BCOP, Interim Director, Humana Pharmacy Solutions Clinical Drug Evaluation & Policy Strategies, Humana	Dr. Wojcicki is a full-time employee of Humana.