Aducanumab for Alzheimer's Disease: Final Policy Recommendations

August 5, 2021

Policy Recommendations

Introduction

The following policy recommendations reflect the main themes and points made during the policy roundtable discussion at the July 15, 2021 California Technology Assessment Forum (CTAF) public meeting on the use of aducanumab for the treatment of 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/patient advocates, two clinical experts, two payers, one policy expert, and one representative from a 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.

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

Multiple Stakeholders

To prevent patients and families from being misled, patient groups, the manufacturer, and clinicians should accurately characterize the potential benefits of aducanumab as a slowing of decline of cognition and function and avoid using terms such as "improvement" or "return of quality of life" in all personal statements and advertising.

- Messaging from the manufacturer and patient groups, such as in patient-oriented websites and advertisements, should make it clear both that aducanumab has not been shown to improve cognitive and functional outcomes—rather it may slow decline—and also that removal of amyloid has not been conclusively demonstrated to affect clinical outcomes. For this last reason, all stakeholders should avoid using the term "amyloid-busting" in reference to aducanumab since that term would easily be interpreted by patients and families as confirmation that removal of amyloid has demonstrated clinical benefits.

- Clinicians and their patients should engage in shared decision-making founded upon a robust discussion of the potential harms and benefits of treatment. This should include discussion about the uncertain clinical significance of the results from EMERGE, uncertainty about whether removal of amyloid affects clinical outcomes, uncertainty about long-term harms, lack of benefit in moderate-to-severe Alzheimer's disease, 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 contraindication to therapy will be active use of anticoagulant medication, and patients and caregivers may be tempted to stop anticoagulation therapy in order to receive treatment with aducanumab; however, the safety and long-term outcomes of stopping anticoagulation must be weighed carefully for each individual patient.

Whether aducanumab is widely prescribed or not, health systems, manufacturers, payers, and the Food and Drug Administration (FDA) should take steps now that will reduce disparities and improve equitable access to dementia diagnosis, management, and future new therapies.

Alzheimer's disease is underdiagnosed and often poorly managed in the United States (US). Studies consistently demonstrate that quality of care for patients with Alzheimer's disease is poorer than that for other chronic diseases,[47] in part due to underuse of effective supportive care programs, lack of integration of community-based programs into the health care system, shortage of dementia care expertise in rural areas, and lack of time for effective coordination of care, particularly in primary care settings. With aducanumab now approved for treatment, the capacity of the US health care system will prove an ongoing limitation to early diagnosis and consideration of treatment.

Additionally, there are significant racial and ethnic disparities in Alzheimer's disease diagnosis and management. Black and Hispanic Americans are 1.5 to two times more likely to have Alzheimer's disease,[8] and individuals with limited English proficiency and persons with low education levels are also more likely to be underdiagnosed and live longer with cognitive dysfunction.[48]

To address these concerns, health systems should take the following actions:

- **Invest resources to increase capacity for screening and diagnosis**. Whether aducanumab is viewed as an effective treatment or not, 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.

- **Implement evidence-based supportive care models such as the Alzheimer's and Dementia Care Program[49] for all Alzheimer's disease patients.**
- **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.[50]

The manufacturer should take the following actions:

- **Work with communities and patient groups to develop reliable methods for recruiting diverse populations for clinical trials and promote retention of such populations**. Out of 3,268 patients enrolled in ENGAGE and EMERGE, 19 (0.6%) were Black and 49 (1.5%) were Hispanic. Lack of information about the potential differences in safety or effectiveness across different patients undermines knowledge necessary for tailored personal care decisions.
- **Biogen should lower the price of aducanumab to a value-based price range determined by independent research to fairly align with demonstrated benefits for patients. Fair pricing is required to fulfill the social responsibility held by manufacturers to avoid financial toxicity that falls hardest on the most vulnerable patients**. Value-based pricing is one method of preserving access and affordability for new therapies. 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. However, when treatments are first launched, which is when pricing and coverage decisions have to be made, the evidence on the long-term value of these treatments may be extremely limited. Fair pricing in the context of such uncertainty should favor a more conservative approach, with initial pricing erring on being more affordable.

Payers and policymakers should take the following action:

- **Work to achieve more equitable access to current and future therapies by changing benefit designs in Medicare and private insurance to reduce the maximum amount patients must pay out of pocket**. 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 Alzheimer's disease 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.

The FDA should take the following action:

- **Incorporate specific targets for pivotal trials to ensure that patients enrolled adequately reflect the population of patients with the condition in the US.**

Payers

Payers should evaluate coverage of aducanumab in the context of the evolving evidence on its benefits and harms. Based on current evidence and the inadequately justified elevation of amyloid clearance into the role of surrogate outcome, it is not unreasonable for payers to deny coverage for aducanumab as lacking evidence to support that it is medically necessary, pending additional data.

Given the known risks and uncertain effectiveness of aducanumab, it is not inherently unethical for health plans to deny coverage. Importantly, non-coverage in this context should not be viewed as contributing to greater disparities in care just because very wealthy individuals would still be able to access the treatment by paying for it completely out of pocket.

Payers who do choose to provide insurance coverage for aducanumab should cover appropriate diagnostic testing for amyloid in the brain.

Perspectives on specific elements of cost sharing and coverage criteria within insurance coverage policy are discussed below.

Coverage Criteria

- **Age**: Patients aged 50 to 85 were eligible for the two pivotal trials of aducanumab and many payers are likely to adopt this age range as a part of formal insurance coverage criteria. However, consideration should be given to including patients age <50 who may have early-onset Alzheimer's disease and who otherwise meet eligibility criteria.
- **Patient eligibility**: The updated FDA label states that "ADUHELM is an amyloid beta-directed antibody indicated for the treatment of Alzheimer's disease. Treatment with ADUHELM 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." Payers are very likely to create specific language to define the terms in the FDA label in order to produce a narrow focus of coverage given the risks of treatment, the uncertainty of benefit, and the potentially very large patient population.

- **Mild cognitive impairment (MCI) or mild dementia**: Payers are likely to require documentation of cognitive decline for some period of time, e.g., six to 12 months. There are multiple cognitive tests to distinguish the level of cognitive impairment. Clinical experts at the public meeting advised that the most practical validated tests are the Mini-Mental State Examination (MMSE), Clinical Dementia Rating—Global Score (CDR-GS), and the Montreal Cognitive Assessment (MoCA). All of these tests are validated and were used as eligibility criteria within the pivotal trials.
    - MMSE score ≥24 (cutoffs for MCI and mild dementia for MMSE vary by study and by educational level. MMSE ≥24 was used as inclusion criteria for aducanumab clinical trials.[51])
    - CDR-GS score 0.5-1
    - MoCA score 19-24

- **Determination of Alzheimer's disease 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 for other causes of dementia, including tests for syphilis, thyroid disease, and vitamin B12 deficiency.

  To establish amyloid presence in the brain, payers will have the choice of covering PET scans and/or cerebrospinal fluid (CSF)-based testing and may choose to cover one or both. Emerging blood tests for neuro-amyloid are not yet adequately validated for routine clinical use. If CSF-based testing is chosen, payers should be aware that lumbar puncture may be more technically difficult or contraindicated in older patients due to spinal degenerative disease.

  Although the clinical trials tested for apolipoprotein E4 (ApoE4) gene status, current dosing protocols do not differentiate between ApoE4+ and ApoE4- patients, and while ApoE4+ patients are at higher risk of developing ARIA, there is no current expert recommendation about ApoE4 testing in this context.

- **Exclusion criteria**: Given the narrow balance between potential benefit and harm for aducanumab, it is not unreasonable to use clinical trial criteria for exclusions. These criteria include:
    - History of stroke or transient ischemic attack or loss of consciousness in the past one year; clinically significant or unstable psychiatric illness within the last six months; history of significant cardiac disease (e.g., myocardial infarction, heart failure within last one year); impaired renal or liver function

    - Use of anti-platelet or anti-coagulant medications other than aspirin at a prophylactic dose
    - Contraindication to amyloid testing (e.g., PET, lumbar puncture) or to MRI brain scan (e.g., metallic implants).

- **Duration of coverage and renewal criteria**: Initial coverage will likely be for a period of six to 12 months, which is long enough for dose titration and potential assessment of side effects or progression to moderate dementia. The language in the FDA label does not formally exclude continuation of treatment for patients who progress to moderate dementia, but some payers are likely to institute a requirement that patients remain in the MCI or mild dementia levels of cognitive testing in order to receive continuation of coverage. Although there are no data on the safety or effectiveness of aducanumab among patients with moderate dementia, some clinicians and patients who may feel that their course of illness has been slowed with treatment will object to any decision to deny continuation of coverage past the mild Alzheimer's disease stage.
- **Provider restrictions**: Because of the narrow benefit/harm balance and the potential for severe side effects, initiation of aducanumab is best managed by specialists, or in consultation with specialists, who have the expertise to accurately diagnose and manage dementia. Relevant specialties include neurology or geriatrics.

Step Therapy

- There is no clinical rationale to justify requiring step therapy with available symptomatic drugs used for patients with Alzheimer's disease.

Coverage Considerations Specific to Medicare

If Medicare chooses to provide coverage following its National Coverage Determination (NCD) process, it should work with input from the National Institutes of Health and other research methodology experts to design a rigorous Coverage with Evidence Development (CED) program requiring patients be enrolled in a randomized controlled trial or a trial using a rigorous quasi-experimental "waitlist" research design.

Although non-coverage of aducanumab would not be unreasonable given the known harms of aducanumab and its uncertain benefits, it is more likely that the culmination of Medicare's NCD process will be approval of coverage. Under this scenario, it is vital that coverage be provided in a way that can speed the ability to gain additional data on the safety and effectiveness of aducanumab. Medicare should therefore explore how to implement a rigorous program for this agent should it be covered. Medicare should seek broad public comment and seek to partner with study design experts at the National Institutes of Health in order to develop an approach to CED for

aducanumab that will allow for appropriate access in all communities while also being rigorous enough to answer the substantial remaining uncertainties regarding this treatment.

CED is most often implemented through observational study designs built upon patient registries, but Medicare should be aware of the difficulties in using this approach to answer the fundamental question about relative effectiveness that remains for aducanumab. The best way to answer this question scientifically would be another randomized trial, but patients may bristle at the idea of having a random chance of receiving the approved drug, and even cluster randomized designs may be viewed as politically unpalatable.

As an alternative, Medicare should consider formal "waitlist" designs. Given the significant limitations in the infrastructure for delivering infused aducanumab to a large number of patients in the short term, a waitlist design study would gather baseline information on all patients qualifying for treatment and then randomize patients or treatment centers to early versus late administration. This quasi-experimental design allows patients to serve as their own controls while they are waiting for treatment and can produce rigorous evaluations of interventions rolled out over a number of months or years. Patients and families may find the idea of a waitlist design objectionable, but if the reality is that some patients will be forced to wait due to infrastructure limitations, it could prove more equitable to formalize a waitlist design and assign treatment in a fashion to assure that patients are not more likely to obtain early treatment on the basis of greater resources, preferential access networks, or geography, all of which may deepen health inequities. Consideration could be given to randomization within a waitlist design as a method of limiting potential bias. Patient advocacy groups, clinical specialty societies, and other stakeholders must all be closely engaged in examining the pros and cons of different options, but it seems imperative that patients, families, and the country find out whether aducanumab works through a rigorous study or set of studies that conclude far earlier than the nine years the FDA allowed Biogen to complete its confirmatory trial.

Regulatory

For Alzheimer's disease, the FDA should act quickly to set a clearer regulatory framework in place by specifying a threshold range for amyloid clearance that will be accepted going forward as "reasonably likely" to provide patient benefit. More broadly, the FDA should take concrete steps to become clearer about the way it engages its advisory committees and to be transparent and consistent in its designation of surrogate outcomes and the timing of its decisions to use the accelerated approval pathway.

The approval process for aducanumab left public confidence in the FDA shaken. The FDA worked more closely with Biogen than usual to perform post-hoc analyses to try to understand the reason for the discrepant outcomes in the pivotal trials for aducanumab. An advisory panel was convened and was highly critical of the conclusions from these post-hoc analyses and voted against approval; after further deliberations at the FDA, however, the drug was approved, not on the basis of the

FDA's interpretation of the clinical outcomes data, but by repurposing amyloid clearance into a surrogate endpoint that was now considered "reasonably likely" to lead to patient benefit. The FDA made this decision without disclosing any data showing patient-level correlation of amyloid clearance with cognitive outcomes from the trials of aducanumab. The FDA also made this decision despite the fact that the accelerated approval pathway was meant for drugs in areas of great need, which do not yet have data on patient-centered clinical outcomes, yet clinical outcome measures for Alzheimer's disease do exist and are not difficult to measure in relatively short trials. Faced with discrepant trial data, the FDA found sudden confidence in an outcome that had been previously dismissed as a "reasonably likely" surrogate outcome, took a detour to accelerated approval, and thereby justified approval using an approach inconsistent with past FDA practice.

Nonetheless, going forward, the precedent for amyloid-clearing drugs has been set, and sponsors of these drugs may assume that it is not necessary to have outcomes data beyond amyloid clearance before applying for regulatory approval. Manufacturers of drugs that clear tau from the brain may assume the same approach will be taken with their drugs. To guide manufacturers, but also to create some semblance of transparency and consistency, the FDA should immediately act to define publicly what degree of amyloid reduction it will consider as a minimum to qualify a drug as "reasonably likely" to lead to clinical benefit.[52] Similarly, they should act now to present how they intend to approach setting thresholds for other potential "reasonably likely" surrogate outcomes as part of regulatory decisions for non-amyloid treatments of dementia. Will these be required to demonstrate improvements in clinical outcomes, putting them at a disadvantage compared to amyloid-decreasing agents? Will they be able to gain approval showing improvements in their own surrogate outcomes linked to their mechanism of action? The FDA should clarify these questions expeditiously in order to improve transparency and to start to rebuild the trust that has been lost through its torturous approval process for aducanumab.

The FDA should be loath to approve plans for manufacturers to combine Phase II and Phase III studies in order to ensure that correct dosing is being tested in adequate patient populations in Phase III trials.

One of the reasons proposed by Biogen that only the results of the EMERGE study should be viewed as definitive was the fact that this study had more patients whose treatment was affected by a dosing protocol change in the ApoE+ group (Protocol Version 4), allowing patients in this group to be titrated to the highest 10 mg/kg dose. Implementation of this protocol change during the course of both pivotal trials reflected the lack of understanding by the manufacturer of the optimal dosing strategy, something that is routinely gained through Phase II trials prior to commencing Phase III trials. In the case of aducanumab, the merging of Phase II and Phase III trials, combined with early discontinuation of both trials due to a pre-specified futility analysis, led to the need to perform post-hoc analyses to try to assess whether the protocol change might be a contributing factor in the disparate trial results. Post-hoc analyses are extremely vulnerable to bias and should not be the

standard by which regulatory approvals are determined. The FDA should shift away from joint Phase II/III trials for future treatments of Alzheimer's disease.

Manufacturer

Biogen should accelerate the timeline of a confirmatory randomized controlled trial conducted internationally to provide more definitive evidence on the clinical efficacy of aducanumab as well as additional safety data.

In its approval of aducanumab via an accelerated pathway, the FDA required Biogen to complete a post-approval confirmatory randomized controlled trial within nine years. Given the conflicting Phase III trial results, the current lack of definitive evidence that reduction in amyloid translates into slowing of cognitive decline, and the high price of aducanumab, it is imperative that Biogen seek to complete the confirmation randomized controlled trial as soon as possible. It is very likely that an adequate randomized controlled trial will not be possible in the US following approval, therefore Biogen will need to perform this trial internationally where the drug is not available.

Clinicians and Clinical Societies

Clinicians and clinical specialty societies should bear witness to the unmet needs of patients and families with Alzheimer's disease to support broad consideration of the value of emerging therapies. But all clinicians and specialty societies should also exercise their obligation to provide objective guidance on interpreting the uncertain data on aducanumab, and should advocate for fair pricing and for affordable and equitable access to all available treatments.

Professional organizations have a critical role to play in helping payers and other policymakers understand the need of patients for effective treatments for dementia. It is equally important that they advocate for affordable and equitable access to new therapies. Statements on aducanumab such as those from the American Academy of Neurology[53] and the American Geriatrics Society[54] expressing concern about the uncertainty of clinical benefits and the high cost of aducanumab are outstanding examples of the type of advocacy professional organizations should engage in during the debate about initial approval of and pricing of new therapies.

Patient Organizations

Patient organizations have a vital role to play to promote objective descriptions of the risks and benefits of new therapies in order to support shared decision-making for every patient. In addition, patient groups have a powerful voice and should apply it to create significant pressure for fair pricing and appropriate insurance coverage across all sectors of the health system.

Patient groups should endeavor to educate patients about the potential risks and benefits of new therapies, particularly those with the potential for substantial harms, and work with other

stakeholders to develop and disseminate evidence-based, balanced materials that are accessible to all patients, including those with low health literacy. Patient groups should also accept responsibility to publicly promote access and fair pricing of new therapies. For example, the Alzheimer's Association made a statement following the announcement of aducanumab's price tag, which included, "This price is simply unacceptable. For many, this price will pose an insurmountable barrier to access, it complicates and jeopardizes sustainable access to this treatment, and [it] may further deepen issues of health equity. We call on Biogen to change this price."[55] This statement is a strong example of the type of advocacy for fair pricing needed when pricing exceeds predicted value of a drug. Patient groups should additionally follow-up such statements with organized campaigns to advocate for fair pricing, for example, by encouraging patients and families to write to Congress or launch public relation campaigns with such messaging.

Future Research

Researchers should focus on finding ways to improve targeting of drugs to find patients who will derive the greatest benefit and decrease utilization in patients who have low probability of benefit and high risk for harm, particularly for diseases with heterogeneous populations and for therapies with narrow therapeutic windows.

For drugs such as aducanumab, where potential benefits are small and potential harms are great, understanding which subset of patients will benefit most and which are most likely to be harmed is critical to increasing the value of treatments and maintaining affordability. Thus, drug development should also be accompanied by robust research into novel diagnostic strategies (e.g., liquid-based amyloid screening tests, genetic markers) that have the potential to identify the target population more accurately, thus potentially lowering the cost of treatment and minimizing harm to patients.

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Appendix

Appendix Tables 1 through 3 contain conflict of interest (COI) disclosures for all participants at the July 15, 2021 public meeting of CTAF.

Table 1. CTAF Member Participants

Ralph G. Brindis, MD, MPH, MACC, FSCAI, FAHA,* Clinical Professor of Medicine, UCSF	**Sei Lee, MD,*** Associate Professor of Medicine, Division of Geriatrics, UCSF
Felicia Cohn, PhD,* Bioethics Director, Kaiser Permanente, Orange County; Clinical Professor of Bioethics, Department of Medicine, University of California, Irvine School of Medicine	**Elizabeth J. Murphy, MD, DPhil,*** Professor of Clinical Medicine, UCSF; Chief, Division of Endocrinology and Metabolism, Zuckerberg San Francisco General Hospital
Sanket Dhruva, MD, MHS, FACC,* Assistant Professor of Medicine, UCSF	**Kathryn A. Phillips, PhD,*** Professor of Health Economics and Health Services Research; Director and Founder, UCSF Center for Translational and Policy Research on Personalized Medicine; Department of Clinical Pharmacy/School of Pharmacy, UCSF Institute for Health Policy Studies, and UCSF Comprehensive Cancer Center
Rena K. Fox, MD,* (Chair) Professor of Medicine, UCSF	**Ann Raldow, MD, MPH,*** Assistant Professor, Department of Radiation Oncology, UCLA David Geffen School of Medicine
Bob Collyar,* Patient Advocate in Research	**Richard Seiden, JD,*** Patient Advocate, Retired Partner, Foley & Lardner LLP
Jeffrey Hoch, PhD,* Associate Director, Center for Healthcare Policy and Research, UC Davis	**Joanna Smith, LCSW, MPH, CHA,*** Chief Executive Officer, Healthcare Liaison, Inc.
Jeffrey Klingman, MD,* Chief of Neurology, Kaiser Permanente, Walnut Creek	**Anthony Sowry,*** Patient Advocate and Lead Volunteer, California, National Patient Advocate Foundation; Senior Vice President, Maritime Container Shipping (Retired)
Annette Langer-Gould, MD, PhD,* Regional Lead for Clinical/Translational Neuroscience, Southern California Permanente Medical Group, Kaiser Permanente; MS Specialist, LA Medical Center	

*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.

Table 2. Policy Roundtable Participants and COI Disclosures

Policy Roundtable Participant	Conflicts of Interest
Matthew Baumgart, Vice President of Health Policy, Alzheimer's Association	The Association received 0.89% of its total 2020 contributed revenue from the biotechnology, pharmaceutical, diagnostics, and clinical research industry, including 0.15% from Biogen and Eisai.
Leslie Fish, RPh, PharmD, Vice President of Clinical Pharmacy, IPD Analytics	Leslie Fish is an employee of IPD Analytics.
Patrick Gleason, PharmD, Assistant Vice President, Health Outcomes, Prime Therapeutics	Patrick Gleason is an employee of Prime Therapeutics.
Victor W. Henderson, MD, MS, Professor, Epidemiology and Population Health and Neurology and Neurological Sciences; Director, Alzheimer's Disease Research Center, Stanford University	No conflicts of interest to disclose.
Laura Jones, Caregiver and Advocate	No conflicts of interest to disclose.
Sarah Kremen, MD, Director, Neurobehavior Program, Jona Goldrich Center for Alzheimer's and Memory Disorders, Cedars-Sinai Medical Center	Sarah Kremen served as a site PI for aducanumab trials PRIME and ENGAGE.
Chris Leibman, PharmD, MS, Head of Value and Access, Biogen	Chris Leibman is an employee of Biogen.
Mark McClellan, MD, PhD, Director, Duke University Margolis Center for Health Policy	Receipt of monetary value, including salary and other payments for services. Equity interests in individual stocks, stock options, or other ownership interests in excess of $10,000. Status as an officer, board member, trustee, owner, or employee of a health care company, or an organization that receives more than 25% of its funding from health care companies.

Table 3. ICER Staff and Consultants

Jonathan D. Campbell, PhD, MS,* Senior Vice President for Health Economics, ICER	**Steven D. Pearson, MD, MSc,*** President, ICER
Laura Cianciolo,* Program Manager, ICER	**David M. Rind, MD, MSc,*** Chief Medical Officer, ICER
Noemi Fluetsch, MSc, MPH,* Research Assistant, Health Economics and Outcomes Research, ICER	**Patricia G. Synnott, MS, MALD,*** Senior Manager, CEA Registry and Global Health Initiatives, Center for the Evaluation of Value and Risk in Health
Grace A. Lin, MD,* Associate Professor of Medicine and Health Policy, UCSF	**Azanta Thakur,*** Program and Event Coordinator, ICER
Avery McKenna,* Research Assistant III, Evidence Synthesis, ICER	**Melanie D. Whittington, PhD, MS,*** Associate Director of Health Economics, ICER
Emily Nhan,* Research Assistant, 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.