



June 1, 2021

Submitted electronically to: publiccomments@icer-review.org

Steven D. Pearson, MD, President
Institute for Clinical and Economic Review
Two Liberty Square, Ninth Floor
Boston, MA 02109

Re: Draft Evidence Report for Aducanumab for Alzheimer's Disease, May 5, 2021

Dear Dr. Pearson:

On behalf of the Institute for Patient Access, I thank you for the opportunity to provide comments regarding ICER's draft evidence report, "Aducanumab for Alzheimer's Disease: Effectiveness and Value," dated May 5, 2021.

About the Institute for Patient Access

The Institute for Patient Access (IfPA) is a physician-led policy research organization dedicated to maintaining the primacy of the physician-patient relationship in the provision of quality health care. To further that mission, IfPA produces educational materials and programming designed to promote informed discussion about patient-centered care. IfPA was established in 2012 by the leadership of the Alliance for Patient Access, a national network of health care providers committed to shaping a patient-centered health care system. IfPA is a 501(c)(3) public charity nonprofit organization.

Draft Evidence Report Comments

As the draft evidence report notes, an estimated 6.2 million Americans aged 65 and older are living with Alzheimer's in 2021.¹ Due to the aging of the Baby Boom generation, this number is projected to more than double to 12.7 million Americans by 2050, and 13.8 million Americans by 2060.² Since the number of Americans living with this disease will increase significantly over the next three decades, Alzheimer's financial and health cost will become an even larger burden in the future without effective treatments.

¹ <https://www.alz.org/media/documents/alzheimers-facts-and-figures.pdf>.

² Rajan KB, Weuve J, Barnes LL, McAninch EA, Wilson RS, Evans DA. Population estimate of people with clinical AD and mild cognitive impairment in the United States (2020-2060).

Should cost-effectiveness assessments fail to account for all of the individual and societal costs imposed by these diseases, in addition to the direct health care costs, access to efficacious treatments for the millions of patients impacted by Alzheimer’s and other forms of dementia will be jeopardized. Toward the goal of access, IfPA commends the inclusion of “a modified societal perspective” as a co-base-case analysis in the draft evidence report. The modified societal perspective includes estimates for patient productivity impacts, caregiver time, caregiver quality of life and caregiver direct medical costs. As noted in the draft evidence report, it is important to include the non-health care costs associated with dementia when evaluating the cost-effectiveness of drugs that treat these diseases.

While the draft evidence report considers these societal costs, however, the coverage is incomplete and the cost estimates are low. Addressing these concerns is crucial for the final evidence report and any future reports that evaluate the cost-effectiveness of drugs designed to treat Alzheimer’s or other forms of dementia. Unless these important considerations are incorporated, the results may undervalue the benefits of effective treatment.

Alzheimer’s Costs Are Significantly Higher Than the Values in the Draft Evidence Report

The draft evidence report cites the total costs of Alzheimer’s to be at least \$500 billion annually, which is likely an understatement of the actual costs. According to the Alzheimer’s Association,³ the direct health care costs alone are projected to be \$355 billion in 2021. A study in the AJMC confirms this estimate, finding that the direct health care costs for treating Alzheimer’s in 2020 were \$305 billion.⁴ A substantial share of these costs, 49% according to a May 2021 Milliman report, are related to long-term residential nursing care.⁵ These costs impose significant financial burdens on families but also on state governments, as Medicaid will ultimately bear a large share.

In addition to these costs, caregivers provide nearly \$257 billion in unpaid care to people living with Alzheimer’s and other dementias as of 2020.⁶ These costs are based on the 15.3 billion hours of unpaid assistance that caregivers must provide patients every year and imply total annual costs in excess of \$600 billion – 20% larger than the number cited in the report. And even this cost estimate is incomplete because it does not account for the many costs of the disease that are difficult to quantify.

Alzheimer’s Imposes a Tremendous Burden on Caregivers

³ <https://www.alz.org/media/documents/alzheimers-facts-and-figures.pdf>.

⁴ https://nccd.cdc.gov/BRFSSPrevalence/rdPage.aspx?rdReport=DPH_BRFSS.ExploreByTopic&irbLocationType=StatesAndMMSA&isIClass=CLASS17&isITopic=TOPIC15&isIYear=2019&rdRnd=24372.

⁵ https://www.agingresearch.org/app/uploads/2021/05/Assessing-the-Value-of-Therapies-in-Alzheimer%E2%80%99s-Disease_FINAL.pdf.

⁶ <https://www.alz.org/media/documents/alzheimers-facts-and-figures.pdf>.

These cost estimates do not account for the emotional burden on caregivers. According to a 2017 survey from the Alzheimer's Association, 64% of those caring for someone with Alzheimer's or dementia felt "isolated or alone" in the task. More than four in every five (84%) said they needed "more help with caregiving, especially from other family members."⁷ These stresses ultimately impact caregiver's health, with surveys showing that caregivers experience higher rates of physical and emotional stress and depression. They even report declines in cognition themselves.

Importantly, Alzheimer's caregivers are enduring a larger burden compared to caregivers for other diseases. According to a survey by Home Care Assistance, "dementia caregivers were seven times more likely to experience daily physical, emotional and mental exhaustion from caregiving than non-dementia caregivers. The survey also found that dementia caregivers were three times more likely to feel extreme stress from their caregiving responsibilities than other types of caregivers." As documented by the \$257 billion in costs referenced above, there are also substantial financial and economic consequences that, as with the formal costs of care, are expected to grow significantly over the next several decades.

As Alzheimer's patients often have multiple caregivers,⁸ these caregiver burdens significantly expand the number of people experiencing negative consequences from this disease. The severity and pervasiveness of these burdens demonstrates that it is essential for a cost-effectiveness model to incorporate the full costs borne by caregivers even if it is challenging to quantify them. Without an accurate assessment of these burdens, the model will significantly undervalue the benefits of any efficacious treatment.

The Lifetime Burden from Alzheimer's Disease Should Be Considered

The cost estimates reviewed above look at the disease's cost from an annual basis. When discussing the financial burden of a degenerative disease, however, it is important to explicitly recognize that the costs are incurred for many years and will increase over time as the degeneration worsens. In short, an estimation of costs is incomplete if it does not incorporate the lifetime burden of the disease (appropriately discounted into the present value).

According to Jutkowitz et al. (2017), over each patient's lifetime, "the discounted cost of care for a person with dementia was \$321,780 (2015 dollars)"⁹ The Alzheimer's Association estimates that in 2020 dollars, these lifetime costs, which reflect only the direct care expenditures, equate to \$373,527.

⁷ <https://alzheimersnewstoday.com/2017/06/01/alzheimers-dementia-caregivers-emotional-toll-need-support-surveys/>.

⁸ As evidence to this reality, the CDC estimates there are more than "16 million Americans providing unpaid care" to patients with Alzheimer's and other dementia (<https://www.cdc.gov/aging/caregiving/alzheimer.htm>) compared to 6.2 million living with the disease.

⁹ Jutkowitz E, Kane RL, Gaugler JE, MacLehose RF, Dowd B, Kuntz KM. Societal and family lifetime cost of dementia: Implications for policy. *J Am Geriatr Soc* 2017;65(10):2169-75.

It is also important to note that a disproportionate share of the financial burden from this disease will be directly borne by families. According to Jutkowitz et al. (2017), families will incur 70% of the total cost burden (\$225,140), compared to Medicaid, which will incur 14% (\$44,090), and Medicare, which will incur 16% (\$52,540).¹⁰

In light of these costs, the \$500 billion cost estimate cited in the report may be an inaccurate basis from which to judge the benefits of effective treatments.

Accounting for Patients' "Loss of Self" and Alzheimer's Less Tangible Costs

Loss of identity is one of the more devastating and terrifying aspects of Alzheimer's and other forms of dementia. Patients struggle to maintain their self-worth while having to accept the inevitable cognitive decline and realization that they will become a burden on loved ones.

According to the aforementioned 2017 survey by the Alzheimer's Association, 70% of participants feared being unable to care for themselves and live independently as they aged. Only 24% were planning financially for their future care needs, and only 20% reported talking with a family member about care preferences.¹¹ Alzheimer's patients also commonly experience depression, have thoughts of suicide, and generally experience a poorer quality of life even before the disease's progression robs them of their memories.^{12 13}

Here, as with many of Alzheimer's burdens on patients and caregivers, the methodologies to quantify impact are underdeveloped. Nevertheless, when it comes to Alzheimer's and dementia, not incorporating these impacts will lead to a vast underestimation of the benefits provided by an efficacious treatment.

It Is Essential to Explicitly Account for Alzheimer's Impact on Communities of Color

As the draft evidence report mentions, Alzheimer's imposes a disproportionate impact on communities of color. According to the Alzheimer's Association, "African Americans are about two times more likely than whites to have Alzheimer's and other dementias, [but] they are only 34% more likely to have a diagnosis. Hispanics are about one and one-half times more likely than whites to have Alzheimer's and other dementias, but they are only 18% more likely to be diagnosed."¹⁴

¹⁰ Jutkowitz E, Kane RL, Gaugler JE, MacLehose RF, Dowd B, Kuntz KM. Societal and family lifetime cost of dementia: Implications for policy. *J Am Geriatr Soc* 2017;65(10):2169-75.

¹¹ <https://alzheimersnewstoday.com/2017/06/01/alzheimers-dementia-caregivers-emotional-toll-need-support-surveys/>.

¹² <https://www.webmd.com/alzheimers/alzheimers-depression>.

¹³ <https://bmcgeriatr.biomedcentral.com/articles/10.1186/s12877-018-0831-2>.

¹⁴ https://www.alz.org/aaic/downloads2020/2020_Race_and_Ethnicity_Fact_Sheet.pdf.

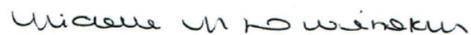
Thus, communities of color have a higher risk of developing this devastating disease and, because it is discovered later, have higher average medical costs. The disproportionate impact on communities of color also means that an efficacious treatment will be particularly valuable for these demographic groups.

Conclusion

Alzheimer's and dementia already afflict too many people, yet their prevalence is expected to more than double in the coming decades. Effective Alzheimer's treatments will reduce the disease's economic costs today and will significantly decrease the expected cost burdens of the disease in the future.

If IfPA can provide further detail or aid the Institute for Clinical and Economic Review in incorporating any of the above recommendations into its analysis, please contact us at 202-499-4114.

Sincerely,

A handwritten signature in black ink that reads "Michelle M. D. Winokur". The signature is written in a cursive, slightly slanted style.

Michelle M. D. Winokur, DrPH
Executive Director