Valuing Alzheimer Disease Therapies—Considering Costs and Benefits Beyond the Patient

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The US Food and Drug Administration (FDA) approval of aducanumab in June 2021 marked a milestone for the Alzheimer disease (AD) community, but the event also served as a pressing call to action for health economists and others who will evaluate the value of new AD therapies. Given the high prices of new agents, it is critical to understand whether they provide reasonable value as measured by the outcomes achieved relative to the costs.

However, there are many questions about how to estimate costs and effects as well as what components to include. The timely work by Ito and colleagues,1 which explores the impact of societal factors (ie, the consequences, such as caregiver health outcomes, beyond those affecting the patients themselves), helps in this regard, highlighting the importance of considering broader value elements and ongoing challenges for the field. The simulation model in the study by Ito et al estimated the cost-effectiveness of a hypothetical treatment that delays progression to dementia for patients with mild cognitive impairment and showed that results vary depending on whether the model included factors beyond a patient’s own health. When caregiver costs and quality-of-life effects were included, the cost-effectiveness of the AD treatment improved substantially, from $183 000 per quality-adjusted life year (QALY) gained to $74 000 per QALY gained—a 60% decrease in the cost-effectiveness ratio. The results support one’s intuition: given the devastating effects of AD, any effective treatment for the condition should have important spillover effects on caregivers.

The findings in the article by Ito et al1 align with prior investigations, demonstrating that incorporating broader impacts related to AD caregiver burden generally makes interventions seem more cost-effective (and in some cases, cost-saving).2,3 Given conventions in the United States that value QALYs in the range of $100 000 to $150 000, their results suggest that including caregiver effects could in theory change conceptions about whether an AD therapy reflects reasonable value even at high prices. That is, depending on the types of nonpatient costs and benefits considered, such changes may be large enough to cross commonly cited cost-effectiveness benchmarks, thus leading to different decisions about whether to cover and pay for the new AD treatments.

The analyses also underline challenges about how best to quantify and incorporate such considerations. Although some prior cost-effectiveness analyses of AD interventions have considered caregiving time costs, other components, such as out-of-pocket payments for transportation expenses borne by caregivers or family members, are often omitted, due in part to the absence of relevant data.

With few exceptions, prior analyses have omitted caregiver quality-of-life effects because data are sparse, because the field lacks consensus on whether to include such consequences, and perhaps because payers have little incentive to consider caregiver outcomes that do not directly affect payer budgets.2 When such effects are considered, most studies, including that by Ito et al,1 simply sum patient and caregiver QALYs, but the approach raises questions—eg, it can be difficult for AD caregivers, who typically serve as proxy respondents for patients, to disentangle their own preferences from the patient’s.

Drug value frameworks, such as the one used by the Institute for Clinical and Economic Review (ICER), have historically excluded societal considerations, although ICER has taken steps more recently to consider broader value elements if supporting evidence is available.4 In light of the...
disproportionate impact of AD on women (both as patients and caregivers), people of color, and low-resourced communities, future value assessments could also give credit to a treatment’s ability to reduce health care disparities.\textsuperscript{5} Furthermore, as Ito et al\textsuperscript{1} note, new work suggests that society may be more willing to pay for therapies addressing severe diseases, such as AD, and thus warrant higher (ie, more lenient) cost-effectiveness benchmarks.\textsuperscript{6}

Ensuring that societal consequences of AD treatments receive attention will require a change in how the field conceptualizes the value of therapies. It will also require better data. In particular, data on caregiver costs and health effects should be core outcome measures and ideally collected alongside AD trials, as Ito et al\textsuperscript{1} helpfully point out. Better estimates of how patient and caregiver utilities vary by disease stage and by care setting, among other data inputs, will also help to generate more robust cost-effectiveness estimates.

\textbf{REFERENCES}


