Published in final edited form as:

Alzheimers Dement. 2020 November ; 16(11): 1568–1570. doi:10.1002/alz.12155.

Preparing the Healthcare System to Pay for New Alzheimer's Drugs

Pei-Jung Lin, PhD, Joshua T. Cohen, PhD, Peter J. Neumann, ScD

Center for the Evaluation of Value and Risk in Health, Institute for Clinical Research and Health Policy Studies, Tufts Medical Center, Boston, MA

Abstract

Biogen's announcement last fall that it will seek FDA approval for its Alzheimer's disease (AD) treatment, aducanumab, seven months after the drug was declared a failure, buoyed patients and families, but put health payers and policymakers on alert. Whether or not aducanumab succeeds, other disease-modifying therapies for AD will follow, and the healthcare system is unprepared for the reimbursement and access challenges. Novel AD therapies are much needed, but we cannot assume substantial cost offsets. With forethought and preparation, however, the healthcare system can accommodate new AD drugs. First, we urge the use of cost-effectiveness of new Alzheimer's treatments as a starting point for setting value-based prices. Second, payments for new AD therapies should ideally incorporate a performance warranty, which helps apportion risk associated with initial therapy value estimates between drug manufacturers and payers. Third, we urge consideration of "subscription" payment agreements to address system affordability issues.

Even in the midst of the COVID-19 pandemic, we shouldn't lose sight of important developments in Alzheimer's disease (AD). Last fall, Biogen's announcement that it will seek FDA approval for its AD treatment, aducanumab, seven months after the drug was declared a failure, buoyed patients and families, but put health payers and policymakers on alert. Whether or not aducanumab is approved, other disease-modifying therapies for AD will follow, and the health system is unprepared for the reimbursement and access challenges.

From 2010 to 2050 the number of individuals in the U.S. age 70 with AD is projected to increase from 3.6 to 9.1 million, with total annual care costs rising from \$307 billion to \$1.5 trillion (2010 dollars), assuming no new treatments.¹ Although there are some expectations that future AD therapies will tame spending growth,² achieving substantial cost offsets will be difficult. First, prices for new Alzheimer's therapies will likely be high. Of nearly 100

Corresponding Author: Pei-Jung Lin, PhD, Associate Professor of Medicine, Center for the Evaluation of Value and Risk in Health, Institute for Clinical Research and Health Policy Studies, Tufts Medical Center, 800 Washington Street, Box 63, Boston, MA 02111, Phone: 617-636-4616; Fax: 617-636-8628, plin@tuftsmedicalcenter.org.

CONFLICTS OF INTEREST This work is supported by funding from the National Institutes of Health (R01AG060165). The authors report consulting income from Biogen; Biogen had no involvement in this manuscript. The authors are employed at the Center for Evaluation of Value and Risk in Health (CEVR) at Tufts Medical Center in Boston. CEVR receives financial support from both pharmaceutical and device manufacturers, in addition to government and nonprofit foundation sources. Patients, physicians, health-care payers, policymakers, and product manufacturers have a vested interest in the issue addressed in our commentary. We drafted the manuscript without support from or consultation with these parties.

AD disease-modifying agents currently in clinical trials, more than a third are biologics.³ If priced like other biologics or immunotherapies (often upwards of \$50,000 per patient per year), annual population costs could run to tens of billions of dollars in the U.S.

Second, diagnostic challenges make savings difficult. Likely, only early diagnosis and treatment will prevent permanent neurological damage. Moreover, as our research shows, care expenditures may increase in the years preceding contemporary AD diagnosis, making earlier diagnosis necessary for any hope of bending the cost curve.⁴ Earlier diagnosis, however, requires assessment of subtler symptoms, and the utility of AD biomarkers (e.g., beta amyloid) on a population scale for disease detection is limited at present. The US Preventive Services Task Force has deemed the current evidence insufficient to support screening for cognitive impairment among community-dwelling older adults.⁵ Neuroimaging diagnostics (e.g., positron emission tomography and magnetic resonance imaging) are imperfect and costly. Further, algorithms to “narrow the funnel” and target patients at highest risk for disease have yet to be established. Hence, many individuals may have to be evaluated, producing substantially more false positive diagnoses. These possibilities point to higher costs.

Third, a new Alzheimer’s drug will not eliminate expensive long-term care and comorbidity management. Multimorbidity is prevalent among older adults and known to increase health care expenditures.⁶ Even if new drugs slow AD progression, many patients will still eventually experience disabling cognitive deficits that compromise their ability to manage multiple chronic conditions that can increase hospitalization risks and limit cost offsets. Further, even if new drugs help delay institutionalization, individual payers will struggle to realize savings. Medicare will not achieve substantial savings because nursing home expenses are paid mostly out-of-pocket by beneficiaries, the Medicaid program, or supplemental insurance policies. Private payers, which typically cover working age populations, will likely see cost increases as novel agents and companion diagnostics target younger patients with early-stage disease. Private payers will gain few cost offsets, as most patients will have exited these plans by the time they require institutional care.

Despite these challenges, the healthcare system can accommodate new AD drugs with forethought and preparation, drawing upon experience with costly innovations for other diseases. For example, hepatitis C treatments costing around \$100,000 per patient when introduced five years ago posed a special challenge because the potentially eligible population in the U.S. numbered around 3 million. To be sure, AD therapies could pose an even greater challenge because the population is larger, diagnostic costs are likely higher, and treatment may well be ongoing, rather than limited in duration (as it is for hepatitis C treatments). Nonetheless, past experiences point to actions that can help ensure access to new medications and the sustainability of the healthcare system.

First, we urge the use of formal cost-effectiveness analysis of new Alzheimer’s treatments as a starting point for consideration of value-based prices. Assessments conducted by the Institute for Clinical and Economic Review (ICER) can serve as a useful model, although as noted in ICER’s newly released guidance⁷ and recommended by the Second Panel on Cost-Effectiveness in Health and Medicine,⁸ assessments should include “societal” impacts –

such as family caregiver outcomes in particular for AD. Measuring costs and health impacts related to caregiving can be challenging but, as our research shows, omitting such impacts risks underestimating the broader value of AD interventions to society.⁹ Likewise, drug pricing should reflect not simply short-term efficacy endpoints recorded in clinical trials (which typically have relatively limited follow-up) but also those outcomes projected beyond the trial period.

Second, payments for new AD therapies should ideally incorporate a performance warranty. For example, some companies are experimenting with value-based contracts for multiple sclerosis (MS) drugs, with payments tied to achieving certain patient-reported outcomes. Given concerns about treatment effectiveness for conditions like MS and AD, such arrangements can help apportion risk associated with initial therapy value estimates between drug manufacturers and payers. If the therapy performs as anticipated, the manufacturer receives full payment. If not, payments decrease. The details will be critical and challenging, as pertinent outcomes can be difficult to measure, especially over a long time period, and effectiveness can depend on factors independent of the therapy, such as treatment adherence and comorbidities. However, with large enough patient populations, payer efforts to refine these arrangements should better optimize payment compared to having no risk sharing at all. The Center for Medicare & Medicaid Innovation, among other stakeholders, should explore novel payment models for AD care.

Third, because the eligible population is likely to be large, AD therapies, even if cost-effective, may be paradoxically unaffordable.¹⁰ That is, a highly effective therapy may deliver good value but have such a large impact on the budget that it forces cuts to other crucial services. Economists address the paradox by noting that when faced with new, cost-effective products, payers with constrained budgets should reduce spending on less cost-effective services so that higher-value ones can be accommodated. However, payers have short-term budget constraints that can prevent them from easily disinvesting from low-value services even if they can identify them.

To address this possibility, we urge consideration of “subscription” agreements, sometimes termed “Netflix models.” For example, agreements now used by Washington state and Louisiana for drugs treating hepatitis C establish a fixed payment to the manufacturers, regardless of the number of patients treated. The arrangement ensures a predictable revenue stream for the drug maker while preventing drug costs from growing uncontrollably. To be sure, the resultant costs for payers will depend on the subscription drug prices. In the case of AD, identifying people who have the condition and are likely to benefit from the therapy will be a crucial first step.

Importantly, government should avoid measures that push therapy prices below levels warranted by clinical benefits. Imposing price controls or reference prices from other countries could reduce threats to financial sustainability and patient access to treatment. Doing so, however, would signal that investments addressing the most substantial health problems affecting the most people – and many will remain even if we conquer AD – will not be substantially rewarded. That signal risks diverting attention away from needed

investments. But manufacturers must likewise be held accountable. They must demonstrate that their products deliver value, and their projections must be validated empirically.

The health system must also address issues other than cost. In particular, clinical capacity must be enhanced.¹¹ Programs to train clinicians to diagnose and treat AD could piggyback on existing policy efforts, such as the Healthy Brain Initiative (a partnership between the Centers for Disease Control and Prevention and the Alzheimer's Association) in developing a "dementia capable" system.¹²

Since Dr. Alois Alzheimer reported "a peculiar severe disease process of the cerebral cortex" in 1906, the world has been waiting for a breakthrough therapy. Novel AD therapies are much welcomed and needed, and the idea that they will save money may seem compelling. However, we cannot assume cost savings or substantial cost offsets. Imperatively, we must prepare the healthcare system in anticipation of the value, access and affordability challenges for future AD treatments.

Funding source:

National Institutes of Health (R01AG060165)

REFERENCES

1. Zissimopoulos J, Crimmins E, St Clair P. The Value of Delaying Alzheimer's Disease Onset. *Forum for health economics & policy* 2014;18:25–39.
2. Alzheimer's Association Changing the Trajectory of Alzheimer's Disease: How a Treatment by 2025 Saves Lives and Dollars. 2015.
3. Cummings J, Lee G, Ritter A, Sabbagh M, Zhong K. Alzheimer's disease drug development pipeline: 2019. *Alzheimer's & dementia (New York, N Y)* 2019;5:272–93.
4. Lin PJ, Zhong Y, Fillit HM, Chen E, Neumann PJ. Medicare Expenditures of Individuals with Alzheimer's Disease and Related Dementias or Mild Cognitive Impairment Before and After Diagnosis. *Journal of the American Geriatrics Society* 2016;64:1549–57. [PubMed: 27295430]
5. Patnode CD, Perdue LA, Rossom RC, et al. Screening for Cognitive Impairment in Older Adults: Updated Evidence Report and Systematic Review for the US Preventive Services Task Force. *Jama* 2020;323:764–85. [PubMed: 32096857]
6. Agency for Healthcare Research and Quality. Screening for Cognitive Impairment in Older Adults: An Evidence Update for the U.S. Preventive Services Task Force. AHRQ Publication No. 19–05257-EF-1. 2019.
7. Institute for Clinical and Economic Review. 2020–2023 Value Assessment Framework. 2020.
8. Sanders GD, Neumann PJ, Basu A, et al. Recommendations for Conduct, Methodological Practices, and Reporting of Cost-effectiveness Analyses: Second Panel on Cost-Effectiveness in Health and Medicine. *JAMA* 2016;316:1093–103. [PubMed: 27623463]
9. Lin PJ, D'Cruz B, Leech AA, et al. Family and Caregiver Spillover Effects in Cost-Utility Analyses of Alzheimer's Disease Interventions. *Pharmacoeconomics* 2019;37:597–608. [PubMed: 30903567]
10. Lomas J, Claxton K, Martin S, Soares M. Resolving the "Cost-Effective but Unaffordable" Paradox: Estimating the Health Opportunity Costs of Nonmarginal Budget Impacts. *Value in health : the journal of the International Society for Pharmacoeconomics and Outcomes Research* 2018;21:266–75. [PubMed: 29566832]
11. Liu JL, Hlávka JP, Hillestad R, Mattke S. Assessing the Preparedness of the U.S. Health Care System Infrastructure for an Alzheimer's Treatment. RAND Corporation, RR-2272-BIOG, 2017 (available at www.rand.org/t/RR2272).

12. Alzheimer's Association and Centers for Disease Control and Prevention. Healthy Brain Initiative, State and Local Public Health Partnerships to Address Dementia: The 2018–2023 Road Map. Chicago, IL: Alzheimer's Association; 2018.

Author Manuscript

Author Manuscript

Author Manuscript

Author Manuscript