

Challenges Surrounding The New Alzheimer's Treatments

By: Rapid Access International, Inc.

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Drugmaker Eli Lilly recently announced that its experimental drug, donanemab, slowed declines in Alzheimer's patients' ability to perform daily tasks. This is on the heels of Biogen and Eisai's new drug, Leqembi, which is on an accelerated approval track with the Food and Drug Administration for its ability to reduce a protein linked to Alzheimer's.

These are impressive breakthroughs in the treatment of Alzheimer's; a disease that affects an estimated 6.7 million Americans.¹ Given the high levels of investment and risk taken by the drug companies, these treatments come at a very high cost for patients and insurers. Costs and politics, as well as wide variances in the resources and investments in the healthcare system, all add up to significant challenges for many suffering with the disease.

Efficacy, Approval & Restrictions

All of these treatments, in fact, target the amyloid protein. Research and clinical trials in recent years have indicated that reducing amyloid buildup offers a clear benefit to patients. It's hopeful progress, but in a late-stage trial with more than 1,700 patients, donanemab slowed cognitive decline on average by 36% over 18 months, and nearly half these patients showed no decline after a year.²

Lilly's treatment is the more impressive of the anti-amyloid treatments, with treatments by Biogen and Eisai showing roughly 25% slower decline.³ The latter of these have not been considered by many critics as clinically significant. And, the Centers for Medicare and Medicaid Services (CMS) have sided with this conclusion by indicating that the treatments are not "reasonable and necessary".⁴

It is possible that CMS will revise its stance on the matter, given the stronger results from Lilly's offering; however, it currently restricts access to all anti-amyloid antibody treatments approved by the FDA. This puts patients and their families who are encouraged by the results in a position where they need to pay significant sums out of pocket if they do not qualify for certain government-approved subsidies. This leaves many shaking their heads, as no other FDA-approved drug has these kinds of coverage restrictions.

Access to Treatment

Major clinics and academic centers in large cities that serve patients with either the ability to pay out of pocket or through private insurance are now recruiting neurologists and buying screening equipment ahead of full FDA approval of these treatments.⁵ But, for many rural health systems, it's a waiting game

¹ "2023 Alzheimer's Disease Facts and Figures". Alzheimer's Association. 2023. Available at: <https://www.alz.org/media/documents/alzheimers-facts-and-figures.pdf>. Accessed on May 12, 2023.

² The Editorial Board. "Denying Alzheimer's Treatment". The Wall Street Journal. May 5, 2023. Available at: https://www.wsj.com/articles/eli-lilly-donanemab-alzheimers-treatment-drug-biden-administration-cms-e750a691?mod=Searchresults_pos2&page=1. Accessed on May 12, 2023.

³ *Ibid.*

⁴ *Ibid.*

⁵ Mosbergen, Dominique and Joseph Walker. "Access to New Alzheimer's Drugs Might Depend on Where You Live". The Wall Street Journal. May 7, 2023. Available at: <https://www.wsj.com/articles/access-to-new->

to see if CMS changes its stance or has to acknowledge the significance of better efficacy with the donanemab treatments.

In short, demand will be strong, but the resources will not be there to provide these treatments across the healthcare system. Further clarity from CMS could help to spur investment, both private and public. However, the equipment (including spinal tap or PET scanners, as well as MRI machines) and specialized personnel needed from the evaluation of patients, through treatment, constitute incredible challenges.

“We will be inundated by patients who are interested in this and we will not have the capacity,” said Suzanne Schindler, a clinical neurologist at Washington University in St. Louis.⁶

Clearly, with such a large group of Americans suffering from this disease, the lack of clarity in this situation is not helpful. Efficacy is a legitimate question, but this is hardly unique to these treatments. Treatments are likely to get more effective in the future, and costs could certainly come down at scale. But, if we are not decisively committing to the best available treatments at any given time, we may not be ready to deal with the demands of even more effective treatments when available.

Equipment is one issue. Specialized personnel may be the bigger issue. A report last year from the American Academy of Neurology (AAN), entitled ‘A Shortage of Neurologists—We Must Act Now’, details the range of factors that have left the US with a shortage of neurologists and constituting a “grave threat”.⁷ Further, the shortage is especially pronounced in rural America. As a case in point, one study indicates that West Virginia has just half of the neurologists that it really needs.⁸ The state is not alone. A 2017 study from the Alzheimer’s Association lists West Virginia among no less than 20 states it refers to as Neurology “Deserts”.⁹

The Future

The population is aging in the United States and other developed nations. Alzheimer’s and other forms of dementia are a reality with which we have needed to deal for some time on an increased scale. As the medical solutions become more advanced, so too must the specialized care and resources. The recent spate of Alzheimer’s drugs constitute a wake up call for a medical system that is proving itself unready for progress against the disease. That situation is unsustainable. Sooner or later, look for a massive increase in demand and investment related to personnel, equipment and possibly technologies that allow for resources to be connected with rural areas to better meet all patient needs.

[alzheimers-drugs-might-depend-on-where-you-live-4829caed?mod=Searchresults_pos1&page=1](https://www.alzheimers.org/about-us/newsroom/2023/05/12/alzheimers-drugs-might-depend-on-where-you-live-4829caed?mod=Searchresults_pos1&page=1). Accessed on May 12, 2023.

⁶ *Ibid.*

⁷ Bender, Kenneth. "The 'Grave Threat' Posed by the Shortage of Neurologists". NeurologyLive. February 17, 2022. Available at: <https://www.neurologylive.com/view/the-grave-threat-posed-by-the-shortage-of-neurologists>. Accessed on May 12, 2023.

⁸ Gupta, Rishika. “State of West Virginia Is short on Neurologists: Study”. MedIndia. March 28, 2019. Available at: <https://www.medindia.net/news/state-of-west-virginia-is-short-on-neurologists-study-186915-1.htm>. Accessed on May 12, 2023.

⁹ Press Release. “Regional Shortage of Neurologists Revealed Across the U.S.”. Alzheimer’s Association. July 16, 2017. Available at: https://aaic.alz.org/releases_2017/AAIC17-Sun-neurology-deserts.asp. Accessed on May 12, 2023.