United States Senate

WASHINGTON, DC 20510

May 16, 2023

The Honorable Xavier Becerra
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, SW
Washington, DC 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Secretary Becerra and Administrator Brooks-LaSure,

I write today to ask the Centers for Medicare & Medicaid Services (CMS) to provide prompt, clear, and publicly available information about how Medicare providers and patients can participate in a registry or submit data under the agency's coverage with evidence development (CED) policy that allows Medicare to cover new Alzheimer's medicines. In January, CMS announced it would provide broader coverage under CED for products that receive full approval from the Food and Drug Administration (FDA). I support the CED policy to gather more information about how these drugs work in the Medicare population, yet feel strongly the agency must use every tool at its disposal to support creation of the approved methods providers and their patients can use in providing this information should one of these medications gain full FDA approval.

As you know, Alzheimer's is a devastating disease that imposes a heavy burden on millions of Americans. More than six million people in the United States currently suffer from Alzheimer's disease, the vast majority of whom are seniors.[1] An estimated 14 million Americans may have Alzheimer's disease by 2060, with minority populations being particularly affected.[2] Developing safe and effective therapies capable of slowing or stopping disease progression has been a long-standing endeavor.

Emerging monoclonal antibody (mAb) therapies may hold promise to modify the trajectory of Alzheimer's disease. These therapies can stimulate the immune system to break down beta-amyloid plaques, which some scientists believe might cause the development and progression of Alzheimer's disease. Aduhelm (aducanumab) was the first Alzheimer's disease mAb to come to

[1] Alzheimer's Association. (2023). "Alzheimer's Disease Facts and Figures." https://www.alz.org/media/Documents/alzheimers-facts-and-figures.pdf

[2] Matthews, K. et al. (September 2018). "Racial and Ethnic Estimates of Alzheimer's Disease and Related Dementias in the United States (2015-2060)." *Alzheimer's & Dementia*. https://alz-journals.onlinelibrary.wiley.com/doi/10.1016/j.jalz.2018.06.3063

market in June 2021. The U.S. Food and Drug Administration (FDA) granted accelerated approval for Aduhelm with great controversy despite overwhelming objection from experts on FDA's own Advisory Committee, who believed the data did not demonstrate sufficient evidence of efficacy to warrant approval.

While the evidence supporting Aduhelm's efficacy remains scant, more studies[3] have since been produced about other Alzheimer's disease mAbs, some of which may have enough evidence to gain full FDA approval as early as this summer. Despite the additional evidence associated with these products, important questions about the overall risk-benefit profile for Alzheimer's disease mAbs persist in the scientific community.[4] Those questions appear to have informed CMS's coverage decision for Alzheimer's drugs and other government coverage decisions. For example, as of March 2023, the Department of Veterans' Affairs (VA) began providing limited coverage of Leqembi (lecanemab). The VA views its coverage policy for Alzheimer's mAbs is generally aligned with the NCD.[5] CMS decided to cover Alzheimer's disease mAbs, including Leqembi, under Medicare when the provider enrolls their patient in a clinical trial. Under this decision, any Alzheimer's disease mAb fully approved by the FDA would be covered by Medicare more broadly with less complex data collection, such as through a patient registry. Registries exist in different formats, with the goal of collecting real-world patient outcomes in a standardized manner.

I support collecting data on Alzheimer's disease mAbs in an efficient manner that does not unduly burden patients or providers as a condition of coverage, as it will provide valuable information about patient safety and clinical benefits. While no mAbs have received full FDA approval thus far, it important that Medicare patients and their providers have the information they need should FDA grant full approval. Medicare providers and patients need timely, critical information from CMS about how registry or other CED studies can be put in place for Alzheimer's disease mAbs and how providers will be able to enroll their patients in all areas of the country without excessive burden. Physicians who administer these medications need a simple, direct way to submit data and provide treatment to qualifying patients. Patient families and a wide array of stakeholders who help Alzheimer's patients also need assurance that information about registries or other CED studies is forthcoming for providers, along with appropriate outreach and education efforts.

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[3] Van Dyck, C. et al. (2023). "Lecanemab in Early Alzheimer's Disease." *New England Journal of Medicine*. https://doi.org/10.1056/nejmoa2212948

[4] Prillaman, M. (December 2022). "Heralded Alzheimer's Drug Works, but Safety Concerns Loom." *Scientific American*. https://www.scientificamerican.com/article/heralded-alzheimers-drug-works-but-safety-concerns-loom/

[5] Martin, J. (May 2023). "Prescribing Policy for Monoclonal Antibodies for Alzheimer's Disease and Plans for Future Implementation: Challenges and Opportunities. VA. https://aspe.hhs.gov/sites/default/files/documents/90bf723e662201ba33c6a9313e146548/napa-may-2023-martin.pdf

With this context in mind, please answer the following questions:

1. Has CMS openly solicited submissions from providers, manufacturers, scientists, and patients on registry and other study models and protocols that could be considered for the CED requirements?

2. When will CMS release more details about registry-based or other studies that will meet the CED requirements for Alzheimer's disease mAbs that are fully approved by FDA?

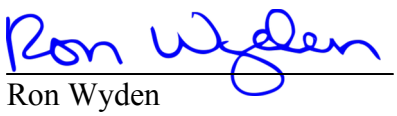
3. What are the considerations and the process for CMS approval of a registry-based study? Does CMS anticipate that patients with Medicare who meet the criteria in FDA's label upon full approval will be eligible to participate in these studies? What factors and variables might influence patient eligibility?

4. Does CMS anticipate that a registry or other platform to support CED studies will be available to patients by the time the first Alzheimer's disease mAb is expected to gain full FDA approval? What factors might contribute to a delay in launching a timely study? How is CMS working to solicit the information the agency needs to promptly stand up these studies?

5. What steps will CMS take to ensure any CED studies or registries are not unnecessarily burdensome for providers to access and use, particularly in rural and underserved areas where resources and the ability to administer to Alzheimer's disease mAbs might already be limited?

Thank you for your prompt attention to this important information and your willingness to facilitate CED that can be used for data collection as appropriate so that Medicare patients seeking access to Alzheimer's disease medications with full FDA approval can do so in a timely manner. We encourage CMS to work closely with providers, manufacturers, patient advocates, and scientists as this process moves forward. If you have any questions, please contact Polly Webster at Polly_Webster@finance.senate.gov.

Sincerely,



Ron Wyden
United States Senator
Chairman, Committee on
Finance