United States Senate
WASHINGTON, DC 20510

June 23, 2021

The Honorable Ron Wyden
Chair
Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Mike Crapo
Ranking Member
Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

Dear Chair Wyden and Ranking Member Crapo:

As you are aware, the Food and Drug Administration (FDA) recently approved Biogen's Aduhelm, making it the first new drug approved to treat Alzheimer's disease in nearly two decades.[1] This is a historic, watershed moment in the fight against Alzheimer's disease, but approval of the new product has dramatic implications for our health care system that stretch well beyond the scope of FDA's jurisdiction. We thus urge you to convene a hearing to examine the vexing new questions and challenges that approval raises for the Medicare program and other health programs within the Senate Finance Committee's jurisdiction.

News of a new Alzheimer's treatment is long-awaited good news for the more than six million Americans who suffer from Alzheimer's disease, and for their families. For them, even short periods of time with improved cognition – perhaps long enough to celebrate one more birthday or experience a child's wedding or grandchild's birth – is something to be treasured. Better treatment and management of Alzheimer's disease could also yield benefits for our health system as Alzheimer's is one of our most costly diseases, with projections that it will cost the nation $355 billion in 2021 – including $239 billion in Medicare and Medicaid payments.[2] At the same time, Aduhelm will bear a list price of $56,000 per year, and has a potential patient population exceeding six million Americans.[3,4] Under the broad label that FDA approved, the drug is available to all Alzheimer's patients, and the agency did not place limits on treatment duration suggesting that patients could remain on the drug indefinitely.[5] We are troubled by reports that those factors could lead the drug to command "somewhere between" the $37 billion we currently spend on Medicare Part B and the $90 billion we currently spend on Medicare Part D.[6] This level of potential new spending, particularly for just one product with limited evidence of clinical efficacy thus far, tests the program's resiliency.

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[1] https://www.fda.gov/news-events/press-announcements/fda-grants-accelerated-approval-alzheimers-drug
[2] https://www.alz.org/alzheimers-dementia/facts-figures
[3] https://investors.biogen.com/news-releases/news-release-details/biogen-and-eisai-launch-multiple-initiatives-help-patients
[4] https://www.alz.org/alzheimers-dementia/facts-figures
[5] https://www.fiercepharma.com/pharma/alzheimer-s-fda-nod-bag-biogen-faces-historic-drug-launch-and-10b-potential-sales-analysts
[6] https://www.healthaffairs.org/do/10.1377/hblog20210609.921363/full/

Notably, FDA approval does not guarantee Medicare coverage, and so the program will need to answer an enormous question: should it cover a new and expensive Alzheimer's medication, and if so, how? Medicare coverage is limited to items and services that are considered "reasonable and necessary" for the diagnosis or treatment of an illness or injury, fit within the scope of a benefit category, and are not otherwise specifically excluded from coverage.[7] The Centers for Medicare and Medicaid Services (CMS) has a number of tools to define the scope of coverage within those bounds in a manner that might – or might not – refine its broad label to limit the types of patients or scenarios in which it may be used. The agency may grapple with questions about whether and how to identify the patients most likely to benefit from the drug and respond to differing opinions in the scientific community regarding its efficacy. CMS may also need to make decisions about coverage for potential ancillary services like amyloid PET scans. CMS might address these issues under its current authorities through the issuance of a national coverage determination, which could authorize coverage without restriction, limit coverage, or delay full coverage pending collection of more evidence. It might also be prudent for Congress to make policy changes to enable Medicare to move towards value-based payment arrangements, which directly connect prescription drug pricing to clinical effectiveness.

Medicare's actions in response to the difficult policy questions it faces will have enduring consequences not just for this product or the millions of potentially eligible patients for whom ensuring access is paramount, but for how our health system responds to other, future novel therapies. As senators, it is our responsibility to carefully investigate the issues facing Medicare in order to ensure that the program works well for our nation's seniors. We are grateful for your long-standing leadership in that regard, and we respectfully request that you hold a hearing as soon as possible to examine these welcome new challenges facing the program. Thank you for your consideration to this important topic.

Sincerely,

Bill Cassidy, M.D. Elizabeth Warren

Bill Cassidy, M.D.
U.S. Senator

Elizabeth Warren
U.S. Senator

[7] https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads//FR09262003.pdf