United States Senate

WASHINGTON, DC 20510

May 17, 2024

Dr. Lester Martinez-Lopez
Assistant Secretary of Defense
for Health Affairs
1200 Defense, Pentagon
Washington, DC 20301

Lieutenant General Telita Crosland
Director
Defense Health Agency
7700 Arlington Boulevard, Suite 5101
Falls Church, VA 22042-5101

Dear Assistant Secretary Martinez-Lopez and Lieutenant General Crosland:

We write today regarding TRICARE's coverage of monoclonal antibodies for the treatment of mild cognitive impairment and early Alzheimer's disease. For the first time in history, treatments shown to reduce the rate of disease progression and to slow cognitive and functional decline are approved for use. Yet, despite U.S. Food and Drug Administration (FDA) approval and unequivocal evidence confirmed by the scientific community, TRICARE continues to deny access to new therapies. This dated, class-wide decision affects not only TRICARE beneficiaries but also individuals who use their TRICARE coverage as a wrap-around supplemental insurance.

An estimated 6.9 million Americans are living with Alzheimer's. In addition to the human toll, the costs of health care and long-term care for individuals living with Alzheimer's or other dementias are substantial. The total lifetime cost of care for a person living with dementia is estimated at almost $400,000.[1] Given the progressive nature of Alzheimer's and the fact that approved treatment options are most effective when administered early in the disease course, we encourage you to take steps to ensure that patients have immediate access to FDA-approved treatments for the treatment of Alzheimer's disease. Continued coverage denials will result in irreversible disease progression and added burdens for caregivers, loved ones, and our health care system.

While we understand that approval of a treatment by the FDA does not guarantee coverage under TRICARE, we believe that TRICARE's current coverage policy, which specifically excludes Leqembi and similar treatments, is outdated and unwarranted. TRICARE's current policy, enacted in 2022, states that, "Monoclonal antibodies (such as aducanumab) for the prevention, treatment, or mitigation of symptoms related to Mild Cognitive Impairment (MCI) or Alzheimer's disease (AD) is unproven."[2] When this policy was put in place, Leqembi, the brand name for lecanemab, was still in clinical development. Therefore, it was accurate at the time of drafting to classify it as "unproven." However, on January 6, 2023, Leqembi was granted accelerated approval by the FDA and was subsequently granted traditional approval on July 6, 2023.[3] Leqembi's FDA approval was based in part on the safety and clinical efficacy

demonstrated in its Phase III CLARITY-AD trial, the results of which have been published in *New England Journal of Medicine*.[4] The results showed that lecanemab produced a clear clinical benefit in people who were in the early stages of Alzheimer's. In comparison with a placebo, the drug slowed the rate of cognitive decline over 18 months and reduced the levels of brain amyloid. This treatment can no longer be classified as "unproven," and there are other promising treatments in the pipeline.

Following FDA traditional approval on July 6, 2023, the Centers for Medicare & Medicaid Services announced broader coverage of the drug.[5] In contrast, TRICARE's current policy continues to deny coverage for this entire class of drugs, based on a decision that was made for a drug that is now leaving the market given a variety of factors, including substantial advancements in the field.

Given the growing prevalence of early-stage Alzheimer's disease in the population served by TRICARE, there is an urgent need to remove barriers to access to these treatments and get them to those who might benefit most. The Defense Health Agency has the authority to update its coverage policy, as it did when making the original decision. We urge you to immediately update TRICARE's coverage policy for monoclonal antibodies for the treatment of mild cognitive impairment and early Alzheimer's disease.

Sincerely,

Susan M. Collins
United States Senator

Jon Tester
United States Senator

Shelley Moore Capito
United States Senator

Mark R. Warner
United States Senator

[1] 2024 Alzheimer's disease facts and figures. (2024). Alzheimer's & Dementia. https://doi.org/10.1002/alz.13809

[2] United States Military Health System, *TRICARE Policy Manual*, Chapter 7, Sec. 15.1, January 20, 2022 https://manuals.health.mil/pages/DisplayManualHtmlFile/2022-05-24/AsOf/TP15/C7S15_1.html

[3] Food and Drug Administration, "FDA Converts Novel Alzheimer's Disease Treatment to Traditional Approval", July 5, 2023 https://www.fda.gov/news-events/press-announcements/fda-converts-novel-alzheimers-disease-treatment-traditional-approval

[4] Thangwaritorn, Lee, Metchikoff, et al. *A Review of Recent Advances in the Management of Alzheimer's Disease*. April 16, 2024. Cureus 16(4): e58416. doi:10.7759/cureus.58416

[5] Centers for Medicare and Medicaid Services, "Broader Medicare Coverage of Leqembi Available Following FDA Traditional Approval", July 6, 2023. https://www.cms.gov/newsroom/press-releases/statement-broader-medicare-coverage-leqembi-available-following-fda-traditional-approval