August 2, 2023

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Ave, SW
Washington, D.C. 20201

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

Dear Secretary Becerra and Administrator Brooks-LaSure:

As members of the Patient, Consumer, and Public Health Coalition, we write to share our expertise and concerns and urge you to consider our recommendations regarding the plans of the Centers for Medicare and Medicaid Services (CMS) regarding coverage of Leqembi (lecanemab) and other similar treatments for Alzheimer's disease through one or more registries. Our coalition consists of a diverse group of two dozen non-profit organizations representing health care providers, researchers, patient and consumer advocates, and public health experts.

We appreciate and support the CMS use of registries to gather additional information about the safety and efficacy of Leqembi. Evidence gathered in patient registries will provide important information about questions that were raised by the data provided to the FDA. As the registries are created and implemented, it will be critical for CMS to balance the goal of gathering evidence needed to determine if the drugs are reasonable and necessary for the Medicare

population with the potential burden on clinicians and patients. Additionally, it is essential that all data collected by any of the registries are made publicly available for research purposes, and all results are available to the public. **We strongly urge you to make this a requirement as a condition of coverage.**

We have outlined a number of recommendations for CMS as private registries seek coverage for their patients.

1. We strongly support CMS' plan for the de-identified data from its Alzheimer's monoclonal antibody drug registry to be available for CMS to analyze, as well as FDA and independent outside researchers. Additional registries developed by medical societies, medical centers, or other NGOs should not have the option of limiting access to their registry data. Medicare coverage for this class of drugs requires participation in a registry so that CMS will have scientific data on their impact on the Medicare population. Therefore, Medicare coverage should not be provided for patients in registries that restrict research access to de-identified population-level patient data. CMS should require that the data from any and all registries be made available to CMS for analysis and to the public.

2. The CMS registry and any other Alzheimer's treatment registries should include information regarding patients who are at the greatest risk for adverse events from the drugs. This includes patients homozygous for APOE ε4 or who are taking anti-platelet or anti-coagulation blood thinners. Concerns about these risks are reflected in the Leqembi label, so these data need to be collected and analyzed for scientific and ethical reasons. Additionally, CMS should require consistency in standardized, data to be collected by the different registries at baseline and again at specified intervals. The instruments should be consistent across different registries, whether they are used to measure ARIA, cognitive impairment, or any other important outcomes. Otherwise, CMS will not be able to conclusively determine the risks and benefits of Leqembi for different types of patients.

We are also concerned the Leqembi label encourages physicians to enroll their patients in the Alzheimer's Network for Treatment and Diagnostics (ALZ-NET) registry, but does not encourage them to enroll patients in the CMS registry.[1] This is especially problematic if CMS does not require all Leqembi-related registries to share de-identified, population-level data with CMS, FDA, and independent researchers, and does not ensure consistency in information among all the registries. ALZ-NET has stated that they will pay providers to enroll and treat patients in their registry, which is likely to reduce the use of the CMS registry.[2] Our above recommendations regarding data sharing and consistency in information collected apply to all private registries, including the ALZ-NET registry. It defeats the purpose and goals of the Coverage with Evidence Development for Leqembi if the largest registry is inaccessible to CMS.

In conclusion, we are urging CMS to ensure that CMS, FDA, and other independent researchers have access to the information from all Leqembi registries, and that the data gathered across registries be consistent so that CMS can draw conclusions about the safety and efficacy of Leqembi for Medicare patients.

Sincerely,

American Medical Student Association UW-Madison

Breast Cancer Action

Breast Implant Safety Alliance

Doctors for America

Government Information Watch

Jacobs Institute for Women's Health

Medical Device Problems

MedShadow

Mothers Against Medical Error

MRSA Survivors Network

National Center for Health Research

National Women's Health Network

Not Putting On A Shirt

Our Bodies Ourselves

Patient Safety Action Network

SCAD Alliance

The TMJ Association

USA Patient Network

Washington Advocates for Patient Safety

Woodymatters

Cc:

The Honorable Ron Wyden, Chair
Senate Finance Committee

The Honorable Mike Crapo, Ranking Member
Senate Finance Committee

The Honorable Jason Smith, Chair
Ways and Means Committee

The Honorable Richard Neal, Ranking Member
Ways and Means Committee

[1] Food and Drug Administration (2023). Highlights of Prescribing Information. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761269s001lbl.pdf

[2] American College of Radiology & Alzheimer's Association (2022). ALZ-NET Protocol Synopsis. https://www.alz.org/media/Documents/ALZ-NET-Protocol-Synopsis_Alzheimers-Association_American-College-of-Radiology.pdf