December 13, 2022

President Joseph R. Biden
1600 Pennsylvania Avenue, NW
Washington, DC 20500

Dear President Biden,

The undersigned organizations ask you to direct the Secretary of the U.S. Department of Health and Human Services to reopen the Aβ PET national coverage determination (NCD) for full reconsideration to ensure that the decision is inclusive of the relevant new data on disease-modifying therapies for Alzheimer's disease (AD). At present, the Centers for Medicare and Medicaid Services (CMS) has limited this reconsideration to only "determine if the current policy of one scan per patient per lifetime should be revised." However, the scan limit is one of many decade-long coverage restrictions in the NCD under "coverage with evidence development" (CED) that have severely limited access for Medicare beneficiaries in need of Aβ PET for AD diagnosis, treatment assessment, and monitoring. Without acting with greater intention and incorporating new information, CMS risks making a limited and inequitable Medicare coverage decision on Aβ PET scans in its draft decision memo, which is scheduled to be released on December 16.

We know you join in our excitement about the promising data shared at the recent Clinical Trials on Alzheimer's Disease (CTAD) meeting on lecanemab, a monoclonal antibody (mAB) therapy for the treatment of mild cognitive impairment/early AD. For the six million individuals currently living with AD in the U.S., and for the millions at risk that will be diagnosed with the disease in the future, the development of effective therapies to prevent, delay, and better manage AD and related dementias is one of the most pressing and complex public health challenges facing our nation.

The ability to test the accumulation and distribution of amyloid and tau tangles in the brain through PET imaging will aid diagnosis and ultimately help physicians make more informed decisions about patient care, including whether to treat with mAB therapies such as lecanemab. PET imaging has significantly helped in the diagnosis and monitoring the progression of AD as well as in identifying which patients are likely to benefit from a potential treatment. Just as importantly, a negative PET result rules the disease out. The IDEAS data analysis, published in *JAMA* in April 2019, found approximately 36% of patients clinically diagnosed with AD were negative for amyloid plaque confirmed by an amyloid PET scan. The study also found that use of Aβ PET scan resulted in changes in clinical management for more than 60% of patients who participated—most notably in the starting, stopping, or modification of AD drug therapy, but also in the use of other drug therapies and/or counseling about safety and future planning.

Despite these steps forward in innovation, people of color are far less likely to have Alzheimer's disease diagnosed and less likely to be referred to dementia specialists. CMS' current NCD on Aβ PET ignores the known disparities for older Black and Hispanic communities by creating an

unharmonized set of diversity requirements and constraints that make access overly challenging to the very same populations who have the highest need. Timely and equitable access to amyloid-beta (Aβ) PET scans will be critical for all Medicare beneficiaries to realize the benefit of therapies like lecanemab. In July, [20 organizations asked CMS to end its coverage limit of one-scan per lifetime and stop forcing Medicare beneficiaries who need the scans into limited clinical trials under "coverage with evidence development" (CED)](). Under existing policy, Medicare beneficiaries who need more than one scan have three flawed options: (1) pay for the scan out-of-pocket, (2) forgo the test, or (3) be forced into limited clinical trials under CED.

Medicare beneficiaries with Alzheimer's deserve better and should not be faced with such terrible choices for one day, let alone the 10 years this NCD CED policy has been in place. Ten years of supplementary data should be more than adequate to have the evidence necessary to inform policymaking. We strongly feel that to ensure equitable access to Aβ PET scans, CMS should end the coverage limit entirely and provide national coverage so all Medicare beneficiaries with Alzheimer's can access the tests they need and deserve.

We greatly appreciate your November 2022 Proclamation on National Alzheimer's Disease Awareness Month, which states, "Alzheimer's is common and especially cruel, robbing people of their memories, thoughts, and identity over many years. Across the Nation, this epidemic is growing: In the next 30 years, the number of Americans with Alzheimer's is expected to reach nearly 14 million, straining families and our health care system. Fortunately, we are on the cusp of life-saving advances that can forever change the course of the disease."[1] We couldn't agree more.

Please—let's stand together with Alzheimer's patients and their families, not in their way.

Sincerely,

ADvancing States
Alliance for Aging Research
Alliance for Patient Access
Alzheimer's Disease Resource Center, Inc.
Alzheimer's Los Angeles
Alzheimer's New Jersey
Alzheimer's San Diego
Alzheimer's Drug Discovery Foundation
Alzheimer's Orange County
American Society of Consultant Pharmacists
Argentum
Black, Gifted & Whole Inc.
Brain Health Center for African Americans

BrightFocus Foundation
Caregiver Action Network
CaringKind
Chronic Care Policy Alliance
Cleveland Clinic Lou Ruvo Center for Brain
  Health, Nevada
Family Caregiver Alliance
From The Bottom Up Foundation
Gerontological Advanced Practice Nurses
  Association (GAPNA)
Global Alzheimer's Platform Foundation, Inc.
Global CEO Initiative on Alzheimer's Disease

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[1] https://www.whitehouse.gov/briefing-room/presidential-actions/2022/10/31/a-proclamation-on-national-alzheimers-disease-awareness-month-2022/.

Global Coalition on Aging Alliance for Health Innovation

HealthyWomen

Incubate

Infusion Providers Alliance

International Association for Indigenous Aging

LEAD Coalition (Leaders Engaged on Alzheimer's Disease)

Livpact

Lupus and Allied Diseases Association, Inc.

Memory Advocate Peers

National Alliance for Caregiving

National Certification Council for Activity Professionals

National Consumers League

National Hispanic Council on Aging

National Hispanic Medical Association

National Minority Quality Forum

National Task Group on Intellectual Disabilities and Dementia Practices

Nevada Chronic Care Collaborative

Noah Homes

Ohio Council For Cognitive Health

Partnership to Fight Chronic Disease

Patients Rising Now

Planetree International

RetireSafe

Second Wind Dreams

The Balm In Gilead, Inc

The Gerontological Society of America

University of South Florida Byrd Alzheimer's Institute

UsAgainstAlzheimer's

Voices of Alzheimer's

Volunteers of America