



February 9, 2022

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Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244



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



Dear Director Jensen and Administrator Brooks-LaSure,

We write to convey our deep concerns regarding the healthcare access implications of the Centers for Medicare and Medicaid Services' draft coverage with evidence development (CED) for monoclonal antibodies that target amyloid for the treatment of Alzheimer's disease.



These coverage restrictions, if finalized, could severely limit access to current and future FDA approved treatments for Alzheimer's, a disease that disproportionately impacts people of color, women, and people with intellectual and developmental disabilities.



African American people are twice as likely and Latino people are 1.5 times as likely to develop Alzheimer's when compared to non-Hispanic White Americans.ⁱ More than 60% of people living with Alzheimer's are women and more than 60% of dementia caregivers are women. Despite this higher risk, these communities face major gaps in access to Alzheimer's diagnostics, treatments, and research. In fact, Black Americans are 35% less likely than Whites to be diagnosed during an initial visit with a physician.ⁱⁱ Further, patients of color frequently go without treatment until the later, more severe stages of the disease.ⁱⁱⁱ



While Alzheimer's has been historically understudied in other communities of color, research suggests health disparities in detection and research access exist for American Indian or Alaskan Native people, Asian American and Pacific Islander (AAPI) people, and among people living with intellectual and developmental disabilities.^{iv} While we agree with CMS's goal of requiring the diversity of patients in clinical trials to be representative of the national population diagnosed with Alzheimer's disease, there are several issues with the way that the CED is structured that work against CMS' health equity objective.



Given the burden of neurological conditions on people of color, the undersigned organizations believe CMS should consider the health equity issues outlined in this letter to ensure equitable access to current and future FDA approved treatments for Alzheimer's disease.





Safeguarding Innovation

CMS's decision, if finalized in its current form, could hinder innovation in a therapeutic area that addresses an area of high unmet need for older Americans. By refusing to cover *any* monoclonal antibody treatment targeting amyloid plaque, CMS could deter future investments in all such therapies, including several that have already shown promise in initial clinical trials.



Defining Representativeness

The CED does not adequately define its requirement for clinical trials for anti-amyloid treatments to be "representative of the national population diagnosed with AD (Alzheimer's Disease)." Given long-standing health disparities, detection and diagnosis of Alzheimer's and other dementias among people of color has lagged non-Hispanic White Americans.



An analysis of 2006 Medicare claims data found that older African Americans and Latinos were more likely than Whites to have a diagnosis of Alzheimer's disease. Rates were 14% for Hispanics, 13% for African Americans, 10% for Whites, 9% for American Indians or Alaskan Natives, and 8% for Asian American and Pacific Islanders. Further, prevalence rates based on diagnosis codes may reflect varying levels of underdiagnosis across populations. For example, an analysis of Health and Retirement Study data has found that among those with cognitive impairment, 46% of Whites over age 55 had been told by a physician that they had a memory-related disease, compared to 34% of Hispanics and 34% of African Americans.^v



To ensure equitable access to FDA approved treatments, CMS must provide clarity in how it will exist in current surveillance data for people at risk for and/or living with Alzheimer's and other dementias. This is especially true for subpopulations that have traditionally been understudied in the Alzheimer's field.



Reliance on Randomized Controlled Trials

CMS's decision to restrict coverage of all monoclonal antibody treatments for Alzheimer's to participants enrolled in qualifying randomized controlled trials (RCT) will severely limit coverage to individuals with access to traditional clinical trial sites.^{vi} This poses major challenges given the severe underrepresentation of people of color in traditional RCTs. Historically, just 1.2% of clinical trial participants for new Alzheimer's drugs have been African American, 5.6% Hispanic, 4.4% Asian, and just 0.9% other or multiracial.^{vii}



The eligibility criteria used to determine who qualifies for enrollment in traditional RCTs disproportionately exclude people of color at greater risk of Alzheimer's disease and other dementias. For example, a recent analysis found that 60% of Alzheimer's trials funded by the National Institute on Aging (NIA) have at least one research exclusion criteria that could disproportionately affect African American and Latino participants compared to non-Hispanic white participants. Further, this analysis found that 55% of NIA funded





Alzheimer’s trials are “English only” — effectively shutting out the 7% of Americans who don’t speak English and the roughly 8% of Americans who speak English less than “very well,” according to the U.S. Census.^{viii}

Limiting clinical trials to hospital-based outpatient facilities could limit the accessibility of CMS trials to traditional academic medical centers and institutions that have dismal track records of engaging and recruiting underrepresented communities into Alzheimer’s research. This requirement limits options for individuals who seek care at neighborhood-based community health centers and smaller, rural hospitals that serve populations with lower socioeconomic status. In fact, according to an analysis of the geographic placement of NIA funded Alzheimer’s Disease Research Centers (ADRCs) by researchers at the University of Wisconsin, access to these marquee research sites “skews toward the most wealthy neighborhoods.”^{ix} Further, a recent study found that just one-third of site personnel based in academic medical centers and community hospitals are representative of minority populations compared to nearly half of personnel in dedicated sites and private practices.^x

Experts in healthy aging and health equity have outlined several innovative trial designs, including pragmatic trials, that could expand access to FDA-approved therapies while enabling rapid evidence collection on clinical benefits across clinical care centers and collaborative networks.^{xi} For example, the integration of practice-based research networks (PBRNs) should be considered given their track record of integrating community-based stakeholders and health providers into the research process and their reach into communities traditionally underrepresented into research. As of August 2020, there are 185 PBRNs registered with the Agency for Healthcare Research and Quality PBRN Resource Center.^{xii}

Innovative and forward-looking clinical trial designs must be considered to overcome the challenges outlined above and CMS should allow options beyond the traditional RCT to ensure equitable access to FDA approved therapies.

Excluding People with Chronic Conditions

We also urge CMS to address the CED’s impact on people of color managing multiple chronic conditions who might benefit from monoclonal antibodies that target amyloid for the treatment of Alzheimer’s. The CED excludes individuals “with medical conditions, other than Alzheimer’s, [that are] likely to increase significant adverse events.” These criteria effectively exclude individuals living with diabetes, cardiovascular disease, or other co-morbidities that are of greater prevalence among African American and Latino people, both of which are disproportionately affected by Alzheimer’s. CMS needs to further define the parameters of this exclusionary criteria and ensure equitable access.

Conclusion

On behalf of over 6 million Americans currently living with Alzheimer's -- as well as the 7 million more who are expected to develop the disease by 2050 -- we urge CMS to



consider how its final decision will ensure equitable access to cutting-edge treatments for diseases with high unmet needs.^{xiii}

Sincerely,

Academy of Medicine of Cleveland & N.
Ohio (AMCNO)
ALLvanza
Alzheimer's Los Angeles
Alzheimer's New Jersey
Alzheimer's of Central Alabama
Alzheimer's & Dementia Resource
Center
The Balm in Gilead, Inc.
Black, Gifted & Whole Foundation
Black Women's Health Imperative
Caregiver Action Network
CaringKind, The Heart of Alzheimer's
Caregiving
Center for Black Equity
Center for Healthcare Innovation
Colorado Gerontological Society
Delaware Ecumenical Council on
Children and Families
Easterseals
Financial Services Innovation Coalition
Health Equity Collaborative

Hispanic Federation
MANA, A National Latina Organization
National Association of Councils on
Developmental Disabilities
National Consumers League
National Council of Urban Indian Health
National Hispanic Council on Aging
National Hispanic Medical Association
National Puerto Rican Chamber of
Commerce
Oncology Managers of Florida
Partnership for Innovation &
Empowerment
RespectAbility
Rush To Live Organization
Southern Christian Leadership
Conference Global Policy Initiative
The Latino Coalition
United Cerebral Palsy
Upequity
UsAgainstAlzheimer's

ⁱ https://www.alz.org/aaic/downloads2020/2020_Race_and_Ethnicity_Fact_Sheet.pdf
ⁱⁱ <https://www.nia.nih.gov/news/data-shows-racial-disparities-alzheimers-disease-diagnosis-between-black-and-white-research>
ⁱⁱⁱ https://www.alz.org/aaic/downloads2020/2020_Race_and_Ethnicity_Fact_Sheet.pdf
^{iv} <https://www.alz.org/media/Documents/alzheimers-facts-and-figures.pdf>
^v <https://aspe.hhs.gov/reports/racial-ethnic-disparities-alzheimers-disease-literature-review-0>
^{vi} <https://www.cms.gov/newsroom/press-releases/cms-proposes-medicare-coverage-policy-mono-clonal-antibodies-directed-against-amyloid-treatment>
^{vii} <https://alz-journals.onlinelibrary.wiley.com/doi/full/10.1002/alz.12433>
^{viii} <https://alz.confex.com/alz/2021/meetingapp.cgi/Paper/54416>
^{ix} <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2767007>
^x <https://f.hubspotusercontent10.net/hubfs/9468915/Nov%202%2c%202021%20-%20Diversity%20of%20Investigative%20Site%20Staff%20Highly%20Associated%20with%20the%20Diversity%20of%20Patients%20Enrolled%20in%20Clinical%20Trials%2c%20According%20to%20Tufts%20Center%20for%20the%20Study%20of%20Drug%20Development%20-%20Press%20Release%20-1.pdf>
^{xi} https://sites.bu.edu/melodem/files/2021/07/Pragmatic-Study-Designs-to-Accelerate-Aducanumab-Evidence_Glymour.pdf
^{xii} <https://pbrn.ahrq.gov/>
^{xiii} <https://www.alz.org/alzheimers-dementia/facts-figures>