April 1, 2022

Tamara Syrek Jensen
Director, Coverage and Analysis Group
Center for Clinical Standards and Quality
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 ask the Centers for Medicare and Medicaid Services to reconsider its proposed decision to curtail coverage of amyloid-targeting monoclonal antibody treatments for Alzheimer's disease.[1]

We are deeply concerned that if CMS goes through with this damaging proposal, patients will be harmed and efforts to develop new treatments jeopardized. As a coalition of California patient groups and health equity advocates, we fear this would worsen existing health inequities.

No state has more Alzheimer's patients than California. As of 2020, 690,000 California residents over 65 had been diagnosed, and another 150,000 are projected to develop the disease by 2025.[2] This will bring the statewide total to 840,000[3] -- close to the population of San Francisco.[4]

The Latino population is likely to be especially hard hit. According to the U.S. Census Bureau, 39.4% of Californians identify as Hispanic,[5] more than double the national figure of 18.5%.[6] Hispanic Americans are 1.5 times as likely as white Americans to have Alzheimer's or another form of dementia.[7] A recent report co-authored by the California Department of Health found that the number of Hispanic Californians with Alzheimer's will increase threefold by 2042.[8]

We are also concerned that CMS's proposal will restrict access to new Alzheimer's drugs to patients who can participate in qualifying clinical trials. This runs the risk of replicating

---

1 https://www.cms.gov/newsroom/press-releases/cms-proposes-medicare-coverage-policy-monoclonal-antibodies-directed-against-amyloid-treatment
2 https://www.alz.org/media/Documents/alzheimers-facts-and-figures.pdf p 22
3 https://www.alz.org/media/Documents/alzheimers-facts-and-figures.pdf p 22
4 https://worldpopulationreview.com/us-cities/san-francisco-ca-population
5 https://www.census.gov/quickfacts/CA
6 https://www.alz.org/aaic/downloads2020/2020_Race_and_Ethnicity_Fact_Sheet.pdf
7 https://www.alz.org/aaic/downloads2020/2020_Race_and_Ethnicity_Fact_Sheet.pdf
8 https://www.independent.com/2022/01/20/alzheimers-expected-to-double-in-california-by-2040-triple-in-hispanic-communities/

Patient Advocates United in San Diego County
c/o Liver Coalition of San Diego
5755 Oberlin Drive, Suite 301 | San Diego, CA 92121
Phone: (858) 800-0116 | Fax: (858) 800-0117 | www.livercoalition.org/advocacy/chronic-care-initiative

historical mistakes, in which medical trials have failed to include minority populations. Past clinical trials of Alzheimer's drugs have had a median Hispanic patient population of just 5.6%.[9]

Alzheimer's disease impacts many people beyond those with the illness. More than a million Californians provide unpaid care to loved ones with this devastating condition, labor worth more than $18 billion in 2021, according to the non-profit Alzheimer's Association.[10] As case counts continue to rise, so, too, will the disease's economic burden, as more and more productive hours go to uncompensated caregiving.

Finally, we fear that the CMS proposal would discourage the sizable investments needed to research and develop the next groundbreaking Alzheimer's treatment. Last year, the FDA approved Aduhelm -- the first amyloid-targeting monoclonal antibody treatment for Alzheimer's -- under its accelerated pathway program. By second-guessing that approval and calling for additional evidence collection, CMS has cast doubt over whether it will cover any Alzheimer's drug -- or indeed any drug at all -- approved via the FDA's accelerated pathway.

The chilling effect on investment and drug development is already visible. For example, Eli Lilly recently paused efforts to submit a novel Alzheimer's treatment -- donanemab -- for accelerated approval.[11] The company's chief medical officer cited the CMS proposal as the reason for the delay.[12]

We ask CMS to reverse course on its proposed decision to limit coverage, which would harm some of America's most vulnerable patients.

Sincerely,



Scott Suckow
Chairperson
Patient Advocates United in San Diego County

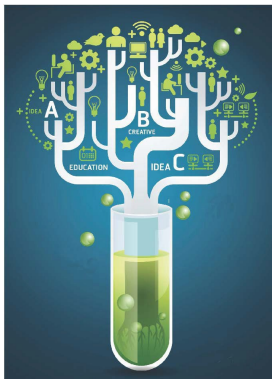
Patient Advocates United in San Diego County supports patients living with chronic health conditions to advocate & engage with policy makers and healthcare leaders to ensure access to quality healthcare.

cc: Members of the California Congressional Delegation

[9] https://alz-journals.onlinelibrary.wiley.com/doi/full/10.1002/alz.12433
[10] https://www.alz.org/media/Documents/alzheimers-facts-and-figures.pdf
[11] https://www.fiercebiotech.com/biotech/completion-lilly-s-alzheimer-s-submission-slips-out-q1-after-cms-s-aduhelm-decision
[12] https://www.fiercebiotech.com/biotech/completion-lilly-s-alzheimer-s-submission-slips-out-q1-after-cms-s-aduhelm-decision

Patient Advocates United in San Diego County
c/o Liver Coalition of San Diego
5755 Oberlin Drive, Suite 301 | San Diego, CA 92121
Phone: (858) 800-0116 | Fax: (858) 800-0117 | www.livercoalition.org/advocacy/chronic-care-initiative

Additional organizations signing on to this letter:



Applied Pharmacy Solutions

CALIFORNIA ACCESS COALITION

California Access Coalition

CALIFORNIA Chronic Care Coalition
We're About People. We're About Health.

California Chronic Care Coalition

CALIFORNIA HEPATITIS C TASK FORCE
HCVTF
PARTNERSHIPS FACING THE CHALLENGE

California Hepatitis C Task Force

California Health Collaborative

California Health Collaborative

CHAN

Community Health Action Network

ELLAS
Embracing Latina Leadership Alliances
Educational, STEM and Leadership Program

Embracing Latina Leadership Alliance

International Association of Hepatitis Task Forces

International Association of Hepatitis Task Forces

Patient Advocates United in San Diego County
c/o Liver Coalition of San Diego
5755 Oberlin Drive, Suite 301 | San Diego, CA 92121
Phone: (858) 800-0116 | Fax: (858) 800-0117 | www.livercoalition.org/advocacy/chronic-care-initiative



Latino Diabetes Association



Liver Coalition of San Diego



Liver Health Foundation



Los Angeles County Medical Association

Patient Advocates United in San Diego County
c/o Liver Coalition of San Diego
5755 Oberlin Drive, Suite 301 | San Diego, CA 92121
Phone: (858) 800-0116 | Fax: (858) 800-0117 | www.livercoalition.org/advocacy/chronic-care-initiative