



May 18, 2023

Dear Members of Congress,

The Partnership to Fight Chronic Disease and 55 undersigned organizations appreciate your attention and ongoing efforts to urge the Centers for Medicare and Medicaid Services (“CMS”) to reconsider its ill-advised National Coverage Decision requiring Coverage with Evidence Development for an entire class of Alzheimer’s disease therapies. During recent hearings with Secretary Becerra on the Biden Administration’s FY2024 budget, Members of Congress, on a bipartisan basis, asked Secretary Becerra important questions that highlighted CMS’s intransigence and downplayed the unprecedented nature of CMS’s actions.

Every day in America, 2,000 people progress from mild to moderate Alzheimer’s disease and any who could have benefitted become ineligible for these treatments. Time is of the essence, and we urge you to continue to press CMS to reconsider its insistence on coverage with evidence development for current and future therapies in this class.

Unfortunately, the testimony of Secretary Becerra in response to the many questions posed to him in recent hearings give even more reason for alarm over CMS’s decision, both in terms of the devastating impact on the Alzheimer’s disease community and in the precedent-setting move that threatens Medicare coverage for other diseases as well. Soon after CMS announced its NCD on an entire class of potential therapies for Alzheimer’s disease, CMS staff rushed to reassure concerned patients and advocates that this was a unique case and did not signal a change of policy.<sup>1</sup>

More recently, however, when asked by members of Congress about this action, Secretary Becerra defended CMS’s action, stating that CMS was “simply following the law” that Congress enacted and added that “CMS has to remain consistent in the way it treats any drugs.”

CMS’s action on an entire class of Alzheimer’s therapies is not “consistent” with past policy. In fact, CMS has never before required Medicare coverage be dependent on evidence development for any FDA-approved therapeutic for medically appropriate use according to its label.<sup>2</sup> Allowing this unprecedented action to stand will set a new standard that, according to Secretary Becerra, CMS must then consistently apply to new FDA-approved drugs. Some of the “most innovative drugs coming to market,” including the new Alzheimer’s therapies, gene and stem cell therapies, and immunotherapy aimed at infectious diseases and cancers are among therapeutic areas noted by experts as potential ones to target for strict Medicare coverage limitations.<sup>3</sup>

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<sup>1</sup> Alzheimer’s Forum. Drilling Down into the CMS Aduhelm Decision—A Primer. Apr 22, 2022. Available at <https://www.alzforum.org/news/community-news/drilling-down-cms-aduhelm-decision-primer>

<sup>2</sup> Ibid.

<sup>3</sup> 2023 CERSI Summit - Panel 2: Cross-Agency Synergy to Accelerate Access to Medical Products, <https://www.youtube.com/watch?v=2acW0KMYCII&t=1398s> (see, e.g., minutes 20:00-22:32)



Further, the reach of this new precedent can be seen in the Center for Medicare and Medicaid Innovation's (CMMI's) recently announced mandatory "demo" to pay less for drugs receiving FDA approval through the accelerated approval pathway. CMMI cited CMS's decision on Alzheimer's therapies and differential approach to coverage for those approved using accelerated approval as supporting CMMI's proposed model to discount payments for drugs approved under the FDA's accelerated approval pathway. Specifically, the CMMI report notes, "CMS has also narrowed Medicare coverage of AAP drugs through its Coverage with Evidence Development (CED) process... providing coverage only to beneficiaries enrolled in qualifying clinical trials."<sup>4</sup>

Requiring Medicare beneficiaries already coping with early-stage Alzheimer's disease to enroll and participate in a clinical study to qualify for Medicare coverage will disproportionately affect already underserved beneficiaries and exacerbate well-documented health disparities. People living in rural areas, African Americans and Hispanics who already have higher disease prevalence, and people with disabilities all stand to lose under this proposal. Requiring enrollment in a clinical study for coverage is not coverage. If allowed to stand, CMS's actions will limit the opportunity to delay Alzheimer's disease to people who can either afford to pay out of pocket or have the means and supports to identify clinical study locations and manage the logistics needed to qualify, enroll, gain access to coverage, and maintain coverage through continued study participation. Even those who could access a study have to wait for these studies to commence – which typically take more than a year to establish before enrollment even begins.

The patient and provider community continue to reach out to CMS, to provide data showing evidence of benefits, to highlight the unprecedented nature of their actions, the disparate impact on vulnerable populations, and the tremendous unmet need that CMS is making worse. We need your help to convince CMS to reconsider by continuing to ask Administration officials tough questions, to urge the Biden White House to push for action, and, if necessary, to pass bipartisan legislation that ensures CMS reconsiders this decision and avoids such actions in the future.

The Partnership to Fight Chronic Disease and the 55 signed organizations stand ready to provide additional information and support needed to continue raising awareness and motivating action around CMS reconsideration of this NCD with CED decision.

Signed,

Alliance for Aging Research  
Alliance for Patient Access  
Alzheimers Orange County  
American Senior Alliance  
American Society of Consultant Pharmacists

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<sup>4</sup> Secretary Xavier Becerra. US Department of Health and Human Services. A Report in Response to the Executive Order on Lowering Prescription Drug Costs for Americans. Available at <https://innovation.cms.gov/data-andreports/2023/eo-rx-drug-cost-response-report>.



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Autoimmune Association  
Caregiver Action Network  
Center for Global Health Innovation  
Center for Patient Advocacy Leaders (CPALs)  
Chronic Disease Coalition  
Dementia Alliance International  
Dementia Alliance of North Carolina  
EveryLife Foundation for Rare Diseases  
Firefly Fund  
Friedreich's Ataxia Research Alliance (FARA)  
Genetic Alliance  
Genome Creative, LLC  
Georgia Bio  
Global Alzheimer's Platform Foundation. Inc.  
Global Coalition on Aging Alliance for Health Innovation  
Global Healthy Living Foundation  
Great Lakes Hemophilia Foundation  
Haystack Project  
HealthyWomen  
Kaleidoscope Fighting Lupus  
Latino Alzheimer's and Memory Disorders Alliance  
LEAD Coalition (Leaders Engaged on Alzheimer's Disease)  
Lewy Body Dementia Association  
Lupus and Allied Diseases Association, Inc.  
Lupus Foundation of America  
Michigan State University Alzheimer's Alliance  
Minnesota Society of Clinical Oncology  
Myositis Support and Understanding  
National Association of State Long Term Care Ombudsman Programs (NASOP)DC Ombudsman  
National Consumers League  
National Grange  
National Kidney Foundation of Wisconsin  
Nevada Oncology Society  
No Patient Left Behind (NPLB)  
Noah Homes Inc  
NTM INFO & RESEARCH  
NutriStyle  
Ohio Council For Cognitive Health



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Patients Rising Now  
Prevent Blindness Wisconsin  
PSC Partners Seeking a Cure  
RetireSafe  
Rio Grande Valley Diabetes Association  
Second Wind Dreams  
Texas Healthcare and Bioscience Institute  
The Balm In Gilead, Inc  
UsAgainstAlzheimer's  
Voices of Alzheimers  
Wisconsin State Grange



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