**CMS Coverage Determination for Alzheimer's Treatments Harms Patients, Sets Troublesome Precedent for Access to Future Cures**

April 13, 2022 – The Alliance for Aging Research is deeply disappointed in the Centers for Medicare and Medicaid Services' (CMS) final [national coverage determination](https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=305) on monoclonal antibodies targeting amyloid for the treatment of Alzheimer's disease.

"Beneficiaries who have paid into Medicare their entire working lives deserve better from their public insurance agency," said Susan Peschin, president and CEO of the Alliance for Aging Research.

Monoclonal antibody treatments are the first drugs to show promise for slowing the progression of Alzheimer's disease. One drug of this kind, Aduhelm, has received Food and Drug Administration approval, but more are in late-stage clinical development. Cruelly, the CMS decision limits access not just to Aduhelm, but to the entire category of drugs, judging future treatments before data is reported on their Phase III clinical trials and effectively choking off an important avenue of research in the fight against Alzheimer's disease.

Under the April 7th CMS ruling, Medicare will only cover amyloid-targeting monoclonal antibody treatments for Alzheimer's patients participating in clinical trials, and, in some limited future cases, patients who are enrolled in a CMS-approved patient registry.

In practice, this means monoclonal antibody treatments will be off limits to most Alzheimer's patients for the foreseeable future. Access to clinical trial participation has never been equitable in the United States, and the CMS decision perpetuates a system in which only the most privileged patients benefit from cutting-edge medicine. Patients who are already more vulnerable -- due to lower income, race, or ethnicity -- will be left out yet again.

Also concerning is the fact that the CMS based its coverage parameters on whether the FDA has approved a drug through accelerated approval or the traditional approval pathway. This poses a threat that goes well beyond treatments for dementia, threatening patients with a wide range of diseases.

In 1992, Congress established the accelerated approval pathway in response to the AIDS-HIV crisis, to allow faster approval of drugs that treat serious conditions for which there are few or no other options of effective treatment. With its new decision, the CMS has undermined the statutory purpose of accelerated approval, which is to allow promising drugs to reach patients with serious medical conditions more quickly.

In 2021, the FDA greenlit 28% of new drugs using the accelerated approval pathway, and 80% of new oncology drugs over the last decade were approved in this manner. Under the new precedent set by CMS, Medicare could decline to cover any of these drugs.

"With this decision, CMS shows they have lost their moral compass. The agency is not advancing health for Medicare beneficiaries with Alzheimer's disease, and is instead limiting access to medicine," Peschin said.

"The coverage determination preemptively judges drugs that have not even completed their clinical trials, and casts doubt on CMS's willingness to cover future treatments for conditions including cancer, amyotrophic lateral sclerosis (ALS), and rare diseases."

Additional information on the CMS national coverage determination can be found [here](https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=305).

**About the Alliance for Aging Research**
The Alliance for Aging Research is the leading nonprofit organization dedicated to accelerating the pace of scientific discoveries that improve the universal experience of aging. The Alliance believes advances in research help people live longer, happier, more productive lives and reduce healthcare costs over the long term. For more than 30 years, the Alliance has guided efforts to increase funding for aging at the National Institutes of Health and the Food and Drug Administration; built coalitions to guide regulatory improvements for age-related diseases; and created high-impact educational materials to improve the health and well-being of older adults. For more information, visit [www.agingresearch.org](https://www.agingresearch.org)

Matthew Thompson
Digital Communications Coordinator
mthompson@agingresearch.org
(202) 688-1209