INFUSION PROVIDERS ALLIANCE

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Ms. Chiquita Brooks-LaSure
CMS Administrator
U.S. Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease Proposed Decision Memo (CAG-00460N)

The Infusion Providers Alliance (IPA) is pleased to provide comments regarding the proposal by the Center for Medicare and Medicaid Services (CMS) to cover FDA-approved monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease (e.g., Aduhelm and other treatments in the pipeline) under Coverage with Evidence Development (CED) in CMS-approved randomized controlled clinical trials. We are deeply concerned that limitation of coverage only to clinical trials under CED and only in certain hospitals will dramatically limit coverage of the only FDA-approved therapy for Alzheimer's.

Background on the Infusion Provider Alliance

The IPA is the leading voice for in-office and freestanding ambulatory infusion providers, with nearly 1,000 community-based, non-hospital infusion sites across 43 states. Our members deliver exceptional care to patients and value to the health care system, typically saving Medicare more than 50 cents on the dollar per infusion compared to hospital administration. Our facilities are major access points of care for patients with complex and chronic health conditions, including Alzheimer's disease (AD), in communities large and small.

Halting Meaningful Coverage is Unwarranted Hinderance to Patient Care

Alzheimer's Disease is a devastating and complicated disease that had no treatments before approval of the monoclonal antibodies meant to clear amyloid plaques in the brain, which are highly associated with the disease. As CMS stated in its January 11, 2022 Proposed Decision Memo, Aduhelm "is the first and only such antiamyloid mAb to be approved by the FDA, and was done so under FDA's "accelerated approval" pathway … CMS is aware of at least three other antiamyloid mAbs currently approaching Phase 3 trials." We are concerned about the downstream implications for other therapies that are in development

for AD and the potential to further hinder access to any solution for this devastating disease, as well as the precedent this sets for CMS exercising similar restrictive approaches for other drugs in development in other therapeutic classes.

CMS's January 11, 2022 Proposed Decision Memo[1] dramatically restricts patient access to a product that has been duly approved by the FDA and is already being utilized in a responsible manner by physicians. Despite policymakers concerns about the substantial potential cost to the Medicare program prior to launch of Aduhelm, there is no evidence whatsoever of overutilization or inappropriate utilization. In fact, utilization has been extremely low – at a small fraction of initial projections. We are perplexed what provoked such extreme action by CMS on a drug approved by the FDA after rigorous review.

The role of CMS is to administer and finance the Medicare and Medicaid programs, not propose and finance additional clinical trials. It is the job of the Food & Drug Administration (FDA) to review clinical data and either approve or not approve a drug, its indications and labelling. FDA has the clinical and scientific expertise to evaluate clinical trials. CMS appears to be supplanting FDA's role and operating in an area beyond its expertise, to the harm of patients. In the history of the Medicare program, CMS has never required an FDA-approved drug to undergo additional clinical trials financed by the Medicare program and restricted coverage to all other beneficiaries not enrolled in that trial. This establishes a very concerning precedent that undermines the authority of the FDA, dramatically limits patient access, and creates enormous uncertainty for drugs still under development. If health care providers cannot trust that FDA approval means the drug will be covered, they will not devote the time and resources preparing for a new product as they will be waiting for when the "real rules" are issued for Medicare coverage.

We do not believe it is ethical to administer a placebo to patients who are in need of help to fight one of the most devastating and insidious diseases that attacks their mental faculties when the drug being "studied" has already been approved by the FDA. Those patients would like the real FDA-approved treatment, not a saline bag of placebo. In addition, it is an entirely inappropriate use of taxpayer dollars to pay for placebos and clinical trials typically funded by pharmaceutical manufacturers. Further, the beneficiaries would be responsible for paying coinsurance amounts for a placebo – that is a concept that is unheard of and unprecedented.

In addition, CMS's CED would disrupt treatment for patients currently in treatment. CMS has not delineated a plan for allowing these patients to remain on therapy, particularly those that are receiving treatment at a facility (hospital, physician office or infusion center) is not involved in the clinical trials. Patients with early stages of dementia would be forced to leave the comfort of a community setting, perhaps in a physician office with the physician and nurses they know and trust, and travel a significant distance to a large hospital in a city center they are unfamiliar with to maybe receive a drug that will help them in their fight with dementia. (They may be given the placebo instead of the FDA-approved therapy.)

[1] (https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?ncaid=305&proposed=Y

Site-of-Care Restrictions Impair Access and Drive up Costs

We also strongly oppose the limitation of Aduhelm infusions to the hospital site of care, as CMS has provided no evidence that patients are not receiving safe and high-quality care in physician offices and infusion centers. Patient access would be limited to large hospitals in urban areas; patients in rural areas and in underserved and economically depressed areas will be summarily excluded due to travel and other restrictions. Also, the clinical data does not support limiting access to hospital outpatient departments. While studies of Aduhelm have indicated a risk of ARIA (small brain bleeds), these are primarily slow bleeds that develop over time and can be addressed once diagnosed. They are not catastrophic emergency issues that develop during or close in time with the infusion. Being in close proximity to advanced life support facilities during or immediately after the infusion is unnecessary.

Further, this unnecessary limitation to certain hospitals undermines CMS's stated goal of enrolling a diversity of patients. The CED explicitly requires the recruitment of "beneficiary subpopulations" and "underrepresented populations." It's hard to see how this arbitrary approach and the exclusion from participation of all physician offices and infusion centers, which are conveniently located in urban, suburban, and rural settings, helps achieve that goal. It is inconceivable that any of these hospitals will be located in rural areas, so rural "subpopulations" will be summarily excluded. Moreover, many of the hospitals with the resources and organizational ability to participate in the proposed trials are likely to be in higher income areas, which may also exclude underserved and minority populations.

Limiting the infusions to hospitals is also a disservice to the program and beneficiaries from a cost standpoint. Medicare pays hospitals more than double the amount for infusions using identical staff time and skills as physician offices and freestanding ambulatory infusion centers, which are paid on the Physician Fee Schedule. Based on the relative complexity of the infusion, we would expect to bill Medicare CPT Code 96413 or 96365 to infuse Aduhelm. Our in-office and ambulatory infusion centers are paid approximately 45 percent of the hospital rate: $309.56 vs $142.55 for CPT code 96413, with similar Medicare savings for CPT code 96365.

CMS chose a highly restrictive methodology when other less restrictive alternatives are readily available, such as post-market surveillance and patient registries. A patient registry -- requiring frequent follow up where physicians and providers report patient progress into a national database for further study, monitoring and analysis -- would provide better and more useful information than the CED CMS proposes.

In summary, we strongly oppose the CED methodology and its downstream impact on current and future AD treatment research and development and believe it is critical that AD treatments not be restricted to large academic centers given their existing capacity issues and relatively limited geographic footprint. Moreover, the lack of adequate coverage in rural areas and the capacity limitations to accommodate urban and minority patients in need of treatment has the potential to meaningfully impact beneficiaries' ability to access appropriate care.

Sincerely,

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