Via Electronic Filing to: https://www.cms.gov/medicare-coverage-database/reports/national-coverage-ncacal-status-report.aspx?ncacaldoctype=NCA&status=Open%20for%20Public%20Comment

February 10, 2022

Tamara Syrek Jensen, JD
Director, Coverage and Analysis Group
Centers for Medicare & Medicaid Services
7500 Security Blvd
Baltimore, MD 21244

Re: National Coverage Analysis (NCA) for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (CAG-00460N)

Dear Ms. Jensen:

The undersigned members of the Council of State Bioscience Associations, a coalition of forty-six state bioscience associations across the United States, wish to submit comments to the Centers for Medicare & Medicaid Services regarding the recent National Coverage Analysis (NCA) for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (CAG-00460N).

Introduction

On January 11, 2022, the Centers for Medicare & Medicaid Services (CMS) issued a proposed decision memo in its National Coverage Analysis (NCA) for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (AD) (Proposed National Coverage Determination (NCD)).

CSBA has serious concerns about CMS's proposed NCD. If finalized, the NCD would set a dangerous precedent, restricting access to a promising class of new amyloid-focused therapies, both current and future. This would have life-altering implications for the over five million Americans struggling with AD. It also would also have far-reaching implications for a variety of patient populations living with unmet medical needs -- patients who stand to benefit from therapies approved for difficult-to-treat diseases, notably those approved by the Food and Drug Administration (FDA) under the Accelerated Approval pathway.

CMS's proposal to limit coverage only to patients enrolled in government-approved Randomized Control Trials (RCTs) is also troubling. It means that the vast majority of individuals suffering from AD will have no meaningful access to an approved medicine simply because of where they live and where they go for care.

CMS's Proposal Will Harm Patient Access to Safe and Effective Drugs

Patients will bear the consequences if CMS's Proposed NCD is finalized. As drafted, the Proposed NCD will have dramatic ramifications for access—not just for the currently approved beta-amyloid for AD but also the entire pipeline of new beta-amyloid AD treatments to come. Moreover, finalization of the Proposed NCD will undoubtedly limit investment in this historically challenging clinical area.

CMS's proposal is fundamentally unworkable for patients living with AD today. AD is a degenerative medical condition; each year an AD patient goes without treatment means the potential for permanent and progressive loss of cognitive ability. Patients with AD cannot afford to wait a year or more for CMS-approved clinical trials to be available.

Further, even when approved trials are initiated, patients will still face the risk of being placed on a placebo. It is untenable for CMS to force patients to make this kind of choice, especially after FDA has determined the drug's safety and efficacy. Beyond this basic premise, CMS is imposing new and stringent clinical trial criteria which strongly suggest that the number of clinical trials approved will be extremely limited. CMS's RCT requirement only compounds the fundamental inequity and risk of harm to patients. Even if a patient is fortunate enough to have reliable access to a CMS-approved trial, they may end up being assigned to a placebo while still being forced to bear out-of-pocket cost-sharing obligations as if they had been guaranteed access to the anti-amyloid therapy. This is simply unacceptable.

CMS's proposed coverage with evidence development (CED) standards also will compound existing inequities in health care delivery. AD disproportionately impacts African American and LatinX populations—who are, respectively, two and 1.5 times more likely than Caucasian Americans to have AD[1] and other dementias—but are nonetheless significantly *less* likely to be diagnosed with AD. CMS's CED criteria will only add to these existing problems of access for already under-served populations.

CMS's Proposal Undermines FDA Authority and Invalidates Sponsor Commitments

Beyond the issue of anti-amyloid treatments discussed in this NCD, CSBA is concerned that the current proposal inappropriately undermines FDA's Accelerated Approval pathway. This pathway enables therapies for serious, life limiting conditions to be approved and available to patients more expeditiously and relies on scientifically validated surrogate endpoints. Such approvals require a commitment from the manufacturer to conduct a confirmatory Phase 4 study. As such, CMS's Proposed NCD not only undermines FDA, but it also invalidates the sponsor's commitment to important post-approval research.

CMS's Proposal Could Chill or Even End Research into Conditions with Serious Unmet Medical Needs

The risk of CED restrictions would make it untenable for developers of novel therapies to pursue the FDA Accelerated Approval pathway. Developing a new drug requires billions of dollars in research and investment. Further, the investment required is exponentially higher for difficult to treat medical conditions like AD. To promote research in difficult-to-treat conditions like AD, manufacturers and investors need certainty that CMS will cover drugs for on-label indications once FDA has determined the therapy to be safe and effective. CMS's

[1] Alzheimer's Association, "2021 Alzheimer's Disease Facts and Figures," March 2021

Proposed NCD threatens to chill research and investment in new drugs targeting challenging disease states and to reduce reliance on a key mechanism that patients rely on to get faster access to desperately needed new therapies.

Conclusion

We believe that taken together, the imposition of restrictions on access to therapies for patients with serious unmet needs, CMS's unprecedented actions questioning the FDA, and the demand for narrow RCT coverage with evidence development (CED) makes this proposed determination troubling. CMS should be encouraging development of new and innovative treatments for conditions like AD—not adopting restrictions on coverage that threaten to chill the development of an entire class of therapies for a degenerative condition that has no viable treatment option. Ultimately, we believe any national coverage policy should help ensure consistent patient access for vulnerable patients – not introduce inappropriate barriers to care.

We thank the Agency for its consideration of these comments and look forward to further engagement with CMS on these issues in the future.

Sincerely,

BioAlabama
Arizona BioIndustry Association, Inc.
Biocom California
California Life Sciences
Southern California Biomedical Council
Colorado BioScience Association
BioCT (Connecticut)
Delaware BioScience Association (DelawareBio)
BioFlorida
Georgia Bio (GABIO)
Idaho Technology Council
Illinois Biotechnology Innovation Organization
Indiana Health Industry Forum
Iowa Biotechnology Association
BioKansas
Kentucky Life Sciences Council
Louisiana BIO
Bioscience Association of Maine (BioME)
Maryland Technology Council
Massachusetts Biotechnology Council (MassBIO)
Michigan Biosciences Industry Association (MichBIO)
Medical Alley Association (Minnesota)
Missouri Biotechnology Association
Montana BioScience Alliance
Bio Nebraska
Nevada Biotechnology & Health Science
BioNJ (New Jersey)
New Mexico Biotechnology and Biomedical Association

NewYorkBIO
North Carolina Biosciences Organization (NCBIO)
Bioscience Association of North Dakota
BioOhio
Oklahoma Bioscience Association
Oregon Bioscience Association
Life Sciences Pennsylvania (LSPA)
INDUNIV (Puerto Rico)
Rhode Island Bio
South Carolina BIO
South Dakota Biotech Association
Life Science Tennessee
Texas Healthcare and Bioscience Institute
BioUtah
Virginia Biotechnology Association (VABIO)
Bioscience Association of West Virginia
BioForward Wisconsin