



August 16, 2023

Administrator Chiquita Brooks-LaSure Centers for Medicare & Medicaid Services Department of Health and Human Services 7500 Security Boulevard  
Baltimore, MD 21244

**RE: NCD Reconsideration for Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease**

Dear Administrator Brooks-LaSure:

The Alliance of Community Health Plans (ACHP) applauds the Centers for Medicare & Medicaid Services (CMS) for its commitment to establish national coverage policies with evidence based on safety and efficacy data. With promising but uncertain treatments of Alzheimer's actively in development, testing and early usage, now is not the appropriate time to change a National Coverage Determination that has been in place and working since 2013 for beta amyloid pet scan in dementia and neurodegenerative disease patients.

**Let's not walk away from what is working today.**

ACHP represents the nation's top-performing, nonprofit health plans that provide high-quality coverage and care to tens of millions of Americans across nearly 40 states and D.C. Our member companies serve diverse populations across all lines of business and support the development and coverage of testing and treatment that improve health outcomes.

The lack of evidence of efficacy for monoclonal antibodies directed against amyloid, unknown safety risks and the need for consistency in treatment and coverage necessitate maintaining the current national coverage policy. Revising the current policy of one scan per patient enrolled in clinical study will not meaningfully advance the available evidence and treatment of individuals with neurodegenerative disease.

ACHP's comments are informed by top clinical leaders, such as member company medical directors and pharmacy leaders. Based on their extensive expertise and decades of experience in the field, there is consensus that beta amyloid positron tomography has not demonstrated effectiveness, safety or enough value to reconsider the current coverage decision. The current national coverage determination balances that admirable goal of advancing evidence and care while not giving individuals and families facing the everyday challenges Alzheimer's disease presents a false hope.

In 2013, CMS determined that the evidence is insufficient to conclude that the use of positron emission tomography (PET) beta amyloid imaging was reasonable and necessary for the diagnosis or treatment of illness or injury and issued a National Coverage Determination (NCD 220.6.20). The NCD covers one PET amyloid-beta scan per patient per lifetime in CMS-approved studies under coverage with evidence development. Since the issuance of the NCD, additional therapies were approved by the Food and Drug Administration (FDA) which target the reduction in beta-amyloid plaques in the brain. The FDA cited beta-amyloid plaques as a surrogate endpoint, a reduction of which "is reasonably likely to result in clinical benefit." CMS agreed with ACHP member concerns and issued a National Coverage Determination (NCD



200.3) that limited coverage to those enrolled in clinical trials under a Coverage with Evidence Development. **ACHP stands with our previous comments submitted during the NCD analysis and reiterates concerns about safety risks, beta-amyloids as a surrogate endpoint and emphasizes the need for consistency in coverage.**

PET imaging is a high radiation examination involving the injection of a radioactive tracer into the body. Although fairly low risk, especially as compared to an invasive lumbar puncture, the impact of increased radioactive exposure over time is not well known. Studies of PET imaging was based on the use in diagnosis of neurodegenerative disease and not continued monitoring. Allowing coverage of additional tests per patient could increase the risk of unnecessary testing without appropriate clinical criteria, unlike what currently exists. Further, imaging should be limited to those for whom diagnosis or related treatment is needed.

Evidence is still inconclusive about the role of beta-amyloid plaques in the pathophysiology of Alzheimer's Disease. Changing the NCD at this time would blunt CMS's ability to continue evidence generation that will likely benefit our collective understanding of beta-amyloid plaques as it relates to the treatment of Alzheimer's disease. **Removing the coverage with evidence determination would create a patchwork of coverage nationwide with variation from local jurisdiction to local jurisdiction. For patients navigating an already complex diagnosis and treatment, this lack of consistency could unnecessarily create challenges to access.**

We appreciate the continued engagement with you and members of your team. We should not change the National Coverage Determination at a time in which there are questions about the efficacy and population who could benefit from monoclonal antibodies targeting amyloid plaque. Please contact Michael Bagel, ACHP Associate Vice President of Public Policy, at [mbagel@achp.org](mailto:mbagel@achp.org) or (202) 897-6121 with any questions.

Sincerely,

Ceci Connolly  
President and CEO ACHP