July 19, 2021

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Brooks-LaSure:

The undersigned are writing jointly to express our deep concern about Medicare's continued limited coverage of beta amyloid positron emission tomography (PET) scans. The recent approval by the Food and Drug Administration (FDA) of aducanumab, an amyloid beta-directed antibody, makes it imperative that clinicians have the full suite of tools that they need for determining if a patient has beta amyloid plaque in order to assure that this drug is only prescribed for patients who might benefit from this treatment.

Collectively, we appreciate that CMS has initiated a national coverage analysis (NCA) for monoclonal antibodies directed against beta amyloid following the FDA approval of aducanumab under its accelerated pathway. In light of the approval, we believe it is critical to shared decision-making between physicians, patients, and caregivers that Medicare beneficiaries have access to amyloid PET scans immediately so that decisions about whether to initiate this treatment are fully informed.

Beta amyloid PET scans are currently covered only as part of a clinical trial that meets the requirements for Coverage with Evidence Development. This limited coverage creates access and equity issues for Medicare beneficiaries. In order to benefit from aducanumab, patients must have beta amyloid present in their brains; therefore, patients without access to amyloid PET scans may be treated with aducanumab even though there is no evidence they will benefit from the treatment. All patients in the Phase 3 clinical trials were required to have a positive beta amyloid PET scan before entering the trial. Furthermore, treating patients who do not have beta amyloid present in their brains may result in harm, since aducanumab therapy carries a risk of significant side effects.

We note that in the Physician Fee Schedule proposed rule for 2022, CMS proposed to retire NCD 220.6, which broadly non-covered non-oncologic indications for PET, but CMS did not propose to change any of the more specific NCDs within the subsection, including NCD

220.6.20. If CMS finalizes the retirement as proposed, then the existing limitation on amyloid PET would remain in place but other uses of PET for Alzheimer's disease, such as Tau PET, could be covered at the discretion of the Medicare Administrative Contractors (MAC). To avoid this illogical and confusing situation, we urge CMS to retire NCD 220.6.20 as soon as possible.

CMS should immediately cover beta amyloid PET to address access and equity issues and ensure that only those patients for whom there might be a clinical benefit based on the secondary endpoint used in the FDA approval (reduction in amyloid plaque) are prescribed aducanumab.

Specifically, we recommend the following:

1. Immediately retire National Coverage Determination (NCD) 220.6.20, - **Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease**, which limits coverage of beta amyloid PET to CMS-approved clinical trials. A beta amyloid PET scan is required to safely treat patients with aducanumab, yet NCD 220.6.20 currently precludes coverage of such scans by Medicare.

   The coverage limitations can be removed very simply by issuing an interim final rule (IFR) announcing the immediate retirement of this NCD (with any necessary conforming changes to other NCDs in the 220 range). We believe that under current CMS policy, NCDs may only be retired through the rulemaking process. Although rulemaking usually requires publication of a proposal, solicitation of comments, and publication of a final rule, CMS has the authority to issue interim final rules that take effect immediately (or retroactively) with comments submitted after publication of the IFR.[1] CMS used this authority three times in 2020 to implement policy changes during the public health emergency.

2. Simultaneous to retiring NCD 220.6.20, CMS could issue a proposed NCD that would limit the coverage of beta amyloid PET scans to patients who are candidates for any anti-amyloid monoclonal antibody after undergoing a comprehensive neurologic exam.

We would be happy to meet with you to discuss these recommendations. Please contact Paul Rudolf at paul.rudolf@arnoldporter.com or call 202-942-6426, if you have any questions.

Sincerely,

American Academy of Neurology
American Geriatrics Society
Society of Nuclear Medicine and Molecular Imaging

[1] Section 553(b)(3)(B) of the Administrative Procedures Act authorize an agency to waive otherwise required publication of proposed rulemaking "when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest."