AGS Geriatrics Healthcare Professionals
Leading Change. Improving Care for Older Adults.

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Coverage and Analysis Group
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Baltimore, MD 21244

Dear Dr. Hutter:

The American Geriatrics Society (AGS) greatly appreciates the opportunity to comment on the *Centers for Medicare and Medicaid Services (CMS)* reconsideration of the national coverage determination (NCD) on beta amyloid positron emission tomography (PET) in dementia and neurodegenerative disease (NCD 220.6.20).

The AGS is a not-for-profit organization comprised of nearly 6,000 geriatrics health professionals who are devoted to improving the health, independence, and quality of life of all older adults. Our members include geriatricians, geriatrics nurse practitioners, social workers, family practitioners, physician assistants, pharmacists, and internists who are pioneers in advanced-illness care for older individuals, with a focus on championing interprofessional teams, eliciting personal care goals, and treating older people as whole persons.

Before we share our feedback on the reconsideration of NCD 220.6.20, AGS would like to take this opportunity to thank CMS for its work that resulted in the April 2022 decision around coverage for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (AD). We believe that the decision to finalize a two-part NCD that addresses coverage of aducanumab and any future FDA-approved monoclonal antibodies directed against amyloid for the treatment of AD is the right decision for the reasons we conveyed in our February 2022 letter to CMS.

In response to the reconsideration of NCD 220.6.20, this NCD limits coverage of beta amyloid PET scans to CMS-approved clinical trials that meet the requirements for Coverage under Evidence Development (CED) and limits the number of beta amyloid PET scans covered per patient to one per lifetime.

We continue to believe that this NCD inappropriately limits coverage of beta amyloid PET for Medicare beneficiaries, including beneficiaries who may be candidates for monoclonal antibodies (mAbs) directed against amyloid for the treatment of AD under the recently finalized mAbs NCD. Furthermore, in order for a PET scan to be covered by Medicare for a patient seeking to participate in a mAb trial, the patient has to enroll in the trial even though the scan may be negative, showing that the patient is not in fact a candidate for mAb therapy. We feel this puts an inappropriate administrative burden on patients and trial sponsors to require patients to enroll in a clinical trial in order to determine whether they are eligible to participate in that trial.

As recommended to CMS previously, AGS believes that NCD 220.6.20 should be retired in its entirety. Retirement of the NCD would mean that beta amyloid PET would be covered at the discretion of Part A/B Medicare Administrative Contractors (MACs) just like every other PET scan, including Tau PET, furnished for non-oncologic indications.

However, if this NCD is not retired, AGS urges CMS to remove the limitation covering only one beta amyloid PET scan per patient per lifetime. All patients in the Phase 2 and 3 clinical trials for aducanumab and other late phase mAbs were required to have a positive beta amyloid PET scan before entering the trial and received additional scans during the trials. The additional scans were used (1) to assess impact on cerebral amyloid plaque content, and (2) to determine whether to continue therapy. In the phase 2 trial of donanemab, amyloid plaque levels were evaluated using PET at 24, 52, and 76 weeks, with an increasing percentage of patients in the donanemab group having amyloid-negative status over time. The authors report that approximately 27.4% and 54.7% of participants in the donanemab group had sufficient lowering of the amyloid plaque level to switch to placebo infusion at 28 and 56 weeks, respectively.[1]

Restriction to one PET scan per lifetime will negatively impact participation in trials under the mAbs NCD and may negatively impact care by not providing physicians the information they need to make appropriate treatment decisions (e.g., to stop monoclonal antibody therapy). If Medicare coverage is limited to one scan per patient, the additional PET scans furnished during the trials will not be covered and those costs will have to be borne by the trial sponsors or beneficiaries. This situation raises major health equity issues and may limit the participation in trials of low-income beneficiaries. It also creates considerable administrative and financial complications for trial sponsors.

We are not aware of any clinical evidence supporting any limit on the number of beta amyloid PET scans whether the number is one or any other number. Central nervous system beta amyloid status can change over time and ongoing clinical trials for monoclonal antibodies have used the results of post treatment beta amyloid PET to inform a decision to discontinue mAb therapy.

We urge CMS to retire NCD 220.6.20. If CMS declines to do so, then the NCD should be revised to provide for coverage of beta amyloid PET at the discretion of the treating physician with no limitation on the number of scans covered per patient per lifetime.

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We look forward to continuing to work with CMS on establishing appropriate coverage for diagnostic and therapeutic services for AD patients. For additional information or if you have any questions, please contact Alanna Goldstein at agoldstein@americangeriatrics.org.

[1] Mintun MA, Lo A, Evans C, et al. Donanemab in Early Alzheimer's Disease. N ENGL J MED 2021: 384 (18): 1691 - 1704.