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May 30, 2023

Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1751–P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: Medicare Coverage of Beta Amyloid Positron Tomography in Dementia and Neurodegenerative Disease (NCD 220.6.20)

Dear Administrator Brooks-LaSure:

The Medical Imaging Technology Alliance (MITA) is writing to urge the Centers for Medicare & Medicaid Services (CMS) to provide coverage for beta amyloid positron emission tomography (PET) for Alzheimer's diseases. MITA represents companies whose sales comprise more than 90 percent of the global market for medical imaging technology, and we are the collective voice of PET and SPECT radiopharmaceutical developers, manufacturers, and distributors.

The agency has been reconsidering the National Coverage Determination (NCD) for Beta Amyloid Positron Emission Tomography (PET) since June 16, 2022, however, CMS has delayed release of the proposed decision based on newly published evidence. There is over a decade of utilization and further clinical data on beta amyloid PET sufficient to support Medicare coverage for beta amyloid imaging. Additionally, the Food and Drug Administration (FDA) has approved LEQEMBI™ (lecanemab-irmb) and is currently reviewing Phase III data for the potential traditional approval of LEQEMBI. We believe that it is critical for CMS to expeditiously finalize the reconsideration of the NCD and establish national coverage, to provide Medicare beneficiaries with access to beta amyloid PET imaging.

Beta amyloid PET has become a key tool in the diagnostic workup of dementia patients, and there is a considerable amount of published evidence that the use of beta amyloid imaging positively impacts patient management and leads to changes in diagnosis, even in the absence of

a disease modifying therapy. MITA and its members have a long history in the development of evidence on the clinical utility of beta amyloid PET imaging agents - to aid diagnosis and management and help identify patients for treatment with monoclonal antibodies for AD. For example, data from the Imaging Dementia—Evidence for Amyloid Scanning (IDEAS) Study support the importance of beta amyloid PET scans. The IDEAS investigators concluded that the use of Alzheimer's drugs was linked to amyloid status, finding that among patients with positive PET results, the overall use of Alzheimer's drugs in the population increased significantly, from 40.4% to 81.5% in patients with mild cognitive impairment (MCI) and from 63.2% to 91.2% in patients with dementia.[1]

Beyond the IDEAS study, at least 30 published studies involving more than 4,000 patients have reviewed the utility of beta amyloid imaging for the diagnostic assessment of patients evaluated for cognitive impairment in memory clinics. Altogether, the data developed over the past several years have consistently demonstrated that the knowledge of amyloid status adds value to the management of patients, minimizes misdiagnosis, reduces the risk of adverse events due to potentially inappropriate treatment, and informs decisions that may offer clinical benefit. Based on the evidence that beta amyloid PET imaging can improve health outcomes, it is appropriate for Medicare to provide coverage.

Furthermore, beta amyloid PET imaging plays an important role in identifying which patients would be appropriate candidates for treatment with anti-amyloid therapies, such as LEQEMBI™. We are concerned that the current Medicare coverage restrictions on diagnostic amyloid PET imaging will limit access to necessary patient testing and diagnosis. Candidates for amyloid-targeted therapies must be assessed to determine whether they actually have amyloid present in their brains. Currently, amyloid PET scans are the only non-invasive FDA-approved method for making this determination.

MITA respectfully recommends that CMS expeditiously finalize the open reconsideration of NCD 220.6.20 to establish national coverage of beta amyloid PET as supported by the clinical evidence. If CMS does not complete reconsideration prior to the potential approval by the FDA of LEQEMBI™ under traditional FDA pathway in July, beneficiaries will not have access to the appropriate diagnostic imaging test qualifying them for FDA-approved therapies.

We appreciate your consideration of this matter and will contact your office to schedule a meeting.

Sincerely,

Patrick Hope
Executive Director, MITA

[1] Rabinovici GDet al. JAMA. 2019.

MITA is the collective voice of manufacturers of medical imaging equipment, radiopharmaceuticals, contrast media, and focused ultrasound therapeutic devices. It represents companies whose sales comprise more than 90 percent of the global market for medical imaging innovations. These products include magnetic resonance imaging (MRI), medical X-Ray equipment, computed tomography (CT) scanners, ultrasound, nuclear imaging, radiopharmaceuticals, and imaging information systems. MITA Member company technologies are an important part of our nation's healthcare infrastructure and are essential for the screening, diagnosis, staging, managing and effectively treating patients with cancer, heart disease, neurological degeneration, and numerous other medical conditions.