

United States Senate

WASHINGTON, DC 20510

June 20, 2024

Ms. Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Administrator Brooks-LaSure:

We write to express our support for Medicare beneficiary access to Positron Emission Tomography (PET) and Single Photon Emission Computed Tomography (SPECT) scans. All PET and SPECT scans use diagnostic radiopharmaceuticals to enable physicians to more effectively diagnose diseases such as Alzheimer's, Parkinson's, advanced cardiovascular disease, and prostate cancer. These scans ensure that patients are put on the proper path for treatment of their medical condition, which saves Medicare's resources. We appreciate CMS's previous actions, which support patient access to PET and SPECT scans, including changes in coverage determinations, reimbursement to imaging centers, and a request for comments during the CY 2024 OPPTS Proposed Rule. We ask that you advance this work during the CY 2025 OPPTS process so that patients can receive these PET and SPECT scans more widely in the hospital outpatient setting.

Today, a new generation of precision radiopharmaceuticals are used in PET and SPECT imaging for targeted patient populations to identify and characterize specific disease states. In some cases, these are the only diagnostic tests for a disease; in other cases, they offer diagnostic advantages over previous generations of radiopharmaceuticals. The radiopharmaceutical is essential to the scan—without it, the scan cannot be performed.

Alzheimer's Disease illustrates the importance of these scans to patients and the impact CMS's payment policies have on the availability of PET scans. In Alzheimer's Disease, precision diagnostic radiopharmaceuticals are used to identify beta-amyloid plaque in the brain, which assists physicians in precisely diagnosing Alzheimer's disease. Because treatments are approved for use on people in the early stages of illness, delayed access to amyloid PET scans means more people lose the opportunity to qualify for treatment as their disease progresses. CMS's IDEAS study team noted that the use of PET scans changed patient care plans in 60.2% of patients initially characterized as having Mild Cognitive Impairment (MCI) and 63.5% of patients initially characterized as having dementia of an unknown cause¹. During their initial study, when payment was equal in all imaging settings, 140 hospital outpatient imaging facilities participated; during the NEW Ideas round, only 19 hospital outpatient imaging facilities participated due to decreased reimbursement as the radiopharmaceuticals had lost separate payment status.²

¹ New IDEAS Study Leadership team comment letter on the CY 2024 Proposed Rule "Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; etc" accessed at: <https://www.regulations.gov/comment/CMS-2023-0120-3315>

² Ibid

In addition to Alzheimer’s Disease, we have heard from patients and providers about similar access issues for patients seeking nuclear medicine scans for Parkinson’s Disease, prostate and other cancers, as well as certain cardiac conditions. We have heard about patients having to drive extremely long distances past several health systems to a provider who offers these scans. Physicians have also stated that they have needed to refer their patients outside their health system to receive the most accurate diagnostic scans due to the inadequacy of the packaged reimbursement methodology.

We appreciate that CMS has previously shown its commitment to ensuring beneficiary access to PET and SPECT scans. In the CY 2024 OPPTS Proposed Rule, CMS acknowledged that interested parties had raised concerns regarding policy packaging of diagnostic radiopharmaceuticals since 2008, when CMS began packaging radiopharmaceutical costs into the ambulatory payment classifications for the scans rather than separately paying for the specific radiopharmaceutical. In the proposed rule, CMS solicited comments on how changes to the current policy would impact beneficiary access and ensure equitable payment for providers. We understand that the overwhelming majority (137 out of 140) of stakeholder comments, which were posted to the CMS docket, favored separate payment for radiopharmaceuticals. However, the final CY 2024 OPPTS rule did not change how diagnostic radiopharmaceuticals are reimbursed.

In the upcoming CY 2025 rulemaking on HOPPS, we urge CMS to address packaging of payment for diagnostic radiopharmaceuticals. This action is critical to ensure that Medicare beneficiaries have access to appropriate care in their communities.

Sincerely,



Marsha Blackburn
United States Senator



Tammy Baldwin
United States Senator



Shelley Moore Capito
United States Senator



Tammy Duckworth
United States Senator



Cindy Hyde-Smith
United States Senator



Jon Tester
United States Senator



James Lankford
United States Senator



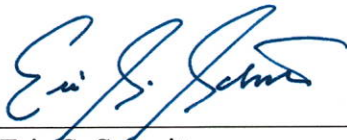
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