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Submitted electronically via www.regulations.gov

August 2, 2021

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: CMS-1751-P — CY 2022 Payment Policies under the Physician Fee Schedule

Dear Administrator Brooks-LaSure:

The Medical Imaging Technology Alliance (MITA) is writing in support of the Centers for Medicare & Medicaid Services' (CMS) proposal in the CY 2022 Physician Fee Schedule (PFS) Proposed Rule to retire section 220.6 of the National Coverage Determinations (NCD) Manual regarding positron emission tomography (PET) imaging. As discussed below, this change will provide for coverage of PET imaging using radiopharmaceuticals for non-oncologic indications at the discretion of the Medicare Administrative Contractors (MACs). MITA has worked with CMS on this policy over the past decade, and we commend CMS consideration of this issue and its proposal to modernize coverage for non-oncologic PET indications.

MITA believes that this jurisdictional change will improve beneficiary access to PET imaging for cardiac, neurologic, and other conditions, while reducing administrative burden on the agency to pursue numerous NCD reconsiderations. To date, PET has had more Medicare NCDs than any other technology over the past two decades. Additionally, the agency's proposed policy for non-oncologic PET imaging aligns with the current policy of MAC discretion for oncologic imaging. We strongly encourage CMS to finalize its proposal to retire section 220.6, and we offer recommended NCD Manual language for the agency's incorporation to clarify that this proposed retirement would not impact coverage of any PET imaging product that is currently covered under an NCD.

The Medical Imaging & Technology Alliance (MITA) represents companies whose sales comprise more than 90 percent of the global market for medical imaging technology. The PET Group within MITA is a collective voice of PET and SPECT radiopharmaceutical developers, manufacturers and distributors. Advances in nuclear medicine allow clinicians to more effectively identify and target disease thereby providing more options for treatment resulting in

better patient outcomes. Advances have been made in cancer, heart disease, Alzheimer's pathology and in other areas. In some cases, there are no alternative diagnostics.

Please note that MITA intends to submit a separate letter addressing other issues in the CY 2022 PFS Proposed Rule.

I. Background on CMS Coverage of PET

PET is the most extensively reviewed technology in CMS history, with 19 National Coverage Analyses (NCAs), including 8 reconsiderations, over the past 20 years. Beginning in December 2000, CMS established a broad national non-coverage policy for FDG PET.[1] Since 2004, Preamble language non-covering all PET not otherwise covered by NCD has been included in section 220.6 of the Manual. Section 220.6 of the NCD Manual states that in general, "a particular use of PET scans is not covered unless this manual specifically provides that such use is covered." However, it is important to note that this blanket non-coverage language was not established by an NCD.

In 2013, CMS updated its coverage policy for PET by removing national non-coverage for labeled oncologic uses of FDA-approved PET imaging agents and assigning coverage to MAC discretion. In its Decision Memorandum,[2] CMS made note of the improved technical performance of PET, the enhanced FDA regulation of nuclear medicine, and better reader training for those who interpret PET images. The agency also acknowledged stakeholder concerns that national non-coverage would "present a substantial barrier to beneficiary access to appropriate and well-validated diagnostic healthcare as new, rigorously-reviewed, FDA approved PET radiopharmaceuticals become available." To date, MACs have reviewed and established coverage for several new oncologic PET imaging agents.[3]

In the CY 2022 PFS Proposed Rule, CMS is proposing to retire section 220.6's language that maintains national non-coverage for non-oncologic PET imaging with radiopharmaceuticals where coverage is not established by a separate NCD. If this retirement is finalized, it will "allow local Medicare contractors to make a coverage determination under section 1862(a)(1)(A) of the Act for beneficiaries" with respect to non-oncologic PET imaging. No changes are proposed to any of the subsections of section 220.6 (i.e. the individual NCDs).

II. MITA Strongly Supports Retirement of Section 220.6

[1] Decision Memo for Positron Emission Tomography (FDG) (CAG-00065N), Dec. 15, 2000, *available at* https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=85&lcd_id=26751&lcd_version=18&basket=lcd%253A26751%253A18%253Ab%253E+Cardiac+Computed+Tomography+(CCT)+-+4X-53AB-R4%252Fb%253E%253AMAC+-+Part+A%253ATrailBlazer+Health+Enterprises%257C%257C+LLC+(04101)%253A&bc=gIAAAAAACCAA&.

[2] Decision Memo for Positron Emission Tomography (CAG-00065R2), Mar. 7, 2013, *available at* https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=261&type=Closed&bc=ACAAAAAAQAAA&.

[3] Novitas Solutions, Inc., for instance, has established coverage under L35391 (Multiple Imaging in Oncology), *available at* https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?lcdid=35391&ver=17&bc=CAAAAAAAAAAA.

A. Removal of National Non-Coverage will Protect Beneficiary Access to Imaging Technology

We strongly support the agency's proposal to retire its national non-coverage language for non-oncologic PET imaging in the CY 2022 PFS rulemaking. MITA agrees with CMS that "local contractor discretion provides an immediate avenue to potential coverage in appropriate candidates for non-oncologic indications," thereby removing restrictions on beneficiary access to well-validated PET imaging services when considered medically necessary by their physician.

As previously discussed, approximately a dozen new PET agents for non-oncologic indications are currently in FDA trials. Retiring the national non-coverage policy for non-oncologic indications when these new PET agents are approved will eliminate the need for beneficiaries to wait for CMS to individually evaluate each agent for coverage through a separate NCD reconsideration. This will avoid both a regulatory "bottleneck" leading to delayed Medicare beneficiary access to critical imaging services and the diversion of CMS resources better devoted to other categories of cutting-edge technologies that have not been subject to extensive review by the agency. For instance, with the retirement of the national non-coverage language in section 220.6, beneficiaries will be able to access FDA-approved PET radiopharmaceuticals FDOPA F 18 for Parkinson's Disease and TAUVID for Alzheimer's disease (AD) and other causes of cognitive decline (as long as they are not non-covered by local MACs). Both of these agents have been FDA-approved for more than a year but have remained nationally non-covered.

B. MAC Discretion Appropriate for Non-Oncologic PET Indications

MITA agrees with the agency that MAC discretion is appropriate for PET imaging for non-oncologic indications. As the agency notes in the Proposed Rule, MAC discretion is now feasible and desirable as "new non-oncologic PET agents have been approved by the FDA and multiple professional medical societies have published guidelines relevant to appropriate use of these agents." In addition, FDA review of PET radiopharmaceuticals has become substantially more in-depth over the past two decades, "shown by more stringent requirements for PET/CT diagnostic equipment, for approval of radiopharmaceuticals, and for demonstrating clinical utility of diagnostic services." The FDA has continued to refine its review of PET imaging agents as it has developed more experience with this technology. The FDA's approval of non-oncologic products includes validated reader training.

Furthermore, as required under § 218(b) of the Protecting Access to Medicare Act of 2014 (PAMA), CMS has developed a program to promote "Appropriate Use Criteria" (AUC) for advanced diagnostic imaging services, including PET. This program requires physicians and practitioners ordering advanced diagnostic imaging services to use a qualified electronic portal at the time of order to determine whether the service to be ordered meets AUC developed by one or more specialty societies or other provider-led entities. AUC consultations under the program become required January 1, 2022 and have been voluntary since 2018.

The implementation of § 218(b) of PAMA has led to the development of AUCs for PET imaging for multiple non-oncologic indications. These AUCs supplement the clinical guideline infrastructure, with the added safeguard that most physicians in Medicare will soon be required

to consult the AUC before ordering PET imaging services. This joint utilization control infrastructure will both inform MAC coverage policies of non-oncologic PET and provide a backstop against inappropriate utilization.

III. Recommended Revisions to Section 220.6

To provide clarity to MACs and providers, MITA believes the Medicare Manual should make clear that this proposed retirement would not impact coverage of any PET imaging product that is currently covered under an NCD. We recommend the below revision to section 220.6 of the NCD Manual to operationalize the retirement of national non-coverage language for PET.

> ***NOTE: This manual section, 220.6 lists all nationally Medicare-covered uses of PET scans.*** ~~***Except as set forth below in cancer indications listed as "Coverage with Evidence Development," a particular use of PET scans is not covered unless this manual specifically provides that such use is covered. Although this section, 220.6 lists some non-covered uses of PET scans, it does not constitute an exhaustive list of all non- covered uses.***~~
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> ~~***Effective for dates of service on or after March 7, 2013, MACs may determine coverage within their respective jurisdictions for positron emission tomography (PET) using radiopharmaceuticals***~~ **that are not otherwise non-covered by a NCD** ~~***for their Food and Drug Administration (FDA) approved labeled indications for oncologic imaging.***~~ **Effective for dates of service on or after March 7, 2013, for oncologic imaging and January 1, 2022 for non-oncologic imaging.**

IV. Conclusion

MITA recognizes the welcome attention CMS has given to issues of PET coverage in recent years, and strongly supports the agency's proposal to allow coverage for PET using radiopharmaceuticals for non-oncologic imaging at the discretion of the MACs. We agree with the agency that this proposed framework better serves the needs of the Medicare program and its beneficiaries. We encourage CMS to finalize its proposed retirement of section 220.6 of the NCD Manual and have offered revisions to accomplish that goal with minimal changes to the Manual.

MITA strongly supports the agency's attention to these important issues and its work to streamline coverage for innovative items and services to improve health outcomes for Medicare beneficiaries. If you have any questions or would like additional information, please contact Sue Bunning at sbunning@medicalimaging.org or (703) 340-4100.

Sincerely,

Patrick Hope
Executive Director, MITA

MITA is the collective voice of medical imaging equipment and radiopharmaceutical manufacturers, innovators and product developers. It represents companies whose sales comprise more than 90 percent of the global market for medical imaging technology. These technologies include: magnetic resonance imaging (MRI), medical X-Ray equipment, computed tomography (CT) scanners, ultrasound, nuclear imaging, radiopharmaceuticals, and imaging information systems. Advancements in medical imaging are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. The industry is extremely important to American healthcare and noted for its continual drive for innovation, fast-as-possible product introduction cycles, complex technologies, and multifaceted supply chains. Individually and collectively, these attributes result in unique concerns as the industry strives toward the goal of providing patients with the safest, most advanced medical imaging currently available.