SOCIETY OF NUCLEAR MEDICINE AND MOLECULAR IMAGING

AMERICAN SOCIETY OF NUCLEAR CARDIOLOGY

ACR AMERICAN COLLEGE OF RADIOLOGY

AMERICAN COLLEGE OF CARDIOLOGY

January 11, 2013

Louis Jacques, M.D.
Director, Coverage and Analysis Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Proposed Decision Memo for Positron Emission Tomography (CAG-00065R2)

Dear Dr. Jacques:

The Society of Nuclear Medicine and Molecular Imaging (SNMMI), the American College of Radiology (ACR), the American College of Cardiology (ACC) and the American Society of Nuclear Cardiology (ASNC) appreciate the opportunity to share our comments on the Centers for Medicare & Medicaid Services (CMS) recent proposed decision memo for positron emission tomography (PET) (CAG-00065R2). This proposal would remove the national non-coverage decision for PET for FDA-approved oncologic applications. While we believe this to be a step in the right direction, we do not think it is comprehensive enough. We respectfully request that CMS modify the proposed decision and finalize that local Medicare Administrative Contractors (MACs) may determine coverage within their respective jurisdictions for positron emission tomography (PET) using radiopharmaceuticals for their labeled indications that are approved by the FDA. The effect of this decision, with change, would be to remove the national non-coverage for any future PET radiopharmaceuticals that have not been more specifically determined nationally. Thus this change would not apply to any use of PET using radiopharmaceuticals FDG (2-deoxy-2-[F-18] fluoro-D-Glucose (fluorodeoxyglucose)), NaF-18 (fluorine-18 labeled sodium fluoride), ammonia N-13, or rubidium Rb-82. This would not prevent CMS from determining national coverage for any of these uses in the future, and if such determinations are made, a future determination would supersede local contractor determinations under §1862(a)(1)(A) of the Social Security Act (the Act).

SNMMI, ACR, ACC, and ASNC previously supported the Medical Imaging Technology Alliance's (MITA) letter that requested a limited revision of the PET national coverage determination (NCD) which would maintain the integrity of the NCD for tracers reviewed within, but would foreclose the inappropriate extension of non-coverage to new FDA-approved tracers that have not received even minimal review by the agency. As a result, we believe CMS's recent proposal, which would allow local Medicare administrative contractors to determine coverage for new oncologic agents for PET within their respective jurisdictions, to be a positive step.

However, we believe this proposal is too limited, and should not be confined to oncologic applications. In our previous letter, dated August 10, 2012, the societies provided examples of how this policy would be beneficial to additional indications, such as clinical cardiac PET. Unless there are specific national restrictions, we believe CMS should expand this proposal beyond oncology to cover all areas. The MACs' expanded authority in this area does not preclude further CMS action. CMS would have the option to specifically exclude indications and products when necessary. Finally, the lengthy process to update national coverage generally requires over a year to complete. The proposed decision memorandum will unnecessarily/unintentionally delay coverage to Medicare patients who would benefit from new FDA-approved indications.

We remain committed to working with CMS and other stakeholders in creating a clear and open dialogue to provide peer-reviewed information for new PET radiopharmaceuticals. Additionally, we plan to work with other organizations to develop educational resources to help ensure appropriate utilization of PET/computed tomography by referring physicians, as well as nuclear medicine physicians and radiologists.

We appreciate your consideration of our recommendations. Should you have any questions, please contact Sue Bunning, Director of Health Policy and Regulatory Affairs at sbunning@snmmi.org or (703) 326-1182.

Respectfully Submitted,

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