

September 24, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS1695-P
P.O. Box 8013
Baltimore, MD 21244-1850

Submitted electronically via: regulations.gov

Re: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model CMS - 1695-P

Dear Ms. Verma:

We are writing in response to the 2019 Hospital Outpatient Prospective Payment System (HOPPS) Proposed Rule. The Society of Nuclear Medicine and Molecular Imaging's (SNMMI) more than 15,000 members set the standard for molecular imaging and nuclear medicine practice by creating guidelines, sharing information through journals and meetings, and leading advocacy on key issues that affect molecular imaging and therapy, research and practice.

The American College of Nuclear Medicine (ACNM) is a professional organization that directly represents the interests of nuclear medicine physicians before legislative and regulatory bodies, other medical organizations, the media and general public. Our goal is to assure a legislative, legal, regulatory and economic framework that encourages and makes practicable the safe, appropriate use of nuclear medicine procedures to improve the quality of health care service available to patients.

We appreciate the opportunity to provide comments to assist the Centers for Medicare and Medicaid Services (CMS) in further refining the HOPPS. Our comments focus on the following areas.

- Nuclear Medicine APC placements

- Radiopharmaceuticals on Pass-through List
- Impact of Proposed Pass-through changes on CMS Approved Coverage with Evidence Studies
- Add-on Payments for non-LEU Sourced Radiopharmaceuticals

Nuclear Medicine APC Payments

We believe that the current APC groupings are appropriate. We appreciate that CMS has not proposed any changes. We recommend that the current status be maintained.

Radiopharmaceuticals on Pass-through List

CMS is proposing to remove three important radiopharmaceuticals from pass-through status at the beginning of 2019. We urge CMS not to remove these radiopharmaceuticals from pass-through status to maintain patient access to these important diagnostic tools.

Radiopharmaceuticals are not interchangeable items in diagnostic imaging. Each of these three is the state-of-the-art diagnostic tool for particular diseases and alternatives are far less accurate. The three involved radiopharmaceuticals are:

Choline C11 (A9515) Geometric Mean Unit Cost - \$3,503.88
Flutemetamol F18 (Q9982) Geometric Mean Unit Cost - \$1,183.76
Florbetaben F18 (Q9983) Geometric Mean Unit Cost - \$1,890.95

All three of these radiopharmaceuticals will be rolled into the nuclear medicine APC payment rates but these payment rates are all less than \$1,400. This means that facilities will have to spend all (or nearly all) of that reimbursement to pay for the radiopharmaceuticals involved in these studies (and sometimes more or even more than double). That is untenable for many facilities and they will simply stop offering patients these important diagnostic tests.

Similar problems with drugs going off the pass-through list in 2018 resulted in legislation overriding CMS's removal of drugs from the pass-through list and providing a two-year moratorium on their removal from the pass-through list. The Government Accountability Office is studying this CMS policy and will be making recommendations to Congress in 2020 about how to resolve these problems. SNMMI strongly suggests that CMS stop withdrawing radiopharmaceuticals from the pass-through list at least until it considers GAO's recommendations.

Impact of Proposed Pass-through changes on CMS Approved Coverage with Evidence Studies

Three radiopharmaceuticals are being evaluated in CMS approved dementia trials and their pass-through status varies. Enrollment in one of those trials has stopped but other trials are being considered. Having radiopharmaceuticals move off pass-through, get back on it for two

years and then being taken off again complicates those studies may new trial impossible to conduct.

Physicians should be able to maintain the ability to choose which diagnostic radiopharmaceutical is used on their patient, not based on which is separately paid. CMS's policies should not favor one company's radiopharmaceutical over others.

The three radiopharmaceuticals in this amyloid PET trial are used to detect levels of amyloid in the human brain. They are Amyvid™ (florbetapir F18), Neuraceq™ (florbetaben F18) and Vizamyl™ (flutemetamol F18). Amyvid™ (florbetapir F18) went off the pass-through list on January 1, 2018 but legislation put it back on pass-through for two years effective October 1, 2018. CMS is now proposing to remove the other two from pass-through status effective January 1, 2019.

Therefore, the SNMMI recommends CMS use their authority to pay for these three by either:

1. Continuing pass-through for all three,
2. Separately paying for all three with individual APCs, or
3. Creating an amyloid APC group and pay for all three as an averaged payment.

Add-on Payments for non-LEU Sourced Radiopharmaceuticals

We have concerns with CMS's payments for the additional costs of radioisotopes produced from non-Highly Enriched Uranium (HEU) sources.

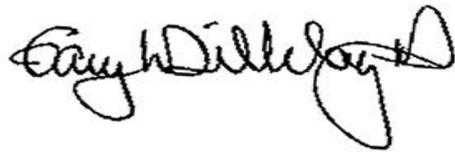
While the text of the Proposed Rule indicates that CMS will continue these payments, the addendum B posting for Q9969 is listed with a status N, packaged. This would deny add-on payments for non HEU sourced radiopharmaceuticals billed with Q9969. We request that CMS clarify this policy and continue the add-on payments by correcting the information in Addendum B.

We appreciate the opportunity to comment on the HOPPS CY 2019 Proposed Rule to CMS. As always, we are ready to discuss any of its comments or meet with CMS on the above issues. In this regard, please contact Wayne Powell by email at wpowell@snmmi.org or by phone at 703-326-1128.

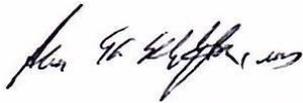
Respectfully Submitted,



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President, SNMMI



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