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Deputy Administrator (Acting)  
Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
Room 445-G, Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

**ATTN: FILE CODE CMS-1392-P**

**Re: Medicare Program: Proposed Changes to the Hospital Outpatient  
Prospective Payment System and CY 2008 Payment Rates; PET/CT  
Scans; OPPS: Packaged Services**

Dear Mr. Kuhn:

The Academy of Molecular Imaging (AMI) is pleased to have the opportunity to comment on the CY 2008 Hospital Outpatient Prospective Payment System proposed rule, CMS-1392-P (the proposed rule). AMI is comprised of academicians, researchers and nuclear medicine providers utilizing molecular imaging technologies, including positron emission tomography (PET) and PET with computed tomography (PET/CT). AMI serves as the focal point for molecular imaging education, training, research and clinical practice through its annual scientific meeting, its educational programs, and its Journal, *Molecular Imaging & Biology*. AMI speaks for thousands of physicians, providers, and patients with regard to this lifesaving technology, and has worked closely with CMS over the past three years to increase beneficiary access to both standard PET and PET/CT through the development of the National Oncologic PET Registry (NOPR).

### Summary

AMI believes that CMS's proposal to reassign PET/CT from a new technology Ambulatory Payment Classification (APC) to APC 308 is inappropriate and unsupported by reliable cost data. By assigning both PET and PET/CT to the same APC, CMS fails to recognize that PET/CT is a clinically distinct technology from conventional PET, with unique clinical benefits. Unlike traditional PET scans, PET/CT is a developing, state-of-the-art technology that will continue to be refined in coming years. The proposed reassignment of PET/CT would risk limiting beneficiary access to a service that now represents the standard of care for most oncology patients.

AMI also urges CMS to continue to pay separately for all diagnostic and therapeutic radiopharmaceuticals that are above the threshold for separate payment. CMS's proposal to bundle all diagnostic radiopharmaceuticals into procedural APCs will

not result in appropriate payment for certain clinically appropriate radiopharmaceuticals and nuclear medicine procedures.

### **Background on Medicare Payment for PET/CT**

PET/CT procedures are identified by three CPT codes (78814, 78815, and 78816). In 2005 and 2006, these codes were assigned to New Technology APC 1514 and the payment rate was \$1,250.

For CY 2007, CMS proposed to assign PET/CT to the same clinical APC as traditional PET. However, based on public comments and a concern regarding the accuracy of cost data, the CY 2007 final rule assigned PET/CT to a separate, new technology APC (1511) that paid \$950, approximately \$100 greater than a single PET scan.

In the current proposed rule, CMS again proposes placing PET/CT in the same clinical APC as traditional PET (0308). In the discussion, CMS states that PET and PET/CT “have obvious clinical similarity.” AMI disputes this characterization.

### **Assign PET/CT to a Separate Clinical APC**

PET and PET/CT are clinically distinct technologies that should be classified separately under the APC system. Separate assignment for these technologies is supported by both Medicare regulations and the differences in the technologies.

As CMS notes, all of the items and services within a given APC group must be “comparable clinically and with respect to resource use.” With regard to CMS’s determination of a clinically appropriate APC, the agency has stated:

After we gain information about actual hospital costs incurred to furnish a new technology service, we will move it to a clinically-related APC group with comparable resource costs. If we cannot move the new technology service to an existing APC because it is dissimilar clinically and with respect to resource costs from all other APCs, *we will create a separate APC for such service.* (65 FR 18476, 18478 (April 7, 2000))

The combination of PET and CT into a single device, known as a PET/CT, represents a clinical breakthrough in imaging. The integration of the two scans provides the most complete non-invasive information available about cancer location and metabolism. PET/CT identifies and localizes tumors more accurately than either of the component images taken alone. In addition, PET/CT technologists can perform both scans without having to move the patient. The resulting images thus leave less room for error in interpretation.

The benefits of PET/CT to the patient are tremendous: earlier diagnosis, more accurate staging, more precise treatment planning, and better monitoring of therapy. A PET/CT image can distinguish between malignant and benign processes, and reveal tumors that may otherwise be obscured by the inflammation and fibrosis that result from therapies such as surgery, radiation,

and drug administration. PET/CT images often reduce the number of invasive procedures required during follow-up care, including biopsies, and may reduce the number of anatomical scans needed to assess therapeutic response. In some cases, the images are so precise that they can locate an otherwise undetectable tumor. For all of these reasons, PET/CT now represents the standard of care for most oncology patients.

FDA has consistently concluded in both premarket approvals and its regulations that PET/CT is a distinct medical device from PET. New PET/CT devices are specifically cleared by FDA for marketing under the 510(k) process on the basis of currently marketed (or predicate) PET/CT devices, not PET devices.

Moreover, PET/CT technology represents the state of the art imaging for oncology patients. Although CMS has found that 2006 claims data indicates similar resource costs for PET and PET/CT, it is likely that over the next few years the costs of PET/CT relative to PET will continue to diverge. No manufacturers are currently developing new PET scanners. As new PET/CT technologies are developed with different costs from PET, the resource dissimilarity will require a separate clinical APC for PET/CT.

### **Continue Separate Payment for Diagnostic Radiopharmaceuticals**

In the proposed rule, CMS proposes packaging diagnostic radiopharmaceuticals into the payment for diagnostic nuclear medicine procedures, including PET and PET/CT, for CY 2008. AMI believes that it is inappropriate to treat diagnostic radiopharmaceuticals differently from other drugs and that claims data may not accurately reflect radiopharmaceutical costs, resulting in inappropriately low payments for PET and PET/CT.

CMS has traditionally paid separately for diagnostic radiopharmaceuticals that meet the cost threshold for packaging of drugs and biologicals under the OPPI. In the proposed rule, CMS proposes to package payment for all diagnostic radiopharmaceuticals, regardless of the per day cost. In the context of this proposal, CMS has argued that they see “diagnostic radiopharmaceuticals . . . functioning effectively as supplies that enable the provision of an independent service.”

AMI believes that this is an inappropriate way to characterize radiopharmaceuticals used in PET/CT scans. Radiopharmaceuticals are unique drugs, and not supplies. Radiopharmaceutical such as FDG clearly qualify under the Medicare statute as specified covered outpatient drugs, and should be paid separately, consistent with the treatment of other drugs and biologicals. This methodology for drug payments is important to ensure that physicians are given the flexibility to use the most appropriate drugs for the clinical circumstances.

Although fluorodeoxyglucose (FDG) is commonly used in PET/CT scans, there are numerous radiopharmaceuticals in development that will be used with PET/CT in the near future. Packaging of radiopharmaceuticals into the PET/CT and PET APCs will undermine the resource homogeneity of the procedure APCs which can involve the use of several different radiopharmaceuticals with widely varying costs. As new drugs for PET/CT come to market, providers will experience substantial resource variation for PET/CT scans based on the different

costs for various radiopharmaceuticals. If CMS packages the costs of radiopharmaceuticals into the procedure APCs, this will be a substantial disincentive for the development of new and better drugs, which will limit research and development of better products.

The packaging approach threatens to undermine CMS's efforts to establish accurate payment for both nuclear medicine procedures as well as radiopharmaceuticals. AMI disagrees with CMS's assertion that the line item estimated costs in CMS "claims data offer an acceptable proxy for average hospital acquisition cost and associated handling and preparation costs for radiopharmaceuticals." Accurate cost data for diagnostic radiopharmaceuticals are needed to set appropriate payment rates, and AMI is concerned that implementation of diagnostic radiopharmaceutical revenue codes have not yet enabled accurate isolation of radiopharmaceutical data and average acquisition costs. CMS claims data may fail to accurately reflect higher cost radiopharmaceuticals. Other methodologies for determining average acquisition cost are more appropriate and accurate.

Finally, the packaging proposal may also raise operational difficulties for providers. CPT and HCPCS Level II coding nomenclature is silent to the indication for each nuclear medicine procedure. Combining these separate codes into one package would create an unnecessarily complex coding system for nuclear medicine procedures. Moreover, combining the costs of these separate codes may create wide variations in costs based on individual patient requirements and physician practices.

AMI requests that CMS continue to pay separately for all radiopharmaceuticals that meet the cost thresholds for drugs and biologicals. We also specifically encourage CMS to work with the Society for Nuclear Medicine, which has done extensive research regarding radiopharmaceutical acquisition costs.

### **Conclusion**

AMI appreciates CMS's continuing efforts to ensure accurate payment for molecular imaging technologies that do not discourage physicians from using the most appropriate tools for their patients. In the final rule, AMI respectfully requests that CMS assign PET/CT to a separate clinical APCs, and continue to pay separately for radiopharmaceuticals that meet the standard cost threshold.

Please do not hesitate to contact me if you would like to discuss these issues further.

Sincerely,



Johannes Czernin, M.D.  
President  
Academy of Molecular Imaging