SOCIETY OF NUCLEAR MEDICINE & MOLECULAR IMAGING

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August 21, 2024

Ms. Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
ATTN: CMS-1809-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: [CMS-1809-P] Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; etc.

Dear Administrator Brooks-LaSure:

We at the Society of Nuclear Medicine and Molecular Imaging (SNMMI) are writing in response to the calendar year (CY) 2025 Hospital Outpatient Prospective Payment System (OPPS) Proposed Rule.[1] SNMMI's 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. We appreciate the opportunity to provide comments to assist the Centers for Medicare & Medicaid Services (CMS) in further refining the OPPS payment policies.

We focus our comments on the unpackaging proposal regarding diagnostic radiopharmaceuticals – a policy of great concern and importance to our members. The SNMMI applauds the agency for its proposal and appreciates CMS' continued engagement with interested parties on this issue. We provide comments about the specific elements of the proposal below, as well as provide input on specific proposed new technology Ambulatory Payment Classification (APC) assignments.

I. CMS Should Finalize Unpackaging Diagnostic Radiopharmaceuticals

CMS proposes to unpackage and pay separately for diagnostic radiopharmaceuticals with per day costs that exceed a threshold of $630, recognizing that there are situations in which the nuclear medicine APC payment may not be adequate and could deny access to diagnostic tools for which there is not a clinical alternative. The SNMMI commends the agency for recognizing the need to pay separately for certain diagnostic pharmaceuticals and addressing the long-standing concerns of interested parties about beneficiary access to nuclear medicine procedures. If finalized, this

[1] 89 Fed. Reg. 59186 (July 22, 2024).

policy will help to reduce financial barriers that may be restricting the ability of many hospitals to offer certain diagnostic services.

We continue to believe that diagnostic radiopharmaceuticals are unique and distinguishable from ordinary supplies. Indeed, such products are a critical element of the nuclear medicine procedure and not interchangeable – the selection of the radiopharmaceutical(s) affects the amount and specificity of the information obtained through the imaging component. The SNMMI is pleased that CMS proposes to provide separate payment for diagnostic radiopharmaceuticals with per day costs above a threshold amount in a manner like other drugs. We firmly believe this is a sound policy and will ensure that opportunities for innovation will not be stifled and will improve beneficiary access to needed services. The SNMMI strongly urges CMS to finalize the unpackaging of diagnostic radiopharmaceuticals with high per -day costs under the OPPS.

A. The SNMMI Recommends that CMS Adopt the Alternative Packaging Threshold Amount of $550 Amount

For CY 2025, CMS proposes to pay separately for diagnostic radiopharmaceuticals with per day costs that exceed a threshold of $630. This threshold is based on double the weighted average offset amount for policy-packaged drugs across all four nuclear medicine APCs ($314). CMS also proposes to update the threshold amount in CY 2026 and subsequent years by the Producer Price Index (PPI) for Pharmaceuticals for Human Use, which is the same update factor applied to the drug packaging threshold under the OPPS.

The agency reasons the proposed threshold would ensure that separate payment would only apply to diagnostic radiopharmaceuticals that have costs significantly in excess of the payment amount included in the nuclear medicine APC payment and, therefore, present a significant financial loss to hospitals. CMS indicates that the proposed multiplier of 2.0 is conceptually consistent with the two-times rule it already applies in assigning APCs and in identifying combinations of codes assigned to comprehensive APCs that quality for the complexity adjustment. CMS also seeks comment on whether an alternative multiplier such as 1.75, should be applied instead, resulting in a threshold of $550.[2] CMS notes that the 1.75 multiplier it considered is used to identify high-cost outliers under the OPPS.

The SNMMI appreciates CMS' thoughtful approach to identifying an appropriate packaging threshold amount for diagnostic radiopharmaceuticals, including a potential alternative. We agree that it is important to consider the amount packaged into the payment for the procedure in order to identify those products for which hospitals are incurring a significant financial loss. The SNMMI believes both approaches CMS sets forth, the $630 and $550 thresholds, are consistent with existing OPPS payment policies and would identify products that we believe should be appropriate to be paid separately.

In response to CMS' request for input on an alternative, the SNMMI recommends that CMS adopt a packaging threshold amount of $550 using a multiplier of 1.75. This multiplier aligns with the methodology that CMS uses to identify *cases with unusually high costs* that qualify for additional

[2] 89 Fed. Reg. 59216.

outlier payments and it is appropriate to use for identifying high-cost diagnostic radiopharmaceuticals that would qualify for separate payment. **While we support the proposed threshold of $630 using a 2.0 multiplier, we believe the alternative threshold of $550 using 1.75 better identifies products that are high-cost outliers and should be paid separately.**

To evaluate the potential alternative 1.75 multiplier that CMS raised in the proposed rule, the SNMMI reviewed claims data posted on the CMS website. Using the Drug Blood and Brachy costs statistics file, updated 7-24-2024, we identified per day costs of diagnostic radiopharmaceuticals by using the arithmetic MUC column multiplied by the units per day and then sorted all diagnostic radiopharmaceuticals from largest to smallest per day costs. We identified the same 26 diagnostic radiopharmaceuticals that met the $630.01 threshold to qualify for separate payment as CMS identified in the proposed rule in Table 5. Setting aside not otherwise classified (NOC) codes, the SNMMI identified 8 diagnostic radiopharmaceuticals, based on our experience with actual costs for these tracers, should be separately payable diagnostic radiopharmaceuticals. Of those 8 products, 4 have per day costs that would exceed a threshold of $550.

Based on our analysis, we believe a multiplier of 1.75 rather than 2.0 is a more appropriate threshold to ensure that appropriately high-cost diagnostic radiopharmaceuticals are separately paid for under the OPPS. Given, as CMS notes, that a multiplier of 1.75 would mirror that used for the outlier policy, we agree that it would be a reasonable alternative to use and would add only four additional (low volume and high cost) diagnostic radiopharmaceuticals to the separately payable status.

We note that our experts believe that there are four other products that we would expect to qualify for separate payment. However, the per day cost for those products calculated using MUC rather than an external cost estimate such as ASP do not exceed either the proposed or alternative cost threshold. We urge CMS to consider using ASP data, when available, in making the separate payment determination in the future.

Regarding the use of the PPI to annually update the packaging amount established for 2025, the SNMMI supports the use of the same update factor that is used under the drug packaging policy. Accordingly, we recommend that CMS finalize the use of the PPI as an update for CY 2026 and subsequent years.

B. SNMMI Supports the Proposed Payment Methodology Using Mean Unit Cost (MUC), but Recommends CMS Average Sales Price (ASP) Data in Unique Circumstances in CY 2025 and More Broadly in Future Years

1. Payment Methodology for Proposed Separately Payable Diagnostic Radiopharmaceuticals

CMS proposes to determine the payment amount for separately payable diagnostic radiopharmaceuticals based on the MUC calculated from Medicare claims data. Specifically, to determine the cost per day, CMS would multiply the arithmetic MUC by the average number of units per day (calculated for each Healthcare Common Procedure Code System (HCPCS) code

from Medicare claims data). Based on its analysis, CMS proposes to pay separately for 26 diagnostic radiopharmaceutical products.

The agency also discusses its concerns about basing payment on ASP, wholesale acquisition cost WAC), and average wholesale price (AWP). CMS does, however, state that it seeks comment on unique situations in which it still may be appropriate for CMS to use ASP information to assess per day costs and payment amounts for diagnostic radiopharmaceuticals for CY 2025. As an example, the agency notes that "one unique situation could be continuing the use of ASP for a particular HCPCS code once its pass-through status has ended, if the HCPCS code was actively being paid based on ASP while on pass-through status."[3]

The SNMMI acknowledges CMS' preference for basing CY 2025 payment rates for diagnostic radiopharmaceuticals on the MUC estimate from claims data. We are in support of that methodology for 2025, but respectfully note that there are some drawbacks to its use. In particular, MUC is calculated using cost-to-charge ratios (CCRs) that reflect the relationship between charges and costs for a wide range of items and services. The CCRs may not be well suited to accurately estimate the cost of an individual item and are based on cost data that are often years out of date because of the lag between when costs are incurred and when they are reported to Medicare on cost reports. In contrast, ASP data are updated on a quarterly basis and provide a much more current and specific estimate of the actual cost of a product to a hospital. Consequently, we recommend that in future years, CMS consider evolving its policy and using MUC only when ASP is not available.

We agree with CMS that there are unique circumstances where it may be appropriate to use ASP information in CY 2025. We agree with the particular scenario CMS identified in the proposed rule and urge the agency to use ASP for a particular HCPCS code once pass-through ends, where such code was actively being paid based on ASP data while on pass-through status. Use of ASP in this unique circumstance will provide consistency for such products coming off pass-through and is reasonable given the availability of ASP data. The SNMMI also supports manufacturers working with CMS to provide this important ASP data following the "per patient" methodology and that may include a "bona fide service fee." We believe that once CMS has this data, it will well represent the cost to hospitals of important diagnostic radiopharmaceuticals.

2. Annual Determination

The agency proposes to annually determine which diagnostic radiopharmaceuticals qualify for separate payment through the OPPS rule and further indicates it would use the same policies it applies to threshold packaged drugs in assessing the packaged status of diagnostic radiopharmaceuticals in the final rule for CY 2025. We note that the cost-based packaging determination for diagnostic radiopharmaceuticals differs in significant ways from the otherwise applicable drug packaging determination and we do not believe that the same rules should be applied.

[3] 89 Fed. Reg. 59220.

For 2025, the agency proposes to use the MUC in calculating the per day cost for diagnostic radiopharmaceuticals whereas the drug packaging determination relies on an external source of product cost by using ASP. In addition, because the drug packaging threshold is much lower than the proposed threshold for diagnostic radiopharmaceuticals, most drugs are paid separately and the packaging rules are likely to default to separate payment. In contrast, all diagnostic radiopharmaceuticals are currently packaged in 2024, and therefore, the proposed packaging rules will likely result in continued packaging if there is a change in the mean cost estimate from the proposed to the final rule. This creates considerable uncertainty around packaging, particularly for low-volume products. In light of this, we recommend that CMS not apply the proposed packaging rules in 2025 and pay separately for any product that was proposed for separate payment or that exceeds the cost threshold in the final rule data. CMS should only consider applying its proposed methodology after the separate payment threshold has been in effect for a reasonable period of time.

CMS also proposes that only diagnostic radiopharmaceutical HCPCS codes that are identified as separately payable in the final rule with a comment period would be subject to quarterly updates.[4] It is not clear how this concept aligns with MUC-based payment, which we expect would be established annually as part of the rulemaking process. The SNMMI requests that CMS further clarify this statement in the proposed rule.

C. Comment Solicitation on ASP Data

The SNMMI is sensitive to CMS' concerns expressed in the proposed rule that it does not believe the limited amount of ASP information submitted currently is adequate for the purposes of determining separate payment for the few products that currently do report ASP. We are pleased that CMS also sees the potential value in the use of ASP data for payment purposes for diagnostic radiopharmaceuticals when reported by all manufacturers who manufacture a product that is described by a given HCPCS code. Moreover, CMS states that "the use of ASP information for OPPS payment could provide an opportunity to improve payment accuracy for separately payable diagnostic radiopharmaceuticals by applying an established methodology that has already been used successfully under the OPPS for separately payable drugs and biologicals, as well as therapeutic radiopharmaceuticals." [5] We strongly agree that the use of ASP information could provide an opportunity to further improve the accuracy of the per day cost calculations and separate payment amounts for diagnostic radiopharmaceuticals.

In the proposed rule, CMS specifically solicits comment on the potential use of ASP in the future and indicates a desire to engage with interested parties to learn about the unique aspects and challenges that may be associated with such data for these types of products.[6] In particular, the agency requests comment on whether interested parties believe CMS should require payment for diagnostic radiopharmaceuticals based on ASP in the future, such as in CY 2026 rulemaking, and the confidence of interested parties in their reporting abilities. We appreciate CMS' willingness to

[4] 89 Fed. Reg. 59217.
[5] 89 Fed. Reg. 59219.
[6] Id.

further engage on this issue and obtain feedback on the use of ASP in the future. The SNMMI welcomes the opportunity to share its thoughts.

We agree with many of the points the agency raises about the value of ASP data and how its use with regard to the proposed unpackaging policy for diagnostic radiopharmaceuticals would ensure consistency with separately payable drugs under the OPPS, including therapeutic radiopharmaceuticals. In particular, we believe that ASP better reflects the actual cost of a particular radiopharmaceutical than MUC cost because it is product-specific, reflects discounts, and is updated quarterly.

As for CMS' concerns that submission of ASP data is currently voluntary for diagnostic radiopharmaceuticals, we believe that paying based on ASP for high-cost products will create a significant incentive for additional manufacturers to report ASP data. We see it as a viable source of payment data in the future. We also appreciate CMS' discussion of the issues related to ASP reporting for radiopharmaceuticals, particularly in relation to the patient-ready dose. We urge CMS to work with manufacturers to identify and resolve any additional issues that may limit the ability to report radiopharmaceutical sales pricing data. We encourage CMS to continue to engage interested parties on the use and reporting of ASP data. In light of this comment solicitation on ASP, the SNMMI recommends that, in future years, the agency consider using ASP in lieu of MUC when ASP data is available. As noted above, we urge CMS to adopt the use of ASP in unique circumstances in 2025.

II. CMS Should Finalize the Proposed New Technology APC Assignments for Myocardial Positron Emission Tomography (PET)/Computed Tomography (CT) Studies (APCs 1520 and 1522)

For CY 2025, CMS proposes to use CY 2023 claims data to determine OPPS payment rates for PET-CT services (CPT codes 78431, 78432, and 78433).[7] CMS proposes to assign CPT code 78431 to APC 1522 (New Technology–Level 22 ($2,001-$2,500)) with a payment rate of $2,250.50 for CY 2025. CMS proposes for CY 2025 to reassign CPT code 78432 to APC 1521 (New Technology–Level 21($1,901-$2,000)) with a payment rate of $1950.50. And for CPT code 78433, CMS proposes to reassign to APC 1522, with a payment rate of $2,250.50. **The SNMMI supports these proposed assignments and recommends that CMS finalize as proposed.**

III. CMS Should Finalize the Proposed Creation of a New G Code to Report Tc-99m Derived from domestically Produced Mo-99

[7] CPT 78431 *Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan*; CPT 78432 *Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (e.g., myocardial viability);* CPT 78433 *Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (e.g., myocardial viability); with concurrently acquired computed tomography transmission scan.* 89 Fed. Reg. 592610-59261 (Table 18).

Since CY 2013, CMS' policy has been to provide an additional payment of $10 for the added cost for radioisotopes produced by non-highly enriched uranium (HEU) sources.[8] Hospitals have been reporting HCPCS code Q9969 *Tc-99m from non-highly enriched uranium source, full cost recovery add-on, per study dose* once per dose along with any diagnostic service furnished using Tc-99m as long as the Tc-99m doses used can be certified by the hospital to be at least 95 percent derived from non-HEU sources. CMS extended this policy through CY 2024 . We thank CMS for recognizing and extending this code through CY 2024 and understand that it will be sunset on December 31, 2024.

In response to unreliable production and periodic shortages of Mo-99 production, Congress passed the American Medical Isotopes Production Act of 2012, which directs the Secretary of Energy to provide financial and technical support to U.S. companies working to build new irradiation and manufacturing facilities to produce Mo-99 without HEU. U.S. companies have made significant progress towards establishing the infrastructure to produce Mo-99 without HEU; however, unlike foreign producers, U.S. companies must price their products high enough to cover the full cost of operating their production facilities.

We applaud CMS for recognizing the payment inequity and proposing to establish a new add-on payment of $10 per dose for radiopharmaceuticals that use Tc-99m derived from domestically produced Mo-99 starting on January 1. 2026. We urge CMS to finalize this policy and create a G code for use by the hospital in CY 2026.

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SNMMI appreciates the opportunity to comment on the CY 2025 OPPS Proposed Rule. If it would be helpful, we are available to discuss any of the above comments or meet with CMS on the above issues. In this regard, please contact Julia Bellinger, Director of Health Policy at jbellinger@snmmi.org or (703) 326-1182.

Respectfully Submitted,

Cathy S. Cutler

Cathy Sue Cutler, PhD, FSNMMI

President, Society of Nuclear Medicine and Molecular Imaging

[8] 77 Fed. Reg. 68323.