



September 11, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20001

Re: [CMS-1786-P] Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Payment for Intensive Outpatient Services in Rural Health Clinics, Federally Qualified Health Centers, and Opioid Treatment Programs; Hospital Price Transparency; Changes to Community Mental Health Centers Conditions of Participation, Proposed Changes to the Inpatient Prospective Payment System Medicare Code Editor; Rural Emergency Hospital Conditions of Participation Technical Correction

Dear Administrator Brooks-LaSure:

On behalf of the American Society of Nuclear Cardiology (ASNC), I appreciate the opportunity to provide comment on the CY 2024 Hospital Outpatient Prospective Payment System (OPPS) proposed rule, published in the *Federal Register* on Monday, July 31, 2022 (88 Fed. Reg. 49552).

ASNC is a greater than 4,900-member professional medical society, which provides a variety of continuing medical education programs related to the role of nuclear cardiology in patient-centered cardiovascular imaging, develops standards and guidelines for training and practice, promotes accreditation and certification within the nuclear cardiology field, and is a major advocate for furthering research and excellence in nuclear cardiology.

ASNC offers comment on the following:

- **COMMENT SOLICITATION ON OPPS PACKAGING POLICY FOR DIAGNOSTIC RADIOPHARMACEUTICALS**
- **CARDIAC POSITRON EMISSION TOMOGRAPHY (PET)/ COMPUTED TOMOGRAPHY (CT) STUDIES (APC 1518, 1521 AND 1522)**



COMMENT SOLICITATION ON OPPTS PACKAGING POLICY FOR DIAGNOSTIC RADIOPHARMACEUTICALS

Under the Hospital Outpatient Prospective Payment System (OPPS), CMS packages several categories of nonpass-through biologicals, and radiopharmaceuticals regardless of the cost of the products. These “policy-packaged” drugs, biologicals, and radiopharmaceuticals function as supplies when used in a diagnostic test or procedure and is packaged with the payment for the related procedure or service. CMS packaged diagnostic radiopharmaceuticals in CY2008 and stakeholders have long presented concerns to CMS regarding the insufficiency of payment rates after pass-through status expires, especially in cases where a particular radiopharmaceutical is high-cost and has low utilization. CMS is interested in stakeholder feedback on how its policy of policy-packaged radiopharmaceuticals has impacted beneficiary access and whether there are specific patient populations or clinical disease states for which this issue has been especially problematic.

In the CY2024 Proposed OPPS rule, CMS seeks comment on new approaches to payment of diagnostic radiopharmaceuticals. In particular, CMS is interested in feedback on four approaches that could enhance beneficiary access to certain radiopharmaceuticals while maintaining the principles of the outpatient prospective payment system. First, CMS solicits feedback on paying separately for diagnostic radiopharmaceuticals with per-day costs above the OPPS drug packaging threshold of \$140. Second, CMS asks for feedback on establishing a specific per-day cost threshold that may be greater or less than the OPPS drug packaging threshold. Third, CMS seeks comment on restructuring the nuclear medicine APCs for services that utilize high cost radiopharmaceuticals used in clinical trials. Finally, CMS asks about an approach to adopt codes that incorporate the disease state being diagnosed or a diagnostic indication of a particular class of diagnostic radiopharmaceuticals.

ASNC is in agreement that packaging policy for diagnostic radiopharmaceuticals in the outpatient setting can create barriers to beneficiary access particularly in the case of high cost, low volume radiopharmaceuticals for certain clinical disease states. Separate payment for radiopharmaceuticals over a certain per day cost threshold may be a reasonable solution to address that issue. Mechanisms to address poor source hospital charge and cost data should be implemented in tandem to mitigate unintended impact.

However, to lend robust support to a particular per-day cost threshold it is imperative that ASNC and other interested stakeholders are able to understand the specific impact on nuclear medicine APCs that would result from this change in policy. It is understood that separate payment for the currently packaged radiopharmaceuticals will necessarily cause a decrease in nuclear medicine APC payment rates. In the case of high cost radiopharmaceuticals it is clear that any decrease to the resulting nuclear medicine APCs would be more than accounted for with the separately paid radiopharmaceutical. However, it is less clear that the same would be true for radiopharmaceuticals with costs only slightly above the OPPS drug packaging threshold. For instance, Rb-82 Rubidium has a 2022 per day geometric mean cost of 232.14. It would be



separately paid if CMS sets the threshold at the OPPS drug packaging threshold but stays packaged if a higher threshold is set.

Furthermore, valuations of per-patient dosing for generator-based radiopharmaceuticals like Rb-82 are complex because each dose is tailored and calibrated for the needs of the particular patient. To understand the full impact on cardiac PET and PET/CT services that use Rb-82, both the impact on the nuclear medicine APCs and the pricing methodology for separate payment would need to be detailed.

The CY2024 OPPS proposed rule indicates that separate payment for radiopharmaceuticals over a certain cost threshold would be determined by “available average sales price (ASP), wholesale acquisition cost, or average wholesale price (AWP) data with the applicable add- on” However, unlike drug manufacturers, radiopharmaceutical manufacturers are not currently required to submit data on average sales price and any submissions would be voluntary. Transparency and clarity around how separately paid drugs are reimbursed is essential. Different resources should be available to develop pricing methodology in different venues to ensure adequate patient access.

In summary, ASNC acknowledges the need to recognize radiopharmaceuticals as unique drugs that require accurate reimbursement to ensure beneficiary access to critical treatment. However, given the complexities of hospital cost data and issues with insufficient hospital reporting on costs in packaged situations, we are concerned about unknown impacts of full implementation of a policy to separately pay for radiopharmaceuticals. ASNC does not believe we have enough data to make a clear recommendation on a per day cost threshold. We believe separate payment for high cost, low volume radiopharmaceuticals would be appropriate particularly in cases where beneficiary access has been negatively impacted. We urge CMS to continue to collaborate with stakeholders to develop a policy that will account for complexities unique to generator isotopes, ensure accurate data collection and utilization, and generate ongoing modeling to monitor for unintended consequences.

CARDIAC POSITRON EMISSION TOMOGRAPHY (PET)/ COMPUTED TOMOGRAPHY (CT) STUDIES (APCs 1522 AND 1523)

Beginning January 1, 2020 CMS assigned three new PET/CT CPT codes (78431,78432,78433) to New Technology APCs. 78431 was assigned to APC 1522 (New Technology – Level 22 (\$2001-\$2500) with a payment rate of \$2,250.50. CPT codes 78432 and 78433 were assigned to APC 1523 (\$2501-\$3000) with a payment rate of \$2,750.50. CMS did not receive any claims data for these services for the CY2021 or CY2022 proposed rules or final rules and continued to place these services in the same APCs for CY2021 and CY2022.

For CY2023, CMS used claims data to determine payment rates for PET/CT codes 78431,78432, and 78433. Based on that data, CMS places 78431 in APC 1523 (New Technology – Level 23 (\$2501-\$3000)) with a payment rate of 2,750.50 and 78432 and 78433 in APC 1521 (New Tech APC- Level 21 \$1901-\$2000)).



For CY2024, CMS used claims data from CY2022 to determine payment rates for PET/CT services 78431, 78432, and 78433. CPT code 78431 had over 22,000 single frequency claims with a geometric mean cost of \$2,300.26. CMS proposes reassigning CPT code 78431 to APC 1522 (New Technology Level 22- (\$2001-\$2500)) with a payment rate of \$2,250.50.

ASNC strongly objects to the reassignment of CPT code 78431 to APC 1522 (New Technology Level 22-(\$2001-\$2500)) from CY 2023 APC assignment APC 1523 (New Technology – Level 23 (\$2501-\$3000)). First, the geometric mean cost for 78431 is slightly higher than the proposed payment rate for APC 1522. In addition, PET/CT services are a new technology that have variations in cost charges on the claim for each service that can differ markedly from the actual costs experienced by the hospital. There can be some volatility in the data for a new service as hospitals grasp the true costs of providing a new technology. This is demonstrated by the variation in minimum costs and maximum costs in one year in the CY2023 vs. the CY2024 NPRM OPSS costs statistics files below¹:

	APC	Payment rate	Min cost	Max cost	Geometric mean
FY2024	1522	2,250.50	742.80	7,024.10	2,300.26
FY2023	1523	2,750.50	837.61	6,138.25	2534.23

As a new service, there are only 110 providers billing HCPCS 78431 in the 2024 OPSS proposed rule rate setting data. A significant change in reimbursement from year to year may impact lab sustainability and patient access to this important modality that is only offered by 110 hospitals.

Moreover, the increase of \$500 in one year followed by a reduction of \$500 in the following year creates substantial instability in hospital service lines. **ASNC urges CMS to consider alternative solutions and not finalize a payment cut of this magnitude to CPT code 78431.**

One alternative CMS could consider is to develop new technology APCs with narrower bands between each APC. For example, New Technology APCs 1503-1521 have anywhere from \$100 to \$200 dollars between each APC grouping, while those from 1522-1537 proceed in \$500 increments. A payment cut from \$2750.50 to \$2250.50 is a substantial reduction of more than 18% from CY2023 to CY2024. Given the variability of the hospital charge data for a new technology like PET/CT, smaller increments between New Tech APC payments could mitigate some of the drastic swings in payment from year to year and provide more financial stability for hospitals.

CY2022 data for CPT code 78432 reports six single frequency claims in CY2022. Based on its universal low volume APC policy, CMS proposes to use the highest of the geometric mean cost, arithmetic mean cost, or median costs based on four years of claims analysis. Using that methodology, CMS found an arithmetic mean cost of \$1658 and proposes to resassign 78432 to APC 1518 with a payment rate of \$1,650.50.

¹ [2023 NFRM OPSS Cost Statistics Files](#) and [2024 NPRM OPSS Cost Statistics Files](#)



For CPT code 78433, data shows 1200 single frequency claims for CY222. CMS proposes maintaining assignment of 7833 to APC 1522 with a payment rate of \$1950.50

ASNC asks CMS not to reassign CPT code 78432 and leave 78432 in its currently assigned APC 1520 for CY2024. Six single frequency claims is not sufficient data to set payment rates. Clinically speaking, 78432 uses more resources than 78431. Services for 78431 requires two full procedures and two separate injections of radiotracer for a perfusion study. 78432 requires identical services but rather than using two injections of the same radiotracer, two different tracers are injected for image acquisition, one for the perfusion study and one for the metabolic study. The tracer used for the metabolic study, fludeoxyglucose (FDG), needs additional prep time than those tracers used in the perfusion study. Thus, services for 78432 require additional staff and clinical workflows than 78431. It is not appropriate the 78432 be assigned to a lower APC than 78431. Part of the problem could be the substantial difference in reported single frequency claims. ASNC urges CMS to consider collecting additional data claims data in CY2024 for 78432 before an APC reassignment based on only six frequency claims.

CONCLUSION

ASNC appreciates the opportunity to comment on the OPPS CY2024 Proposed Rule. As always, ASNC welcomes discussion of questions or concerns regarding any of the above comments. Please contact Georgia Lawrence, Director, Regulatory Affairs at glawrence@asnc.org.

Sincerely,

Mouaz Al-Mallah, MD

President,
American Society of Nuclear Cardiology