

September 6, 2022

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1772-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1772-P: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating

Dear Administrator Brooks-LaSure:

The American College of Radiology, representing over 40,000 diagnostic, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists, appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services' (CMS) calendar year 2023 proposed rule on Hospital Outpatient Prospective Payment (HOPPS) and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs.

The ACR provides comment on the following important issues:

1. Proposed Ambulatory Payment Classification (APC) Placement of Newly Established CPT Codes
2. Proposed Ambulatory Payment Classification (APC) Placement of Existing CPT Codes
3. Payment Policy for Therapeutic Radiopharmaceuticals
4. OPSS Payment for Software as a Service
5. Requirements for the Hospital Outpatient Quality Reporting (OQR) Program
6. ICRs for Addition of a New Service Category for Hospital Outpatient Department (OPD) Prior Authorization Process

Proposed APC Placement of Newly Established CPT Codes

Proposal

Newly established CY 2023 Category I CPT codes 368X1 (Percutaneous arteriovenous fistula creation, upper extremity, single access of both the peripheral artery and peripheral vein, including fistula maturation procedures) and 368X2 (Percutaneous arteriovenous fistula creation, upper extremity, separate access sites of the peripheral artery and peripheral vein, including fistula maturation procedures) are proposed to be placed in APC 5194 with a J1 status indicator.

ACR Perspective and Comments

The ACR would like to thank CMS for the opportunity to share ACR's recommendations for the placement of newly established CPT codes into appropriate APCs for CY 2023. **The ACR is pleased CMS agreed with the ACR's recommendation for the APC placement of the new Category I codes 368X1 and 368X2 into APC 5194 due to clinical similarity and resource use to the predecessor codes G2170 and G2171.**

Proposed APC Placement of Existing CPT Codes

Proposal

CMS is proposing to place CPT code 76145 (Medical physics dose evaluation for radiation exposure that exceeds institutional review threshold, including report) in APC 5612 with status indicator S.

ACR Perspective and Comments

ACR does not agree with CMS's placement of CPT code 76145. ACR recommends that CPT 76145 be reassigned to APC 5724 to better align with clinical homogeneity and cost/resource utilization. APC 5724 currently has 18 services that vary by clinical specialty (e.g., neurology, urology, cardiology, internal medicine, allergy). The proposed 2023 payment for APC 5724 is \$952.52. The resource consumption in APC 5724 more closely aligns with the resources used to perform CPT 76145. **Alternatively, CMS could reassign CPT 76145 to APC 1510 New Technology Level 10 (\$801-\$900), which more closely aligns reimbursement to the current 2022 Medicare Physician Fee Schedule payment rate of \$832.97.**

The American Association of Physicists in Medicine (AAPM) presented to the Hospital Outpatient Payment (HOP) Advisory Panel on August 22, 2022. Although the Panel did not accept the AAPM's recommendation for reassignment of CPT 76145, the Panel did recognize that this is not a radiation oncology service and remarked on the lack of outpatient claims data for 2021 used for 2023 rate setting.

The ACR agrees with the HOP Advisory Panel that CPT 76145 should be assigned to a New Technology APC. This imaging medical physics service meets the criteria for assignment to a New Technology APC and we agree that assigning this service to a New Technology APC will allow CMS to gather claims data to price the service and assign it to the APC with services that use similar resources and are clinically comparable in future rulemaking. Assignment to New Technology APC 1510 effective January 1, 2023 would allow the Agency time to collect and analyze outpatient claims data for more appropriate assignment to a clinical APC in the future.

Proposal:

CMS is proposing to place CPT code 0503T (Analysis of fluid dynamics and simulated maximal coronary hyperemia, and generation of estimated FFR model) for computed tomography fractional flow reserve (CT-FFR) in APC 5724 with status indicator S.

ACR Comments:

ACR supports CMS' proposal to assign CT-FFR to APC 5724 (Level 4 Diagnostic Tests and Related Services). We agree that this APC family is the appropriate fit for the service as CT-FFR provides actionable information on the severity of coronary artery disease (CAD) that allows physicians to

determine the most appropriate course of treatment. It is also our understanding that the Level 4 APC with payment of approximately \$953 is the highest-level APC in this family, and therefore is likely the best fit for CT-FFR.

Proposed APC Placement of Cardiac PET/CT CPT Codes

Proposal

Effective January 1, 2020, CMS assigned three CPT codes (78431- 78433) describing services associated with cardiac PET/CT studies to New Technology APCs (APCs 1522, 1523, and 1523, respectively). CMS did not receive any claims data for these services for either of the CY 2021 or CY 2022 OPSS proposed or final rules. For CY 2023, CMS proposes to use CY 2021 claims data to determine the rates.

ACR Perspective and Comments

The ACR agrees with CMS's proposal to reassign CPT 78431 to APC 1523 given the higher costs associated with the procedure and urges CMS to finalize this proposal. The claims data for this code does appear to be representative of the service provided. However, the claims volumes for 78432 and 78433 are not currently at a level that represents accurate cost data to use for ratesetting for CY2023. **The ACR recommends that CMS maintain both 78432 and 78433 in APC 1523 similarly as the data represents for 78431.** Given the work involved in both 78432 and 78433, it makes clinical sense for them to be in the same APC as 78431.

For example, 78431 includes two separate full PET procedures using two separate injections of a tracer. While services for 78432 and 78433 are similar to 78431, the difference is that instead of one tracer there are two types of tracers- one for each of the two separate procedures bundled into these codes. CPT 78432 and 78433 represent one perfusion study (reported separately when not bundled as CPT 78491 or 78430) and one metabolic study (reported separately when not bundled as CPT 78459 or 78431). Finally, the tracer F-18 FDG takes a lot more prep time to be sure the study will be valid, clinically. CMS does not have enough data for those two new services to move them. **Therefore, the ACR recommends CMS maintain CPT 78432 and 78433 in APC 1523 which would keep all three of these cardiac PET/CT codes in the same APC for CY 2023.**

Payment Policy for Therapeutic Radiopharmaceuticals

Proposal

For CY 2023, CMS proposes to continue paying for therapeutic radiopharmaceuticals at ASP+6 percent. For therapeutic radiopharmaceuticals for which ASP data are unavailable, CMS also proposes to determine 2023 payment rates based on 2021 geometric mean unit costs.

ACR Perspective and Comments

CMS should modify the OPSS payment methodology in CY 2023 to establish separate payment for certain diagnostic radiopharmaceuticals based on ASP + 6%. Advanced imaging diagnostic radiopharmaceuticals continue to be inappropriately packaged in the Medicare hospital outpatient setting. Under the current payment methodology, hospital payment for the diagnostic radiopharmaceuticals is packaged with the scan even though the radiopharmaceuticals are separately approved by the FDA as drugs or biologicals. This policy results in reduced payments to hospitals, and limits beneficiary access to new,

targeted diagnostic radiopharmaceuticals that provide important clinical information. As a result, less precise diagnostic information may lead to suboptimal clinical decisions and outcomes for Medicare beneficiaries.

The Agency's position that packaging incentivizes hospitals to use a lower cost alternative does not apply to newer diagnostic radiopharmaceuticals where there may be no alternative. In the final rule, the ACR recommends that CMS align diagnostic radiopharmaceutical payment with the methodology for separately covered outpatient drugs that are approved by the FDA. At present, the CMS packaging policy applies to drugs that exceed a cost threshold of \$135. For the same reasons, CMS should modify the OPPS payment methodology for diagnostic radiopharmaceuticals to establish separate payment based on ASP + 6% that exceed a cost threshold of \$500. Such an approach would also be consistent with legislation currently under consideration by Congress (S. 2609/H.R. 4479) to require CMS to pay separately for diagnostic radiopharmaceuticals that are approved by the FDA on or after January 1, 2008 and exceed a cost of \$500. We support this bipartisan legislation and request CMS use their authority to adopt the provisions of the bill.

OPPS Payment for Software as a Service

Proposal

In CY 2018, HeartFlow was the first ever Software as a Service (SaaS) procedure for which CMS made separate payment under the OPPS. Since then, there have been several SaaS products that CMS has made payment for. From 2021 to 2022, CMS has reviewed and approved New Technology applications for the LiverMultiScan, Optellum, and QMRCP SaaS procedures. CMS proposes not to recognize the select CPT add-on codes that describe SaaS procedures under the OPPS. CMS proposes to instead establish HCPCS codes, specifically, C-codes, to describe the add-on codes as standalone services that would be billed with the associated imaging service. CMS believes the payment for the proposed C-codes describing the SaaS procedures with add-on CPT codes, when billed concurrent with the acquisition of the images, should be equal to the payment for the SaaS procedures when the services are furnished without imaging and described by the standalone CPT code because the SaaS procedure is the same regardless of whether it is furnished with or without the imaging service.

ACR Perspective and Comments

The ACR is pleased with CMS's decision to solicit feedback from stakeholders on how to appropriately identify and reimburse for SaaS procedures. This complex topic requires broad stakeholder input to ensure this growing field is appropriately identified and reimbursed. Machine learning applications (artificial intelligence [AI]) in healthcare can add significant value to the healthcare system by providing tools to help physicians provide better care for their patients. The number of AI tools cleared by the FDA is escalating, and the vast majority are related to diagnostic imaging. The ACR understands the complexity of these SaaS procedures and the complex coding and payment structures that will compound the solutions. It is crucial that CMS consider that regardless of the algorithm, physician supervision, interpretation, and/or synthesis is always necessary; therefore, these services should always carry a PC payment component. The ACR has developed comments on the specific feedback requested by CMS.

How to identify services that should be separately recognized as an analysis distinct from both the underlying imaging test or the professional service paid under the PFS

ACR believes for CMS to appropriately recognize which services should be separately recognized as an analysis distinct from both the underlying imaging test or the professional service paid under the PFS, CMS must rely on both physician partners, industry partners, and other expert stakeholders. Realizing the maximum potential of artificial intelligence will require a collaborative process that ensures development and implementation of appropriate policy and reimbursement. **The ACR acknowledges the many challenges with incorporating AI into the existing OPSS reimbursement framework but cautions against relying on C-codes as a long-term solution.**

The ACR applauds the CPT Editorial Panel's commitment to creating a limited number of AI codes that can be broadly applied to multiple clinical scenarios. This approach will prevent a potentially unsustainable number of new codes and recognizes that these codes share the same underlying technology. It is the ACR's belief that several of the Category III CPT codes already approved could be folded into these broader AI codes. **Having only a few well-crafted codes will allow for a more appropriate determination of costs and better-defined relationships with codes for professional services and imaging acquisition.**

How to identify costs associated with these kinds of services

As previously stated above, the ACR recommends pursuing a more limited and structured family of AI codes that can be applied broadly to clinical scenarios. As for SaaS codes currently under consideration for reimbursement, **the ACR reiterates prior recommendations made to CMS to move these codes to an APC with appropriately lower reimbursement as they are not intended to reimburse for the technical costs of image acquisition, only computer analysis.** These Category III services have also not gone through the RUC process to independently evaluate costs. The ACR will continue to work closely with CMS to ensure appropriate reimbursement is identified for these SaaS procedures. The ACR supports the innovation of these services while ensuring appropriate payment is identified to allow for broad uptake for SaaS procedures that offer clinical benefits to beneficiaries.

How these services might be available and paid for in other settings (physician offices for example)

Given the budget neutrality constraints and stagnating reimbursement within the Medicare Physician Fee Schedule (MPFS), properly valuing and reimbursing AI codes remains a concern for providers. We believe the RUC process allows for the best determination of value.

Furthermore, the reimbursement of these codes solely under HOPPS could potentially create an unfair reimbursement environment between the hospital and contracted physicians. Many radiology practices that contract with hospitals bill their own PC under the MPFS separate from the hospitals HOPPS/IPPS charges. Maintaining reimbursable PC/TC modifiers is important for maintaining current contractual agreements. **In the current proposal, it is not clear that a PC claim for these codes would be reimbursed.** This would be very problematic for the large number of hospital-based practices that bill PC claims separately.

As these types of services are likely to grow in popularity within other settings of service, such as the Inpatient Prospective Payment System's New Technology Add-on Payment (NTAP), the ACR looks forward to working with CMS and other stakeholders to ensure that new SaaS procedures are adequately reimbursed for its costs in all settings.

How CMS should consider payment strategies for these services across settings of care.

The ACR believes that payment strategies for SaaS procedures across settings of care will need to account for the different costs associated with each setting. CMS should also consider whether the SaaS is associated with a new imaging order or a pre-existing imaging service. It is vital that the code descriptions accurately define these services so that they are applied appropriately by hospitals for the most accurate claims data for future ratesetting and these factors will require different payment strategies. Implementation of AI and establishing AI payment pathways within the HOPPS, and thus for only the technical component, does not diminish the need for physician interpretation. The ACR notes that the professional component should not be changed when a TC payment has been established.

Requirements for the Hospital Outpatient Quality Reporting (OQR) Program

Proposal

CMS agrees with the public's concern regarding the selection of measures accommodating rural emergency hospitals that lack sufficient case volume to ensure that the performance rates for such measures are reliable. The proposed rule includes CMS' methods for ensuring this reliability.

ACR Perspective and Comments

ACR appreciates CMS' attention to the burdens faced by rural emergency hospitals. Providing an opportunity for such hospitals to participate in a quality program specifically addressing these hospitals' characteristics will inform policy makers, hospital leadership, and other stakeholders on the resources and advocacy most needed.

ICRs for Addition of a New Service Category for Hospital Outpatient Department (OPD) Prior Authorization Process

Proposal

CMS established a prior authorization process for certain hospital OPD services in the CY 2020 OPSS final rule, with additional service categories being added in the CY 2021 final rule. For CY 2023, CMS proposes to require prior authorization for a new service category: Facet Joint Interventions, effective for dates of service on or after March 31, 2023. The information collection requirement (ICR) associated with prior authorization requests is the required documentation submitted by providers. This includes all relevant documentation necessary to show that the service meets applicable Medicare coverage, coding, and payment rules and the request must be submitted before the service is provided to the beneficiary, and before the claim is submitted for processing. Table 83 in the proposed rule details the total burden and associated costs for the provisions.

ACR Perspective and Comments

Prior authorizations can create significant barriers for Medicare beneficiaries by delaying the start or continuation of necessary treatment, thus negatively affecting patient outcomes. The prior authorization process is time-consuming and burdens hospitals and providers by diverting valuable resources away from patient care. **The ACR advises that CMS considers the implications process before adding additional service categories to the HOPD prior authorization process.** If prior authorizations must be done, it is imperative that the process be streamlined to reduce associated burdens and shorten the delays in care. Also, it is important to have increased transparency around prior authorization requirements and their use.

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Medicare must ensure that beneficiaries receive timely access to medically necessary, evidence-based care. **The ACR asks that CMS approach prior authorization proposals with caution as it might negatively impact the care of Medicare patients.**

The ACR appreciates the opportunity to comment on the HOPPS proposed rule. We hope you find these comments provide valuable input for your consideration. For any questions, please contact Kimberly Greck (kgreck@acr.org) or Christina Berry (cberry@acr.org).

Respectfully submitted,



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