AMERICAN ASSOCIATION of PHYSICISTS IN MEDICINE

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Chiquita Brooks-LaSure, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Service Category for Hospital Outpatient Department Prior Authorization Process; Proposed Rule; CMS-1772-P

Dear Administrator Brooks-LaSure:

The American Association of Physicists in Medicine[1] (AAPM) is pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) in response to the July 26, 2022 *Federal Register* notice regarding the 2023 Medicare Hospital Outpatient Prospective Payment System (HOPPS) proposed rule.

Reassignment of CPT 76145

CPT 76145 *Medical physics dose evaluation for radiation exposure that exceeds institutional review threshold, including report* is a new medical physics code that was implemented on January 1, 2021.

CPT 76145 is used to describe the medical physicist's work in performing a patient-specific peak organ dose calculation subsequent to an interventional radiology or interventional cardiology procedure exceeding the facility's established threshold for radiation air kerma from one or more procedures.

Typically, the medical physicist will review the request and verify that the institutional review threshold has been exceeded. In addition, the medical physicist will ascertain if adverse skin or other organ injuries have been reported, consistent with typical time-dose response effects. The medical physicist reviews the procedure with the physician and imaging staff.

[1] The American Association of Physicists in Medicine (AAPM) is the premier organization in medical physics, a broadly-based scientific and professional discipline encompassing physics principles and applications in biology and medicine whose mission is to advance the science, education and professional practice of medical physics. Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g., mammography CT, MRI, ultrasound). They contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery), collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to insure that cancer patients receive the prescribed dose of radiation to the correct location. Medical physicists are responsible for ensuring that imaging and treatment facilities meet the rules and regulations of the U.S. Nuclear Regulatory Commission (NRC) and various State regulatory agencies. AAPM represents over 9,000 medical physicists.

The work includes a patient specific calculation and tabulation of the input calculation data for each imaging segment [and sub-segments if there is a significant change in x-ray parameter(s)], resultant organ dose for each segment and total peak organ dose for all segments for the maximally exposed tissue. Further, there is a review of the anticipated tissue response based on time/dose/effect literature. The medical physicist will verify the recorded reference air kerma, entrance skin air kerma, and other relevant radiation parameters input to the calculation by independent radiation exposure measurements in the procedural room using the same equipment and techniques as were used for the clinical procedure.

CMS proposes to maintain assignment of the medical physics code 76145 to APC 5612 *Level 2 Therapeutic Radiation Treatment Preparation* with a 2023 proposed payment of $365.15. APC 5612 has ten, clinically similar, radiation oncology therapeutic radiation treatment codes. CPT 76145 is not a radiation oncology code used in the treatment of cancer patients. CPT 76145 describes a patient-specific peak organ dose calculation that can be utilized across a broad spectrum of interventional radiology or interventional cardiology services. The dose evaluation service is not provided as part of treatment preparation but after an interventional radiology or interventional cardiology service(s).

The 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.

In contrast to the present APC placement and payment of CPT 76145 within HOPPS, CPT 76145 is a technical component only code under the Medicare Physician Fee Schedule with 2022 payment of $832.97 and a 2023 proposed payment of $907.65.

We agree with the HOP Advisory Panel that CPT 76145 should be assigned to a New Technology APC, however, the recommended payment band may not provide appropriate reimbursement to hospitals. We believe that the current underpayment for the amount of time required for an imaging medical physicist to provide this service may result in hospitals not receiving appropriate payment for the resources used. This could lead to the performing physician not receiving quantitative dose information necessary to predict and prepare the patient for possible effects resulting from multiple high dose procedures.

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.

The AAPM supports the Hospital Outpatient Payment (HOP) Advisory Panel recommendation that CMS reassign CPT code 76145 *Medical physics dose evaluation for radiation exposure that exceeds institutional review threshold, including report* to New Technology APC beginning January 1, 2023. We recommend that CMS reassign CPT 76145 to APC 1510 *New Technology Level 10 ($801-$900)*, which more closely aligns reimbursement to the current 2022 and proposed 2023 Medicare Physician Fee Schedule payment rate.

Software as a Service

Algorithm-driven services that assist practitioners in making clinical assessments can include clinical decision support software, clinical risk modeling, and computer aided detection (CAD). CMS refers to these technologies as software as a service (SaaS). For CY 2023, CMS is seeking comments on the specific payment approach they might use for these services and how to identify services that should be analyzed as distinct, how to identify the related costs and how the services might be paid for in other settings. CMS also seeks comments on the best payment approach as these technologies become more common outside imaging services.

We recognize that many of the current examples of SaaS involve diagnostic imaging and appreciate that the Agency recognizes the importance of separate and distinct payments, sometimes through add-on payments, for these services. The AAPM has concerns regarding the CMS packaging methodology that does not recognize component coding or the complexity of some services.

Machine learning applications (e.g., artificial intelligence) 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 artificial intelligence (AI) tools cleared by the FDA is escalating, and the vast majority are related to diagnostic imaging. To prevent an overwhelming number of potential AI codes, a limited number of CPT codes should be created with broad descriptor language that is inclusive of many clinical scenarios. The current method of creating a new code for each instance where a new AI-use case develops is not sustainable, is unnecessary given similarities in underlying technology, and is administratively burdensome.

In 2021, the AMA CPT Editorial Panel issued guidance for classifying various artificial intelligence/augmented intelligence (AI) applications. The guidance divides the work associated with the use of AI enabled medical services and/or procedures into one of three categories: assistive, augmentative, or autonomous.

The AAPM supports the CPT Editorial Panel's current efforts to simplify the AI code set to a handful of broad codes. It is our belief that many of the Category III CPT codes already approved should be folded into these new AI codes being established. 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.

The AAPM encourages CMS to pursue future software as a service code development and valuation through the American Medical Association (AMA) CPT/RUC process, which allows for transparency and dialogue with involved stakeholders.

AI, SaaS, and Software as a Medical Device (SaMD) should not be viewed as “operating in the background” simultaneously for patients. Some types of AI, SaaS, and SaMD should be paid separately because of the added value they provide for a specific patient’s condition, while other types may not need to be paid separately. Furthermore, AI, SaaS, and SaMD may be unique to a specific service and patient diagnosis, warranting an approach to value practice expense on a case-by-case basis.

The AMA AI taxonomy could serve as a starting point for establishing a comprehensive framework for how AI and SaaS can be covered across Medicare's benefit categories if patients are to benefit from the wide variety of digital advances in health care delivery and providers are to be encouraged to incorporate these advances into their practices. This framework should include principles that apply across Medicare's benefit categories.

Payment strategies for SaaS procedures across settings of care will need to account for the different costs associated with each setting. CMS should consider solutions that can be applied consistently across all services in a benefit category that would provide appropriate coverage and reimbursement for new technology across all payment systems.

Comprehensive APC Methodologies for Surgical Insertion Codes for Brachytherapy

CMS continues to utilize 70 Comprehensive Ambulatory Payment Classifications (C-APC) in CY 2023. Under the C-APC policy, CMS provides a single payment for all services on the claim regardless of the span of the date(s) of service. Conceptually, the C-APC is designed so there is a single primary service on the claim, identified by the status indicator (SI) of "J1". All adjunctive services provided to support the delivery of the primary service are included on the claim.

Since the inception of the Comprehensive APC methodology, the AAPM has commented on concerns around the claims data used for rate setting due to significant variations in clinical practice and billing patterns across the hospitals that submit these claims. We met with CMS staff in February 2018 and in our 2019, 2020 and 2021 HOPPS proposed rule comment letters, the AAPM proposed a modified C-APC methodology for the surgical codes related to brachytherapy that mirrors the current CMS payment policy for single-session cranial stereotactic radiosurgery codes 77371 and 77372, which allows separate payment for specified preparation and planning codes. For CY 2023, CMS proposes to continue the flawed C-APC payment methodology for the surgical insertion codes for brachytherapy treatment. To date, the Agency has not addressed these concerns and the impact on Medicare beneficiary access to brachytherapy in the hospital outpatient setting is evident.

While AAPM supports policies that promote efficiency and the provision of high-quality care, we have long expressed concern that the C-APC methodology lacks the appropriate charge capture mechanisms to accurately reflect the services associated with the C-APC.

The AAPM remains concerned that the rates associated with C-APCs do not accurately or fully reflect the services and costs associated with the primary procedure. The current C-APC methodology is of particular concern as CMS continues to expand the number of packaged and bundled services. Given the complexity of coding, serial billing for cancer care, and potentially different sites of service for the initial surgical device insertion and subsequent treatment delivery or other supportive services, the AAPM continues to oppose the current comprehensive APC payment methodology for cancer care. **We urge the Agency to explore alternatives to the C-APC methodology so that it appropriately values this life saving service.**

The current Comprehensive APC payment methodology for brachytherapy does not accurately reflect the true cost of providing the procedures.

The AAPM recommends that CMS discontinue the Comprehensive APC payment policy in 2023 for all brachytherapy insertion codes. CMS should revert to status indicator "T" for CPT codes 19296, 19298, 19499, 20555, 31643, 41019, 43241, 55874 55875, 55920, 57155 and 58346.

Alternatively, CMS could continue to pay for "J1" brachytherapy insertion codes under the C-APC payment methodology but exclude and make separate payment for designated preparation and planning services in addition to the C-APC payment (see Attachment A).

Low Volume APC Policy

Beginning in 2022, CMS established a Low Volume APC policy that designates clinical APCs, brachytherapy APCs, and New Technology APCs with fewer than 100 single claims that can be used for rate setting purposes in the claims year used for rate setting for the prospective year (the CY 2021 claims year for this CY 2023 proposed rule) as Low Volume APCs. **We agree with CMS that low utilization of services can lead to wide variation in payment rates from year to year, especially as it relates to brachytherapy sources and new procedures and services.** Under the proposed Low Volume APC policy, the payment rates for these APCs would be set at the highest amount among the geometric mean, median, or arithmetic mean, calculated using up to four years of data.

The AAPM supports the proposed Low Volume APC policy effective January 1, 2023.

Prior Authorization for Certain Hospital Outpatient Procedures

CMS believes that prior authorization is an effective method for controlling unnecessary increases in the volume of covered outpatient services. Beginning July 1, 2020, CMS implemented a prior authorization process for five categories of services: blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty and vein ablation. CMS expanded this policy to include two new categories of service effective July 1, 2021: Cervical fusion with disc removal and implanted spinal neurostimulators. CMS proposes to add facet joint injections and nerve destruction as a category of services to the prior authorization process for hospital outpatient department beginning for dates of service on or after March 1, 2023.

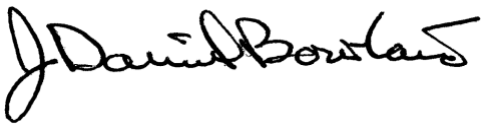
The AAPM opposes prior authorization for procedures and services under "traditional" Medicare Part B services provided in a hospital outpatient department.

Prior authorization impedes delivery of cancer care. Patients deserve the ability to receive the cancer care that is prescribed by their provider. Prior authorization is an effort to decrease Medicare expenditures at the expense of patient care. **The AAPM recommends that CMS carefully consider health care delays and the resulting impact on beneficiaries' health when evaluating any prior authorization requirements.**

Appropriate payment for medical physics services, radiology and radiation oncology procedures is necessary to ensure that Medicare beneficiaries continue to have full access to diagnostic imaging and high-quality radiation therapy cancer treatments. We hope that CMS will consider these issues during the development of the 2023 Medicare HOPPS/ASC final rule.

Should CMS staff have additional questions, please contact Wendy Smith Fuss, MPH at (904) 844-2503.

Sincerely,



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ATTACHMENT A

The AAPM identified a list of twenty-eight (28) codes proposed for separate payment in addition to the C-APC payment for the brachytherapy insertion codes (CPT 19296, 19298, 19499, 20555, 31643, 41019, 43241, 55874, 55875, 55920, 57155, 58346) effective January 1, 2022 (see below). Not all planning and preparation codes would be utilized for each brachytherapy insertion procedure code listed above. This C-APC modified policy mirrors the current CMS payment policy for single-session cranial stereotactic radiosurgery codes 77371 and 77372, which allows separate payment for specified preparation and planning codes.

- 10035 Placement of soft tissue localization device (egg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous, including image guidance; first lesion
- 32553 Placement of interstitial devices for radiation therapy guidance (egg fiducial markers, dosimeter), percutaneous, intra-thoracic, single or multiple
- 49411 Placement of interstitial devices for radiation therapy guidance (egg fiducial markers, dosimeter), percutaneous, intra-abdominal, intra-pelvis (except prostate), and/or retroperitoneum, single or multiple
- 55874 Transperineal placement of biodegradable material, peri-prostatic, single or multiple injection(s), including image guidance
- 55876 Placement of interstitial device(s) for radiation therapy guidance, prostate, single or multiple
- 76000 Fluoroscopy, up to 1 hour physician or other qualified health care professional time
- 76872 Ultrasound, transrectal
- 76873 Ultrasound, transrectal; prostate volume study for brachytherapy treatment planning
- 77280 Therapeutic radiology simulation-aided field setting; simple
- 77285 Therapeutic radiology simulation-aided field setting; intermediate
- 77290 Therapeutic radiology simulation-aided field setting; complex
- 77295 3-dimensional radiotherapy plan, including dose-volume histograms
- 77300 Basic radiation dosimetry calculation
- 77301 Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications
- 77306 Teletherapy isodose plan; simple, include basic dosimetry calculation(s)
- 77307 Teletherapy isodose plan; complex, include basic dosimetry calculation(s)
- 77316 Brachytherapy isodose plan; simple, include basic dosimetry calculation(s)
- 77317 Brachytherapy isodose plan; intermediate, include basic dosimetry calculation(s)
- 77318 Brachytherapy isodose plan; complex, include basic dosimetry calculation(s)
- 77321 Special teletherapy port plan
- 77331 Special dosimetry, only when prescribed by treating physician
- 77332 Treatment devices; simple
- 77333 Treatment devices; intermediate
- 77334 Treatment devices; complex
- 77336 Continuing medical physics consultation
- 77338 Multi-leaf collimator devices for IMRT
- 77370 Special medical radiation physics consultation
- C9728 Placement of interstitial devices for radiation therapy/surgery guidance (e.g., fiducial markers, dosimeter), for other than the following sites (any approach); abdomen, pelvis, prostate, retroperitoneum, thorax, single or multiple