September 28, 2020

Seema Verma, 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 Categories for Hospital Outpatient Department Prior Authorization Process; Proposed Rule; CMS-1736-P

Dear Administrator Verma:

The American Association of Physicists in Medicine¹ (AAPM) is pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) in response to the August 12, 2020 Federal Register notice regarding the 2021 Medicare Hospital Outpatient Prospective Payment System (HOPPS) and Ambulatory Surgical Center (ASC) proposed rule.

The AAPM provides the following recommendations:

- Reassign new CPT code 7615x Medical physics dose evaluation for radiation exposure that exceeds institutional review threshold, including report from APC 5611 Level 1 Therapeutic Radiation Treatment Preparation to APC 5724 Level 4 Diagnostic Tests and Related Services.
- Remove the Deficit Reduction Act (DRA) cap designation for new CPT 7615X Medical physics dose evaluation for radiation exposure that exceeds institutional review threshold, including report.
- Discontinue the Comprehensive APC payment policy for all brachytherapy insertion codes. Alternatively, modify the C-APC methodology to pay for "J1" brachytherapy insertion device and make separate payment for related planning and preparation services in addition to the C-APC payment effective January 1, 2021.
- Discontinue the current CT and MRI cost centers and revert to the previous policy to set weights based on a single diagnostic cost-to-charge ratio effective January 1, 2021.

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 7,000 medical physicists.
• Oppose prior authorization for procedures and services under “traditional” Medicare Part B services provided in a hospital outpatient department.

1. **Reassignment of CPT 7615X**

CPT 7615x is a new medical physics code that will be implemented on January 1, 2021.

- 7615X Medical physics dose evaluation for radiation exposure that exceeds institutional review threshold, including report

CPT 7615X 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.

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 has proposed assignment of the medical physics code 7615X to APC 5611 *Level 1 Therapeutic Radiation Treatment Preparation* for 2021. APC 5611 currently has nine, clinically similar, radiation oncology therapeutic radiation treatment codes. CPT 7615X is not a radiation oncology code used in the treatment of cancer patients. CPT 7615X describes a patient-specific peak organ dose calculation that can be utilized across a broad spectrum of radiology or cardiology services. The dose evaluation service is not provided as part of treatment preparation but after an interventional radiology or interventional cardiology services. AAPM recommends that CPT 7615X be reassigned to APC 5724 *Level 4 Diagnostic Tests and Related Services*. APC 5724 currently has 17 services, with a range of clinical variability (urology, neurology, internal medicine, radiology, dermatology, allergy, etc.). The resource consumption in APC 5724 more closely aligns with the resources used to perform CPT 7615X.

The AAPM recommends that CMS reassign new CPT code 7615X *Medical physics dose evaluation for radiation exposure that exceeds institutional review threshold, including report* from APC 5611 *Level 1 Therapeutic Radiation Treatment Preparation* to APC 5724 *Level 4 Diagnostic Tests and Related Services* effective January 1, 2021.
2. **Deficit Reduction Act and CPT 7615X**

Effective January 1, 2007, the Deficit Reduction Act of 2005 (DRA) imposed new payment caps on imaging and computer-assisted imaging services, limiting reimbursement for the technical component (including the technical component of global fees) to the lesser of what would be paid under Medicare’s Hospital Outpatient Prospective Payment System (HOPPS) or Physician Fee Schedule (MPFS) payment. These caps apply to X-rays, ultrasound (including echocardiography), nuclear medicine (including positron emission tomography), magnetic resonance imaging, computed tomography and fluoroscopy.

The AAPM is concerned that CMS has included new CPT code 7615X in the 2021 MPFS proposed rule Outpatient Cap List (i.e. codes subject to the DRA cap). CPT 7615X is not an imaging service but a patient-specific peak organ dose calculation that can be utilized across a broad spectrum of radiology or cardiology services. These dose calculations are commonly associated with interventional procedures and not diagnostic imaging studies or radiation oncology services.

The AAPM urges CMS to remove the Deficit Reduction Act (DRA) cap designation for new CPT 7615X *Medical physics dose evaluation for radiation exposure that exceeds institutional review threshold, including report.*

3. **Comprehensive APC Methodologies for Surgical Insertion Codes for Brachytherapy**

CMS continues to expand the Comprehensive Ambulatory Payment Classification (C-APC) methodology by proposing two new C-APCs. The proposed new C-APCs include C-APC 5378 Level 8 Urology and Related Services and C-APC 5465 Level 5 Neurostimulator and Related Procedures. The addition of these new C-APCs increases the total number of C-APCs to 69 in 2021. 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 ratesetting 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 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 (see attached comment letters). Yet for 2021, 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 2021 for all brachytherapy insertion codes. CMS should revert to status indicator “T” for CPT codes 19296, 19298, 19499, 20555, 31643, 41019, 43241, 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 attached comment letters for list of 28 codes proposed for separate payment in addition to the C-APC payment).

4. CT & MRI Cost Centers

For 2021, CMS proposes to continue to use all claims with valid CT and MRI cost to charge ratios (CCRs), including those that use a “square feet” cost allocation method, to estimate costs for the CT and MRI APCs.

The CCRs for CT and MRI cost centers are inaccurate, too low and depressing the valuation of APCs that include CT and MRI. The HOPPS rate for CT thorax without contrast agent is now the same as that for an ultrasound of the abdomen and for an X-ray of the lumbar spine with 2-3 views. Under the current policy, advanced and non-advanced imaging are being paid at the same levels. It is illogical to provide the same reimbursement for a CT scan, ultrasound or X-ray when the CT scan equipment is far more expensive than ultrasound or X-ray equipment.

The change required to create standard cost centers for CT and MRI is complex and hospitals are unable to respond. The CCRs for selected CT and MRI procedures show a significant number of CCRs that are close to zero. These near zero CCRs indicate that even when hospitals create standard cost centers, they are likely unable to accurately re-allocate many costs that are already allocated across hospital departments to new CT and MRI departmental cost centers. For these hospitals, the CCRs probably reflect allocations of staffing and dedicated departmental expenses, while the costs of equipment, some costs associated with space (e.g., lead in walls), other administrative costs have been spread across all hospital departments and have not been moved.
The presence of these near zero CCRs will contribute to underestimated costs used in rate setting, pulling rates for CT and MRI procedures down below their actual cost and further eroding payment accuracy. No other high cost technologies are treated in this manner. Hospitals have standard accounting practices for high cost moveable equipment and it is inconsistent and burdensome to expect hospitals to account CT and MRI in a different manner than they deal with other types of equipment.

More importantly, the use of separate CT and MRI CCRs creates unintended consequences on the technical component of CT and MRI codes in the Medicare Physician Fee Schedule (MPFS). The resulting reductions in hospital payments would also affect the physician office practice setting. This is because the HOPPS technical payments would fall below the payment rates in the MPFS causing further cuts as mandated by the Deficit Reduction Act of 2005 (DRA). The DRA mandates that the MPFS technical payments be paid at the MPFS rate or HOPPS rate, whichever is the lower.

The AAPM recommends elimination of CT and MRI standard cost centers and requests that CMS revert to the previous policy to set weights based on a single diagnostic cost-to-charge ratio effective January 1, 2021. The evidence demonstrates that the CCRs for CT and MRI are incorrect and causing inadequate payments for CT and MRI services.

5. **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 proposes to expand this policy to include two new categories of service effective July 1, 2021: Cervical fusion with disc removal and implanted spinal neurostimulators.

CMS Administrator Seema Verma has previously stated that prior authorization shouldn’t interfere with the practice of medicine or delay patient care. We agree with Administrator Verma. 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.
We hope that CMS will consider these issues during the development of the 2021 HOPPS final rule. Should CMS staff have additional questions, please contact Wendy Smith Fuss, MPH at (904) 844-2503.

Sincerely,

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