

September 20, 2018

Seema Verma, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1695-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; CMS-1695-P

Dear Administrator Verma:

The American Association of Physicists in Medicine¹ (AAPM) is pleased to submit comments¹ to the Centers for Medicare and Medicaid Services (CMS) in response to the July 31, 2018 *Federal Register* notice regarding the 2019 Medicare Hospital Outpatient Prospective Payment System (HOPPS) and Ambulatory Surgical Center (ASC) proposed rule.

The AAPM provides the following concerns and recommendations:

- Discontinue 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.
- Discontinue Comprehensive APC payment policy for Single Session Cranial Stereotactic Radiosurgery codes 77371 and 77372. Alternatively, continue separate payment for the 10 planning and preparation services in effect and add IMRT planning code 77301 effective January 1, 2019.
- Implement Transitional Pass-Through Payments for the SpaceOAR[®] System effective January 1, 2019.
- Discontinue the CT and MRI cost centers effective January 1, 2020.
- Concern regarding the continue low volume claims frequency for Low Dose Rate Brachytherapy procedures 77761, 77762 and 77763 due in part to a decrease in the number of brachytherapy procedures provided in the hospital setting and the shift to more costly cancer treatments.

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.

- Update ASC payment rates using the hospital market basket rather than the consumer price index-urban (CPI-U) for 2019-2023.
- Continue hospital payment for the additional cost of using Tc-99m radioisotopes from a non-highly enriched uranium source.

1. Comprehensive APC Methodologies for Cancer Care

Since the inception of the Comprehensive APC (C-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. The episode of care for cancer is complex and the treatment time varies significantly not only based on the type of cancer but on the treatment modality. The assumption that a patient is being treated exclusively in the outpatient hospital setting for a single problem represented on a single claim is not representative of complex oncology care.

The AAPM is concerned that the rates associated with C-APCs do not accurately reflect all of 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, AAPM continues to oppose the current comprehensive APC payment methodology for cancer care.

A. *Brachytherapy Procedures*

In the 2017 HOPPS final rule, CMS finalized several new C-APCs that describe surgical procedures for brachytherapy (see Table 1). CMS proposes to continue the C-APC payment methodology for the brachytherapy insertion codes in 2019.

Table 1: Comprehensive APCs Related to Brachytherapy Insertion Codes

C-APC	CPT Codes
5091 <i>Level 1 Breast Surgery</i>	19499 Unlisted breast procedure
5092 <i>Level 2 Breast Surgery</i>	19298 Breast brachytherapy button & tube catheter placement
5093 <i>Level 3 Breast Surgery</i>	19296 Breast brachytherapy balloon catheter placement
5113 <i>Level 3 Musculoskeletal Procedures</i>	20555 Placement needles/catheters into muscle and/or soft tissue for subsequent interstitial radioelement application
5153 <i>Level 3 Airway Endoscopy</i>	31643 Diagnostic bronchoscope, catheter placement
5165 <i>Level 5 ENT Procedures</i>	41019 Placement needles/catheters into head and/or neck region for radioelement application
5302 <i>Level 2 Upper GI Procedures</i>	43241 Upper GI endoscopy, catheter placement
5341 <i>Abdominal/ Peritoneal/ Biliary Procedures</i>	55920 Placement needles/catheters into pelvic organs and/or genitalia (except prostate) for radioelement application
5375 <i>Level 5 Urology Services</i>	55875 Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy
5414 <i>Level 4 Gynecological Procedures</i>	57155 Insertion uterine tandem and/or vaginal ovoids 58346 Insertion of Heyman capsules for clinical brachytherapy

As noted, the episode of care for cancer is complex, especially as it relates to brachytherapy treatment. Most brachytherapy insertion procedures and brachytherapy treatments occur on the same day or within the same week and therefore the services should appear on the same claim. However; in other cases, the needles or catheters are surgically placed prior to the brachytherapy treatment delivery, which often consists of multiple fractions over several days or weeks and therefore may appear on different claims. Furthermore, brachytherapy surgical insertion procedures may be provided in the outpatient setting but brachytherapy treatment or other supportive services occur at another site of service outside of the hospital setting (e.g., freestanding cancer center). This is common for the breast brachytherapy catheter codes (19296 and 19298) and certain GYN brachytherapy procedures. Regarding CPT 19296, the breast catheter is always placed after a partial mastectomy, typically days after the surgical procedure. The catheter may be placed in the outpatient department or another site of service such as a physician office. The patient may then receive brachytherapy treatment delivery at another site of service, including a hospital outpatient department, freestanding cancer center or ambulatory surgical center. Similarly, with CPT 57155, the uterine tandem and ovoids may be placed under anaesthesia in the hospital outpatient setting, after which the patient is transported to a nearby freestanding center, where the treatment preparation, treatment planning, and treatment delivery services are performed.

Furthermore, brachytherapy procedures may be provided concurrently with external beam radiation therapy delivery services. Such services, which are not supportive to the brachytherapy procedure, would not be paid separately if they appear on the same claim as the J1 code under the C-APC methodology.

AAPM is concerned that the flaws in the C-APC ratesetting methodology for brachytherapy does not accurately reflect the true cost of providing the procedures.

AAPM recommends that CMS discontinue the Comprehensive APC payment policy in 2019 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.

AAPM has created a list of twenty-eight (28) codes proposed for separate payment in addition to the C-APC payment for the brachytherapy insertion codes effective January 1, 2019 (see below). Not all planning and preparation codes would be utilized for each brachytherapy insertion procedure code listed in Table 1 above. This recommendation 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

List of Codes Described as Brachytherapy Insertion

As noted above, CMS identifies a list “brachytherapy insertion codes” defined in Table 1. The AAPM has concerns regarding two (2) of the codes (CPT 43241 and 19499) because these codes are not used exclusively for brachytherapy but may be used for other radiation oncology related or non-radiation oncology related procedures.

- 43241 Esophagogastroduodenoscopy, flexible, transoral; with insertion of intraluminal tube catheter
- 19499 Unlisted procedure breast

AAPM recommends that CMS remove CPT 43241 and 19499 from the list of brachytherapy insertion codes, as they are not used exclusively for brachytherapy treatment.

B. Single Session Cranial Stereotactic Radiosurgery Payment Policy (CPT 77371 & 77372)

In the 2019 proposed rule, CMS maintains CPT 77371 and 77372 single session cranial stereotactic radiosurgery (SRS) in Comprehensive APC 5627 *Level 7 Radiation Therapy*.

In the 2016 HOPPS proposed rule, CMS recognized that the planning and preparation codes for SRS could be spread out over several days. This raised the problem of hospitals not being able to ensure that the set of codes related to the primary “J1” procedure could be captured in the C-APC methodology. CMS identified some, but not all, planning and preparation codes, and proposes continued separate payment in 2019 for the 10 codes listed below. We understand that CMS calculates the C-APC 5627 rate without including the cost associated with these codes.

- CT localization (CPT 77011 and 77014)
- MRI imaging (CPT 70551, 70552 and 70553)
- Clinical treatment planning (CPT 77280, 77285, 77290 and 77295)
- Physics consultation (CPT 77336)

In addition, the AAPM has previously commented that IMRT planning (CPT 77301) has become more common in single fraction radiosurgery treatment planning, and the omission from the list of planning and preparation codes subject to separate payment in 2016, 2017, 2018 and 2019 is inappropriate.

AAPM supports continued separate payment for the ten (10) planning and preparation codes related to CPT 77371 and 77372. Further, the AAPM recommends that IMRT planning code 77301 be added to list of separately paid planning and preparation codes related to stereotactic radiosurgery codes 77371 and 77372 effective January 1, 2019.

We believe hospitals are not appropriately coding for SRS and stereotactic body radiation therapy (SBRT) services. CMS’s continued separate payment for these services will not offer any solution within the C-APC methodology for how best to overcome the problem of this work being spread over several days, of related procedures falling on the same claim, or the prevention of hospitals splitting of claims (inadvertently or by design).

Also important to understand, is that the planning and preparation code sets are used in a wide range of radiation therapy procedures and are not, in themselves, identifiable to any one radiation therapy procedure.

Further, the C-APC methodology is also capturing costs for other therapeutic radiation oncology procedures, often delivered during the same time span as the SRS procedures, which treat different lesions (e.g., presence of SBRT procedures on same claims with SRS procedures). This reporting of two separate treatments areas during the same time span is not an uncommon clinical scenario. Handling of SBRT claims in rate setting for SRS distorts costs for the SRS C-APC and removes important SBRT data from rate setting for the SBRT APC.

The current Comprehensive APC methodology is not suited to single-session stereotactic radiosurgery (CPT 77371 and 77372). The AAPM has long-standing concerns about this policy. The AAPM believes that the recent experience with bundling related to this Comprehensive APC has been unnecessarily complex and clearly has caused both confusion and inaccuracy in coding for stereotactic radiosurgery procedures. The AAPM is concerned that the existence of a variety of claim

durations and claim processes will continue to lead to incorrect coding and inconsistent reimbursement.

As CMS addresses more complex Comprehensive APC configurations, the assumption that a patient is being treated in the outpatient hospital setting for a single problem represented on a single claim is not representative of complex oncology care. When complex interventions are introduced for patients with metastatic or other very severe/complex conditions, treatment for multiple conditions may be observed more often and spread out over several days or weeks. If rate setting always targets the average situation (e.g., single conditions treated on a claim), hospitals that treat the poorest and most seriously ill patients will not realize payment that captures their actual costs of care.

AAPM urges CMS to eliminate the Comprehensive APC payment policy for single-session stereotactic radiosurgery code 77371 and 77372. CMS should work with stakeholders to develop a more appropriate payment methodology for these services.

2. Transitional Pass-Through Payment for SpaceOAR® System

Augmenix, Inc. submitted an application for a new device category for transitional pass-through payment status for the SpaceOAR® System. The SpaceOAR® System is a polyethylene glycol hydrogel spacer that temporarily positions the anterior rectal wall away from the prostate to reduce the radiation delivered to the anterior rectum during prostate cancer radiotherapy treatment. We agree with the applicant that the SpaceOAR® System reduces side effects associated with radiotherapy, which are collectively known as “rectal toxicity” (diarrhea, rectal bleeding, painful defecation, and erectile dysfunction, among other conditions). When used prior to IMRT treatment delivery, the SpaceOAR® is implanted several weeks before radiotherapy. When used with brachytherapy treatment, the SpaceOAR® is typically implanted at the same time as transperineal placement of needles or catheters into prostate for interstitial radioelement application (i.e. CPT 55875). The hydrogel maintains space between the prostate and rectum for the entire course of radiotherapy and is completely absorbed by patient’s body within 6 months.

In the 2019 proposed rule, CMS states that there is insufficient evidence that the SpaceOAR® System provides a substantial clinical improvement over other similar products. The AAPM is not aware of any other FDA-approved alternative biodegradable biomaterials currently utilized for spacing in the context of prostate radiotherapy.

On a related note, CPT code 55874 *Transperineal placement of biodegradable material, peri-prostatic, single or multiple injection(s), including image guidance, when performed* was established on January 1 2018. Required criteria for a new CPT code includes clinical efficacy of the procedure or service as documented in the literature. All Medicare Administration Contractors, with the exception of NGS, provide coverage and reimbursement for the service that utilizes the SpaceOAR® System. Based on a review of the literature, the AAPM believes that the overwhelming evidence does support reduced side effects. We believe that the SpaceOAR® System meets the substantial clinical improvement criterion.

Based on the Augmenix application as described in the 2019 proposed rule, AAPM believes that the SpaceOAR® System meets all of the CMS required criteria for newness, eligibility and cost. **AAPM recommends that CMS implement Transitional Pass-Through Payments for the SpaceOAR® System effective January 1, 2019.**

3. CT & MRI Cost Centers

In the 2014 HOPPS final rule, CMS finalized a policy of creating new cost centers and distinct cost-to-charge ratios (CCRs) for implantable devices, magnetic resonance imaging (MRIs), computed tomography (CT), and cardiac catheterization. However, in response to the 2014 HOPPS proposed rule, commenters reported that some hospitals currently use an imprecise “square feet” allocation methodology for the costs of large moveable equipment like CT scan and MRI machines. They indicated that while CMS recommended using two alternative allocation methods, “direct assignment” or “dollar value,” as a more accurate methodology for directly assigning equipment costs, industry analysis suggested that approximately only half of the reported cost centers for CT scans and MRIs rely on these preferred methodologies. In response to concerns from commenters, CMS finalized a policy for the 2014 HOPPS to remove claims from providers that use a cost allocation method of “square feet” to calculate CCRs used to estimate costs associated with the APCs for CT and MRI. Further, CMS finalized a transitional policy to estimate the imaging APC relative payment weights using only CT and MRI cost data from providers that do not use “square feet” as the cost allocation statistic. CMS stated that this policy would sunset in 4 years to provide a sufficient time for hospitals to transition to a more accurate cost allocation method and for the related data to be available for rate setting purposes. Therefore, beginning in 2018, CMS would estimate the imaging APC relative payment weights using cost data from all providers, regardless of the cost allocation statistic employed. In both the 2018 HOPPS final rule and the 2019 HOPPS proposed rule, CMS extended the transition policy for 1 additional year and continues to remove claims from providers that use a cost allocation method of “square feet” to calculate CT and MRI CCRs.

CMS notes that stakeholders have raised concerns regarding using claims from all providers to calculate CT and MRI CCRs, regardless of the cost allocations statistic employed. Stakeholders noted that providers continue to use the “square feet” cost allocation method and that including claims from such providers would cause significant reductions in the imaging APC payment rates.

CMS analysis shows that since the 2014 HOPPS, the number of valid MRI CCRs has increased by 17.4 percent to 2,174 providers and the number of valid CT CCRs has increased by 14.8 percent to 2,244 providers. However, nearly all imaging APCs would see an increase in payment rates for 2019 if claims from providers that report using the “square feet” cost allocation method were removed. This is attributed to the generally lower CCR values from providers that use a cost allocation method of “square feet.”

According to data from the American College of Radiology (ACR), approximately half of all hospitals paid under the HOPPS had CT and/or MRI cost centers that were reporting CCRs using the preferred methods (“dollar value” or “direct assignment”). Hence current rates have declined based on using partial data. These data show that hospitals have either been unable or unwilling to make the changes CMS regulations mandated.

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.

Further, the use of separate CT and MRI CCRs created unintended consequences on the technical component of CT and MRI codes in the Medicare Physician Fee Schedule (MPFS). If this policy is finalized and fully implemented, the resulting reductions in hospital payments would also affect the 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 effective January 1, 2020. The evidence demonstrates that the CCRs for CT and MRI are incorrect and causing inadequate payments for CT and MRI services.

4. Low Volume Claims Frequency for Low Dose Rate Brachytherapy

The typical brachytherapy encounter involves multiple services. As a result, exclusive reliance on "natural" single claims means that the APC payment rates are based on atypical encounters that are most likely erroneous claims submissions. The AAPM supports the changes that CMS made several years ago, which permits the Agency to include data from multiple procedure claims within the database used by CMS for rate setting for radiation oncology codes. The methodology developed by CMS relies upon the "date of service" on the claims and a list of codes to be "bypassed" to create "pseudo-single" claims from multiple procedure claims. However, the existing methodology to create additional "pseudo" single claims from multiple procedure claims is not yielding a significant number of outpatient claims for Low Dose Rate (LDR) Brachytherapy procedures 77761, 77762 and 77763. This is a continuing trend that is worrisome as the other radiation oncology procedures seem to have a reasonable volume of data to determine payment rates. The number of single claims is sparse and continues to show a decrease in the number of LDR Brachytherapy procedures reported in the hospital outpatient setting (see Table 2).

Table 2: LDR Brachytherapy Single Claim Frequency (2014-2019)

CPT	2014 Single Claims	2015 Single Claims	2016 Single Claims	2017 Single Claims	2018 Single Claims	2019 Proposed Single Claims
77761 Intracavitary radiation source application; simple	16	8	7	6	21	8
77762 Intracavitary radiation source application; intermediate	0	0	0	6	7	1
77763 Intracavitary radiation source application; complex	23	13	25	38	27	9

The AAPM is concerned regarding the continued low volume claims frequency for Low Dose Rate Brachytherapy procedures 77761, 77762 and 77763 due in part to a decrease in the number of brachytherapy procedures provided in the hospital setting and the shift to more costly cancer treatments.

5. Updating the ASC Relative Payment Weights

CMS updates the ASC relative payment weights each year using the Hospital Outpatient Prospective Payment System (HOPPS) relative payment weights (and Medicare Physician Fee Schedule nonfacility practice expense relative value based amounts, as applicable) for that same calendar year and uniformly scale the ASC relative payment weights for each update year to make them budget neutral. CMS bases the HOPPS relative payment weights on geometric mean costs, therefore, the ASC system also uses geometric means to determine relative payment weights under the ASC standard rate setting methodology. CMS currently updates ASC payment rates annually by the percentage increase in the Consumer Price Index for all urban consumers (CPI-U). The Medicare statute specifies a multifactor productivity (MFP) adjustment to the ASC annual update.

In the 2018 proposed rule, CMS solicited public comment on the ASC payment system update factor and noted that average ASC payment rates have declined relative to HOPPS payments rates over the past 10 years.

For 2019, in response to the comments received, CMS is proposing to update ASC payment rates using the hospital market basket rather than the consumer price index-urban (CPI-U) for 2019-2023. CMS is proposing this payment update methodology for a 5-year period, during which they would assess whether there is a migration of procedures from the hospital setting to the ASC setting as a result of the use of a hospital market basket update, as well as whether there are any unintended consequences (for example, an unnecessary increase in the overall volume of services or beneficiaries' out-of-pocket costs). CMS believes that 5 years would be an appropriate number of years to assess changes in the migration of services, as it should provide enough time to confirm that trends in the data are consistent over time.

Given that the ASC payment system is based on the same principles as the HOPPS, AAPM supports the CMS proposal to utilize the same annual update factor as the HOPPS, which is the hospital market basket in 2019-2023.

6. Payment Adjustment Policy for Radioisotopes Derived from Non-Highly Enriched Uranium Sources

CMS proposes to continue the policy of providing an additional \$10 payment for radioisotopes produced by non-highly enriched uranium (HEU).

AAPM supports the CMS proposal to pay hospitals for the additional cost of using Tc-99m radioisotopes from a non-highly enriched uranium source.

We hope that CMS will consider these issues during the development of the 2019 HOPPS final rule. Should CMS staff have additional questions, please contact Wendy Smith Fuss, MPH at (904) 844-2487.

Sincerely,



Bruce R. Thomadsen, Ph.D., FAAPM
President, AAPM



Jonas Fontenot, Ph.D.
Chair, Professional Economics Committee



Michele Ferenci, Ph.D.
Vice-Chair, Professional Economics Committee