

September 6, 2016

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
US Department of Health and Human Services
Attention: CMS-1656-P
P.O. Box 8013, 7500 Security Boulevard
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Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; Electronic Health Record (HER) Incentive Programs; Payment to Certain Off-Campus Outpatient Departments of a Provider; Hospital Value-Based Purchasing (VBP) Program

The American Society for Radiation Oncology (ASTRO) appreciates the opportunity to provide written comments on the “Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; Electronic Health Record (HER) Incentive Programs; Payment to Certain Off-Campus Outpatient Departments of a Provider; Hospital Value-Based Purchasing (VBP) Program” (HOPPS), published in the Federal Register as a proposed rule on July 14, 2016.

ASTRO members are medical professionals practicing at hospitals and cancer treatment centers in the United States and around the globe. They make up the radiation treatment teams that are critical in the fight against cancer. These teams include radiation oncologists, medical physicists, medical dosimetrists, radiation therapists, oncology nurses, nutritionists and social workers. They treat more than one million cancer patients each year. We believe this multi-disciplinary membership makes us uniquely qualified to provide input on the inherently complex issues related to Medicare payment policy and coding for radiation oncology services. In this letter we address a number of topics that will impact our membership and the patients they serve, including:

- Comprehensive APCs
- Therapeutic Radiation Treatment Preparation
- Advisory Panel on Hospital Outpatient Payment

Composite APC (C-APC) Methodology

CMS' Comprehensive-Ambulatory Payment Classification (C-APC) methodology packages payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure under the HOPPS at the claim level. CMS is proposing to further expand their C-APC methodology for 2017. ASTRO continues to have great concern that the one-size-fits-all C-APC methodology is poorly suited and wholly inappropriate for radiation oncology services. Radiation oncology essentially requires component coding to account for several steps in the process of care (consultation; preparing for treatment; medical radiation physics, dosimetry, treatment devices and special services; radiation treatment delivery; radiation treatment management; and follow-up care management). Cancer treatment is complex, as patients are often treated concurrently with different modalities of radiation therapy for different disease sites. CMS' C-APC methodology does not account for this complexity and fails to capture appropriately coded claims, resulting in distorted data leading to inaccurate payment rates that will jeopardize access to certain radiation therapy services if continued and expanded. Below we identify examples of several flaws of the C-APC methodology when applied to radiation oncology and make several recommendations to address these concerns.

C-APC 5627 (Level 7 Radiation Therapy)

C-APC 5627 is a clear example of how the C-APC methodology can be dysfunctional for radiation oncology. CMS is required, by statute, to pay CPT code 77371 *Stereotactic Radiosurgery (SRS), Multi-source Cobalt-60 Based* and CPT Code 77372 *Stereotactic Radiosurgery, Linear Accelerator Based* at the same HOPPS rate. However, the Agency is not required to use a C-APC methodology to calculate that rate.

The practice patterns for multisource Cobalt-60-based SRS (77371) vs linear accelerator-based (77372) SRS are dramatically different, which is evident in HOPPS claims data. Specifically, there are significant differences in the amount of time between planning and preparation and treatment delivery depending on whether Cobalt-60 based SRS (77371) or linear accelerator-based (77372) SRS is used for treatment. The mean number of days between SRS treatment delivery and the 10 planning and preparation codes identified by CMS range from 0.17-4.32 for 77371 and 1.43-22.00 for 77372. This explains why more than 15 percent of the 77372 claims don't include planning and preparation charges, resulting in an error in the geometric mean calculation and an inappropriately low geometric mean for 77372.

Additionally, the SRS claims are also contaminated with charges for CPT Code 77373 *Fractionated Stereotactic Body Radiation Therapy (SBRT)*. Patients being treated for brain metastases (with SRS) may concurrently or consecutively be treated for a primary lung cancer (with SBRT). The CMS/HOPPS C-APC methodology is not designed to differentiate which charges are linked to which major procedure, as such the methodology does not appropriately capture charges for these services.

C-APCs 5414 & 5415 (Gynecologic Procedures)

CPT code 57155 *Insertion of Uterine Tandem and/or Vaginal Ovoids for clinical brachytherapy* is used for gynecologic brachytherapy, which is often done two or three times a week over the course of two to three weeks. A correctly coded claim will typically have at least one insertion

code and a treatment delivery code combination. However, several code combinations are appropriate. ASTRO notes that CMS approved the use of complexity adjustments when two 57155s appear on the same claim. On such occasions, the two codes would be assigned to C-APC 5415 for an increased payment. (*Two insertion codes would not be done on the same day but would be done each day of treatment.*) When analyzing the claims it is apparent that the HDR treatment delivery charges are often inappropriately excluded from rate setting under the C-APC. The methodology does not appropriately capture the various treatment manifestations. Implementation of these incorrect payment models will adversely impact the availability of brachytherapy procedures for gynecologic cancer patients.

C-APCs 5113, 5165, 5165, 5302, 5341 and 5414

Similar to the scenario described above for gynecologic brachytherapy (using CPT Code 57155), other insertion codes used to prepare for radiation treatment delivery (i.e. 20555, 31643, 41019, 43241, 55920, 58346, etc) yield similar problems. The C-APCs don't appropriately capture the charges for these radiation oncology services.

C-APCs 5092 & 5093 (Breast/Lymphatic Surgery and Related Procedures)

For 2017, CMS is proposing to move CPT Code 19298 *Placement of radiotherapy afterloading brachytherapy catheters into the breast for interstitial radioelement application following partial mastectomy, includes image guidance* to newly converted C-APC 5092. That proposed move results in a 42 percent lower payment for 19298. It is most interesting to note that under a C-APC methodology, when the mean cost data for CPT Code 19298 remains similar (\$6,269 vs \$5,172) the payment goes down significantly even though the C-APC methodology is now intended to include all services on the claims instead of the traditional APC methodology. This is not logical, the resultant payment level is clearly incorrect.

CPT Codes 77424 and 77425 are intraoperative radiation treatment (IORT) delivery codes assigned to C-APC 5093 Level 3 Breast/Lymphatic Surgery and Related Procedures. IORT is not clinically similar to the breast procedures included in these APCs.

Conclusion

None of the current CMS HOPPS rate setting methodologies described above provides an accurate representation of costs for radiation oncology services. Several of these issues were highlighted in our 2015 and 2016 proposed and final rule comments. However, CMS has ignored our concerns and expanded this flawed methodology resulting in grossly inappropriate charge capture for radiation oncology services in the HOPPS setting.

Recommendations

For 2017, while CMS further analyzes the C-APC methodology and the issues outlined above, ASTRO is making the following the recommendations:

1. Move CPT Codes 77424 and 77425 to the Radiation Therapy section.
2. Leave CPT Code 19298 in C-APC 5093.
3. Introduce an edit to allow separate payment for SBRT, when it appears on an SRS claim.
4. Expand the list of planning and preparation procedures to be excluded from the C-APC methodology for the SRS APC, allowing separate payment for these services.
5. Maintain assignment of CPT Code 57155 in a traditional APC or consider an alternative

payment methodology that only utilizes correctly coded claims for rate setting.

For 2018, ASTRO makes the following recommendations:

1. Consider creating a modified C-APC methodology for radiation oncology services.

If CMS wants to continue the use of C-APC methodology for radiation oncology services the Agency must revise the methodology to adequately capture appropriately coded claims. CMS should introduce edits to exclude inappropriate procedures from rate setting, in an effort to mitigate major distortions in data. The Agency will also need to consider how to expand the list of planning and preparation (and other codes reflected in the process of care) code exclusions, so they are appropriately paid separately.

2. Consider modifying the complexity adjustment methodology for radiation oncology services.

CMS only considers J1 codes in the complexity adjustment formulas and the majority of radiation oncology services are assigned a status indicator of S. The treatment delivery codes are assigned a status indicator S, although not “ancillary” in the spirit of ‘ancillary’ services definition. CMS could consider some of the following modifications:

- Gynecologic Brachytherapy (57155+Brachy x Number of sessions on claim)
- SRS + SBRT = [5628] (Claims with SRS and SBRT)

3. Consider using the traditional APC methodology for radiation oncology services.

ASTRO recognizes that the Agency is moving away from traditional APC methodology toward more bundled services. However, the complexity of radiation therapy claims due to the related planning and preparation procedures, varying patterns in time prior to ‘major’ treatments, and the potential for multiple treatment sites in varying time spans suggest that separate traditional APCs may be the most accurate way to pay for these services in HOPPS. If CMS reverts back to traditional APC methodology for radiation oncology services, the Agency will need to expand the bypass list again to ensure appropriately coded claims are used in rate setting.

4. ASTRO strongly recommends the CMS Advisory Panel on Outpatient Payment create a fourth subcommittee to specifically address Radiation Oncology HOPPS Methodology.

Therapeutic Radiation Treatment Preparation APCs 5611, 5612 and 5613

CMS proposed to move CPT codes 77295 *Three-Dimensional Radiotherapy Plan* and 77301 *Intensity Modulated Radiotherapy Plan* to Level 3 Therapeutic Radiation Treatment Preparation. **ASTRO appreciates CMS proposed reassignment for CPT Codes 77295 and 77301. However, we remain concerned that the significant costs associated with the simulation services bundled into CPT Code 77301 are not appropriately reflected in the 2015 and 2016 data. ASTRO urges CMS to create a new Level 4 Therapeutic Radiation Treatment Preparation APC and assign CPT Code 77301 to the new APC.**

CMS is also proposing to move CPT code 77370 *Radiation physics consult*, along with CPT codes 77280 *Set radiation therapy field* and 77333 *Radiation treatment aid(s)*, from APC 5612 *Level 2 Therapeutic Radiation Treatment Delivery* to APC 5611 *Level 1 Therapeutic Radiation Treatment Preparation*. The geometric means have remained consistent for all three of these services. This proposed change will result in a 30 percent decrease in reimbursement.

ASTRO urges CMS not to reassign these three services to the lower Therapeutic Radiation Treatment Preparation APC.

Advisory Panel on Hospital Outpatient Payment

Beginning in 2017, CMS is proposing to reduce the number of public meetings of the Advisory Panel on Hospital Outpatient Payment from two meetings per year to one meeting per year. CMS states that the interest and participation in the meetings has waned in recent years. The Agency believes it can accomplish the same work in one multi-day meeting in the summer of each year.

ASTRO urges CMS to reconsider this proposed change, as the work of the panel will continue to be of critical importance as the Agency continues to expand packaging. The Panel plays a key role in reviewing CMS proposals, verifying APC assignments, and providing a public forum for stakeholders to raise concerns with regard to existing and proposed HOPPS methodologies.

We believe that the decline in participation may be due how the meetings are timed. CMS should give consideration to aligning the meeting dates more appropriately with the issuance of proposed rules. For example, stakeholders had a limited amount of time to prepare and submit comments for the recent August 22, 2016 meeting. The proposed HOPPS rule was issued on July 6 and the deadline to submit comments for the panel's consideration at the August meeting was July 18. Efforts should be made to schedule the Panel meetings when there has been sufficient time for analysis and review of proposed rules. This will improve meeting content and ensure a robust and informed discussion.

Electronic Health Records Incentive Program (Meaningful Use)

Reduced Reporting Period

CMS proposes to reduce the 2016 reporting period from a full calendar year to a 90-day reporting period for new and returning Meaningful Use participants. CMS proposes a continuous 90-day period for the Meaningful Use objective and measures, as well as for the attestation of Clinical Quality Measures (CQMs). The attestation for the CQMs can be for a different 90-day period than is reported for the Meaningful Use objectives and measures. CMS proposes no changes for electronically reporting CQMs, which would still be subject to a full calendar-year reporting period.

ASTRO supports this proposal and urges the agency to extend the 90-day reporting period for 2017 to all providers. We also urge the agency to reduce the reporting period for the

CQMs from a full calendar-year period to a 90-day period. We believe this alignment would reduce confusion and help ensure that more providers meet the Meaningful Use reporting requirements.

CY 2017 New Participants and Hardship Exception Application

CMS proposes a Modified Stage 2 for providers who have not successfully demonstrated Meaningful Use in the past. These providers would be exempt from reporting and attesting to Stage 3 of the Meaningful Use program, and would have to attest to the Modified Stage 2 by October 1, 2017. Furthermore, providers who have not successfully demonstrated Meaningful Use in previous years, who intend to attest to Meaningful Use in 2017, and who intend to transition to and report the MIPS Advancing Care Information objectives and measures, may apply for a new hardship exception. These providers will be required to submit their hardship application by October 1, 2017, explaining why participating in both Meaningful Use and reporting the Advancing Care Information category in 2017 would result in a significant hardship. This hardship exception will allow providers to avoid the 2018 Meaningful Use payment adjustment.

ASTRO believes that the overlap of the Meaningful Use program and the Medicare Access and CHIP Reauthorization Act Merit-based Incentive Payment System program is unnecessarily complicated and confusing. As proposed, providers will be required to understand and meet the new MIPS requirements for all four categories, which are still not finalized, and simultaneously meet the Meaningful Use requirements. Requiring participation in both programs will be a significant hardship and an undue burden for providers. ASTRO strongly urges CMS to merge the Meaningful Use program with the MIPS Advancing Care Information (ACI) category, so that providers who meet the ACI category requirements are automatically deemed as meeting the Meaningful Use program requirements. Additionally, we encourage CMS to continue the hardship exceptions that currently exist under the Meaningful Use program and carry them over to the MIPS ACI category for 2017 and beyond.

Thank you for the opportunity to comment on this proposed rule. We look forward to continued dialog with CMS officials. Should you have any questions on the items addressed in this comment letter, please contact Anne Hubbard, Director of Health Policy, at 703-839-7394 or anne.hubbard@astro.org.

Respectfully,



Laura I. Thevenot
Chief Executive Officer