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September 7, 2023

Chiquita Brooks-LaSure, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1786-P
P.O. Box 80010
Baltimore, MD 21244-1810

Submitted electronically: <http://www.regulations.gov>

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Payment for Intensive Outpatient Services in Rural Health Clinics, Federally Qualified Health Centers, and Opioid Treatment Programs; Hospital Price Transparency; Changes to Community Mental Health Centers Conditions of Participation, Proposed Changes to the Inpatient Prospective Payment System Medicare Code Editor; Rural Emergency Hospital Conditions of Participation Technical Correction

Dear Administrator Brooks-LaSure:

The American Society for Radiation Oncology (ASTRO)¹ appreciates the opportunity to provide written comments on the “Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Payment for Intensive Outpatient Services in Rural Health Clinics, Federally Qualified Health Centers, and Opioid Treatment Programs; Hospital Price Transparency; Changes to Community Mental Health Centers Conditions of Participation, Proposed Changes to the Inpatient Prospective Payment System Medicare Code Editor; Rural Emergency Hospital Conditions of Participation Technical Correction,” published in the Federal Register as a proposed rule on July 31, 2023.

¹ 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 patients with cancer 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, ASTRO seeks to provide input on the policy change proposals that will impact our membership and the patients they serve, including:

- Comprehensive Ambulatory Payment Classifications (C-APCs)
- Proposed OPSS Payment for Dental Services
- Solicitation of Comments on OPSS Packing Policy for Diagnostic Radiopharmaceuticals
- Health Equity – Addressing the Impact of APC Payment Methodology on Beneficiaries

Comprehensive Ambulatory Payment Classifications (C-APCs)

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.

While ASTRO 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. In the 2024 HOPPS proposed rule, this issue remains unresolved. CMS continues to assign CPT codes 57155 *Insertion of uterine tandem and/or vaginal ovoids for clinical brachytherapy* and 58346 *Insertion of Heyman capsule* to C-APC 5415, which undervalues these services. In 2024, this C-APC category is expected to be reimbursed at a rate of \$4,783.96, which is significantly less than the actual cost of the services delivered. In a later section of these comments, *Health Equity – Addressing the Impact of APC Payment Methodology on Beneficiaries*, ASTRO will elaborate on how this policy disproportionately impacts socio-economically disadvantaged women diagnosed with cervical cancer.

ASTRO again urges CMS to consider allowing brachytherapy to be reported through the traditional APC methodology. If CMS remains committed to the C-APC methodology, we recommend that the Agency move brachytherapy for cervical cancer treatment to C-APC 5416 *Level 6 Gynecologic Procedures*, which is expected to be reimbursed at a rate of \$7,248.41 (our own analysis shows that a more accurate reimbursement for brachytherapy for cervical cancer is significantly more than current CMS reimbursements).

Proposed OPSS Payment for Dental Services

For CY 2024, CMS proposes to assign 229 HCPCS codes describing dental services to various clinical APCs to align with Medicare payment provisions regarding dental services in the CY 2023 Medicare Physician Fee Schedule (MPFS) final rule. Assigning additional dental codes to clinical APCs would result in greater consistency in Medicare payment for different sites of service and help ensure patient access to dental services for which payment can be made when performed in the hospital outpatient setting. However, HOPDs would only receive payment for a dental service assigned to an APC when the appropriate Medicare Administrative Contractor (MAC) determines that the service meets the relevant conditions for coverage and payment. The Agency seeks comments on the list of 229 dental codes that it proposes to assign to APCs.

ASTRO applauds the Agency for assigning codes describing dental services to clinical APCs to align with the MPFS. We appreciate the Agency's attention to coverage for dental services, particularly involving radiation therapy. For patients undergoing radiation therapy for any type of head and neck cancer, it is important to receive a thorough initial dental evaluation, including dental x-rays, with special attention to any teeth that may require timely procedures, such as root canals and extractions, prior to radiation therapy. Cleaning and preparation work for radiation therapy also is critical to the clinical success of radiation therapy, including the preparation of a fluoride carrier to protect teeth in an ongoing fashion. After radiation therapy, patients should receive continued dental evaluations for possible problems.

Solicitation of Comments on OPPS Packing Policy for Diagnostic Radiopharmaceuticals

CMS packages several categories of non pass-through drugs, biologicals, and radiopharmaceuticals, regardless of the cost of the products (policy-packaged). Payment for drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure is packaged with the payment for the related procedure or service.

For 2024, CMS is seeking comments on potential modifications to its packaging policy for diagnostic radiopharmaceuticals. Specifically, the Agency is seeking comments on the following new approaches to payment of diagnostic radiopharmaceuticals under the OPPS:

1. Paying separately for diagnostic radiopharmaceuticals with per-day costs above the OPPS drug packaging threshold of \$140;
2. Establishing a specific per-day cost threshold that may be greater or less than the OPPS drug packaging threshold;
3. Restructuring APCs, including by adding nuclear medicine APCs for services that utilize high-cost diagnostic radiopharmaceuticals;
4. Creating specific payment policies for diagnostic radiopharmaceuticals used in clinical trials; and
5. Adopting codes that incorporate the disease state being diagnosed or a diagnostic indication of a particular class of diagnostic radiopharmaceuticals.

ASTRO is concerned that packaging payment for diagnostic radiopharmaceuticals in the outpatient setting creates barriers to beneficiary access, particularly when hospitals have a high proportion of Medicare beneficiaries or are serving underserved communities. While pass-through payment status helps the diffusion of new diagnostic radiopharmaceuticals into the market, CMS's current packaging policy for diagnostic radiopharmaceuticals impedes access to new and innovative diagnostic tools for Medicare beneficiaries.

ASTRO recommends CMS use its statutory authority to always pay separately for diagnostic radiopharmaceuticals, not just when the products have pass-through payment status. ASTRO encourages CMS to adopt an average sales price (ASP) + 6% payment policy for diagnostic radiopharmaceuticals, similar to payment for therapeutic radiopharmaceuticals and other drugs and biologicals.

We believe separate payments for diagnostic radiopharmaceuticals (ASP+6%) is the best policy approach to ensure beneficiary access to diagnostic radiopharmaceuticals and equitable payment for innovative and effective technologies. Restructuring APCs will not address the frequent

scenario of APC payment rates being lower than the actual cost of the diagnostic radiopharmaceutical. Per-day payment thresholds only encourage manufacturers to manipulate their rates, and indication-specific coding will cause administrative burden.

Health Equity – Addressing the Impact of APC Payment Methodology on Beneficiaries

In the 2024 OPSS proposed rule, CMS seeks comments regarding how to structure an impact analysis that would allow the Agency to better understand how OPSS and ASC methodology changes impact different beneficiary groups. ASTRO appreciates that the Agency is considering ways to analyze the impact of payment system methodology changes on disadvantaged patient populations. As previously stated, ASTRO continues to be concerned about how the C-APC methodology impacts the delivery of brachytherapy for the treatment of cervical cancer. This type of cancer disproportionately impacts disadvantaged and minority women, who are less likely to have access to screening services that would allow preventive intervention prior to the emergence of life-threatening invasive cancer. Studies show that Black women are less likely to receive appropriate treatment for cervical cancer compared to White women, and treatment differences have been reported for other minorities as well, including Hispanics and American Indians.² Black and Hispanic women are also more likely to be diagnosed with late-stage cervical cancer.³ Finally, cervical cancer incidence rates are higher in rural areas, such as Appalachia, than in other regions of the country.⁴

The standard of care for the nonsurgical curative management of cervical cancer includes concurrent chemotherapy with external beam radiation therapy (EBRT) and brachytherapy. Brachytherapy is a surgical procedure to introduce radioactive elements directly into or adjacent to the tumor. Patients who receive this specific combination of treatment experience high quality outcomes, including longer survival times and lower mortality rates. The effectiveness of this multimodality approach to cervical cancer hinges on evidence that optimal treatment is achieved when all chemotherapy and radiation therapy (both EBRT and brachytherapy) is completed within 56 days, or 8 weeks.⁵ Exceeding this period results in decreased local tumor control and survival for the patient with each day of delay.⁶

In the United States, the most commonly used regimens are 45Gy EBRT to the pelvis (possibly with a sidewall boost) with concurrent cisplatin-based chemotherapy and either 5.5 Gy per fraction for five fractions (insertions) of brachytherapy (for patients treated with concurrent chemotherapy who have

² Wentzensen N, Clarke MA, Perkins RB. Impact of COVID-19 on cervical cancer screening: Challenges and opportunities to improving resilience and reduce disparities. *Prev Med.* 2021;151:106596.

doi:10.1016/j.yjmed.2021.106596, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8241689/>

³ Holt HK, Peterson CE, MacLaughlan David S, et al. Mediation of Racial and Ethnic Inequities in the Diagnosis of Advanced-Stage Cervical Cancer by Insurance Status. *JAMA Netw Open.* 2023;6(3):e232985. doi:10.1001/jamanetworkopen.2023.2985

⁴ National Cancer Institute – Cancer Disparities. Accessed August 10, 2023 - <https://www.cancer.gov/about-cancer/understanding/disparities>

⁵ Song MD, Suisui, et al. (January 15, 2013) The Effect of Treatment Time in Locally Advanced Cervical Cancer in the Era of Concurrent Chemoradiotherapy. *Cancer*, 325-331.

⁶ Petereit MD, Daniel G., et al. (1995) The Adverse Effect of Treatment Prolongation in Cervical Carcinoma. *International Journal of Radiation Oncology Biology Physics*, Volume 32, No. 5, 1995, 1301-1307.

had either a complete response or have <4 cm of residual disease) or 6 Gy for five fractions (insertions) of brachytherapy (for patients with tumors >4 cm after EBRT).⁷

Unfortunately, the C-APC methodology packages payments for adjunctive services into the payments for the primary services. This results in a single prospective payment for each of the primary, comprehensive services based on the costs of all reported services at the claim level. This methodology has the unintended consequence of not recognizing concurrent or overlapping services, which is particularly challenging when services unrelated to the primary service code or multiple encounters of the same primary service appear on the same claim. In the case of brachytherapy treatment for cervical cancer, the “primary code” (status indicator of J1) is CPT Code 57155. The related treatment planning and delivery codes are considered adjunctive services.

Given the poorly reimbursed bundled charges available for brachytherapy, it is difficult to balance the costs of equipment and source acquisition and replacement. As a result, access to care issues have become exacerbated as fewer centers are able to continue offering brachytherapy for cervical cancer treatment. ASTRO raised this concern in a September 2019 letter to the Agency regarding the RO Model and its potential impact on brachytherapy services. In that letter, we highlighted an analysis of the CMS data files based on hospital outpatient claims data that were issued with the RO Model proposed rule. Of the 2,946 cervical cancer episodes that occurred between 2015-2017, only 629 (or 21%) of the episodes were treated with combination EBRT and brachytherapy—the standard of care described above. At the time, this underscored our concerns that the CMMI case rates for cervical cancer were too low but also brought to light the frequency with which Medicare beneficiaries diagnosed with cervical cancer are not provided with guideline concordant care.

More recently, ASTRO has performed a utilization analysis of CPT codes 77771, *Remote afterloading high dose rate interstitial or intracavitary radionuclide brachytherapy; includes basic dosimetry, when performed one channel*, and CPT code 57155, which are frequently billed for the treatment of cervical cancer. The CMS Medicare Physician & Other Practitioners – by Provider and Service database indicates that use of these codes has declined significantly in recent years. Between 2016 and 2020, the number of physicians billing CPT Code 77771 is down 48% and the number of physicians billing CPT Code 57155 is down 81%. Additionally, the number of Medicare beneficiaries treated has declined by 44% and 76% for each code, respectively. At the same time, Centers for Disease Control (CDC) incidence rate data indicates little change in the over 65 patient population diagnosed with cervical cancer.⁸

CDC CERVICAL CANCER INCIDENCE RATES 65+			
Year	Black	Hispanic	All Races and Ethnicities
2016	465	345	2665
2017	496	333	2796

⁷ National Comprehensive Cancer Network. Cervical Cancer (Version 1.2017). <https://www.tri-kobe.org/nccn/guideline/gynecological/english/cervical.pdf> Accessed March 21, 2018.

⁸ United States Cancer Statistics: Data Visualizations <https://gis.cdc.gov/Cancer/USCS/#/RaceEthnicity/> Accessed August 10, 2023

2018	488	348	2784
2019	478	397	2725
2020*	400	380	2525

* Per the CDC, a decline in 2020 incidence counts may be due to the COVID-19 PHE

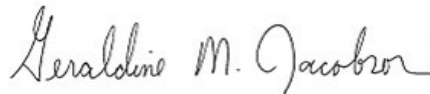
ASTRO has raised concerns about the challenges that the current C-APC payment methodology poses to cervical cancer treatment for more than five years. We appreciate CMS's recent efforts to address this by increasing the C-APC level for CPT code 57155, but that additional payment remains inadequate. We are hopeful that through the lens of health equity, the Agency will commit to ensuring that cervical cancer patients have access to guideline concordant care. We appreciate CMS's interest in determining ways that impact analyses can be applied to identify and address the impact of APC methodologies on Medicare beneficiaries. Similar to the approach we laid out above, ASTRO recommends that CMS engage with stakeholders to identify instances in which payment policy negatively impacts patient care; then use clinical guidelines, as well as the Agency's own data, to determine whether APCs may be having a negative impact on beneficiary care.

Thank you for the opportunity to comment on this proposed rule. We look forward to continued dialogue with CMS officials. Should you have any questions on the items addressed in this comment letter, please contact Adam Greathouse, Assistant Director, Health Policy, at (703) 839-7376 or Adam.Greathouse@astro.org.

Respectfully,



Laura I. Thevenot
Chief Executive Officer



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