ASTRO
TARGETING CANCER CARE

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September 5, 2024

Chiquita Brooks-LaSure, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1809-P
P.O. Box 8010
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Submitted electronically: http://www.regulations.gov

Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicaid Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities

Dear Administrator Brooks-LaSure:

The American Society for Radiation Oncology (ASTRO)[1] appreciates the opportunity to provide written comments on the "Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicaid Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and

[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.

Tribal Facilities," published in the Federal Register as a proposed rule on July 22, 2024.

The proposed rule updates the payment policies, payment rates, and quality provisions for services furnished under the Hospital Outpatient Prospective Payment System (HOPPS) effective January 1, 2025.

In the following letter, ASTRO seeks to provide input on the policy change proposals that have a significant impact on radiation oncology. Key issues addressed in this letter include:

- Comprehensive Ambulatory Payment Classifications (C-APCs)
- Brachytherapy Sources
- Changes to the Review Timeframes for the Hospital Outpatient Department (OPD) Prior Authorization Process
- Diagnostic Radiopharmaceuticals Separate Payment
- Add-on Payment for Radiopharmaceutical Technetium-99m (Tc-99m)
- Procedures Assigned to New Technology APCs for CY 2025 – Biology Guided Radiation Therapy
- All-Inclusive Rate (AIR) Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities

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 remain concerned that the C-APC methodology lacks the appropriate charge capture mechanisms to accurately reflect the services associated with the C-APC. Furthermore, ASTRO has long expressed concern that the Medicare Claims Processing Manual does not provide clear guidance regarding how hospital-based practices should bill for repetitive services included in the C-APC methodology, particularly brachytherapy.

Guideline concordant care for cervical cancer requires five insertions of a tandem and ovoid device (CPT code 57155) to achieve a curative outcome. CPT Code 57155 is currently assigned to a C-APC. The Medicare Claims Processing Manual does not provide clear guidance regarding how hospital-based practices should bill for *repetitive* services included in the C-APC methodology. Data indicates that many hospitals are not billing per encounter for tandem and ovoid insertions.

CMS's MLN Matters Publication MM4047 addresses the Frequency of Billing to Fiscal Intermediaries (FIs) for Outpatient Services. However, the MLN publication does not address billing associated with services that are included in a C-APC. The publication states *"repetitive Part B services furnished to a single individual by providers who bill FIs should be billed monthly (or at the conclusion of treatment)."* The publication goes on to address radiation therapy service:

> *Revenue codes usually reported for chemotherapy and radiation therapy are not on the list of revenue codes that may only be billed monthly. Therefore, hospitals may bill*

> *chemotherapy or radiation therapy sessions on separate claims for each date of service. However, because it is common for these services to be furnished in multiple encounters that occur over several weeks or over the course of a month, hospitals have the option of reporting charges for those recurring services on a single bill, as though they were repetitive services. If hospitals elect to report charges for recurring, non-repetitive services (such as chemotherapy or radiation therapy) on a single bill, they must also report all charges for services and supplies associated with the recurring service on the same bill.*

ASTRO has engaged with CMS regarding billing for CPT code 57155 as part of the C-APC methodology. The Agency has indicated that services delivered over multiple patient encounters can be reported per encounter. Per the Agency's recommendation, ASTRO has contacted the Medicare Administrative Contractors (MAC) to ask for guidance or clarification for billing for brachytherapy insertion codes that are included in the C-APC payment methodology, but the MACs' responses have indicated that no guidance publications will be forthcoming.

ASTRO encourages CMS to issue an MLN Matters Publication (or other guidance) to clarify that services assigned a J1 indicator and delivered over multiple patient encounters may be reported per encounter.

Brachytherapy Sources

CMS is proposing to designate six brachytherapy APCs as Low Volume APCs for CY 2025 (see below).

Proposed Low Volume APCs Using Comprehensive (OPPS) Ratesetting Methodology for CY 2025

APC	APC Description	CY 2023 Claims Available for Ratesetting	CY 2025 Proposed APC Cost
2632	Iodine I-125 sodium iodide	0	$196.73
2635	Brachytx, non-str, HA, P-103	13	$67.73
2636	Brachy linear, nonstr, P-103	1	$51.81
2642	Brachytx, stranded, C-131	90	$105.40
2645	Brachytx, non-str, gold-198	86	$867.00
2647	Brachytx, NS, Non-HDRIr-192	2	$552.59

Beginning in 2022, CMS established a Low Volume APC policy that can be used for rate setting purposes. The policy states that when a clinical or brachytherapy APC has fewer than 100 claims that can be used for rate setting then CMS determines the APC cost as the highest of the median cost, arithmetic mean cost, or geometric mean cost based on up to four years of claims data. ASTRO agrees that low utilization of services can lead to wide variation in payment rates from year to year, especially as it relates to brachytherapy sources.

ASTRO supports continuation of the Low Volume APC policy and its application to the aforementioned six brachytherapy APCs.

Changes to the Review Timeframes for the Hospital Outpatient Department (OPD) Prior Authorization Process

For 2025, CMS is changing the review timeframe for prior authorization (PA) requests for certain OPD services from 10 *business* days to 7 *calendar* days for standard reviews, aligning its Medicare FFS PA review timeframe for standard review requests for OPD services with the timeframe for Medicare Advantage organizations under the Interoperability and Prior Authorization final rule (89 FR 8758).

PA is a cumbersome process, which negatively impacts radiation oncology and cancer patients. **ASTRO applauds the Agency's proposal to align PA processes across payers, helping to reduce provider burden and decrease the time beneficiaries must wait for a decision on their care.**

Diagnostic Radiopharmaceuticals Separate Payment

CMS is proposing to pay separately for diagnostic radiopharmaceuticals that cost more than $630/day (about two-times the volume weighted average cost (WAC) currently associated with diagnostic radiopharmaceuticals). The $630/day threshold would increase in future years by the Producer Price Index (PPI) for Pharmaceutical Preparations. The Agency also proposes to pay for separately payable diagnostic radiopharmaceuticals based on their Mean Unit Cost (MUC) derived from OPPS claims and is asking for comment on the use of ASP for payment in future years.

ASTRO supports the Agency's proposal for a separate payment for diagnostic radiopharmaceuticals. Hospitals may choose not to provide specific diagnostic radiopharmaceuticals to Medicare beneficiaries if the cost to purchase them exceeds what Medicare pays, which can create access to care issues. Today's advanced diagnostic radiopharmaceuticals are often not interchangeable with lower-cost, older alternatives. In some cases, there may be no comparable diagnostic option to these advanced radiopharmaceuticals, leading to physicians resorting to less effective alternatives, which can result in inaccurate diagnoses or treatment plans. Separate payment helps address these access issues and ensures patients can receive the most effective diagnostic radiopharmaceutical options available.

Add-on Payment for Radiopharmaceutical Technetium-99m (Tc-99m)

For CY 2025, an add-on payment will apply for radiopharmaceuticals that use Tc-99m produced with use of highly enriched uranium (HEU). For 2026, CMS proposes replacing this add-on payment with one for radiopharmaceuticals that use Tc-99m derived from domestically produced molybdenum-99 (Mo-99). Foreign Mo-99 production has historically been subsidized by foreign governments, making the price far below the true cost of production and a disincentive for domestic investments in Mo-99 production infrastructure. To address this payment inequity, CMS is proposing an add-on payment of $10 per dose for radiopharmaceuticals that use Tc-99m derived from domestically produced Mo-99.

ASTRO supports this add-on payment proposal for Tc-99m derived from domestically produced Mo-99. This add-on payment can incentivize investment in domestic infrastructure and ensure a stable and secure supply of Tc-99m for patient care.

Procedures Assigned to New Technology APCs for CY 2025 – Biology Guided Radiation Therapy

CMS generally retains a procedure in the New Technology APC to which it is initially assigned until it has obtained sufficient claims data to justify reassignment of the procedure to a clinically appropriate APC. In addition, in cases where it finds that its initial New Technology APC assignment was based on inaccurate or inadequate data, where it obtains new information that was not available at the time of the initial New Technology APC assignment, or where the New Technology APCs are restructured, it may, based on more recent resource utilization information (including claims data) or the availability of refined New Technology APC cost bands, reassign the procedure or service to a different New Technology APC that more appropriately reflects its cost.

CMS proposes to maintain HCPCS codes C9794 and C9795 for biology guided radiation therapy in APCs 1521 and 1525, respectively, since the codes only became effective on January 1, 2024, and there is no claims data available for either code.

ASTRO generally supports New Technology APCs because they can provide for quicker market access for innovative medical technologies. Radiation oncology innovation requires significant upfront costs, and this financial risk can hinder technological advancement and patient care. The availability of reimbursement pathways such as the New Technology APC pathway are critical to facilitate continued investment in state-of-the-art medical technology. **Therefore, ASTRO supports maintaining HCPCS codes C9794 and C9795 in APC 1521 and APC 1525, respectively.**

All-Inclusive Rate (AIR) Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities

For CY 2025, CMS is proposing to separately pay IHS and tribal hospitals for high-cost drugs furnished in hospital outpatient departments through an add-on payment, in addition to the all-inclusive rate (AIR), using the authority under which the annual AIR is calculated. The add-on payment would have no effect on the calculation of the annual AIR payment amount. The Agency proposes to define "high-cost drugs" for the purpose of this policy as all drugs covered under Medicare Part B and for which payment would otherwise be made under the OPPS whose per day cost exceeds two times the lower 48 states' AIR ($1,334 in CY 2024). The threshold is greater than the lower 48 AIR to account for the fact that IHS and tribal hospitals would continue to receive the lower 48 AIR payment, in addition to the add-on payment, for encounters that include a high-cost drug.

The proposed amount of the add-on payment would be the average sales price (ASP) for the drug with no additional payment (i.e., not ASP + 6% like most drugs under HOPPS), but CMS is seeking comment on whether it should pay under an alternative method.

The proposal to provide Medicare add-on payments for high-cost drugs in IHS and tribal hospitals is a positive step toward addressing the unique challenges faced by these facilities. The current AIR payment system often fails to adequately compensate these hospitals for the complex and expensive services they provide, including the treatment of cancer. Adequate reimbursement for high-cost drugs is crucial for ensuring that tribal hospitals can continue to offer essential cancer care services to their communities.

While the proposal to address high-cost drugs is commendable, it is essential to consider expanding the scope of add-on payments to include other high-cost services beyond drugs, such as radiation therapy services. These services often require significant investments in specialized equipment and personnel, which are not adequately covered by the current AIR, which may lead to access-to-care issues in areas served by the IHS and tribal hospitals. Many radiation therapy treatments are provided over the course of several days and weeks, and having to travel a far distance to receive these services can create a significant burden for patients.

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,

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Chief Executive Officer

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