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TARGETING CANCER CARE

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December 3, 2018

Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
US Department of Health and Human Services
Attention: CMS-1695-FC
P.O. Box 8013, 7500 Security Boulevard
Baltimore, MD 21244-1850

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

Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs

Dear Administrator Verma,

The American Society for Radiation Oncology (ASTRO) appreciates the opportunity to provide written comments on the "Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model," published in the Federal Register as a final rule on November 21, 2018.

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 APC Methodology
- New Device Pass-Through Application - SpaceOAR®

Comprehensive APC (C-APC) Methodology

CMS continues to expand the Comprehensive Ambulatory Payment Classification (C-APC) methodology in the 2019 Hospital Outpatient Prospective Payment System (HOPPS) final rule. 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.

We are particularly disappointed that in this final rule, CMS indicated that no empirical evidence was provided to support concerns regarding the C-APC methodology. To the contrary, ASTRO, in collaboration with the American College of Radiology, the American Brachytherapy Society and the American Academy of Physicists in Medicine, have committed significant time and resources to the analysis of the C-APC methodology and its impact on radiation oncology reimbursement. We shared analysis specific to the treatment of cervical cancer with CMS in March 2018. We reiterate the analysis below (clearly empirical evidence) and continue to believe that this verifies how the C-APC methodology undervalues certain services.

Cervical Brachytherapy

Brachytherapy for the treatment of cervical cancer is just one example that demonstrates how the C-APC methodology does not fully account for the complexities of cancer care. 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.[1] Exceeding this period results in decreased local tumor control and survival for the patient with each day of delay.[2]

Delivery of brachytherapy for cervical cancer results in cancer control rates as high as 100 percent for stage IB, 96 percent for stage IIB, and 86 percent for stage IIIB patients. However, an analysis of the National Cancer Data Base indicated that of 7,654 patients diagnosed with curative cervical cancer, the use of brachytherapy declined from 98 percent to 86 percent between 2004 and 2011. The median survival time was 70.9 months for those treated with brachytherapy compared to 47.1 months for those treated with other modalities.[3]

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

[1] 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.
[2] 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.
[3] Petereit MD, Daniel G., et al. (March 20, 2015) Brachytherapy: Where Has It Gone? *Journal of Clinical Oncology*, Volume 33, No. 9, 980-983.

a complete response or have <4 cm of residual disease) or 6 Gy for **five** fractions (for patients with tumors >4 cm after EBRT).[4]

In summary, the standard of care for a cervical cancer patient will be external beam radiation therapy/5 brachytherapy insertions/chemotherapy all completed within 56 days of treatment start.

Charge Capture:
Let's look at CMS 2018 HOPPS rates for cervical cancer. We assume that the hospital bills CMS monthly for the cervical cancer treatment, which is standard practice in the field.

The primary service (J1) in the case of cervical cancer is CPT Code 57155. That service is assigned to APC 5414 with a 2018 payment rate of $2,272.61.

APC	HCPCS	Group Title	Short Descriptor	SI	Relative Weight	Payment Rate	National Unadjusted Copayment	Minimum Unadjusted Copayment
5414		Level 4 Gynecologic Procedures		J1	28.9004	$2,272.61	.	$454.53

All the radiation delivery, planning and preparation, etc. are considered adjunctive services and designated with status indicator S. Those charges will appear on the same bill as the J1 service (CPT Code 57155).

HCPCS	SI	APC	Payment Rate	Single Frequency	Total Frequency	Minimum Cost	Maximum Cost	Median Cost	Geometric Mean Cost
57155	J1	5414O	$2,272.61	1719	1729	$600.56	$16,316.39	$3,079.38	$3,013.71
77470	S	5623	$522.28	41039	57294	$91.53	$2,116.61	$443.11	$442.63
77370	S	5611	$125.35	26766	34844	$35.03	$797.28	$172.27	$172.34
77771	S	5624	$714.06	5687	11435	$151.64	$3,074.26	$715.92	$730.89

Planning and Preparation codes									
HCPCS	SI	APC	Payment Rate	Single Frequency	Total Frequency	Minimum Cost	Maximum Cost	Median Cost	Geometric Mean Cost
77290	S	5612	$323.07	111404	140318	$87.82	$1,851.20	$392.67	$393.94
77295	S	5613	$1,186.60	72804	96841	$239.99	$5,269.28	$1,136.40	$1,129.38
77336	S	5611	$125.35	646839	657097	$30.49	$584.58	$135.66	$132.25

2018 NFRM Final Rule CPT Cost Stats 10.27.17

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

Packaged Services	
76942	N
77417	N
99151-99157	N

The brachytherapy sources will also appear on the bill. However, sources have a status indicator designation of "U" and are separately reportable/paid.

Brachy Source								
HCPCS Code	**Short Descriptor**	**CI**	**SI**	**APC**	**Relative Weight**	**Payment Rate**	**National Unadjusted Copayment**	**Minimum Unadjusted Copayment**
C1717	Brachytx, non-str,hdr ir-192		U	2646	3.7462	$294.59	.	$58.92

For purposes of this analysis and our recommendations, we are using the CMS 2016 mean data for CPT Code 57155. CPT Code 57155 currently has a status indicator of J1, thus including other services in the mean data. As such, the 2016 mean data for CPT Code 57155, which had a status indicator T at the time, reflects costs associated with just the insertion.

2016 Mean*
$797.17

**2016 FR CPT Cost Stats 2015-12-16*

As discussed above, the current standard of practice for cervical cancer is five fractions (insertions) of (1) brachytherapy:

HCPCS	SI	Geometric Mean Cost	UoS	
57155	J1	$797.17	5	$3,985.85
77470	S	$442.63	1	$442.63
77370	S	$172.34	1	$172.34
77771	S	$730.89	5	$3,654.45
77290	S	$393.94	5	$1,969.70
77295	S	$1,129.38	5	$5,646.90
77336	S	$132.25	1	$132.25
				$16,004.12

and (2) external beam radiation therapy. Again, assuming the hospital is billing monthly, that external beam cost, based on CMS 2018 mean data file, will be greater than $25,000.

The 2018 Medicare HOPPS payment for cervical brachytherapy treatment is $2,272.61, which is:

- $13,731.51 less than average cost for the brachytherapy portion of the treatment; and
- $40,000 less than the average cost for brachytherapy and external beam radiation therapy (partial treatment).

Recommendations:

We recognize that CMS is committed to the C-APC methodology and support CMS policies that promote efficiency and the provision of high-quality care. However, the methodology used to create C-APCs lacks the appropriate charge capture mechanisms; as it is currently applied, it grossly undervalues cancer treatments, particularly brachytherapy.

Based on our analysis, we urge CMS to consider allowing brachytherapy to be reported through the traditional APC methodology. If CMS insists on the continued use of the C-APC methodology, we recommend that the Agency move brachytherapy for cervical cancer treatment to C-APC 5416 Level 6 Gynecologic Procedures. This C-APC is reimbursed at $6,286.92, which is closer to the actual cost of treatment delivery as noted above. Additionally, we would request that CMS allow the planning and preparation services to be separately reportable. This is a similar approach that the Agency has taken with the methodology used for the SRS C-APC, in which the planning and preparation codes are separately reportable. Finally, we ask that CMS recognize the multimodality process involved in the treatment of cervical cancer by allowing separate reporting for the external beam radiation therapy services that occur during a course of care. We believe that these changes will result in more appropriate reimbursement and address concerns regarding access to appropriate care.

ASTRO urges the Agency to strongly consider these issues. Radiation oncology requires component coding to account for the multiple steps that comprise 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). Additionally, cancer treatment is complex, as patients are often treated concurrently with different modalities of radiation therapy, combined with other specialty modalities, and often at different sites of service. The 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.

New Device Pass-Through Application - SpaceOAR®

In the 2019 HOPPS rule, CMS finalizes its decision to deny a transitional pass through payment for SpaceOAR®. The Agency justifies this decision by stating that there is not sufficient evidence indicating SpaceOAR® provides a substantial clinical improvement for Medicare beneficiaries receiving treatment for prostate cancer over other products.

SpaceOAR® 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 radiation therapy. A recent randomized clinical trial has shown that the biodegradable gel material reduces toxicity for patients treated with radiotherapy for prostate cancer[5]. Specifically, this Level I clinical data demonstrates greater than 70 percent reductions in acute rectal pain and chronic rectal complications and improved bowel quality of life scores for patients treated with a rectal spacer versus those patients treated without a spacer. Based on published clinical outcomes data from this pivotal trial, the perirectal hydrogel spacer provides physicians with an option to help ensure patients are provided with the best clinical outcomes with the fewest adverse effects.

The benefits documented in this initial report were confirmed with a subsequent report of the same trial, with a median follow-up period of 3 years. At 3 years, more men in the control group than in the spacer group had experienced a decline in bowel quality of life (41 percent versus 14 percent). Additionally, the control group were more likely to experience large declines in bowel quality of life (21 percent versus 5 percent). Use of rectal spacer resulted in a sustained 75 percent reduction in any rectal toxicity persisting at 3 years, as well as significant reductions in urinary toxicity.[6]

ASTRO strongly disagrees with the CMS' decision to deny transitional pass through payment for SpaceOAR® and urges the Agency to reconsider.

Thank you for the opportunity to comment on this final 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 Anne Hubbard, Director of Health Policy, at 703-839-7394 or anne.hubbard@astro.org.

Respectfully,

Laura Thevenot

Laura I. Thevenot
Chief Executive Officer

[5] Mariados N, Sylvester J, Shah D, et al: Hydrogel spacer prospective multicenter randomized controlled pivotal trial: dosimetric and clinical effects of perirectal spacer application in men undergoing prostate image guided intensity modulated radiation therapy. Int J Radiat Oncol Biol Phys 92:971-977, 2015.

[6] Hamstra, D.A. et al: Continued Benefit to Rectal Separation for Prostate RT: Final Results of a Phase III Trial. Int J Radiation Oncol Biol Phys, 97:5:976-985, 2017.