



## 2023 Hospital Outpatient Prospective Payment System – Final Rule Summary

On Tuesday, November 1, 2022, the Centers for Medicare & Medicaid Services (CMS) released the 2022 Hospital Outpatient Prospective Payment System (HOPPS) <u>final rule</u>, which includes modest payment increases for radiation therapy services, effective January 1, 2023.

In the Medicare hospital outpatient environment, hospital reimbursement is based on Ambulatory Payment Classifications or APCs. CMS assigns CPT codes to an APC based on clinical and resource use similarity. All services in an APC are reimbursed at the same rate. Cost data collected from OPPS claims are used to calculate rates. Certain services are considered ancillary, and their costs are packaged into the primary service. Packaged services do not receive separate payment. For example, in the hospital outpatient environment, imaging is not paid separately when reported with treatment delivery services. Below is a summary of key issues impacting radiation oncology.

# **Conversion Factor Update**

CMS is increasing the payment rates under the OPPS by an Outpatient Department (OPD) fee schedule increase factor of 3.8%. This increase factor is based on the hospital inpatient market basket percentage increase of 4.1% for inpatient services paid under the hospital inpatient prospective payment system (IPPS), minus a proposed 0.3% productivity adjustment.

Based on this update, CMS estimates that total payments to HOPPS providers (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix) for CY 2023 will be approximately \$86.5 billion, an increase of \$6.5 billion compared to 2022 HOPPS payments.

## **Ambulatory Payment Classifications (APC)**

CMS is making modest changes to the payment rates of traditional radiation oncology APCs in the 2023 HOPPS final rule. Below is a list of radiation oncology APCs with their final 2023 payment rates:

Radiation Oncology - Ambulatory Payment Classification Proposed 2023 Payment Rates					
APC	Descriptor	2022 Rate	2023 Final Rate	% Change	
5611	Level 1 Therapeutic Radiation Treatment Preparation	\$129.59	\$133.38	2.92%	
5612	Level 2 Therapeutic Radiation Treatment Preparation	\$345.85	\$358.72	3.72%	
5613	Level 3 Therapeutic Radiation Treatment Preparation	\$1,289.67	\$1,340.67	3.95%	
5621	Level 1 Radiation Therapy	\$122.34	\$122.39	0.004%	
5622	Level 2 Radiation Therapy	\$246.87	\$262.93	6.50%	
5623	Level 3 Radiation Therapy	\$554.12	\$572.47	3.31%	
5624	Level 4 Radiation Therapy – HDR Brachytherapy	\$724.50	\$721.72	-0.38%	
5625	Level 5 Radiation Therapy – Proton Therapy	\$1,321.12	\$1,323.22	0.19%	
5626	Level 6 Radiation Therapy – SBRT	\$1,771.28	\$1,767.45	-0.22%	

On June 15, 2022, the U.S. Supreme Court issued a decision related to 340B payment rates, which reverses the 2018 CMS policy that set payment rates at Average Sales Price (ASP) minus 22.5%. In the 2023 HOPPS final rule, CMS reverts to the previous policy, which established a general payment rate of ASP plus 6% for drugs and biologicals acquired through the 340B Program. To achieve budget neutrality, as required by statue, CMS is implementing a –3.09% reduction to the payment rates for non-drug services for CY 2023 (the rates in the table above reflect this reduction). CMS will address the remedy for 340B drug payments from 2018-2022 in future rulemaking prior to the CY 2024 OPPS/ASC proposed rule but claims for 340B-acquired drugs paid after the district court's September 28, 2022 ruling are paid at the default rate (generally ASP plus 6%).

## **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.

CMS did respond to ASTRO's comments reflecting concern over applying the C-APC methodology to brachytherapy services, stating that,

"We believe that the current C-APC methodology is appropriately applied to these surgical procedures and is accurately capturing costs, particularly as the brachytherapy sources used for these procedures are excluded from C-APC packaging and are separately payable. This methodology also enables hospitals to manage their resources with maximum flexibility by monitoring and adjusting the volume and efficiency of services themselves."

CMS also reviewed ASTRO's request to move brachytherapy procedures, CPT codes 57155 and 58346, to a higher-paying C-APC, but it believes 57155 is being paid at the appropriate level in its C-APC 5415 placement, and that 53846 does not have enough claims data available to move it to a higher C-APC. CMS said, "We will continue to examine these concerns and will determine if any modifications to this policy are warranted in future rulemaking."

Below is a comparison table of the 2022 payment rates and 2023 payment rates for the radiation oncology services in several key C-APCs:

C-APC 5627 Level 7 Radiation Therapy					
CPT Code	Descriptor	2022 Rate	2023 Final Rate	% Change	
77371	SRS Multisource	\$7,942.98	\$7,690.57	-3.18%	
77372	SRS Linear Based	\$7,942.98	\$7,690.57	-3.18%	
77424	IORT delivery by x-ray	\$7,942.98	\$7,690.57	-3.18%	
77425	IORT delivery by electrons	\$7,942.98	\$7,690.57	-3.18%	
C-APC 5092 Level 2 Breast/Lymphatic Surgery and Related Procedures					
19298	Place breast rad tube/caths	\$5,652.10	\$5,943.15	5.15%	

C-APC 5093 Level 3 Breast/Lymphatic Surgery and Related Procedures						
19296	Place po breast cath for rad	\$9,106.41	\$8,805.74	-3.30%		
	C-APC 5113 Level 3 Musculoskeletal Procedures					
20555	Place ndl musc/tis for rt	\$2,892.28	\$2,976.66	2.92%		
	C-APC 5165 Level 5 ENT Procedures					
41019	Place needles h&n for rt	\$5,194.27	\$5,339.67	2.80%		
	C-APC 5302 Level 2 Upper GI Procedures					
43241 Egd tube/cath insertion \$1,658.81 \$1,741.59				4.99%		
	C-APC 5375 Level 5 Urology and Related Services					
55875	Transperi needle place pros	\$4,505.89	\$4,702.18	4.36%		
C-APC 5415 Level 5 Gynecologic Procedures						
55920	Place needles pelvic for rt	\$4,503.49	\$4,635.11	2.92%		
57155	Insert uteri tandem/ovoids	\$4,503.49	\$4,635.11	2.92%		
58346	Insert heyman uteri capsule	\$4,503.49	\$4,635.11	2.92%		

Although most radiation oncology services see a modest increase in the proposal, ASTRO remains concerned that these services are still undervalued due to the C-APC methodology. As reflected in the Agency's response, CMS remains committed to the methodology and does not intend to modify it for radiation oncology services. ASTRO will continue to educate CMS on the impact the C-APC methodology has on radiation oncology services, particularly brachytherapy.

### **Two-Times Rule Exception**

CMS established two-times rule criteria within the APC methodology that requires that the highest calculated cost of an individual procedure categorized to any given APC cannot exceed two times the calculated cost of the lowest-costing procedure categorized to that same APC. However, the Agency can exempt any APC from the two-times rule for any of the following reasons:

- Resource homogeneity
- Clinical homogeneity
- Hospital outpatient setting utilization
- Frequency of service (volume)
- Opportunity for upcoding and code fragments

Based on CY 2021 claims data, CMS will apply the two-times rule exception to APC 5611 *Level 1 Therapeutic Radiation Treatment Preparation* for CY 2023. This is in addition to APC 5612 *Level 2 Therapeutic Radiation Treatment Preparation* and APC 5627 *Level 7 Radiation Therapy*, which were on the two-times rule exception list in previous years.

### **Brachytherapy Sources**

In the 2023 HOPPS final rule, CMS will continue to base the payment rates for brachytherapy sources on the geometric mean costs for each source, which is consistent with the methodology used for other services under HOPPS. Additionally, the Agency will use the costs derived from 2021 claims data to set the proposed 2023 payment rates for brachytherapy sources. However, C2645 *Brachytherapy planar source, palladium-103, per square millimeter* had insufficient claims data, so the Agency will continue the CY 2019 payment rate of \$4.69 per mm² in CY 2023.

CMS will pay for HCPCS codes C2698 *Brachytherapy source, stranded, not otherwise specified* and C2699 *Brachytherapy source, non-stranded, not otherwise specified*, at a rate equal to the lowest stranded or non-stranded prospective payment rate for such sources, respectively on a per source basis. For 2023, the final rates are \$38.15 for C2698 and \$35.31 for C2699. This is a -2.30% change in payment for C2698 and a 1% change for C2699 from the 2022 rates.

In the 2022 HOPPS final rule, CMS established a Low Volume APC policy for brachytherapy APCs (also for New Technology APCs and clinical APCs—it is universal). For those APCs with fewer than 100 single claims that can be used for rate setting purposes in the existing claims year, CMS uses up to four years of claims data to establish a payment rate for each item or service, which is a similar methodology that the Agency applies to low volume services assigned to New Technology APCs. Further, the Agency calculates the cost based on the greatest of the arithmetic mean cost, median cost, or geometric mean cost.

For CY 2023, CMS will designate 4 brachytherapy APCs as Low Volume APCs for CY 2023 (See Table 32 below). These are the same APCs that were designated as Low Volume APCs in 2022, except APC 2647, *Brachytherapy, non-stranded, Gold-198*, which did not meet the claims threshold for the CY 2023 final rule.

Table 32: Cost Statistics for Proposed Low Volume APCs Using Comprehensive (OPPS) Ratesetting Methodology for CY 2023

APC	APC Description	CY 2021 Claims Available for Ratesetting	Geometric Cost without Low Volume APC Designation	Final Median Cost	Final Arithmetic Mean Cost	Final Geometric Mean Cost	Final CY 2023 APC Cost
2632	Iodine I-125 sodium iodide	10	\$167.11	\$31.74	\$44.35	\$37.26	\$44.35
2635	Brachytx, non-str, HA, P-103	28	\$130.24	\$34.04	\$52.09	\$43.30	\$52.09
2636	Brachy linear, nonstr, P- 103	0	*	\$49.65	\$53.38	\$38.80	\$53.38
2645	Brachytx, non-str, Gold-198	14	\$144.37	\$180.76	\$355.64	\$141.57	\$355.64

<sup>\*</sup>For this final rule, there are no CY 2021 claims that contain the HCPCS code assigned to APC 2636 (HCPCS code C2636) that are available for CY 2023 OPPS/ASC ratesetting.

### **OPPS Payment for Software as a Service**

Algorithm-driven services that assist practitioners in making clinical assessments can include clinical decision support software, clinical risk modeling, and computer aided detection (CAD). CMS refers to these technologies as software as a service (SaaS). For CY 2023, CMS sought comments on the specific payment approach it might use for these services under the OPPS as SaaS-type technology becomes more

widespread. CMS is concerned about the potential for bias in algorithms and predictive modeling and is seeking comments on how they could encourage software developers to prevent or mitigate the possibility of bias in new applications of this technology.

CMS received several comments in response to this request for comments and will consider them in future rulemaking.

### **OPPS** Payment for Drugs, Biologicals, and Radiopharmaceuticals

Transitional pass-through payments are provided for certain "new" drugs and biologicals that were not being paid for as an HOPD service as of December 31, 1996, and whose cost is "not insignificant" in relation to the OPPS payments for the procedures or services associated with the new drug or biological. In the proposed rule, CMS clarified that for pass-through payment purposes, radiopharmaceuticals are included as "drugs." Transitional pass-through payments for a drug can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made for the drug as a hospital outpatient service under Medicare Part B.

#### Payment Policy for Therapeutic Radiopharmaceuticals

For CY 2023 and subsequent years, CMS will continue the payment policy for therapeutic radiopharmaceuticals that began in CY 2010. Medicare pays for separately payable therapeutic radiopharmaceuticals under the Average Sales Price (ASP) + 6% methodology adopted for separately payable drugs and biologicals. If ASP information is unavailable for a therapeutic radiopharmaceutical, they base therapeutic radiopharmaceutical payment on mean unit cost data derived from hospital claims.

CMS believes that this rationale continues to be appropriate for non pass-through, separately payable therapeutic radiopharmaceuticals in CY 2023. Therefore, for CY 2023 and subsequent years, it will pay all non passthrough, separately payable therapeutic radiopharmaceuticals at ASP+6%. Where there is no ASP, it will use mean unit cost data derived from hospital claims.

### New HCPCS Codes Effective July 1, 2022

For the July 2022 update, 63 new HCPCS codes were established and made effective on July 1, 2022. Through the July 2022 OPPS quarterly update, CMS recognized several new codes for separate payment and assigned them to appropriate interim OPPS status indicators and APCs.

In proposed rule, CMS sought comments on the proposed APC and status indicator assignments for the codes implemented on July 1, 2022. In the final rule, the Agency is finalizing the APC and status indicator assignments of codes for which it received no comments, including the two that were relevant to radiation oncology (listed in Table 8 below).

Table 8: New HCPCS Codes Effective July 1, 2022

CY 2022 HCPCS	CY 2023 HCPCS	CY 2023 Long Descriptor
Code	Code	
0174T	0174T	Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance
0735T	0735T	Preparation of tumor cavity, with placement of a radiation therapy applicator for intraoperative radiation therapy (IORT) concurrent with primary craniotomy (List separately in addition to code for primary procedure)

## **Applications Received for Device Pass-Through Status for CY 2023**

CMS establishes specific criteria for hospitals to receive pass-through payments for devices that offer substantial clinical improvement in treatment of Medicare beneficiaries. Devices must meet the following criteria: 1) receive FDA approval or clearance; 2) the device is determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part; and 3) the device is an integral part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted, or applied in or on a wound or other skin lesion. Finally, the device must not be an item for which depreciation and financing expenses are recovered and it is not a supply or material furnished incident to a service.

In addition to meeting criteria for pass-through payment, a device must meet specific criteria for CMS to establish a new category of devices. The criteria for establishing a new category of devices require that the device is not appropriately described by any other category; and that it has an average cost that is not insignificant relative to the payment amount for the procedure or service with which the device is associated by demonstrating:

- 1) The estimated average reasonable costs of devices in the category exceeds 25% of the applicable APC payment amount for the service related to the category of devices;
- 2) The estimated average reasonable cost of the devices in the category exceeds the cost of the device-related portion of the APC payment about for the related service by at least 25%; and
- 3) The difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device exceeds 10% of the APC payment amount for the related service.

The following are pass-through applications received that are of interest to radiation oncology.

### NavSlim<sup>TM</sup> and NavPencil

Elucent Medical, Inc. submitted an application for a new device category for transitional pass-through payment status for CY 2023 for the NavSlim<sup>TM</sup> and NavPencil (referred to collectively as "the Navigators"). The applicant described the Navigators as single-use (disposable) devices for real-time, stereotactic, 3D navigation for the excision of pre-defined soft tissue specimens.

CMS agreed that the Navigators met the eligibility criteria for pass-through status and the device category eligibility criteria. However, the Agency maintained its concerns with the evidence submitted with the application in that it did not demonstrate that the use of the Navigators reduces surgical site infection rates or the risk of tissue marker migration, as claimed by the applicant.

After consideration of the public comments received, and its review of the device pass-through application, CMS did not approve the Navigators for transitional pass-through payment status in CY 2023 because the device did not meet the substantial clinical improvement criterion. Because it determined that the Navigators do not meet the substantial clinical improvement criterion, CMS did not evaluate whether the device met the cost criterion.

#### $SmartClip^{TM}$

Elucent Medical, Inc. also submitted an application for a new device category for transitional pass-through payment status for CY 2023 for the SmartClip<sup>TM</sup> Soft Tissue Marker (SmartClip<sup>TM</sup>). They described the SmartClip<sup>TM</sup> as an electromagnetically activated,

single-use, sterile soft tissue marker used for anatomical surgical guidance. According to the applicant, the SmartClip<sup>TM</sup> is the only soft tissue marker that delivers independent coordinates of location when used in conjunction with the applicant's EnVisio<sup>TM</sup> Navigation System (which includes the Navigators discussed previously).

CMS did not approve SmartClip<sup>TM</sup> for transitional pass-through payment status in CY 2023 because it determined that the device did not meet the newness or substantial clinical improvement criterion. The Agency did not make a determination of whether it met the cost criteria.

## **Proposed New Technology APCs**

Services that are assigned to New Technology APCs are typically new services that do not have sufficient claims history to establish an accurate payment for the services. One of the objectives of establishing New Technology APCs is to generate sufficient claims data for a new service so that it can be assigned to an appropriate clinical APC.

A procedure of interest to radiation oncology within the New Technology APCs is *Bronchoscopy with Transbronchial Ablation of Lesion(s) by Microwave Energy*. Effective January 1, 2019, CMS established HCPCS code C9751 for the procedure. This microwave ablation procedure utilizes a flexible catheter to access the lung tumor via a working channel and may be used as an alternative procedure to a percutaneous microwave approach.

For CY 2023, the only available claims for HCPCS code C9751 are four claims from CY 2019. Therefore, given the low number of claims for this procedure, CMS is utilizing its equitable adjustment authority, which is a policy it adopted in CY 2019 under which it calculates the geometric mean, arithmetic mean, and median costs to calculate an appropriate payment rate for purposes of assigning a procedure to a New Technology APC. CMS used the same claims as it did for CY 2021 and 2022, so it found the same values for the geometric mean cost (\$2,693), arithmetic mean cost (\$3,086), and the median cost (\$3,708) for CY 2022. Therefore, the payment rate calculated falls again within the cost band for New Technology APC 1562 (New Technology—Level 25 (\$3501–\$4,000)), and the Agency will continue to assign HCPCS code C9751 to APC 1562 (New Technology—Level 25 (\$3501–\$4,000)), with a proposed payment rate of \$3,750.50 for CY 2023. Details regarding HCPCS code C9751 are included in Table 14.

Table 14: Final CY 2022 OPPS APC and Status Indicator for HCPCS Code C9751 Assigned to New Technology APC

CY 2023 HCPCS Code	Long Descriptor	Final CY 2022 OPPS SI	Final CY 2022 OPPS APC	Final CY 2023 OPPS SI	Final CY 2023 OPPS APC
C9751	Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3-D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (eg, aspiration[s]/biopsy[ies]	T	1562	T	1562

# **Cancer Hospital Payment Adjustment**

Since the inception of OPPS, Medicare has paid the 11 hospitals that meet the criteria for "cancer hospitals" under OPPS for covered outpatient hospital services to reflect their higher outpatient costs and to protect them from drastic cuts when OPPS was created. By law, they are "held harmless" and do not receive payment that is lower in amount under OPPS than the payment they would have received before OPPS was implemented. In the final rule, CMS will continue to provide additional payments to cancer hospitals so that a cancer hospital's payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for the other OPPS hospitals using the most recently submitted or settled cost report data.

However, the 21<sup>st</sup> Century Cures Act requires that this weighted average PCR be reduced by 1%. Based on the data and the required 1% reduction, CMS will use a target PCR of 0.89 to determine the CY 2023 cancer hospital payment adjustment to be paid at cost report settlement. That is, the payment adjustments will be the additional payments needed to result in a PCR equal to 0.89 for each cancer hospital.

Table 6 shows the estimated percentage increase in OPPS payments to each cancer hospital for CY 2023, due to the cancer hospital payment adjustment policy. It is important to note that the estimates in this table are likely less accurate than in other years because the cost reporting period for these hospitals overlaps with CY 2020, and the COVID-19 PHE would have significantly impacted the figures. The percentage increases in cancer hospital payments for CY 2023 are likely overstated, and the actual amount of the CY 2023 cancer hospital payment adjustment will be determined at cost report settlement and will depend on each hospital's CY 2023 payments and costs.

Table 6: Estimated CY 2023 Hospital-Specific Payment Adjustment for Cancer Hospitals to be

**Provided at Cost Report Settlement** 

Provider Number	Hospital Name	Estimated Percentage Increase in OPPS Payments for CY 2023 due to Payment Adjustment
050146	City of Hope Comprehensive Cancer Center	45.5%
050660	USC Norris Cancer Hospital	31.7%
100079	Sylvester Comprehensive Cancer Center	24.1%
100271	H. Lee Moffitt Cancer Center & Research Institute	23.1%
220162	Dana-Farber Cancer Institute	42.7%
330154	Memorial Sloan-Kettering Cancer Center	69.2%
330354	Roswell Park Cancer Institute	15.2%
360242	James Cancer Hospital & Solove Research Institute	12.9%
390196	Fox Chase Cancer Center	23.5%
450076	M.D. Anderson Cancer Center	49.4%
500138	Seattle Cancer Care Alliance	46.1%

#### **Health Equity**

Similar to proposals put forth in the Agency's other proposed rules, CMS sought ways to make reporting of health disparities based on social risk factors and race and ethnicity more comprehensive and actionable. One approach being considered to measure equity across CMS programs is the expansion of efforts to report quality measure results stratified by patient social risk factors and demographic variables.

The Agency received several responses, and it will take the commenters' feedback in consideration for

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future rulemaking.

# Additional information about the 2023 HOPPS final rule can be found at the following links:

A display copy of the final rule can be found at:

 $\underline{https://www.cms.gov/files/document/cy2023-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center-final-rule.pdf}$ 

The addenda relating to the HOPPS final rule are available at:

https://www.cms.gov/httpswwwcmsgovmedicaremedicare-fee-service-paymenthospitaloutpatientppshospital-outpatient/cms-1772-fc

A fact sheet on this final rule is available at:

 $\underline{https://www.cms.gov/newsroom/fact-sheets/cy-2023-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center-2}$