



# Calendar Year 2021 Hospital Outpatient Prospective Payment System Final Rule

On December 2<sup>nd</sup>, 2020 the Centers for Medicare and Medicaid Services (CMS) released the calendar year (CY) 2021 Hospital Outpatient Prospective Payment System (HOPPS) final rule. The finalized changes are effective January 1, 2021. The HOPPS final rule also included a Radiation Oncology (RO) Model interim final rule with comment period. The RO Model interim final rule provisions are applicable beginning July 1, 2021.

#### **Conversion Factor**

CMS has increased the conversion factor by 2.4 percent bringing it up to \$82.797 for CY 2021. CMS finalized an overall budget neutrality factor of 1.0012 for wage index changes. This adjustment is comprised of a 1.0020 budget neutrality adjustment; using the standard calculation of comparing total estimated payments from the simulation model utilizing the final FY 2021 IPPS wage indexes to those payments using the FY 2020 IPPS wage indexes, as adopted on a calendar year basis for the HOPPS, as well as a 0.9992 budget neutrality adjustment. For CY 2021, the 5 percent cap on wage index decreases to ensure that this transition wage index is implemented in a budget neutral manner. This resulted in a conversion factor for CY 2021 of \$82.797.

CMS will continue to mandate that hospitals that fail to meet the reporting requirements of the Hospital Outpatient Quality Reporting (OQR) Program would be subject to a further reduction of 2.0 percentage points by applying a reporting factor of 0.9805 to the OPPS payments and copayments for all applicable services. CMS states that the reduced conversion factor for hospitals not meeting the OQR requirements will be \$81.183.

#### **Estimated Impact on Hospitals**

The total 2021 increase in HOPPS spending due only to changes in the CY 2021 HOPPS final rule is estimated to be approximately \$1.49 billion. CMS estimates that OPPS expenditures, including beneficiary cost-sharing, for CY 2021 to be approximately \$83.888 billion, an increase of approximately \$7.541 billion compared to estimated CY 2020 OPPS payments.

#### AMBULATORY PAYMENT CLASSIFICATION GROUP POLICIES

#### **APC Placement of New Radiology CPT Codes**

In March 2020, the ACR presented CMS with recommendations for new CPT codes within APCs for CY 2021. CMS only accepted ACR's recommendation for the placement of new CPT code 32408 (Core ndl bx lng/med perq) placement in APC 5072 (Level 2 Excision/ Biopsy/ Incision and Drainage).

#### CY 2021 CMS APC Placement for New CPT Codes

CPT Code	Description	ACR Recommendation APC Placement	CY 2021 Proposed APC Placement	CY 2021 Final APC Placement	CY 2021 Payment Rate
32408	Core needle biopsy, lung or mediastinum, percutaneous, including imaging guidance, when performed (Do not report 324X0 in conjunction with 76942, 77002, 77012, 77021)	5072	5072	5072	\$1407.00
71271	Computed tomography, thorax, low dose for lung cancer screening, without contrast material(s)	5523	5521	5521	\$80.90
76145	Medical physics dose evaluation for radiation exposure that exceeds institutional review threshold, including report (medical physicist/dosimetrist)	5724	5611	5611	\$126.87

## CT Lung Cancer Screening

CMS finalized their proposal to place new CPT code 71271 (Ct thorax lung cancer scr c-) in the lowest Imaging without Contrast APC (5521), with payment rate of \$80.90. In addition, CMS finalized their proposal to place G0296 (visit to determine lung LDCT eligibility) in APC 5822, with a payment rate of \$74.87. The ACR has raised concerns about the inadequate payments for CT lung screening based on flawed hospital data in the past comment letters to CMS.

### **Imaging APCs**

CMS did not make any changes to the APC structure for imaging codes. The seven payment categories remain. However, CMS has moved codes within these payment categories which will change pricing for 2021.

**CY 2021 Imaging APCs** 

APC	Group Title	SI	Relative Weight	CY 2020	CY 2021 Payment
AIC	Gloup Title	51	Relative Weight	Payment Rate	Rate
5521	Level 1 Imaging without Contrast	S*	0.9771	\$82.15	\$80.90
5522	Level 2 Imaging without Contrast	S	1.3161	\$111.39	\$108.97
5523	Level 3 Imaging without Contrast	S	2.7794	\$235.05	\$230.13

5524	Level 4 Imaging without Contrast	S	5.8322	\$490.52	\$482.89
5571	Level 1 Imaging with Contrast	S	2.1565	\$181.41	\$178.55
5572	Level 2 Imaging with Contrast	S	4.4460	\$375.33	\$368.12
5573	Level 3 Imaging with Contrast	S	8.6377	\$722.74	\$715.18

<sup>\*</sup>Procedure or Service, Not Discounted When Multiple; Paid under OPPS; separate APC payment.

### **APC Exceptions to the 2-Times Rule**

CMS finalized exceptions to the 2-times rule based on the following criteria: resource homogeneity; clinical homogeneity; hospital outpatient setting utilization; frequency of service (volume); and opportunity for up-coding and code fragments. In the CY 2021 HOPPS proposed rule, CMS identified 18 APC exceptions to the 2-times rule for 2021. In this final rule, CMS identified a total of 23 APCs with violations of the 2 times rule in which they would make exceptions. Table 9, shows the 23 APC exceptions to the 2 times rule for CY 2021 based on the criteria described earlier and a review of updated claims data for dates of service between January 1, 2019 and December 31, 2019, that were processed on or before June 30, 2020, and updated CCRs, if available.

Table 9. APC Exceptions to the 2 Times Rule for 2021

2021 APC	APC Title
5051	5051 Level 1 Skin Procedures
5055	5055 Level 5 Skin Procedures
5071	5071 Level 1 Excision/ Biopsy/ Incision and
	Drainage
5101*	Level 1 Strapping and Cast Application
5112	5112 Level 2 Musculoskeletal Procedures
5161*	Level 1 ENT Procedures
5301	5301 Level 1 Upper GI Procedures
5311	5311 Level 1 Lower GI Procedures
5521	5521 Level 1 Imaging without Contrast
5522	5522 Level 2 Imaging without Contrast
5523	5523 Level 3 Imaging without Contrast
5524	5524 Level 4 Imaging without Contrast
5571	5571 Level 1 Imaging with Contrast
5593*	Level 3 Nuclear Medicine and Related Services
5612	5612 Level 2 Therapeutic Radiation Treatment
	Preparation
5627	5627 Level 7 Radiation Therapy
5673*	Level 3 Pathology
5691	5691 Level 1 Drug Administration
5721	5721 Level 1 Diagnostic Tests and Related
	Services
5731	5731 Level 1 Minor Procedures
5734*	Level 4 Minor Procedures
5821	Level 1 Health and Behavior Services

5823 Level 3 Health and Benavior Services	5823	Level 3 Health and Behavior Services
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\*Indicates newly identified APC with violation of the 2 times rule

# **Comprehensive APCs**

A Comprehensive APC (C-APC) is defined as a classification for a primary service and all adjunctive services provided to support the delivery of the primary service. When such a primary service is reported on a hospital outpatient claim, Medicare makes a single payment for that service and all other items and services reported on the hospital outpatient claim that are integral, ancillary, supportive, dependent, and adjunctive to the primary service. For CY 2021, CMS will create two new comprehensive APCs (C-APCs). These new C-APCs include the following: C-APC 5378 (Level 8 Urology and Related Services) and C-APC 5465 (Level 5 Neurostimulator and Related Procedures). Adding these C-APCs increases the total number of C-APCs to 69.

# Changes to New Technology APCs

# Changes to MRgFUS

There are currently four CPT/HCPCS codes that describe magnetic resonance image-guided, high-intensity focused ultrasound (MRgFUS) procedures, three of which CMS will continue assigning to standard APCs, and one that CMS will continue to assign to a New Technology APC for CY 2021. These codes include CPT codes 0071T, 0072T, and 0398T, and HCPCS code C9734. Based on available 2019 claims data, CMS has identified 169 paid claims for CPT code 0398T (MRgFUS for treatment of essential tremors) with a geometric mean of \$12,027.76. Since the service no longer meets the definition for a low-volume new technology service, CMS will assign the service to a clinical APC. Based on the 2019 claims, CMS determined that the most appropriate APC would be the Neurostimulator and Related Procedures APC series (APC 5461-5464). CMS will restructure this APC family and create an additional payment level within the clinical APC family, now APC 5461-5465. CMS believes that creating an additional payment level between the two existing APC levels (5462 and 5463) would allow for a smoother distribution of the costs between the different levels based on their resource costs and clinical characteristics. CMS will reassign CPT code 0398T to APC 5463 with a payment rate of \$11,236.21.

Table 10. CY 2021 Status Indicator (SI), APC Assignment, And Payment Rate for the MRgFUS Procedures

CPT/	Long Descriptor	CY	CY	CY 2020	CY 2021	CY 2021	CY 2021
HCPCS	_	2020	2020	OPPS	OPPS SI	OPPS	OPPS
Code		OPPS	OPPS	Payment		APC	Payment
		SI	APC	Rate			Rate
0071T	Focused ultrasound	J1*	5414	\$ 2,497.83	J1	5414	\$2,623.21
	ablation of uterine						
	leiomyomata,						
	including mr						
	guidance; total						
	leiomyomata						
	volume less than						
	200 cc of tissue.						
0072T	Focused	J1	5414	\$ 2,497.83	J1	5414	\$2,623.21
	ultrasound						

	ablation of uterine leiomyomata, including mr guidance; total leiomyomata volume greater or equal to 200 cc of tissue.						
0398T	Magnetic resonance image guided high intensity focused ultrasound (mrgfus), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed.	S**	1575	\$12,500.50	J1	5463	\$11,236.21
C9734	Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (mr) guidance.	J1	5115	\$11,899.39	J1	5115	\$12,314.76

<sup>\*</sup>Hospital Part B Services Paid Through a Comprehensive APC; aid under OPPS; all covered Part B services on the claim are packaged with the primary "J1" service for the claim, except services with OPPS status indicator of "F", "G", "H", "L" and "U"; ambulance services; diagnostic and screening mammography; rehabilitation therapy services; new technology services; self-administered drugs; all preventive services; and certain Part B inpatient services.

#### Fractional Flow Reserve Derived From Computed Tomography (FFRCT)

FFRCT (trade name HeartFlow) is a noninvasive diagnostic service that measures coronary artery disease by CT scans (CPT code 0503T). For 2021, based on 2019 claims data, CMS identified 2,820 claims with a geometric mean cost of approximately \$851. CMS considered reassigning CPT code 0503T to APC 5724 (Level 4 -Diagnostic Tests and Related Services) which has a payment rate of \$903 based on clinical and resource similarity to other services within the APC. Because of the payment rate, CMS did not propose this reassignment and instead proposed to reassign CPT code 0503T to New Technology APC 1510 (New Technology Level 10 (\$801-\$900). CMS finalized their proposal, with modifications, and continues the CY 2020 APC assignment and assigns CPT code 053T to APC 1511 (New Technology – Level 11) with a payment rate of \$950.50.

<sup>\*\*</sup> Procedure or Service, Not Discounted When Multiple; Paid under OPPS; separate APC payment.

Cardiac Positron Emission Tomography (PET)/Computed Tomography (CT)

Since January 1, 2020, CMS assigned three CPT codes (78431-78433) describing services associated with cardiac PET/CT studies to New Technology APCs (APCs 1522, 1523, and 1523, respectively). CMS has not received any claims with these CPT codes. CMS will continue to assign the three CPT codes 78432, 78432, and 78433 into the New Technology APCs. CPT code 78341 will be in APC 1522, CPT codes 78432 and 78433 in APC 1523.

# **Brachtherapy**

Since 2010, CMS has used the standard OPPS payment methodology for brachytherapy sources, with payment rates based on source-specific costs as required by statute. CMS did not make changes to their brachytherapy policy for 2021.

#### **CT and MR Cost Centers**

In the CY 2014 HOPPS final rule, CMS created distinct cost-to-charge (CCRs) for implantable devices, MRIs, CT scans, and cardiac catheterization. However, in response to public comment, CMS removed claims from providers that use a cost allocation method of "square feet" to calculate CCRs used to estimate costs associated with the CT and MRI APCs because of concerns about the accuracy of this cost allocation method. CMS indicated that it would provide hospitals with a four year transition period. CMS later extended the transition policy through 2018 and 2019. Beginning in CY 2021, CMS will fully implement the CT and MR cost center policy that allows hospitals to submit data regardless of the cost allocation method. The ACR has raised concerns many times in the past regarding the use of claims from hospitals that continue to report under the "square foot" cost allocation method noting that it would underestimate the true costs of CT and MR studies. CMS has given the hospitals six years to adjust their cost allocation methods from "square foot" to either the "direct" or the "dollar" method. These changes are the result of a study conducted by the Research Triangle Institute (RTI) back in 2007<sup>1</sup>. Although the ACR has argued that the RTI study, and data which back it up, are outdated, CMS is adamant to continue with fully implementing its recommendations on how to better represent cost center data in the hospital setting.

Table 1 of the final rule shows the relative effect on imaging APC payments after removing cost data for providers that report CT and MRI standard cost centers using square feet as the cost allocation method. Table 2 of the final rule provides statistical values based on the CT and MRI standard cost center CCRs using the different cost allocation methods. Tables 1 and 2 are shown below.

Table 1. Percentage Change in Estimated Cost for CT and MRI APCS When Excluding Claims From Provider Using "Square Feet" As the Cost Allocation Method

APC	APC Descriptor	Percentage Change
5521	Level 1 Imaging without Contrast	-2.8%
5522	Level 2 Imaging without Contrast	5.5%
5523	Level 3 Imaging without Contrast	4.3%
5524	Level 4 Imaging without Contrast	5.3%

<sup>&</sup>lt;sup>1</sup> Cromwell, J., & Dalton, K. (2007, January). *A Study of Charge Compression in Calculating DRG Relative Weights* (Rep.). Retrieved July 1, 2019, from Centers for Medicare and Medicaid Services website: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/downloads/Dalton.pdf

5571	Level 1 Imaging with Contrast	6.8%
5572	Level 2 Imaging with Contrast	8.2%
5573	Level 3 Imaging with Contrast	2.3%
8007	MRI and MRA without Contrast Composite	13.9%
8008	MRI and MRA with Contrast Composite	10.8%
8007	MRI and MRA without Contrast Composite	7.6%
8008	MRI and MRA with Contrast Composite	7.2%

Table 2. CCR Statistical Values Based on Use of Different Cost Allocation Methods

<b>Cost Allocation</b>	C	CT	MR		
Method	Median CCR	Mean CCR	Median CCR	Mean CCR	
All Providers	0.0342	0.0483	0.0752	0.1008	
Square Feet Only	0.0285	0.0435	0.0660	0.0919	
Direct Assign	0.0459	0.0557	0.0910	0.1151	
Dollar Value	0.0405	0.0546	0.0858	0.1126	
Direct Assign and Dollar Value	0.0406	0.0548	0.0862	0.1128	

Furthermore, CMS will continue to monitor OPPS imaging payments and consider the potential impacts of payment changes on the physician fee schedule (PFS) and ambulatory surgical center payment systems.

### Policy Packaged Drugs, Biologicals, and Radiopharmaceuticals

CMS will continue paying for drugs and therapeutic radiopharmaceuticals at ASP + 6% as set forth in the CY 2010 HOPPS Final Rule. CMS received many public comments regarding the reimbursement of radiopharmaceuticals. Despite these comments, CMS will also maintain the threshold payment for therapeutic radiopharmaceuticals at \$130, where CMS will package those that are priced less or equal to \$130 into the APC payments and pay separately for those that meet or exceed this threshold amount.

### **Other HOPPS Payment Policies**

# Payment Adjustments to Certain Cancer Hospitals

The ACA requires an adjustment to cancer hospitals' outpatient payments to bring each hospital's payment-to-cost ratio (PCR) up to the level of the PCR for all other hospitals, the target PCR. The changes in additional payments from year to year are budget neutral. The 21<sup>st</sup> Century Cures Act reduced the target PCR by 1.0 percentage point and excludes the reduction from OPPS budget neutrality.

The cancer hospital adjustment is applied at cost report settlement rather than on a claim by claim basis. For 2021, CMS updated its calculations using the latest available cost data through June 30<sup>th</sup>, 2020 and finalized a PCR of 0.90. CMS is reducing the target PCR from 0.90 to 0.89. CMS did not receive any public comments on their proposal. Table 5, below, shows the hospital-specific payment adjustment for each of the 11 cancer hospitals, with increases in OPPS payments for 2021 ranging from 9.2 percent to 43.2 percent. The actual amount of the CY 2021 cancer hospital payment adjustment for each cancer hospital will be determined at cost report settlement and will depend on each hospital's CY 2021 payments and costs.

Table 5. Estimated CY 2021 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 2020 due to Payment Adjustment
050146	City of Hope Comprehensive Cancer Center	31.8%
050660	USC Norris Cancer Hospital	9.9%
100079	Sylvester Comprehensive Cancer Center	11.6%
100271	H. Lee Moffitt Cancer Center & Research	19.2%
	Institute	
220162	Dana-Farber Cancer Institute	34.3%
330154	Memorial Sloan-Kettering Cancer Center	37.9%
330354	Roswell Park Cancer Institute	12.3%
360242	James Cancer Hospital & Solove Research Institute	11.5%
390196	Fox Chase Cancer Center	9.2%
450076	M.D. Anderson Cancer Center	40.3%
500138	Seattle Cancer Care Alliance	43.2%

# **Measure Changes within the Hospital OQR Program**

CMS did not propose changes to any measure additions for the Hospital OCR Program.

### **Inpatient Only List**

Services on the IPO list are not paid under the OPPS. Currently, the IPO list includes approximately 1,740 services. CMS annually reviews the IPO list to identify any services that should be removed from or added to the list based on the most recent data and medical evidence available using criteria specified annually in the OPPS rule. In previous years, CMS received comments from stakeholders who believe the IPO list should be eliminated and deference given to the clinical judgment of physicians for selecting where to perform a service. CMS has finalized their proposal to eliminate the IPO list over a transitional period beginning in 2021 and ending in 2024. For 2021, CMS will remove 266 musculoskeletal services from the IPO list. CMS will also be removing 32 additional HCPCS codes from the IPO list for CY 2021 based on public comments they received.

## **Supervision of Outpatient Therapeutic Services**

In the CY 2020 HOPPS final rule, CMS finalized a policy to change the generally applicable minimum required level of supervision for hospital outpatient therapeutic services from direct supervision to general supervision for services furnished by all hospitals and critical access hospitals (CAHs). For those services that maintained direct supervision, CMS changed the supervision level to general during the COVID-19 PHE in an interim final rule. This policy was adopted to provide additional flexibility for Medicare beneficiaries, while minimizing the overall risk to public health. CMS believes that these policies are appropriate outside of the PHE and should apply permanently. For CY 2021 and subsequent years, CMS is changing the minimum default level of supervision for non-surgical extended duration therapeutic services (NSEDTS) to general supervision for the entire service, including the initiation portion of the service, for which previously required direct supervision.

This is consistent with the minimum required level of general supervision that currently applies for most outpatient hospital therapeutic services.

CMS is also finalizing the proposed policy to permit direct supervision of pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services using virtual presence of the physician through audio/video real-time communications technology subject to the clinical judgment of the supervising physician until the later of the end of the calendar year in which the PHE ends or December 31, 2021.

# Radiation Oncology Model- Interim Final Rule with Comment Period

CMS has formally delayed the Radiation Oncology (RO) Model start date to July 1, 2021 and made other provisions that accompany this delay through an interim final rule with comment period. The RO Model will now run for 4.5 years: from July 1, 2021 through December 31, 2025.

Because the model will begin on July 1, 2021, both episodes and RO episodes from 2021 will determine eligibility for the low-volume opt-out for PY3. For PY3, eligibility for the low-volume opt-out is determined by counting episodes from January 1, 2021 through June 30, 2021 and RO episodes from July 1, 2021 through December 31, 2021.

Collection of quality measures during PY1 of the RO Model has been delayed; and will now begin starting in PY2 (January 1, 2022-December 31, 2022). In PY2, RO Model participants must submit quality measures from January 1, 2022 through December 31, 2022 in March of 2023. Similarly, the collection for clinical data elements (CDEs) will now begin in PY2 on January 1, 2022, and the first submission of CDEs for January 1, 2022 through June 30, 2022 will be due in July 2022. Because CMS is delaying the collection of quality measures and CDEs, there will not be a 2 percent quality withhold in PY1 of the RO Model, and this withhold will instead begin in PY2. Additionally, as a result of CDEs and quality measures beginning in PY2, the aggregate quality score will be applied beginning in PY2 and Professional and Dual Participants will not have a quality reconciliation for PY1. The reconciliation amount for PY1 will be based solely on the incorrect episode payment reconciliation amount and any stop-loss reconciliation amount, if applicable.

The CMS-approved contractor that will administer the CAHPS Cancer Care Survey for Radiation Therapy will now do so starting October 2021.

CMS has determined that the RO Model will not meet the criteria to be either an Advanced APM or a MIPS APM under the Quality Payment Program in PY1 and will instead qualify in PY2. As a result, in PY1 the individual practitioner list will only be used to assign an automatic 50 percent score for the Improvement Activity performance category in MIPS for RO participants. Starting in PY2, the individual practitioner list will be used to identify Qualifying APM Participants. Additionally, Certified Electronic Health Record Technology (CEHRT) will not be required until PY2 due to the delay of the model. There is a 60-day public comment period following the publication of the interim final rule on December 2, 2020.