2019 Hospital Regulatory Update

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The Hospital Outpatient Prospective Payment System (HOPPS or OPPS) is one of the Medicare payment systems that applies to facility-based settings, including hospitals, ambulatory surgical centers (ASCs), critical access hospitals (CAHs), and excepted off-campus provider-based departments (PBDs). The Centers for Medicare & Medicaid Services (CMS) indicated in the CY 2019 OPPS final rule that the overarching goal is *"to make payments for all services under the OPPS more consistent with those of a prospective payment system and less like those of a per-service fee schedule, which pays separately for each coded item."* To accomplish this goal in the past few years, CMS has continued to package more ancillary services into what are considered primary services, establishing reimbursement for the primary service only. Another route taken by CMS to control spending is to neutralize payments, reimbursing for the same service in a manner that is "neutral" to where it was performed—hospital, physician office, or ASC.

CMS estimates expenditures for CY 2019 will be approximately $74.1 billion—an increase of approximately $5.8 billion from CY 2018 OPPS payments. There is an increase in payments rates of 1.35 percent under the Outpatient Department (OPD) fee schedule. This increase will mean approximately a 1.4 percent increase for urban hospitals and a 1.3 percent increase for rural hospitals. The CY 2019 conversion factor was finalized at $790.49 for hospitals meeting the Hospital Outpatient Quality Reporting (OQR) Program requirements; CMS will decrease the conversion factor by 2 percent for hospitals that fail to meet quality reporting requirements. The overall estimated expenditures also take into consideration a 0.8 percent decrease in reimbursement for the multifactor productivity (MFP) adjustment and the required 0.75 percent decrease due to the Affordable Care Act for years 2010 through 2019.

Certain rural sole community hospitals will continue to see a rural adjustment factor of 7.1 percent applied to OPPS payments for CY 2019 and subsequent years. This payment adjustment will continue to exclude separately payable drugs, biologicals, and devices paid under the pass-through payment policy. ASC payments were finalized to increase by 2.1 percent for those meeting quality reporting under the Ambulatory Surgical Center Quality Reporting (ASCQR) Program.

Frontier state hospitals will continue to apply a wage index of 1.000 for CY 2019, and 11 cancer-designated hospitals will continue to receive additional payment adjustments. The payment-to-cost ratio (PCR) used to determine the payment adjustments for cancer hospitals was weighted to account for the 1.0 percent decrease required by the 21st Century Cures Act, resulting in a PCR of 0.88 for CY 2019. Additionally, CMS will provide outlier payments to hospitals to mitigate the financial risk associated with some high-cost procedures and services. In order to qualify for the additional outlier payment, the cost of the procedure must exceed 1.75 times the ambulatory payment classification (APC) payment and exceed it by more than $4,825. If the threshold is met, then 50 percent of the difference between the cost and APC payment will be an additional payment to the hospital.

APC Two-Times Rule Exceptions

CMS identified several APCs in violation of the two-times rule for CY 2019. Two were new since the proposed rules were released, and one was resolved without intervention. The two-times rule does not allow codes to be assigned to an APC where the highest costing code is more than two times that of the lowest costing code. When a two-times rule violation is identified, CMS and the Hospital Outpatient Payment (HOP) Panel will reassign codes or create a new APC. When determining if there is a two-times-rule violation, CMS only considers Healthcare Common Procedure Coding System (HCPCS) codes that are significant based on the number of claims.

For CY 2019, CMS made exceptions for all the two-times-rule violating APCs, meaning no adjustments or movement of codes to other APCs was required to balance the codes of highest and lowest cost. This exception included the three APCs related to oncology services: **APC 5612** (Level 2 Therapeutic Radiation Treatment Preparation), **APC 5691** (Level 1 Drug Administration), and **APC 5692** (Level 2 Drug Administration).

Site-Neutral Payments for Hospital Outpatient Clinic Visits

In response to the Bipartisan Budget Act of 2015, CMS established new guidelines to address the difference in reimbursement payments for the exact same procedure between varying places of service—primarily hospital, ASC, and physician office. The Act set Nov. 2, 2015 for the establishment of any new provider-based departments (PBDs) and the distance (250 yards) the new department could be from the main buildings of the hospital and still receive payment rates established under OPPS. Due to what was considered the alarming rate of hospitals acquiring physician practices and the tendency for PBDs of a hospital to be paid more than a physician office setting, changes were made.

Excepted off-campus PBDs are settings which were established and billing for services prior to Nov. 2, 2015 and are within the previously set distance of 35 miles. Excepted off-campus PBDs are paid at the OPPS full established rate for each service and are considered "grandfathered" into the payments under OPPS, even if the new distance threshold is not met. Non-excepted off-campus PBDs are settings that were established on or after Nov. 2, 2015 and are outside the newly set distance of 250 yards from the main buildings of the hospital. Non-excepted PBDs are paid under the Physician Fee Schedule (PFS) but are still considered a facility setting for the purposes of following guidelines about supervision, packaging, and more.

CMS's practice of neutralizing payments for services based on utilization is not new. It first occurred in the CY 2008 OPPS/ASC final rule. At that time, the agency had concerns about expenditures for some hospital outpatient services that showed significant growth. As a result, CMS established a set of packaging policies intended to encourage efficiency and potentially control future growth in the number of OPPS services. Effective CY 2008, CMS packaged seven categories of services and items specific to primary diagnostic or therapeutic modalities believed to be ancillary or supportive, including the packaging of imaging services in radiation oncology into treatment delivery.

In CY 2015, CMS introduced another method of spending control with the introduction of comprehensive APCs (C-APCs). CMS expanded the packaging of services to include items involved in many same-day or surgical procedures. To do so, CMS designated a primary service and packaged all ancillary services reported on the same claim into the primary service, meaning no separate payment for ancillary services. The idea was to make OPPS more like a prospective payment system and less like a per-service fee schedule.

The OPPS is the fastest growing sector of Medicare payments out of all of payment systems under Part A and B. The growth rate—approximately 8 percent each year—is concerning to CMS. Total spending for the OPPS is projected to increase by more than $5 billion—from $70 billion in CY 2018 to nearly $75 billion in CY 2019. This increase is approximately twice the estimated spending of CY 2008.

For CY 2019, CMS expressed concerned about code **G0463** (Hospital outpatient clinic visit for assessment and management of a patient), which is the most widely reported code under the OPPS. CMS proposed a site-neutral method for controlling *"unnecessary increases in the volume of covered outpatient department services."* The agency believed the increase in reporting of code **G0463** was related to the payment incentive in the high-cost setting and that these services could be provided effectively and safely in a low-cost setting. By reducing the rate to one equivalent to the PFS rate, CMS looked to remove the incentive and decision about where to perform the service so it has the most favorable financial impact.

For CY 2019, CMS proposed to use a PFS payment rate for code **G0463** when billed in excepted off-campus PBDs, setting reimbursement for this code at 40 percent of the HOPPS rate—the same reimbursement amount for non-excepted off-campus PBDs.

After review of comments, the agency is moving forward with the payment adjustment for code **G0463** in excepted off-campus PBDs, but the agency will implement this change over 2 years. When a reduction is greater than 20 percent for a given year, the reduction is phased in over time. In CY 2019, the reimbursement rate for **G0463** in an excepted off-campus PBD will be 70 percent of the HOPPS full rate. In CY 2020, the reimbursement rate for **G0463** will be the PFS rate for the service, equating to 40 percent of the full HOPPS rate—unless the PFS rate is changed.

Only on-campus hospital outpatient departments will be reimbursed at the full OPPS value for code **G0463** in CY 2019. Excepted off-campus PBDs would continue to report **G0463** with the modifier **PO**.

Oncology Comprehensive APCs

C-APCs were first implemented in CY 2015 and have continued to grow and evolve since that time. Primary services are designated with a status indicator code of "**J1**" or for certain coding scenarios, with "**J2**" to identify the C-APC. All ancillary codes with status indicators of "**S**," "**T**," or "**V**" are packaged into the C-APC and are not separately reimbursed.

In CY 2019 and subsequent years, CMS is continuing to apply the C-APC payment methodology, "**J1**," and certain "**J2**" status indicators to reflect the C-APC designation. New C-APCs were finalized for CY 2019, but none were specific to or included services for oncology. CMS did receive several comments requesting the discontinuation of the C-APC payment policy for several brachytherapy insertion procedures and single session stereotactic radiosurgery (SRS) procedures. Commenters also requested that CMS include Current Procedural Terminology (CPT) code **77301** for IMRT planning on the list of other codes reimbursed separately with SRS, stating the service has become more common in single fraction SRS planning. The following is the response by CMS to the requests by commenters for changes to the C-APCs impacting radiation oncology, brachytherapy, and stereotactic radiosurgery:

"At this time, we do not believe that it is necessary to discontinue the C-APCs that include brachytherapy insertion procedures and single session SRS procedures. We continue to believe that the C-APC policy is appropriately applied to these surgical procedures for the reasons cited when this policy was first adopted and note that the commenters did not provide any empirical evidence to support their

claims that the existing C-APC policy does not adequately pay for these procedures. Also, we will continue in CY 2019 to pay separately for the 10 planning and preparation services (HCPCS codes 70551, 70552, 70553, 77011, 77014, 77280, 77285, 77290, 77295, and 77336) adjunctive to the delivery of the SRS treatment using either the Cobalt-60-based or LINAC based technology when furnished to a beneficiary within 1 month of the SRS treatment for CY 2019 (82 FR 59242 and 59243)."

Payments of Drugs, Biologicals, and Radiopharmaceuticals

Each year, CMS assesses the drug packaging threshold. For CY 2019, CMS finalized the packaging of drugs and biologicals estimated to have a per-day administration cost of less than or equal to $125. In other words, the agency will only pay separately for items with an estimated per-day cost greater than $125, with the exception of diagnostic radiopharmaceuticals, contrast agents, anesthesia drugs, drugs and biologicals, radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, and drugs and biologicals that function as supplies or devices when used in a surgical procedure.

CMS also finalized the proposal to continue the policy of making packaging determinations on a drug-specific basis rather than by HCPCS code for codes that describe the same drug or biological in different dosages. For all other drugs and biologicals that have HCPCS codes describing different doses, CMS aggregated the CY 2017 claims data and pricing information at average sales price (ASP) plus 6 percent for all HCPCS codes that describe each distinct drug or biological. This provided the mean units per day with respect to the HCPCS code with the lowest dosage descriptor. For other drugs and biologicals that have HCPCS codes describing different doses, CMS multiplied the weighted average ASP plus 6 percent per unit across all dosage levels of a specific drug or biological by the estimated units per day for all HCPCS codes that describe each drug or biological; this determined the estimated per-day cost of each drug or biological at less than or equal to the proposed CY 2019 drug packaging threshold of $125.

CMS did not receive any public comments related to this proposal; therefore, it was finalized without modification. The drugs and biologicals commonly used in oncology for which this final packaging status applies for CY 2019 are listed in Table 2 below.

For CY 2019, CMS will continue the current policy, in effect since CY 2013, to pay for separately payable drugs and biologicals at ASP plus 6 percent. These separately payable drugs and biologicals are listed in Addenda A and B to the final rule. CMS will also continue to pay for separately payable non-pass-through drugs acquired with a 340B discount at ASP minus 22.5 percent.

Table 2. HCPCS Codes to Which the CY 2019 Drug-Specific Packaging Determination Methodology Applies

CY 2019 HCPCS CODE	CY 2019 LONG DESCRIPTOR	CY 2019 STATUS INDICATOR (SI)
C9257	Injection, bevacizumab, 0.25mg	K
J9035	Injection, bevacizumab, 10 mg	K
J1020	Injection, methylprednisolone acetate, 20 mg	N
J1030	Injection, methylprednisolone acetate, 40 mg	N
J1040	Injection, methylprednisolone acetate, 80 mg	N
J1460	Injection, gamma globulin, intramuscular, 1 cc	K
J1560	Injection, gamma globulin, intramuscular over 10 cc	K
J1642	Injection, heparin sodium, (heparin lock flush), per 10 units	N
J1644	Injection, heparin sodium, per 1000 units	N
J2920	Injection, methylprednisolone sodium succinate, up to 40 mg	N
J2930	Injection, methylprednisolone sodium succinate, up to 125 mg	N
J7030	Infusion, normal saline solution, 1000 cc	N
J7040	Infusion, normal saline solution, sterile (500 ml=1 unit)	N
J7050	Infusion, normal saline solution, 250 cc	N
J8520	Capecitabine, oral, 150 mg	N
J8521	Capecitabine, oral, 500 mg	N
J9250	Methotrexate sodium, 5 mg	N
J9260	Methotrexate sodium, 50 mg	N

For drugs or biologicals with insufficient data on sales price during the initial sales period, payments will be based on wholesale acquisition cost (WAC). The Social Security Act states that certain payments must be made with a 6 percent add-on; however, the Act does not require the same add-on amount when utilizing WAC-based pricing. To be consistent with the CY 2019 PFS proposed rule, CMS proposed to use a 3 percent add-on instead of a 6 percent add-on for WAC-based drugs in the hospital outpatient setting. For drugs and biologicals acquired under the 340B Program, the 340B Program rate (WAC minus 22.5 percent) would apply.

After consideration of the comments received, CMS finalized its proposal without modification. Starting Jan. 1, 2019, a 3 percent add-on will be used instead of a 6 percent add-on for drugs paid based on WAC.

CMS previously finalized the payment policy for biosimilar biological products based on the payment allowance of the product as determined under the Social Security Act in CY 2016 and CY 2017. For CY 2019, CMS proposed to continue the policy from CY 2018, making all biosimilar biological products eligible for pass-through payment, not just the first biosimilar biological product for a reference product. CMS also proposed to pay non-pass-through biosimilars acquired under the 340B Program at ASP minus 22.5 percent of the biosimilar's ASP instead of the biosimilar's ASP minus 22.5 percent of the reference product's ASP.

Upon review of the public comments, CMS finalized its proposal without modification to make all biosimilar biologicals products eligible for pass-through payment, not just the first product for a reference. CMS will also pay non-pass-through biosimilars acquired under the 340B Program at the biosimilar's ASP minus 22.5 percent rather than that of the reference product's ASP.

As proposed, CMS also finalized to expire pass-through status of 23 commonly-used oncology drugs and biologicals on Dec. 31, 2018. These drugs and biologicals will have received OPPS pass-through payment for at least 2 years and no more than 3 years by this date. Table 3, page 14, identifies the drugs and biologicals to be removed from the pass-through list.

For CY 2019, CMS will continue to pay for 45 commonly-used drugs and biologicals, plus an additional 4 drugs and biologicals that were extended pass-through status for an additional 2 years even though they reached the 3-year maximum, at ASP plus 6 percent. The additional 4 drugs and biologicals were required to be extended pass-through by additional legislation. CMS will continue to update pass-through payment rates on a quarterly basis through the its website. Table 4, page 15, lists the drugs and biologicals that will remain on the pass-through list for CY 2019.

340B Drug Discount Program

In the CY 2018 OPPS final rule, CMS finalized the policy to pay for drugs purchased under the 340B Drug Discount Program (not including drugs on pass-through payment status or vaccines) at the rate of ASP minus 22.5 percent—a dramatic reduction to the previous rate of ASP plus 6 percent. CMS stated the goal is to make Medicare payments for separately payable drugs more in alignment with resources expended by hospitals to acquire the drugs while also recognizing the intention of the 340B Program: to allow hospitals to stretch resources and provide access to care for Medicare beneficiaries and other patients.

For CY 2019, CMS proposed to continue the policies as finalized in CY 2018 with a few exceptions. As previously addressed, CMS proposed to pay biosimilar biological products at minus 22.5 percent of the biosimilar's ASP, not the reference drug's ASP. Drugs not purchased under the 340B Program will continue to be paid at ASP plus 6 percent. Hospitals will continue to report drugs purchased through the 340B Drug Discount Program with modifier **JG** on the same claim line items as the drug HCPCS code. Additionally, rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals continue to be excepted from the 340B payment adjustment and will report modifier **TB** for 340B-acquired drugs on claim forms and paid at ASP plus 6 percent.

For CY 2019, CMS finalized the proposal without modification and will continue to apply policies implemented in CY 2018 with the exception of the methodology in calculating payment for 340B-acquired biosimilars.

New for CY 2019, CMS proposed to apply the 340B Drug Payment Policy to non-excepted off-campus PBDs. Due to provisions in the Bipartisan Budget Act of 2015, non-excepted off-campus PBDs as of Nov. 2, 2015 had not billed for services to CMS and were outside of 250 yards from the main building of the hospital. Since these departments are not considered outpatient departments of the hospital, they are currently paid under the PFS. For this reason, CMS did not apply the 340B payment policy to non-excepted off-campus PBDs in CY 2018; however, because hospitals can acquire drugs and biologicals under the 340B Program for use in a non-excepted off-campus PBD, CMS felt this could result in incongruity between payment amounts, depending on where drugs were provided. Accordingly, due to the potential for hospitals to move services from excepted off-campus PBDs to non-excepted off-campus PBDs and to be paid at a higher rate, thereby creating a non-neutral payment structure, CMS proposed changes. CMS proposed to pay under the PFS an amount equal to ASP minus 22.5 percent for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B Program and furnished and billed by non-excepted off-campus PBDs of a hospital.

CMS received comments from organizations representing oncology practices, pharmaceutical research and manufacturing companies, a large network of community-based oncology practices, and health insurers supporting the proposal. A pharmaceutical company commented, *"the 340B Program has grown beyond its original intent and needs to be refocused to better meet the needs of vulnerable patients."* This commenter indicated there is an incentive to

Table 3. Drugs and Biologicals for Which Pass-Through Payment Status Expires Dec. 31, 2018

CY 2019 HCPCS CODE	CY 2019 LONG DESCRIPTOR	FINAL CY 2019 STATUS INDICATOR	FINAL CY 2019 APC	PASS-THROUGH PAYMENT EFFECTIVE DATE
J7202	Injection, Factor IX, albumin fusion protein (recombinant), Idelvion, 1 i.u.	K	9171	10/01/2016
J7207	Injection, Factor VIII (antihemophilic factor, recombinant) PEGylated, 1 i.u.	K	1844	04/01/2016
J7209	Injection, Factor VIII (antihemophilic factor, recombinant) (Nuwiq), per i.u.	K	1846	04/01/2016
J9022	Injection, atezolizumab, 10 mg	K	9483	10/01/2016
J9145	Injection, daratumumab, 10 mg	K	9476	07/01/2016
J9176	Injection, elotuzumab, 1 mg	K	9477	07/01/2016
J9205	Injection, irinotecan liposome, 1 mg	K	9474	04/01/2016
J9295	Injection, necitumumab, 1 mg	K	9475	04/01/2016
J9325	Injection, talimogene laherparepvec, 1 million plaque forming units (PFU)	K	9472	04/01/2016
J9352	Injection, trabectedin, 0.1 mg	K	9480	07/01/2016
Q5101	Injection, filgrastim-sndz, biosimilar, (zarxio), 1 microgram	k	1822	07/01/2015

shift administration of drugs from excepted to non-excepted off-campus PBDs to secure higher payment.

Some commenters, including organizations representing community oncology practices, indicated, *"the opportunity for 340B-participating hospitals to get substantial revenue from cancer drugs has created financial incentives for hospitals to expand oncology services, notably through the acquisition of independent community oncology practices,"* which results in *"further fueling the program's staggering growth."* Commenters also cited a report that states, *"over the last decade, 658 community oncology practices have been acquired by hospitals, and 3 out of 4 of these acquisitions were by hospitals already eligible for the 340B Program."* The commenters believe that growth in Part B drug spending has been driven by higher payments in the hospital outpatient setting.

Upon review of comments received related to this proposal, CMS finalized it without modification, making payment for separately payable 340B-acquired drugs furnished by non-excepted off-campus PBDs of a hospital under the PFS, setting the payment rate for those drugs at ASP minus 22.5 percent. In addition, starting Jan. 1, 2019, non-excepted off-campus PBDs of a hospital paid under PFS will be required to report modifier **JG** on the claim line identifying drugs purchased under the 340B Program.

Brachytherapy Sources

CMS will continue to use costs derived from CY 2017 claims data to set the CY 2019 payment rates and base the payment rates for brachytherapy sources on the geometric mean unit costs for each source. Brachytherapy sources, unless otherwise noted, are assigned status indicator "**U**." Codes with status indicator "**U**" are not packaged into C-APCs; the sources are paid separately in addition to the brachytherapy insertion code in the hospital setting.

One commenter expressed concern over the significantly fluctuating rates for low-volume brachytherapy sources over the years. A request was made for CMS to use the general OPPS methodology of cost-based claims data to set the relative payment rates. CMS responded that per the CY 2012 final rule period, the payment for brachytherapy sources for OPPS relies on the concept of averaging; this may result in a payment that is more or less than the actual estimated cost of providing the service. However, CMS believes this process is adequate for setting

Table 4. Drugs and Biologicals with Pass-Through Payment Status in CY 2019

CY 2018 HCPCS CODE	CY 2019 HCPCS CODE	CY 2019 LONG DESCRIPTOR	CY 2019 STATUS INDICATOR	CY 2019 APC	PASS THROUGH PAYMENT EFFECTIVE DATE
C9016	J3316	Injection, triptorelin extended release, 3.75 mg	G	9016	01/01/2018
C9024	J9153	Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine	G	9302	01/01/2018
C9028	J9229	Injection, inotuzumab ozogamicin, 0.1 mg	G	9028	01/01/2018
C9030	J9057	Injection, copanlisib, 1 mg	G	9030	07/01/2018
C9033	J1454	Injection, fosnetupitant 235 mg and palonosetron 0.25 mg	G	9099	10/01/2018
C9463	J0185	Injection, aprepitant, 1mg	G	9463	04/01/2018
C9464	J2797	Injection, rolapitant, 0.5 mg	G	9464	04/01/2018
C9467	J9311	Injection, rituximab 10 mg and hyaluronidase	G	9467	04/01/2018
C9468	J7203	Injection, factor ix (antihemophilic factor, recombinant), glycopegylated, Rebinyn, 1 i.u.	G	9468	04/01/2018
C9492	J9173	Injection, durvalumab, 10 mg	G	9492	10/01/2017
J1627	J1627	Injection, granisetron extended release, 0.1 mg	G	9486	04/01/2017
J2350	J2350	Injection, ocrelizumab, 1 mg	G	9494	10/01/2017
J7179	J7179	Injection, von willebrand factor (recombinant), (Vonvendi), 1 i.u. vwf:rco	G	9059	01/01/2017
J7210	J7210	Injection, factor viii, (antihemophilic factor, recombinant), (afstyla), 1 i.u.	G	9043	01/01/2017
J9023	J9023	Injection, avelumab, 10 mg	G	9491	10/01/2017
J9034	J9034	Injection, bendamustine hcl (Bendeka), 1 mg	G	1861	01/01/2017
J9203	J9203	Injection, gemtuzumab ozogamicin, 0.1 mg	G	9495	01/01/2018
J9285	J9285	Injection, olaratumab, 10 mg	G	9485	04/01/2017
N/A	Q2042*	Tisagenlecleucel, up to 600 million CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9194	04/01/2018
Q2041	Q2041	Axicabtagene Ciloleucel, up to 200 million autologous anti-CD19 CAR T cells, including leukapheresis and dose preparation procedures, per infusion	G	9035	04/01/2018
N/A	Q2042*	Tisagenlecleucel, up to 600 million CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9194	04/01/2018
Q9993	J3304	Injection, triamcinolone acetonide, preservative-free, extended-release, Microsphere formulation, 1 mg	G	9469	04/01/2018
Q5106	Q5106	Injection, epoetin alfa, biosimilar, (Retacrit) (for non-ESRD use), 1000 units	G	9097	10/01/2018
Q9995	J7170	Injection, emicizumab-kxwh, 0.5 mg	G	9257	07/01/2018
N/A	C9038	Injection, mogamulizumab-kpkc, 1 mg	G	9182	01/01/2019

*HCPCS code Q2040 (Tisagenlecleucel, up to 250 million CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per infusion) will be deleted on December 31, 2018 and will be replaced by Q2042 (Tisagenlecleucel, up to 600 million CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose) on January 1, 2019.

Table 5. CY 2015-2018 OPPS Payment for Brachytherapy Sources

CY 2019 APC	SHORT DESCRIPTOR	CY 2015 OPPS PAYMENT RATE	CY 2016 OPPS PAYMENT RATE	CY 2017 OPPS PAYMENT RATE	CY 2018 OPPS PAYMENT RATE
2616	Brachytx, non-str, Ytrrium-90	$15,582.68	$16,021.70	$16,507.73	$16,717.59
2632	Iodine I-35 sodium iodide	$13.25	$7.14	$29.93	$26.65
2634	Brachytx, non-str, HA, I25	$85.81	$85.18	$120.52	$117.66
2635	Brachytx, non-str, HA, P103	$25.81	$35.24	$25.70	$25.94
2636	Brachy linear, non-str P103	$19.44	$14.24	$18.65	$27.08
2638	Brachytx, stranded, I-25	$42.42	$38.09	$37.97	$34.73
2639	Brachytx, non-stranded, I-25	$37.05	$36.64	$35.70	$34.66
2640	Brachytx, stranded, P-103	$65.50	$68.78	$73.22	$78.72
2641	Brachytx, non-stranded, P-103	$67.93	$66.23	$65.45	$64.27
2642	Brachytx, stranded, C131	$105.39	$86.59	$87.61	$87.89
2643	Brachytx, non-stranded, C-131	$54.71	$52.18	$59.19	$87.40
2645	Brachytx, non-str, Gold198	$37.31	$45.54	$135.30	$122.61
2646	Brachytx, non-str, HDRIr-192	$272.38	$294.04	$281.58	$294.59
2647	Brachytx, NS, NonHDRIr-192	$53.73	$93.11	$33.83	$19.16
2648	Brachytx planar, p-103	N/A	N/A	$4.69	$4.69
2698	Brachytx, stranded, NOS	$42.42	$38.09	$37.97	$34.73
2699	Brachytx, non-stranded, NOS	$19.44	$14.24	$18.65	$19.16

Note: N/A reflects brachytherapy APCs that did not have a payment rate for a payment year because the brachytherapy source did not have an established C-code.

the rates, even though this may result in variations to rates year-to-year for low-volume brachytherapy sources when compared to sources that are reported with a higher number of claims.

Additionally, CMS provided data that showed that reimbursement for sources has been relatively consistent from CY 2015 to CY 2018. CMS also believes this provides incentive to hospitals to provide brachytherapy services with greater efficiency. Table 5 above reflects the OPPS payment rates over the last four years as set by CMS and provided within the final ruling.

CMS assigned code **C2645** (Brachytherapy planar source, palladium-103, per square millimeter) status indicate "**U**" (Brachytherapy Sources, paid under OPPS; separate APC payment) and used external data like invoice price to establish the APC payment for the code in CY 2019. CMS also finalized assigning status indicator "**E2**" (Items and Services for Which Pricing Information and Claims Data Are Not Available) to source code **C2644** (Brachytherapy cesium-131 chloride) because this code was not reported on CY 2017 claims; therefore, CMS was not able to set a rate per the standard methodology.

Device Pass-Through Application for the SpaceOAR System

CMS received seven applications for specific devices to be granted pass-through payment status for CY 2019. One of the applications submitted was for a new device category for transitional pass-through payment status by Augmenix, Inc., for the SpaceOAR® System. The FDA granted a De Novo request for the SpaceOAR System and identified it as a class II device. CMS sought comments on whether the SpaceOAR System met the newness criterion.

For a new device to be considered for pass-through status, it must meet several criteria. One criterion is that there cannot already be a category to which the device could be included, and it cannot have been paid as an outpatient service as of Dec. 31, 1996. After reviewing comments, CMS did not identify an existing pass-through category and indicated the system did meet this eligibility criterion. Another criterion is that CMS must evaluate if the cost of the device; three cost significance criteria must be met. CMS believed all cost criteria were met. CMS could not find that the device met this criterion: the device substantially improves the diagnosis or treatment of an illness or injury or improves function to a malformed body part when compared to other options or devices that are similar.

Further, CMS indicated concerns within the rules about the phase 3 trial, the inclusion of only low- to moderate-risk prostate cancer patients, and failure to use a clinical outcome as the endpoint. The agency indicated it is unclear that the SpaceOAR System is superior to other existing biodegradable biomaterials used for spacing of the prostate and rectum for radiotherapy treatment. CMS stated it is also unclear if there is further reduction in radiation dose effects with the added use of the SpaceOAR System, translating to a substantial clinical improvement maintained over time when compared to the patients who did not receive the SpaceOAR System as part of their treatment course.

Additional review of treatment plans by an independent lab did not quell the agency's questions and concerns that the planning supported low toxicity in the group that received the SpaceOAR System relative to the control group of standard practices. Instead CMS stated the independent review *"further calls into question the direct role of the SpaceOAR System in reducing toxicity versus more precise planning protocols and the importance of adhering to guidance protocols."*

After review of all the criteria and public comments, CMS did not believe the SpaceOAR System qualified for pass-through status because it did not meet the substantial clinical improvement criterion, even though there may be clinical benefit for certain patients. Therefore, the application for pass-through status in CY 2019 was not approved.

Payment for Therapeutic Radiopharmaceuticals

New drugs, biologicals, and radiopharmaceuticals are granted pass-through status by Medicare as a means of establishing a transitional payment until enough data is acquired to determine if the new agent is to be paid separately or packaged into an APC. For CY 2019, CMS proposed to continue providing payment for diagnostic and therapeutic radiopharmaceuticals granted pass-through payment status based on ASP methodology, as CMS considers these to be drugs under the OPPS. The ASP methodology is the ASP plus 6 percent; however, if no ASP data is available, CMS proposed to provide pass-through payment at WAC plus 3 percent. If this data is not available, then payment will be 95 percent of average wholesale price (AWP).

Commenters requested that CMS explore ways to compensate hospitals for the high expenses of overhead and handling costs associated with radiopharmaceuticals. CMS stated that the payment rate of ASP plus 6 percent is appropriate for radiopharmaceuticals with pass-through payment and that this amount appropriately accounts for the acquisition cost and associated handling and compounding costs.

CMS finalized to pay for all pass-through therapeutic radiopharmaceuticals at ASP plus 6 percent. CMS will also rely on CY 2017 mean unit cost data derived from hospital claims when ASP data is not available for therapeutic radiopharmaceuticals.

Radiopharmaceutical Lutetium 177 (Lu-177)

CMS introduced a new Category III code (**C9031**) effective July 1, 2018 for Lutetium 177, but as part of the CY 2019 ruling, a new code was assigned: **A9513** (Lutetium Lu 177, dotatate, therapeutic, 1 mCi). Radiopharmaceutical Lu-177 is used for the treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors, including foregut, midgut, and hindgut neuroendocrine tumors in adults. The recommended treatment course is to give 200 mCi by IV infusion over 30 minutes every 8 weeks for a total of 4 doses.

Radiopharmaceutical Lu-177 was granted pass-through status on July 1, 2018, meaning for no longer than 3 years from that date, Lu-177 will be reimbursed at ASP plus 6 percent as long as there is ASP data. If there is no ASP data, then reimbursement is set at WAC plus 3 percent; if no WAC data is available, then reimbursement is set at 95 percent of the most recent AWP. OI