2019 Oncology Coding Update

BY TERI BEDARD, BA, RT(R)(T), CPC, AND TAMARA SYVERSON, BSRT(T)

Coding updates have been finalized by Medicare for calendar year (CY) 2019. In comparison to previous years, the code changes outlined for CY 2019 are not significant for oncology, but it is important to be prepared and ensure coding practices and chargemasters are updated to reflect any necessary code changes. The following outlines oncology-specific coding changes.

New and Revised Procedure Codes

Coding guidelines for imaging services under the wing of radiology were updated for CY 2019 to reiterate that image guidance is not separately billable when it is included in a base service; many primary services indicate image guidance is included in the definition of the code. When imaging is *not* included in a primary procedure, it may be separately reported, but there are documentation requirements for the codes. Documentation should include images in the medical record and description of the image guidance provided in the procedure report. In addition to the updated guidelines, below are several new, revised, and deleted codes applicable to services provided to oncology patients.

The following codes have been added for CY 2019:

- **77046**: Magnetic resonance imaging, breast, without contrast material; unilateral
- **77047**: Magnetic resonance imaging, breast, without contrast material; bilateral
- **77048**: Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis), when performed; unilateral
- **77049**: Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis), when performed; bilateral
- **99451**: Interprofessional telephone/Internet/electronic health record assessment and management service provided by a consultative physician, including a written report to the patient's treating/requesting physician or other qualified healthcare professional, 5 minutes or more of medical consultative time
- **99452**: Interprofessional telephone/Internet/electronic health record referral service(s) provided by a treating/requesting physician or other qualified healthcare professional, 30 minutes
- **G2012**: Brief communication technology-based service, e.g., virtual check-in, by a physician or other qualified healthcare professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion.

The following codes have been revised for CY 2019:

- **77021**: Magnetic resonance imaging guidance for needle placement (e.g., for biopsy, needle aspiration, injection, or placement of localization device) radiological supervision and interpretation
- **77022**: Magnetic resonance imaging guidance for, and monitoring of, parenchymal tissue ablation
- **77387**: Guidance for localization of target volume for delivery of radiation treatment, includes intrafraction tracking, when performed
- **99446**: Interprofessional telephone/Internet/electronic health record assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 5-10 minutes of medical consultative discussion and review
- **99447**: Interprofessional telephone/Internet/electronic health record assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 11-20 minutes of medical consultative discussion and review
- **99448**: Interprofessional telephone/Internet/electronic health record assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 21-30 minutes of medical consultative discussion and review
- **99449**: Interprofessional telephone/Internet/electronic health record assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 31 minutes or more of medical consultative discussion and review.

The following codes have been deleted for CY 2019:

- **0190T**: Placement of intraocular radiation source applicator (List separately in addition to primary procedure)
- **76001**: Fluoroscopy, physician or other qualified healthcare professional time more than 1 hour, assisting a non-radiologic physician or other qualified healthcare professional (e.g., nephrostolithotomy, ERCP, bronchoscopy, transbronchial biopsy)
- **77058**: Magnetic resonance imaging, breast, without and/or with contrast material(s); unilateral
- **77059**: Magnetic resonance imaging, breast, without and/or with contrast material(s); bilateral

Modifiers

Effective April 1, 2018, the Centers for Medicare & Medicaid Services (CMS) deleted modifiers that were applied to biosimilars to identify the manufacturer. CMS created individual HCPCS codes effective April 1, 2018, for the biosimilar biologicals to identify each manufacturer separately; therefore, the modifiers were no longer necessary. The deleted modifiers include:

- **ZA**: Novartis/Sandoz
- **ZB**: Pfizer/Hospira
- **ZC**: Merck/Samsung Bioepis

Drug Codes

New codes for therapeutic radiopharmaceuticals will go into effect Jan. 1, 2019. These will replace the current codes for the same therapeutic radiopharmaceutical.

New codes 2019:

- **A9513**: Lutetium Lu 177, dotatate, therapeutic, 1 millicurie
- **Q2042**: Tisagenlecleucel, up to 600 million CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose

Deleted codes in 2019:

- **C9031**: Lutetium Lu 177, dotatate, therapeutic, 1 millicurie
- **Q2040**: Tisagenlecleucel, up to 250 million CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per infusion

Table 1 below shows code changes from CY 2018 to CY 2019 for drugs specific to oncology/hematology services.

Table 1. CY 2018 to CY 2019 Code Changes for Drugs Specific to Oncology/Hematology Services

CY 2018 HCPCS CODE DELETED DEC. 31, 2018	CY 2019 LONG DESCRIPTOR	CY 2019 HCPCS CODE BEGINS JAN. 1, 2019
C9016	Injection, triptorelin extended release, 3.75 mg	J3316
C9024	Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine	J9153
C9028	Injection, inotuzumab ozogamicin, 0.1 mg	J9229
C9030	Injection, copanlisib, 1 mg	J9057
C9033	Injection, fosnetupitant 235 mg and palonosetron 0.25 mg	J1454
C9463	Injection, aprepitant, 1mg	J0185
C9464	Injection, rolapitant, 0.5 mg	J2797
C9467	Injection, rituximab 10 mg and hyaluronidase	J9311
C9468	Injection, factor ix (antihemophilic factor, recombinant), glycopegylated, Rebinyn, 1 i.u.	J7203
C9492	Injection, durvalumab, 10 mg	J9173
N/A	Tisagenlecleucel, up to 600 million CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose	Q2042
Q9993	Injection, triamcinolone acetonide, preservative-free, extended-release, Microsphere formulation, 1 mg	J3304
Q9995	Injection, emicizumab-kxwh, 0.5 mg	J7170
N/A	Injection, mogamulizumab-kpkc, 1 mg	C9038

2019 Hospital Regulatory Update

BY TERI BEDARD, BA, RT(R)(T), CPC, AND TAMARA SYVERSON, BSRT(T)

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 7, 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 8, 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

2019 Physician and Freestanding Facility Regulatory Update

BY TERI BEDARD, BA, RT(R)(T), CPC, AND TAMARA SYVERSON, BSRT(T)

The Medicare Physician Fee Schedule (PFS) is one of the Medicare payment systems that applies to physicians (even those employed by hospitals) and non-facility-based settings including physician offices, freestanding facilities, and non-excepted off-campus provider-based departments. Reimbursement under the PFS is based on relative value units (RVUs), which represent the work, practice expense (direct and indirect), and malpractice values assigned to each code. The RVUs are then factored with geographic practice cost indices—the geographic locale as identified by Medicare—to determine the exact payments based on location. Finally, and still a factor for calendar year (CY) 2019, the conversion factor (CF) is set by the Centers for Medicare & Medicaid Services (CMS) each year; this value, when multiplied into the equation of RVUs for a given code, will convert the value to a recognized dollar amount.

CY 2019 is the final year in which the conversion factor will be adjusted by CMS to contribute to the overall reimbursement under the PFS. Per the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), 2019 is the final year the CF will be adjusted to account for Medicare payments. Beginning in CY 2020, the CF will freeze per the value set in CY 2019, and reimbursement for CYs 2020–2025 will be based on quality reporting under the Quality Payment Program (QPP).

Each year CMS must operate within a budget of $20 million above or below the estimated reimbursement impacts. When CMS estimates that impacts from reimbursements will result in an over-budget situation, a budget neutrality factor is applied. Typically, these over-budget situations result from CMS adjusting reimbursement for mis-valued codes, resulting in increased payments. Per MACRA, the CF was to increase by 0.5 percent from CY 2018, but the Bipartisan Budget Act of 2018 changed this to 0.25 percent. To calculate the CF for CY 2019, CMS calculated using the CY 2018 CF of $35.9996, applying the statutory update of 0.25 percent while also applying a budget neutrality adjustment of -0.14 percent. The finalized CF for CY 2019 is calculated at $36.0391, a slight increase from CY 2018.

Even with the slight overall increase by CMS, both hematology/oncology and radiation oncology will experience slight decreases for CY 2019. Both are estimated to see a combined impact of -1 percent overall. These decreases are related to the RVUs finalized for many of the codes associated with each specialty (see Table 6, page 12).

RVU Updates

Malpractice RVUs attempt to quantify the risk associated with a given specialty in alignment with the premiums paid by that specialty in relation to the services performed and reported through claims data. For CY 2019, CMS requested feedback related to the next update to malpractice RVUs as required by CY 2020—specifically, how improvements in the way specialties in state-level raw rate filings data are cross-walked to the CMS specialty codes, which are used to develop specialty-level risk factors and medical practitioner RVUs. CMS received comments in response to the request and indicated the suggestions would be considered for future rulemaking—specifically the CY 2020 required update.

Practice expense (PE) accounts for the resources provided by the physician and practitioner, including office rent and personnel wages, but excluding expenses for malpractice. PEs are further classified into direct and indirect. Direct PE categories include clinical labor, medical supplies, and medical equipment. Indirect expenses include administrative labor, office expenses, and all other expenses.

For CY 2019, CMS proposed changes to address inconsistencies resulting from alerts from the Relative Value Scale Update Committee (RUC). Per the RUC, 165 Current Procedural Terminology (CPT) codes are billed with office visits more than 50 percent of the time in the non-facility setting; these codes have more minimum multi-specialty visit supply packs (**SA048**) than post-operative visits included in the global period for the respective code. CMS indicated that either the inclusion of the E/M services was not accounted for in the code's global period, or the minimum multi-specialty visit supply pack approved for these codes was not assessed for overlap with the E/M supply pack (**SA047**). The RUC felt the overlapping supply packs were duplicative and requested adjustment by CMS.

Upon review, CMS proposed to refine the quantity of the minimum multi-specialty

Table 6. CY 2019 PFS Estimated Impact on Total Allowed Charges by Specialty

(A) SPECIALTY	(B) ALLOWED CHARGES (MILLIONS)	(C) IMPACT OF WORK RVU CHANGES	(D) IMPACT OF PE RVU CHANGES	(E) IMPACT OF MP RVU CHANGES	(F) COMBINED IMPACT*
Hematology/Oncology	$1,741	0%	-1%	0%	-1%
Radiation Oncology and Radiation Therapy Centers	$1,765	0%	0%	0%	-1%

*Column F may not equal the sum of columns C, D, and E due to rounding.

packs in order to align the number of visit packs with the number of post-operative visits included within the codes. Included in the 165 codes outlined is **CPT 38220** for diagnostic bone marrow aspiration. CMS has finalized the proposal to align the number of minimum multi-specialty visit packs with the number of post-operative office visits proposed—with the exception of **CPT 43200**, which is reported for esophagostomy procedures.

CMS contracted to a third party to review pricing and values for equipment, supplies, and labor of services provided as part of the direct PE values for codes in CY 2019. This new pricing methodology and the values finalized for CY 2019 will impact radiation oncology. One example is the pricing for the stereotactic radiosurgery (SRS) system stereotactic body radiotherapy (SBRT), reflected under **ER083** (Supply/Equipment Code). CMS indicated that the value reflected in the proposed ruling was improperly priced because a specific component was omitted—the value of the linear accelerator. CMS indicated the value in the CY 2019 PFS proposed rule only included the value for equipment purchased to retrofit a system to perform SBRT, not the pricing for the linear accelerator itself. The SBRT pricing was updated to include the linear accelerator in the final rule pricing, but there is still a decrease in value for CY 2019. Additionally, the treatment planning system equipment value—HDR afterloader treatment equipment—also saw a decrease in value, while the brachytherapy treatment vault saw an increase finalized for CY 2019.

Table 7, page 13, lists the radiation oncology-specific supply and equipment codes with price changes based on feedback from commenters resulting in additional research into pricing for CY 2019.

CMS received comments regarding the direct PE RVU changes proposed for the Healthcare Common Procedure Coding System (HCPCS) codes **G6001-G6015** reported for IGRT (image-guided radiation therapy) and radiation treatment delivery in the office setting, which were felt to be inappropriate. As outlined in the Patient Access and Medicare Protection Act (PAMPA) and the Bipartisan Budget Act of 2018, the direct PE values shall be the same for CYs 2017, 2018, and 2019 as established in CY 2016. The proposals by CMS for CY 2019 reflected changes to the direct PE RVUs.

CMS disagreed, indicating that the value changes were in response to the market-based study of commercial pricing for the supply and equipment inputs, which are not protected by the statutory provisions in the congressional legislation. CMS also indicated that the overall effect of incorporating new pricing in calculating payment rates results in higher overall RVUs on the whole for these codes than relying on previous years' values. These codes reflect an increase in RVUs and therefore an increase in reimbursement:

- **G6001**: IGRT (a global increase of $29.42)
- **G6002-26**: professional component for stereoscopic x-ray guidance IGRT (an increase of $0.45)
- **G6015**: IMRT MLC-based treatment (an increase of $5.10)
- **G6016**: IMRT compensator-based treatment (an increase of $5.10).

The remaining G-codes reflect decreases in the direct PE RVUs and an overall decrease in reimbursement.

Superficial Radiation Therapy (SRT)

For CY 2019, CMS posted a request for comment regarding superficial radiation therapy (SRT) treatment code **77401**. In CY 2015, significant changes were made to code **77401** (Radiation treatment delivery, superficial and/or ortho voltage, per day). As a result, many ancillary services, such as clinical treatment plan, devices, planning, physics, and management, are excluded from being billed with the treatment delivery code.

CMS sought comments on the possibility of creating multiple G-codes specific to the services associated with SRT. The codes would be used separately to report services such as SRT planning, initial patient simulation, treatment device design, and construction associated with SRT, SRT management, and medical physics consultation. CMS wanted to know the thoughts of stakeholders on creating G-codes similar to the structure of other radiation treatment delivery services, such as HCPCS code **G6003** (Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks: up to 5 mev). CMS also considered contractor pricing for the new G-codes, since this would bypass the usual national assignment of

Table 7. Radiation Oncology-Specific Supply and Equipment Prices Updated in Response to Comments

SUPPLY AND/OR EQUIPMENT CODE	DESCRIPTION	CY 2018 PRICE	PROPOSED CY 2019 PRICE	FINAL CY 2019 PRICE
ED033	Treatment planning system, IMRT (Corvus Peregrine 3D Monte Carlo)	$350,545	$157,394	$197,247
ER003	HDR Afterload System, Nucletron - Oldelft	$375,000	$111,426	$132,575
ER083	SRS system, SBRT, six systems, average	$4,000,000	$931,965	$2,973,722
ES052	Brachytherapy treatment vault	$175,000	$134,998	$193,114

rates utilizing input from the CPT Editorial Panel and the RUC. Since the codes would be created by CMS and not through the normal process for coding changes, this option was seen as an interim approach to a coding gap until it could be addressed by the CPT Editorial Panel and the RUC.

Many commenters stated that there should be recognition of new technology such as image-guided superficial radiation therapy (IGSRT) as it is more advanced than standard SRT technology. Other commenters suggested G-codes to represent the work of various components of SRT services, but that IGSRT specifically should not be billed with superficial treatments. Other commenters requested a professional component to code 77401 to account for physician work.

CMS indicated it would take into consideration all of the submitted comments, but the agency continues to believe and reiterates that input from the American Medical Association (AMA) and RUC process is the ideal way to develop coding specificity and evaluation. CMS is not making any changes but continues to direct stakeholders and providers to the fact that appropriate E/M codes may be reported as supported and appropriate to the course of treatment; this currently accounts for the professional work associated with SRT.

Potential Model for Radiation Therapy

As discussed previously, PAMPA, which was enacted on December 28, 2015, outlined that radiation therapy treatment delivery and imaging services require the Secretary of Health and Human Services to develop an episodic alternative payment model (APM) for payment under the Medicare program. The episodic APM would outline reimbursement for the G-codes, which are in effect under the PFS through Dec. 31, 2019.

A radiation therapy payment model is needed by the agency effective Jan. 1, 2020. CMS delivered a report to Congress in November 2017 discussing the status of radiation therapy services and payments. The report also reviewed model design considerations for a potential APM for radiation therapy services. CMS believes that radiation oncology is a promising area of healthcare for bundled payments.

CMS did not finalize a payment model for CY 2019 or outline specifics for a payment model for CY 2020. Instead, the Center for Medicare & Medicaid Innovation (CMMI) will continue to use public information regarding commercial initiatives and stakeholder feedback to assist in payment model development, implementation, refinement, and design.

On Nov. 8, 2018, CMS announced that a mandatory payment model specific to radiation oncology would soon be unveiled, but the agency did not give a specific timeline for release. This is a change from legislation, which indicated a voluntary payment model.

Evaluation and Management (E/M) Guidelines

According to CMS, E/M visits account for approximately 40 percent of the allowed charges for PFS services, and 20 percent are office or outpatient E/M visits. This accounts for a high expenditure by CMS for services to beneficiaries. In CY 2018 rulemaking, CMS requested feedback and comments on how to best update and change E/M guidelines.

Stakeholders have long commented on the need for change due to the outdated and administratively burdensome guidelines. CMS agreed, and in the CY 2018 proposed rules indicated that the history and physical exam were the most outdated of the guidelines given current clinical practices, technology advances, and the use of EHRs in the documentation process. CMS requested feedback from stakeholders on how best to approach the changes and what changes to make, admitting this would be a multi-year process.

In the CY 2019 proposed rules, CMS outlined sweeping changes to new and established patient E/M guidelines. After considerable feedback, CMS indicated thousands of comments were received, and CMS is delaying many of the more significant E/M changes until CY 2021. CMS did outline several changes for CY 2019, which are summarized as follows along with the finalized E/M changes in CY 2021.

Due to complexity and the need for providers and stakeholders to be prepared for the upcoming changes, it is important to be aware and prepare to ensure a smooth transition. In a call summarizing the three main PFS final rule changes, CMS indicated it is working on an FAQ related to E/M services based on comments by stakeholders. CMS expects this FAQ will be available before the end of CY 2018.

E/M Changes for CY 2019

To ease documentation burden for practitioners, CMS finalized a proposal effective for CY 2019—for new and established patient E/M outpatient visits, practitioners do not need to re-enter information into the medical record on the patient's chief complaint and history that has already been entered by ancillary staff or the beneficiary. The practitioner can indicate in the medical record that the information was reviewed and verified. This is optional for practitioners as a means of reducing any documentation redundancy. If a practitioner chooses to continue the documentation of the chief complaint and history, it is at the practitioner's discretion.

Additionally, key components of history and exam for established patients and only those corresponding items that have or have not changed since the last visit would be documented. This would replace the need to document all the components as outlined in the current guidelines. Practitioners would still be expected to conduct medically necessary inquiries and exams of the patient in order to support the visit and gather the necessary information; however, if documentation to support the repetitive components has been reviewed elsewhere, the components would not need to be repeated. Practitioners would still need to review the documentation in the medical record, update as necessary, and document that the practitioner reviewed the information.

To eliminate duplicative efforts and notations in the medical record, CMS is simplifying teaching physician E/M service documentation requirements. CMS is adjusting language to indicate that medical records must document the teaching physician was present at the time the service is furnished. E/M service may be documented with a note in the medical record made by a physician, resident, or nurse. CMS also eliminated the requirement that the teaching physician document the extent of his or her participation in the review and direction of services. A new paragraph would be added to the guidelines to require the teaching physician to document the extent of the participation and direction of services provided to the beneficiary. The extent of the participation can be demonstrated by notes in the medical record by a physician, resident, or nurse.

For CYs 2019 and 2020, CMS will continue with the current coding and payment structure for E/M outpatient office visits. Practitioners are to continue using the 1995 or 1997 E/M guidelines—with the exception of the previously mentioned redundant data recording.

Due to changes in technology, patients and physicians alike have changed expectations about how information—both in quality and quantity—is exchanged. One of the services increasing in volume is a brief check-in service provided to determine whether an office visit or other service is needed. Currently, when this kind of service is provided prior to an office visit, it is bundled into the payment for the office visit. However, there are circumstances where the check-in does not result in an actual office visit to which the service can be bundled. When brief check-ins are used correctly, they can prevent unnecessary office visits, resulting in reduced costs and waste.

Effective for CY 2019, CMS will begin separately reimbursing for a newly-defined physician service using communication technology. This service would be billable when a physician or other healthcare provider has a brief face-to-face check-in with a patient via communication technology to assess whether the patient's condition requires an office visit. Code **G2012** (Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified healthcare professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion) will begin Jan. 1, 2019.

As with other services, medical necessity is needed to support the work and billed check-in. CMS will also allow audio-only real-time telephone interactions in addition to synchronous, two-way audio interactions that are enhanced with video or other kinds of data transmission. Phone calls that only involve clinical staff are not billable with code **G2012**, as this code requires direct interaction between the patient and billing practitioner.

Practitioners must also obtain verbal consent from the patient to indicate that they approve the physician to bill for these services and note this in the medical record. If the brief check-in originates from a related E/M service provided within the previous 7 days by the same physician or other practitioner, the service is bundled into the E/M services. In the event that a brief check-in leads to an E/M service with the same physician or practitioner, it would be considered part of the pre- or post-visit time and is not separately billable.

The brief check-in service will only be available to established patients due to the need for familiarity with the patient. CMS is not requiring any service-specific documentation requirements for this service, only that the services must be medically necessary and reasonable in order to be reimbursed.

E/M Changes for CY 2021

Based on comments and feedback, CMS has finalized choices to E/M documentation for CY 2021:

- Continue to utilize the framework of the 1995 or 1997 guidelines
- Utilize a framework based around medical decision-making (MDM) as the main component
- Utilize a time-based framework.

These changes would allow practitioners to better select the type of documentation based on the type of visits performed. For some practitioners, a time-based framework would better support the type of work and visits provided to patients. Other practitioners who are comfortable with the 1995

or 1997 guidelines would be able to continue this approach to documenting the E/M visits for outpatients.

CMS believes that adjusting documentation practices will lessen the burden to practitioners by no longer documenting components irrelevant to the visit or those that are burdensome to include. The changes would also mean that CMS would not have to create another set of standardized guidelines as happened in 1995 and 1997. Regardless of which method a practitioner selects to document the E/M visit, CMS would apply the same new reimbursement values to outpatient services.

Current CPT codes (**99201–99215**) will still be reported on the claim form by the practitioner to reflect the level of visit the practitioner believes was provided to the beneficiary—regardless of the type of documentation framework selected. These choices will allow for consistency in code reporting and consistency when billing to non-Medicare payers, as it is unclear how commercial payers will react to these changes or if they will implement the newly-extended timeline for activation.

CMS will use the code reported to apply the appropriate reimbursement from one of three levels. In CY 2021, CMS will reimburse the Level 1 codes of **99201** and **99211** at a separately designated rate. Levels 2-4 (**99202–99204** and **99212–99214**) will be reimbursed the same amount regardless of level supported, and Level 5 codes (**99201** and **99215**) will be reimbursed at a separate level. The reimbursement of Level 5 outside of Levels 2-4 is a change from the CY 2019 proposed ruling. CMS indicated that there was a need to recognize the work and resources provided to patients at the highest-level visit separate from other levels.

CMS will be implementing a minimum level of documentation for Levels 2-4 if the practitioner selects to continue using the already established guidelines of 1995 or 1997 requirements or an MDM framework; in other words, at minimum at least Level 2 documentation must be met. If time is the selected framework, CMS will require the billing practitioner to document the medical necessity of the visit and that the practitioner personally spent the current typical time associated with the individual codes. CMS will also be engaging the public to further assist in refining policies.

In CY 2021, Level 5 visits for payment purposes will continue with the current framework for a Level 5 visit under the 1995 or 1997 guidelines or the current definition of Level 5 MDM. Time will also be available as a means for documenting a Level 5 visit. The documentation of a Level 5 visit based on time will account for the medical necessity for the visit and note that the practitioner personally spent at least the typical time associated with Level 5 CPT coding reported for the new or established patient visit. There will be no intra-service time associated with Level 5 visit codes. CMS is finalizing the typical time associated with CPT codes **99205** or **99215** when counseling and/or coordination of care accounts for more than 50 percent of the face-to-face physician/patient encounter.

Due to the significant changes and the impact that some specialties may experience, CMS is adding additional measures to better capture resource costs and offset their impact. The first add-on code accounts for complexity, one for primary care and another for other specialties; neither is required nor restricted by physician specialty. The codes are specifically intended to describe services that some clinicians practicing in some specialties are more likely to perform than others. The G-code for primary care will not be summarized here as they are intended for use in specialties such as family medicine, internal medicine, pediatrics, and geriatrics.

The code CMS finalized for specialized complexity is expected to be used mostly by practitioners in the code descriptor but is not limited to those specialties. Add-on code **GCG0X** (Visit complexity inherent to evaluation and management associated with nonprocedural specialty care including endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, interventional pain management, cardiology, nephrology, infectious disease, psychiatry, and pulmonology) (Add-on code, list separately in addition to level 2 through 4 office/outpatient evaluation and management visit, new or established) is to be used beginning CY 2021.

CMS provided an example in which an oncologist sees a patient to discuss their cancer diagnosis and the treatment plan, including surgical and chemotherapy options. Since the E/M focuses on oncologic care, the physician would report the specialty add-on code in addition to the E/M visit code. The physician's specialty should be reflected on the claim form, and the medical record would support the diagnosis and clinician's assessment and plan for the visit. According to CMS, this information would be sufficient documentation; the visit met the description of the non-procedural specialty care complexity, and no other additional documentation would be needed.

Currently there are CPT codes (**99354** and **99355**) to account for prolonged services. The minimum time to meet the threshold in order to bill **99354** is one hour. Many stakeholders commented it is difficult to meet this threshold and that it is an impediment to many specialties in reporting the codes. Given the changes to Levels 2-4, CMS created a new HCPCS code for CY 2021 to represent prolonged E/Ms:

- **GPRO1** (Prolonged evaluation and management or psychotherapy service[s] beyond the typical service time of the primary procedure in the office or other outpatient setting requiring direct patient contact beyond the usual service; 30 minutes) (List separately in addition to code for office or other outpatient Evaluation and Management or psychotherapy service).

This code may be billable by oncologists given the nature of some E/M visits, but only with codes in Levels 2-4, it is not allowed with Level 5 E/M visits.

CMS did not finalize the proposal to reduce payments when multiple services are performed on the same date of service. CMS established separate podiatric E/M visit codes or standardized allocation of PE RVUs for codes that describe these services.

Payment Rates for Non-Excepted Off-Campus Provider-Based Departments

The Bipartisan Budget Act of 2015 established new guidelines to address the difference in reimbursement payments for the exact same procedure between varying places of service—primarily hospitals, ambulatory surgical centers (ASCs), and physician offices. 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 the Hospital Outpatient Prospective Payment System (HOPPS). Due to what was considered the alarming rate of hospitals acquiring physician practices and the tendency for hospital PBDs to be paid more than a physician office setting, CMS made changes.

Excepted off-campus PBDs are settings that were established and billing for services prior to Nov. 2, 2015, and which are within the previously set distance of 35 miles. Excepted off-campus PBDs are paid fully at the HOPPS established rate for each service (excepting clinic visit code **G0463**) and considered "grandfathered" into HOPPS payments 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 which are outside the newly set distance of 250 yards from the main buildings of the hospital. Non-excepted PBDs are paid under the PFS but are still considered a facility setting for the purposes of following guidelines about supervision, packaging, and more.

For CY 2019, CMS will continue with the PFS Relativity Adjuster (reimbursement) of 40 percent of the HOPPS rate for non-excepted off-campus PBDs. This is the same rate that was applied in CY 2018.

Additionally, non-excepted off-campus PBDs will continue to bill for services on the UB04 claim form and apply the modifier **PN** to billed services. Non-excepted off-campus PBDs are still subject to hospital supervision rules and other practice guidelines. Radiation oncology departments will continue to bill for daily treatments and image guidance in the non-excepted off-campus PBD setting using the G-codes used by freestanding facilities, with modifier **PN** applied to each billing through the end of CY 2019 as mandated by law. The G-codes for daily treatment (**G6003-G6015**) and image guidance (**G6001**, **G6002**, **G6017**, and **77014**) are not paid at 40 percent of the HOPPS rate; instead they are paid at the technical non-facility rate under the PFS. Hospital on-campus departments and excepted off-campus PBDs continue to bill the CPT codes for daily treatment (**77402**, **77407**, **77412**, **77385**, and **77386**) and image guidance code **77387** where appropriate.

Changes to Part B Drugs

Per the requirements in the Social Security Act, many Medicare payments for drugs and biologicals include an add-on payment set at 6 percent of the volume-weighted average sales price (ASP) or wholesale acquisition costs (WAC). While the Act does not indicate what is included in the add-on payment, CMS believes it includes services related to drug acquisition that are not separately paid, such as handling, storage, and drug distribution mark-ups. Concerns were raised related to this practice within the MedPAC June 2015 Report to Congress, since more revenue can be generated for expensive drugs and may create an incentive. This report also stated that administrative complexity and costs are not proportional to the price of the drug.

The Act specifies the use of the add-on percentage for ASP; however, this same percent has also been applied to the WAC in specific situations. These situations include single source drugs where the payment is made using the lesser of the ASP or WAC; drugs and biologicals where ASP during the first quarter of sales is unavailable, and drugs where pricing determined by Medicare Administrative Contractors (MACs) does not appear on the ASP pricing files and new drugs.

CMS addressed that the ASP includes various discounts such as volume discounts, prompt pay discounts, and rebates; however, the WAC is defined as the manufacturer's list price to wholesalers and direct purchasers and does not include these discounts. As a result, the WAC typically exceeds the ASP and results in higher dollar payments.

For CY 2019, CMS proposed to utilize a 3 percent add-on in place of the current 6 percent add-on for WAC–based payments for Part B drugs made under the Act. CMS indicated that the proposal is consistent with the MedPAC's recommendations from its June 2017 Report to Congress. CMS noted that the number of new drugs priced using the WAC is limited; however, the average difference between WAC- and ASP-based payments for three recently approved drugs was 9 percent, including one biosimilar biological product. Excluding the biosimilar, the difference was 3.5 percent. The findings of the CMS review were in agreement with MedPAC findings. CMS anticipates this reduction will result in a savings to the Medicare program by bringing payment amounts for new drugs closer to acquisition costs.

While CMS provides examples of differences between the WAC- and ASP-based payment limits, the agency indicated it is not able to estimate the true savings over time, as it is not known how many new drugs and biologicals will require partial-quarter pricing or how many of the Part B claims will be paid. CMS also mentioned that contractor-priced drugs and drugs and biologicals billed using miscellaneous or not otherwise classified codes, such as **J3490** and **J3590**, cannot be calculated. Of the three drugs assessed by Medicare, Part B payments for individual doses ranged from $3,000 to $10,000; proposed changes would have resulted in $100 to $300 savings per dose.

CMS explained that this change would likely decrease co-payments for individual beneficiaries prescribed new drugs. CMS states, *"A 3 percentage point reduction in the total payment allowance will reduce a patient's 20 percent Medicare Part B copay-*

ment—for a drug that costs many thousands of dollars per dose, this can result in significant savings to an individual. The proposed approach would help Medicare beneficiaries afford to pay for new drugs by reducing out of pocket expenses and would help counteract the effects of increasing launch prices for newly approved drugs and biologicals."

In response to commenters, CMS indicated the markup defined by the Act does not specify what the add-on represents; however, CMS is interested in striking a balance between financial concerns related to costs and concerns about financial incentives that can lead to excessive drug use. CMS indicated that if the add-on is intended to account for increased handling, storage, and other overhead costs, these are not proportional to the current price of the drug. The add-on is proportional only to the price of the drug, and the difference between the acquisition cost and payment can be hundreds to thousands of dollars. As a result, CMS is concerned that this will lead to financial incentive for use of new Part B drugs. CMS also expressed concern with the costs of new drugs and the assumption that these drugs have higher overhead costs than those under ASP-based payment.

After considering the comments received, CMS finalized its proposal to reduce the add-on percentage for WAC-based payments for new drugs effective Jan. 1, 2019. CMS also noted this policy is consistent with the President's budget and the previous MedPAC's analysis and recommendations in the June 2017 Report to Congress. CMS also clarified this policy does not apply to single-source drugs or biologicals paid under the Act where payment is made using the lesser of ASP or WAC. The Act requires a 6 percent add-on regardless of payment under the WAC or ASP amount.

Appropriate Use Criteria for Advanced Diagnostic Imaging Services

The appropriate use criteria (AUC) program was mandated as part of PAMA and MACRA and outlined that CMS must establish a program to promote appropriate use criteria for advanced diagnostic services. This program covers the ordering of advanced diagnostic imaging services, e.g., CT, MRI, and nuclear medicine, including PET).

In the CY 2019 final rule, CMS reaffirmed the mandatory Jan. 1, 2020 implementation date. The first year will be an "educational and operations testing period" with an official go-live date of Jan. 1, 2021. To meet this time frame, CMS will develop a series of G-codes and modifiers during the 2020 rulemaking cycle that must be applied to the claim. The agency will continue to pay claims whether or not the information or the agency on the claim is completely accurate.

CMS did indicate it will continue to consider future opportunities to use a unique claim identifier (UCI) number, but did not commit to a timeline or transition towards UCI. The advantage of a UCI is that this information would come straight from the clinical decision support mechanism (CDSM) instead of manual intervention to assign G-codes and modifiers. Additionally, CMS is not indicating how long it will use the G-code with modifier approach to claims-based reporting.

During the initial testing period, ordering professionals will consult AUC through a qualified CDSM, and furnishing providers will report the corresponding G-codes and modifiers information on their claims (facility and physician).

CMS finalized its proposal to add independent diagnostic testing facilities (IDTFs) to the list of applicable settings. The services provided in an IDTF require physician supervision, and written orders must be furnished. CMS believes this means the IDTF is a provider-led outpatient setting and appropriate to be added to the list. Additionally, CMS believes that adding IDTFs to the list will ensure the AUC program is in place across outpatient settings where advanced diagnostic imaging is provided. Other applicable settings include a physician's office, hospital outpatient department (including the emergency department), and an ambulatory surgery center (ASC).

CMS finalized its proposal that any ordering professional experiencing insufficient internet access, EHR or CDSM vendor issues, or extreme and uncontrollable circumstances (including natural or manmade disasters) would not be required to consult the AUC using a qualified CDSM, and the claim would not be required to list the AUC consultation information.

CMS confirmed these circumstances will be self-attested at the time of placing an advanced diagnostic imaging order. The claim submitted by the rendering provider and facility would report the necessary HCPCS modifier to reflect the hardship self-attestation.

After considering comments received, CMS changed its proposal regarding who would potentially be allowed to consult the AUC on behalf of the ordering provider. CMS revised its proposed language, clarifying that *"when delegated by the ordering professional, clinical staff under the direction of the ordering professional may perform the AUC consultation with a qualified clinical decision support mechanism."* The ordering professional is still responsible for the consultation, as it is the NPI of the ordering physician reported on the furnishing professional claim form. Additionally, it is the ordering professional that would be identified as an outlier and subjected to prior authorization requirements based on ordering patterns.

Even though the program does not officially begin until Jan. 1, 2020, the testing period is currently in effect through Dec. 31, 2019. The initial list of outlier ordering professionals established in the CY 2017 PFS final rule did not change. This list of outliers impacts providers ordering advanced diagnostic imaging services for coronary artery disease (suspected or diagnosed), suspected pulmonary embolism, headache (traumatic and non-traumatic), hip pain, low back pain, shoulder pain (to include suspected rotator cuff injury), cancer of the lung (primary or metastatic, suspected or diagnosed), and cervical or neck pain.

Quality Payment Program (QPP) Summary

CMS estimates approximately 798,000 clinicians would be MIPS-eligible clinicians for the 2019 MIPS performance period. This

estimate is an increase of nearly 148,000 from the estimated total in the CY 2019 proposed rule. CMS estimates payment adjustments will be approximately $390 million—negative and positive. Since the program is budget-neutral, the amount negatively adjusted from eligible clinicians is the amount used to positively adjust payments in CY 2021. If the majority of eligible clinicians meet and exceed the threshold and very few fail to meet the threshold, then the amount taken and paid out will decrease or be impacted.

CMS added six additional eligible clinicians to participate in the MIPS program for performance year 2019. CMS also aligned the determination period to be the same for the low-volume threshold, non-facing patient status, small practice status, hospital-based status, and ASC-based statuses. Finally, CMS changed the low-volume threshold criteria for CY 2019 performance year and future years to be:

- Those who have allowed charges for covered professional services less than or equal to $90,000;
- Those who provide covered professional services to 200 or fewer Part B-enrolled individuals; or
- Those who provide 200 or fewer covered professional services to Part B-enrolled individuals.

CMS created a low-volume opt-in that allows any eligible clinician or group who exceed one, but not all, of the low-volume threshold criteria to choose to voluntarily report by electing this option through the QPP portal. This opt-in would be irrevocable for the performance period, and clinicians that opt in will be subject to the applicable payment adjustment.

One adjustment impacting the CY 2019 payment year is a payment adjustment applied to Part B payments for covered services, excluding Part B drugs and other items furnished by the MIPS eligible clinician.

Weighting of the performance categories is as follows:

- Quality (45 percent)
- Cost (15 percent)
- Improvement Activities (15 percent)
- Promoting Interoperability (previously Advancing Care Information) (25 percent).

The performance threshold is 30 points for CY 2019 performance period and set at 75 points for the additional exceptional performance threshold. Points below 30 will receive a negative payment adjustment (maximum of 7 percent) applied in the CY 2021 payment period. The positive payment adjustment can be up to 7 percent, but is required to remain budget-neutral; thus the adjustment may be less depending on the number of eligible clinicians who do not meet the threshold and are penalized. OI

Teri Bedard, BA, RT(R)(T), CPC, is a principal and Tamara Syverson, BSRT(T), is director of Client Services at Coding Strategies, Inc.