Oncology Coding Update 2018

BY CINDY PARMAN, CPC, CPC-H, RCC

The 2018 Medicare final regulations, code updates, and other reimbursement changes will bring significant compensation shifts for oncology providers. As usual, healthcare providers will need to update their respective chargemasters, fee schedules, and other documents to ensure compliance with coding and billing guidelines.

New and Revised Procedure Codes

Each year there are new codes, revised codes, and updates to coding guidelines. For calendar year (CY) 2018, the following new procedure codes affecting oncology practices have been released:

- **+19294:** Preparation of tumor cavity, with placement of a radiation therapy applicator for intraoperative radiation therapy (IORT) concurrent with partial mastectomy (List separately in addition to code for primary procedure).
- **93792:** Patient/caregiver training for initiation of home international normalized ratio (INR) monitoring under the direction of a physician or other qualified non-physician professional, face-to-face, including use and care of the INR monitor, obtaining blood sample, instructions for reporting home INR test results, and documentation of patient's/caregiver's ability to perform testing and report results.
- **93793:** Anticoagulant management for a patient taking warfarin, must include review and interpretation of a new home, office or lab INR test result, patient instructions, dosage adjustment (as needed), and scheduling of additional test(s), when performed.

In addition, the section for bone marrow biopsy and aspiration has been revised, including the addition of three new procedure codes for CY 2018:

- **38220:** Diagnostic bone marrow; aspiration(s).
- **38221:** Diagnostic bone marrow; biopsy(ies).
- **38222:** Diagnostic bone marrow biopsy(ies) and aspiration(s).

Effective Jan. 1, 2018, the following HCPCS procedure code has been deleted: **G0364:** Bone marrow aspiration performed with bone marrow biopsy through the same incision on the same date of service.

Temporary Category III code 0438T will be replaced with new CPT® code **55874:** Transperineal placement of biodegradabe material, peri-prostatic, single or multiple injection(s), including image guidance, when performed.

The following procedure codes have undergone a change in descriptor for CY 2018:

- **32998:** Ablation therapy for reduction or eradication of 1 or more pulmonary tumor(s) including pleura or chest wall when involved by tumor extension, percutaneous, including imaging guidance when performed, unilateral; radiofrequency.
- **76000:** Fluoroscopy (separate procedure), up to 1 hour physician or other qualified healthcare professional time.

Last, the following procedure codes have been deleted for CY 2018:

- **77422:** High energy neutron radiation treatment delivery; single treatment area using a single port or parallel-opposed ports with no blocks or simple blocking.
- **0301T:** Destruction/reduction of malignant breast tumor with externally applied focused microwave, including interstitial placement of disposable catheter with combined temperature monitoring probe and microwave focusing sensocatheter under ultrasound thermotherapy guidance.
- **0438T:** Transperineal placement of biodegradable material, peri-prostatic (via needle), single or multiple, includes image guidance.

HCPCS Level II Modifier Updates

In addition to changes in procedure codes, there are new and updated HCPCS modifiers, some of which are discussed in more detail in other sections of this article. Modifier CP (Adjunctive service related to a procedure assigned to a comprehensive ambulatory payment classification [C-APC] procedure, but reported on a different claim) is the only oncology-related HCPCS modifier deleted for CY 2018.

As a result of changes to the 340B Drug Pricing Program, the following modifiers have been created for CY 2018:

- **JG:** Drug or biological acquired with 340B Drug Pricing Program discount.
- **TB:** Drug or biological acquired with 340B Drug Pricing Program discount, reported for informational purposes.

The following modifier was created for imaging providers to use on a voluntary basis starting July 1, 2018, to show that the ordering professional consulted Appropriate Use Criteria (AUC) for advanced diagnostic imaging (CT, MRI, PET, other nuclear medicine): **QQ:** Ordering professional consulted a qualified clinical decision support mechanism for this service and the related data was provided to the furnishing professional.

New modifiers have been created for reporting patient relationship categories as required by MACRA, effective Jan. 1, 2018, on a voluntary basis:

- **X1:** Continuous/broad services: for reporting services by clinicians, who provide the principal care for a patient, with no planned endpoint of the relationship; services in this category represent comprehensive care, dealing with the entire scope of patient problems, either directly or in a care coordination role; reporting clinician service examples include, but are not limited to: primary care, and clinicians providing comprehensive care to patients in addition to specialty care.
- **X2:** Continuous/focused services: for reporting services by clinicians whose expertise is needed for the ongoing management of a chronic disease or a condition that needs to be managed and followed with no planned endpoint to the relationship; reporting clinician service examples include but are not limited to: a rheumatologist taking care of the patient's rheumatoid arthritis longitudinally but not providing general primary care services.
- **X3:** Episodic/broad services: for reporting services by clinicians who have broad responsibility for the comprehensive needs of the patient that is limited to a defined period and circumstance such as a hospitalization; reporting clinician service examples include but are not limited to the hospitalist's services rendered providing comprehensive and general care to a patient while admitted to the hospital.
- **X4:** Episodic/focused services: for reporting services by clinicians who provide focused care on particular types of treatment limited to a defined period and circumstance; the patient has a problem, acute or chronic, that will be treated with surgery, radiation, or some other type of generally time-limited intervention; reporting clinician service examples include but are not limited to, the orthopedic surgeon performing a knee replacement and seeing the patient through the postoperative period.
- **X5:** Diagnostic services requested by another clinician: for reporting services by a clinician who furnishes care to the patient only as requested by another clinician or subsequent and related services requested by another clinician; this modifier is reported for patient relationships that may not be adequately captured by the above alternative categories; reporting clinician service examples include but are not limited to, the radiologist's interpretation of an imaging study requested by another clinician.

Longstanding modifiers **Q5** and **Q6** were revised effective July 1, 2017, to show that they can be used for substitute physical therapists in HPSAs (health professional storage areas). Also, CMS has substituted the term "fee for time" for "locum tenens":

- **Q5:** Service furnished under a reciprocal billing arrangement by a substitute physician or by a substitute physical therapist furnishing outpatient physical therapy services in a health professional shortage area, a medically underserved area, or a rural area.
- **Q6:** Service furnished under a fee-for-time compensation arrangement by a substitute physician or by a substitute physical therapist furnishing outpatient physical therapy services in a health professional shortage area, a medically underserved area, or a rural area.

Drug Codes

One drug code has been discontinued as of Dec. 31, 2017 (refer to new drug codes **J1726** and **J1729** for coding options): **J1725:** Injection, hydroxyprogesterone caproate, 1 mg.

In addition, the following code has been discontinued effective Dec. 31, 2017, **A9599**: Radiopharmaceutical, diagnostic, for beta amyloid positron emission tomography (PET) imaging, per study dose, not otherwise specified.

The Q-codes for pathogen-reduced platelets have been replaced with P-codes. Specifically, **Q9987:** Pathogen(s) test for platelets has been replaced with **P9100:** Pathogen(s) test for platelets, and **Q9988:** Platelets, pheresis, pathogen-reduced, each unit has been replaced with **P9100:** Pathogen(s) test for platelets.

In addition, HCPCS code **P9072:** Platelets, pheresis, pathogen-reduced or rapid bacterial tested, each unit is deleted effective Dec. 31, 2017.

Effective Jan. 1, 2018, there are new codes, revised codes, and replaced codes for drugs, biologicals and substances. Following are new drug HCPCS codes:

- **C9014:** Injection, cerliponase alfa, 1 mg.
- **C9015:** Injection, C-1 esterase inhibitor (human), Haegarda, 10 units.
- **C9016:** Injection, triptorelin extended release, 3.75 mg.
- **C9024:** Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine.
- **C9028:** Injection, inotuzumab ozogamicin, 0.1 mg.
- **C9029:** Injection, guselkumab, 1 mg.
- **J0604:** Cinacalcet, oral, 1 mg, (for ESRD on dialysis).
- **J0606:** Injection, etelcalcetide, 0.1 mg.
- **J1555:** Injection, immune globulin (Cuvitru), 100 mg.
- **J7211:** Injection, factor VIII, (antihemophilic factor, recombinant), (Kovaltry), 1 IU.
- **J7345:** Aminolevulinic acid HCl for topical administration, 10% gel, 10 mg.
- **Q2040:** Tisagenlecleucel, up to 250 million CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per infusion.

At the request of the American Society of Addiction Medicine, the Centers for Medicare & Medicaid Services (CMS) created three new codes for insertion and removal of subdermal buprenorphine implants for opioid addiction:

- **G0516:** Insertion of non-biodegradable drug delivery implants, 4 or more (services for subdermal rod implant).
- **G0517:** Removal of non-biodegradable drug delivery implants, 4 or more (services for subdermal implants).
- **G0518:** Removal with reinsertion, non-biodegradable drug delivery implants, 4 or more (services for subdermal implants).

Table 1, page 3, lists drugs that have been assigned new J-codes, effective Jan. 1, 2018. OI

Table 1. Drugs Assigned New J-Codes in 2018 Cross-Walked with the Deleted C-Codes

NEW 2018 CODE		DELETED 2017 CODE	
J0565	Injection, bezlotoxumab, 10 mg.	**C9490**	Injection, bezlotoxumab, 10 mg.
J1428	Injection, eteplirsen, 10 mg.	**C9484**	Injection, eteplirsen, 10 mg.
J1627	Injection, granisetron, extended-release, 0.1 mg.	**C9486**	Injection, granisetron extended release, 0.1 mg.
J1726	Injection, hydroxyprogesterone caproate, (Makena), 10 mg.	**Q9986**	Injection, hydroxyprogesterone caproate, (Makena), 10 mg.
J1729	Injection, hydroxyprogesterone caproate, not otherwise specified, 10 mg.	**Q9985**	Injection, hydroxyprogesterone caproate, not otherwise specified, 10 mg.
J2326	Injection, nusinersen, 0.1 mg.	**C9489**	Injection, nusinersen, 0.1 mg.
J2350	Injection, ocrelizumab, 1 mg.	**C9494**	Injection, ocrelizumab, 1 mg.
J3358	Ustekinumab, for intravenous injection, 1 mg.	**Q9989**	Ustekinumab, for intravenous injection, 1 mg.
J7210	Injection, factor VIII, (antihemophilic factor, recombinant), (Afstyla), 1 IU	**C9140**	Injection, factor VIII (antihemophilic factor, recombinant) (Afstyla), 1 IU
J7296	Levonorgestrel-releasing intrauterine contraceptive system, (Kyleena), 19.5 mg.	**Q9984**	Levonorgestrel-releasing intrauterine contraceptive system (Kyleena), 19.5 mg.
J9022	Injection, atezolizumab, 10 mg.	**C9483**	Injection, atezolizumab, 10 mg.
J9023	Injection, avelumab, 10 mg.	**C9491**	Injection, avelumab, 10 mg.
J9203	Injection, gemtuzumab ozogamicin, 0.1 mg.	**J9300**	Injection, gemtuzumab ozogamicin, 5 mg.
J9285	Injection, olaratumab, 10 mg.	**C9485**	Injection, olaratumab, 10 mg.

2018 Hospital Regulatory Update

BY CINDY PARMAN, CPC, CPC-H, RCC

The Hospital Outpatient Prospective Payment System (HOPPS or OPPS) is not intended to be a fee schedule, in which separate payment is made for each coded line item. Instead, the OPPS is currently a prospective payment system that packages some items and services, but not others. CMS' overarching goal is to make payments for all services covered under the OPPS more consistent with those of a prospective payment system and less like those of a per-service fee schedule. CMS estimates that total OPPS payments for CY 2018 (including beneficiary cost-sharing) to the approximately 3,900 facilities paid under the OPPS will increase by approximately $690 million over CY 2017 payments.

In calendar year CY 2018, CMS estimates that outpatient hospital payment rates will increase on average by 1.4 percent, with urban hospitals experiencing a 1.3 percent increase and rural hospitals receiving an average 2.7 percent increase. The CY 2017 conversion factor of $75.001 increases to $78.636 for CY 2018, and CMS will continue the statutory 2.0 percentage point reduction in payments for hospitals that fail to meet the hospital outpatient quality reporting requirements. CMS will also maintain the policy of providing additional payments to the 11 designated cancer hospitals so that the hospital's payment-to-cost ratio, with the adjustment, is equal to the weighted average for the other OPPS hospitals.

Outlier payments will be triggered in CY 2018 when the hospital's cost for furnishing a service exceeds a fixed-dollar threshold of $4,150, combined with the multiple threshold of 1.75 times the APC payment rate.

Critical Access Hospital Supervision

In both the CY 2009 and CY 2010 OPPS final rules with comment period, CMS clarified that direct supervision is required for hospital outpatient therapeutic services covered and paid by Medicare that are furnished in hospitals, Critical Access Hospitals (CAHs), and in provider-based departments (PBDs) of hospitals. Since CY 2011, there has been a suspension on the enforcement of the direct supervision requirement for CAHs and small rural hospitals (less than 100 beds), with the latest freeze on enforcement expiring on Dec. 31, 2016. Stakeholders commented that some small rural hospitals and CAHs have insufficient staff available to furnish direct supervision.

The primary reason stakeholders cited for this difficulty is that CAHs and small rural hospitals have in recruiting physicians and non-physician practitioners to practice in rural areas. These commenters noted that it is particularly difficult to furnish direct supervision for critical specialty services, such as radiation oncology services, that cannot be directly supervised by a hospital emergency department physician or non-physician practitioner because of the volume of emergency patients or lack of specialty expertise.

In the 2018 final rule with comment period, CMS is reinstating the non-enforcement policy for direct supervision of outpatient therapeutic services furnished in CAHs and small rural hospitals for both CY 2018 and CY 2019. The purpose of this non-enforcement policy is to give these CAHs and small rural hospitals additional time to comply with the supervision requirements for outpatient therapeutic services and to give all parties time to submit specific services to be evaluated by the Hospital Outpatient Payment (HOP) Advisory Panel for a recommended change in supervision level.

340B Drug Pricing

The 340B Program, which was established by section 340B of the Public Health Service Act by the Veterans Health Care Act of 1992, is administered by the Health Resources and Services Administration (HRSA) within the Department of Health and Human Services (HHS). The 340B Program allows participating hospitals and other healthcare providers to purchase certain "covered outpatient drugs" at discounted prices from drug manufacturers. The statutory intent of the 340B Program is to maximize scarce federal resources as much as possible, reaching more eligible patients and providing care that is more comprehensive.

The Medicare Payment Advisory Commission (MedPAC) examined Medicare Part B spending for chemotherapy drugs and drug administration services at both 340B and non-340B hospitals for a five-year period from 2008 to 2012 and found that "Medicare spending grew faster among hospitals that participated in the 340B Program for all five years than among hospitals that did not participate in the 340B Program at any time during [the study] period." According to CMS, this is just one example of drug spending increases that are correlated with participation in the 340B

Program and calls into question whether Medicare's current policy to pay for separately payable drugs (assigned status indicator "K") at average sales price (ASP)+6 percent is appropriate in view of the discounted rates at which 340B hospitals acquire such drugs.

In addition, the Government Accountability Office (GAO) found that "in both 2008 and 2012, per beneficiary Medicare Part B drug spending, including oncology drug spending, was substantially higher at 340B disproportionate share hospitals than at non-340B hospitals." The GAO believes that this indicates beneficiaries at 340B hospitals were either prescribed more drugs or more expensive drugs than beneficiaries at the non-340B hospitals in GAO's analysis. Based on a study of almost 500 drugs billed in the hospital outpatient setting in 2013, the Office of Inspector General (OIG) found that, for 35 drugs, the "difference between the Part B [payment] amount and the 340B ceiling price was so large that, in at least one quarter of 2013, the beneficiary's coinsurance alone was greater than the amount a covered entity spent to acquire the drug."

It is estimated that covered entities saved $3.8 billion on outpatient drugs purchased through the 340B Program in 2013. In addition, the number of hospitals participating in the program has grown from 583 in 2005, to 1,365 in 2010, and 2,140 in 2014. In its November 2015 report, "Part B Payments for 340B-Purchased Drugs," the OIG found that Part B payments were 58 percent more than 340B ceiling prices, which allowed covered entities to retain approximately $1.3 billion in 2013. Both MedPAC and the OIG have recommended alternative drug payment methodologies for hospitals that participate in the 340B Program. Such changes would allow the Medicare program and Medicare beneficiaries to pay less for drugs when hospitals participating in the 340B Program furnish drugs to Medicare beneficiaries that are purchased under the 340B Program.

For CY 2018 CMS is exercising the Secretary's authority to adjust the applicable payment rate as necessary for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B Program from ASP plus 6 percent to ASP minus 22.5 percent. Rural sole community hospitals (SCHs), children's hospitals, and PPS-exempt cancer hospitals are excluded from this payment adjustment in CY 2018. CMS did not propose to adjust payment for 340-acquired drugs in non-excepted off-campus provider-based departments (paid under a non-OPPS reimbursement methodology), but may consider adopting such a policy in CY 2019.

In addition, in this final rule with comment period, CMS established two modifiers to identify whether a drug billed under the OPPS was purchased under the 340B Program—one for hospitals that are subject to the payment reduction and another for hospitals not subject to the payment reduction but that acquire drugs under the 340B Program. CMS will collect information on an ongoing basis on which drugs billed to Medicare were acquired under the 340B Program.

Therefore, pediatric hospitals, cancer hospitals, and SCH hospitals that are excluded from the 340B Program payment reduction will be required to report the following informational modifier for tracking and monitoring purposes: **TB:** Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes.

Effective Jan. 1, 2018, this informational modifier will facilitate collection and tracking of 340B claims data for OPPS providers that are excepted from the payment adjustment in CY 2018; use of this modifier will not trigger a payment adjustment and these providers will continue to receive ASP+6 percent payment for separately payable drugs.

Also effective Jan. 1, 2018, providers who are subject to the 340B payment adjustment will report the following modifier to identify that a drug was acquired under the 340B Program: **JG:** Drug or biological acquired with 340B drug pricing program discount.

The application of the JG modifier will trigger the adjustment for the 340B-acquired drug to be paid at ASP minus 22.5 percent. This Medicare requirement aligns with modifiers already mandated in several states under their Medicaid programs. Therefore, this option should pose less of an administrative burden for providers.

To maintain budget neutrality within the OPPS, the estimated $1.6 billion in reduced drug payments from adoption of this final 340B payment methodology will be redistributed in an equal offsetting amount to all hospitals paid under the OPPS through increasing the payment rates by 3.2 percent for non-drug items and services furnished by all hospitals paid under the OPPS for CY 2018.

Site-of-Service Price Transparency

Section 4011 of the 21st Century Cures Act enacted on Dec.13, 2016, added information to facilitate price transparency with respect to items and services for which payment may be made either to a hospital outpatient department or to an ambulatory surgical center (ASC). For CY 2018 and each subsequent year, HHS will make available to the public via a searchable website the estimated payment amount for many items and services under the OPPS and ASC payment system and the estimated beneficiary liability applicable to the item or service. CMS anticipates that this website will be available in early CY 2018.

Packaged Services

CMS states that packaging is an inherent principle of a prospective payment system. The OPPS, like other prospective payment systems, relies on the concept of averaging, where the payment may be more or less than the estimated costs of providing a service or package of services for a particular

patient, but with the exception of outlier cases, is adequate to ensure access to appropriate care. Packaging and bundling payments for multiple interrelated services into a single payment create incentives for providers to furnish services in the most efficient way by enabling hospitals to manage their resources with maximum flexibility, resulting in long-term cost containment.

In the CY 2015 OPPS final rule, CMS conditionally packaged payment for ancillary services assigned to APCs with a geometric mean cost of less than or equal to $100; these were primarily minor diagnostic tests and procedures frequently performed with a primary service. Conditional packaging means that the services will be separately paid by Medicare when they are the only procedure performed on a date of service. Excluded from this packaging in CY 2015 were certain low-cost drug administration services.

According to CMS, the exclusion of these drug administration services is an example of inconsistent application of their packaging policy. Based on the analysis of CY 2016 claims data, the geometric mean cost for **APC 5691** (Level 1 Drug Administration) is approximately $37 and the geometric mean cost for **APC 5692** (Level 2 Drug Administration) is approximately $59. In addition, Medicare data show that these drug administration services are generally provided as part of another separately payable service, which meets the intent of the ancillary services conditional packaging policy.

Last, CMS believes that conditional packaging of these drug administration services will promote equitable payment between the physician office and the hospital outpatient department. After reviewing the comments submitted, CMS finalized the policy to conditionally package low-cost drug administration services assigned to **APCs 5691** and **5692**, with the exception of add-on codes and preventive services. Tables 2 and 3, page 8, list the drug administration services relating to oncology that will be conditionally packaged (Status Indicator Q1) for CY 2018.

With respect to payment for a conditionally packaged low-cost drug administration service and an unconditionally packaged drug, the drug administration service is separately payable when not billed on the same claim as a HCPCS code with status indicator "S", "T", or "V". Payment for the threshold-packaged drug would be packaged with the payment for the highest paying separately payable procedure reported on the claim. For example, if a threshold-packaged drug, a low-cost drug administration service, and a clinic visit are reported on the same claim, payment for both the drug and drug administration service would be packaged with the clinic visit payment.

In the CY 2014 OPPS final rule, CMS finalized a policy to unconditionally package procedures described by add-on codes. However, in response to stakeholder comments on the appropriateness of packaging drug administration add-on codes, these services were not packaged at that time. CMS did not propose to package drug administration add-on codes for CY 2018, but solicited comments on this policy in the proposed rule. Many commenters raised concerns about the appropriateness of packaging drug administration add-on codes, given the variation in clinical treatment protocols. The commenters believed that packaging drug administration service add-on codes could create a barrier to access for drugs and biologicals with a long infusion time. CMS indicated that it appreciated all comments, and would take them into consideration for future rulemaking.

Oncology Comprehensive-APCs

A comprehensive APC, by definition, will provide a single payment that includes the primary service and all adjunct services performed to support the delivery of the primary service. For services that trigger a comprehensive APC payment, the comprehensive APC will treat all individually reported codes on the claim as representing components of the comprehensive service, resulting in a single prospective payment for the comprehensive service. This means that hospitals will continue to report procedure codes for all services performed on one claim submission, regardless of service date, and will receive a single payment for the total service and collect a single beneficiary copayment for the procedure and related services and supplies.

Effective Jan. 1, 2015, CMS implemented **C-APC 5627** (Level 7 Radiation Therapy) for single fraction stereotactic radiosurgery (SRS, procedure codes **77371** and **77372**). For CY 2018, CMS will continue to make separate payments for the 10 planning and preparation services adjunctive to the delivery of the SRS treatment using either the Cobalt-60-based or LINAC-based technology when furnished to a beneficiary within 30 days of the SRS treatment.

CMS also performed data collection through the use of modifier "CP" (Adjunctive service related to a procedure assigned to a comprehensive ambulatory payment classification [C-APC] procedure, but reported on a different claim) and identified some additional services that are adjunctive to the primary SRS treatment and reported on a different claim submission. CMS stated that the "CP" modifier was actually used by only a small number providers, in spite of the mandatory requirement for its application. The data collection period for SRS claims with modifier "CP" will conclude on Dec. 31, 2017. Accordingly, CMS is deleting this modifier for CY 2018 and discontinuing its required use. CMS will continue to analyze the CY 2016 and CY 2017 data, and will consider whether or not to repackage all adjunctive services into the cranial SRS C-APC.

In the CY 2017 OPPS final rule, CMS finalized 25 new C-APCs. Some of the HCPCS codes assigned to these C-APCs described surgical procedures for inserting brachytherapy catheters or needles, and other related brachytherapy procedures such as the insertion of tandem and/or ovoids or

Heyman capsules. In this prior final rule, CMS noted that public comments were received indicating that some claims for brachytherapy insertion did not also include a brachytherapy treatment delivery code. The brachytherapy insertion codes with concerns included:

- **20555:** Placement of needles or catheters into muscle and/or soft tissue for subsequent interstitial radioelement application.
- **31643:** Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of catheter(s) for intracavitary radioelement application.
- **41019:** Placement of needles, catheters or other devices into head and/or neck region for subsequent interstitial radioelement application.
- **43241:** Esophagogastroduodenoscopy, flexible, transoral; with insertion of intraluminal tube catheter.
- **55920:** Placement of needles or catheters into pelvic organs and/or genitalia (except prostate) for subsequent interstitial radioelement application.
- **57155:** Insertion of uterine tandem and/or vaginal ovoids for clinical brachytherapy.
- **58346:** Insertion of Heyman capsules for clinical brachytherapy.

CMS analyzed claims that included brachytherapy insertion codes assigned to this group and determined that several of these codes are frequently billed without an associated brachytherapy treatment code. Although CMS proposed to establish a code edit that requires that a brachytherapy treatment code with a brachytherapy insertion code is billed, in this final rule the agency decided not to implement this edit. However, CMS reminded hospitals to bill all HCPCS codes accurately in accordance with their code descriptors and CPT and CMS instructions, as applicable. CMS added that it will continue to examine the issues involving rate setting for brachytherapy insertion procedures assigned to C-APCs.

CMS is also finalizing its proposal to delete composite **APC 8001** (LDR Prostate Brachytherapy Composite), assign HCPCS code **55875** (Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy) to status indicator "**J1**" and to provide payment for this procedure through the C-APC methodology. This means that when code **55875** is the primary service reported on a hospital outpatient claim, payment for all adjunctive services reported on that claim will be packaged into the primary service.

In CY 2017, CMS finalized C-APC **5244** (Level 4 Blood Product Exchange and Related Services) for allogeneic hematopoietic stem cell transplantation. As provided in the Medicare Claims Processing Manual, donor acquisition charges for allogeneic HSCT include charges for the costs of several services. These services include, but are not necessarily limited to, National Marrow Donor Program fees, tissue typing of donor and recipient, donor evaluation, physician pre-procedure donor evaluation services, costs associated with the collection procedure (for example, general routine and special care services, procedure/operating room and other ancillary services, apheresis services, among others), post-operative/post-procedure evaluation of donor, and the preparation and processing of stem cells.

When the allogeneic stem cell transplant occurs in the hospital outpatient setting, providers are instructed to report stem cell donor acquisition charges for allogeneic HSCT separately in Field 42 on Form CMS-1450 (or UB-04) by using revenue code **0815** (Organ Acquisition: Other Donor). Revenue code **0815** charges should include all services required to acquire hematopoietic stem cells from a donor, as defined earlier, and should be reported on the same date of service as the transplant procedure in order to be appropriately packaged for payment purposes.

HCPCS code **38205** describes blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogeneic; a donor acquisition cost for an HSCT. In order to be consistent with other donor acquisition costs and ensure that the costs for allogeneic HSCT are captured accurately, CMS will change the status of procedure code **38205** from "**B**" (OPPS non-allowed service) to "**S**" (Significant procedure not subject to multiple procedure discounting) and assign this code to APC **5242** (Level 2 Blood Product Exchange and Related Services).

Pass-Through Drug & Biological Payments

Section 1833 of the Social Security Act permits CMS to make pass-through payments for a period of at least two, but not more than three years after the product's first payment as a hospital outpatient service under Medicare Part B. The longstanding practice has been to provide pass-through payment for a period of two to three years, with expiration of pass-through status proposed and finalized through the annual rulemaking process. Beginning in CY 2017, pass-through status expired on a quarterly basis so that the biological will receive pass-through status for as close to three full years as possible. Table 4, page 9, lists the drugs and biologicals whose pass-through status will expire on Dec. 31, 2017.

Payment for drugs and biologicals with pass-through status under the OPPS in CY 2018 will be made at the rate of ASP+6 percent. However, hospitals will actually receive no extra payment for most of these pass-through drugs because they would receive the difference between the regular OPPS drug payment and the pass-through payment. At this time, both of these payment amounts are ASP+6 percent, so the difference is $0. Hospitals will receive payment for pass-through drugs that are classified as "policy-packaged," such as diagnostic radiopharmaceuticals, contrast agents, and anesthesia drugs, since the regular OPPS drug payment for these biologicals is $0. Table 5, page 9, lists drugs and biologicals with pass-through status in CY 2018.

Drugs and therapeutic radiopharmaceuticals without pass-through status are paid

separately only if the average per diem cost is greater than that year's packaging threshold. For CY 2018, the threshold is $120, up from $110 in CY 2017. CMS adds that packaging costs into a single aggregate payment for a service, procedure or episode-of-care is a fundamental principle that distinguishes a prospective payment system from a fee schedule. CMS is also continuing its policy of making a single packaging decision for all dosages of a drug that is available in multiple dosages that have separate HCPCS codes.

Last, CMS finalized a policy in the CY 2018 Medicare Physician Fee Schedule (PFS) final rule to implement separate HCPCS codes for biosimilar biological products. After considering public comments, CMS stated that all biosimilar biological products will be eligible for pass-through payment and not just the first biosimilar for a reference product.

Blood and Blood Products

In the CY 2018 OPPS final rule, CMS finalized the proposal to establish payment rates for blood and blood products using the current blood-specific cost-to-charge ratio (CCR) methodology. CMS also finalized its proposal for reporting pathogen-reduced platelets and rapid bacterial testing for platelets. Essentially, the changes involve replacing the temporary HCPCS Q codes with permanent HCPCS Level II codes. Specifically, **Q9987:** Pathogen(s) test for platelets will be replaced with **P9100:** Pathogen(s) test for platelets and **Q9988:** Platelets, pheresis, pathogen-reduced, each unit will be replaced with **P9073:** Platelets, pheresis, pathogen-reduced, each unit.

In addition, HCPCS code **P9072** (Platelets, pheresis, pathogen-reduced or rapid bacterial tested, each unit) is deleted effective Dec. 31, 2017.

Brachytherapy Sources

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 requires CMS to continue to separate payment for brachytherapy sources. These sources are reimbursed on a prospective basis, with 2018 payment rates set using the 2016 geometric mean unit costs for each source. For CY 2018, CMS assigned status indicator "**U**" (Brachytherapy sources, paid under OPPS; separate APC payment) to HCPCS codes **C2636** (Brachytherapy, linear, non-stranded, palladium-103, per 1 mm), and **C2645** (Brachytherapy planar, palladium-103, per square millimeter).

Other Provisions

In addition to the major provisions listed above, the 2018 OPPS final rule addresses the Ambulatory Surgical Center (ASC) payment update, the hospital value-based purchasing program, the hospital outpatient quality reporting (OQR) program, reimbursement for diagnostic imaging for specific services, and New Technology APC groups. Refer to the PFS summary, pages 11–17, for information on Appropriate Use Criteria (AUC) for advanced diagnostic imaging services.

Table 2. APC 5691—Level 1 Drug Administration Services Packaged in CY 2018

CODE	DESCRIPTOR	SI
96377	Application of on-body injector (includes cannula insertion) for timed subcutaneous injection	Q1
96379	Unlisted therapeutic, prophylactic, or diagnostic intravenous or intra-arterial injection or infusion	Q1
96549	Unlisted chemotherapy procedure	Q1

Table 3. APC 5692—Level 2 Drug Administration Services Packaged in CY 2018

CODE	SHORT DESCRIPTOR	SI
96371	Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); additional pump set-up with establishment of new subcutaneous infusion site(s) (List separately in addition to code for primary procedure)	Q1
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular	Q1
96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal antineoplastic	Q1
96402	Chemotherapy administration, subcutaneous or intramuscular; hormonal antineoplastic	Q1
96405	Chemotherapy administration; intralesional, up to and including 7 lesions	Q1

Table 4. Drugs and Biologicals for Which Pass-Through Status Will Expire Dec. 31, 2017

CY 2018 HCPCS CODE	CY 2018 LONG DESCRIPTOR	FINAL CY 2018 SI	FINAL CY 2018 APC
A9586	Florbetapir fl8, diagnostic, per study dose, up to 10 mci	N	N/A
C9447	Injection, phenylephrine and ketorolac, 4 ml vial	N	N/A
J0596	Injection, c-1 esterase inhibitor (human), Ruconest, 10 units	K	9445
J0695	Injection, ceftolozane 50 mg and tazobactam 25 mg.	K	9452
J0875	Injection, dalbavancin, 5 mg.	K	1823
J1833	Injection, isavuconazonium sulfate, 1 mg.	K	9456
J2407	Injection, oritavancin, 10 mg.	K	1660
J2502	Injection, pasireotide long acting, 1 mg.	K	9454
J2547	Injection, peramivir, 1 mg.	K	9451
J2860	Injection, siltuximab, 10 mg.	K	9455
J3090	Injection, tedizolid phosphate, 1 mg.	K	1662
J7313	Injection, fluocinolone acetonide intravitreal implant, 0.01 mg.	K	9450
J8655	Netupitant (300 mg) and palonosetron (0.5.mg.)	K	9448
J9032	Injection, belinostat, 10 mg.	K	1658
J9039	Injection, blinatumomab, 1 mcg.	K	9449
J9271	Injection, pembrolizumab, 1 mg.	K	1490
J9299	Injection, nivolumab, 1 mg.	K	9453
Q4172	PluraPly, & PluraPly Antimicrobial, any type, per sq cm.	N	N/A
Q9950	Injection, sulfur hexafluoride lipid microsphere, per ml.	N	N/A

Table 5. Drugs and Biologicals With Pass-Through Status in CY 2018

CY 2017 HCPCS CODE	CY 2018 HCPCS CODE	CY 2018 LONG DESCRIPTOR	CY 2018 SI	CY 2018 APC
A9515	**A9515**	Choline C 11, diagnostic, per study dose	G	9461
A9587	**A9587**	Gallium ga-68, dotatate, diagnostic, 0.1 mci	G	9056
A9588	**A9588**	Fluciclovine f-18, diagnostic, 1 mci	G	9052
C9140	**J7210**	Injection, Factor VIII (antihemophilic factor, recombinant) (Afstyla), I IU	G	9043
C9460	**C9460**	Injection, cangrelor, 1 mg.	G	9460
C9482	**C9482**	Injection, sotalol hydrochloride, 1 mg.	G	9482
C9483	**J9022**	Injection, atezolizumab, 10 mg.	G	9483
C9484	**J1428**	Injection, eteplirsen, 10 mg.	G	9484
C9485	**J9285**	Injection, olaratumab, 10 mg.	G	9485
C9486	**J1627**	Injection, granisetron extended release, 0.1 mg.	G	9486
C9488	**C9488**	Injection, conivaptan hydrochloride, 1 mg.	G	9488
C9489	**J2326**	Injection, nusinersen, 0.1 mg.	G	9489

(Table 5 continued on page 10)

(continued from page 9)

Table 5. Drugs and Biologicals With Pass-Through Status in CY 2018

CY 2017 HCPCS CODE	CY 2018 HCPCS CODE	CY 2018 LONG DESCRIPTOR	CY 2018 SI	CY 2018 APC
C9490	**J0565**	Injection, bezlotoxumab, 10 mg.	G	9490
C9491	**J9023**	Injection, avelumab, 10 mg.	G	9491
C9492	**C9492**	Injection, durvalumab, 10 mg.	G	9492
C9493	**C9493**	Injection, edaravone, 1 mg.	G	9493
C9494	**J2350**	Injection, ocrelizumab, 1 mg.	G	9494
J0570	**J0570**	Buprenorphine implant, 74.2 mg.	G	9058
J1942	**J1942**	Injection, aripiprazole lauroxil, 1 mg.	G	9470
J2182	**J2182**	Injection, mepolizumab, 1 mg.	G	9473
J2786	**J2786**	Injection, reslizumab, 1 mg.	G	9481
J2840	**J2840**	Injection, sebelipase alfa, 1 mg.	G	9478
J7179	**J7179**	Injection, von Willebrand factor (recombinant), (Vonvendi), 1 IU vwf:rco	G	9059
J7202	**J7202**	Injection, Factor IX, albumin fusion protein (recombinant), Idelvion, 1 IU	G	9171
J7207	**J7207**	Injection, Factor VIII (antihemophilic factor, recombinant) PEGylated, 1 IU	G	1844
J7209	**J7209**	Injection, Factor VIII (antihemophilic factor, recombinant) (Nuwiq), per IU	G	1846
J7322	**J7322**	Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg.	G	9471
J7328	**J7328**	Hyaluronan or derivative, Gelsyn-3, for intra-articular injection, 0.1 mg.	G	1862
J7342	**J7342**	Instillation, ciprofloxacin otic suspension, 6 mg.	G	9479
J7503	**J7503**	Tacrolimus, extended release, (Envarsus xr), oral, 0.25 mg.	G	1845
J9034	**J9034**	Injection, bendamustine HCl (Bendeka), 1 mg.	G	1861
J9145	**J9145**	Injection, daratumumab, 10 mg.	G	9476
J9176	**J9176**	Injection, elotuzumab, 1 mg.	G	9477
J9205	**J9205**	Injection, irinotecan liposome, 1 mg.	G	9474
J9295	**J9295**	Injection, necitumumab, 1 mg.	G	9475
J9325	**J9325**	Injection, talimogene laherparepvec, 1 million plaque forming units (PFU)	G	9472
J9352	**J9352**	Injection, trabectedin, 0.1 mg.	G	9480
N/A	**J9203**	Injection, gemtuzumab ozogamicin, 0.1 mg.	G	9495
Q5101	**Q5101**	Injection, filgrastim (G-CSF), biosimilar, 1 microgram	G	1822
Q5102	**Q5102**	Injection, infliximab, biosimilar, 10 mg.	G	1847
Q9982	**Q9982**	Flutemetamol F18, diagnostic, per study dose, up to 5 mci	G	9459
Q9983	**Q9983**	Florbetaben F18, diagnostic, per study dose, up to 8.1 mci	G	9458
Q9989	**J3358**	Ustekinumab, for intravenous injection, 1 mg.	G	9487
N/A	**C9014**	Injection, cerliponase alfa, 1 mg.	G	9014
N/A	**C9015**	Injection, c-1 esterase inhibitor (human), Haegarda, 10 units	G	9015
N/A	**C9016**	Injection, triptorelin extended release, 3.75 mg.	G	9016
N/A	**C9024**	Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine	G	9302
N/A	**C9028**	Injection, inotuzumab ozogamicin, 0.1 mg.	G	9028
N/A	**C9029**	Injection, guselkumab, 1 mg.	G	9029
N/A	**J7345**	Aminolevulinic acid HCl for topical administration, 10% gel, 10 mg.	G	9301

Physician and Freestanding Center Regulatory Update

BY CINDY PARMAN, CPC, CPC-H, RCC

Since 1992, Medicare has paid for the services of physicians, non-physician practitioners, and certain other suppliers under the Medicare Physician Fee Schedule (MPFS or PFS). For reimbursement purposes, relative values are assigned to more than 7,000 services to reflect the amount of work, the direct and indirect (overhead) practice expenses, and the malpractice expenses typically involved in furnishing that specific service. After applying a geographic practice cost indicator, the resulting relative value units (RVUs) are summed for each service and multiplied by a fixed-dollar conversion factor to establish the payment amount for each visit or procedure.

The CY 2018 conversion factor is estimated to be $35.9996, which is only slightly higher than the 2017 conversion factor of $35.8887. The Estimated Impact Table (Table 6, page 16) projects payment increases or decreases by specialty (without considering the potential conversion factor change).

The most widespread specialty impacts of the final RVU changes are generally related to the changes to RVUs for specific services resulting from the Misvalued Code Initiative, including finalized RVUs for new and revised codes. The estimated impacts for some specialties, including behavioral health specialists, radiation oncology, and podiatry, reflect increases relative to other physician specialties. These increases can largely be attributed to increases in value for particular services following the recommendations from the American Medical Association (AMA) Relative Value Scale Update Committee (RUC).

Evaluation and Management Guidelines

Most physicians and other billing practitioners bill patient visits to the PFS under a relatively generic set of codes that distinguish level of complexity, site of care, and in some cases, between new or established patients. These codes are called Evaluation and Management (E/M) visit codes. For example, there are generally three levels of hospital and nursing facility inpatient E/M visit codes, and five levels of office or hospital outpatient E/M visit codes, that vary based on complexity and whether the patient is a new or established patient.

Billing practitioners must maintain information in the medical record to document that they have reported the appropriate level of E/M visit code. CMS maintains guidelines that specify the kind of information that is required to support Medicare payment for each level. According to CMS, stakeholders have long maintained that both the 1995 and 1997 guidelines are administratively burdensome and outdated with respect to the practice of medicine, stating that they are too complex, ambiguous, and that they fail to distinguish meaningful differences among code levels. The guidelines have also not been updated to account for significant changes in technology, especially electronic health record (EHR) use, which presents challenges for data and program integrity and potential upcoding given the frequently automated selection of code level.

CMS specifically sought comment on whether it would be appropriate to remove the documentation requirements for the history and physical exam for all E/M visits at all levels. CMS believes medical decision-making (MDM) and time are the more significant factors in distinguishing visit levels, and that the need for extended histories and exams is being replaced by population-based screening and intervention, at least for some specialties. In addition, an increase in the utilization of EHRs, and to some extent, shared health information via EHRs, may have changed the character of extended patient histories since the guidelines were established. Although CMS believes that MDM guidelines may also need to be updated, the agency believes that in the near term, it may be possible to eliminate the current focus on details of history and physical exam, and allow MDM and/or time to serve as the key determinant of E/M visit level.

As long as a history and physical exam are documented and generally consistent with complexity of MDM, CMS believes there may no longer be a need to maintain such detailed specifications for what must be performed and documented for the history and physical exam (for example, which and how many body systems are involved). CMS cautions that there may still be clinical or legal reasons for individual practitioners to document an extended history or physical exam (for example, where there are negative findings for certain body systems in support of differential diagnosis).

The public comments received illustrate the difficulty of utilizing or relying on such a relatively small set of codes to describe and pay for the work of a wide range of physicians and practitioners in many vastly different

clinical contexts. In addition, the public comments illustrate that many of the issues with the E/M documentation guidelines are not simply a matter of undue administrative burden. CMS expects to continue to work on all of these issues with stakeholders in future years though the agency remains focused on revision of the current E/M guidelines in order to reduce unnecessary administrative burden. No changes to the E/M guidelines were issued as part of the CY 2018 final rule.

Patient Relationship Categories and Codes

The Quality Payment Program (QPP) aims to improve health outcomes, promote smarter spending, minimize the burden of participation, and provide fairness and transparency in operations. These aims are centered on improving beneficiary outcomes and engaging patients through patient-centered policies, and enhancing clinician experience through flexible and transparent program design and interactions with easy-to-use program tools.

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) was enacted on April 16, 2015. Section 101 of MACRA amended Section 1848 of the Act to create a new subsection entitled Collaborating with the Physician, Practitioner, and Other Stakeholder Communities to Improve Resource Use Measurement. This section requires the development of care episode and patient condition groups, and classification codes for such groups. To facilitate the attribution of patients and episodes to one or more clinicians, this section requires the development of patient relationship categories and codes that define and distinguish the relationship and responsibility of a physician or applicable practitioner with a patient at the time of furnishing an item or service.

Section 1848 of the Act requires that claims submitted for items and services furnished by a physician or applicable practitioner on or after Jan. 1, 2018, shall include the applicable codes established for care episode groups, patient condition groups, and patient relationship categories, as well as the NPI of the ordering physician or applicable practitioner (if different from the billing physician or applicable practitioner). Applicable practitioners are defined as a physician assistant, nurse practitioner, clinical nurse specialist, and a certified registered nurse anesthetist; and beginning Jan. 1, 2019, such other eligible professionals as specified by the Secretary. Procedure code modifiers that describe patient relationship categories include:

- **X1:** Continuous/broad services.
- **X2:** Continuous/focused services.
- **X3:** Episodic/broad services.
- **X4:** Episodic/focused services.
- **X5:** Only as ordered by another clinician.

CMS also finalized the requirement that Medicare claims submitted for items and services furnished by a physician or applicable non-physician practitioner on or after Jan. 1, 2018, should include one of the HCPCS modifiers listed above, as well as the NPI number of the ordering physician or applicable practitioner (if different from the billing physician or applicable practitioner). During the initial period while clinicians are gaining familiarity with these requirements, the HCPCS modifiers may be voluntarily reported. By allowing for a voluntary approach to reporting, CMS plans to gain information about the patient relationship codes, allow for a longer period of education and outreach to clinicians on the use of the codes and refine the codes as necessary.

CMS will provide a voluntary 25-minute training/instruction manual and a one-time 60-minute webinar for practice manager or billing/coding staff who seek further knowledge to be able to report these new HCPCS modifiers correctly. Although there are a total of five HCPCS modifiers, CMS expects one out of the five will usually be reported. The practice manager or billing/coding staff who may decide to study only one HCPCS modifier or only the whole training manual or participate in just the webinar may experience a lesser burden than the estimate provided above, resulting in a lower information burden cost.

Payment Rates under the PFS for Non-excepted Items and Services Furnished by Non-excepted Off-Campus PBDs of a Hospital

Sections 1833(t)(1)(B)(v) and (t)(21) of the Act require that certain items and services furnished by certain off-campus provider-based departments (PBDs) (collectively referenced in this final rule as non-excepted items and services furnished by non-excepted off-campus PBDs) shall not be considered covered OPD services for purposes of payment under the OPPS, and payment for those non-excepted items and services furnished on or after Jan. 1, 2017, shall be made under the applicable payment system. In the CY 2017 OPPS final rule with comment period, CMS finalized the PFS as the "applicable payment system" for most non-excepted items and services furnished by off-campus PBDs.

CMS estimated that for CY 2017, scaling the OPPS payment rates downward by 50 percent would strike an appropriate balance that avoided potentially underestimating the relative resources involved in furnishing services in non-excepted off-campus PBDs as compared to the services furnished in other settings for which payment was made under the PFS. CMS called this adjustment the "PFS Relativity Adjuster." The PFS Relativity Adjuster refers to the percentage of the OPPS payment amount paid under the MPFS for a non-excepted item or service to the non-excepted off-campus PBD under this policy.

CMS considered the 50 percent PFS Relativity Adjuster for CY 2017 to be a transitional policy until such time as there was more precise data to better identify and value non-excepted items and services furnished by non-excepted off-campus PBDs and billed by hospitals. In addition, certain services are not subject to the application of the Relativity Adjuster, such as clinical

laboratory, drugs and biologicals, and ambulance services. In addition, the radiation oncology G-codes will continue to be reported with modifier PN, but are not subjected to the Relativity Adjuster; instead, payment is made at the technical non-facility based rate.

CMS believes it has been as transparent as possible in its approach, including the limitations related to data availability, and the inability to develop a precise adjustment to the relative payment rates that would account for differences between the two payment systems, while including OPPS packaging. Therefore, for CY 2018 CMS finalized a PFS Relativity Adjuster of 40 percent, meaning that non-excepted items and services furnished by non-excepted off-campus PBDs would be paid under the PFS at a rate that is 40 percent of the OPPS rate. CMS estimates that this change will result in total Medicare Part B savings of $12 million for CY 2018.

The 2018 final rule added that hospital supervision rules continue to apply for non-excepted off-campus PBDs that furnish non-excepted items and services. In addition, CMS did not propose to adjust payment for 340B acquired drugs in non-excepted off-campus PBDs in CY 2018 but will be monitor drug utilization in these PBDs.

Telehealth Services

Section 1834 of the Act established the Medicare telehealth originating site facility fee for telehealth services furnished from Oct. 1, 2001, through December 31, 2002, at $20. For telehealth services furnished on or after Jan. 1 of each subsequent calendar year, the telehealth originating site facility fee is increased by the percentage increase in the Medicare Economic Index (MEI) as defined in Section 1842 of the Act. Therefore, for CY 2018, the payment amount for HCPCS code **Q3014** (Telehealth originating site facility fee) is 80 percent of the lesser of the actual charge or $25.76.

CMS finalized the addition of the following services to the telehealth list for CY 2018:

- **G0296:** Counseling visit to discuss need for lung cancer screening using low dose CT scan (LDCT) service is for eligibility determination and shared decision making.
- **90839:** Psychotherapy for crisis; first 60 minutes.
- **90840:** Psychotherapy for crisis; each additional 30 minutes. List separately in addition to code for primary service.

Although CMS did not receive specific requests for additional telehealth codes, four additional services will be added to the telehealth list. All four of these codes are add-on codes that describe additional elements of services currently on the telehealth list and would only be considered telehealth services when billed as an add-on to codes already on the telehealth list. These codes are:

- **90785:** Interactive complexity. List separately in addition to the code for primary procedure.
- **96160:** Administration of patient-focused health risk assessment instrument (e.g., health hazard appraisal) with scoring and documentation, per standardized instrument
- **96161:** Administration of caregiver-focused health risk assessment instrument (e.g., depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument.
- **G0506:** Comprehensive assessment of and care planning for patients requiring chronic care management services. List separately in addition to primary monthly care management service.

In the case of CPT codes **96160** and **96161**, and HCPCS code **G0506**, CMS recognized that these services may not always be performed in-person with a physician or billing practitioner. Ordinarily, services that are typically not considered to be face-to-face services do not need to be on the list of Medicare telehealth services; however, these services would only be considered Medicare telehealth services when billed with a base code that is also on the telehealth list and would not be considered Medicare telehealth services when billed with codes not on the Medicare telehealth list.

Payment for Biosimilar Biological Products

In the CY 2016 Medicare Physician Fee Schedule final rule with comment period, CMS finalized a proposal to amend regulation text to clarify that the payment amount for a biosimilar biological product is based on the average sales price (ASP) of all National Drug Codes (NDCs) assigned to the biosimilar biological products included within the same billing and payment code. In general, this means that products that rely on a common reference product's biologics license application (that is, the FDA's previous finding of safety, purity, and potency for the common reference product) are grouped into the same payment calculation for determining a single ASP payment limit and that a single HCPCS code is used for such biosimilar products.

CMS indicated that it wants to promote innovation, provide more options to patients and physicians, and encourage competition to drive prices down. Based on the review of the comments received, CMS will change the Part B biosimilar payment policy to provide for the separate coding and payment for products approved under each individual abbreviated application, rather than grouping all biosimilars with a common reference product into a single code. This policy change should encourage greater manufacturer participation in the marketplace and the introduction of more biosimilar products, thus creating a stable and robust market, driving competition and decreasing uncertainty about access and payment.

In addition, CMS anticipates that this policy change will provide physicians with greater certainty about biosimilar payment. In turn, this should affect utilization of these products, creating more demand that would

help increase competition. As a result of the policy change CMS anticipates greater access to biosimilar biological products and that more price competition between more products will occur because there will be more products available. The change in policy could lead to additional savings for Medicare and its beneficiaries over the long-term by increasing the utilization of products that are less expensive than reference biologicals.

Effective Jan. 1, 2018, newly approved biosimilar biological products with a common reference product will no longer be grouped into the same HCPCS code. CMS will issue detailed guidance on coding, including instructions for new codes for biosimilars that are currently grouped into a common payment code and the use of modifiers. Completion of these changes is planned to occur as soon as possible, but is not expected to be complete by Jan. 1, 2018. CMS anticipates that this will be done by mid-2018 and the agency will issue further instructions using sub-regulatory means, such as change requests, transmittals to contractors, and the ASP website.

Superficial Radiation Treatment Planning

In the CY 2015 PFS final rule, CMS noted that changes to the CPT prefatory language limited the codes that could be reported with superficial radiation treatment (SRT) delivery, described by CPT code **77401** (radiation treatment delivery, superficial and/or orthovoltage, per day). The changes effectively meant that many other related services were bundled with CPT code **77401**, instead of being separately reported. For example, CPT guidance clarified that certain codes used to describe clinical treatment planning, treatment devices, isodose planning, physics consultation, and radiation treatment management cannot be reported when furnished in association with superficial radiation treatment.

In the CY 2016 PFS final rule with comment period, CMS commented that the RUC did not review the inputs for SRT procedures, and therefore did not assess whether changes in valuation were appropriate in light of the bundling of associated services. In addition, CMS solicited recommendations from stakeholders regarding whether or not it would be appropriate to add physician work for this service, even though physician work is not included in other radiation treatment services. As commenters were not in agreement as to whether the service should be valued with physician work, CMS introduced the possibility of creating a HCPCS G-Code to describe total work associated with the course of treatment for these services.

In the CY 2018 PFS proposed rule, CMS proposed to make separate payment for the professional planning and management associated with SRT using HCPCS code **GRRR1** (Superficial radiation treatment planning and management related services). However, given the various concerns expressed by commenters, and the variety of potential solutions offered, CMS did not finalize the proposed separate payment and coding for planning and management services associated with SRT at this time. CMS will continue considering alternative solutions, but believes additional analysis is necessary.

CMS adds that it did not propose and is not making any changes to the coding or valuation for CPT code **77401** (radiation treatment delivery, superficial and/or orthovoltage, per day) in this final rule. However, under the CPT guidance that has been in effect for several years, certain codes used to describe clinical treatment planning, treatment devices, isodose planning, physics consultation, and radiation treatment management cannot be billed in addition to CPT code **77401** .

Work RVUs for New, Revised and Potentially Misvalued Codes

The 2018 final rule includes RVU updates; Table 7, page 17, lists the oncology codes that are impacted:

Several codes for infusion and injection services were reviewed as part of this final rule, but no Work RVU changes were made.

AUC for Advanced Diagnostic Imaging Services

The Protecting Access to Medicare Act of 2014 (PAMA) requires CMS to establish a program to promote utilization of appropriate use criteria (AUC) for advanced diagnostic imaging services. Advanced diagnostic imaging services include diagnostic imaging exams performed using CT, MR, and nuclear medicine (including PET). AUC are criteria that help professionals who order and furnish imaging services to make the most appropriate treatment decision for a specific clinical condition for an individual patient. CMS can only approve AUC that are developed or endorsed by provider-led entities (PLEs) such as national professional medical specialty societies. In most cases the AUC will be evidence-based and CMS can approve more than one set of AUC for a given imaging service.

The CY 2018 PFS final rule lists the first eight priority clinical areas for the AUC:

- 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)
- Cervical or neck pain

Ordering professionals will be required to consult AUC for all advanced imaging services, not just those in priority clinical areas, as long as the service is furnished in an applicable setting such as office or outpatient hospital and paid under an applicable payment system like the PFS or OPPS. However, the priority clinical areas will be used to identify outlier ordering professionals in the future. Medicare

will initially pay for the imaging study regardless of whether it was recommended by the AUC. Eventually, however, CMS will identify those ordering professionals who are consistently failing to follow AUC recommendations, and these "outliers" will be required to obtain prior authorization for advanced imaging studies they wish to order.

Clinical Decision Support Mechanisms (CDSMs) are "electronic tools through which a clinician consults AUC to determine the level of clinical appropriateness for an advanced diagnostic imaging service for that particular patient's clinical scenario." CMS also established a timeline and process for CDSM developers to apply to have their CDSMs qualified, and the first list of qualified CDSMs was published in July 2017.

In the CY 2017 PFS final rule, CMS identified the circumstances specific to ordering professionals under which consulting and reporting requirements are not required. These include orders for applicable imaging services: 1) for emergency services when provided to individuals with emergency medical conditions as defined in Section 1867 of the Act; 2) for an inpatient and for which payment is made under Medicare Part A; and 3) by ordering professionals who are granted a significant hardship exception to the Medicare EHR Incentive Program payment adjustment for that year.

Numerous commenters requested clarification regarding who is required to perform the consultation of AUC through a qualified CDSM. Commenters questioned whether a designee within an ordering professional's practice could consult on behalf of the ordering professional and whether an ordering professional could delegate consultation authority to another individual, a third party vendor, or contracted agent. Several commenters supported this notion, noting that state laws allow professionals to delegate to qualified individuals in practice under the supervision of a physician the ability to assist with advanced imaging orders. Some commenters supported delegation only to the ordering professional's staff while other commenters opposed allowing consultation by anyone other than the ordering professional, and are concerned that other types of individuals and stakeholders are preparing to circumvent this requirement by performing consultations on behalf of ordering professionals.

According to CMS, Section 1834 of the Act requires an ordering professional to consult specified AUC through a qualified CDSM, and communicate information on that consultation to the furnishing professional. Based on the varying opinions presented by stakeholders and the number of commenters who raised these questions, CMS will consider developing policy to address this issue. CMS is also not moving forward with requiring reporting of AUC consultation information on Medicare claims using a combination of G-codes and modifiers. Rather, CMS will evaluate a simplified method of reporting during the voluntary reporting period using a single modifier while continuing to work with stakeholders to explore using a standardized unique AUC consultation identifier.

CMS finalized a voluntary period during which early adopters can begin reporting limited consultation information on Medicare claims from July 2018 through Dec. 2019. During the voluntary period there is no requirement for ordering professionals to consult AUC or furnishing professionals to report information related to the consultation. On Jan. 1, 2020, the program will begin with an educational and operational testing period and during this time, CMS will continue to pay claims whether or not they correctly include such information. Ordering professionals must consult specified applicable AUC through qualified CDSMs for applicable imaging services furnished in an applicable setting, paid for under an applicable payment system, and ordered on or after Jan. 1, 2020, and furnishing professionals must report the AUC consultation information on the Medicare claim for these services.

The following modifier was created for imaging providers to use on a voluntary basis starting July 1, 2018, to show that the ordering professional consulted Appropriate Use Criteria for advanced diagnostic imaging: **QQ:** Ordering professional consulted a qualified clinical decision support mechanism for this service and the related data was provided to the furnishing professional.

Applicable settings currently include physician offices, hospital outpatient departments, and ambulatory surgical centers. Critical Access Hospital (CAH) patients who are furnished an advanced diagnostic imaging service in an applicable setting, but the claim for that imaging service is not paid under one of the applicable payment systems, would not require consultation and reporting of the AUC consultation.

CMS recognizes that the number of clinicians impacted by the scope of this program is massive as it will apply to every physician or other practitioner who orders or furnishes applicable imaging services (CT, MRI and PET scans). This crosses almost every medical specialty and could have a particular impact on primary care physicians since their scope of practice can be quite broad.

CMS estimates the AUC consulting requirement to result in an annual burden of 1,425,000 hours at a cost of $275,139,000. These updates to the AUC program will not result in claims denials in CY 2018; therefore, these proposals would not impact CY 2018 physician payments under the PFS. The Congressional Budget Office estimates that this initiative would save approximately $200 million over 10 years from FY 2014 through 2024, which could be the result of identification of outlier ordering professionals and also includes a payment deduction for computed tomography equipment that is not up to a current technology standard.

2018 Updates to the Quality Payment Program

On Nov. 2, 2017, CMS issued the CY 2018 Updates to the Quality Payment Program (QPP), which included information on the launch of the "Patients Over Paperwork" initiative, a collaborative process that evaluates and streamlines regulations with a goal to reduce unnecessary burden, increase efficiencies, and improve the beneficiary experience. In addition, CMS states that it is working to implement the Quality Payment Program in a way that provides provider flexibility and simplifies the program.

The 21st Century Cures Act, enacted in 2016, includes provisions affecting the Advancing Care Information performance category for the QPP's current transition year and future years. CMS is implementing these provisions, some of which apply to the MIPS transition year. Last, CMS worked to provide clarity and additional details on many aspects of the program including the APM scoring standard and the All-Payer Combination Option.

Other Issues

In addition to the major provisions listed above, the 2018 PFS final rule addresses the potentially misvalued codes, payment incentive for the transition from traditional X-ray imaging to digital radiography, the 2018 PQRS program, the value-based modifier, the Medicare Diabetes Prevention Program, Physician Self-Referral Update, and the Medicare Shared Savings Program. OI

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Table 6. CY 2018 Estimated Impact Table

SPECIALTY	ALLOWED CHARGES (MIL)	IMPACT OF WORK RVU CHANGES	IMPACT OF PE RVU CHANGES	IMPACT OF MP RVU CHANGES	COMBINED IMPACT
Hematology/Oncology	$1,809	0%	0%	0%	0%
Radiation Oncology & Radiation Therapy Centers	$1,745	0%	1%	0%	1%

Specialty: The Medicare specialty code as reflected in the physician/supplier enrollment files.

Allowed Charges: The aggregate estimated PFS allowed charges for the specialty based on CY 2013 utilization and CY 2014 rates.

Impact of Work RVU Changes: This column shows the estimated CY 2015 impact on total allowed charges of the changes in the work RVUs, including the impact of changes due to new, revised, and misvalued codes.

Impact of Practice Expense RVU Changes: This column shows the estimated CY 2015 impact on total allowed charges of the changes in PE RVUs, including the impact due to new, revised, and misvalued codes and miscellaneous minor provisions.

Impact of Malpractice RVU Changes: This column shows the estimated CY 2015 impact on total allowed charges of the changes in the MP RVUs, which are primarily driven by the required five-year review and update of MP RVUs.

Combined Impact: This column shows the estimated CY 2015 combined impact on total allowed charges of all the changes in the previous columns.

Table 7. Work RVUs for New, Revised, and Potentially Misvalued Codes

HCPCS CODE	LONG DESCRIPTOR	CY 2017 WORK RVU	CY 2018 WORK RVU
19294	Preparation of tumor cavity with placement of a radiation therapy applicator for intraoperative radiation therapy (IORT) concurrent with partial mastectomy	NEW	3.00
38220	Diagnostic bone marrow; aspiration(s)	1.08	1.20
38221	Diagnostic bone marrow; biopsy(ies)	1.37	1.28
38222	Diagnostic bone marrow; biopsy(ies) and aspiration(s)	NEW	1.44
55874	Transperineal placement of biodegradable material, peri-prostatic, single or multiple injection(s), including image guidance, when performed	NEW	3.03
77261	Therapeutic radiology treatment planning; simple	1.39	1.30
77262	Therapeutic radiology treatment planning; intermediate	2.11	2.00
77263	Therapeutic radiology treatment planning; complex	3.14	3.14
96377	Application of on-body injector (includes cannula insertion) for timed subcutaneous injection	0.00	0.17

Resources

The following is a list of resources used when compiling these coding and regulatory updates:

2018 Medicare OPPS Final Rule: federalregister.gov/documents/2017/11/13/2017-23932/medicare-programs-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment

2018 Medicare Physician Fee Schedule Final Rule: federalregister.gov/documents/2017/11/15/2017-23953/medicare-programs-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other-revisions

2018 Updates to the Quality Payment Program: federalregister.gov/documents/2017/11/16/2017-24067/medicare-programs-cy-2018-updates-to-the-quality-payment-program-and-quality-payment-program-extreme