compliance

2020 Oncology Coding Update

BY TERI BEDARD BA, RT(R)(T), CPC

he coding updates for calendar year (CY) 2020 have been finalized by the Centers for Medicare & Medicaid Services (CMS) and the American Medical association (AMA). In comparison to previous years, the code changes outlined for CY 2020 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. This column outlines coding changes specific to services provided by oncology specialties and services for patients with cancer. There are new codes added under evaluation and management (E/M) services that may be appropriate for oncology providers, including both CPT[®] and HCPCS (Healthcare Common Procedure Coding System) code additions or revisions. As discussed in the previous "Compliance" column (November/December 2019 Oncology Issues), the Appropriate Use Criteria (AUC) Program kicks off Jan. 1, 2020. Several new modifiers and codes for AUC are available for reporting in 2020. Finally, there are several updates to codes for SPECT (single-photon emission computerized tomography), and these are included for reference should they be applicable to any oncology patients.

New and Revised Procedure Codes

The following codes have been added for CY 2020:

 99421: Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 5-10 minutes

- **99422:** Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 11-20 minutes
- **99423**: Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 21 or more minutes
- **99473**: Self-measured blood pressure using a device validated for clinical accuracy, patient education/training, and device calibration
- 99474: Separate self-measurements of two readings one minute apart, twice daily over a 30-day period (minimum of 12 readings), collection of data reported by the patient and/or caregiver to the physician or other qualified health care professional, with report of average systolic and diastolic pressures and subsequent communication of a treatment plan to the patient
- 99458: Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; each additional 20 minutes (List separately in addition to code for primary procedure)
- 74221: Radiologic examination, esophagus, including scout chest radiograph(s) and delayed image(s), when performed; double-contrast (e.g., high-density barium and effervescent agent) study
- 74248: Radiologic small intestine follow-through study, including multiple serial images (List separately in addition

to code for primary procedure for upper GI radiologic examination)

- 78830: Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT) with concurrently acquired computed tomography (CT) transmission scan for anatomical review, localization and determination/detection of pathology, single area (e.g., head, neck, chest, pelvis), single day imaging
- 78831: Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT), minimum 2 areas (e.g., pelvis and knees, abdomen and pelvis), single day imaging, or single area imaging over 2 or more days
- 78832: Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT) with concurrently acquired computed tomography (CT) transmission scan for anatomical review, localization, and determination/detection of pathology, minimum 2 areas (e.g., pelvis and knees, abdomen and pelvis), single day imaging, or single area imaging over 2 or more days
- **78835**: Radiopharmaceutical quantification measurement(s) single area (List separately in addition to code for primary procedure).

The following codes have been revised for CY 2020:

- 99457: Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; first 20 minutes
- 74022: Radiologic examination, complete acute abdomen series, including 2 or more views of the abdomen (e.g., supine, erect, and/or decubitus views), and a single view chest
- 74210: Radiologic examination, pharynx and/or cervical esophagus, including scout neck radiograph(s) and delayed image(s), when performed, contrast (e.g., barium) study
- 74220: Radiologic examination, esophagus, including scout chest radiograph(s) and delayed image(s), when performed; single-contrast (e.g., barium) study
- 74230: Radiologic examination, swallowing function, with cineradiography/video radiography, including scout neck radiograph(s) and delayed image(s), when performed, contrast (e.g., barium) study
- 74240: Radiologic examination, upper gastrointestinal tract, including scout abdominal radiograph(s) and delayed image(s), upper when performed; single-contrast (e.g., barium) study
- 74246: Radiologic examination, upper gastrointestinal tract, including scout abdominal radiograph(s)and delayed image(s), when performed; double-contrast (e.g., high-density barium and effervescent agent) study, including glucagon, when administered
- 74250: Radiologic examination, small intestine, including multiple serial images and scout abdominal radiograph(s), when performed; single-contrast (e.g., barium) study
- **74251**: Double-contrast (e.g., high-density barium and air via enteroclysis tube) study, including glucagon, when administered
- 74270: Radiologic examination, colon, including scout abdominal radiograph(s) and delayed image(s), when performed; single contrast (e.g., barium) study
- **74280**: Double-contrast (e.g., high density barium and air) study, including glucagon, when administered

- 78800: Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); planar, single area (e.g., head, neck, chest, pelvis), single day of imaging
- **78801**: Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); planar, 2 or more areas (e.g., abdomen and pelvis, head and chest), 1 or more days of imaging or single area imaging over 2 or more days
- 78802: Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); planar, whole body, single day imaging
- 78804: Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); planar, whole body, requiring 2 or more days imaging
- 78803: Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT), single area (e.g., head, neck, chest, pelvis), single day of imaging.

Codes Deleted for CY 2020

- 99444: Online evaluation and management service provided by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient or guardian, not originating from a related E/M service provided within the previous 7 days, using the Internet or similar electronic communications network
- 78205: Liver imaging (SPECT)
- **78206**: Liver imaging (SPECT); with vascular flow
- 78320: Tomographic (SPECT)
- **78607**: Brain imaging, tomographic (SPECT)

- **78647**: Cerebrospinal fluid flow, imaging (not including introduction of material); tomographic (SPECT)
- **78710**: Kidney imaging morphology; tomographic (SPECT)
- **78805**: Radiopharmaceutical localization of inflammatory process; limited area
- **78806**: Radiopharmaceutical localization of inflammatory process; whole body
- **78807**: Radiopharmaceutical localization of inflammatory process; tomographic (SPECT).

AUC HCPCS Modifiers

The following AUC HCPCS modifiers have been added for CY 2020:

- MA: Ordering professional is not required to consult a clinical decision support mechanism due to service being rendered to a patient with a suspected or confirmed emergency medical condition
- MB: Ordering professional is not required to consult a clinical decision support mechanism due to the significant hardship exception of insufficient internet access
- MC: Ordering professional is not required to consult a clinical decision support mechanism due to the significant hardship exception of electronic health record or clinical decision support mechanism vendor issues
- **MD**: Ordering professional is not required to consult a clinical decision support mechanism due to the significant hardship exception of extreme and uncontrollable circumstances
- **ME**: The order for this service adheres to appropriate use criteria in the clinical decision support mechanism consulted by the ordering professional
- **MF**: The order for this service does not adhere to the appropriate use criteria in the clinical decision support mechanism consulted by the ordering professional
- **MG**: The order for this service does not have applicable appropriate use criteria in the qualified clinical decision support mechanism consulted by the ordering professional
- MH: Unknown if ordering professional consulted a clinical decision support mechanism for this service, related information was not provided to the furnishing professional or provider.

AUC HCPCS Codes

- G1000: Clinical decision support mechanism applied pathways, as defined by the Medicare appropriate use criteria program
- **G1001**: Clinical decision support mechanism eviCore, as defined by the Medicare appropriate use criteria program
- G1002: Clinical decision support mechanism MedCurrent, as defined by the Medicare appropriate use criteria program
- G1003: Clinical decision support mechanism Medicalis, as defined by the Medicare appropriate use criteria program
- **G1004**: Clinical decision support mechanism National Decision Support Company, as defined by the Medicare appropriate use criteria program
- **G1005:** Clinical decision support mechanism National Imaging Associates, as defined by the Medicare appropriate use criteria program
- **G1006**: Clinical decision support mechanism Test Appropriate, as defined by the Medicare appropriate use criteria program
- **G1007:** Clinical decision support mechanism AIM Specialty Health, as defined by the Medicare appropriate use criteria program
- G1008: Clinical decision support mechanism Cranberry Peak, as defined by

the Medicare appropriate use criteria program

- **G1009**: Clinical decision support mechanism Sage Health Management Solutions, as defined by the Medicare appropriate use criteria program
- G1010: Clinical decision support mechanism Stanson, as defined by the Medicare appropriate use criteria program
- G1011: Clinical decision support mechanism, qualified tool not otherwise specified, as defined by the Medicare appropriate use criteria program.

HCPCS Codes Added for 2020

- **A9590**: lodine i-131, iobenguane, 1 millicurie
- G2061: Qualified nonphysician healthcare professional online assessment, for an established patient, for up to seven days, cumulative time during the 7 days; 5-10 minutes
- G2062: Qualified nonphysician healthcare professional online assessment service, for an established patient, for up to seven days, cumulative time during the 7 days; 11-20 minutes
- **G2063**: Qualified nonphysician qualified healthcare professional assessment service, for an established patient, for up to seven days, cumulative time during the 7 days; 21 or more minutes.

HCPCS Code Deleted for 2020

• **GD:** Units of service exceeds medically unlikely edit value and represents reasonable and necessary services.

HCPCS Codes with Changes in Definition for 2020

- **Q5105:** Injection, epoetin alfa-epbx, biosimilar, (retacrit) (for esrd on dialysis), 100 units
- Q5106: Injection, epoetin alfa-epbx, biosimilar, (retacrit) (for non-esrd use), 1000 units.

New HCPCS Drug Codes Added for 2020

- **J9030**: Bcg live intravesical instillation, 1 mg
- J9036: Injection, bendamustine hydrochloride, (belrapzo/bendamustine), 1 mg
- **J9118:** Injection, calaspargase pegolmknl, 10 units
- **J9119:** Injection, cemiplimab-rwlc, 1 mg
- J9199: Injection, gemcitabine hydrochloride (infugem), 200 mg
- J9204: Injection, mogamulizumab-kpkc, 1 mg
- J9210: Injection, emapalumab-lzsg, 1 mg
- **J9269:** Injection, tagraxofusp-erzs, 10 micrograms
- **J9309**: Injection, polatuzumab vedotinpiiq, 1 mg
- **J9313**: Injection, moxetumomab pasudotox-tdfk, 0.01 mg
- **J9356:** Injection, trastuzumab, 10 mg and hyaluronidase-oysk.

2020 Hospital Regulatory Update

BY TERI BEDARD, BA, RT(R)(T), CPC

he Hospital Outpatient Prospective Payment System (OPPS) is one of the Medicare payment systems that applies to facility-based settings, which include, hospitals, ambulatory surgical centers (ASCs), critical access hospitals (CAHs) and excepted off-campus provider-based departments. As indicated in the CY 2019 OPPS final rule, the overarching goal of the Centers for Medicare & Medicaid Services (CMS) 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, over the last several years CMS has continued to package more ancillary services into what are considered primary services, establishing reimbursement for the primary service only. Another approach to control spending pursued by CMS is implementation of policies to make payments site-neutral so that the same service is reimbursed similarly regardless of the setting in which it was performed—hospital, physician office, or ASC.

CMS projects CY 2020 OPPS expenditures to be approximately \$79 billion, an increase of approximately \$6.3 billion compared to projected CY 2019 OPPS payments. The agency finalized an increase of payment rates under the CY 2020 OPPS of 2.6 percent to the conversion factor of CY 2019, which is slightly lower than proposed. The CY 2020 conversion factor is finalized at \$80.784; however, hospitals that fail to meet the Hospital Outpatient Quality Reporting (OQR) Program requirements will continue to be penalized with a 2 percent reduction to the finalized CF. To determine this payment rate, CMS utilized data released in the inpatient prospective payment system (IPPS) final rule for FY 2020, which had a 3 percent increase for inpatient services, slightly lower than proposed, and minus 0.4 percent for the multifactor productivity (MFP) adjustment. Due to wage index changes, a budget neutrality factor of 0.9981 was also applied for CY 2020.

CMS is maintaining the rural adjustment factor of 7.1 percent to OPPS payments to certain rural sole community hospitals (SCHs), including essential access community hospitals (EACHs) for CY 2020 and subsequent years, until data support application of a different factor. This payment adjustment will continue to exclude separately payable drugs, biologicals, and devices paid under the pass-through payment policy.

CMS estimates the increase to the OPPS will result in increases of 2.7 percent and 2.8 percent for urban hospitals and rural hospitals, respectively. Comparing those hospitals which are classified as teaching versus nonteaching, CMS estimates minor teaching hospitals will experience an increase of approximately 2.9 percent, major teaching hospitals 2.4 percent, and nonteaching hospitals 2.8 percent increase.

For ASC payments CY 2019 through CY 2023, CMS has updated its policy for using a market basket update. For CY 2020 ASCs will see an increase of 2.6 percent for centers that meet quality reporting under the ASCQR program, slightly lower than proposed. CMS projects expenditures for beneficiaries in ASCs to be approximately \$4.96 billion, an increase of approximately \$230 million from CY 2019 payments.

CMS finalized to continue applying a wage index of 1.000 for frontier state hospitals (Montana, Wyoming, North Dakota, South Dakota, and Nevada), this policy has been in place since CY 2011. This ensures that lower population states are not "penalized" for reimbursement due to the low number of people per square mile when compared to other states. CMS also finalized for CY 2020 to continue additional payments to cancer hospitals. The payment-to-cost ratio (PCR) is applied as an additional payment and equal to the weighted average PCR for the other OPPS hospitals using the most recently submitted or settled cost report data. CMS finalized to use a target PCR of 0.89 to determine the CY 2020 cancer hospital payment adjustment to be paid at cost report settlement.

APC Two-Times Rule Exceptions

CMS identified several ambulatory payment classifications (APCs) in violation of the two-times rule for CY 2020. The two-times rule does not allow codes to be assigned to an APC where the highest cost code is more than two times that of the lowest cost code. If a two-times rule violation is identified, CMS and the advisory panel on Hospital Outpatient Payment (HOP) will reassign codes or create a new APC. When determining if there is a two-times rule violation, CMS only considers HCPCS codes that are significant based on the number of claims. Within the final rule, CMS was able to remedy two of the APC violations but identified an additional one **APC 5593** (Level 3 Nuclear Medicine and Related Services). After consideration of comments and data, CMS is making exceptions to 17 of the APC two-times rule violations. This means no adjustments or movement of codes to other APCs to balance the highest and lowest costing codes. This exception included the two APCs related to oncology services **APC 5612** (Level 2 Therapeutic Radiation Treatment Preparation) and **APC 5691** (Level 1 Drug Administration).

Standardizing APC Payment Weights

APCs group services that are considered clinically comparable to each other with respect to the resources utilized and the associated cost. Ancillary services or items are necessary components of the primary service and are packaged into the APC rates and are not separately reimbursed. CMS instructs providers to apply current procedure-to-procedure edits and then report all remaining services on the claim form. CMS will only pay for services that are considered not packaged into another service.

CMS will continue using HCPCS code **G0463** (Hospital outpatient clinic visit for assessment and management of a patient) in **APC 5012** (Level 2 Examinations and Related Services) as the standardized code for the relative payment weights. A relative payment weight of 1.00 will continue to be assigned to **APC 5012** (code **G0463**). CMS will use the factor of 1.00 and then divide the geometric mean cost of each APC by the geometric mean cost of **APC 5012** to derive the unscaled relative payment weight for each APC.

CY 2020 will mark the second and final adjustment year based on CY 2019 finalized changes to how the clinic visit, represented by code **G0463**, is reimbursed in all off-campus provider-based departments. Due to the high volume of reporting for code **G0463**, CMS finalized reimbursement adjustments to the most widely reported code under OPPS for what is seen as "unnecessary increases in the volume of outpatient service." For CY 2019, CMS finalized a site-neutral reimbursement methodology for code **G0463**. In any setting considered off-campus, i.e., more than 250 yards from the main buildings of the hospital, either excepted or nonexcepted, CMS set a site-neutral payment rate. This means that in excepted or nonexcepted off-campus locations, in CY 2019 the reimbursement for code **G0463** was 40 percent of the on-campus outpatient reimbursement amount. Because this was a high rate change, CMS implemented this site-neutral payment approach over a two-year period, rather than all at once.

For CY 2019, reimbursement for code **G0463** was set at 40 percent of the OPPS payment rate—a decrease of 60 percent. However, to phase-in this payment reduction, the decrease was split in half so that in CY 2019 the reimbursement rates for **G0463** in all off-campus provider-based departments decreased by 30 percent, not the full 60 percent. For CY 2020 CMS finalized the remaining 30 percent decrease, so that in 2020 the overall total reimbursement reduction aimed at achieving site neutrality will reach 60 percent (or 40% of the OPPS rate). This decision is not without considerable push-back and potential controversy.

Due to a lawsuit filed by the American Hospital Association challenging CMS' authority to make this payment reduction, many commenters argued that the Sept. 17, 2019, decision by the U.S. District Court for the District of Columbia, to vacate the portion of the CY 2019 OPPS proposed rule related to the volume control method for clinic visits, did not support the decision by CMS to move forward with the second-year implementation in payment reduction. CMS filed an appeal in late September 2019, but the motion to modify and request for stay was denied. In addition, the HOP unanimously recommended that CMS freeze the policy for paying clinic visits provided in an excepted off-campus provider-based department (PBD) at the CY 2019 rate. Thus, CMS would have an opportunity evaluate the impact to patient care and access and whether this volume-control method was resulting in a decrease in volume of outpatient services.

In the CY 2020 final rule, CMS responded that it will be working to ensure affected 2019 claims for clinic visits are paid in a manner consistent with the court's order, but the agency did not agree that it was appropriate at this time to make a change to the second year of the two-year phase-in policy. Within the CY 2020 final rule, CMS expressed the agency's belief that the U.S. Department of Health and Human Services (HHS) Secretary does have the authority to make changes as a means of controlling unnecessary increases in the volume of outpatient department services. Specifically, CMS argues, the agency has the authority to remove potential reimbursement incentives or differences that may unnecessarily increase the volume of services provided based on location or setting. Implementing a site-neutral payment policy for clinic visits will, CMS believes, appropriately and effectively impact and adjust any unnecessary services or continued increases in services due to higher reimbursement in a particular setting.

Based on evaluation of all the comments, legal action, and recommendations by the HOP, as indicated above, for CY2020 CMS is moving forward with the reduction. This means that the full reduction in payments will be applied (i.e., a 60 percent reduction to the on-campus reimbursement for code **G0463**) for those services provided in off-campus excepted provider-based departments. These departments will also bill services with modifier PO to identify the classification of setting. CMS will continue to monitor the services and volumes provided, as well as the ongoing litigation and judicial decisions.

Changes to Supervision of Therapeutic Outpatient Services

Since April 2000, CMS has required direct supervision of therapeutic services in the outpatient setting. In CYs 2009, 2010, and 2011, CMS continued to clarify what direct supervision means and the expectations for meeting requirements. During this period, CAHs and many rural hospitals pushed back citing difficulty in finding staff or hiring appropriate physicians for all therapeutic services to meet the requirement. Many stakeholders specifically called out difficulty in finding appropriately trained physicians with specialty expertise, such as in radiation oncology, for rural locations.

In consequence, over the years CMS has enforced and then not enforced the need for direct supervision of all therapeutic services in CAHs and most recently rural hospitals with 100 or fewer beds. The most recent round of nonenforcement for CAHs and rural hospitals with 100 or fewer beds was set to expire December 31, 2019. Given this fast-approaching expiration deadline, CMS decided to review the requirement for direct supervision across all hospitals regardless of size or location.

In the 2020 proposed rule CMS expressed concern that currently two tiers of supervision exist for the same services. General supervision applied for CAHs and rural hospitals with 100 or fewer beds, while direct supervision was required for all other hospitals. Additionally, CMS indicated that the agency was not aware of any data or information that would support the contention that application of only general supervision in designated areas has affected the services or care of patients. To alleviate these differences for CY 2020, CMS proposed one supervision standard (general supervision) for all hospital outpatient therapeutic services provided in hospitals and CAHs, and specifically sought comments on whether services, such as radiation therapy and chemotherapy administration should be excluded.

General supervision is defined as, "procedure is furnished under the physician's overall direction and control, but that the physician's presence is not required during the performance of the procedure." Direct supervision is defined as, "the physician or nonphysician practitioner must be present on the same campus where the services are being furnished." Additionally, the physician must be able to respond without interval of time and not be providing another service for which they cannot step away from.

After review of comments, for CY 2020 and subsequent years CMS finalized its proposal to change the generally acceptable minimum required level of supervision for all hospital outpatient therapeutic services, including radiation therapy and chemotherapy administration, to general supervision. This means the same level of supervision will be required for hospitals and CAHs.

However, CMS did stress that the change to general supervision will not prevent any of the hospitals from providing services under direct supervision when the physician administering that service determines it is appropriate to do so. There are many therapeutic services provided in the outpatient setting that are highly complex and need the direct supervision of the qualified physician. Under the final 2020 OPPS rule, hospitals and physicians will now be able to set the supervision level that they believe is appropriate, which could result in direct or personal supervision for some outpatient therapeutic services.

Further, hospitals and physicians must also consider hospital policies, CAH CoPs (conditions of participation), and state scope of work regulations, as well as state and federal laws that may and do define supervision requirements for certain services and supersede the changes in supervision level as indicated by CMS. For example, brachytherapy services would still be bound by the Nuclear Regulatory Commission (NRC) and Agreement State Program regulations for the presence of the physician and authorized user.

Additionally, for service which have technical and professional components, like those in radiation oncology, the supervision changes pertain to the technical services, there is no supervision of professional work components. Physician work and personal presence for the work is not the same as supervision. There is no indication at this time if commercial payers will adopt this change in supervision of outpatient therapeutic services provided to their beneficiaries. Lastly, direct supervision is still the requirement of therapeutic services provided in the freestanding center/office setting as these are not governed by the supervision rules under OPPS and as outlined in the Medicare Benefit Policy Manual.

Typically, any changes to supervision are addressed by the HOP advisory panel, and CMS indicated it will continue to seek the panel's advice for appropriate supervision levels of hospital outpatient services. CMS also indicated that it will retain the ability to adjust the supervision levels of individual hospital outpatient services to something more intensive than general supervision through the usual notification of changes and comment periods of the rules.

MedPAC (Medicare Payment Advisory Commission) strongly encouraged CMS to monitor outpatient therapeutic services that Medicare beneficiaries receive to ensure the quality of care is not compromised and error rates do not increase due to lack of physician presence and supervision of services.

CMS also noted, failure of a physician to provide the adequate supervision in accordance with hospital and CAH CoPs would not cause payment to be denied for that service, but consistent violations of the supervision requirements would result in corrective action plans, and finally in termination of the hospital or CAH from Medicare participation for ongoing failure to comply.

Comments Received for C-APCs for SRS and Brachytherapy

CMS did not propose any changes to the comprehensive APCs (C-APCs) for radiation oncology for CY 2020; however, comments requesting changes were received.

One commenter requested that CMS discontinue C-APC payment for SRS procedures, stating it does not account for the complexity of delivering radiation and fails to capture appropriately coded claims. The commenters also requested that **CPT 77301**, IMRT planning, be added to the group of 10 codes that are excluded from the C-APC and paid separately in addition to the treatment delivery codes (**77371** and **77372**), as it has become more common with SRS.

CMS responded that the agency does not believe any changes are needed at this time. The C-APC is accomplishing the intent of the initial ruling and no evidence or data was provided by the commenter to support otherwise. Additionally, CMS indicated that the 10 separately paid codes will continue to be the 10 codes paid. There was no mention of why IMRT planning, **77301**, would not be added.

The agency also received comments requesting discontinuation of the brachytherapy C-APC for all surgical insertion codes for brachytherapy treatment. Commenters expressed concern that the payment methodology impacts radiation oncology, specifically for brachytherapy treatment of cervical cancer. Comments cited the complexity of cases and that the insertion of the surgical device at one site and subsequent treatment at another site creates reimbursement issues. CMS indicated it believes that the C-APC is appropriately applied to these surgical procedures and it will continue to examine the concerns presented to determine if any modifications are needed in future rulemaking.

Payments of Drugs, Biologicals and Radiopharmaceuticals

Each year CMS assesses the drug packaging threshold in accordance with section 1833(t) (16)(B) of the Social Security Act. For CY 2020, the agency proposed and finalized to package drugs and biologicals estimated at a per day administration cost less than or equal to \$130. (In CY 2019, the packaging threshold was set at \$125.) CMS also finalized, as proposed, to continue to pay separately for items with an estimated per day cost greater than \$130 with the exception of diagnostic radiopharmaceuticals, contrast agents, anesthesia drugs, drugs, biologicals and 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.

Payment rates for HCPCS codes for separately payable drugs and biologicals are published in Addenda A and B Average Sales Price (ASP) data from the first quarter of CY 2019. This published data will be used for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective April 1, 2019. These payment rates will also be updated in the January 2020 OPPS update, based on the most recent ASP data to be used for physician's office and OPPS payment as of January 1, 2020. For items that do not currently have an ASP-based payment rate, CMS will recalculate its mean unit cost from all claims data of the CY 2018.

CMS proposed and finalized, after receiving no comments, to continue the policy of making packaging determinations on a drug-specific basis rather than by HCPCS code for those codes that describe the same drug or biological, but in different dosages. For all other drugs and biologicals that have HCPCS codes describing different doses, Medicare aggregated the CY 2018 claims data and pricing information at ASP+6 percent for all HCPCS codes that describe each distinct drug or biological. This provided the mean units per day in terms of the HCPCS code with the lowest dosage descriptor. For other drugs and biologicals that have HCPCS codes describing different doses, CMS multiplied the proposed weighted average ASP+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 to determine the estimated per day cost of each drug or biological at less than or equal to the CY 2020 drug packaging threshold of \$130. The drugs and biologicals for which that would apply in CY 2020 are displayed in Table 1, right.

For CY 2020, CMS continues the current payment policy, which has been in effect since CY 2013, that pays for separately payable drugs and biologicals at ASP+6 percent. These separately payable drugs and biologicals are listed in Addenda A and B of the final rule. CMS will also continue to pay for separately payable non-pass-through drugs acquired with a 340B discount at ASP-22.5 percent, but the agency must address issues due to pending litigation for CYs 2018 and 2019.

For drugs or biologicals without sufficient data on sales price during the initial sales period, section 1847A(c)(4) of the Act allows for payments based on Wholesale Acquisition Cost (WAC). The Act defines 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. CMS will utilize a 3 percent add-on instead of a 6 percent add-on for WAC-based drugs. For drugs and biologicals acquired under the 340B Program, the 340B Program rate (WAC-22.5 percent) would apply.

CMS previously finalized the payment policy for biosimilar biological products based on the payment allowance of the product as determined under section 1847A of the Act in CY 2016 and CY 2017. For CY 2020, CMS will continue the policy finalized in CY 2019 to make all biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product. CMS will also continue to pay non-pass-through biosimilars acquired under the 340B Program at ASP-22.5 percent of the biosimilar's ASP, instead of the biosimilar's ASP-22.5 percent of the reference product's ASP.

CMS also finalized expiration of the pass-through status of six drugs and biologicals on December 31, 2019. These drugs and biologicals have received OPPS pass-through payment for at least 2 years and no more than 3 years by December 31, 2019. Table 2, page 10, lists drugs and biologicals losing pass-through status in 2020.

For CY 2020, Medicare finalized that 61 drugs and biologicals will continue to receive pass-through CMS will continue to pay for pass-through drugs and biologicals at the ASP+6 percent and continue to update pass-through payment rates on a quarterly basis through the CMS website. Table 3, pages 10-11, lists drugs and biologicals commonly utilized within oncology or hematology that will have pass-through status for CY 2020.

340B Drug Pricing Program

The 340B Drug Pricing Program was established by section 340B of the Public Health Service Act by the Veterans Health Care Act of 1992 and is administered by the Health Resources and Services Administration (HRSA) within HHS. This program allows participating hospitals and other healthcare providers to purchase certain "covered outpatient drugs" at discounted prices from drug manufacturers.

HRSA calculates the ceiling price for each covered outpatient drug, which is the average manufacturer price (AMP) minus the unit rebate amount (URA). This ceiling price

Table 1. HCPCS Codes to Which the CY 2020 Drug-Specific Packaging Determination Methodology Would Apply

CY 2020 HCPCS CODE	CY 2020 LONG DESCRIPTOR	CY 2020 STATUS INDICATOR (SI)
C9257	Injection, bevacizumab, 0.25mg	К
J9035	Injection, bevacizumab, 10 mg	К
J1020	Injection, methylprednisolone acetate, 20 mg	N
J1030	Injection, methylprednisolone acetate, 40 mg	Ν
J1040	Injection, methylprednisolone acetate, 80 mg	Ν
J1460	Injection, gamma globulin, intramuscular, 1 cc	К
J1560	Injection, gamma globulin, intramuscular over 10 cc	К
J1642	Injection, heparin sodium, (heparin lock flush), per 10 units	Ν
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	Ν
J7040	Infusion, normal saline solution, sterile (500 ml=1 unit)	Ν
J7050	Infusion, normal saline solution, 250 cc	N
J7515	Cyclosporine, oral, 25 mg	Ν
J7502	Cyclosporine, oral, 100 mg	Ν
J8520	Capecitabine, oral, 150 mg	Ν
J8521	Capecitabine, oral, 500 mg	Ν
J9250	Methotrexate sodium, 5 mg	Ν
J9260	Methotrexate sodium, 50 mg	Ν

represents the maximum price a drug manufacturer can charge a 340B covered entity for the drug. It is noted that covered entities have the option to participate in HRSA's Prime Vendor Program (PVP), which may allow for negotiation of additional discounts (known as "sub-ceiling prices").

In the CY 2018 OPPS final rule, CMS finalized the policy to pay for drugs purchased under the 340B Drug Pricing Program (this does not include drugs on pass-through payment status or vaccines) to be reimbursed at the rate of ASP-22.5 percent. This differed significantly from the previous payment rate of ASP+6 percent. Since the implementation of the drastic reduction in reimbursement for drugs purchased under 340B program (ASP-22.5 percent), lawsuits have been filed alleging CMS does not have the authority to make these changes. Recent litigation concluded that for CY 2018, Secretary Azar "exceeded his statutory authority" by adjusting the reimbursement rate to ASP-22.5 percent.

After a request by CMS for a final judgement so that the agency could file an appeal, the District Court entered final judgment on July 10, 2019. The court did not order CMS to repay the monies that resulted as part of the 340B drug pricing reduction due to the complex nature of the reimbursement.

CMS has appealed the court's decision and is working to create a policy to address what the court sees as an overstep and the reimbursement of monies back to hospitals and adjustment to beneficiary cost-sharing in the event the appeal is overturned. Should it lose on appeal, the agency will present its solution in the CY 2021 proposed rule. Comments received to the CY 2020 proposed rule would be used to assist in crafting the agency's new proposal.

Awaiting a decision on its appeal, and after consideration of the comments received to the proposed 2020 rule, CMS finalized the following for CY 2020:

 Continue paying ASP-22.5 percent for drugs and biosimilar biologicals acquired under 340B program and furnished in on-campus hospital departments, exempted off-campus provider-based departments, and nonexempted off-campus provider-based departments paid under MPFS

- Pay for biosimilar biological products at -22.5 percent of the biosimilar's ASP, not the reference drug's ASP
- Continue paying ASP+6 percent for drugs purchased outside the 340B program
- Hospitals will continue to report drugs purchased through the 340B Drug Pricing Program with modifier JG on the same claim line items as the drug HCPCS code
- Rural sole community hospitals (SCHs), children's hospitals, and PPS-exempt cancer hospitals will continue to be exempt from the 340B payment adjustment and report TB modifier for 340B-acquired drugs on claim forms and paid at ASP+6 percent.

Brachytherapy Sources

CMS did not finalize any significant changes to how reimbursement for brachytherapy sources is calculated. CMS used costs derived from CY 2018 claims data for the CY 2020 payment rates and based the payment rates for brachytherapy sources on the geometric mean unit costs for each source. Brachytherapy sources, unless otherwise noted, are assigned status indicator (SI) "U." Codes with SI "U" are not packaged into C-APCs; the sources are paid separately in addition to the brachytherapy insertion code in the hospital setting.

CMS will continue to pay for the stranded and non-stranded not otherwise specified (NOS) codes, HCPCS codes **C2698** and **C2699**, at a rate equal to the lowest stranded or non-stranded prospective payment rate for such sources, respectively, on a per source basis (as opposed to, for example, a per mCi).

CMS assigned HCPCS code **C2645** (Brachytherapy planar, p-103), a SI "U" (Brachytherapy Sources, Paid under OPPS; separate APC payment). When valuing the code, CMS had two sets of claims data, with units totaling over 9,000, for **C2645** for CY 2018. CMS believed this was adequate to discontinue the practice of using external data for the rate setting of this brachytherapy source. For CY 2020, the agency had proposed to set the payment rate for **C2645** at \$1.02 per mm2, a decrease from the CY 2019 rate of \$4.69 per mm2. CMS did not finalize the change in reimbursement for **C2645** for CY 2020.

CMS indicated in response to comments that the geometric mean cost and payment for brachytherapy sources has fluctuated significantly since 2013, and the agency will consider removing outliers from the data for future rate setting. Commenters believe this would ensure better payment stability for low-volume brachytherapy sources in any future rate setting. CMS stated that it continues to believe the geometric mean costs do a better job of accounting for the variations in cost for brachytherapy sources and that the removal of outliers would be inappropriate to reflect the spectrum of costs.

Hospitals and other parties are invited to submit recommendations to CMS for new codes to describe new brachytherapy sources. Recommendations can be directed to the Division of Outpatient Care: Mail Stop C4-01-26, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD, 21244. CMS will continue to add new brachytherapy source codes and descriptors on a quarterly basis.

Removal of Hospital Quality Measure for Bone Metastases

CMS is removing measure **OP-33:** External Beam Radiotherapy (NQF# 1822) beginning with Jan. 1, 2020 encounters; this is a change from what was proposed. The final data submission date for CY 2019 encounters will be May 15, 2020. CMS believes the data is important, but the benefit of the measure is no longer supported.

The removal of this measure is primarily due to the costs and administrative burden associated with the measure in order to accurately report it. In addition, for this measure CMS receives more questions about how to report than any other measure in the program. Difficulties with reporting for this measure stem from the nature of how radiation oncology is delivered and the measure's data requirements—a full review of the medical record is needed to determine any previous treatment or details about the current treatment.

Each area treated for bone metastases is considered a different case for reporting. The data for the numerator is guite broad and applies to "all patients, regardless of age, with painful bone metastases, and no previous radiation to the same anatomic site who receive EBRT with any of the following recommended fractionation schemes: 30Gy/10fxns, 24Gy/6fxns, 20Gy/5fxns, 8Gy/1fxn." The denominator is all patients with same bone mets, no previous radiation to the same anatomical site. To determine this data-and because coding is not based on total dose delivered-staff would have to review all medical records to determine the dose and the components of the numerator and denominator at that time.

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 2020, CMS will continue providing payment for diagnostic and therapeutic radiopharmaceuticals that are granted pass-through payment status based on average sales priced (ASP) methodology, as CMS considers these to be drugs under the OPPS. These agents are paid at ASP+6 percent; however, if no ASP data is available, CMS will provide pass-through payment at whole acquisition cost (WAC) +3 percent. If that data is not available, then payment will be 95 percent of average wholesale price (AWP). CMS will continue to update pass-through payment rates on a quarterly basis on its website during CY 2020.

Table 2. Drugs and Biologicals for Which Pass-Through Payment Status Expires Dec. 31, 2019							
CY 2019 HCPCS CODE	CY 2019 LONG DESCRIPTOR	CY 2019 STATUS INDICATOR	СҮ 2019 АРС	PASS-THROUGH PAYMENT EFFECTIVE DATE			
J9205	Gallium ga-68, dotatate, diagnostic, 0.1 millicurie	G	9056	01/01/2017			
J9295	Fluciclovine f-18, diagnostic, 1 millicurie	G	9052	01/01/2017			
J9352	Buprenorphine implant, 74.2 mg	G	9058	01/01/2017			
Q5101	Injection, bendamustine hcl (Bendeka), 1 mg	G	1861	01/01/2017			

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Table 3. Drugs and Biologicals with Pass-Through Payment Status in CY 2020

CY 2019 HCPCS CODE	CY 2020 HCPCS CODE	CY 2020 LONG DESCRIPTOR	CY 2020 STATUS INDICATOR	CY 2020 APC	PASS THROUGH PAYMENT EFFECTIVE DATE	
A9513	A9513	Lutetium lu 177, dotatate,	G	9067	07/01/2018	
C9038	J9204	Injection, mogamulizumab-kpkc, 1 mg	G	9182	01/01/2019	
C9040	J3031	Injection, fremanezumabvfrm, 1 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)	G	9197	7 04/01/2019	
C9041	C9041	Injection, coagulation factor Xa (recombinant), inactivated (andexxa), 10mg	G	9198	04/01/2019	
C9043	J0642*	Injection, levoleucovorin, 1 mg	G	9334	04/01/2019	
C9044	J9119	Injection, cemiplimabrwlc, 1 mg	G	9304	04/01/2019	
C9045	J9313	Injection, moxetumomab pasudotox-tdfk, 0.01 mg	G	9305	04/01/2019	
C9047	C9047	Injection, caplacizumabyhdp, 1 mg	G	9199	07/01/2019	
J0185	J0185	Injection, aprepitant, 1 mg	G	9463	04/01/2018	
J0517	J0517	Injection, benralizumab, 1 mg	G	9466	04/01/2018	
J0565	J0565	Injection, bezlotoxumab, 10 mg	G	9490	07/01/2017	
J1303	J1303	Injection, ravulizumabcwvz,10 mg	G	9312	07/01/2019	
J1454	J1454	Injection, fosnetupitant 235 mg and palonosetron 0.25 mg	G	9099	10/01/2018	
J1627	J1627	Injection, granisetron extended release, 0.1 mg	G	9486	04/01/2017	
J1628	J1628	Injection, guselkumab, 1 mg	G	9029	01/01/2018	
J2350	J2350	Injection, ocrelizumab, 1 mg	G	9494	10/01/2017	
J2797	J2797	Injection, rolapitant, 0.5 mg	G	9464	04/01/2018	
J3111	J3111	Injection, romosozumabaqqg,1 mg	G	9327	10/01/2019	
J3245	J3245	Injection, tildrakizumab, 1 mg	G	9306	04/01/2019	
J3316	J3316	Injection, triptorelin, extended-release, 3.75 mg	G	9016	01/01/2018	

Table 3. Drugs and Biologicals with Pass-Through Payment Status in CY 2020						
CY 2019 HCPCS CODE	CY 2020 HCPCS CODE	CY 2020 LONG DESCRIPTOR	CY 2020 STATUS INDICATOR	CY 2020 APC	PASS THROUGH PAYMENT EFFECTIVE DATE	
J3358	J3358	Ustekinumab, for intravenous injection, 1 mg	G	9487	04/01/2017	
J7170	J7170	Injection, emicizumabkxwh,0.5 mg	G	9257	07/01/2018	
J7345	J7345	Aminolevulinic acid hcl for topical administration, 10% gel, 10 mg	G	9301	01/01/2018	
J9023	J9023	Injection, avelumab, 10 mg	G	9491	10/01/2017	
J9036	J9036	Injection, bendamustine hcl (belrapzo), 1 mg	G	9313	04/01/2019	
J9057	J9057	Injection, copanlisib, 1 mg	G	9030	07/01/2018	
J9153	J9153	Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine	G	9302	01/01/2018	
J9173	J9173	Injection, durvalumab, 10 mg	G	9492	10/01/2017	
J9203	J9203	Injection, gemtuzumab ozogamicin, 0.1 mg	G	9495	01/01/2018	
J9210	J9210	Injection, emapalumablzsg,1 mg	G	9310	07/01/2019	
J9229	J9229	Injection, inotuzumab ozogamicin, 0.1 mg	G	9028	01/01/2018	
J9269	J9269	Injection, tagraxofusp-erzs, 10 micrograms	G	9309	07/01/2019	
J9285	J9285	Injection, olaratumab, 10 mg	G	9485	04/01/2017	
J9311	J9311	Injection, rituximab 10 mg and hyaluronidase	G	9467	04/01/2018	
J9313	J9313	Injection, moxetumomab pasudotox-tdfk, 0.01 mg	G	9305	04/01/2019	
J9356	J9356	Injection, trastuzumab, 10 mg and Hyaluronidaseoysk	G	9314	07/01/2019	
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	
Q2042	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	
Q5103	Q5103	Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg	G	1847	04/01/2017	
Q5104	Q5104	Injection, infliximab-abda, biosimilar, (renflexis), 10 mg	G	9036	04/01/2018	
Q5105	Q5105	Injection, epoetin alfaepbx, biosimilar, (retacrit) (for esrd on dialysis), 100 units	G	9096	10/01/2018	
Q5106	Q5106	Injection, epoetin alfa, biosimilar, (retacrit) (for non-esrd use), 1000 units	G	9097	10/01/2018	
Q5107	Q5107	Injection, bevacizumabawwb, biosimilar, (mvasi), 10 mg	G	9329	01/01/2020	
Q5108	Q5108	Injection, pegfilgrastimjmdb, biosimilar, (fulphila), 0.5 mg	G	9173	04/01/2019	
Q5110	Q5110	Injection, filgrastim-aafi, biosimilar, (nivestym), 1 microgram	G	9193	04/01/2019	
Q5111	Q5111	Injection, pegfilgrastimcbqv, biosimilar, (udenyca), 0.5 mg	G	9195	04/01/2019	
Q5117	Q5117	Injection, trastuzumabanns, biosimilar, (kanjinti), 10 mg	G	9330	01/01/2020	
N/A	J9309	Injection, polatuzumab vedotin-piiq (Polivy), 1 mg	G	9330	01/01/2020	

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*HCPCS Code C9043 (Injection, levoleucovorin, 1 mg) will be deleted on December 31, 2019, and will be replaced by HCPCS code J0642 (Injection, levoleucovorin (khapzory), 0.5 mg) on January 1, 2020.

2020 Physician and Freestanding Facility Regulatory Update

BY TERI BEDARD, BA, RT(R)(T), CPC

he Medicare Physician Fee Schedule (MPFS) is one of the Medicare payment systems that applies to physicians (even those employed by hospitals) and non-facility-based settings, which include offices, freestanding facilities, and nonexcepted off-campus provider-based departments. Reimbursement under MPFS is based on relative value units (RVUs) that represent the work, practice expense (direct and indirect), and malpractice values assigned to each code. RVUs are then factored with the geographic practice cost indices (GPCI)-the geographic locale as identified by Medicare-to determine exact payments based on location.

CY 2020 begins the MPFS payment system's transition away from the traditional, historical, fee-for-service model that is impacted by the changing conversion factor (CF) to a payment system that is set, with the only potential changes related to budget neutrality. This transition was mandated as part of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). Under MACRA, beginning in CY 2020 the CF is frozen at the CY 2019 value with no increases for the next five years. The CY 2019 CF is \$36.0391. Therefore, this value is still used for CY 2020 with direct adjustment.

The CMS budget must be maintained within \$20 million each year. When projections anticipate that the impact from any RVU changes will be outside the expected budget, a budget neutrality factor is applied to the CF to bring it back into range and maintain budget neutrality. For CY 2020, CMS is applying a positive 0.14 percent budget neutral adjustment to the CF, which will result in an overall increase in payments, with a CF value of \$36.0896. Even with the slight increase overall by CMS, the impact on both hematology/oncology and radiation oncology reflects no percentage adjustment for CY 2020.

Relative Value Units (RVUs) Updates

Malpractice RVUs attempt to quantify the risk associated by a given specialty in alignment with the malpractice premiums paid by that specialty in relation to the services performed and reported through claims data. For CY 2019, CMS requested feedback regarding the next update of malpractice RVUs as required by CY 2020, specifically how improvements in the way specialties in the state-level raw rate-filings data are cross-walked to the CMS specialty codes, which are used to develop the specialty-level risk factors and the malpractice RVUs.

For CY 2020 CMS proposed that the values of the malpractice RVUs and the malpractice GPCI be coordinated because updates to both are based on the same malpractice premium data. Thus, CMS believes any changes to the malpractice RVUs would be aligned and relative to the changes in the malpractice GPCI. No comments to this proposal were received; CMS finalized the proposed changes without revision. This change puts the next mandated review for implementation in CY 2023.

Practice expense (PE) accounts for the resources provided by the physician and practitioner such as, office rent and

personnel wages, but excludes expenses for malpractice. Practice expenses are further classified as 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.

Beginning in CY 2020, CMS will recognize two new specialties for which it will be calculating specific values related to practice expense (PE) RVUs— Medical Toxicology and Hematopoietic Cell Transplantation and Cellular Therapy. Both specialties were recognized by CMS during 2018. Each will have values related to the direct practice expense category (clinical labor, medical supplies, and medical equipment), as well as indirect expense category (administrative labor, office expense, and all other expenses) valued into their procedure codes.

Comments were received related to several specific radiation oncology items. Commenters stated that the non-facility PE RVUs for CPT 55874, (transperineal placement of biodegradable material, periprostatic, single or multiple injections, including image guidance, when performed), are projected to decrease by 13 percent for CY 2020 when compared to CY 2019. Commenters believed this was attributable to the mix of specialties utilizing and billing for the service. The value of the code was based on claims data from the first year in which the mix was urology and radiation oncology specialties reporting the code and this differs from the current reporting mix which can change the value of the code.

CMS agreed with commenters that the proposed decreases in the PE RVUs for **CPT**

Table 4. Revaluation of HCPCS Add-on G code Finalized for CY 2021							
HCPCS CODE	PROPOSED CODE DESCRIPTOR REVISIONS	FR 2019 TOTAL TIME (MINS)	FR 2019 WORK RVU	TOTAL TIME (MINS)	WORK RVU		
GPC1X	Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious, or complex chronic condition. (Add-on code, list separately in addition to office/ outpatient evaluation and management visit, new or established)	8.25	0.25	11	0.33		

55874 were due to changes in the specialty mix shifting from the projected utilization to reported claims data. However, CMS did not agree that the specialty mix needed to be corrected and that it is important to use actual claims data. The final PE RVUs reflect a decrease from 2019 (95.24) to 2020 (83.79) for a total change of 11.45.

Comments were also received requesting that CMS update the pricing used for the Biodegradable Material Kit – PeriProstatic, i.e., the gel used with placement code **55874**. The commenter provided invoices to support the requested updated value for the supply. CMS agreed the values of the periprostatic kit did increase in value from \$2,850 to \$2,965 based on submission of eight invoices and finalized a price increase. This will have an impact on the non-facility value of code **55874** that includes the supply, Biodegradable Material Kit - PeriProstatic, but not enough to off-set the previously described reduction in PE RVUs to code 55874. So there will be no positive increase for code **55874** in CY 2020.

Comments were also received about the pricing of the "HDR Afterload System, Nucletron – Oldelft" equipment, the "treatment planning system, IMRT (Corvus w-Peregrine 3D Monte Carlo)" equipment, and the "SRS system, SBRT, six systems, average" equipment. Commenters indicated that all the equipment items had values of prices well below industry standards. Undervalue of the equipment used for treatment planning results in lower valued codes related to the services that use them. CMS was urged to conduct additional research into the equipment pricing to ensure fair market values. One commenter believed that the value reflected for the HDR afterload system may have inadvertently used electronic brachytherapy system pricing, which is considerably lower.

In its response, CMS agreed with the importance of fair market values for the equipment; however, the agency noted that commenters did not provide invoices to support their statements. Without anything to back up the comments, CMS believes the values it has reflected are appropriate and accurate. Stakeholders are welcome to submit invoices over the ongoing four-year transition period for equipment pricing.

The only codes specific to radiation oncology, which CMS addressed regarding proper valuation, are the G-codes **G6001** to G6017 for treatment delivery and IGRT. In place since Jan. 1, 2015, these codes were set to expire on Dec. 31, 2019, when replaced with an alternative payment model under MPFS. In early July 2019 CMS released a Radiation Oncology (RO) Payment Model proposed rule. At publication of the CY 2020 MPFS final rule, the RO Model was still proposed. In the final CY 2020 MPFS rule, CMS states it will continue the valuation of the G-codes with the current work RVUs and direct PE inputs. Further, for 2020 CMS will continue to include the utilization rate assumption of 60 percent in the values for the IMRT accelerator.

CMS also received comments regarding code **G6107**, Intrafraction localization and

tracking of target or patient motion during delivery of radiation therapy (e.g., 3D positional tracking, gating, 3D surface tracking), and the request to assign RVUs to the contractor priced code as well as CPT 77387. Guidance for localization of target volume for delivery of radiation treatment, includes intrafraction tracking, when performed, which is not recognized under MPFS, but is recognized under OPPS. Commenters stated that if CMS would assign a value to **77387** under MPFS this would assist providers as they work to negotiate values with commercial payers and clear the confusion created by the use of the G-codes in place of the CPT codes.

CMS stated that introduction of the RO Payment Model necessitates maintaining the current values and recognition of the codes as they exist now. To add values to codes that did not previously exist would create issues and disruption to the proposed RO Payment Model and ongoing reimbursement policies. Table 4, above, lists the finalized RVUs of the G-codes for 2020.

Evaluation and Management (E/M) Guidelines

After publication of the CY 2019 MPFS final rules, it was clear that CMS was aiming to make sweeping changes to E/M guidelines. Most of the changes outlined in the 2019 MPFS final rule were slated for CY 2021 so that stakeholders would have time to prepare and the AMA would have time to jump on board and align its guidelines with CMS. However, in the CY 2020 MPFS proposed ruling, CMS outlined the cancelation of most, if not all, of the proposed changes and adjustment to the initial updates for E/M guidelines that were intended for release by the AMA for CY 2021. CMS indicated that the agency had received thousands of comments to the CY 2020 proposed rule specific to E/M changes.

Some of the changes finalized by CMS were established by the AMA and approved by CMS for their beneficiaries, including the following:

- Only the option of using either time or medical decision-making (MDM) to select of the code level
- Elimination of the ability to use the history and exam, or time in combination with the MDM to select the final code level
- Deletion of code **99201**; effective Jan. 1, 2021
- Time values assigned to code levels
- Inclusion of all time spent on the date of the visit.

After several CMS stakeholder meetings, much of the feedback the agency received related to the single payment rate for E/M levels 2 through 4 of outpatient office visits. Many stakeholders voiced concerns that paying the same amount regardless of level would incentivize providers to spend as little time as necessary or just the minimum to qualify for payment, rather than spend more time as beneficial for patients. Other feedback included requests that time be the only tool for determining the level of visit as it is easy to audit, document, consistently interpret, and better accounts for complexity levels. To assist in understanding what these changes may mean, the AMA published an estimate of anticipated burden reduction relative to its policies that CMS has also accepted for use and provided within the final rule. The estimate can be found on the AMA website, ama-assn.org/

cpt-evaluation-and-management. Given the information and feedback the AMA

received when conducting its own surveys, CMS proposed and finalized the following for CY 2021:

 Assign separate reimbursement amounts to each visit code level instead of one rate for levels 2 through 4, except code **99201**, which will be deleted in CY 2021

- Recognition and reimbursement for the new prolonged visit add-on code (CPT code 99XXX, still to be revealed by AMA) and allow for its use with levels 2 through 4 and level 5
- CMS to no longer recognize prolong services codes **99358** and **99359** for separate reimbursement when associated with outpatient E/M visits
- Deletion of HCPCS add-on code GPRO1 for extended visits
- Elimination of history and/or physical exam in determining billable code level
- Choice of either time or MDM to decide level of outpatient, new or established patient visit, using the AMA CPT guidelines for MDM
- Consolidate and revalue primary care and non-procedural medical care codes (GPC1X and GCG0X) into one HCPCS code: GPC1X, which will have an increased value and be reportable with all of the outpatient E/M visit codes.

With CMS adoption of these new guidelines for CY 2021, history and exam will no longer affect code level. The visit will only include history and exam if they are pertinent to the visit and when performed. The number of body systems reviewed will no longer be documented and, again, will only be included as pertinent to the visit itself. Level 1 visits (**99211**) will describe or include those visits performed by clinical staff for established patients and will not include medical decision-making.

The individual levels of codes 2 through 5 would be based on MDM, as defined in the updated AMA guidelines, or based on time personally spent by the billing provider. Time will account for both face-to-face and non-face-to-face time. Time ranges for each code will match those revised by the AMA. There will also be an add-on for prolonged time that will be available when the time used for the code level and the base level 5 time were exceed by 15 minutes or more on the date of service of the visit. The long description for the new add-on code to be used is "prolonged office or other outpatient evaluation and management service(s) (beyond the total time of the primary procedure which has been selected using total time), requiring total time with or

without direct patient contact beyond the usual service, on the date of the primary service; each 15 minutes (List separately in addition to codes **99205**, **99215** for office or other outpatient Evaluation and Management services)."

CMS finalized that the prolonged service code will account for all time spent within the 24-hour period for the date of service of the primary E/M service code. Additionally, CMS finalized that any work performed on dates of service prior to or post the E/M visit to review medical records or tests cannot count toward the time value for the E/M outpatient visit or use of the prolonged services code, **99XXX** or **99358** or **99359**. This follows the valuation of the E/M codes to account for all-time 3 days prior to or 7 days post the actual E/M visit.

CMS published a table of the estimated financial impact of the E/M changes in CY 2021 by specialty (see Table 5, page 15).

Lifting Restrictions Related to E/M Documentation

CMS finalized several changes for CY 2020 regarding the amount of documentation necessary in the medical record related to teaching situations with residents and medical students. After considerable feedback, CMS is also extending lifting of the restrictions as they relate to teaching situations to also include PAs and APRNs paid under MPFS.

Based on stakeholder feedback, CMS finalized the following proposals with some modification:

- PA and NP, CNS, CNM and CRNA students, and APRN students, along with medical students, as the types of students who may document notes in a patient's medical record that may be reviewed and verified rather than re-documented by the billing professional
- To include CRNAs as a category of APRNs for purposes of this policy, and to include CRNA students under the reference to APRN students
- There is no requirement by CMS that the billing physician is the only person who can review and verify documentation in the medical record when added by physicians, residents, nurses or students,

Table 5. Estimated Specialty Level Impacts of Finalized E/M Payment and Coding Policies								
(A) SPECIALTY	(B) ALLOWED CHARGES (MIL)	(C) IMPACT OF WORK RVU CHANGES	(D) IMPACT OF PE RVU CHANGES	(E) IMPACT OF MP RVU CHANGES	(F) COMBINED IMPACT*			
Hematology/Oncology	\$1,673	8%	4%	1%	12%			
Radiation Oncology and Radiation Therapy Centers	\$1,756	-2%	-2%	0%	-4%			

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

or other members of the medical team

- This policy is not limited to E/M, but includes all types of service (E/M, procedure, diagnostic test) or setting in which the service is furnished
- The reviewer of the medical documentation does not have to be of the specialty of the student or medical team that provided the notation in the medical record

Utilization of State Scope of Practice Requirements Non-Physician Practitioners

CMS recognizes that the scope of work provided by non-physician practitioners (NPPs) has greatly changed since 1965 when the Medicare program was signed into law. At that time, it was predominantly nurses who aided physicians. Now, non-physician practitioners includes NPs and PAs. Due to these changes, CMS proposed to adjust language to include how these NPPs provide assistance.

The CY 2020 MPFS finalizes changes specific to CRNAs in the ambulatory surgical center setting and PAs in hospice. For beneficiaries in hospice care, the finalized changes mean patients can select their PA as their attending physician. Historically, PAs could not write scripts for medications or orders for care to the hospice and have them accepted without intervention by a physician. CMS is amending this language to allow for hospice to accept drug orders from a physician, NP, or PA as designated by the patient. The PA must have within their state scope of practice the ability to provide these services, and they must be designated as the patient's attending physician and not contracted with the hospice itself.

CMS believes this will allow for continuity of care to patients as they approach the end of life. In the event the patient's attending physician or NPP does not agree to provide this care, they do not feel comfortable with the request, the hospice is equipped to provide a hospice employed physician or NPP who will practice as the attending for the patient.

Physician Supervision of Physician Assistant (PA) Services

CMS indicated that it received ongoing requests to allow PAs to practice medicine without the requirement for supervision by a physician, to align their roles and the regulations with those for NPs and CNSs. As mentioned previously, the scope of work provided by PAs has changed over the years and many provide and deliver healthcare more broadly than ever before. Many of these changes have resulted in changes to the scope of work and laws in different states. Some states have relaxed their requirements related to the necessary supervision, while others have yet to make any changes.

Currently CMS requires general supervision of the PA by the physician. CMS sought comments to fully understand the roles of PAs and how the current supervision requirements impede or burden their ability to provide services to beneficiaries. Either the state scope of practice will define the supervision levels of services provided by the PA or if there is nothing defined by the state, the practice must define the relationship and have this in writing available in the practice. Provided below is verbiage provided by CMS regarding physician supervision for PAs:

- PAs must furnish their professional services in accordance with state law and state scope of practice rules for PAs in the state in which the PA's professional services are furnished. Any state laws or state scope of practice rules that describe the required practice relationship between physicians and PAs, including explicit supervisory or collaborative practice requirements, describe a form of supervision for purposes of section 1861(s)(2)(K)(i) of the Act.
- For states with no explicit state law or scope of practice rules regarding physician supervision of PA services, physician supervision is a process in which a PA has a working relationship with one or more physicians to supervise the delivery of health care services. Such physician supervision is evidenced by documenting at the practice level the PA's scope of practice and the working relationships the PA has with the supervising physicians when furnishing professional services. Image of the procession of the procession of the physicians

Teri Bedard, BA, RT(R)(T), CPC, is director, Client Services at Coding Strategies, Inc., Powder Springs, Ga., and Revenue Cycle, Inc., Cedar Park, Tex.