2020 Hospital Regulatory Update

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The 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 that 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 services that 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 17, 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 17-18, 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	K
J9035	Injection, bevacizumab, 10 mg	K
J1020	Injection, methylprednisolone acetate, 20 mg	N
J1030	Injection, methylprednisolone acetate, 40 mg	N
J1040	Injection, methylprednisolone acetate, 80 mg	N
J1460	Injection, gamma globulin, intramuscular, 1 cc	K
J1560	Injection, gamma globulin, intramuscular over 10 cc	K
J1642	Injection, heparin sodium, (heparin lock flush), per 10 units	N
J1644	Injection, heparin sodium, per 1000 units	N
J2920	Injection, methylprednisolone sodium succinate, up to 40 mg	N
J2930	Injection, methylprednisolone sodium succinate, up to 125 mg	N
J7030	Infusion, normal saline solution, 1000 cc	N
J7040	Infusion, normal saline solution, sterile (500 ml=1 unit)	N
J7050	Infusion, normal saline solution, 250 cc	N
J7515	Cyclosporine, oral, 25 mg	N
J7502	Cyclosporine, oral, 100 mg	N
J8520	Capecitabine, oral, 150 mg	N
J8521	Capecitabine, oral, 500 mg	N
J9250	Methotrexate sodium, 5 mg	N
J9260	Methotrexate sodium, 50 mg	N

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 mm^2, a decrease from the CY 2019 rate of $4.69 per mm^2. 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 quite 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. OI

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	CY 2019 APC	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

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	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

*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..