

ISSUES | 2022 Hospital Regulatory Update

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On November 2, 2021, the Centers for Medicare & Medicaid Services (CMS) issued a final rule for the Hospital Outpatient Prospective Payment System (HOPPS) for CY 2022. The HOPPS Final Rule can be accessed online at: [federalregister.gov/public-inspection/2021-24011/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment](https://www.federalregister.gov/public-inspection/2021-24011/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment). This rule applies to facility settings (i.e., outpatient hospitals and ambulatory surgical centers). As has been the case over the last few years, CMS did not finalize any dramatic reimbursement changes, but there are some nuanced changes which can and do have an impact, including finalizing the Radiation Oncology (RO) Model. A comprehensive update on the RO Model can be found on pages XX-XX.

HOPPS Payment Rates

CMS finalized use of CY 2019 claims data for rate-setting rather than CY 2020 claims data out of concern for the significant decrease in utilization of services due to the COVID-19 public health emergency and pandemic. Based on these data, CMS finalized a 2 percent increase to the outpatient department fee schedule. This percentage is based on the proposed market update from the Inpatient Prospective Payment System of 2.7 percent and a minus 0.7 percent productivity adjustment. The agency used a conversion factor of \$84.177 for hospitals that meet the reporting criteria and applied the 2 percent reduction to those hospitals that do not meet reporting requirements. CMS estimates total HOPPS payments to providers to be approximately \$82.078 billion—an increase of approximately \$5.913 billion compared to CY 2021 HOPPS payments.

CMS will continue applying a wage index of 1 for frontier state hospitals, a policy that has been in place since CY 2011. This policy ensures the lower population states are not penalized for reimbursement due to the low number of people per square mile when compared to other states.

For CY 2022, CMS will continue additional payments to cancer hospitals utilizing a payment-to-cost ratio factor (PCR). Beginning in CY 2018, the 21st Century Cures Act required the weighted average PCR be reduced by 1 percent. CMS finalized the target PCR of 0.90, an increase from the proposed value, to determine the CY 2022 cancer hospital payment adjustment to be paid at cost report settlement, which includes the 1 percent reduction.

Standardizing Ambulatory Payment Classifications Payment Weights

Ambulatory payment classifications (APCs) group services are considered clinically comparable to each other with respect to the resources utilized and associated costs. CMS will continue using HCPCS code **G0463**, a hospital outpatient clinic visit for the 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 was assigned to APC **5012** (code **G0463**). For CY 2022, CMS will continue to pay code **G0463** at a payment rate of 40 percent of the HOPPS rate for any outpatient, off-campus hospital setting that is excepted or nonexcepted.

Ambulatory Payment Classification Updates CY 2022

All services (codes) associated with an APC are paid the exact same amount. If the resources and costs of services change enough that the code with the highest cost of resources within an APC is more than 2

times that of the code with the lowest cost, CMS must adjust the placement of these codes. This would be considered a 2 times rule violation and to correct it, codes would need to be moved to APCs that better match their resource cost(s) or CMS would need to create a new APC for the identified services. Over the past few years, CMS has provided an exception to the identified 2 times rule violation based on the belief that many will work themselves out in the next claims data period with more accurate reporting. CMS identified 23 APCs with 2 times rule violations that the agency will exempt.

Brachytherapy Sources

CMS did not propose any significant changes to how reimbursement for brachytherapy sources is calculated. The agency did propose and finalize to use costs derived from CY 2019 claims data to set the CY 2022 payment rates and base the payment rates for brachytherapy sources on the geometric mean unit costs for each source. Brachytherapy sources, unless otherwise noted, are assigned the status indicator "U." Codes with status indicator "U" are not packaged into C-APCs; the sources are paid separately in addition to the brachytherapy insertion code in the hospital setting.

CMS will continue to pay for the stranded and non-stranded, not otherwise specified, 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). The agency invites recommendations for new codes to describe new brachytherapy sources by email to outpatientpps@cms.hhs.gov or by mail to the Division of Outpatient Care, Mail Stop C4 – 01 –26, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244.

CMS also proposed and finalized the creation of low-volume APCs for designated clinical, brachytherapy, and new technology services. These would be APCs with fewer than 100 single claims in the year used for rate setting for clinical and brachytherapy APCs. As stated previously, brachytherapy APCs **C2698** (Brachytx, stranded, nos) and **C2699** (Brachytx, non-stranded, nos) would not be included in this payment process. These non-specific APCs already have an established method for determining pricing. Instead, CMS will designate five brachytherapy APCs as low volume. Payment rates will use claims data from 2016-2019, a four-year span. The five brachytherapy APCs are:

- **C2632**: Iodine I-125 sodium iodide
- **C2635**: Brachytx, non-str, HA, P-103
- **C2636**: Brachy linear, nonstr, P-103
- **C2645**: Brachytx, non-str, Gold-198
- **C2647**: Brachytx, NS, Non-HDRIr-192.

Device Intensive Procedures

CMS sought comments on the proposal to establish the CY 2022 device offset percentage using CY 2019 claims data when there is no data from CY 2020 for device intensive procedures. Device intensive status is assigned to procedures when the device cost exceeds a threshold of 40 percent related to the APC. After reviewing comments, the agency finalized using CY 2019 claims data for 11 procedures, 3 of them included in the list may impact interventional radiology departments and should be noted for specific billing guidelines.

- **C9757**: Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and excision of herniated intervertebral disc, and repair of annular

defect with implantation of bone anchored annular closure device, including annular defect measurement, alignment and sizing assessment, and image guidance; 1 interspace, lumbar.

- **C9765:** Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed.
- **C9767:** Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel(s), when performed.

CMS will continue to recognize HCPCS **C1889** (Implantable/insertable device, not otherwise classified) for billing the device as part of a device intensive procedure when there is no specific Level II HCPCS Category C-code to represent it.

Payments of Drugs, Biologicals, and Radiopharmaceuticals

Each year, CMS assesses the drug packaging threshold. For CY 2022, CMS will continue to package drugs and biologicals estimated at a per day administration cost less than or equal to \$130, as they did in CYs 2020 and 2021. CMS will continue to separate payment for items with an estimated per day cost greater than \$130, except for diagnostic radiopharmaceuticals, contrast agents, anesthesia drugs, drugs, biologicals, radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, and drugs and biologicals that function as supplies or devices when used in a surgical procedure.

CMS will continue the policy of making packaging determinations on a drug-specific basis rather than by HCPCS code for codes that describe the same drug or biological in different dosages. For all other drugs and biologicals that have HCPCS codes describing different dosages, the agency aggregated claims data and pricing information at ASP+6 percent for all HCPCS codes that describe each distinct drug or biological. This calculation 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 dosages, CMS multiplied the 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 2022 drug packaging threshold of \$130.

For CY 2022, CMS will continue the current payment policy that has been in effect since CY 2013. This payment policy reimburses 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. The agency will also continue to pay for separately payable, non-pass-through drugs acquired with a 340B discount at ASP-22.5 percent, see the section on the 340B Drug Program for more details (page XX).

For drugs or biologicals without sufficient data on sales price during the initial sales period, CMS will base payments on the wholesale acquisition cost (WAC). Certain payments must be made with a 6 percent add-on; however, the same add-on amount when utilizing WAC-based pricing is not required. CMS will continue using 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 to be based on the payment allowance of the product. CMS will continue the policy that was finalized to make all biosimilar

biological products eligible for pass-through payment, not just a reference product's first biosimilar biological product. The agency will 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 reference product's ASP.

CMS will expire pass-through status for several drugs and biologicals between March 31, 2021, and December 31, 2021. These drugs and biologicals will have received HOPPS pass-through payment for at least 2 years (no more than 3 years).

Medicare finalized several drugs and biologicals to continue pass-through payment status for CY 2022. CMS will continue to pay for pass-through drugs and biologicals at the ASP+6 percent and update pass-through payment rates on a quarterly basis through its website.

Due to the use of CY 2019 claims data for rate setting, CMS is extending for up to four quarters an equitable adjustment for 27 drugs and biologicals and one device that will expire pass-through status at various quarters in CY 2022 and extend pricing through the end of CY 2022.

340B Drug Discount Program

CMS will continue to pay for drugs purchased under the 340B Drug Program in CY 2022 at ASP-22.5 percent. In addition, the agency will continue to exempt rural sole community hospitals, children's hospitals, and prospective payment system (PPS)-exempt cancer hospitals from the 340B payment adjustment. These hospitals are still required to report modifier TB for 340B-acquired drugs on claims forms, and exempt entities will be paid at ASP+6 percent. CMS will continue to pay for drugs not purchased under the 340B program at ASP+6 percent. Drugs and biosimilar biologicals acquired under the 340B program and furnished in on-campus hospital departments, exempted off-campus provider-based departments, and non-excepted off-campus provider-based departments paid under the Medicare Physician Fee Schedule will be paid at ASP-22.5 percent. Biosimilar biological products will be paid at minus 22.5 percent of the biosimilar's ASP, not the reference drug's ASP.

Payment for Therapeutic Radiopharmaceuticals

CMS grants pass-through status to new drugs, biologicals, and radiopharmaceuticals 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 2022, CMS will continue providing payment for diagnostic and therapeutic radiopharmaceuticals granted pass-through payment status at ASP+6 percent; however, if no ASP data is available, CMS will continue to provide pass-through payment at WAC+3 percent. If those data are not available, payment will be 95 percent of the average wholesale price (AWP). CMS will also continue to update pass-through payment rates on a quarterly basis on its website during CY 2022.

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