CY 2022 Proposed Rule Summary
Hospital Outpatient Prospective Payment System (HOPPS)

On July 19, 2021, the Centers for Medicare and Medicaid Services (CMS) issued the proposed rules for the Hospital Outpatient Prospective Payment System (HOPPS) for CY 2022.

The CY 2022 proposed rule is 863 pages in length and located in its entirety at the following link: https://www.federalregister.gov/public-inspection/2021-15496/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment. The format of the following information is intended to serve as a summary to the proposed changes and readers are encouraged to view the document in its entirety for further details.

Highlights

- CMS is proposing a 2.3 percent increase to the Outpatient Department (OPD) fee schedule. This is based on the proposed market update from the Inpatient Prospective Payment System (IPPS) of 2.5 percent and a 0.2 percent proposed productivity adjustment decrease.
    - CMS estimates total payments to HOPPS providers will be approximately $82.704 billion, an increase of approximately $10.757 billion compared to CY 2021 HOPPS payments.
    - CMS is proposing they maintain the policy to implement a wage index of 1.0000 for frontier states.
    - CMS is proposing to continue to use code G0463 (clinic visit) as the base code for establishing ambulatory payment classification (APC) for services paid under HOPPS.
        - CMS is also proposing to continue to pay code G0463 at 40 percent of the hospital outpatient rate when billed in the excepted provider-based department of the hospital.
    - CMS is proposing an increase of 2.3 percent to payment rates for ambulatory surgical centers (ASCs). CMS is anticipating a $20 million decrease in payments to ASCs for CY 2022.
- CMS is proposing to continue to apply a 2 percent reduction to the conversion factor for hospitals that fail to meet the hospital quality reporting requirements.
- Due to the impact related to the COVID-19 public health emergency (PHE) and pandemic, CMS is proposing to use CY 2019 claims data for ratesetting rather than CY 2020 due to significant impact in utilization of services.
- CMS is proposing to stop and reverse the 298 services removed from the inpatient only (IPO) list in CY 2021. These are services which CMS indicated could be performed in an office setting. After review of previous administration changes, CMS believes many of the procedures could not in fact be performed anywhere but in the inpatient hospital setting, so they are reversing the removed services by reinstating them as inpatient only and halting any future changes to dismantle the list.
- CMS is proposing to re-adopt the ASC Covered Procedures List (CPL) that was in effect in CY 2020 and removed 258 of the 267 procedures added to the list in CY 2021. CMS is also proposing to change the

notification process adopted for CY 2021 to a nomination process, allowing stakeholders to nominate procedures they believe meet the criteria to be included on the list.

- CMS is seeking comments on 26 new HCPCS codes established and made effective April 1, 2021, and 55 new HCPCS codes established and made effective July 1, 2021.
- CMS is proposing to except 23 APCs from the 2 times rule violation. Typically, codes within the APCs violating this rule would need to be moved or a new APC created, CMS is proposing to allow the classifications to continue as is.
- CMS is proposing to continue the payment policy to pay for drugs purchased under the 340B Drug Program at average sales price (ASP) minus 22.5 percent. They are proposing to continue to exempt rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals from this policy.
- Due to the proposal to use CY 2019 claims data for ratesetting, CMS is proposing to extend, for up to four quarters, an equitable adjustment for 27 drugs and biologicals and one device which would expire pass-through status at various quarters in CY 2022. This would extend pricing through the end of CY 2022.
    - Proposing to continue the ASP +6 percent payment policy for all drugs and biologicals granted pass-through status and update the list on quarterly basis.
- CMS is proposing to continue the packaging threshold for drug administrations at $\leq$$130, this is the same threshold from CYs 2020 and 2021.
    - CMS is proposing to make drug packaging determination on a drug-specific basis rather than HCPCS code specific basis for HCPCS codes that describe the same drug but different dosages.
    - CMS is proposing to continue the payment policy for biosimilar biologicals, pass-through status eligibility will be made at the biosimilar biological product not the reference product.
    - CMS is proposing to continue paying for biosimilar biologicals purchased under the 340B Drug Program at ASP minus 22.5 percent of the biosimilar biological, not the reference product, a continuation of this policy from CY 2021.
- CMS is proposing to continue to establish payment rates for blood and blood products using their blood-specific cost-to-charge (CCR) methodology that has been the standard since CY 2005.
- CMS received eight complete applications for device pass-through payments for CY 2022. Of the eight device applications one included the Eluvia™ Drug-Eluting Vascular Stent System. CMS is seeking stakeholder feedback if the applicant has met the criteria for pass-through payment status beginning in CY 2022.
- CMS is seeking 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. There are 11 procedures this would impact, specifically HCPCS C9757, C9765, and C9767.
    - CMS is also proposing to continue recognition of HCPCS C1889 for billing of the device as part of a device intensive procedure when there is no specific Level II HCPCS Category C-code to represent it.

- CMS is proposing to continue the additional payments to the 11 designated cancer hospitals. The proposed adjustment, a payment-to-cost ratio (PCR) of 0.89, is applied at the cost report settlement for each cancer hospital, this is the same value finalized for CY 2021.
- CMS is proposing to create 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 ratesetting for clinical and brachytherapy APCs.
    - Brachytherapy APCs 2698 (Brachytx, stranded, nos) and APC 2699 (Brachytx, non-stranded, nos) would not be included in this proposed payment process. These non-specific APCs already have an established method for determining pricing.
    - CMS is proposing to designate five brachytherapy APCs as low volume. Payment rates will use claims data from a 4-year span, 2016 -2019.
        - The five brachytherapy APCs are 2632 (Iodine I-125 sodium iodide), 2635 (Brachytx, non-str, HA, P-103), 2636 (Brachy linear, nonstr, P-103), 2645 (Brachytx, non-str, Gold-198), and 2647 (Brachytx, NS, Non-HDRIr-192).
- CMS is proposing updates to the requirement for hospitals to make public their list of standard charges. Proposed changes include:
    - Increase the amount of the penalties for noncompliance through the use of a proposed scaling factor based on hospital bed count;
    - Deem state forensic hospitals that meet certain requirements to be in compliance with the requirements of 45 CFR part 180; and
    - Prohibit certain conduct that [CMS has] concluded are barriers to accessing the standard charge information.
- CMS is seeking comments on several waivers and extensions as part of the PHE for COVID-19. They are seeking comments as to whether services can continue through telehealth to beneficiaries in their homes, direct supervision for certain designated services by real time audio/video capabilities, and code and payment for COVID-19 testing.
- CMS is proposing to implement effective January 1, 2022 – December 31, 2026, the Radiation Oncology (RO) Payment Model. CMS is proposing several updates to the RO Model including the removal of liver diagnosis as one of the cancer types and removal of brachytherapy services from the list paid under the RO Model.

Addition Summary of Key Items

Payment Rates

Due to the impact related to the COVID-19 public health emergency (PHE) and pandemic, CMS is proposing to use CY 2019 claims data for ratesetting rather than CY 2020 due to significant impact in utilization of services. Based on this, CMS is proposing a 2.3 percent increase to the Outpatient Department (OPD) fee schedule. This is based on the proposed market update from the Inpatient Prospective Payment System (IPPS) of 2.5 percent and a 0.2 percent proposed productivity adjustment decrease. CMS is proposing to use a conversion factor (CF) of $84.457 for hospitals meeting the reporting criteria and applying the 2 percent reduction to those that do

not with a CF equal to $82.810. CMS estimates total payments to HOPPS providers will be approximately $82.704 billion, an increase of approximately $10.757 billion compared to CY 2021 HOPPS payments.

Wage Index

CMS is proposing to continue applying a wage index of 1.000 for frontier state hospitals, this policy has been in place since CY 2011. This 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.

Standardizing Ambulatory Payment Classifications (APCs) Payment Weights

Ambulatory payment classifications (APCs) group services which are considered clinically comparable to each other with respect to the resources utilized and the associated costs. CMS is proposing to 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 is proposed to be assigned to APC 5012 (code G0463).

For CY 2022, CSM is proposing to pay code G0463 at a payment rate of 40 percent of the HOPPS rate for any outpatient off-campus hospital setting, excepted and nonexcepted.

Multiple Imaging Composite APC

CMS is proposing to continue to pay for all multiple imaging procedures within an imaging family performed on the same date of service using the multiple imaging composite APC payment methodology. Standard APC assignments will continue to apply for single imaging procedures and multiple imaging procedures performed across imaging families. A single imaging session performed "with contrast" is part of a composite APC when at least one or more imaging procedures from the same family are also performed with contrast on the same date of service. For example, if a hospital performs one MRI without contrast during the same session as one with, the payment rate will be for the "with contrast" composite APC.

The five multiple imaging composite APCs established in CY 2009 are:

- APC 8004 (Ultrasound Composite);
- APC 8005 (CT and CTA without Contrast Composite);
- APC 8006 (CT and CTA with Contrast Composite);
- APC 8007 (MRI and MRA without Contrast Composite); and
- APC 8008 (MRI and MRA with Contrast Composite).

Table 2 within the CY 2022 HOPPS proposed rule contains the imaging families and multiple imaging procedures for the composite APCs.

Device Applications Received for Pass-Through Payment CY 2022

CMS received eight complete applications for device pass-through payments for CY 2022. Of the eight device applications one includes the Eluvia™ Drug-Eluting Vascular Stent System. CMS is seeking stakeholder feedback if the applicant has met the criteria for pass-through payment status beginning in CY 2022.

Eluvia™ Drug-Eluting Vascular Stent System

Boston Scientific submitted an application for the Eluvia™ Drug-Eluting Vascular Stent System for device pass-through in CY 2022. According to the vendor the Eluvia™ Drug-Eluting Vascular Stent System *"is a combination product composed of an implantable endoprosthesis, a non-bonded freely dispersed drug layer (a formulation of paclitaxel contained in a polymer matrix), and a stent delivery system indicated for the treatment of symptomatic de novo or restenotic lesions in the native superficial femoral artery (SFA) and/or proximal popliteal artery (PPA)."*

The application indicates the Eluvia™ system is designed to restore blood flow in the peripheral arteries above the knee, specifically the superficial femoral artery and the proximal popliteal artery. In addition, the Eluvia™ system is intended to facilitate sustained elution of the drug paclitaxel beyond 12 months. The applicant asserts there is no other endovascular technology approved for treatment of peripheral arterial disease (PAD) to provide sustained elution of a drug over at least 12 months to prevent restenosis. The other technology referenced by the applicant, Zilver™ PTX™, only lasts for two months as a drug-coated stent.

In order for devices to be considered for pass-through status, they must meet basic criteria. The following is how CMS has indicated the information within the application fits into the necessary criteria.

Newness

The Eluvia™ system received FDA premarket approval on September 18, 2018. The application was received on February 26, 2021, within the 3-year requirement from initial FDA approval or clearance to be considered. The criterion per CMS has been met.

Substantial Clinical Improvement

The applicant indicates the Eluvia™ system provides a substantial clinical improvement over existing technologies based on following reasons:

1. The Eluvia™ system achieves superior primary patency;
2. The Eluvia™ system achieves reduced lesion revascularization, leading to a reduced rate of subsequent therapeutic interventions at one year and a statistically significant reduction of target lesion revascularization (TLR) at two years;
3. The Eluvia™ system decreases the number of future hospitalizations or physician visits;
4. The Eluvia™ system reduces hospital readmission rates;
5. Eluvia™ reduces the rate of device related complications; and
6. The Eluvia™ system achieves similar functional outcomes and quality of life index values while associated with half the rate of TLRs.

Based on new information related to a previous application, CMS no longer has concerns regarding the increased long-term mortality signal described in the CY 2020 HOPPS final rule.

Cost

There are three cost criterion that must be met. These criteria look at the APC(s) the codes used to bill for the device are assigned to and determine if they exceed a threshold to support significant cost. To understand how these criteria are measured, the APC for this device needs to be defined.

The applicant indicated the use of the Eluvia™ system would be reported with CPT® 37226 *(Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed)* and 37227 *(Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed).*

The three criteria were indicated as follows:

1. Average reasonable cost of devices must exceed 25 percent for the service related to the category of devices for this applicable APC payment.
    a. CMS estimates the Eluvia™ system is 56 percent of the applicable payment amount, this meets the first criteria.
2. Adding to the first criterion, the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list).
    a. CMS estimates the Eluvia™ system is 117 percent of the cost for the device-related portion, this does not meet the second criteria.
3. The difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service.
    a. CMS estimates the Eluvia™ system is 8 percent of the APC payment amount for the device, this does not meet the third criteria.

CMS is inviting comments whether this device meets the three criteria outlined. Based on CMS comments to this point, the cost criteria have not been met in its entirety.

Device Intensive Procedures

CMS is seeking 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, then the status is awarded.

CMS is proposing to use CY 2019 claims data for 11 procedures, three of them included in the list may be impactful to 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);* and
- 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 is also proposing to continue recognition of HCPCS C1889 *(Implantable/insertable device, not otherwise classified)* for billing of the device as part of a device intensive procedure when there is no specific Level II HCPCS Category C-code to represent it.

Inpatient Only List of Services

CMS is proposing to stop further removals and reverse the 298 services removed from the inpatient only (IPO) list in CY 2021. These are services which CMS indicated could be performed in an office setting. After review of previous administration changes, CMS believes many of the procedures could not in fact be performed anywhere but in the inpatient hospital setting, so they are reversing the removed services by reinstating them as inpatient only and halting any future changes to dismantle the list.

In addition, CMS is proposing to codify the five longstanding criteria used for determining if a service or procedure can or should be removed from the IPO list. The full list of IPO services is provided by CMS on their website in Addendum E, part of the 2022 NPRM OPPS Addenda or Table 35 of the ruling contains the list of 298 services proposed to be added back to the IPO list. The following is the list of services performed by interventional radiologists which may be impacted by the proposed change.

Addendum E.- Proposed HCPCS Codes That Would Be Paid Only as Inpatient Procedures for CY 2022			
HCPCS Code	**Short Descriptor**	**CI**	**Status Indicator**
0075T	Perq stent/chest vert art		C
0076T	S&i stent/chest vert art		C
0235T	Trluml perip athrc visceral		C
33017	Prcrd drg 6yr+ w/o cgen car		C
33018	Prcrd drg 0-5yr or w/anomly		C
33019	Perq prcrd drg insj cath ct		C
33880	Endovasc taa repr incl subcl		C
33881	Endovasc taa repr w/o subcl		C
33883	Insert endovasc prosth taa		C
33884	Endovasc prosth taa add-on		C
33886	Endovasc prosth delayed		C
33889	Artery transpose/endovas taa		C
33891	Car-car bp grft/endovas taa		C
34701	Evasc rpr a-ao ndgft		C
34702	Evasc rpr a-ao ndgft rpt		C
34703	Evasc rpr a-unilac ndgft		C
34704	Evasc rpr a-unilac ndgft rpt		C
34705	Evac rpr a-biiliac ndgft		C
34706	Evasc rpr a-biiliac rpt		C

34707	Evasc rpr ilio-iliac ndgft		C
34708	Evasc rpr ilio-iliac rpt		C
34709	Plmt xtn prosth evasc rpr		C
34710	Dlyd plmt xtn prosth 1st vsl		C
34711	Dlyd plmt xtn prosth ea addl		C
34712	Tcat dlvr enhncd fixj dev		C
34717	Evasc rpr a-iliac ndgft		C
34718	Evasc rpr n/a a-iliac ndgft		C
34808	Endovas iliac a device addon		C
34812	Opn fem art expos		C
34813	Femoral endovas graft add-on		C
34820	Opn iliac art expos		C
34830	Open aortic tube prosth repr		C
34831	Open aortoiliac prosth repr		C
34832	Open aortofemor prosth repr		C
34841	Endovasc visc aorta 1 graft		C
34842	Endovasc visc aorta 2 graft		C
34843	Endovasc visc aorta 3 graft		C
34844	Endovasc visc aorta 4 graft		C
34845	Visc & infraren abd 1 prosth		C
34846	Visc & infraren abd 2 prosth		C
34847	Visc & infraren abd 3 prosth		C
34848	Visc & infraren abd 4+ prost		C
35355	Rechanneling of artery		C
35371	Rechanneling of artery		C
35372	Rechanneling of artery	CH	C
35556	Art byp grft fem-popliteal		C
37182	Insert hepatic shunt (tips)	CH	C
61624	Transcath occlusion cns	CH	C
37215	Transcath stent cca w/eps		C
37217	Stent placemt retro carotid		C
37218	Stent placemt ante carotid		C
47380	Open ablate liver tumor rf		C
49425	Insert abdomen-venous drain		C
50250	Cryoablate renal mass open		C
61624	Transcath occlusion cns	CH	C
61630	Intracranial angioplasty		C
61635	Intracran angioplsty w/stent		C
61645	Perq art m-thrombect &/nfs		C
61650	Evasc prlng admn rx agnt 1st		C
61651	Evasc prlng admn rx agnt add		C
75956	Xray endovasc thor ao repr		C
75957	Xray endovasc thor ao repr		C
75958	Xray place prox ext thor ao		C
75959	Xray place dist ext thor ao		C

Submitting Comments

Comments to CMS regarding the MPFS proposed rule must refer to file code **CMS-1753-P** and be received no later than **5 pm EST September 17, 2021**. Electronic submission is encouraged by CMS, http://www.regulations.gov. Follow the instructions under the "submit a comment" tab.