



September 24, 2020

Submitted electronically via: <https://www.regulations.gov>

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1715-P
P.O. Box 8016
Baltimore, MD 21244-8013

RE: [CMS-1736-P] Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule; Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician-owned Hospitals

Dear Administrator Verma:

The American College of Gastroenterology (ACG), American Gastroenterological Association (AGA) and the American Society for Gastrointestinal Endoscopy (ASGE) welcome the opportunity to provide comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule (CMS-1736-P), published on August 12, 2020 in the Federal Register, regarding the proposed policy revisions to the CY 2021 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment Systems. Together, our three societies represent virtually all practicing gastroenterologists who provide preventive, consultative and therapeutic care for the U.S. population.

There are several provisions in the proposed rule that adversely impact Medicare beneficiaries and the practicing gastroenterologists who treat them. Below, we offer comments that address these areas:

- April 2020 Healthcare Common Procedure Coding System (HCPCS) Codes
- July 2020 HCPCS Codes
- Proposed Pass-Through Payment for Devices
 - Expiration of Transitional Pass-Through Payments for Certain Devices
- Alternative Pathway Device Pass-through Applications
 - EXALT™ Model D Single-Use Duodenoscope
- Traditional Device Pass-through Applications
 - Hemospray® Endoscopic Hemostat

- Comment Solicitation on Continuing to Provide Separate Payment in CYs 2022 and Future Years for Devices with OPPS Device Pass-Through Payment Status During the COVID-19 Public Health Emergency
- Proposed Device-Intensive Procedures
 - HCPCS Code-Level Device-Intensive Determination
- Proposed Changes to the List of ASC Covered Surgical Procedures for CY 2021
- Controlling Unnecessary Increases in the Volume of Covered OPD Services

A summary of our recommendations can be found on page 10.

April 2020 HCPCS Codes

We thank CMS for adding two new gastroenterology related Proprietary Laboratory Analyses (PLA) HCPCS codes in the April 2020 OPPS quarterly update (Transmittal 10013, Change Request 11691). These tests are important in diagnosing and caring for patients with irritable bowel syndrome (IBS) and liver disease.

CY 2020 HCPCS Code	CY 2020 Long Descriptor	Proposed CY 2021 CI	Proposed CY 2021 SI	Proposed CY 2021 APC
0164U	Gastroenterology (irritable bowel syndrome [IBS]), immunoassay for anti-CdtB and anti-vinculin antibodies, utilizing plasma, algorithm for elevated or not elevated qualitative results	NP	Q4	NA
0166U	Liver disease, 10 biochemical assays (α 2-macroglobulin, haptoglobin, apolipoprotein A1, bilirubin, GGT, ALT, AST, triglycerides, cholesterol, fasting glucose) and biometric and demographic data, utilizing serum, algorithm reported as scores for fibrosis, necroinflammatory activity, and steatosis with a summary interpretation	NP	Q4	NA

We agree with CMS that the Status Indicator (SI) should be Q4 (*Conditionally Packaged Laboratory Tests*) paid under the Clinical Laboratory Fee Schedule.

July 2020 HCPCS Codes

We thank CMS for adding three gastroenterology related HCPCS codes in the July 2020 OPPS quarterly update (Transmittal 10207, Change Request 11814).

CY 2020 HCPCS Code	CY 2020 Long Descriptor	Proposed CY 2021 CI	Proposed CY 2021 SI	Proposed CY 2021 APC
C1748	Endoscope, single-use (i.e., disposable), upper gi, imaging/illumination device (insertable)	NP	H	2029
Q5119	Injection, rituximab-pvvr, biosimilar, (Ruxience), 10 mg	NP	G	9367
Q5121	Injection, infliximab-axxq, biosimilar, (AVSOLA), 10 mg	NP	E2	N/A

Regarding C1748, we agree with CMS that the SI should be H (*Pass-Through Device Categories*) and we agree the proposed Ambulatory Payment Classification (APC) should be 2029 (*Endoscope, single, ugi*). We understand that HCPCS code C1748 can be used for both the Boston Scientific EXALT™ and Ambu aScope™ Duodeno and any FDA approved single-use, disposable duodenoscope.

Regarding Q5119, we agree with CMS that the SI should be G (*Pass-Through Drugs and Biologicals*) and the proposed APC should be 9367 (*Inj ruxience, 10 mg*).

Regarding, Q5121, CMS designated the SI as E2 (Items, codes and services for which pricing information and claims data are not available). **We understand CMS cannot assign an APC or set an SI if there are no claims data available and we urge CMS to access the data as quickly as possible so the price can be set. Ideally, as Q5119 and Q5121 have the same classifications, CMS could use SI "G" and APC 9367 in the interim until claims data is available.**

Alternative Pathway Device Pass-through Applications

EXALT™ Model D Single-Use Duodenoscope

The EXALT™ Model D Single-Use Duodenoscope application was preliminarily approved for transitional pass-through payment under the alternative pathway effective July 1, 2020. **Our societies recommend that the EXALT™ Model D Single-Use Duodenoscope should continue to receive transitional pass-through payment under the alternative pathway for devices that are FDA market authorized and that have an FDA Breakthrough Device designation.**

Single-use duodenoscopes are an important tool to eliminate the risk of nosocomial infections due to improper reprocessing. We agree with CMS that EXALT™ Model D satisfies all criteria under the alternative pathway for transitional pass-through payment as finalized by CMS in the

2020 OPPS Final Rule. **We support CMS' preliminary approval of HCPCS code C1748 (Endoscope, single-use (i.e. disposable), upper gi, imaging/illumination device (insertable)) for all single-use duodenoscopes as well as of the pass-through payment for C1748 for a full three years.**

In the 2021 OPPS/ASC proposed rule, CMS provided two different expiration dates for HCPCS code C1748 for the new device category. The text of the proposed rule on page 48843 of the Federal Register (Vol. 85, No. 156, Aug. 12, 2020) indicates the pass-through payment status for C1748 will end on June 30, 2022; however, in Table 20, the pass-through expiration date is listed as 6/30/2023. **We believe the transitional pass-through payment should be available for a full three years and we urge CMS to finalize the 2023 date in the final rule.**

Lastly, **we recommend the device offset for C1748 should be applied to only one endoscopic retrograde cholangiopancreatography (ERCP) code per patient encounter on the same date of service.** We are concerned there are some clinical scenarios that could result in removal of the device offset amount for C1748 twice during the same patient encounter. For example, patients with common bile duct stone undergo ERCP using a disposable scope and have a sphincterotomy (CPT code 43262) and stone removal (CPT code 43264). HCPCS code C1748 code is submitted for the device in addition to CPT codes 43262 and 43264. As per Table 9 from Transmittal 10166 of the CMS Manual System, “July 2020 Update of the Hospital Outpatient Prospective Payment System (OPPS)”, dated June 5, 2020, an offset of \$382.68 would be removed from the reimbursement for HCPCS code C1748 for the device as if two devices were used even though only one device was used because two CPT codes (43262 and 43264) were reported.

Excerpt from [Transmittal 10166](#):

Table 9. – CPT Codes Reportable With HCPCS Code C1748 Effective July 1, 2020

CPT Code	Short Descriptor	CY2020 OPPS SI	CY2020 OPPS APC	Device Offset Amount
43260	Ercp w/specimen collection	J1	5303	\$376.68
43261	Endo cholangiopancreatograph	J1	5303	\$320.30
43262	Endo cholangiopancreatograph	J1	5303	\$382.68
43263	Ercp sphincter pressure meas	J1	5303	\$128.36
43264	Ercp remove duct calculi	J1	5303	\$376.38
43265	Ercp lithotripsy calculi	J1	5331	\$816.09
43274	Ercp duct stent placement	J1	5331	\$1,287.96
43275	Ercp remove forgn body duct	J1	5303	\$323.30
43276	Ercp stent exchange w/dilate	J1	5331	\$1,392.66
43277	Ercp ea duct/ampulla dilate	J1	5303	\$483.45
43278	Ercp lesion ablate w/dilate	J1	5303	\$452.56

Therefore, we recommend the device offset for C1748 should be applied to only one ERCP code per patient encounter on the same date of service.

Traditional Device Pass-through Applications

Hemospray® Endoscopic Hemostat

Our societies agree with CMS' assessment that Hemospray® meets all criteria for pass-through payment and should be granted pass-through status. Hemospray® is a rescue intervention that is used after a failure in one or more standard of care therapies (e.g., injection, cautery and/or clipping) and a primary intervention for malignant bleeding.

The first criterion at § 419.66(c)(1) provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. In the 2021 OPPS/ASC proposed rule, CMS noted that it has not yet identified an existing pass-through payment category that describes Hemospray® and invited public comment on whether Hemospray® meets the device category criterion. ***We agree with CMS' assessment that there are no existing pass-through payment categories that describe Hemospray® and, therefore, it meets the device category criterion.***

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device has received FDA marketing authorization and is part of the FDA's Breakthrough Devices Program. While we understand CMS' critique that the majority of studies submitted by the applicant provided lack a comparator when assessing the effectiveness of Hemospray®, because it can be used if one or more standard of care rescue interventions fail, it is difficult to conduct one-to-one comparisons for each intervention, especially when multiple interventions are commonly used together (e.g., injection with cautery or injection with cautery and clipping). We agree with CMS' concern that in one study 50 percent of the control patients received injection therapy alone. This has not been the standard of care for many years (Laine L, Jensen DM. Management of patients with ulcer bleeding. Am J Gastroenterol. 2012 Mar;107(3):345-60; quiz 361. doi: 10.1038/ajg.2011.480. Epub 2012 Feb 7. PMID: 22310222). However, ***we believe the studies provided are sufficient to establish that Hemospray® substantially improves control of malignant bleeding and as a rescue intervention when standard of care therapies have failed.***

We understand CMS' concern that the samples chosen in many of the studies presented were performed in Europe on predominately males and, therefore, do not reflect the Medicare population, which is approximately 54 percent female and 46 percent male. However, we are satisfied that Hemospray® operates the same in male and female patients in Europe as well as the United States.

CMS was also concerned about the potential for adverse events resulting from Hemospray®. Adverse events occur with emergent endoscopy and with current standard interventions to control GI hemorrhage including oxygen desaturation, respiratory arrest, aspiration pneumonia, myocardial infarction, stroke and shock. Perforation can occur from 2-4 percent using current standard equipment to control hemorrhage. Most of these perforations can be handled

endoscopically. (ASGE Standards of Practice Committee. Adverse events of upper GI endoscopy. Gastrointest Endosc. 2012 Oct;76(4):707-18. doi: 10.1016/j.gie.2012.03.252. PMID: 22985638). Use of carbon dioxide during endoscopy for control of hemorrhage is protective as the CO₂ diffuses into the mucosa and is eliminated with respiration.

We agree with CMS that Hemospray® meets the third criterion for establishing a device category, at § 419.66(c)(3), that the cost of the device is not insignificant, as described in § 419.66(d). We agree with the applicant that Hemospray® would be reported with HCPCS codes 43227, 43255, 44366, 44378, 44391, 45334, and 45382. We agree with the use of APC 5312 in the cost calculation, which had a CY 2020 payment rate of \$1,004.10 at the time the application was received.

We agree with CMS that Hemospray® meets the cost significance requirement that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of \$2,500 for Hemospray® is 249 percent of the applicable APC payment amount for the service related to the category of devices of \$1004.10 ($(\$2,500/\$1,004.10) \times 100 = 249$ percent).

We agree with CMS that Hemospray® meets the second cost significance requirement at § 419.66(d)(2) which provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent. The estimated average reasonable cost of \$2,500 for Hemospray® is 7,454 percent of the cost of the device-related portion of the APC payment amount for the related service of \$33.54 ($(\$2,500/\$33.54) \times 100 = 7,453.8$ percent).

We agree with CMS that Hemospray® meets the third cost significance requirement at § 419.66(d)(3) which provides that 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. The difference between the estimated average reasonable cost of \$2,500 for Hemospray® and the portion of the APC payment amount for the device of \$33.54 is 246 percent of the APC payment amount for the related service of \$1004.10 ($((\$2,500-\$33.54)/\$1004.10) \times 100 = 245.6$ percent).

Comment Solicitation on Continuing to Provide Separate Payment in CYs 2022 and Future Years for Devices with OPPS Device Pass-Through Payment Status During the COVID-19 Public Health Emergency

We thank CMS for the opportunity to provide comments on whether the agency should adjust future payments for devices currently eligible to receive transitional pass-through payments that may have been impacted by the PHE. **We believe CMS should use its authority to provide separate payment for an additional one year after pass-through status of pass-through devices ends for devices whose data collection was impacted by the COVID-19 PHE pause on elective procedures.**

We agree with the rationale from stakeholders that CMS published in the proposed rule that healthcare resources have been triaged to assist in the COVID-19 pandemic response effort,

which has reduced utilization for devices receiving transitional pass-through payment, particularly for devices used in services that could be considered elective. We agree that devices on pass-through status are frequently used during elective procedures, and that CMS' ability to calculate appropriate payment for services that include these devices once the devices transition off of pass-through status could be hindered by a reduction in claims being submitted with these devices during the PHE.

We ask CMS to utilize the equitable adjustment authority it has under section 1833(t)(2)(E) of the Act to provide separate payment for some period of time after pass-through status ends for these devices to account for the period of time that utilization for the devices was reduced due to the PHE. We recommend CMS to extend payment for one additional year after pass-through status ends.

Proposed Device-Intensive Procedures

Prior to CY 2017, device-intensive status for procedures was determined at the APC level for APCs with a device offset percentage greater than 40 percent. Beginning in CY 2017, as noted in this proposed rule, CMS began determining device-intensive status at the HCPCS code level. In assigning device-intensive status to an APC prior to CY 2017, the device costs of all the procedures within the APC were calculated and the geometric mean device offset of all of the procedures had to exceed 40 percent. CMS subsequently modified the device offset percentage to 30 percent. ***Our societies agree that CMS should continue to determine device-intensive status at the HCPCS level. We also urge CMS to employ the lowest offset percentage possible, in order to allow a greater number of procedures to qualify as device-intensive.***

We concur with CMS that a HCPCS code-level device offset may be a better representation of a procedure's cost than an APC-wide average device offset, based on the average device offset of all of the procedures assigned to an APC. Our societies also agree that allowing these additional procedures to qualify for device-intensive status will help ensure these procedures receive more appropriate payment in the ASC setting, which will help encourage the provision of these services in the ASC setting.

Proposed Changes to the List of ASC Covered Surgical Procedures for CY 2021

Our societies thank CMS for soliciting feedback on proposed changes to the ASC covered surgical procedures list (ASC-CPL). Our societies agree that Medicare beneficiaries can have lower out-of-pocket costs when receiving care in an ASC rather than a hospital outpatient department. The general standard criteria for covered surgical procedures in the ASC are that the service is separately paid under OPPS, that it would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure. While CMS proposes to continue applying these current criteria, CMS is seeking comment on two alternative options to adding surgical procedures to the ASC-CPL.

The first is a proposed nomination process with modifications to certain regulatory criteria. Beginning in 2021, stakeholders would submit codes for consideration by March 1. If not added,

CMS would have to indicate its rationale for exclusion. Under the second alternative proposal, CMS would revise regulatory criteria by removing certain general exclusion criteria and revise the criteria for covered surgical procedures for the ASC payment system by keeping the general standards and eliminating five of the general exclusions.

We thank CMS for expanding the ASC-CPL while maintaining the balance between safety and access for Medicare beneficiaries. Our societies thank CMS for considering improving the process to society and professional organizations' input during this process. **However, we believe these two proposed options need not be mutually exclusive. We ask CMS to include a nomination process for adding new procedures in any policy change to the ASC-CPL.**

Controlling Unnecessary Increases in the Volume of Covered OPD Services

Our societies believe that CMS' comment regarding the value of prior authorization in the Medicare Program are disconcerting. CMS states in this proposed rule that prior authorization is an effective mechanism to mitigate unnecessary increases in volume by virtue of improper payments, without adding onerous new documentation requirements. CMS also believes prior authorization can be an effective method for controlling unnecessary increases in the volume of these services and will reduce the instances in which Medicare pays for services that are determined not to be medically necessary. Our societies believe these comments are untrue and counter the agency's efforts to reduce burden and improve efficiencies through the Patients Over Paperwork Initiative. Furthermore, the continued advancement toward alternative payment models that put clinicians at risk for health care expenditures encourages the wise use of health care resources, making burdensome cost control mechanisms, like prior authorization, unnecessary.

Prior authorizations and "step therapy" medication requirements can be detrimental to patient care, notably in diseases such as inflammatory bowel disease (IBD). These insurance coverage requirements infringe on the physician-patient relationship when they are not based on medical literature, do not improve patient outcomes, and may not even lower health care costs.

According to the [Medical Group Management Association \(MGMA\) Annual Regulatory Burden Report](#) released in October 2019:

Administrative requirements, such as prior authorization, not only delay patient care but also increase costs and burden. For years, payers have required medical practices to obtain prior authorization before providing certain medical services and prescription drugs to patients. These health plan cost-control mechanisms often delay care unnecessarily at the expense of the patient's health and the practice's resources.

The report found 83 percent of physicians found prior authorization to be very or extremely burdensome, ranking it the most burdensome regulatory issue in 2019.

In addition to being burdensome, performing prior authorization is also expensive. The [seventh annual report from the Council for Affordable Quality Healthcare, Inc.](#) (CAQH) found that processing prior authorizations amounted to a \$528 million administrative cost for providers in

2019. On average, providers spent nearly \$11 to conduct each prior authorization manually, up \$6.60 from 2018, and nearly \$4 per prior authorization conducted via a web portal.

GI practices spend a significant amount of resources dealing with insurance denials and coverage issues. This is overly burdensome for GI practices, leads to poor health outcomes, and takes valuable time away that could be spent seeing patients. According to a [June 2019 American Medical Association \(AMA\) survey](#) of more than 1,000 physicians, nearly 1 in 4 physicians say prior authorization led to a serious adverse event for one of their patients. Another 16 percent of physicians reported prior authorization caused at least one of their patients to be hospitalized. And more than 9 in 10 physicians said prior authorization regularly delays access to necessary care for their patients. These results suggest that insurers, including Medicare, have made little progress in reforming prior authorization. More importantly, prior authorization impacts patient care. Over one-quarter (28 percent) of physicians reported in this survey that prior authorizations has led to a serious adverse event (e.g., disability, hospitalization, death) for a patient in their care.

Our societies appreciate Administrator Verma for recognizing the problems of prior authorizations and its impact on patient care, noting in her [March 2020 presentation](#) that “prior-authorization requirements are a primary driver of physician burnout,” she said. “And, even more importantly, patients are experiencing needless delays in care that are negatively impacting the quality of care.” **We urge CMS to revisit the value of prior authorization.**

Conclusion

Our societies urge CMS to:

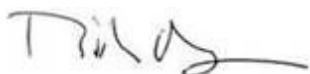
- Finalize the status of the EXALT™ Model D Single-Use Duodenoscope to receive transitional pass-through payment under the alternative pathway for devices that are FDA market authorized and that have an FDA Breakthrough Device designation for a full three years, ending in 2023.
- Apply the device offset for HCPCS code C1748 to only one ERCP code per patient encounter on the same date of service when more than one ERCP procedure code is reported during a single surgery.
- Grant pass-through status to Hemospray® as it meets all criteria for pass-through payment.
- Extend payment for one additional year after pass-through status ends for devices impacted by the COVID-19 PHE in order to account for the period of time that utilization for the devices was reduced due to the PHE.
- Continue to determine device-intensive status at the HCPCS level and to employ the lowest offset percentage possible, in order to allow a greater number of procedures to qualify as device-intensive.
- Adopt both of its proposed plans for expanding the number of procedures performed in the ASC setting and include a nomination process for adding new procedures in any policy change CMS finalizes.
- Align all actions to control unnecessary increases in the volume of covered OPD services with objectives of the administration’s “Patients Over Paperwork” initiative or provide evidence-based validation of its assumptions regarding the “value” of prior authorization in achieving its goals.

The ACG, AGA and ASGE appreciate the opportunity to provide comments on the CY 2021 OPPS and ASC Payment Systems proposed rule. If we may provide any additional information, please contact Brad Conway, ACG, at 301-263-9000 or bconway@gi.org; Kathleen Teixeira, AGA, at 240-482-3222 or kteixeira@gastro.org; or Lakitia Mayo, ASGE, at 630-570-5641 or lmayo@asge.org.

Sincerely,



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