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**Via Electronic Mail**

Chiquita Brooks-LaSure, Administrator  
Centers for Medicare & Medicaid Services  
Attn: CMS-1772-P  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals; Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating

Dear Administrator Brooks-LaSure,

On behalf of the Advanced Medical Technology Association (AdvaMed), we are pleased to offer comments on proposed changes to the CY 2023 Medicare hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system proposed rule, published in the *Federal Register* on July 26, 2022 (CMS-1772-P). AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies. We are committed to ensuring patient access to lifesaving and life-enhancing devices and other advanced medical technologies in the most appropriate settings.



AdvaMed’s comment letter offers support for specific CMS proposals and also recommends modifications to ensure Medicare beneficiary access to high-quality medical technologies and procedures. Our comments cover the following categories:

- Proposed Updates Affecting OPPS Payments
- Comprehensive APCs for CY 2023 – Complexity Adjustments
- Device Edits
- OPPS APC Groups Policies – Proposed OPPS APC-Specific Policies
- OPPS Payment for Devices
- Proposed OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals
- Proposed Services That Will Be Paid Only as Inpatient Services
- OPPS Payment for Software as a Service
- Proposed Updates to the ASC Payment System
- Requirements for the Rural Emergency Hospital Quality Reporting (REHQR) Program—Request for Comment on Additional Measurement Topics and for Suggested Measures for REH Quality Reporting
- Addition of a New Service Category for Hospital Outpatient Department Prior Authorization Process

## **Proposed Updates Affecting OPPS Payments**

### Hospital Market Basket Update

For CY 2023, CMS proposes a market basket update of 3.1 percent, less a productivity adjustment of 0.4 percentage points—the same update that CMS proposed for FY 2023 under the inpatient prospective payment system (IPPS). In the FY 2023 IPPS final rule that was publicly released a short time after the CY 2023 OPPS/ASC proposed rule displayed, CMS adopted an update of 4.1 percent less a total factor productivity adjustment of 0.3 percentage points. Following past practice, we expect CMS will adopt the same market basket update for OPPS as it did for IPPS or 3.8 percent (4.1 percent less 3.8 percentage points) for CY 2023.

This update, as well as the CY 2022 payment update of 2.7 percent, are inadequate for reflecting the impact of current inflationary trends on costs that hospitals are incurring now and are expected to continue to incur through FY 2023. Because the market basket is a time-lagged estimate using historical data to forecast into the future, it is not a good predictor of future costs when the inflation rate is at a 40-year high.

Because this high rate of inflation is not projected to abate in the near term, and inflationary pressures are also likely to continue to work their way into wage expectations, it is critical to account for these challenges when considering hospital and health system financial stability in CY 2023 and beyond.

***AdvaMed requests CMS take into account some portion of current inflationary trends by:***



- ***Implementing a retrospective adjustment for CY 2023 to account for the difference between the market basket update that was implemented for CY 2022 and what the market basket is currently projected to be for CY 2022; and***
- ***Eliminating the productivity cut for FY 2023.***

These updates occur before application of budget neutrality adjustments for various factors, which would further reduce the increase for most OPSS services as proposed. There are two specific adjustments that relate to CMS' 340B policy that we discuss below that are important to apply correctly in order to avoid reductions to the OPSS update that are greater than either is necessary or required by law.

#### Proposed Conversion Factor Update

Earlier this summer, the U.S. Supreme Court struck down CMS' previous policy of varying reimbursement rates for 340B hospitals. In light of this decision, we urge CMS to ensure payments to these hospitals are restored in a timely manner by repaying affected hospitals the difference between ASP+6 percent and what they were actually paid for CYs 2018-2022. Prompt repayment will enable these hospitals to continue providing services for low-income and rural communities. We further urge CMS to hold the entire hospital field harmless for payments received from CY 2018-2022 by not recouping funds received during this period. Retrospective recoupment, aside from being difficult to implement, would effectively penalize hospitals for the Agency's own decision-making, and stands to further put patients and communities at risk.

#### ***AdvaMed therefore requests CMS:***

- ***Revert to the prior policy of payment at ASP+6 percent for CY 2023, regardless of whether a drug was acquired through the 340B program;***
- ***Promptly repay any hospital the difference between ASP+6 percent and what they were actually paid for drug claims as a result of this unlawful policy for CYs 2018-2022; and***
- ***Hold the entire hospital field harmless for this policy for CYs 2018-2022 (i.e., not seek recoupment of funds received during this period).***

In addition, for CY 2023, CMS is proposing a new budget neutrality adjustment to the OPSS conversion factor to account for the increase in payment associated with restoring payment to 340B hospitals. We have concerns the Agency's calculation of this adjustment is incorrect and will result in further underpayment to all hospitals.

Specifically, when CMS first implemented the 340B payment policy, the Agency applied a +3.19 percent budget neutrality adjustment for non-drug services, which has remained in place without further adjustment despite public comments asking CMS to update the adjustment.<sup>1</sup> CMS' practice with respect to the 340B budget neutrality adjustment is inconsistent with its practice for other adjustments such as outliers and pass-through. These adjustments are updated annually by

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<sup>1</sup> 85 FR 86054 and 86 FR 63648



removing the prior year adjustment and then applying the payment year adjustment based on more recent data.<sup>2</sup>

Now, CMS is proposing to implement a revised budget neutrality adjustment of -4.04 percent to reflect the reversal of the 340B payment policy. As CMS never updated the 340B adjustment, it cannot now remove 4.04 percent from OPPS rates when it only ever added 3.19 percent, and because doing so at this point will result in a permanent reduction in OPPS payments inconsistent with the budget neutrality requirement at section 1833(t)(9)(B) of the Act. Based on information in the proposed rule, CMS is proposing a permanent reduction in OPPS payments of 0.85 percentage points (the difference between 3.19 percent and 4.04 percent) or approximately \$410 million annually that will compound and increase from year to year.

AdvaMed is concerned about CMS' proposed permanent underpayment to outpatient hospitals. These payments are critical for hospitals to cover the costs associated with caring for Medicare patients, and hospitals cannot afford to endure further underpayments. ***AdvaMed therefore urges CMS to correct the proposed adjustment to ensure the appropriate amount is added back into the CY 2023 OPPS conversion factor and no hospital is underpaid.***

The implication of CMS' proposal to remove 4.04 percent from OPPS rates is significant. The budget neutrality adjustment in prior years was too low as a result of CMS' failure to update it to account for more recent data (i.e., if CMS had updated the 340B adjustment as requested in public comments, non-drug OPPS payments for all services would have been higher). CMS should analyze the extent of this underpayment to hospitals in prior years, at least beginning with CY 2020 when CMS had information on the "JG" modifier to determine the precise adjustment that would have been required to maintain budget neutrality for application of the 340B payment adjustment. ***AdvaMed therefore urges CMS to provide an analysis of its underpayment to hospitals beginning in 2020 to determine how much more hospitals would have been paid for non-drug OPPS services for 2020 to 2022.***

Once CMS knows how much hospitals were underpaid for non-drug OPPS services for 2020 through 2022, it must propose a method to compensate hospitals for that underpayment. One model CMS can consider following was used in the past when it conceded that the Agency could not support a budget neutrality adjustment made for adoption of the 2-midnight rule under the IPPS. For FY 2014, CMS applied a budget neutrality adjustment of -0.2 percent for adoption of the 2-midnight rule.<sup>3</sup> In response to litigation, CMS decided to reverse that adjustment prospectively by permanently increasing rates by 0.2 percent effective for FY 2017 and also compensating hospitals for the effect of that reduction in past years by temporarily increasing IPPS rates by 0.6 percent (0.2 for each of the three years the adjustment was in effect) for FY 2017.<sup>4</sup> ***AdvaMed requests CMS temporarily adjust OPPS rates in 2023 to reflect past year underpayments for non-drug OPPS services.***

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<sup>2</sup> Medicare CY 2023 Outpatient Prospective Payment System (OPPS) Proposed Rule Claims Accounting, 2023-nprm-opps-claims-accounting.pdf (cms.gov), page 24

<sup>3</sup> 78 FR 50987

<sup>4</sup> 81 FR 57058



Another adjustment CMS must consider relates to how reversal of CMS' 340B payment policy affects its budget neutrality adjustment for pass-through payments. CMS indicates that the net budget neutrality adjustment for pass-through payment will be 0.34 percent (the difference between pass-through payments of 1.24 percent in 2022 and 0.9 percent in 2023).<sup>5</sup> However, CMS indicates that a large portion of the pass-through payments for 2023 are associated with drugs that are acquired under the 340B program and paid ASP+6 percent instead of ASP-22.5 percent using pass-through payments under CMS' proposed rule. Under the final rule policy, these drugs will be paid at ASP+6 percent without needing any pass-through payments. CMS indicates that pass-through payment will be 0.21 percent of OPPI in 2023 with its final rule 340B policy.<sup>6</sup> Therefore, in the final rule the net pass-through payment budget neutrality adjustment will be 1.03 percent (the difference between pass-through payments of 1.24 percent in 2022 and 0.21 percent in 2023). ***AdvaMed requests CMS apply a net budget neutrality adjustment for pass-through payments of 1.03 percent reflective of the reversal of its 340B policy.***

### **Comprehensive APCs (C-APCs) for CY 2023 – Complexity Adjustments**

CMS has developed a process for identifying and applying complexity adjustments to certain combinations of codes as a part of the comprehensive APC policy. AdvaMed supports the complexity adjustment as an important tool to help ensure adequate payment under the comprehensive APC methodology. We supported the changes made to the complexity adjustment criteria in the CY 2019 final rule but believe that important opportunities to refine the methodology remain.

#### ***AdvaMed recommends CMS:***

- ***Expand its review of procedure combinations to include clusters of -J1 and add-on codes, rather than only code pairs, to better reflect medical practice when multiple procedures are performed together; and***
- ***Continue to monitor and report on the impact of applying complexity criteria on APC assignments for code combinations within the comprehensive APCs.***

#### **Complexity Adjustment for Venous Balloon Angioplasty and Venous Thrombectomy**

Under CMS' complexity adjustment policy, when two CPT codes with a J1 status also meet established frequency and cost criteria, a complexity adjustment can be applied. As captured in Addendum J, CPT codes 37187 (venous thrombectomy) and 37248 (venous balloon angioplasty) meet the frequency threshold and are very close to meeting the cost threshold:

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<sup>5</sup> 87 FR 44528

<sup>6</sup> 87 FR 44661



Addendum J for CY 2023 evaluation statistics for complexity adjustments of combinations of comprehensive HCPCS codes													
Primary HCPCS Code	Primary Short Descriptor	Primary SI	Primary APC Assignment	Secondary J1 or Add-on HCPCS Code	Secondary Short Descriptor	Secondary SI	Secondary APC Assignment	Complexity Adjusted APC Assignment	Evaluation Subset Combination Frequency	Evaluation Subset Combination Geometric Mean Cost	Comparison Low Cost HCPCS	Cost Threshold	Qualifying Complexity Adjustment
37187	Venous mech thrombectomy	J1	5193	37238	Open/perq place stent same	J1	5193	5194	251	\$23,431	36905	\$15,962	Y
37187	Venous mech thrombectomy	J1	5193	37248	Trluml balo angiop 1st vein	J1	5192	5194	224	\$15,197	36905	\$15,962	N

In 2021, these procedures were performed together in 33 percent of the claim subsets, and these two codes have met the complexity adjustment criteria in previous years.

Clinical coherence is also critical when evaluating codes pairs. Since 2019, CPT codes 37187 and 37238 (venous stent) have led to a complexity adjustment on both frequency and cost thresholds. The clinical presentation of patients, procedure preparation, time, skill, and procedure intensity are similar whether performing a venous thrombectomy (37187), venous balloon angioplasty (37248), or placing a venous stent (37238) alone or in combination, and therefore should have the same complexity adjustments applied.

*AdvaMed requests CMS apply a complexity adjustment when CPT codes 37187 and 37248 are used together, moving these two procedures to APC 5194.*

### Device Edits

AdvaMed has previously expressed concern regarding the elimination of device edits outside of the context of device-intensive procedures. Device edits have historically been especially useful in ensuring the collection of accurate cost data.

*AdvaMed recommends CMS:*

- *Monitor claims to evaluate the need to reinstate all device edits; and*
- *Require hospital outpatient departments to report the appropriate device code or codes rather than “any device code”, consistent with long-standing Medicare billing guidelines.*

### OPPS APC Groups Policies – Proposed OPPS APC-Specific Policies

AdvaMed supports ongoing, annual review of APC families and assignments, and the opportunity to provide comments on these policies in the proposed rule. Moving forward, we continue to recommend that CMS outline a process that describes the criteria used to determine which stakeholder requests regarding APC placement for procedures are included in the OPPS rule or to, at a minimum, either notify stakeholders of the decision to include or the basis for not including their request in a proposed rule. We also request that CMS include all future requests related to APC structure and procedure assignment in proposed OPPS rulemaking. Failure to include all APC structure and assignment requests is tantamount to de facto decision making, on the part of CMS, not to support or accommodate the request. By not including these requests CMS also eliminates the opportunity for stakeholders to know about the request and provide comment. We believe that these are important steps to ensure transparency and stakeholder input in the hospital outpatient prospective payment program going forward. We recommend CMS



consider implementing a process similar to that in place for the Hospital Inpatient Prospective Payment System, under which CMS establishes an annual deadline for MS-DRG reassignment requests, then discusses those requests and CMS' proposed response and any MS-DRG changes in the following year's proposed rule.

### Anterior Abdominal Hernia Repair Procedures

Anterior abdominal hernia repair procedures will be reported with a new range of CPT codes, 49X01 to 49X15 beginning on January 1, 2023. AdvaMed is concerned that the proposed CY 2023 APC placement of the new codes will result in inadequate payments to hospitals relative to the costs of performing many of these procedures.

In the CY 2023 OPPI/ASC proposed rule, CMS is proposing to assign all of the new CPT codes for abdominal hernia repair procedures to APC 5341 (Abdominal/Peritoneal/Biliary and Related Procedures) with a proposed payment rate of \$3,236. In contrast, in CY 2022, the current abdominal hernia procedures are payable under three different APCs based on procedure cost and clinical homogeneity:

- APC 5341 – Abdominal/Peritoneal/Biliary and Related Procedures, with a proposed geometric mean cost of \$3,264
- APC 5361 – Level 1 Laparoscopy and Related Procedures, with a proposed geometric mean cost of \$5,537
- APC 5362 – Level 2 Laparoscopy and Related Procedures, with a proposed geometric mean cost of \$9,608

The existing CPT codes used to report abdominal hernia repair are not a one-to-one mapping to the new CPT codes. In some cases, the existing CPT code may map to six or more new CPT codes. Furthermore, the new CPT codes differentiate based on size of hernia (<3 cm, 3 to 10cm, or >10 cm) in addition to indicating whether the hernia repair is initial or recurrent, and reducible or incarcerated/strangulated. Finally, each code includes *all* approaches (open, laparoscopic, robotic) and for these reasons it is difficult to model the costs of the new anterior abdominal hernia procedure codes.

Based on the CMS 2023 NPRM CPT Cost File, only 35 percent of the 31,000 abdominal hernia repair procedures currently fall into APC 5341. The remaining 65 percent of abdominal hernia repairs are in APC 5361 or 5362, with the weighted geometric mean costs for abdominal hernia repair procedures in each APC of \$6,438 and \$7,899, respectively.

We recognize the challenge of mapping new CPT codes to APCs for rate setting, however, CMS' proposed APC assignment of abdominal hernia repair codes conflicts with the ratesetting methodology established by CMS that aligns procedure costs to payment.

***AdvaMed requests CMS implement an alternative to the proposed placement of all abdominal hernia procedures in APC 5341 in order to ensure continued beneficiary access to minimally invasive surgical procedures.***

### Phrenic Nerve Stimulation for Treating Central Sleep Apnea



The phrenic nerve stimulation therapy represented in CPT 0424T treats an underserved population of Central Sleep Apnea patients. CPT 0424T has a reported cost of \$52,471 as represented in the geometric mean cost, and is placed in APC 5465, which has a proposed payment of \$29,932. This results in a significant disparity of (\$22,539) between the geometric mean cost of the implant procedure and Medicare payment for this therapy option, which may significantly limit Medicare beneficiary access to this therapy. We recognize that the APC system is meant to average out among numerous procedures. However, phrenic nerve stimulation is and will continue to be a low-volume procedure which is adversely impacted by the other, more established, technologies that dominate the claim volume for APC 5465. We recommend CMS temporarily reclassify CPT code 0424T to New Technology APC 1581 to provide appropriate payment for this new procedure until sufficient claims data is gathered to assign it to an APC with more appropriate payment. We are concerned hospitals simply can't absorb this level of procedure loss and restricting access to such a clinically important therapy based on a small data sample of 60 claims would be devastating for Medicare beneficiaries.

***AdvaMed requests CMS temporarily assign CPT code 0424T to New Technology APC 1581 for CY 2023, given the disparity between the procedure cost and the proposed APC 5465 payment.***

#### Insertion of Central Venous Catheter Through Central Venous Occlusion via Inferior and Superior Approaches

HCPCS code C9780 was created on October 1, 2021, to describe the procedure associated with the insertion of central venous catheter through central venous occlusion via inferior and superior approaches (e.g., inside-out technique), including imaging guidance, using the Surfacor® Inside-Out® Access Catheter System. The code was assigned to New Technology APC 1534 with a payment rate of \$8250.50. In the CY 2023 OP/ASC proposed rule, CMS is proposing to continue assigning C9780 to APC 1534 with this same payment rate.

Subsequent to the implementation of the above HCPCS code, hospital providers have noted the cost of performing the procedure greatly exceeds the proposed 2023 APC payment. One such hospital presented during the August 22, 2022, meeting of the CMS Advisory Panel on Hospital Outpatient Payment, noting their calculated cost for performing this procedure was approximately \$12,500. Given the timing of when this code was created, no claims data was available for this procedure in CY 2020 to support APC assignment, nor is claims data available for this proposed rule. However, we are concerned that, should this procedure remain in the proposed APC, there will be a significant and inappropriate financial disincentive and negatively impact Medicare beneficiary access to this important technology.

***AdvaMed requests CMS reassign HCPCS code C9780 to APC 1575 as this APC is more reflective of its resource requirements.***

#### Magnetic Resonance guided Focused Ultrasound (MRgFUS)

MRgFUS is a non-invasive, real-time monitored and controlled acoustic surgery procedure that uses continuous diagnostic-quality magnetic resonance imaging with high-power, focused ultrasound energy (non-ionizing radiation) to provide an efficient, single day treatment.





Currently, the Food and Drug Administration (FDA) has approved three distinct neurosurgical applications of MRgFUS using INSIGHTEC equipment: Essential Tremor, Tremor Dominant Parkinson's Disease, and most recently Parkinson's Disease. These uses fill a gap between medication therapy (first line) and the highly invasive deep brain stimulation. The neurosurgical use of MRgFUS is reported using CPT code 0398T (Magnetic resonance image guided high intensity focused ultrasound (MRgFUS), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed). For CY 2023, CMS is proposing to place CPT code 0398T APC 5463, which has a proposed payment of \$12,866.

We are concerned this proposed placement in APC 5463 and resulting payment amount fails to compensate hospitals for the resources expended to furnish intracranial MRgFUS, and thus impedes Medicare beneficiary access to this important treatment. This is reflected in the hospital claims data for this service, both from 2021 claims and prior years, which show a trend of increasing volume and geometric means for this procedure. The geometric mean for the procedure from 2020 claims data was a little over \$15,000, and that geometric mean increases using 2021 claims data – to over \$16,000 if 2019 cost report data with the latest updated information is used, and to over \$18,000 if 2020 cost report data are used. These geometric means are much closer to the geometric mean costs for procedures assigned to APC 5464 than procedures assigned to APC 5463.

***AdvaMed requests CMS reassign CPT code 0398T to APC 5464 (Level 4 Neurostimulator and Related Procedures) for CY 2023, given the disparity between the procedure cost and the proposed APC 5463 payment.***

#### Placement of Breast Localization Devices

In the CY 2023 OPPTS/ASC proposed rule, CMS is proposing to move CPT code 19281 (Placement of breast localization device(s) (eg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including mammographic guidance) from APC 5071 to 5072. ***AdvaMed supports reassignment of CPT code 19281 to APC 5072.***

We further request CMS consider reassigning CPT codes 19283, 19285, and 19287 to APC 5072. CPT codes 19281 through 19288 are a series of codes that represent breast localization placement procedures, differing by imaging guidance. From a clinical perspective, all of the first lesion percutaneous placement of breast localization device codes should be assigned to the same APC. Additionally, APC 5072 houses the related series of percutaneous image-guided breast biopsy procedures, 19081-19086, which makes the move clinically relevant. Finally, given the similarity of the geometric mean costs for CPT codes 19283 and 19285 to that of CPT code 19281, which are well above the geometric mean for APC 5071, ***AdvaMed requests CMS reassign CPT codes 19283, 19285, and 19287 to APC 5072.***

#### Establishing Additional APC(s) for Musculoskeletal Procedures

In recent years, CMS has at different times considered whether to establish a seventh musculoskeletal APC to reflect the broad array of orthopedic procedures performed in hospital outpatient settings. In the CY 2021 OPPTS/ASC final rule, CMS discussed whether to add another



musculoskeletal APC. While CMS opted to take no action, the Agency noted that it would consider these comments for future rulemaking.

As CMS evaluates payment policy issues for future rulemaking, AdvaMed urges CMS to consider such a change for CY 2024 and future years. The gap in geometric mean costs between APCs 5114 and 5115 is almost \$6,000, and the gap between APCs 5115 and 5116 is over \$9,000, both of which are too significant a gap in payment categories, especially given the payment impact on ASC payment rates.

An additional APC level within the family of Musculoskeletal APCs—for example, between APCs 5114 and 5115—would smooth out some of the substantial payment gaps and provide a more even distribution of APCs that better align resource consumption with payment rates. These gaps also have far-reaching implications on the appropriateness of payment rates for procedures performed in ASCs, given the close linkage between OPPS payment rates and ASC payment rates.

***AdvaMed requests CMS, for future rulemaking, consider creating one or more additional Musculoskeletal Procedures APCs to achieve a more even distribution of APC levels and support improve rate setting accuracy.***

### **OPPS Payment for Devices**

#### Proposal to Publicly Post OPSS Device Pass-Through Applications

Beginning with applications submitted on or after January 1, 2023, CMS proposes to post online the completed application forms and certain related materials it receives from OPSS device pass-through applicants, as well as updated application information and additional clinical study information as it becomes available. CMS clarifies that with this proposal it would not post cost and volume information for either the traditional or alternative pathway applications as part of the materials that would be posted online. Nor would it post online any material that the applicant indicates is not releasable to the public because the applicant does not own the copyright or the applicant does not have the appropriate license to make the material available to the public.

***AdvaMed supports this proposal because it would enhance transparency in the evaluation process for applications and facilitate input from other stakeholders and would also streamline CMS's internal process for evaluating applications. However, we request CMS make clear in the final rule, if it moves forward with its proposal, that it will retain a mechanism to enable applicants to submit proprietary or trade secret information that is not posted online, consistent with the Agency's current policy.***

#### Technical Clarification to the Alternative Pathway to the OPSS Device Pass-Through Substantial Clinical Improvement Criteria for Certain Transformative New Devices

AdvaMed commends CMS for the strides that have been made in ensuring coverage and payment for innovative medical technologies that have received FDA breakthrough designation. In the CY 2020 outpatient rule the Agency approved policies that streamlined the process to gain pass-through payment status for these technologies. CMS finalized changes that allowed FDA



designated breakthrough devices that have also received FDA marketing authorization to be deemed to have met the substantial clinical improvement requirements for consideration for transitional passthrough payment (TPT). This change was significant in allowing access to add-on payments for these devices in the outpatient setting. However, the CMS changes did not impact the other requirements needed to qualify for TPT including cost and that the device is not included in an established device category as described by an HCPCS code used or previously used for pass-through payment. While AdvaMed understands the need to continue to meet the cost criterion we remain concerned that these devices must continue to prove that they are not described by an existing TPT category.

FDA breakthrough designation implies that the device/procedure is a first of its kind in addressing the condition for which it was designed. This would suggest that it meets the “newness” criteria for TPT. Indeed, when it established an alternative pathway for breakthrough devices seeking New Technology Add-On Payment (NTAP) in the inpatient hospital setting, CMS stated, “if a medical device is part of the FDA’s Breakthrough Devices Program and received FDA marketing authorization, it would be considered new and not substantially similar to an existing technology for purposes of the new technology add-on payment.” Not recognizing newness in the same way in the outpatient hospital setting is inconsistent and goes against the spirit of the change to accommodate these devices and to recognize their novelty and impact on patient care and is contrary to the purpose of this designation by the FDA.

***AdvaMed requests CMS modify the TPT criteria for FDA breakthrough designated devices to indicate that an FDA designated breakthrough device is automatically considered to not be described by any of the existing (either currently active or expired) categories established for transitional device pass-through payments and therefore is considered to meet the newness criteria for TPT.***

#### TPT Threshold Issues

##### *TPT Payment Device Category Criteria*

As discussed in our pre-rulemaking letter to CMS, we continue to be concerned the Agency has adopted an overly restrictive interpretation of the requirements for a technology to qualify for a TPT new device category. CMS’ recent interpretation of the criteria for a new device category under TPT suggests that any new technology that could be aligned to an existing category—however tenuously—would automatically fail to meet the threshold for a new device category.<sup>7</sup> This overly strict interpretation of the device category criterion will result in inappropriate restrictions upon the use of the TPT pathway, and we encourage CMS to consider the totality of evidence when assessing whether a device falls into an existing TPT device category or qualifies for new device category. Factors such as differentiated clinical benefits (as reflected in substantial clinical improvement), different mechanisms of action, or other evidence-based improvements should be considered.

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<sup>7</sup> See 86 FR 63596, where CMS discusses the Eluvia™ system, finding the technology meets the substantial clinical improvement criterion but fails the device category criterion on the grounds a device category dating back over 20 years appropriately describes this breakthrough technology.



These considerations are particularly important in the context of devices with FDA breakthrough designation. Breakthrough designation implies a device is a first of its kind in addressing the condition for which it was designed or offers significant advantage over other alternatives. When CMS established an alternative pathway for breakthrough devices seeking New Technology Add-On Payment (NTAP) in the inpatient hospital setting, the Agency stated, “if a medical device is part of the FDA’s Breakthrough Devices Program . . . and received FDA marketing authorization, such a device . . . would be considered new and not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS.”<sup>8</sup> While we understand NTAP does not use device categories, we believe the concept of breakthrough—indicating innovation—should automatically qualify a breakthrough device for a new device category for TPT purposes. The current lack of alignment between NTAP and TPT can result in additional payment in the hospital inpatient setting but not the hospital outpatient setting. This may create an inadvertent incentive favoring inpatient over outpatient care, and further perpetuates inconsistencies in the criteria between NTAP and TPT.

***AdvaMed requests CMS reconsider its interpretation of the criteria for a new TPT device category. We urge CMS to include the totality of evidence, including evidence-based clinical improvements, mechanisms of action, and other relevant technological changes that have been demonstrated to improve performance and beneficiary outcomes.***

#### *TPT Payment Substantial Clinical Improvement Clarification*

In the FY 2019 Hospital Inpatient Prospective Payment System (IPPS) proposed rule, CMS solicited comment on specific changes or clarifications to the IPPS and OPSS substantial clinical improvement criterion used to evaluate applications for new technology add-on payments (NTAP) under the IPPS and TPT under the OPSS in order to provide applicants greater clarity and predictability. While some of these clarifications were subsequently proposed and adopted for NTAP, no such clarifications have been provided for TPT. We therefore recommend CMS consider providing additional clarity on the types of evidence or study designs that may be considered in evaluating substantial clinical improvement. Specifically, we recommend CMS consider providing guidance on study methods beyond randomized clinical trials that may yield equivalent evidence for decision-making sooner and using fewer resources. For example, retrospective analysis of large real-world evidence data sets may provide adequate support for reimbursement of off-label applications of a technology.

***AdvaMed requests CMS consider specifying non-inferiority studies, retrospective studies, case studies, Real World Evidence (RWE), registries, and meta-analyses on its non-exhaustive list of data sources that may be used to meet the substantial clinical improvement criterion for TPT.***

#### *TPT Payment Cost Test Thresholds*

Currently, CMS requires that technologies meet several criteria in order to satisfy the cost test for TPT payment, including that the new device must exceed the cost of the device-related portion of the APC payment amount for the service by at least 25 percent between the cost of the device

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<sup>8</sup> 84 FR 42047



seeking pass-through and the device-related portion exceeds 10 percent of the total APC payment.

In many cases, a device that meets the newness and significant clinical improvement criteria for TPT payment may only replace a portion of the devices included in the device-related portion. In some cases, the novel device may not replace any of the devices included in the device-related portion. In these cases, the device-related threshold that a new device must meet may be inappropriately high since many of the devices it includes will still be utilized in the procedure.

Based on these concerns, we note two key opportunities for improvement in CMS' application of the TPT cost test criteria. First, in cases where a new device does not replace any existing devices used in a procedure, we recommend CMS not apply the TPT cost test at all. Second, in cases where a new device replaces some, but not all, of the devices used in a procedure, we recommend CMS revise the cost test to assess the new device's cost using only the cost of the devices the new device replaces in the associated procedure. This revised cost test would address shortcomings of the current TPT methodology, under which a new device that is not intended to replace or does not replace the entirety of all devices used in a procedure could meet the requirements for substantial clinical improvement but fail on the cost criteria.

***AdvaMed requests CMS:***

- ***Revise the TPT methodology to eliminate the cost criteria for new devices that do not replace any other devices used in a procedure; and***
- ***Revise the TPT methodology's cost criteria for devices that replace some, but not all, of the devices used in a procedure by assessing cost using only the cost of the devices the new device replaces in the procedure.***

***Clarifying TPT Payment Guidance in the ASC Setting***

As new, innovative devices enter the marketplace and receive TPT payment, it is imperative CMS ensure these devices are appropriately reimbursed in both the outpatient and ASC settings. Currently, ASC payment for procedures using these devices is calculated by establishing the procedure payment rate, subtracting the applicable device offset percentage, and then adding the J7 payment for the TPT device. However, there is currently no CMS-level guidance on how MACs should establish this J7 payment price for TPT devices. This lack of clear, consistent payment guidance has resulted in instances where the MAC payment for a procedure using a TPT device fails to appropriately account for the cost associated with the new device. We are concerned that, absent CMS intervention, inadequate reimbursement will disincentivize ASCs from using these devices and, in turn, reduce Medicare beneficiaries' access to new, innovative technologies. We therefore request CMS provide additional clarity on how MACs should establish payments for TPT devices. Specifically, we recommend CMS specify that J7 payment should be at least equal to the device cost, as reported by the ASC in box 19 or the electronic equivalent.

***AdvaMed requests CMS clarify how MACs should establish payment for TPT devices in the ASC setting to account for the additional costs of the new device.***

***Consideration of Capital Costs for New Technology APCs and Pass-Through Devices***



Under TPT and the new technology APC policies for eligible new devices CMS provides higher payments to aid with the uptake by hospitals of eligible new medical devices.

The eligibility criteria for pass-through payments for medical devices are in Chapter 42 of the Code of Federal Regulations (CFR) at §419.66(b), and specifically exclude capital costs that are considered as depreciable assets from eligibility for pass-through costs. CMS references this section in the proposed rule and states it relies “on hospitals to make their decisions regarding the acquisition of high-cost equipment with the understanding that the Medicare program must be careful to establish its initial payment rates...”<sup>9</sup>

Capital costs allocated to outpatient services are included in establishing the OPPS payment rate.<sup>10</sup> However, CMS distinguishes between how it treats the operating costs of new medical technologies eligible for new technology APCs or pass-through payments from how it treats capital costs associated with the technologies.

CMS should reconsider this exclusion of capital costs from its pass-through payment policies for new medical technologies. Particularly as more technologies are developed utilizing digital technologies that have components that qualify as capital expenses, it is time for CMS to update its treatment of capital costs under the pass-through policy. The logic for special treatment of operating costs of new medical devices applies equally to capital costs. These costs are not included initially in the APC payment rate until CMS has sufficient claims two or three years after market introduction. CMS could use its standard allocation methodologies to ensure it does not pay more than its share of the capital costs.

***AdvaMed requests CMS reconsider the exclusion of capital costs from its pass-through payment policies for new medical technologies.***

## **Proposed OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals**

### **High/Low-Cost Thresholds for Packaged Skin Substitutes**

#### **Proposals for Packaged Skin Substitutes for CY 2023**

For CY 2023, CMS proposes to continue the high cost/low-cost categories policy established since CY 2016. AdvaMed continues to urge CMS to adopt a single uniform policy in the OPPS that applies to all skin substitute products.

In the CY 2023 Physician Fee Schedule (PFS) proposed rule, CMS indicates that one of its objectives for refining Medicare policies related to skin substitutes is “ensuring a consistent payment approach for skin substitute products across the physician office and hospital outpatient department setting.”<sup>11</sup> CMS’ proposal would consider skin substitutes to be separately billable medical supplies that are contractor priced effective January 1, 2024, while CMS researches bundling skin substitutes into Medicare’s PFS payment using the practice expense methodology

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<sup>9</sup> 87 FR 44551 (July 26, 2022)

<sup>10</sup> (42 CFR 419.2(b)(8))

<sup>11</sup> 87 FR 46027



over an unspecified time period. Meanwhile, CMS proposes to continue packaging skin substitutes into Medicare’s OPPS payments.

Consistent with CMS’ objective to have a “consistent payment approach” across settings, AdvaMed notes that the easiest way to achieve this objective would be to revert to separate payment for skin substitutes under the OPPS as CMS did prior to 2014. Such consistency would actually be improved today relative to 2014 as section 1847A(f)(2) of the Act requires ASP reporting effective January 1, 2022, for “products that are payable under this part as a drug or biological.” This policy would allow CMS to price all skin substitutes across all settings the same way at ASP+6 percent if ASP pricing for all skin substitutes were made available in its Part B drug pricing files available on the CMS web site. AdvaMed would support this policy if CMS were to adopt it in the OPPS final rule.

***AdvaMed urges CMS to adopt a single uniform policy in the OPPS that applies to all skin substitute products. This could be best achieved by reverting to separate payment for skin substitutes under the OPPS as CMS did prior to 2014.***

Proposed Retirement of HCPCS Code C1849 (Skin Substitute, Synthetic, Resorbable, by per Square Centimeter)

AdvaMed supports efforts to assign product-specific codes for skin substitute products. By assigning a single C-code (C1849) that may only be used under the OPPS, rather than product-specific codes that could be used in any setting, synthetic skin substitutes are only able to be billed under the OPPS rather than across all settings of care like other skin substitutes. AdvaMed supports product-specific codes and continues to advocate that, consistent with prior policy, CMS provide all skin substitutes with product specific Q-codes, not A-codes<sup>12</sup>. Due to the movement to specific codes, AdvaMed agrees with CMS that C1849 can be retired. Like other codes, the products previously coded using C1849 should be assigned based on their product-specific per day or mean unit cost to the high or low-cost group.

CMS proposes to assign HCPCS code A4100 (Skin substitute, FDA cleared as a device, not otherwise specified) to the low-cost skin substitute group, stating that this is consistent with their existing payment policy that unclassified graft skin substitute products be assigned to the low-cost skin substitute group. AdvaMed supports this proposal as it avoids new products automatically being placed into a high-cost category regardless of available cost data.

***AdvaMed supports CMS’ recommendation that C1849 be retired and recommends that the products previously coded to C1849 be assigned based on their product-specific per day or mean unit cost to the high or low-cost group.***

***AdvaMed supports CMS’ recommendation to assign HCPCS code A4100 to the low-cost skin substitute group.***

Key Objectives/Roadmap for Consistent Treatment of Skin Substitutes

<sup>12</sup> See 78 FR 74932 “...HCPCS Q-codes are typically assigned to drugs and biologicals and are used to describe skin substitutes...” and 86 FR 63563 “The CY 2014 OPPS/ASC final rule with comment also described skin substitutes as “...a class of products that we treat as biologicals...”



As already noted, AdvaMed believes CMS' objective for consistency on payment of skin substitutes between the hospital outpatient department and the physician office is best achieved through separate payment across all settings at ASP+6 percent. In the OPPS/ASC proposed rule, CMS indicates that if its proposed PFS policy is finalized, manufacturers would not report ASP for skin substitute products starting in CY 2023; and CMS would no longer be able to use ASP+6 percent pricing to determine whether a skin substitute product should be assigned to the high-cost group or the low-cost group. CMS would instead use WAC or AWP for this purpose.

AdvaMed notes that ASP includes all discounts and will generally be a lower price than WAC, which does not include discounts, and AWP, which is a list price that may be unrelated to the actual price of the product sold on the market. Under the Physician Fee Schedule policy that gives authority to the MACs to price skin substitutes, it is certainly possible, if not likely, that absent any other methodology to price skin substitutes, the MACs may use WAC or AWP pricing and Medicare's payments will increase instead of decline. Under the OPPS, it will mean that CMS is using less accurate pricing mechanisms to assign skin substitutes to the high-cost and low-cost groups than if it continued to allow ASP reporting for skin substitutes for payment in physician offices.

***AdvaMed recommends that CMS price skin substitutes consistently according to ASP+6 percent in all settings where those data are available. AdvaMed recommends that CMS display reported ASP pricing for skin substitutes, as applicable, on its Part B drug files on the CMS website.***

***If CMS maintains its policy of packaging skin substitutes into OPPS payments, AdvaMed recommends that ASP continue to be reported by manufacturers of skin substitutes, as applicable, and pricing continue to be at ASP+6 percent in the physician office setting to enable ASP to be the basis for assigning skin substitutes to the high-cost or low-cost group for the OPPS.***

#### Changing the Terminology of Skin Substitutes

Outlined by CMS in both the CY 2023 PFS proposed rule and CY 2023 OPPS/ASC proposed rule, CMS aims to clarify policies for skin substitute products and believes improving how these products are referenced will address confusion on how these products are defined and ultimately paid. CMS is proposing to replace the term "skin substitutes" with the term "wound care management" or "wound care management products" and solicits feedback on this proposal. CMS also expresses interest in other possible terms that could be used to "more meaningfully and accurately describe" the suite of products currently referred to as skin substitutes.

As communicated in comments to CMS in the CY 2023 PFS proposed rule, AdvaMed opposes the proposal to replace the term "skin substitutes" with "wound care management" or "wound care management products." As a foundational issue, AdvaMed does not believe the term "skin substitutes" is problematic or confusing. Indeed, what seems most confusing is to depart from language that has been for years and remains in pertinent Current Procedural Terminology (CPT) codes, such as 15271-15728, which is the phrase "skin substitute". CMS' only stated reason for replacing the terminology is that skin substitutes "do not actually function like human skin that is





grafted onto a wound.” While CMS’ statement may be accurate such as it is, AdvaMed is unaware that the use of the term “skin substitutes” has ever been conflated with human skin that is grafted onto a wound, commonly referred to as a “skin graft.”

Indeed, use of the term “wound care management product” is far more likely to create a problem rather than solving one that we do not believe exists today. The term “wound care management product” does not sufficiently distinguish skin substitutes from wound care dressings or bandages that are also used to treat wounds but without a mechanism of action that stimulates the host to regenerate lost tissue. CMS itself distinguishes wound care dressings and bandages from skin substitutes<sup>13</sup> yet proposes new nomenclature that—when considering that CMS intends to treat all products as incident to supplies—could easily be misinterpreted to include both types of products as opposed to the term “skin substitutes” where the distinction between skin grafts, skin substitutes and wound care dressings or bandages is clear.

CMS acknowledges in the proposed rule potential issues with the use of the term “care management” and its likely conflation with AMA CPT evaluation and management (E/M) codes. AdvaMed agrees that by adopting these terms, there is likely to be confusion and believes this concern is significant enough to not support the use of the terms “wound care management” or “wound care management products”. Instead, AdvaMed recommends the term “Cellular and/or tissue-based products (CTPs)” as a replacement term for “skin substitutes”. We think this term will better achieve CMS’ goal of more accurately describing the entire suite of products but without the possible misinterpretation as other medical products or services. Not only would this term better align with FDA categorization and review process for these products, it would align with the ASTM International definition of a CTP, which is, “CTPs are defined primarily by their composition and comprise of cells and/or the extracellular components of tissue. CTPs may contain cells (viable or nonviable), tissues, proteins, and other materials for which there is a rationale for benefit beyond that achievable with conventional wound coverings. CTPs may additionally include synthetic components.”<sup>14</sup>

***AdvaMed opposes the proposal to replace the term “skin substitutes” with the term “wound care management” or “wound care management products,” and instead recommends CMS replace the term “skin substitutes” with the term “Cellular and/or tissue-based products (CTPs).”***

## **Proposed Services That Will Only Be Paid as Inpatient Services**

### Removing Biliary Endoscopy (Choledochoscopy) from the OPPS Inpatient Only Procedure (IPO) List

Patients with complex gastroduodenal or hepatobiliary anatomy who need treatment for biliary obstruction, may benefit from Percutaneous Transhepatic Cholangioscopy (PTCS), or choledochoscopy. These patients may have undergone a previous surgery such as a Roux-en-Y

<sup>13</sup> 87 FR 46028

<sup>14</sup> Standard Guide for Classification of Cellular and/or Tissue Based Products (CTPs) for Skin Wounds. ASTM International. Current edition approved Feb15, 2022. Published March 2022 Last previous edition approved in 2016 as F3163-16DOI:10.1520/F3163-22



gastric bypass, a pancreaticoduodenectomy (Whipple procedure), or a liver transplant that resulted in altered hepatopancreaticobiliary anatomy. These conditions may cause the anatomy to differ from normal, posing a challenge for management of subsequent bile duct stones or biliary obstruction via surgery. There are also cases in which peripheral stones need to be treated beyond first-line therapy, even with normal anatomy. These patients cannot be treated with a traditional endoscopic retrograde cholangiopancreatography (ERCP) procedure and have limited treatment options, such as percutaneous biliary drainage for symptom management. Intraoperative biliary endoscopy (e.g., PCTS or choledochoscopy) is a safe and clinically effective method to treat these complex patients.

Intraoperative biliary endoscopy, as reported by CPT Add-On Code +47550, has been on the IPO List for more than 20 years. As an add-on code, +47550 is only reported as secondary to a primary procedure and allows for direct visualization and identification of abnormalities of tortuous anatomy and aids in the facilitation of the primary procedure, including diagnostic brushing/washing, biopsy(ies), stone removal, strictures, and stenting within the biliary tract. The table below reflects several primary procedures for +47550, along with their assigned OPPS Status Indicators and OPPS APC Assignments from this year’s proposed rule. *Importantly, none of these primary procedures are included on the IPO List.*

CPT Code	Description	PROPOSED 2023 OPPS Status Indicator	PROPOSED 2023 OPPS APC Assignment
47533	Placement of biliary drainage catheter, percutaneous; external	J1	5341
47534	Placement of biliary drainage catheter, percutaneous; internal-external	J1	5341
47535	Conversion of external biliary drainage catheter to internal-external biliary drainage catheter, percutaneous	J1	5341
47536	Exchange of biliary drainage catheter, percutaneous	J1	5341
47537	Removal of biliary drainage catheter, percutaneous	J1	5301
47538	Placement of stent(s) into a bile duct, percutaneous; existing access	J1	5361
47539	Placement of stent(s) into a bile duct, percutaneous; new access, without placement of separate biliary drainage catheter	J1	5361
47540	Placement of stent(s) into a bile duct, percutaneous; new access, with placement of separate biliary drainage catheter	J1	5361



47541	Placement of access through the biliary tree and into small bowel to assist with an endoscopic biliary procedure (eg, rendezvous procedure), percutaneous	J1	5341
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Biliary endoscopy procedures, including choledochoscopy, have been deemed safe in the outpatient setting through peer-reviewed clinical evidence for more than 20 years.<sup>15,16,17,18</sup>

Medicare claims data demonstrates hospitals are equipped to perform this procedure outpatient, and it can be safely performed in the outpatient setting. Since 2013, Medicare outpatient procedure volumes for CPT code +47550 have been consistent, ranging from 13.3 percent to 21.5 percent.<sup>19</sup>

Both the clinical literature and claims volume demonstrate that choledochoscopy can be performed safely and effectively in an outpatient setting. Removing CPT code +47550 from the IPO List will increase access for Medicare beneficiaries and allow physicians to determine the most appropriate setting of care for their patients. ***AdvaMed therefore requests, in alignment with the recommendation of the Advisory Panel on Hospital Outpatient Payment, CMS remove CPT code +47550 from the IPO List effective January 1, 2023.***

**OPPS Payment for Software as a Service (SaaS)**

AdvaMed applauds CMS’ leadership in seeking stakeholders’ input for providing greater clarity and specificity for defining pathways to coverage and payment for software as a service in the outpatient hospital setting. We commend CMS for its specific proposals and requests for information in this proposed rule that would begin to chart directions for coverage and payment for SaaS both in the immediate short term and the longer term as well.

We appreciate CMS’ recognition that SaaS can be separate and distinct services that should be paid separately and not be considered as ancillary packaged services that are a part of a primary service. ***We support CMS’ proposal not to recognize the CPT add-on codes for SaaS procedures under the OPPS and instead establish HCPCS C-codes to describe the add-on SaaS as standalone services for billing with the associated imaging service. We also support CMS’s proposal to assign these C-codes to the identical APCs and have the same status indicator assignments as their standalone code.*** AdvaMed has raised concerns that CPT codes designed to describe physician services do not always facilitate payment under the OPPS, and we

<sup>15</sup> Berci G. *Intraoperative and postoperative biliary endoscopy (choledochoscopy)*. Surg Clin North Am. 1989 Dec;69(6):1275-86. doi: 10.1016/s0039-6109(16)44988-1. PMID: 2595523.

<sup>16</sup> Venbrux AC, Robbins KV, Savader SJ, Mitchell SE, Widlus DM, and Osterman FA, *Endoscopy as an adjuvant to biliary radiologic intervention*. Jr Radiology 1991 180:2, 355-361.

<sup>17</sup> Bower BL, Picus D, Hicks ME, Darcy MD, Rollins ES, Kleinhoffer MA, Weyman PJ. *Choledochoscopic stone removal through a T-tube tract: experience in 75 consecutive patients*. J Vasc Interv Radiol. 1990 Nov;1(1):107-12. doi: 10.1016/s1051-0443(90)75213-4.

<sup>18</sup> Hazey JW, McCreary M, Guy G, Melvin WS. *Efficacy of percutaneous treatment of biliary tract calculi using holmium:YAG laser*. Surg Endosc. 2007 Jul;21(7):1180-3. doi: 10.1007/s00464-006-9168-6. Epub 2007 Feb 8. PMID: 17287911.

<sup>19</sup> 2013-2020 Medicare PPSF Medicare Claims Data File.



support CMS's acknowledgement of the need to create HCPCS codes to support payment for a separate and distinct service under the OPPS.

Within the OPPS, we believe that CMS should not establish one policy that would apply to all SaaS-type technology but instead separately evaluate each new technology to determine the appropriate HCPCS coding, including whether or not a potential CPT code can be used to support payment for the separate and distinct service under the OPPS. We do not support the creation of broad G-codes that could describe the diagnostic image and the SaaS procedure. We also do not support expansion of composite APCs to provide a single payment for groups of services that are performed together during a single clinical encounter. CMS should not assume that the cost and resources are similar for all SaaS procedures for a given imaging modality and should not limit payment for SaaS procedures that are only used with imaging modalities. As CMS acknowledges in the proposed rule, SaaS procedures are a heterogeneous group of services that are becoming more widespread across healthcare and are not limited to use with imaging modalities.<sup>20</sup>

***AdvaMed recommends CMS consider the third approach discussed in the proposed rule and develop a pathway for SaaS similar to new technology APCs. We believe it is important to consider each SaaS and as necessary assign HCPCS codes that also recognize the SaaS as a standalone code and as a combined service and assign each code to the appropriate New Technology APC.***

In response to the comment solicitation on a broad payment approach for SaaS procedures, we would first like to suggest that, as important as these proposals are for SaaS for the specific examples that CMS cites in the OPPS proposed rule, a broader vision and framework are needed for accommodating FDA's rapid approval and provider adoption of a wide array of digital technologies across the diverse settings of health care delivery that Medicare covers.

We urge CMS to publish a separate Request for Information (RFI) for all stakeholders to provide their recommendations for a comprehensive rethinking of the overall assumptions and payment methodologies across, not just SaaS, but also AI in its many variations and roles, as well as software as a medical device (SaMD) in all Medicare payment systems. In this RFI, we believe that CMS should first of all clarify how SaaS is different from SaMD. It is our understanding that SaMD is an FDA regulatory term for medical devices that comprise solely of software. It is used by FDA and other global regulators, but it does not have any regulatory relevance. That is to say: FDA refers to software-only devices as SaMD, but SaMD is not a defined term in the FDA law or rules. As a result, it has no special treatment in law. There are guidances and general policy positions that refer to SaMD, but they are not legally binding as a rule or the statute would be. It is also our understanding that not all SaMD are SaaS. Some SaMD may be a component of a larger medical device system that provides certain analysis functions, and in this case, the analysis is not SaaS in the traditional sense. Clarification on these issues will be useful for AdvaMed going forward.

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<sup>20</sup> 87 FR 44688



We also note that at the end of 2020 AdvaMed released a report, *Modernizing Medicare’s Coverage of Digital Health Technologies*<sup>21</sup>, that took such an approach and offered recommendations for specific ways that Medicare’s regulatory policies could be amended across each of the program’s benefit categories to create pathways to coverage and payment for a broad spectrum of digital health technologies. We are now preparing a follow-on report that will look at a subset of digital health technologies—specifically AI, software, and algorithms—and make recommendations of coverage and payment pathways for those digital technologies, again for each of Medicare’s benefit categories and expect to do so with an overarching framework that would result in a consistent approach to considering coverage and payment pathways for AI, SaaS, and SaMD across the benefit categories. In this regard, we believe that the AMA’s new language for defining how AI services support clinical decisions in CPT Appendix S for AI is an appropriate starting point of reference for the type of broad framework that should be used for considering coverage issues related to these and other digital health technologies.

AI, SaaS, and SaMD should not be viewed as “operating in the background” simultaneously for patients. Some types of AI, SaaS, and SaMD should be paid separately because of the added value they provide for a specific patient’s condition, while other types may not need to be paid separately. Furthermore, AI, SaaS, and SaMD may be unique to a specific service and patient diagnosis, warranting an approach to value PE on a case-by-case basis. CMS should also consider the different business models through which AI, SaaS, and SaMD are made available to hospitals, physicians, and other providers, including: (1) a subscription model where the customer pays a monthly fee independent of the number of uses; (2) a per-click model where the customer pays each time the AI is used; (3) a yearly fee; (4) a licensing model; and (5) an add-on payment to a piece of capital equipment. The contractor should analyze how and when these models are used and how they can be incorporated Medicare’s payment systems.

It is urgent that CMS develop a comprehensive framework for how AI, SaaS, and SaMD can be covered across Medicare’s benefit categories if patients are to benefit from the wide variety of digital advances in health care delivery and providers are to be encouraged to incorporate these advances into their practices. This framework should include principles that might apply across Medicare’s benefit categories. For example, a first order principle should recognize that costs for AI, SaaS, and SaMD should be similar across all sites of care and benefit categories, assuming comparable complexity, value, and cost in their applications.

A second principle might be thinking of pathways for coverage and payment beyond conventional approaches of the past. For example, AdvaMed enthusiastically supports CMS in its proposal to act independently of CPT to find new ways to recognize the value of SaaS, and we add, SaMD and AI, in outpatient hospital care and to recognize their value with specific payment. CMS’s proposal demonstrates the need to go beyond CPT and acknowledges implicitly that not one model will fit all applications of these digital technologies to health care across the variety of Medicare’s benefit categories and settings in which beneficiaries seek and receive

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<sup>21</sup> <https://www.advamed.org/wp-content/uploads/2020/09/advamed-modernizing-medicare-coverage-of-digital-health-technologies-september-2020.pdf>



care. We stress that this principle is not limited to radiology and needs to consider SaaS, SaMD, and AI used with all categories of clinical services.

A third principle might be to apply a solution consistently across all services in a benefit category that would provide appropriate reimbursement for this new technology across all payment systems. CMS should consider how the New Technology APC, including the application process, could be consistently used for SaaS, AI, and SaMD and how they could also be used within the Physician Fee Schedule to recognize appropriate payment.

***AdvaMed urges CMS to publish a separate RFI for stakeholders to provide recommendations for a comprehensive reevaluation of the overall assumptions and payment methodologies across SaaS, AI, and SaMD in all Medicare payment systems. We further urge CMS to consider using a comprehensive framework for how these technologies can be covered across Medicare's benefit categories to ensure Medicare beneficiaries can benefit from the wide variety of digital advances in health care delivery and providers are incentivized to incorporate these advances into their practices.***

## **Proposed Updates to the ASC Payment System**

### Device-Intensive ASC Covered Surgical Procedures

#### *Application of the Device Offset to Low-Volume Procedures*

In the CY 2019 OPPS/ASC final rule, CMS established a policy that the default device offset for new codes that describe procedures involving the implantation of medical devices is 31 percent, reflecting the reduction of the device-intensive threshold from 40 percent to 30 percent. As stated by CMS, the purpose of applying a default device offset to new codes that describe procedures that implant or insert medical devices is to ensure ASC access for new procedures until claims data become available.<sup>22</sup>

An important aspect of this policy is CMS's acknowledgement that, in rare instances, a higher offset percentage may be justified by additional information such as pricing data from a device manufacturer (for example, in the case of a very expensive implantable device).

We request that CMS consider a modification to this established policy that would allow for the continuation of the default device offset of 31 percent for procedures with fewer than 100 claims that can be used to calculate the device offset percentage under the C-APC or standard OPPS methodology and which have a device offset under both methodologies of less than 30 percent. CMS should also continue to allow for a higher offset percentage than 31 percent to be applied on a case-by-case basis as warranted for very expensive implantable or insertable devices. The proposed policy modification would essentially serve as an extension of the ASC default device offset policy already in effect, so that it would apply until sufficient claims are available that can be used to calculate a reliable device offset, and not just in the first year a code is created.

In other OPPS/ASC rate setting contexts, services with fewer than 100 claims annually are considered low-volume services, and CMS has acknowledged that there is a higher probability

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<sup>22</sup> 83 FR 58945



the payment data for such services may not have a normal statistical distribution, which could affect the quality of payment rate calculations.<sup>23</sup> Accordingly, to create more stable payment rates, CMS uses alternative statistical methodologies for low-volume new technology services. Some procedures have such a low volume of claims in a given year that it is not possible for CMS to get an accurate representation of the cost of the device relative to the total cost of the procedure. These instances are comparable as when there are no claims data for a procedure, and AdvaMed suggests that CMS follow the same process for determining whether the procedure is device-intensive. CMS should accept pricing data or invoices from manufacturers of devices used in the very low-volume procedures for the device-intensive procedure assessment.

Allowing for the continuation of the default device offset policy beyond the first year a code is available will similarly result in more stable payment rates under the ASC payment system when limited claims data are available. This modification to the existing policy aligns with the policy goal of ensuring ASC access for new procedures, informed by the recognition that diffusion of some valuable new technologies may take longer than one year to result in adequate claims upon which to reliably base ASC device-intensive status and calculate the ASC payment rates.

***AdvaMed recommends CMS:***

- ***Allow for continuation of the default device offset policy beyond the first year a code is available; and***
- ***Consider additional data, such as invoices, in determining the device offset percentage for very low-volume procedures.***

**Proposed ASC Special Payment Policy for OPPS Complexity-Adjusted C-APCs**

CMS proposes to adopt a new ASC payment policy that would apply to certain code combinations in the ASC payment system where CMS would pay for those code combinations at a higher rate to reflect that the code combination is a more complex and costlier version of the procedure performed, similar to the way in which the OPPS APC complexity adjustment is applied to certain paired code combinations that exhibit materially greater resource requirements than the primary service. CMS proposes the ASC payment system code combinations eligible for additional payment under this proposed policy would consist of procedural C-codes for use by ASCs to report encounters involving the procedure combinations that qualify for complexity adjustment under the OPPS. We believe this proposed policy removes a payment disincentive for performing these more complex procedures in the ASC setting, therefore making them a viable option for physicians and improving patient access to these services in the ASC. ***AdvaMed therefore supports this proposal.***

**Improving Transparency in ASC Weight Scalar Adjustment**

In the proposed rule, CMS follows its historical practice to determine the ratio of estimated total ASC expenditures for an upcoming year with estimated total expenditures based on current relative weights and policies. This ratio is known as the ASC weight scalar and is then applied to the OPPS relative weights to ensure overall budget neutrality relative to current ASC payment

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<sup>23</sup> 85 FR 85935



policies (excluding changes in volume or case mix). The proposed CY 2023 ASC weight scalar is 0.8474.

This proposed scaling factor continues the constant decline in this factor since 2008. In fact, the negative adjustment has grown each year from approximately a -6 percent adjustment in 2008 to now over -15 percent. This uninterrupted decline over so many years suggests the cause is an unexplained systematic factor rather than simple year-to-year case-mix variation. As more procedures migrate to the ASC setting and CMS seeks to encourage care provided at the least expensive setting consistent with ensuring the best outcome for the patient, it is imperative that CMS and providers are confident in the accuracy of the ASC payment system.

For CY 2019, CMS changed its basis for determining the annual update to the ASC conversion factor from the consumer price index (CPI) to the hospital market basket in response to the growing payment disparity occurring due to using the consistently lower CPI to update ASC payments. CMS wrote at the time “To the extent that it is clinically appropriate for a beneficiary to receive services in a lower cost setting, we believe it would be appropriate to continue to develop payment incentives and remove payment disincentives to facilitate this choice.”<sup>24</sup> In that same vein, we believe it is appropriate for CMS to undertake an analysis to understand any systemic factors widening the gap between ASC and OPPS payments due to the ASC weight scalar and, if so, to determine whether this administrative (non-statutory) adjustment should be revised or discontinued.

One apparent factor in the CMS methodology is that it begins with the OPPS relative weights for the upcoming year, after applying a similar OPPS scaling factor for budget neutrality, so any change from the prior year is carried over to the ASC scalar calculation. As the OPPS scalar has increased from year-to-year, it introduces an upward bias into the ASC scaling factor calculation of payments for the upcoming year. Unless the same factor driving the upward trend in the OPPS scalar is present in the ASC claims, it will be offset by a downward adjustment in the ASC scalar. While these countering-trends have occurred consistently, further analysis is required to understand particularly what factor has driven the rise in the OPPS scalar and whether a similar factor would likely not be present for ASCs.

Absent an analysis of the factors causing the falling ASC scaling factor, we believe CMS should reconsider the need for the factor. CMS has the discretionary authority to cease the adjustment in light of its effect of widening the payment gap between OPPS and ASCs.

***AdvaMed requests CMS conduct an analysis of the factors driving the rising OPPS scalar and whether a similar factor would likely not be present for ASCs.***

#### Proposed New Technology Intraocular Lenses (NTIOLs)

Since 1999 when CMS first transitioned to paying for NTIOLs in ambulatory surgical centers (ASCs) at a flat rate from a percentage of the standard IOL allowance, the flat rate has remained the same at \$50 for more than two decades.<sup>25</sup> During this period of time, the national Consumer

<sup>24</sup> 83 Fed. Reg. 59076 (November 21, 2018)

<sup>25</sup> 64 Fed. Reg. 32201 (June 16, 1999)





Price Index inflation rate has increased 166 percent.<sup>26,27,28</sup> Therefore, in real dollar terms, the flat rate payment for NTIOLs has significantly lagged behind the overall economic inflation rate and is not reflective of the increased costs associated with research and development to bring new technologies to market.

CMS has previously stated it would revisit the appropriateness of the fee established for cataract surgery with IOL insertion when a lens determined to be an NTIOL is furnished. Specifically, the Agency stated in 2006 that “[o]nly after we have implemented the revised ASC payment system in CY 2008 will we be able to evaluate whether or not the ASC facility fee established for cataract surgery with IOL insertion is appropriate when a lens determined to be an NTIOL is furnished. Therefore, we are retaining for now the current \$50 payment adjustment for a new NTIOL class.”

The IOL industry is at the brink of major innovations. There are several innovative monofocal IOL technologies in development that may provide meaningful outcomes to patients in need of cataract surgery. In order to meet CMS’ original objectives to enable Medicare beneficiaries’ quick access to new technologies, we strongly encourage CMS to consider increasing the per lens payment from \$50 to \$86.49 in CY 2023. Our recommendation for an increase in the payment rate to \$86.49 is based on updating the \$50 payment rate from 1999 to 2022 using the CPI, which results in an updated amount of \$86.49.<sup>29</sup> Additionally, we request that the NTIOL payment be updated annually to reflect CMS’ decision to increase the NTIOL payment will help ensure Medicare beneficiaries have expanded access to future innovation.

***AdvaMed requests CMS:***

- ***Consider increasing the per lens payment from \$50 to \$86.49; and***
- ***Update NTIOL payment on an annual basis.***

**Resolving ASC Co-pay Inequities**

AdvaMed also asks the Agency to examine the feasibility of addressing a longstanding concern regarding the beneficiary co-payment for certain high-cost procedures when performed in the ASC. There are several procedures that have a higher associated patient co-pay when performed in an ASC versus the hospital outpatient department, including procedures that include devices that have received TPT. In the hospital outpatient setting, any incremental TPT payment is not subject to the 20 percent patient coinsurance, while any TPT payment made in the ASC setting is subject to the 20 percent patient coinsurance. This poses a potential financial challenge to beneficiaries who, especially in light of ongoing concerns of contracting COVID-19, may be reticent to have a procedure performed in a hospital as opposed to an ASC.

Patients, in conjunction with their healthcare provider, should have the choice to select the facility where they believe they can safely have a procedure performed and this should not be

<sup>26</sup> CPI Inflation Calculator, [https://www.bls.gov/data/inflation\\_calculator.htm](https://www.bls.gov/data/inflation_calculator.htm)

<sup>27</sup> CMS NHE Factsheet, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet>

<sup>28</sup> National Library of Medicine, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4194743/>

<sup>29</sup> CPI Inflation Calculator, [https://www.bls.gov/data/inflation\\_calculator.htm](https://www.bls.gov/data/inflation_calculator.htm)



dictated by co-pay costs. This is especially important for Medicare patients that may be part of vulnerable and “high-risk for poor outcomes” populations.

***AdvaMed recommends CMS work with Congress to limit the maximum co-pay amounts for ASC procedures to match the maximum co-pay paid by beneficiaries to have these same procedures performed in the hospital outpatient department.***

#### Payment for Non-Opioid Products under Section 6082 of the SUPPORT Act

AdvaMed supports CMS’ discussion to change its payment policies for certain non-opioid therapies and encourages CMS to promote the use of alternatives to opioids, including devices, to combat the opioid epidemic. There are many innovative medical technologies that are already available that can help play a role in combatting this national crisis. These medical devices, including ones that provide effective pain management solutions, have the potential to reduce Medicare beneficiaries’ dependence on opioids and help curb opioid misuse, abuse, and overdose.

AdvaMed has raised concerns in the past regarding the impact of surgical supply packaging policies on the use of non-opioid alternative technologies. Specifically, we have commented on the need to unbundle certain of these supplies to incentivize use of devices which could be instrumental in helping to combat the opioid epidemic facing our nation. Evaluating the impact of packaging policies by focusing solely on whether there has been a decline in the use of non-opioid medical devices misses the mark. In order to make a more reasonable determination regarding the need to unpackage opioid alternative devices in the outpatient setting, CMS should evaluate the utilization of all said devices and assess their rate of utilization as compared to post-surgical prescribing of opioids.

Removing the barriers created by bundled payment and establishing separate payment for the opioid alternative devices used in surgical procedures gives healthcare providers the freedom to evaluate pain management treatments based on effectiveness and appropriateness without being unduly influenced by the costs of the available options.

***AdvaMed urges CMS to pay separately for non-opioid device alternatives in both the outpatient and ASC setting, especially when there is peer-reviewed, published evidence demonstrating opioid reduction and effective pain management.***

#### **Requirements for the Rural Emergency Hospital Quality Reporting (REHQR) Program**

##### Request for Comment on Additional Measurement Topics and for Suggested Measures for REH Quality Reporting

AdvaMed previously submitted comments to CMS regarding improvements to quality metrics as a mechanism for improving, advancing, and monitoring health equity including via modifications to the maternal health structural measures to facilitate improvements in maternal health disparities. We appreciate the Agency’s ongoing commitment to increasing health equity through this request for comment regarding Rural Emergency Hospitals (REH). REHs can be the closest, most accessible, and most reliable source of care for patients living in rural areas. For these patients the services available at an REH may mean the difference between delayed or



denied care due to the distance and proximity of care from both primary care doctors and specialists.

The proposed rule lays out several options for improving equity including telehealth, maternal health, mental health, Emergency Department services, and equity. These areas are distinct yet the means for addressing them is, in many ways, interconnected. As CMS develops additional quality metrics for these facilities, we would ask that the Agency be cautious in ensuring that those metrics take into consideration the unique challenges of REHs and does not penalize these entities because of their unique attributes. For instance, because of the distance between some patients and the nearest health care provider they may rely on REHs, including the emergency departments within these facilities, for routine care. Therefore, CMS should be mindful that metrics related to “bounce back” visits do not penalize these facilities in instances where patients may be returning for follow-up care or presenting for treatment of a new condition.

The proposed rule also asks for feedback on the use of telehealth and remote monitoring services to render care and to support REHs in addressing the needs of mental and maternal health patients. AdvaMed continues to strongly support the use of remote monitoring and telehealth services as a viable alternative for receiving needed care. We are cognizant, however, of the limitations of telehealth services in certain rural areas that lack sufficient infrastructure and broadband connectivity. Additionally, certain patients lack access to the internet and other services that will allow them to utilize these alternative care options. CMS must ensure that there are regulations and policies which accommodate the use of and ongoing access to remote monitoring and telehealth services by REHs post termination of the public health emergency, including continued expansion of the ability to provide telehealth services. CMS must also ensure that these REHs, their surrounding communities, and patients have the financial and continuing infrastructure support to allow use of these novel approaches to care—this includes improving familiarity with these services and providing education, resources, and technology for patients.

AdvaMed looks forward to continuing to work with CMS and other stakeholders as additional approaches are developed to expand health equity through the use and creation of quality measures and other resources.

### **Addition of a New Service Category for Hospital Outpatient Department Prior Authorization Process**

The proposed rule recommends facet joint interventions (CPT codes 66490-64495 and 64633-64636) be subject to prior authorization for dates of service on or after March 1, 2023. The information in the proposed rule suggests CMS believes increases in the outpatient volume for these procedures is unnecessary.

While we understand CMS’ desire to protect the Medicare Trust Funds from unnecessary increases in volume of services and improve program integrity as a whole, we remain concerned with the use of prior authorization programs within Medicare and their impact on patient access to care. Requiring prior authorization, while necessary in some cases, can lead to delayed care and increased administrative burden for providers—which seems to contradict CMS’ ongoing



efforts to reduce burdens for patients and providers. Moreover, if prior authorization requests are administered incorrectly or unnecessarily denied for any reason, this may cause further delays to care, which can have dire consequences for the patient. AdvaMed members, their customers, and the patients they serve have experienced significant frustrations with prior authorization programs, both in Medicare Advantage and commercial payer plans, which often curtail or deny access to patient management products or treatments and provide few opportunities for redress or appeal.

***AdvaMed urges CMS to exercise caution in implementing prior authorization requirements in Medicare programs, and further requests the Agency closely monitor and publicly report on the outcomes of its prior authorization program to ensure patient access to these procedures is not unduly affected by the increased administrative burden of these reviews.***

Once again, we appreciate this opportunity to provide our input and recommendations for CMS' consideration in development of the CY 2023 OPPS/ASC final rule. If you have any questions or need additional information, please contact Kirsten Tullia ([ktullia@advamed.org](mailto:ktullia@advamed.org)).

Sincerely,



Chandra N. Branham, J.D.

Senior Vice President and Head of Payment & Healthcare Delivery Policy

