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**Comments to
Centers for Medicare and Medicaid Services
Advisory Panel on Hospital Outpatient Payment
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On behalf of the
Advanced Medical Technology Association**

AdvaMed appreciates the opportunity to address the Advisory Panel on Hospital Outpatient Payment (the Panel) and commends the Panel on its efforts to evaluate and improve the APC groups under the hospital outpatient prospective payment system (OPPS) and to ensure Medicare beneficiaries have timely access to new technologies.

AdvaMed member companies produce the medical devices, diagnostic products, and health information systems 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.

AdvaMed is committed to ensuring patient access to lifesaving and life-enhancing devices and other advanced medical technologies in the most appropriate settings and supports a system with payment weights and payment rates that include sufficient resources to account for the costs of the medical technologies associated with hospital outpatient and ambulatory surgical center procedures.

Our comments today will address the following topics:

- Reconfiguring APCs
- Comments on Specific APCs

Reconfiguring APCs

Complexity Adjustment for Coronary Intravascular Lithotripsy

Percutaneous coronary lithotripsy (PCI) procedures involving coronary intravascular lithotripsy (coronary IVL) are described by an add-on CPT code, +92972.¹ Coronary IVL is exclusively utilized in complex artery disease; PCI procedures utilizing coronary IVL require additional

¹ From July 2022 to December 2023, coronary IVL was described by Category III CPT +0715T.



hospital resources than standard PCI procedures. CMS did not perform a complexity adjustment analysis for this code in the CY 2025 OPPTS/ASC proposed rule. However, claims analysis demonstrates that when coronary IVL is performed, select primary J1 procedures currently assigned to APCs 5192 and 5193 qualify for a complexity adjustment.

We believe one factor why this analysis was not completed in the proposed rule is that CPT code +92972 (previously +0715T) was eligible for transitional pass-through payment (TPT) (C1761) through June 30, 2024. This mid-year TPT expiration may have inadvertently excluded this code from CMS' complexity adjustment analyses because the TPT code was still listed as active in data sets used during development of the proposed rule. However, we are concerned failure to perform this analysis to determine whether coronary IVL is eligible for complexity adjustments with qualifying J1 procedure code combinations beginning January 1, 2025 will hinder access to coronary IVL.

AdvaMed recommends the Panel:

- *Request CMS conduct a complexity adjustment for coronary IVL as part of the CY 2025 OPPTS/ASC final rule.*

Complexity Adjustments for Noncoronary IVUS, Coronary IVUS, and FFR/iFR

AdvaMed is concerned that the volume of claims for certain code combinations of cardiovascular J1 primary and related add-on services are not being appropriately accounted for in evaluating for complexity adjustments. In particular, analysis of 2022 OPPTS Medicare claims data (rate setting file) conducted by Braid-Forbes Health Research (BFHR) found that the volume of claims with 1 J1 code and an add-on code for either noncoronary IVUS (37252), coronary IVUS (92978), or FFR/iFR (93571) was significantly greater than the volume CMS evaluated for complexity adjustments in Addendum J of the CY 2024 OPPTS/ASC proposed rule.²

The table below summarizes how many J1 codes were billed with each of these add-on codes, as reflected in the rate-setting file. Line 2 shows the volume of claims with the code combination of 1 J1 and add-on service (i.e., 37252, 92978, or 93571). Line 6 shows the volume of claims for the same code combinations used to evaluate complexity adjustments in Addendum J. The volume of claims for all the J1 and add-on code combinations, as reflected in the rate-setting file (Line 2), was greater than the volume reflected in Addendum J (Line 6) and evaluated for a complexity adjustment. For example, only 1,336 instances of 37252 were evaluated for a complexity adjustment despite 4,533 claims with 37252 and 1 J1 code found in the rate-setting file. Note, a similar divergence in volume of claims used to evaluate the complexity adjustment for these code combinations can be found in the CY 2025 OPPTS/ASC proposed rule.

² See CY2022 OPPTS data file released with the CY 2024 OPPTS/ASC proposed rule.



Table. Count of J1 Codes by Add-on Codes of Interest

Line #	Combination	37252	92978	93571
1	Add-on with no J1 codes	697	123	118
2	With 1 J1 Code	4,533	12,434	27,645
3	With 2 J1 Codes	2,318	23,117	12,844
4	With 3 or more J1 Codes	487	3,925	1,734
5	Total Claims w/ Add-on	8,035	39,599	42,341
6	In Addendum J Evaluation	1,336	4,047	9,307

We appreciate that one reason why the volume count may not match the analysis in Addendum J is because other add-on codes that could be billed with the same J1 code may also be found on the claim. As AdvaMed continues to recommend, expanding review of procedure combinations to include clusters of J1 and add-on codes, rather than only code pairs, would address this issue and better reflect medical practice when multiple procedures are performed together. However, even with this constraint, we expect additional volume of claims to be used in the evaluation of complexity adjustment for these code combinations. For example, the CY 2024 proposed rule Addendum J revealed that the code combinations of the J1 code 93457 and add-on code 93571 had a frequency of 17 claims – less than the requisite 25 or more claims to meet the complexity adjustment criteria. However, Braid-Forbes found 60 claims in the rate-setting file with the J1 code 93457 and the add-on code 93571, and no other J1 or add-on codes. This divergence in claim frequency is critical given that the code combination did not trigger a complexity adjustment for CY 2024 due to failing the frequency criteria, not the geometric cost criteria. BFHR was only able to match the Addendum J count when limiting the claims to only add-on code 93571 with no modifiers coded. CMS has specified in the claims accounting document and OPPTS regulation text that primary procedure codes with modifiers -73 and -74 are removed from the complexity adjustment evaluation but does not reference any others.³

AdvaMed therefore recommends the Panel:

- *Request CMS to provide additional information and greater transparency on the methodology used to evaluate the complexity adjustment frequency criteria for the code combinations of cardiovascular J1 primary and related add-on services including noncoronary IVUS (37252), coronary IVUS (92978), and FFR/iFR (93571). In particular, we request CMS to indicate the rationale for not counting claims that reflect code combinations of these services that would otherwise meet the frequency criteria including whether CMS removes claims from the complexity evaluation if there is a modifier coded on any J1 procedure or add-on procedure.*

³ See Medicare CY 2024 OPPTS Proposed Rule Claims Accounting document released with the CY 2024 OPPTS/ASC proposed rule.



Comments on Specific APCs

Transcatheter Therapeutic Drug-Delivery by Intracoronary Drug Delivery Balloon

CPT code 0913T was established this year by the American Medical Association (AMA), with the recognition of the need to establish unique and accurate codes separate from coronary angioplasty and stenting procedures to describe coronary drug-coated balloon procedures. 0913T is a new PCI service intended to treat a complex patient population—coronary in-stent restenosis—and like other PCI base codes, 0913T is a bundled service that includes mechanical dilation and intravascular imaging prior to drug-delivery. In the CY 2025 OPSS/ASC proposed rule, CMS is proposing to assign this new code to APC 5192. We are concerned the proposed assignment of 0913T inaccurately reflects the clinical complexity and resource utilization associated with this procedure. Below is data from the first 2.5 months of commercial availability of this technology at the top enrolling hospital for the associated IDE trial, analyzed using the most recent cost reports from the CY 2023 OPSS ratesetting file:

Summary of Total Coverage Costs

Total Frequency	Minimum Cost	Maximum Cost	Median Cost	Geometric Mean Cost	CV
11	\$13,124.80	\$28,297.18	\$17,989.85	\$18,935.69	24.425

While this sample size is small, these procedures involve little to no learning curve; therefore, we believe these costs to be representative of true population costs as these procedures are performed by more hospitals over time.

AdvaMed therefore recommends the Panel:

- *Recommend CMS assign 0913T (XX23T) to APC 5193 for CY 2025.*

Quantitative Magnetic Resonance Tissue Composition Analysis

CPT codes 0648T/0649T⁴ and 0697T/0598T⁵ are currently assigned to New Technology APC 1511 at a payment rate of \$950.50. In the CY 2025 OPSS/ASC proposed rule, CMS is proposing to reassign CPT codes 0648T/0649T to APC 1504 at a rate of \$250.50 and to reassign codes 0697T/0698T to APC 1509 at a rate of \$750.50. In proposing to reassign these codes, CMS applied its universal low volume APC policy; however, the proposed payment adjustments for these technologies would not accurately or appropriately pay for these services.

The arithmetic mean cost of CPT codes 0648T/0649T was calculated as \$234, a difference of \$716.50 from its current payment rate, or a 75% decrease. The reason for this disparity is the

⁴ CPT Codes 0648T/0649T describe a Software as a medical Service (SaaS) that is intended to aid the diagnosis and management of chronic liver disease, the most prevalent of which is Non-Alcoholic Fatty Liver Disease (NAFLD). It provides standardized, quantitative imaging biomarkers for the characterization and assessment of inflammation, hepatocyte ballooning, and fibrosis, as well as steatosis, and iron accumulation.

⁵ Codes 0697T/0698T describe a medical image management and processing software package that analyzes MR data and provides quantified metrics of multiple organs such as the heart, lungs, liver, spleen, pancreas, and kidney.



wide variability in the claims data which therefore distorts applicability of the universal low volume APC for the appropriate and accurate payment rate and skews the arithmetic mean value. By assessing collated claims data from CY 2021 – CY 2023 to reach the threshold of 100 claims, CMS has assessed periods of fluctuating reimbursement assigned to these codes, ranging from \$0 to \$250.50 to \$950.50 that in itself will distort the analysis of billed charges.

The CY 2025 proposed rule also applies the universal low volume APC policy to CPT codes 0697T/0698T, which had zero claims and 46 claims for codes 0697T and 0698T, respectively. The median cost is estimated by CMS to be \$786. However, we have similar concerns regarding data instability in the claims on which the APC classification and payment rates are assigned due to limitations in technologies available to perform this procedure in the U.S. market.

We are concerned these proposed assignments will result in significant underpayment to hospitals and, in turn, limit beneficiary access to these services. In addition, the new proposed rates do not adequately cover either the cost of the service provided, nor the additional administrative burden that a hospital site must manage to implement the service (MRI technicians, exam scheduling, information security, Radiology reading time, legal contracting). By reducing the reimbursement rate to an unfeasibly low amount, the Medicare payment determination would create a significant impediment to access for patients that need this procedure as prescribed by their physician. That would be detrimental to Medicare beneficiaries, and that is particularly problematic when the proposed APC reassignment is based on insufficient claims data, as CMS has recognized in connection with this and other SaaS services.

AdvaMed therefore recommends the Panel:

- *Recommend CMS not finalize its proposal to reassign CPT codes 0648T and 0649T to APC 1504 and instead maintain their current assignment to APC 1511 (New Technology – Level 11 (\$950.50) for CY 2025.*
- *Recommend CMS not finalize its proposal to reassign CPT codes 0697T/0698T to APC 1509 and instead maintain their current APC 1511 (New Technology – Level 11 (\$950.50) for CY 2025.*

Neurostimulator and Related Procedures

APC Placement for Implantation or Replacement of Carotid Sinus Baroreflex Activation Device and Phrenic Nerve Stimulation System

HCPCS codes 0424T and 33276 and CPT Code 0266T are currently assigned to New Tech APC 1580, with a payment rate of approximately \$45,000. CMS is proposing to reassign these codes to APC 5465, Level 5 Neurostimulator and Related Services. The proposed payment for APC 5465 is \$30,197. However, the geometric mean costs for these codes significantly exceed this payment rate, as demonstrated in the table below.

Code	Proposed Payment Rate	Single Frequency	Total Frequency	Geometric Mean Cost
0424T/33276	\$30,197.67	102	104	\$45,816.29



0266T	\$30,197.67	256	262	\$41,069.38
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This absolute difference between the cost of the implant procedure and the APC payment is significant, and AdvaMed is concerned that hospitals will limit access to this important technology given the severe financial loss incurred on each Medicare patient. We therefore request the HOP Panel recommend to CMS that HCPCS codes 0424T and 33276 and CPT code 0266T remain in New Tech APC 1580 for CY 2025 payments. This will help alleviate the pending financial loss to hospitals beginning in CY 2025 as this APC assignment more closely reflects the cost of the procedure. CMS has previously reassigned other procedures in a similar situation to New Technology APCs, including CPT codes 0424T and 0100T.

AdvaMed therefore recommends the Panel:

- *Recommend CMS maintain assignment of HCPCS codes 0424T and 33276 and CPT code 0266T to New Tech APC 1580 for CY 2025.*

APC Placement for Incision for Implantation of Cranial Nerve (e.g., Vagus Nerve) Neurostimulator Electrode Array and Pulse Generator

CPT Code 64568 is currently assigned to APC 5465, Level 5 Neurostimulator and Related Services. The proposed payment for APC 5465 is \$30,197. However, the geometric mean cost (GMC) of CPT code 0266 is \$44,127, which is a difference of \$13,930. This absolute difference between the cost of the implant procedure and the APC payment is significant, and AdvaMed is concerned that hospitals will limit access to this important technology given the severe financial loss incurred on each Medicare patient. We therefore request the HOP Panel recommend to CMS that CPT code 64568 be reclassified from APC 5465 to APC 1580 based on the GMC of the procedure. This will help alleviate the pending financial loss to hospitals beginning in CY 2025 as this APC assignment more closely reflects the cost of the procedure.

AdvaMed therefore recommends the Panel:

- *Recommend CMS reassign CPT code 64568 from APC 5465 to APC 1580 for CY 2025.*

APC Placement for Integrated Vagus Nerve Neurostimulation

XX32T is a new code recently created by the AMA to report services for integrated neurostimulator system for vagus nerves. CMS is proposing to assign this code to APC 5462, Level 2 Neurostimulator and Related Procedures, with a payment rate of \$6,557. While the technology associated with this code is still undergoing FDA review with approval expected in 2025, its clinical complexity and resource use are most analogous to procedures currently captured under APC 5465, Level 5 Neurostimulator and Related Procedures. The surgical procedure to access the cervical vagus nerve, including the procedure time, surgical tools and techniques, as well as physicians performing the procedure is very similar to the placement of the traditional (non-integrated) vagus nerve stimulation devices described by CPT code 64568. The clinical homogeneity between these procedures can be verified through clinical trial experience for the integrated vagus nerve neurostimulator, which includes over 250 implant procedures to date. Based on CY 2022 claims for this code, procedure costs are \$6,101 (excluding the device



related portion). As a result, this code's proposed assignment to APC 5462 falls far short of covering the resource costs associated with this procedure. We are therefore concerned this proposed assignment inaccurately reflects the clinical complexity and resource utilization associated with this procedure.

AdvaMed therefore recommends the Panel:

- *Recommend CMS assign CPT code XX32T to APC 5465 for CY 2025.*

APC Placement for Integrated Sacral Neurostimulation

CPT code 0786T was created to distinguish integrated from non-integrated permanent sacral nerve stimulation procedures. This Category III code was made effective January 2024, despite the fact that no FDA-cleared device/procedure exists, making it challenging for CMS to assign an accurate APC at that time. There is technology in clinical trial that is expected to receive FDA clearance and be commercially available in 2025.

CMS is proposing to assign 0786T to APC 5463, Level 3 Neurostimulator and Related Procedures. However, procedures performed with an integrated system (reported with CPT code 0786T) and a non-integrated system (reported with CPT code 64590) are equivalent in terms of both procedural and cost considerations, and clinical homogeneity between these procedures can be verified through clinical trial data, including more than 130 procedures performed to date. Additionally, the proposed APC assignment for CPT code 0786T is inadequate based on resource homogeneity with non-integrated technology because the integrated system has all of the same components as the non-integrated system, only configured in a different manner, and the anticipated outpatient hospital ASP for an integrated system is similar to or higher than that of non-integrated technology.

AdvaMed therefore recommends the Panel:

- *Recommend CMS reassign CPT code 0786T from APC 5463 to APC 5464.*

CMS Payment for Wound Care Products

In addition to the above, we express support for the recommendations provided by the Alliance of Wound Care Stakeholders, as detailed below. These recommendations stem from two patient access issues related to the prohibitive costs HOPDs incur if they provide medically necessary skin substitutes or Cellular and/or Tissue-Based Products for Skin Wounds (CTPs) to patients with larger wounds/ulcers.

Assignment of Wound Care Add-On Codes to Appropriate APCs

The first barrier to access relates to the add-on codes. When the payment for CTPs were packaged into the payment for the application, the add-on codes were also packaged. Because the add-on codes represent wounds and ulcers that require the purchase of additional product, patients with wounds larger than 25 sq. cm. up to 99 sq. cm. and also those greater than 100 sq. cm. are not being offered medically necessary CTPs in the HOPDs. The reason for this is the add-on codes that are packaged into the OPSS bundled rates are not adequate to allow the



HOPDs to purchase the sizes of CTPs necessary to apply to all wound sizes. In fact, none of the add-on codes have been available for additional payment.

To remedy this issue, AdvaMed urges the Panel to recommend that CMS issue an exception for the payment of CTP application add-on codes. Allowing payment for the add-on codes is an easy remedy for CMS to implement and there has been precedent set in CMS providing these types of exceptions (e.g., chemotherapy).

AdvaMed therefore recommends the Panel:

- *Recommend CMS assign the existing CPT add-on codes (15272 and 15276; and 15274 and 15278) to an appropriate APC group allowing for payment and issue an exception for the payment of CPT add-on codes.*

Assignment of APC for the Same Size Wound Regardless of Anatomical Location

The second access issue relates to the anatomic location of the wound/ulcer and the APC group that CMS has assigned to the application procedure code. The APC group assignment should be the same for the same size wound/ulcer whether the ulcer is located on the leg or foot, since the same resources and amount of product must be purchased. However, that is not how CMS has assigned the APCs. Currently, coding for a wound/ulcer on the leg differentiates procedures based on wound size. For example, a 75 sq. cm. wound/ulcer would be coded to CPT code 15271 and assigned to APC 5054, while a 125 sq. cm. wound/ulcer would be coded to CPT code 15273 and assigned to APC 5055 based on the increased resource use. By contrast, current codes for a wound/ulcer on the foot of 75 sq. cm. (CPT code 15275) or 125 sq. cm. (CPT code 15277) are both assigned to APC 5054, despite the HOPD using 50 sq.cm. more product for the latter procedure.

AdvaMed therefore recommends the Panel:

- *Assign the application codes for 100 sq. cm. wounds/ulcers on the feet to the same APC (5055) as the application codes for 100 sq. cm. wounds/ulcers on the legs.*

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