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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 life-saving 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 Adjustments

CMS has developed a process for identifying and applying complexity adjustments to certain combinations of codes as 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 OPPS/ASC final rule but believe important opportunities to refine the methodology remain.

AdvaMed recommends the Panel:

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

Comments on Specific APCs

Proposed APC Placement for Imaging of the Retina for Detection or Monitoring of Disease; with Point-of-Care Autonomous Analysis and Report

CPT code 92229 is currently assigned to APC 5733, Level 3 Minor Procedures. CMS is proposing to reassign this code to APC 5732, Level 2 Minor Procedures with payment rate $37.05. In proposing to reassign CPT code 92229 to APC 5732, CMS relies on geometric mean cost data from 2021, a brief period where the code was carrier priced and there were only 174 single claims.[1] During this time, Medicare Administrative Contractor (MAC) pricing for this code varied significantly, with some MACs recognizing the complete service in the primary care setting[2] while others priced the code as low as $11[3]. CMS subsequently finalized a policy to crosswalk CPT code 92229 to CPT code 92325 based on similar resource costs,[4] which remains in effect today.

CMS should maintain consistency in its recognition of resource costs to deliver the services described in CPT code 92229, and we note that while CMS is proposing to reassign CPT code 92229 to a lower APC, it is maintaining assignment of CPT code 92325 to a higher APC (5734), despite the Agency's own acknowledgement of the similar resource costs between these codes. The service described by CPT 92229 represents a major advance in health equity and reaches underserved populations with diabetes. The CPT code 92229 describes a complete diagnostic service using autonomous AI authorized by the FDA at the point-of-care and not simply an imaging service with lower resource costs. We believe APC 5733 (with payment rate $58.13) appropriately reflects the resource costs of providing these services in

[1] Centers for Medicare & Medicaid Services, "Revisions to Payment Policies under the Medicare Physician Fee Schedule, Quality Payment Program and Other Revisions to Part B for CY 2021," CMS-1734-F.
[2] Novitas, "Fee Lookup." Available at https://www.novitas-solutions.com/webcenter/portal/MedicareJH/FeeLookup. Accessed: Aug 26, 2021.
[3] Pricing provided by National Government Services, or NGS.
[4] 86 FR 64996 through 66031

the outpatient setting and is consistent with assignment for other similar clinical services.

AdvaMed therefore recommends the Panel:

- *Recommend CMS not finalize its proposal to reassign CPT Code 92229 to APC 5732 and instead maintain the current assignment of CPT Code 92229 to APC 5733 with a status indicator of S effective January 1, 2024.*

APC Placement for Implantation or Replacement of Carotid Sinus Baroflex Activation Device

CPT Code 0266T currently is assigned to APC 5465, Level 5 Neurostimulator and Related Services. The proposed payment for APC 5465 is $30,355. However, the geometric mean cost (GMC) of CPT code 0266 is $45,996, which is a difference of $15,641. 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 0266T 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 2024 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.

A*dvaMed therefore recommends the Panel:*

- *Recommend CMS reclassify CPT code 0266T from APC 5465 to APC 1580 effective January 1, 2024.*

APC Placement for Endovascular Lower Limb Procedure for Patients with No-Option Chronic Limb-Threatening Ischemia

CPT code 0620T describes transcatheter arterialization of the deep veins (TADV) with the LimFlow System, a new implant procedure for patients with chronic limb-threatening ischemia (CLTI) who have no suitable surgical or endovascular revascularization options and are at risk of major amputation. This code is currently assigned to APC 5194, Level 4 Endovascular Procedures; however, the GMC of CPT code 0620T is well above the GMC for APC 5194 ($29,305 for CPT code 0620T versus $17,655 for APC 5194), and also exceeds the two times threshold ($27,065).

We are concerned continued assignment of CPT code 0620T to APC 5194 will result in significant underpayment to hospitals and, in turn, significantly limit beneficiary access to this procedure both within the ongoing LimFlow TADV Medicare-Covered Continued Access Study and after FDA approval.

A*dvaMed therefore recommends the Panel:*

- *Recommend CMS reclassify CPT code 0620T from APC 5194 to New Tech APC 1579 to more accurately reflect the resources used in this procedure.*

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 OPPS 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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