AdvaMed
Advanced Medical Technology Association

Comments to
Centers for Medicare and Medicaid Services
Advisory Panel on Hospital Outpatient Payment
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Submitted By: DeChane L. Dorsey, Esq.
On behalf of the
Advanced Medical Technology Association (AdvaMed)

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 that Medicare beneficiaries have timely access to new technologies.

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.

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 two topics:

- **Reconfiguring APCs**
- **Comments on Specific APCs**

I. Reconfiguring APCs

There are several issues related to reconfiguring APCs that we would like to address.

Complexity

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 that the Panel request that 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.***
- ***AdvaMed recommends that the Panel request that CMS continue to monitor and report on the impact of applying complexity criteria on APC assignments for code combinations within the comprehensive APCs.***

Lowering the Device Offset Threshold to 25%

In 2019, CMS changed its device offset policy, decreasing its previous threshold from 40% to 30%. This change recognized more of the costs for device-intensive procedures across different sites of service, specifically for procedures migrating to ambulatory surgical centers (ASCs).

The logic supporting this CMS policy change is compelling. However, as more procedures become suitable for ASCs, the risk of excessive payment gaps increases when device costs do not reach the 30% thresholds currently needed to "carry over" device costs from HOPD to ASC rates. For instance, if the device cost constitutes 25% of the mean procedure cost it is not recognized when the procedure is performed in an ASC. This 5% difference can impact an ASCs decision on which types of cases to perform, due to concerns regarding costs exceeding payment levels, and can result in reduced access to care in ASC settings that can be more convenient and, in some cases, less costly for beneficiaries.

Recognizing the full device costs of procedures is imperative as more procedures with varying degrees of device-intensity shift from outpatient to ASC settings.

- ***AdvaMed urges the Panel to recommend that CMS reduce the device offset threshold to 25%, from its current level of 30%, to better recognize the costs of device-intensive procedures migrating to ASC settings.***

Elimination of the Inpatient Only Procedure List

The proposed rule contains a recommendation to begin phasing out the Inpatient Only (IPO) Procedure list by removing 266 procedures from the list and allowing them to be performed in the outpatient setting effective January 2021. The rule goes on to propose that the entire list would be eliminated by CY 2024.

AdvaMed, while understanding the sentiments expressed regarding allowing providers to determine appropriate settings taking safety and other factors into account and the need to have patients have more choices over where to access care, is still concerned by the pace at which these changes are proposed for implementation, the lack of clarity regarding the process CMS will use to identify which procedures will be removed and when over the course of the next 3 years, and the lack of available data upon which to calculate payment rates that accurately reflect the costs of the many procedures that will be affected in the short- and long-terms. We are similarly concerned that the assignment of IPO procedures to existing APC groupings may result in inadequate payment—especially placement in groupings that have historically presented challenges in terms of the clinical and resource homogeneity. Additionally, we are concerned

that there may be unintended consequences for site of service practice patterns more broadly that could negatively impact patient outcomes.

- ***AdvaMed urges the Panel to recommend that CMS work closely with all interested stakeholders, including medical technology manufacturers, as it determines the criteria for determining removal of families of codes from the IPO list and before finalizing a proposal that would altogether eliminate the IPO list.***
- ***We also urge the Panel to recommend that CMS work with and allow stakeholder feedback on the assignment of these procedures to appropriate clinical APC and New Technology APC groupings.***
- ***We urge the Panel to recommend that if CMS proceeds, a plan should be in place to monitor any impact shifts in site of service may have on patient outcomes.***

Removing Total Ankle Replacement (TAR) and Total Shoulder Replacement (TSR) from the IPO

CMS is proposing to remove total ankle replacement (TAR) and total shoulder replacement (TSR) from the IPO and is recommending outpatient payment for these procedures be assigned to level 5 of the musculoskeletal APC grouping 5115. The proposed payment may compromise patient access to TAR and TSR in the outpatient setting.

- ***AdvaMed urges the Panel to recommend that CMS consider input from interested stakeholders and work with these stakeholders to determine the appropriate APC assignment and reimbursement rate for the TAR and TSR procedures.***

Lastly, if CMS removes TAR and TSR from the IPO list, CMS should continue to provide a two-year exemption from site-of-service denials and Recovery Audit Contractor (RAC) referrals. CMS should also inform providers that CMS policy allows for case-by-case exceptions to the "Two Midnights" rule based on patient history, co-morbidities and risk of adverse events. This would help ensure that concerns about such audits do not unduly influence the selection of an outpatient setting unless it is medically appropriate.

II. Comments on Specific APCs

Review of Electrocorticograms from an Implanted Brain Neurostimulator

CPT code 95836 was approved for use effective January 1, 2019. This code, for the review of electrocorticograms from an implanted brain stimulator, was assigned to APC 5741 (Level I Electronic Analysis of Devices) and is proposed to remain in that same grouping for CY 2021. AdvaMed has concerns regarding the placement of this code into APC 5741 as we do not believe that payment for this grouping adequately reflects the resources used by hospitals in performing this procedure.

- ***AdvaMed urges the Panel to recommend that CMS assign CPT code 95836 to APC 5742 (Level 2 Electronic Analysis of Devices) for CY 2021.***

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AdvaMed encourages the Panel to continue to recognize the unique challenges associated with device-dependent procedures and urges the Panel and CMS to carefully consider the timeliness, adequacy, and accuracy of the data and the unique perspective that manufacturers bring to these issues.

Thank you.

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