



**Comments to
Centers for Medicare and Medicaid Services
Advisory Panel on Hospital Outpatient Payment
August 22-23, 2016**

**Submitted By: DeChane L. Dorsey, Esq. July 18, 2016
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 three key topics:

- **Reconfiguring APCs**
- **Comments on Specific APCs**
- **Timing of HOPs Meetings**

I. Reconfiguring APCs

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

Comprehensive APCs

CMS introduced the concept of comprehensive APCs (C-APCs) in the CY 2014 Outpatient Prospective Payment System rule. Since that time the agency has continued to create additional comprehensive APCs (C-APCs) and to make modifications to the policies governing development and use of these payment groupings.

C-APCs were first used on Medicare claims in CY 2015. The claims data used to generate the CY 2017 OPPS rates represents the first full year of claims data that has been used for rate

setting since establishment of C-APCs-- presenting the first real opportunity to see the impact of these changes on reimbursement for and utilization of these services.

AdvaMed has previously expressed concerns regarding whether the rates associated with the comprehensive APC's adequately or accurately reflect all of the procedures and costs associated with those APCs. This is of particular concern as CMS continues to expand the number of packaged and bundled services.

- *AdvaMed encourages the Panel to recommend that CMS analyze the claims data and to provide a report on the impact of the conversion to C-APCs for the 25 C-APCs that went into effect on January 1, 2015.*
- *AdvaMed encourages the Panel to recommend that CMS monitor and report on the impact of comprehensive APC changes on all affected codes and any potential impacts to patient access to services that are bundled under the comprehensive APCs.*

Lastly, the timing of the release of the proposed CY 2017 OPSS rule and the inability to analyze the claims data in advance of the statement due date for this meeting makes it impossible to assess the potential impact of the proposed CY 2017 C-APC expansion at this time. However, AdvaMed plans to evaluate these changes and to provide additional comments to CMS as part of our comments on the rule.

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 has repeatedly expressed concerns regarding appropriate application of complexity criteria and the resulting APC assignments for codes within the comprehensive APCs. We are pleased that CMS has proposed to discontinue the requirement that a code combination that qualifies for complexity adjustment must not create a 2 times violation in the new or higher level APC. AdvaMed views this as a positive step in ensuring appropriate application of the policy and resultant appropriate APC placement.

- *AdvaMed requests that the Panel recommend that CMS finalize the proposal to discontinue the 2 times rule violation requirement as it applies to complexity adjustments for codes combinations.*
- *AdvaMed requests that the Panel recommend that CMS continue to monitor and report on the impact of applying complexity criteria on APC assignments for code combinations within the comprehensive APCs*

Device-Intensive APCs/Procedures

For CY 2017, CMS proposes that the payment rate for any device-intensive procedure that is assigned to an APC with fewer than 100 total claims for all procedures in the APC be based on the median cost instead of the geometric mean cost.

AdvaMed agrees that this statistical approach for low volume APC claims can reduce unnecessary payment rate fluctuations.

- ***AdvaMed asks the Panel to recommend that CMS determine payment rates based on median cost for an APC with fewer than 100 total claims.***

CMS also proposes to revise the device intensive calculation methodology to calculate the device offset amount at the HCPCS code level rather than at the APC level-- to ensure that device intensive status is properly assigned to all device-intensive procedures.

AdvaMed proposed this change in comments on the CY 2016 proposed rule. This change will likely result in more accurate ASC payment for device intensive procedures, particularly those recently assigned to non-intensive APCs. Since the ASC list payment rates are determined at the HCPCS level, assignment of device intensity at this level is both logical and efficient.

AdvaMed also supports CMS' proposal to assign a default level of at least 41 percent device offset to new procedures that are device-intensive until claims data are available to calculate the actual device offset for the new code.

- ***AdvaMed asks the Panel to recommend that CMS finalize the proposal to calculate device offset at the HCPCS level and that the agency amend the applicable regulations to reflect that CMS would no longer be designating APCs as device-intensive, and instead would be designating procedures as device-intensive.***

- ***AdvaMed asks the Panel to recommend that CMS finalize the proposal to assign a default device offset of at least 41 percent to new HCPCS procedures that involve implantation of medical devices but do not have associated claims data. We further recommend that device offset be calculated during the first rule year for which sufficient claims data are available.***

Device Edits

AdvaMed has previously expressed concern regarding the elimination of device edits. Device edits have historically been very useful in ensuring the collection of accurate cost data.

CMS previously stated that it will monitor claims to determine whether reinstatement of the edits is needed at some time in the future. The CY 2016 rule finalized a proposal requiring device codes on claims for devices assigned to device-intensive APCs. AdvaMed is supportive of the decision to reinstate device edits for these procedures.

- ***AdvaMed requests that the Panel recommend that CMS continue to monitor claims to evaluate the need to reinstate all device edits.***

Packaging Items and Services Into APCs
Skin Substitute Products

For CY 2017 CMS is proposing to continue its policy of packaging payment for skin substitute products and paying for these products via a low or high cost APC structure. The agency will continue to consider either mean unit cost (MUC) **or** per day cost (PDC) in determining and identifying the appropriate cost threshold.

Despite changes to the method for calculating the thresholds, AdvaMed continues to be concerned about the payment rates for low cost products when used to treat wounds less than 100 sq. cm.

- ***AdvaMed asks the Panel to recommend that CMS permit exceptions to any general packaging policy in cases where packaging could unreasonably impede patient access to new or existing devices, diagnostics, or other advanced medical technologies.***
- ***AdvaMed also asks the Panel to create an APC Group for the application of low cost skin substitutes for wounds less than 100 sq. cm that reflects the true cost of the low cost products and the work to apply them.***

While some of the negative impacts on the pricing for skin substitute products appear to have been helped by the changes implemented for CY 2016, AdvaMed is concerned by the level of payment cuts that will be applied to both high and low cost products for CY 2017. These substantial decreases in payment will result in packaged payment rates that do not cover the procurement and other costs for many of these products and could create access issues for Medicare beneficiaries. For example the changes in the prices for some products are expected to result in decreases in payment of more than \$700. These changes impact products in APC 15277 which will see a change in price from \$2137.49 to \$1411.92 and APC C5277 which will see a decrease from \$1411.21 to \$453.92. Other low and high cost products see more modest decreases in payment. However, taken in its totality the scope of this proposed change causes AdvaMed great concern.

- ***AdvaMed asks the Panel to recommend that CMS continue to monitor the impact of the high and low cost threshold pricing on the use and availability of skin substitute products and to continue considering other approaches for covering these products if necessary.***
- ***AdvaMed asks the Panel to recommend that CMS implement changes to ensure continued beneficiary access to these products and to establish an APC structure that limits the extent of changes in the reimbursement of these products from year-to-year.***

- *AdvaMed asks the Panel to recommend that CMS work with relevant stakeholders to obtain data regarding the actual cost of high and low cost products included in the various packages.*

II. Comments on Specific APCs

Imaging APCs

CMS is proposing consolidation of the 17 imaging APCs into 8 APCs for CY 2017. The 8 proposed APCs would be designated based on general names that are differentiated by level and whether they do or do not include contrast.

There are significant, unintended consequences of this imaging restructuring proposal that if adopted, would have a negative impact on beneficiary access to mandated preventive screening for osteoporosis. CMS is proposing to move the Axial Skeleton Dual Energy X-ray absorptiometry (DXA) (CPT 77080), the current gold standard of bone mineral density studies, from APC 5522 to APC 5521 for CY 2017. This would decrease the payment rate for Axial DXA by 59% or \$37, making it unaffordable for hospitals to perform this required baseline test in the outpatient setting for any patient being put on osteoporosis therapy. Proposed APC 5521 would also group all bone mineral tests, along with unrelated services (such as chest x-rays) into the same APC without regard for clinical and resource differentiation among these modalities.

- *AdvaMed asks the Panel to not finalize the proposed payment cut for CPT code 77080.*

Musculoskeletal APCs

In the CY 2016 final rule, CMS made revisions to its proposed policies to assure appropriate resource-coherent groupings and to mitigate inordinately large payment reductions for identified therapies. In particular, AdvaMed was pleased that CMS revised the Musculoskeletal APC structure to assure appropriate placement of percutaneous vertebral augmentation (PVA) procedures (CPT codes 22513-22514). In the CY 2017 proposed rule, CMS has proposed significant modifications to the Musculoskeletal APCs that once again result in significant reductions for PVA (-26% in APC 5114). The geometric mean costs for these procedures are approximately \$1,500 (or 28%) above the payment rate for APC 5114, which would result in significant underpayment for PVA.

- *AdvaMed asks the Panel to recommend that CMS reassess the Musculoskeletal APC groupings to establish an APC structure that limits the extent of changes on a year-by-year basis and results in a more adequate payment classification for PVA.*

III. Timing of HOPs Meetings

Beginning in CY 2017 the HOPs Panel will meet once a year. This schedule change will limit the ability of stakeholders to raise comments and concerns to CMS, via the Panel, to issues included

in the proposed OPSS rule. In light of this it is imperative that the comments that stakeholders submit for consideration during future HOPs meetings be adequately vetted and reflect the available claims data. Unfortunately, the current scheduling and deadline requirements for HOPs meetings, coupled with the timing for the release of the claims data file, do not allow adequate time for analysis of proposed OPSS changes in advance of the meeting.

- ***AdvaMed asks that the Panel recommend to CMS that the summer HOPs meeting date and the statement submission deadlines be more closely aligned with release of the rule (and associated comment deadlines) and permit adequate time for release and analysis of the claims data.***

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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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