



AdvaMed
Advanced Medical Technology Association

**Comments to
Centers for Medicare and Medicaid Services
Advisory Panel on Hospital Outpatient Payment
March 10-11, 2014**

Submitted By: DeChane L. Dorsey, Esq. January 31, 2014

**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**
- **Improving the Data Used to Determine APC Rates**
- **Comments on Specific APCs**

I. Reconfiguring APCs

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

Creation of Comprehensive APCs

The final CY 2014 OPPS rule delayed the proposal to convert 29 device-dependent APCs into “comprehensive APCs” that would encompass the procedures billed with the device-dependent APC along with any other charges that would typically appear on a claim associated with said APC. In the final rule CMS made a determination to not implement comprehensive APCs until January 1, 2015.

A change from device-dependent APCs to “comprehensive APCs” represents a major shift in the way that APCs are developed and paid. AdvaMed remains concerned about the potential impact that a conversion to comprehensive APCs could have on payment rates and on the ability of patients to continue to receive the technology and care that they require. Analysis of the final rule suggests that CMS resolved many of the comprehensive APC data concerns in the proposed rule. However, we continue to have concerns with the projected impact of comprehensive APCs on several significant procedures.

These concerns pertain specifically to APCs 0083 and 0229. The payment calculations for these APCs, which include several critical and commonly performed cardiovascular procedures, were very difficult to replicate in the proposed rule. We are experiencing similar difficulties understanding the final rule data for these APCs. We believe these payment calculations and data discrepancies may be linked to the method that was used by CMS to assign complex device procedures to APCs. AdvaMed’s review of the available data suggests that some of the procedures assigned to APC 0083 should be assigned to APC 0229 due to resource similarities. We are continuing our efforts to replicate the data for these APCs and plan to present additional information to CMS, in advance of the CY 2015 proposed rule, once our analysis is complete.

AdvaMed continues to have concerns within this new policy since the anticipated impact of these changes cannot be fully modeled. In light of payment calculation concerns and our overarching concerns about comprehensive APCs:

- ***AdvaMed encourages the Panel to recommend that CMS further explore the impact of comprehensive APC changes on all affected codes.***
- ***AdvaMed also encourages the Panel to recommend that CMS examine the procedures that were assigned to APCs 0083 and 0229 to ensure that, in addition to satisfying the other CMS criteria, these assignments best reflect the procedures’ resource and clinical similarities.***

The final CY 2014 OPPS rule also includes a method for more accurately accounting for the costs associated with complex cases with multiple device-dependent procedures. In replicating this methodology, AdvaMed experienced difficulty in determining the APC to which the complex case claims will be assigned. This methodology was not discussed in the final rule and is not apparent from the associated tables— making it difficult for stakeholders to determine whether the new methodology assigns the complex procedures to appropriate APCs that adequately account for the costs associated with performing the procedures and which are clinically similar.

- ***AdvaMed urges the Panel to recommend that CMS clarify the APC to which the various complex procedures are being assigned and provide opportunity for comment.***
- ***AdvaMed also urges the Panel to recommend that CMS develop a comprehensive addendum that lists the key complexity APC reassignments. This reference would allow stakeholders to better understand the process for assigning complex procedures to various APCs.***

Lastly, AdvaMed would like to raise a concern related to the impact of CMS's new add-on code packaging policy. Our analysis of the final rule suggests that the complexity APC procedures could be affected by the packaging of add-on codes. Data suggest that CMS's treatment of add-on codes included in complexity re-assignment APCs may vary based on the procedure. However, the process used by CMS to determine how an add-on code should be evaluated under this methodology is not discussed. AdvaMed believes that any methodology that takes add-on codes into account should be applied consistently across procedures.

- ***AdvaMed recommends that CMS clarify the methodology that it applied to add-on codes in the various complexity APC assignments.***

The final rule also finalized a recommendation to eliminate procedure-to-device and device-to-procedure edits for all APCs. Device edits have historically been very useful in ensuring the collection of accurate cost data. AdvaMed is concerned that elimination of these edits, especially in an environment of increased bundling, will jeopardize data accuracy.

In finalizing the decision to remove these edits CMS suggested that they will continue to monitor claims to determine whether reinstatement of the edits is needed at some time in the future.

- ***AdvaMed requests that the Panel recommend that CMS monitor claims and that the agency reinstate the device edits in CY 2015.***

Packaging Items and Services Into APCs

While AdvaMed recognizes the rationale for expanding packaging, we remain concerned that the payment development process for packaged procedures is not transparent, may lead to inappropriate payments, and could compromise patient access to high quality care.

The implementation of five new packaging policies in CY 2014 represents the first expansion of these policies since 2008. AdvaMed is concerned that several of CMS's new packaging policies will adversely impact payment rates and/or patient access.

- ***AdvaMed requests that the Panel recommend that CMS not implement any additional packaging policies until it has evaluated the effects of the newly implemented, CY 2014, policies on beneficiary access to care.***
- ***AdvaMed also requests that the Panel recommend that CMS allow adequate opportunity for stakeholder evaluation and feedback of future packaging proposals prior to their implementation.***

We are additionally very concerned about the decision to package several skin substitute products with their accompanying procedures. While the final rule partially addressed the impact of this change by sub-dividing the skin substitutes into high and low cost products, this modification is still inadequate to address the significant impact of the change.

Historically, skin substitute products were paid using average sales price (ASP). Packaging the cost of these products with all associated procedure codes without the benefit of ASP pricing has a significant impact on the portion of the procedure costs allocated to cover the skin substitute. While AdvaMed appreciates CMS's statement that the agency expects manufacturers to continue reporting ASP to facilitate cost category assignment we are concerned that cost category assignment will continue to not have its intended impact if the rates associated with these cost categories are not adjusted to more accurately capture the product costs. Even accounting for the changes related to allocation of different packaging combinations for high versus low cost products, the costs of the packaged procedure does not adequately cover the cost of procuring the skin substitute. This deficit places facilities and providers who utilize these products in a precarious situation in terms of their ability to have necessary products. Failure to correct this problem will create access issues and create potential patient harm.

- ***AdvaMed asks the Panel to recommend that CMS revisit the method used to price skin substitute procedures that are included in the “Drugs and Biologicals That Function as Supplies When Used in a Surgical Procedure” packaging policy.***
- ***AdvaMed asks the Panel to recommend that CMS rescind this packaging policy, as it relates to skin substitutes, until the agency is able to more accurately capture the costs of these products in any packaged payment policy.***
- ***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.***

II. Improving the Data Used to Determine APC Rates

AdvaMed appreciates the significant effort on the part of CMS to stabilize variation in APC payment rates. We would like to raise two issues, related to the data used to determine the APC rates.

First, AdvaMed commends CMS on their decision to continue using the single and “pseudo” single procedure claims rate-setting methodology which has yielded data that appear to more accurately capture the estimated costs of procedures. We do, however, have concerns that all of the codes associated with a procedure are not being reported. This is especially a concern with regard to coding for supplies. Code utilization data are used by CMS to identify the resources associated with a procedure and ultimately to appropriately adjust the APC Payment.

- ***AdvaMed recommends that the Panel urge CMS to focus on coding education as it impacts the use and development of HCPCS supply codes and revenue codes so that these codes are appropriately reported by hospital coders.***

Second, AdvaMed commends CMS's decision to continue using data from the implantable device cost center in setting the rates for certain OPPS services for CY 2014.

Despite expected improvement in reporting, using the cost center over time, AdvaMed believes that additional educational efforts are still needed to ensure that hospitals complete the implantable device cost center, thereby improving the validity of payment weights based on estimated costs. Additionally, AdvaMed believes that CMS should work to ensure the validity of the data collected through the new cost center.

AdvaMed therefore makes the following recommendations related to the use of the cost center:

- ***AdvaMed recommends that the Panel urge CMS to initiate actions to undertake additional outreach and educational activities to ensure that hospitals and the Medicare Administrative Contractors (MACs) are educated fully about the cost center requirements to ensure common knowledge, consistent and accurate audit processes, and to ensure that cost report changes are implemented effectively and accurately.***
- ***AdvaMed recommends that the Panel urge CMS to continue to monitor the accuracy of data reported under the cost center to ensure that they are correct and lead to more accurate rate-setting.***

AdvaMed was supportive of CMS's decision, in the final rule, to not use data from the cost centers for CT and MRI from facilities that use a square footage cost allocation methodology. Data from all facilities, including those presently using the square footage methodology, will be used to calculate the CT and MRI cost centers beginning in 2018.

- ***In preparation for this transition AdvaMed urges the Panel to recommend that CMS engage in education efforts, targeted at facilities using the square footage cost allocation methodology, to make them aware of the changes and to urge them to modify their cost methodology in preparation for the impending changes.***

III. Comments on Specific APCs

Vascular Ligation APCs (APCs 0091 and 0092)

In the final rule, CMS determined that CPT codes 36475 (Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated) and 36478 (Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated) are comparable in terms of clinical homogeneity and resource costs and should be assigned to the same APC. Historically, CPT code 36475 has been assigned to APC 0091 and CPT code 36478 has been assigned to APC 0092. CMS further determined that existing APCs 0091 and 0092 should be combined into a single APC, APC 0219 (Vascular Ligation).

- ***AdvaMed disagrees with CMS's decision to place CPT codes 36475 and 36478 in the same APC and encourages the Panel to recommend that CMS reverse the decision.***
- ***AdvaMed further urges the Panel to recommend that CMS consider additional data, from interested stakeholders, in support of placing these codes into separate APCs.***

Female Reproductive APCs (APCs 0193, 0195, and 0202)

In the final rule, CMS finalized policy changes significantly impacting the payment for several female reproductive CPT codes that fall within APCs 0193, 0195, and 0202. CMS finalized its proposal to package the costs of CPT Code 57267, a mesh add-on code, into certain prolapse repair procedures within APCs 0195 and 0202. While CMS acknowledged the potential impact of this change on procedures utilizing a high cost implantable device and made exemptions for other add-on codes, the agency did not provide an exemption for CPT Code 57267. The final rule also includes new changes to several female reproductive CPT code assignments that fall within APCs 0193 and 0195 due to an evaluation of 2 times rule violations. CMS's implementation of these policies fails to consider standard clinical practice or utilization differences for the procedure codes within these APCs.

Shifting certain procedures from APC 0193 into 0195 based upon a 2 times rules **violation and packaging the add-on procedure for the mesh have resulted in reimbursement** reductions for prolapse repair procedures in a range from 36% to over 50% from the 2013 payment rates as illustrated below:

CPT Code	Short Descriptor	2013	2014 DRAFT	% CHANGE	2014 FINAL	% CHANGE
57240	Anterior colporrhaphy	\$2,639	\$2,991	13%	\$2,523	-4.4%
57267	Insertion of mesh at 50%	\$1,320	\$0	-100%	\$0	-100%
Total		\$3,959	\$2,991	-24%	\$2,523	-36.3%
57260	Combined anterior-posterior colporrhaphy	\$2,639	\$2,991	13%	\$2,523	-4.4%
57267	Insertion of mesh, each site (x2) at 50%	\$2,639	\$0	-100%	\$0	-100%
Total		\$5,278	\$2,991	-43%	\$2,523	-52.2%

The compounded impact of the changes to the female reproductive CPT codes that fall within APCs 0195 and 0202 have resulted in devastating payment reductions. Asking providers and facilities to accept these reductions, in advance of potential reductions linked to comprehensive APCs, will likely have an adverse impact on clinical practice and beneficiary access to important and necessary medical procedures related to prolapse repair.

- ***AdvaMed asks that the Panel recommend that CMS reconsider the policies for APCs 0193, 0195, and 0202 and work with stakeholders to ensure appropriate APC placement for pelvic floor procedures that utilize a medical technology taking standard clinical practice and variation in use into consideration.***

Breast Biopsy APCs (APCs 0005 and 0037)

Effective January 1, 2014, CPT codes for standard (mechanical) core needle (19102) and vacuum-assisted biopsy (19103) were deleted from CPT and replaced with several new bundled CPT codes for image-guided percutaneous breast biopsy procedures (19081-19086). Prior to CY 2014, CPT code 19102 was assigned to APC 0005 and CPT code 19103 was assigned to APC 0037.

The CY 2014 OPPS final rule, assigned all of the image-guided percutaneous breast biopsy procedure codes to APC 0005. However, CMS incorrectly continued to include the cost data for CPT code 19103 in calculating the payment rate for APC 0037 creating a technical error. CMS should have included the costs for CPT codes 19102 and 19103 in APC 0005 or should have assigned the new bundled CPT codes, in addition to the cost data for CPT code 19102, to APC 0037.

To remedy this technical error and to create better alignment between the costs associated with the image-guided percutaneous breast biopsy procedure codes and the payment rates for the APC groupings to which the new bundled CPT codes are assigned:

- *AdvaMed requests that the Panel recommend that CMS move the cost data for CPT code 19103 to APC 0005 so that the cost data for both deleted image-guided percutaneous breast biopsy procedure codes (19102 and 19103) are used to establish the payment rate for APC 0005.*
- *Alternatively, AdvaMed requests that the Panel recommend that CMS move the cost data for all of the image-guided percutaneous breast biopsy procedure codes currently assigned to APC 0005 (19102, 19081, 19083, and 19085) to APC 0037 where the cost data for CPT code 19103 is currently being used to establish the payment rate.*

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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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