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**

**I. Reconfiguring APCs**

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

*Creation of Comprehensive APCs*

CY2015 marks the initial implementation of the new comprehensive APC system. 25 comprehensive APCs that cover 12 clinical families will be used to pay for device-dependent and other services along with the cost of related services and procedures.

AdvaMed remains uncertain as to whether the rates associated with the comprehensive APC’s adequately or accurately reflect all of the procedures and costs associated with those APCs.
• 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.

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 provided CMS with several comments on this issue in response to the proposed CY 2015 rule and CMS made further refinements to the complexity criteria and the process for complexity assignment in the final rule. Despite these changes AdvaMed continues to have concerns regarding appropriate application of complexity criteria and the resulting APC assignments for codes within the comprehensive APCs.

• AdvaMed requests that the Panel recommend that CMS monitor and report on the impact of applying complexity criteria on APC assignments for code combinations within the comprehensive APCs.

AdvaMed remains concerned with the broader 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.

• 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

For CY2015 finalized a policy to package payment for skin substitute products and to pay for these products via a low or high cost threshold APC structure based on mean unit cost per cm².

• 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 consider other approaches for covering these products if necessary.

II. Comments on Specific APCs

Urogenital Procedures (APC 0385) and Gynecologic Procedures (APC 0202)

The CY2015 final OPPS regulation included fifteen pairs of procedure codes within C-APC 0202 (Gynecologic Procedures) that meet its complexity adjustment criteria. CMS reassigned these pairs of codes (roughly 7,500 services) to C-APC 0385 (Level I Urogenital Procedures).

C-APC 0385 includes prostate cryoablation and other reconstructive male urological surgical procedures that utilize high-cost medical technology and are typically performed by subspecialist
surgeons. The prostate cryoablation procedure was previously assigned to APC 0674 (in CY2014) and the other procedures were previously part of APC 0385, Level I Prosthetic Urology APC.

The male urological surgical procedures within APC 0385 vastly differ from the female reproductive procedure complexity pairs and other gynecologic surgical procedures within C-APC 0202. Adding the new combinations of female reproductive procedure codes to C-APC 0385 disrupts the clinical homogeneity and resource similarity of the C-APC and has resulted in payment rates that do not accurately reflect the cost of performing the complex male urological procedures housed within this C-APC. AdvaMed is concerned that these payment shifts could negatively impact patient access to needed procedures.

- **AdvaMed urges the Panel to recommend that CMS reconsider its placement of C-APC 0202 complexity adjustment pairs into C-APC 0385.**

- **AdvaMed further recommends that CMS work with stakeholders to identify the appropriate placement of any proposed complexity reassignments from C-APC 0202 into another APC that is more clinical and resource similar.**

**Disposable Negative Pressure Wound Therapy (NPWT) (APC 0015)**

In CY2015 CMS moved two G-codes (G0456 and G0457) from APC 0016 to APC 0015 and renamed APC 0015 (Level II Debridement and Destruction). The two G-codes are used to bill for NPWT services that use a disposable device and were converted to CPT codes in 2015. The G-codes have historically experienced low utilization due to lack of clarity regarding their use and the anticipated issuance of the new CPT codes. AdvaMed is concerned that the resulting payment rate may not cover the cost of the disposable device used in these services and that this may adversely affect patient access to these innovative technologies.

- **AdvaMed urges the Panel to recommend that CMS evaluate the appropriateness of the payment for APC0015 in light of the introduction of the new disposable NPWT CPT codes.**

- **AdvaMed also asks the Panel to recommend that CMS continue to work with stakeholders to ensure appropriate APC payment and placement for disposable NPWT procedures.**

**Skin Substitute Products**

For CY2015 CMS is continuing its policy of packaging payment for skin substitute products and paying for these products via a low or high cost APC structure that considers mean unit cost in identifying the appropriate cost threshold. AdvaMed is pleased with CMS’s decision to revise its methodology in an effort to more accurately establish the low and high cost thresholds for skin substitute products. However, we still have concerns regarding the potential impacts of these changes on the ability of providers and beneficiaries to access the products that they require.
AdvaMed asks the Panel to recommend that CMS monitor the impact of the mean unit cost approach on the grouping of skin substitute products into low and high cost threshold buckets and to make adjustments where needed to ensure continued beneficiary access to these technologies.

AdvaMed also 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.

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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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