



* These comments are for the panels review and will not be presented during the panel meeting in March.

February 6, 2014

Chuck Braver
Designated Federal Official,
HOP Panel
CMS/CMM/HAPG/DOC
7500 Security Blvd.,
C4-05-17
Baltimore, MD 21244-1850

Dear Mr. Braver,

The Alliance of Wound Care Stakeholders is a nonprofit multidisciplinary trade association of health care professional and patient organizations whose mission is to promote quality care and access to products and services for people with wounds through effective advocacy and educational outreach in the regulatory, legislative, and public arenas. Our members are clinical specialty societies and organizations that not only possess expert knowledge in complex chronic wounds, but also in wound care research. These clinicians treat patients with wounds in all settings – including the hospital outpatient arena. A list of our members can be found on our website (www.woundcarestakeholders.org).

The Alliance would like to offer comments for consideration on two topics: the packaging of cellular and/or tissue based products for wounds (CTPs) – referred to as skin substitutes in the regulation and negative pressure wound therapy.

Packaging of CTPs and Add-on Codes

At the conclusion of the August 26-27, 2013 APC panel meeting, the Panel recommended that CMS delay implementation of the CY 2014 proposals regarding: comprehensive APCs, expanded packaging, visit reconfiguration, and cost-center-based reimbursement changes for computed tomography (CT) and magnetic resonance imaging (MRI) until data can be reviewed by the Panel at its spring 2014 meeting regarding interactions between the proposals and their potential cumulative impact.

While we had hoped that CMS would have accepted the Panel's recommendation, the Alliance is now very concerned that CMS has not analyzed the impact of packaging CTPs and the add on codes for skin substitutes on net payments for patient care and are concerned that CMS has not provided detailed information regarding the impact of these changes on payment rates or patient access.

The problematic consequences of CMS's policy to unconditionally package add-on code procedures are the following: it completely undermines the AMA CPT coding framework; it does not ensure that hospitals are

reimbursed for all medically-necessary services performed; and it ultimately could threaten beneficiary access to important medical services. Add-on codes are distinct clinical procedures that have been valued by the AMA independently from the primary procedure which is specified by the AMA to be listed separately, in addition to the primary procedure. CMS's packaging policy inappropriately voids the AMA's separate valuation of these codes. CMS's policy also essentially results in hospitals not being reimbursed for the additional clinical care and supplies required, including the additional amount of CTPs, that may be required when performing an add-on service, which ultimately could adversely impact patient access to these services. Specifically, we are concerned that CMS has not demonstrated how it accounts for the full range of supplies and devices that may be used and/or the typical number of levels furnished to a patient that requires wound care in an outpatient encounter in setting the packaged APC rate.

The Alliance believes that packaging all add-on codes is an overly-broad, indiscriminate proposal that does not promote payment accuracy or advance patient care. As CMS develops the 2015 OPPS rule, we encourage the Panel to recommend that CMS reassess this policy and defer packaging of all add-on codes until further analysis is performed. Should CMS contemplate continuing packaging add-on codes in 2015, we hope that the Panel can recommend that CMS establish a clear and transparent method for identifying and reviewing add-on codes that could potentially be packaged. As part of this process, CMS should consult with the AMA CPT Editorial Panel for a determination regarding which primary CPT codes should be revised to include add-on procedures and which add-on codes should remain separate codes available for separate billing and payment as appropriate. CMS also should make publicly available more detailed data underlying payments for packaged services, including a cross-walk to utilization assumptions. As long as add-on codes are packaged, we recommend that CMS instruct hospitals to report add-on codes and codes for all packaged items (including the correct number of units being utilized for CTPs) to ensure that all charges are included on the claims. CMS should provide detailed information regarding the impact of packaging of add-on codes and CTPs and has to be confident that there will be no negative unintended consequences. CMS cannot assume there will be no patient harm and no patient access problems.

For a variety of reasons, the Alliance does not agree with the APC placement or rates for the newly packaged "skin substitutes". CMS based the threshold between low and high cost products upon the ASP+6% payment rate. However, the APC-based payments are based upon charge-based cost estimates in the OPPS database-not on ASP-based costs. This creates anomalies in that higher cost products by ASP-based payments may not necessarily translate in higher-cost products in terms of charge-based costs. Consequently, a product may be assigned to a higher cost APC even when the OPPS cost data do not support such and vice versa.

Furthermore, the cost offset for the policy packaged products in the relevant APCs is relatively low compared with true cost. This creates a strong financial incentive toward use of new pass-through products even where these may not be more appropriate for a patient than established products. CMS should review the basis for its policy-packaged portion for the products in the relevant APCs and adjust these to assure that hospitals are not getting a windfall when they purchase pass-through products.

The Alliance requests that the panel recommend to CMS to work with stakeholders to achieve a more balanced, equitable system for the packaging of CTPs. Additionally, the Alliance requests that the panel urge CMS not to package add on codes for skin substitutes. CMS erroneously assumes that "when you have seen one wound you

have seen them all"-- no matter how big or small the wound, where the wound is located, or even the wound type. The size of the ulcer is hugely important with respect to the amount of resources a clinician/facility will use to treat the patient.

Negative Pressure Wound Therapy

The Alliance also respectfully requests that the Panel recommend to CMS a reassignment of disposable negative pressure wound therapy (NPWT) G codes into different APC codes and specifically from APC 0016 (Level IV Debridement & Destruction) to APC 0186 (Level III Skin Repair).

CMS created G codes for reporting disposable NPWT services on January 1, 2013, and assigned these services to APC 0016 (Level IV Debridement & Destruction). While some of the services contained within APC 0016 do involve wound care, we believe APC 0135 (Level III Skin Repair) would be a more appropriate grouping for these services. (This APC was proposed to be renumbered in 2014 to APC 0186, but for the purposes of this letter we will refer to this APC as APC 0135.) The G codes and their descriptors are shown below.

G0456 Negative pressure wound therapy, (e. g. vacuum assisted drainage collection using a mechanically-powered device, not durable medical equipment, including provision of cartridge and dressing(s), topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters

G0457 Negative pressure wound therapy, (e. g. vacuum assisted drainage collection) using a mechanically-powered device, not durable medical equipment, including provision of cartridge and dressing(s), topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area greater than 50 square centimeter

Reasons Supporting Reassignment of Disposable NPWT G codes from APC 0016 to APC 0135 (Level III Skin Repair)

There are several strong reasons for reclassifying the disposable NPWT G codes to APC 0135 (Level III Skin Repair).

The reclassification would group disposable NPWT with similar wound care codes describing treatment of complicated wounds (CPT codes 13100, 13101) and cleaning and preparing viable wound surfaces for substitute skin grafting (CPT codes 15002, 15003). APC 0135 also includes a procedure for closing split wounds (CPT code 12020), a service which similarly matches the healing objective of disposable NPWT.

The costs for disposable NPWT equipment have been under-calculated for HCPCS G0456/G0457 through placement into APC 0016. This APC band results in a loss to the facility and will likely reduce access to mechanical NPWT for Medicare patients. APC 0135 has a geometric mean payment which would be more applicable to the total cost of the average equipment and the service provided. Please see the table below for national average pricing data on disposable NPWT used in conjunction with G- 0456/7.

CPT	Work RVU Facility/Office	PE RVU	MP RVU	Total RVU	APC FEE 2013
Complicated wound and skin graft prep and closing split wounds					
13100	3.07/6.03	2.51	0.45	6.03/8.99	APC 0135 \$393.38
13101	3.05/7.21	3.32	0.52	6.89/11.05	APC 0135 \$393.38
15002	3.65/5.57	2.28	0.62	6.55/8.47	APC 0135 \$393.38
12020	2.67/5.03	2.40	0.40	5.47/7.83	APC 0135 \$393.38
Disposable NPWT placement – including the device					
G0456 < 50 cm					APC 0016 \$209.65
G0457 > 50 cm					APC 0016 \$209.65
Placement of DME NPWT					
97605 < 50 cm	0.55/0.57	0.14	0.08	0.77/0.79	APC 0013 \$71.54
97606 > 50 cm	0.60/0.63	0.15	0.10	0.85/ 0.88	APC 0015 \$106.98

In addition, the title of APC 0135 (Level III Skin Repair) accurately captures the wound treatment and healing aspects of disposable NPWT. The reassignment would support CMS policy objectives of organizing families of similar procedures and services into clinically homogenous APCs. This contrasts with the current APC assignment of the G codes, which are now mapped to APC 0016 (Level IV Debridement and Destruction). This APC contains codes describing destruction of skin lesions, removal of foreign bodies, and debriding subcutaneous tissue. While APC 0016 broadly relates to skin care, its procedures are more related to extraction, ablation and removal of foreign bodies, as opposed to the healing and wound repairing nature of disposable NPWT. Disposable NPWT are devices that treat different types of wounds using various energy sources to

remove exudate and promote healing, which aligns more with the wound care services contained in APC 0135.

The Alliance requests that the Panel recommend that CMS reclassify the G codes describing disposable NPWT to APC 0135 (Level III Skin Repair), as this would better align these services with an APC containing similar services and consuming comparable resources.

We appreciate the opportunity to offer our comments. We are happy to provide any additional information.

Sincerely,

A handwritten signature in black ink that reads "Marcia Nusgart R.Ph." in a cursive script.

Marcia Nusgart R.Ph.
Executive Director