ALLIANCE OF

Wound Care Stakeholders

August 24, 2010

Donald Berwick, M.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention CMS 1503 P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: CMS-1503-P - Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011; Proposed Rule

Dear Dr Berwick:

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), I am submitting the following comments in response to the Proposed Payment Policies under the Physician Fee Schedule for CY 2011. I serve as the Executive Director of the Alliance, a multidisciplinary consortium of over 15 physician, clinical, provider, manufacturer and patient organizations, whose mission is to promote quality care and patient access to wound care products and services. These comments were written with the advice of Alliance organizations who possess expert knowledge in complex acute and chronic wounds. This proposed rule will have a major impact on our Alliance organizations and as such, we appreciate the opportunity to offer our comments.

Our specific comments center around the section entitled, "Application of Tissue-Cultured Skin Substitutes to Lower Extremities (HCPCS Codes GXXX1 and GXXX2"). The Alliance would like to separate our comments into three distinct areas; 1) areas of concern, 2) areas of agreement, and 3) recommendations.

Areas of Concern

The Alliance has four general concerns regarding this section of the rule:

1. The Alliance submits that CMS has circumvented the normal process in making CPT®[1] coding changes and relative value unit changes. CMS has proposed to eliminate 6 CPT codes, disallow the appropriate use of the -58 modifier, remove the global periods assigned to some but not all similar procedures, and package site

[1] CPT is a registered trademark of the American Medical Association

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preparation and debridement into procedures where they are not routinely required, without going through the AMA or the RUC. In addition, CMS has inappropriately declared that only 2 of the products, APLIGRAF®[2] and DERMAGRAFT®[3], are indicated for use on lower extremity ulcers, which is not true.

While ultimately it may make sense to revise the CPT codes in the skin replacement and skin substitute section of the CPT book and to revalue the revised codes through the RUC process, the **Alliance is concerned about the precedent that CMS is setting by circumventing the exact process under which these and all other procedure codes were/are created.**

CMS has also proposed to eliminate the use of the -58 modifier with these new G codes. While ultimately it may make sense to eliminate the use of the -58 modifier, the Alliance is concerned that due process has not been followed. The Alliance believes that CMS reacted to a problem stemming from one Medicare Administrative Contractor (MAC) who wrote a Local Coverage Determination (LCD) that violates both CMS policy and AMA guidance and thus has created inconsistencies in the way physicians will bill for cultured dermal and dermal/epidermal replacement procedures – without going through the normal process.

It is our understanding that Noridian, in their LCD, eliminated the use of the -58 modifier, even when these procedures are appropriately staged during their global periods. If a physician appropriately stages a procedure during a global period, both CMS and AMA instruct the physician to use the -58 modifier. Again, without going through the normal process, CMS is allowing a MAC to create policy that is contrary to current CMS policy and AMA guidance.

2. CMS has not gone through the normal RUC process to determine appropriate work RVUs for these new procedure codes and believes that CMS may arbitrarily assign RVU rates.

   The Alliance believes that, since CMS has not gone through the RUC process to determine appropriate work RVU assignment for these new codes, the proposed work RVU calculation for the new codes may not be sufficient and therefore result in inadequate payments to physicians. Currently it costs about $100 per application to apply these grafts in the office. Unless the RVUs are significantly adjusted upward or the global periods eliminated altogether, the Alliance is concerned that providers will not be able to afford to provide these valuable services to those Medicare beneficiaries in need of them.

3. Finally, CMS has inadvertently created an “unlevel” playing field. The proposed G codes only impact two specific products; Apligraf® and Dermagraft®. All other grafting procedures and skin substitute products are not affected and will continue with the current 90-day global period, which does not result in a “level playing field”.

[2] APLIGRAF is a registered trademark of Organogenesis
[3] DERMAGRAFT is a registered trademark of AdvancedBiohealing

As a result, all other grafting materials and skin substitute products are at a distinct advantage with the global day assignments.

Unless CMS makes changes that pertain to all the procedure codes in this section of the CPT book, the agency will not achieve its goal of leveling the playing field. In fact, the proposed changes will cause providers to use the two more expensive products, that have no global period, rather than other less expensive products that will still have 90-day global periods.

Areas of Agreement

The Alliance agrees with the following CMS concepts:

- Financial incentives to choose one product over another should be eliminated.
- Global periods should be eliminated for the application of all skin replacements and skin substitutes and not just for the new G codes.
- The sizing provided in the new temporary G code definitions is appropriate. The Alliance agrees that the application descriptions should be in 25 sq cm units rather than 100 sq cm units.

Recommendations

As stated previously, the changes that CMS is seeking to make in the proposed rule applies to only two skin substitute/grafting products and does not address all the other products utilized in tissue replacement procedures. As such, CMS is creating an unintended advantage for Apligraf® and Dermagraft® at the expense of other products in the market - or entering the market - with clinical efficacy. As such, the Alliance **recommends that CMS eliminate the global period for all skin substitute procedures** and not just for two products.

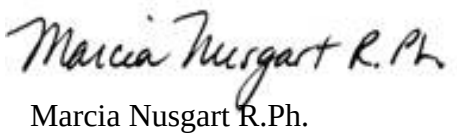
Furthermore, the Alliance believes that CMS has not gone through the normal process in making the changes proposed. As we stated earlier in our comments, while ultimately it may make sense to revise the CPT codes in the skin replacement and skin substitute section of the CPT book and to revalue the revised codes through the RUC process, CMS has not gone through the AMA or the RUC prior to issuing this proposed rule. On January 1, 2006 approximately 45 new codes were created by AMA and valued through the RUC process. If revisions are needed, the same AMA and RUC process should be used for the application of all the products, not just for 2 products. **As such, the Alliance would like to recommend that CMS work with the AMA and the RUC to review the codes and propose their recommendations in the next round of rulemaking.**

Finally, the Alliance recommends that **CMS instruct its MAC to continue to utilize the -58 modifier until CMS can bring this issue to the AMA and the RUC to address it properly**.

Conclusion

The Alliance appreciates the opportunity to provide CMS with input on the proposed physician fee schedule regulation for CY 2011. As stated earlier in our comments, due to the diversity of organizations with wound care knowledge and experience which comprise the Alliance, we would be pleased to serve as a resource to you now or in the future. We look forward to working with you as you finalize this policy. If you have any questions, or would like further additional information, please feel free to contact me.

Sincerely,



Marcia Nusgart R.Ph.
Executive Director