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May 27, 2022

RE: DL36377 and DL35041: Skin Substitutes for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers

Dear Novitas and First Coast Service Options, Inc. Medical Directors,

The Advanced Medical Technology Association (AdvaMed) is pleased to submit the following comments to First Coast Service Options, Inc., and Novitas Solutions in response to the proposed Local Coverage Determination (LCD): *Skin Substitutes for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers* (DL36377 and DL35041*)* and accompanying billing and coding articles (DA54117 and DA57680).

AdvaMed's member companies produce the life-saving and life-enhancing 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.

LCDs ensure beneficiary access to life saving and medically necessary products and procedures. The local coverage process has resulted in coverage decisions on items and services that benefit Medicare beneficiaries through an open and participative decision-making process. This process also provides information about new technologies and procedures and helps inform long-term decisions on effectiveness and value. We thank First Coast and Novitas in advance for reviewing our recommendations to this LCD. Incorporation of these recommendations will help to ensure clarity and alliance with current medical practice.

AdvaMed's comments will focus on the following areas of the LCD:

I. History/Background and/or General Information
   a. Classification of skin substitutes
   b. Definition of Diabetic Foot Ulcers (DFU) and Venous Foot Ulcers (VFU)

II. Limitations
   a. Changes to the allowed frequency of skin substitute applications

III. Coding and billing requirements
   a. Requirement of L and R modifiers
   b. Documentation requirements

I. History/Background and/or General Information

a. Classification of Skin Substitutes:

The draft policy states that skin substitutes "are best characterized as surgical supplies or devices because of their required surgical application and their similarity to other surgical supplies." This sentence is inconsistent with CMS' characterization of these products. As discussed in the CY 2014 OPPS/ASC final rule, CMS has previously acknowledged the distinction between skin substitutes and surgical dressings.[1] Skin substitutes are applied surgically to wounds to enhance wound management through various mechanisms of action that stimulate the host to replace lost tissue and should be defined as such.

> **Recommendation:** AdvaMed requests that the final LCD align its definition of skin substitutes to conform with CMS' characterization. Skin substitutes include extracellular matrices, biologicals, and synthetic products.

b. Diabetic Foot and Venous Leg Ulcers are not Acute Wounds:

The focus of this draft local coverage determination is limited to skin substitutes for diabetic foot ulcers (DFU) and venous leg ulcers (VLU). DFUs and VLUs are not acute wounds. However, within the draft LCD there is terminology used for acute wounds (e.g., surgical and trauma

[1] *See* 78 FR 74932 "…HCPCS Q-codes are typically assigned to drugs and biologicals and are used to describe skin substitutes…" and 86 FR 63563 "The CY 2014 OPPS/ASC final rule with comment also described skin substitutes as "…a class of products that we treat as biologicals…"

wounds). Inclusion of these terms creates confusion as to the scope of the policy.

> **Recommendation:** In order to provide clear guidance to the scope of the policy, AdvaMed recommends First Coast Options LLC and Novitas streamline language within the LCDs to be specific to DFUs and VLUs.

II. Limitations

a. *Greater than two applications of a specific skin substitute graft product within the episode of skin replacement surgery for wound care*

AdvaMed is very concerned about the limited number of applications deemed as reasonable and necessary within these draft LCDs. The current active Novitas LCD states that a provider is not to exceed 10 applications or treatments within a 12-week period, which is consistent with most other LCDs. The draft LCDs now limit applications to two within a 12-week period and state that treatment will consist of "fewest repeat applications and amount of product to heal the wound. It is expected that products are used per the labeling." First, the specific number of applications needed are not contained on any skin substitute product labeling and will vary significantly based on the patient's clinical condition. Additionally, the dLCD does not cite evidence for this reduction in applications, and in many cases limiting applications to only two will significantly limit the ability for skin substitutes to be fully effective for patients.

If the limitation remains at a maximum of two applications, there must be a process in place for providers to be able to obtain authorization prior to subsequent applications when medically necessary. There will always be outliers that fall outside these parameters. The decisions must be timely as providers will need to provide an ABN to beneficiaries for services that may not be covered by Medicare.

> **Recommendation:** AdvaMed recommends that the final LCDs align with the current Novitas LCD to allow for up to 10 applications in a 12-week period. The final LCD should create a process for providers to be able to obtain approval for additional applications regardless of whether the limit is two or 10.

III. Billing and Coding Guidelines (DA54117 and DA57680)

a. L and R modifiers:

The coding guidance within the articles state "that application codes must use the appropriate modifier (e.g., RT, LT) to identify the location where the skin substitute was applied, or the service will be denied." However, right (RT) and left (LT) modifiers are inappropriate for skin substitutes as this requirement conflicts with how skin substitutes are measured and coded. The correct CPT code to identify the service is determined by the depth of the wound. The appropriate code for a patient that has multiple wounds is determined by the sum of all the patients' wounds by depth and site. The AMA CPT manual states "for multiple wounds, sum the surface area of all wounds from all anatomic sites that are grouped together in the same code descriptor." Thus, mandating right and left modifiers could create confusion if the patient has multiple wounds on both the left and right side of the body. Moreover, granularity of ICD-10-CM diagnosis codes will in most cases provide information on which side(s) of the body the ulcers occur.

> **Recommendation:** AdvaMed recommends that the requirement to use L and R modifiers be removed to both avoid potential confusion and better align with CPT guidelines and proper coding of these services.

b. Documentation requirements

AdvaMed understands the need to properly document services rendered to patients, however some of the requirements listed, specifically requirements eight and 9, are not able to be entered in the patient's electronic medical record (EMR) (i.e., no prompts exist within the EMR to provide information specific to skin substitutes). This would create a significant administrative burden for providers.

> **Recommendation:** Documentation requirements 8 and 9 are unable to be addressed in many electronic records resulting in manual documentation that must supplement the electronic record.

The documentation requirement to submit an FDA approval letter, listing and package insert for each bill submitted

represents a redundant documentation requirement as CMS has this information included with all HCPCS applications for skin substitutes. This requirement should be deleted as it would be expected that CMS has reviewed this information in order to provide coverage for any skin substitute on the market.

Due to the redundant and burdensome nature of requirements 8 and 9, AdvaMed recommends that they not be retained in the final LCD.

We appreciate this opportunity to share our recommendations for your consideration as you work to finalize these local coverage determinations. If you have any questions, please contact Tara Burke (tburke@advamed.org).

Sincerely,

Chandra N. Branham, J.D.

Senior Vice President and Head of Payment & Healthcare Delivery Policy