ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

August 8, 2016

Earl Berman, MD
Medical Director
Cigna Government Services
Attn: Medical Review
Two Vantage Way
Nashville, TN 37228-

Submitted electronically to: cmd.inquiry@cgsadmin.com

RE: DRAFT Local Coverage Determination (LCD) for Application of Skin Substitute for Wounds, of Lower Extremities (DL36690)

Dear Dr. Berman:

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), we are pleased to submit the following comments in response to the Cigna Government Services (CGS) draft local coverage determination for Application of Skin Substitute for Wounds, of Lower Extremities (DL36690). The Alliance is a nonprofit multidisciplinary trade association of health care professional societies and 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. These comments were written with the advice of Alliance clinical specialty societies and organizations that not only possess expert knowledge in complex chronic wounds, but also in wound care research. Many of our members utilize skin substitutes or more accurately Cellular and/or Tissue Based Products for Wounds (CTPs) in their practices as an adjunctive therapy when treating a patient with a chronic non-healing wound. As such, we have a vested interest in this policy. A list of our members can be found at www.woundcarestakeholders.org.

General Comments

The Alliance was so pleased when several years ago CGS – being a thought leader - created an LCD for this product sector with the title – "Cellular and Tissue Based products for Wounds". That term certainly described the products more accurately from a scientific perspective than skin substitutes. The Alliance is extremely disappointed that CGS has proposed to change the title of its LCD from Cellular and/or Tissue Based Products for Wounds back to Skin Substitutes.

While CGS has on occasion referred to skin substitutes as "Cellular and Tissue based products" within this draft LCD, the primary nomenclature used in this policy for these products is still skin

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substitutes. As mentioned above, the term "skin substitutes" is clinically inaccurate and should be replaced with more inclusive descriptor "Cellular and/or tissue based products for wounds (CTPs)". The term is not a technically accurate and does not describe the technology. Instead, the Alliance recommends that CGS continue to use the term "Cellular and/or tissue based products for wounds" which does accurately describe all technologies in this sector and is broad and inclusive of both current and future technology.

The Alliance adopted this term in 2013 after a year long effort - working with leading wound care scientists, clinical organizations, and business entities - to develop a more appropriate term to represent this product sector. Thus, we will be using the acronym "CTPs" when referring to "Cellular and/or tissue based products for wounds" in this document.

The Alliance believes that the term "skin substitute" is misleading and inaccurate to describe the products that are the subject of this LCD for the following reasons:

- The FDA does not allow these products to be called ''skin substitutes'' because they do not actually substitute for skin.
- Both CMS and AHRQ have concerns with the terms and did the following:
    a. AHRQ in its draft technology assessment on skin substitutes stated that these products were not "skin substitutes"
    b. CMS abandoned the term in the code descriptors for these products in 2010 when the Agency agreed that these products are not skin substitutes and instead issued Q codes for each individual product by its brand name.
- ASTM, the international standard setting organizations thought so highly of this new unique terminology that in February 2016 it published a new standard devoted to the nomenclature for these products. The workgroup that created this standard included FDA (who agreed with the term!), scientists, engineers and clinicians who worked collaboratively to ensure that the standard is inclusive of all the products in this space. It will be used by not only them but by those who do wound care research. The new ASTM standard (F3163-16) is titled, "Standard Guide for Classification of Cellular and/or Tissue-Based Products for Skin Wounds."
- Payers in their LCDs are using this term. Several MACs refer to CTPs in their LCDs, but have not fully converted to the correct term. The rest of the MACs describe CTPs in a variety of ways.
- This term has been adopted by the wound care community and is currently used by physicians when speaking at national wound care conferences and in clinical studies in scientific journals. For instance, at this year's American Podiatric Medical Association national conference, both Drs. Jeremy and Emily Cook used the term in their breakfast and other presentations.

As stated above, the ASTM adopted the CTP nomenclature and we believe that it is only a matter of time before the AMA CPT panel makes an editorial change to reflect this terminology. As such, the Alliance recommends that CGS not utilize the term "skin substitute" in its policy and instead use the more clinically correct term "cellular and/or tissue based products for wounds (CTPs)" as you have done in the past.

The Alliance has provided specific comments below. We have presented them not necessarily in order of importance but in order that they appear in the draft LCD. The issues are as follows:

Specific Comments

Classification of Products

The Alliance believes that the CGS policy is problematic in terms of how the products are actually defined. The definitions of "Allografts," "Human Skin Allografts," and "Acellular Matrices" are confusing and misleading. For instance, in the definition of an "Allograft" the draft LCD specifically states "from human skin" which is exactly the same as the fourth category definition of "Human Skin Allograft". The term "Acellular Matrices" is limited to "derived from other than human skin". There are ample acellular matrices derived from human skin (e.g., AlloPatch Pliable, Graftjacket, DermACELL, and AlloSkin AC]. Furthermore, it is unclear where amniotic products that are acellular [e.g., AmnioBand (MTF), Biovance (Alliqua) and Dermavest (Aedicell)] fit in to the classifications/definitions contained in the policy. These products are not composed of skin, but rather derived from placental (amniotic) membranes.

The Alliance suggests that if CGS is attempting to define the different product types in this product sector within the LCD, that it is done correctly. As stated above, the ASTM standard (F3163-16) has developed and approved the "Standard Guide for Classification of Cellular and/or Tissue-Based Products for Skin Wounds." We recommend that CGS utilize the classifications developed by the ASTM.

Coverage Indications and Limitations: FDA Approval/Clearance/361 designated HCT/Ps

The Alliance agrees with the following statement: **all products with FDA clearance/approval or designated 361 HCT/P exemption** used in accordance with that product's individualized application guidelines will be equally considered for the purpose of this LCD and may be considered reasonable and necessary. We appreciate that CGS has recognized certain HCT/Ps - notably those that are designated as 361 - do not receive FDA approval or clearance as part of their regulatory pathway and requirements through the FDA. However, the draft policy does contain a statement in the limitations section that contradicts this language. Notably, that language reads: All listed products, unless they are specifically **FDA-labeled or cleared** for use in the types of wounds being treated, will be considered to be biologic dressings and part of the relevant Evaluation and Management (E/M) service provided and **not separately reimbursed**. Based on your language, all 361 HCT/P products are considered biologic dressings under this draft policy and therefore not separately reimbursed despite the previous statement – that they will be equally considered.

The Alliance suggests that the language contained in this policy is contradictory and urges CGS to remedy the conflict so that 361 designated CTPs will be treated equally and not considered biologic dressings – which they are not. The language which reads "All listed products, unless they are specifically **FDA-labeled or cleared** for use in the types of wounds being treated" should be revised to read as follows: "All listed products, unless they are specifically **FDA-labeled, cleared or 361 HCT/P exempt** for use in the types of wounds being treated".

Independent of the issue we have raised above, the Alliance is concerned and has significant issues with the following language, "all products, unless they are specifically FDA-labeled or clear for use

in the types of wounds being treated, will be considered to be **wound dressings** and part of the relevant E/M service provided and not separately payable." The FDA recognizes different regulatory pathways for CTPs: PMA, 510K, HDE, BLA and HCT/Ps. CTPs have different regulatory pathways depending on the source of the tissue. HCT/Ps do not have a specific indication for use like PMA and 510K products. Instead, they have a broad intended use statement. Just because a CTP product is not labeled for use in the types of ulcers listed in this policy – does NOT deem them to be a wound dressing. A CTP promotes wound healing by interacting directly or indirectly with the body tissues. There is direct biological effect in the wound bed as a result. The role of CTPs is not to cover and protect wounds but rather to stimulate endogenous healing, although whether or not an individual CTP is capable of exerting effects on wound healing must be determined by adequate evidence. Yet, a wound dressing is a material that is utilized for covering and protecting a wound, helping to maintain an optimal wound environment, and shield the wound against the environment without exerting any direct effect in the wound bed. As such, it is not correct for CGS to determine that a CTP, which is being regulated as a human HCT/P with the FDA and has broad indications not specified in its labeling, to eliminate its use based on its regulatory classification, or to designate it as a wound dressing. Furthermore, none of the products that maintain a HCPCS Q code are or should be considered a wound dressing. This is simply clinically and scientifically inaccurate.

The Alliance recommends that CGS remove from its LCD the verbiage regarding products not being separately payable and included in the relevant E/M service unless they are labeled for use in the types of ulcers considered in the LCD. Instead, the section should read: "each marketed product is eligible for Medicare reimbursement if it is provided in accordance with its package label or Instructions for Use."

Podiatrists and other Clinicians

The Alliance is concerned that CGS will not be providing coverage for the service or the product when they are applied by a podiatrist or other clinicians when their state practice act permits this procedure to be done.. The draft LCD states, "patients receiving a skin substitute graft must be under the care of a physician licensed by the state with full scope of practice for the treatment of their systemic disease process". It may simply be an oversight, however, the Alliance urges CGS to recognize podiatrists as providers who can and do treat patients with wounds – especially diabetic foot ulcers, as well as any other qualified health care professional in which this service is permitted to be performed within their state practice act.

12 Weeks of Treatment and Number of Applications

Language in the Policy: It is the expectation that a specific skin substitute product will be used for the episode of each documented wound, and in compliance with FDA assessments and submitted guidelines for the specific product. Greater than ten (10) applications for the treatment of a single wound within a 12-week period of time, will be considered Not Reasonable and Necessary and will be subject to review.

AND

Separately billed repeated use of the skin substitute after 12 weeks for a single wound or episode is non-covered. Alternative or additional skin substitute products used within the 12 week initial wound episode are similarly non-covered when the sum of applications of all Skin Substitutes is greater than ten (10) for a single wound.

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The Alliance has concerns about the timeframe of "only 12 weeks treatment", which may be in conflict with the FDA labeling and clinical practice for many of the CTPs that are only applied every 2-3 weeks to allow incorporation and to see results.

Moreover, if the LCD limits treatment to 12 weeks, some of these products will not be able to be used as some of the products, per their FDA labeling, require multiple treatments in a span of time that would exceed 12 weeks. The Alliance is concerned that clinicians would always have to justify utilizing the product chosen to treat their patients – even though they are following the FDA labeling. Therefore, the physicians will always have to overcome the documentation hurdles and will need to further justify why they need to continue to use the product for more than the allotted time frame.

The Alliance appreciates that CGS has contained language in this draft policy that allows clinicians to utilize more than one CTP in the course of a patients' treatment. However, we do not believe that the number of applications is satisfactory when a clinician needs to change treatment options. If a physician begins to utilize one CTP product – with the expectation that the product chosen will work for their patient – yet finds it is unsuccessful – OR if the patients health status changes and/or the presentation of the wound changes – a clinician should be able to change the course of treatment and be able to utilize the product chosen in the most optimal manner. However, based on the limitation to the number of applications – and treatment time - the clinician will not only be ignoring the labeling requirements for the new product chosen, the patient will not be able to get the full benefit of the new treatment option. Realistically, while CGS is permitting a clinician to change treatment options, this policy is still limiting a physician's ability to change course in treating their patients upon the realization that the product chosen is not successfully working in their patient, or when the health status or wound changes. As such, this policy is not only limiting treatment options for the clinician, it is inhibiting a patient from receiving the best optimal treatment.

Furthermore, our clinicians often use one CTP to achieve a certain goal – such as to initiate granulation. Depending on the presentation of the wound and the patient's current health status, they may change to another product to close the wound – which may require more than the number of applications left in the total number of applications permitted under this draft policy. In order to afford our clinicians the type of autonomy to customize their treatment plan to individual patients that this policy seems to suggest – we recommend allowing treatment according to the FDA label and placing the burden on the physicians to document the need for multiple products.

The Alliance recommends that CGS utilize a simple statement that the products should be applied in accordance with their FDA labeling places the responsibility on the physician to apply the product correctly and documentation in their files should be sufficient to show that the physician was following labeling instructions for the product being utilized.

Indications for Use – DFU and VLU

CGS makes a distinction when providing coverage for DFU and VLU. The policy stated that the application of a CTP on a DFU will be covered when the DFU fails to respond to documented conservative measures of greater than 4 weeks. Yet, while the policy states that the application of a CTP on a VLU will be covered when the wound fails to respond to appropriate wound care after 30 days, the policy also requires that the patient "have the presence of a VLU for at least 3 months". The Alliance has two concerns. First how does CGS define appropriate wound care? Why does CGS utilize different language between a VLU and DFU? Both should simply state that the application of a CTP will be covered when they fail to respond to documented conservative measures after 30 days. Second, the Alliance is concerned that CGS is requiring the presence of a VLU for 3 months AND the failure to respond to treatment after 30 days. It is unclear what evidence CGS is using to support their decision to require the presence of a VLU for 3 months prior to being covered for the application of a CTP. The Alliance does not agree with this distinction and requests that CGS provide the evidence supporting this separation. The Alliance believes that the percentage of change after 4 weeks of healing is a robust indicator of healing at 12 weeks. Delays in alternative or additional therapies contradict prevailing thoughts on ulcer treatment. As such, the Alliance recommends that application of CTPs for both DFU and VLU should be covered when the wound fails to respond to conservative measures after 4 weeks**.**

The policy provides coverage for chronic wounds of the lower extremity that have failed conservative treatment includes; "partial-or full-thickness diabetic ulcers, and venous ulcers not involving tendon, muscle, joint capsule or exhibiting exposed bone or sinus tracts, with a clean granular base" and, "full-thickness skin loss ulcers that are the result of abscess, injury or trauma that has failed to respond to appropriate control of infection, foreign body, tumor resection, or other disease process for a period of 4 weeks or longer".

We agree CTPs should not be used for wounds with a sinus tract. However, full-thickness wounds due to diabetes or venous disease as well as full thickness wounds that are the result of an abscess, trauma or injury often have exposed tendon, muscle or bone that can be appropriately treated with some CTPs that are indicted for with for wounds with exposed tendon, muscle or bone. Therefore the policy should provide coverage for those difficult-to-heal ulcers and wounds whether in the lower or not. Non-healing full thickness chronic wounds due to abscess, trauma or injury can be found in ay part of the body and should be allowed coverage for the application of CTPs per medical necessity.

Therefore, the Alliance requests that CGS revise the language to read as follows:

- "lower extremity partial-or full-thickness diabetic ulcers, and venous ulcers not involving tendon, muscle, joint capsule or exhibiting exposed bone or sinus tracts, with a clean granular base" (**except when a CTP has an indication for use over tendon, muscle, joint or bone. Use of a CTP in a wound with a sinus tract is not covered.)**
- "Presence of a full thickness skin loss ulcer (any location) that is the result of abscess, injury or trauma that has failed to respond to appropriate control of infection, foreign body, tumor resection, or other disease process for a period of 4 weeks or longer." **If these full-thickness wounds involve exposed tendon, muscle or bone, only CTPs with indications for use over these structures will be covered.**

Limitations - Combination Therapy

The Alliance is very concerned with the statement, "combination therapy with any skin substitute (CTP) will be considered not reasonable and necessary. CGS is placing the onus on the physician to treat patients with the best possible treatment options to optimize outcomes. Yet, in wound care, often Alliance members treat their patients with combinations of therapies to enhance their patients' abilities to heal their wounds. There are instances where the products are used for different purposes. For example, using Integra or Epifix to cover bone in the OR (could even be done in clinic), then another product may be used to close the soft tissue, Dermagraft or Oasis. Similarly, this language seems to prohibit the use of compression and off-loading at the same time. Not permitting clinicians to utilize combination therapy that is in the best interest of their patients is not only clinically inappropriate it will significantly impact patient care. The Alliance urges CGS to eliminate the sentence as it restricts physicians' ability to treat their patients with the best treatment options available.

Conclusion

On behalf of the Alliance of Wound Care Stakeholders, we appreciate the opportunity to submit these comments. If you have any questions or would like further information, please do not hesitate to contact me.

Sincerely,

Marcia Nusgart R.Ph.
Executive Director