ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

November 27, 2015

Dr. Antonietta Sculimbrene
Medical Director
Palmetto Government Benefits Administration
Part B Policy
PO Box 100238
AG-275
Columbia, SC 29202-3238

Submitted electronically to: B.Policy@PalmettoGBA.com

RE: DRAFT Local Coverage Determination (LCD) for Application of Skin Substitutes to Lower Extremity Chronic Non Healing Wounds (DL364166**)**

Dear Dr. Sculimbrene:

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), we are pleased to submit the following comments in response to the draft local coverage determination for Application of Skin Substitutes to Lower Extremity Chronic Non Healing Wounds ((DL364166). The Alliance 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.

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 (now known as 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

We appreciate the opportunity to have participated in Palmetto's public meetings in October and value the openness of the conversation between the Medical Directors and the meeting participants.

As I stated in my speech at the Columbia, South Carolina Palmetto meeting, the Alliance would like to convene an educational seminar with you and your staff on CTPs similar to the one we did with CMS coverage, coding and payment staffs in 2012. During that educational inservice, we invited Alliance clinicians who use CTPs to address the science, as well as, how and when they use them in their practice. We also had an FDA lawyer address the FDA regulatory status of CTPs.

5225 Pooks Hill Rd | Suite 627S | Bethesda, MD 20814
T 301.530.7846 | C 301.802.1410 | F 301.530.7946
marcia@woundcarestakeholders.org

At the Richmond, Virginia public meeting, I asked Dr. Brunetti if it might be helpful for the Alliance to include in our comments a model LCD for CTPs; he said a model LCD would be helpful. The Alliance is in the process of drafting a model LCD, Although we were not able to complete before the DRAFT LCD comment deadline, we would like your permission to send it to you as soon as it is drafted- which should be shortly.

In addition to the model LCD, we worked hard to update the attached CTP bibliography which should be very helpful to you. We started with the 2013 bibliography that we provided to CMS and then asked both the Alliance and the Coalition of Wound Care Manufacturers to update it with pertinent published clinical evidence. We also reviewed the bibliographies that the other A/B MACs attached to their LCDs; if we were able to locate the studies and identify the products to which they pertained, we also included those studies in the bibliography.

The Alliance recognizes the challenges and difficulties that the A/B MACs, such as Palmetto GBA, face in managing the LCD development process with new CTPs entering the marketplace. We appreciate that Palmetto GBA has attempted to establish a fair, balanced, and accurate coverage policy.

This draft policy, however, surprised everyone because it is very different from the original draft policy issued in July. In the original draft LCD, the Alliance clinicians could use their clinical judgement to select the CTP that best fit their patients' needs. This new draft LCD limits clinicians' choice to 11 CTPs without an explanation of the scientific evidence that Palmetto GBA used as the rationale for their coverage. In addition, the Alliance has identified the following areas in the draft LCD which are confusing and/or contain inaccurate language:

- Draft LCD contains several clinical inaccuracies
- CTPs are not surgical dressings and the distinctions between them
- Draft LCD is too restrictive compared to the previous draft LCD and does not provide explanation of clinical evidence required for coverage
- Bibliography in the draft LCD is incomplete does not reflect current clinical evidence
- "Skin Substitute" terminology does not clinically describe CTP Technology

Throughout our comments, we refer to "Skin Substitutes" as "Cellular and/or Tissue Based Products for Wounds (CTPs)." After much discussion among the Alliance's scientists, the Alliance voted to adopt this term in 2013 as it is a more clinically appropriate term. Over the past few years, it has widely been accepted in the clinical community when referring to these types of products.

We will address each of these areas in more detail in our specific comments which are presented below in order of importance-not in the order that they appear in the draft LCD.

We highly recommend that any inconsistencies and/or inaccurate language be addressed and corrected prior to issuing a final LCD. This is imperative to our member clinicians, because they may be subjected to payment audits based on the provisions contained in this policy.

Specific Comments

CLINICAL INACCURACIES

Under Coverage Indications, Limitations and/or Medical Necessity

- 2nd paragraph under coverage indications:
  - Concern- Palmetto limits other etiologies of wounds/ulcers.
  - Recommendation: It omits atypical wounds and needs to add them.
- 3rd paragraph – Concern: when describing standard of care, there is no mention of edema management
  - Recommendation- Add "management of edema."
- 4th paragraph- DFU are described as diabetic neuropathic ulcers which is not always accurate.
  - Recommendation: We would recommend only stating diabetic ulcers to keep it more generalized since it also could be a neuroischemic ulcer etc.
- Page 3 of the draft:
  - Draft states that "diabetic ulcers can be particularly difficult to heal and may require additional interventions?" Why only diabetic foot ulcers? All chronic non-healing wounds can be difficult to heal and may require additional interventions. We recommend deleting this sentence.
  - There is a statement that acute wounds "tend to heal within 8 weeks or so with standard care". We disagree with the 8 weeks and would request a reference for this. We believe that the whole paragraph should be rewritten. Instead, it should state" If a chronic wound treated with standard of care has not closed by 40% within 3 weeks, then it is not likely to heal. It is appropriate for the clinician then to consider using advanced wound care therapies such as CTPs." This has been well documented in the literature by Margolis, Sheehan and Phillips.
  - 2nd paragraph – We question the statement that CTPs have been shown to improve management of severe burns. This statement should be deleted. Also, we question the accuracy of the draft stating that CTP can be used when the patients are too ill to have more wound sites created.

Under Indications

- 3rd bullet states that "failed response… has been less than 30% closure from baseline?" We request the references that validate that statement.
- 4th bullet- conservative measures include…..
  - Change "elimination" of edema to "reduction"
  - Appropriate debridement of necrotic tissue. We recommend the addition of nonviable/bioburden. It's not always just necrotic.

- Page 5- Issue- "Medicare will provide payment for one primary skin substitute and one application per date of service"
  - Concern: Patients often have more than one wound that needs to be treated. Draft language precludes clinicians from treating more than one wound in a day when the patient has more than one wound.
  - Recommendation: "Medicare will provide payment for one primary substitute and (one of each CPT code…) application per wound per date of service"

The following HCPCS Codes are considered to be Surgical Dressings

This is an important clinical issue which needs to be corrected in this draft policy. These Q codes listed on page 4 are not "surgical dressings" but CTPs. The distinction between CTPs and surgical dressings are so critical that we have devoted the following section to this issue

CTPs ARE NOT SURGICAL DRESSINGS- DISTINCTIONS BETWEEN THEM.

The Alliance is concerned and has significant issues with the following language on pages 4- 5 of the draft LCD under the heading: *The Following HCPCS Codes are Considered to be* ***Surgical Dressings*** (emphasis added) which states: that the "*Non-graft wound dressings are included in the standard wound care management and as such may preclude the need for skin substitute application. Examples of products considered to fall under this distinction include codes: Q4100, Q4104….. These* ***wound dressings*** *(emphasis added) are not discussed in this LCD*."

Our concerns with these statements are:
1. The products represented by the mentioned Q and C codes are CTPs, not surgical dressings.
2. CTPs are not surgical dressings
3. We are not sure whether Palmetto believes that the terms "wound dressings" and "surgical dressings" are interchangeable.

Please note that CMS and the CMS HCPCS Workgroup do not assign C and Q codes to surgical dressings. In fact, if one looks at the HCPCS Level II coding books, list the CTPs assigned C and Q HCPCS codes under the heading of "skin substitute." (We are also working on the coding organizations to change the name to CTPs!)In the Palmetto public meetings, clinicians and manufacturers all addressed distinctions between surgical dressings and CTPs. The following are some of the distinctions:

Materials and Function

CTPs
- Made of cells, extracellular matrix or a combination of both
- Derived from human tissue (autologous or allogeneic), nonhuman tissue (xenogenic), synthetic materials, or a composite of these materials.
- Are either acellular or cellular
    - Acellular products (e.g., dermis with cellular material removed) contain a matrix or scaffold composed of materials such as collagen, hyaluronic acid, and fibronectin
        - Tissue sources vary (human, bovine, porcine)
        - Components vary (e.g., dermis, pericardium, intestinal mucosa
        - Additives, if used, vary (e.g., antibiotics, surfactants)
        - Processing varies (e.g. wet, freeze dried), and

        - Preparation for use varies (multiple rinses, rehydration).
    - Cellular products contain living cells, e.g. fibroblasts and keratinocytes within a matrix.
- Are uniquely utilized for their ability to enhance wound healing or closure

Surgical Dressings

- Include both primary dressings (i.e., therapeutic or protective coverings applied directly to wounds or lesions either on the skin or caused by an opening to the skin) and secondary dressings (i.e., materials that serve a therapeutic or protective function and that are needed to secure a primary dressing). *(from DMEMAC Surgical Dressing LCD)*
- Cover and protect the wound against the environment

HCPCS Coding Distinctions/Sites of Service

CTPs

- CMS HCPCS Workgroup as assigns Q codes to qualified CTPs
- CTPs must be applied by a qualified health care professional and billed using a CPT® code which describes the application (and preparation of the wound bed)
- CTPs should only be applied in clinical settings e.g. hospitals, hospital-based outpatient departments, , Ambulatory Surgery Centers, skilled nursing facilities, long term care hospitals, and Offices
- Physicians must report the CPT®[1] codes 15271-15278 when they apply CTPs. HOPDs and ASCs must report CPT® codes 15271-15278 when "high cost" CTPs are applied in their facilities, and must used HCPCS codes C5271-C5278 when "low cost" CTPs are applied in their facilities

Surgical Dressings

- CMS HCPCS Workgroup assigns A codes to qualified surgical dressings. Some of the surgical dressing categories are, but are not limited to,
    - :Absorptive - (A6251-A6256), Contact dressing - (A6206-A6208), Foam (A6209-A6215) and Impregnated gauze - (A6222-A6233, A6266, A6456)
- Physicians and facilities may not report procedure codes when they cover wounds with surgical dressings because surgical dressings are "incident to" their work. .
- Durable medical equipment suppliers may report the "A" codes when they provide surgical dressings to 1) patients who self-apply their dressings, at home or 2) to patients who are in nursing facilities not covered by Medicare Part A stays. NOTE: Skilled nursing facilities may also report the "A" codes when they provide surgical dressings to patients who are not covered by Medicare Part C. .

Palmetto uses the words "surgical dressing' and "wound dressing" interchangeability in pages 4-5 of the draft LCD. In the Alliance's verbal and PowerPoint presentation on October 13, 2015, we stated that the FDA asked the Alliance to work with them to modernize its 2006 guidance document on wound care entitled *"Guidance for Industry Chronic Cutaneous Ulcer and Burn Wounds-Developing Products for Treatment"* . At a recent meeting with the FDA, .we discussed payers' confusion about the use of the term "wound dressing" because FDA's definition is different from CMS's definition of "surgical dressing."

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

FDA uses the term "wound dressings" to describe certain type of CTPs. Currently 510(k) and PMA biological CTP products have been put into FDA product classifications indicating that they are "wound dressings." The Alliance educated FDA that the "wound dressing" terminology used for these product categories is outdated and does not represent the true nature of CTPs (as stated above). The Alliance made the distinction that many CTPs are resorbed in the body and that "wound dressing" usually means inert temporary coverings. The Alliance educated FDA that payers often interpret the FDA label of CTPs as "wound dressings" and often believe they are topically applied protective covers and pay them as part of an office visit E&M service rather than separately as CTPs. Could this be the case with Palmetto GBA?

To correct this confusion, the Alliance recommends the following:

- All CTPs that meet Palmetto GBA's published criteria for coverage should be included as covered within this policy and should be referred to as "cellular and/or tissue based products (CTPs)"
- Products that are not covered by Palmetto GBA should not be listed or discussed in the LCD

DRAFT LCD IS TOO RESTRICTIVE COMPARED TO PREVIOUS DRAFT POLICY AND DOES NOT GIVE EXPLANATION OF CLINICAL EVIDENCE FOR COVERAGE

As stated in our general comments, this new policy is very different from the original draft policy issued in July. In the previous July draft LCD, the Alliance clinicians could use their clinical judgement to select the CTP that best fit their patients' needs. Yet, this new draft LCD limits their choice to 11 CTPs and there is no explanation for them to understand the scientific evidence for the rationale in the decision making.

The Alliance values the openness of the conversation between the Medical Directors and the meeting participants. We appreciate when both you and Dr. Brunetti stated that acceptable clinical evidence for coverage would include: well-designed clinical studies appearing in peer reviewed journals inclusive of randomized controlled clinical trial results, prospective case series, retrospective studies, and registry data. Your recognition of accepting real world data (e.g.., case studies, retrospective studies), and not necessarily RCTs, is very important since it accurately reflects the Medicare patients who need CTPs. For the wound care community who utilize CTPs, real-life data more accurately reflects the population that is being treated. Therefore, Palmetto GBA should provide clear direction on acceptable evidence in the final LCD.

Palmetto GBA should make it easier for clinicians to know quickly which products are covered under the final LCD. The Alliance believes the direction can be accomplished in one of two ways:

1. Publish brand specific policy articles for each covered product, similar to the articles in the NGS LCD "Biologic Products for Wound Treatment and Surgical Interventions (L33391)". Each article should include the covered indications, utilization guidelines, appropriate CPT® codes, appropriate HCPCS codes, and a complete list of covered ICD-10-CM codes, prescriptive for the products covered by Palmetto. These articles should include references to the published articles that Palmetto used to establish positive coverage. SEE ATTACHED ARTICLE EXAMPLES.
2. Includes brand-specific information, such as indications and utilization guidelines, in a chart embedded within the LCD. Please see below as an example.

CTP	Covered Indications	Criteria for Coverage	Utilization Guidelines	Application CPT HCPCS Codes
GraftjJacket® Regenerative Tissue Matrix	Full-thickness diabetic foot ulcers greater than three week duration that extend through the dermis, but without tendon, muscle, joint capsule or	Covered as medically necessary when ALL of the following criteria are met: • partial or full-thickness, diabetic foot ulcer of greater than four weeks duration for which standard wound therapy has failed • type 1 or type 2 diabetes mellitus with a hemoglobin A1c (HbA1C) less than 12% • treated foot has adequate blood supply as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of ≥ 0.70 When the above medical necessity criteria are met, one application is considered medically necessary.		15275-15278

(We ran out of space in the above chart but the covered ICD-10 codes should also be included)

BIBLIOGRAPHY

The Alliance is concerned that the bibliography in the DRAFT LCD is incomplete and that the coverage decisions were based on this incomplete reference list. Therefore, The Alliance has attached an updated bibliography which should be very helpful to you.

"SKIN SUBSTITUTE" TERMINOLOGY DOES NOT CLINICALLY DESCRIBE CTP TECHNOLOGY

Throughout our comments, we have used the term "Cellular and/or tissue based products" (CTPs) for wounds instead of "skin substitutes". The Alliance believes that the term "skin substitutes" is not a technically accurate term and does not describe the technology that is either currently or will be in the marketplace for products that contain living cells or constitute tissue-based products intended for use in the management, treatment, or healing of skin wounds.

Historically, these products have been referred to as "skin substitutes" in reference to their initial use as substitutes for skin grafts in clinical procedures. However, over time, the usage of these products shifted toward chronic ulcers where skin grafts are infrequently used and not standard of care. Moreover, newer products in

this category may look nothing like skin and, indeed, have not been designed to function as skin replacements. Thus, there is a need to define terminology in the context of skin wounds as opposed to skin grafting procedures.

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:

- This term is not used by either the FDA in its classification of these products nor by CMS in its coding descriptors.

- The CMS HCPCS Work Group abandoned the term "skin substitute" effective in 2010 when a manufacturer requested that CMS delete this term since it was an incorrect descriptor. The manufacturer stated at the 2010 CMS HCPCS Public Meeting that this language was incorrect since allografts are mislabeled as "skin substitutes." Allografts differ in structure, tissue origin, and in some cases, differ from biologic products in terms of how they are approved by the FDA (human skin for transplantation not devices). CMS thus changed the descriptors and eliminated the term "skin substitutes" from all of the Q-HCPCS codes for these items.

- In addition, the Agency for Healthcare Research and Quality (AHRQ), in its 2011 draft technology assessment on skin substitutes stated that these products are not "skin substitutes."

In 2012, the Alliance embarked on a yearlong effort to determine an appropriate term. In order to achieve a fair and inclusive process for determining this new term, a workgroup of scientists, clinical organizations, and business entities was created from the Alliance to address this issue. Such diverse multidisciplinary clinical specialties societies as the American Podiatric Medical Association, Society of Vascular Medicine, American College of General Surgeons, Association for the Advancement of Wound Care, American Professional Wound Care Association and the American Physical Therapy Association participated in this process.

The following were the criteria used to select the new term:

- be based on science
- be inclusive of all products in marketplace today with an eye towards products in the "pipeline"
- be neutral in regards to FDA--- nothing that would be offensive to FDA and not allow manufacturers to gain clearance to market their products in the future
- ensure that all products are eligible for Medicare coverage as drugs and biological consistent with their USP monographs
- easily understood by clinicians
- easily linked to the existing CPT®/HCPCS codes for the application of the products

The Alliance reviewed over 18 different names during this process and selected the term "Cellular and/or tissue based products for wounds (CTPs)" because it meets the criteria listed above. As such, the Alliance recommends that Palmetto GBA use the more clinically correct term "cellular and/or tissue based products for wounds (CTPs)", rather that "skin substitutes" in its final LCD.

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