COALITION OF
Wound
Care
Manufacturers

November 27, 2015

Palmetto GBA
Part B Policy
PO Box 100238
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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 Drs. Sculimbrene and Brunetti:

The Coalition of Wound Care Manufacturers ("Coalition") is pleased to be submitting our comments to Palmetto GBA on its draft local coverage determination (LCD) for Application of Skin Substitutes to Lower Extremity Chronic Non Healing Wounds (DL364166). The Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds including those products that are subject to provisions contained in this draft LCD. As such we have a particular interest in this draft document.

For your reference, throughout our comments, we refer to "Skin Substitutes" as Cellular and/or Tissue Based Products for Wounds (CTPs) as it is a more clinically appropriate term and has widely been accepted in the clinical community when referring to these types of products.

General Comments

The Coalition appreciates the effort that Palmetto has made in drafting the LCDs.

We recommend that Palmetto retain the current version of its draft LCD but consider changing it to reflect the suggestions and language that we have included in these comments in its final LCD.

We have the following concerns with the most recent draft LCD:

1. The current draft LCD is drastically different from the previous draft LCD without any written explanation as to why this change occurred.
2. The policy does not identify any evidence parameters

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3. While the policy identifies 11 products for coverage, Palmetto inaccurately describes the remaining products as "wound dressings" which is scientifically incorrect
4. The term "skin substitutes" does not accurately describe the technologies discussed in the LCD
5. The bibliography provided in this draft policy is incomplete.
6. There are clinical inaccuracies within the draft policy.

Our specific comments follow for each of the areas identified above.

Specific Comments

Restrictive Policy with No Evidence Parameters Identified

The Coalition members are concerned that the draft LCD is drastically different from the previous draft and until the public meetings, Palmetto had not provided any written explanation as to why there was such a change in the draft policy. At the public meeting in Richmond, VA, the medical directors mentioned that the current draft was the result of comments received on the previous draft policy.

While we recognize that Palmetto has the discretion to issue such a draft, we do not understand why Palmetto made the change when it seems as though the trend in the A/B MAC LCDs is to move to a less restrictive policy in which clinicians have the ability to choose the product that they deem to be appropriate for their patients based on the reasonable and necessary criteria as well as documentation to support clinician choice of product. Noridian, Novitas and First Coast have adopted this approach. The Coalition historically supported that approach and submitted comments accordingly on your original draft policy. However, our views on this have evolved based on our discussions with you during the public meetings. We are in agreement with you that clinical evidence should be required for coverage which we will address further in our comments.

Because Palmetto does not have a published policy for CTPs, it currently processes claims for all CTPs based on reasonable and necessary criteria. Now, with this draft LCD, Palmetto has proposed a policy in which limits coverage to 11 products and does not provide rationale that was used to determine coverage. If the basis for inclusion of these products was reliant upon published evidence, then additional products should also be covered under this policy as there are other products in the marketplace with supportive clinical evidence.

In addition, it is now unclear from this draft LCD whether CTPs would be covered based on package labeling to treat non-DFU or VLU wounds, whether non-DFU or VLU wounds wound be non-covered, or if such non-DFU or VLU wounds are not addressed by this LCD and will continue to be covered as medically necessary if used in accordance with the product's package label. Clarification of allowed indications for use is necessary

in the final LCD. Given that Palmetto has historically not published a policy on indications of use, Palmetto should consider the continuum of patient care and healing prior to any new restriction in coverage to only DFU or VLU wounds of the lower extremity. Therefore, we would encourage Palmetto to allow coverage per product package labeling for the products which meet the minimum evidence of efficacy and safety in the marketplace, as described below.

Palmetto should provide the clinical evidence required for other products to gain positive coverage.

The Coalition is in agreement with the discussions held at the Palmetto public meetings and specifically when the medical directors stated that acceptable clinical evidence 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. We appreciate that the medical directors stated that they would accept real-life data (e.g., case studies, retrospective studies and not necessarily RCTs). For the wound care community who utilize CTPs, real-life data would more accurately reflect the population that is being treated. This approach is consistent with the widely accepted definition of evidence-based medicine that is also adopted by the Patient Centered Outcomes Research Institute or PCORI. In addition, as we stated in our July 2015 comments, the Coalition believes that Palmetto should cover CTPs supported by clinical evidence in peer reviewed journals showing positive outcomes of their products without regard to either how they are regulated by the FDA—Class II, III or HCT/Ps or to how they compare to other products in the marketplace.

Recommendations:

1. Palmetto should keep its current draft LCD with modification. Palmetto should provide clear direction on acceptable clinical evidence needed to gain positive coverage in the final policy.
2. The Coalition recommends that the Palmetto policy include as covered CTPs supported by the clinical evidence clearly defined in its policy. For example, we agree with the statements, made by the Palmetto medical directors in the Richmond, Virginia public meeting, that one or more of the following types of well-designed clinical studies published in peer reviewed journals should be acceptable for coverage:
    1. randomized controlled clinical trial results,
    2. prospective case series
    3. retrospective studies
    4. studies using registry data.

    We have provided sample language for Palmetto to consider with respect to evidence requirements.

3. Palmetto should utilize brand-specific policy articles, such as the ones used in the NGS LCD "*Biologic Products for Wound Treatment and Surgical Interventions (L33391),"* which are prescriptive for the products covered by Palmetto. These articles should include the covered indications, utilizations guidelines, correct CPT® codes and HCPCS codes for the application of the products, correct HCPCS codes for the covered brand, a complete listing of the covered ICD-10-CM codes, and a bibliography of the scientific articles used to establish positive coverage. These articles will provide clear direction to the clinicians. In addition they will display the level of clinical evidence that is acceptable to Palmetto.

Below you will find sample language for consideration by Palmetto regarding the allowed types of clinical evidence that manufacturers should submit for coverage of their CTP:

- *The trials/studies should come from different centers and be published in national or international peer-reviewed (editorial committee is comprised of physicians) journals. Peer-reviewed medical literature includes scientific and medical publications; it does not include in-house publications of manufacturing companies or abstracts (including meeting abstracts).*
- *In principle, rankings of research design should be based on the ability of each study design category to minimize bias. The following is a representative list of study designs (some of which have alternative names):*
    - *-meta-analysis*
    - *-Randomized controlled trials*
    - *-Non-randomized controlled trials*
    - *-Prospective cohort studies*
    - *-Retrospective case control studies*
    - *-Cross-sectional studies*
    - *-Surveillance studies (e.g., using registries or surveys)*
    - *-Consecutive case series*
    - *-Single case reports*
- *The design, conduct and analysis of studies/trials are important factors as well. For example, a well-designed and conducted observational study with a large sample size may provide stronger evidence than a poorly designed and conducted randomized controlled trial with a small sample size.*
- *In determining whether there is supportive clinical evidence for a particular use of a product, the quality of the published evidence must be considered. Such consideration involves the assessment of the following study characteristics:*
    - *The study is adequately powered and is statistically significant (not solely based on the number of study subjects);*
    - *The effect on key status indications. That is, the effect on the healing of the wound and other responses to therapy that indicate effectiveness (e.g.,*

reduction in wound size and/or depth, morbidity, decrease in limb amputation rate);

- *The appropriateness of the study design, that is, whether the experimental design in light of the products and conditions under investigation is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover)*

Wound Dressings versus CTPs

Within the draft LCD, 11 CTP products have been included for coverage while those products not identified would be classified as wound dressings. The Coalition is in disagreement with the designation of CTPs being equivalent to wound dressings. We are in support of the multiple discussions during the Palmetto GBA public meetings whereby scientists, clinicians and manufacturers provided information to distinguish CTPs from wound dressings. The differences between the two include the following:

Definition and Function:

CTPs

- Are made up of cells, extracellular matrix or a combination of both
- May be derived from human tissue (autologous or allogeneic), nonhuman tissue (xenogenic), synthetic materials, or a composite of these materials.
- Can be 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, may vary (e.g., antibiotics, surfactants)
        - Processing may vary(e.g., wet, freeze dried), and
        - Required preparation may vary (e.g., multiple rinses, rehydration).
    - Cellular products contain living cells such as fibroblasts and keratinocytes within a matrix.
- CTPs are uniquely utilized for their ability to enhance wound healing or closure

Surgical Dressings

- 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). *(quoted from DMEMAC Surgical Dressing LCD)*

- Surgical dressings are materials that cover and protect the wound against the environment

How applied to the wound:

CTPs

- Secured with the physician's choice of fixation and then covered with surgical dressings. Qualified healthcare professionals report the application of CTPs with CPT®[1] codes 15271-15278. Hospital-based outpatient wound care departments and ambulatory surgery centers report the applications of "high cost" CTPs with 15271-15278 and report the applications of "low cost" CTPs with C5271 – C5278.

Surgical Dressings

- Adheres by adhesive or tape. No CPT® code utilized for application of the product.

HCPCS Coding Distinctions/Sites of Service

CTPs

- CMS HCPCS Workgroup assigns Q codes to qualified CTPs
- CTPs must be must be applied by a qualified healthcare professional.
- CTPs may be applied in hospitals, hospital-based outpatient wound care departments, ambulatory surgery centers, long term care hospitals, skilled nursing facilities, and qualified healthcare professionals' offices.

Surgical Dressings

- CMS HCPCS Workgroup assigns A codes to surgical dressings based on the categories outlined in the Surgical Dressing LCD. Some, but not all of the categories are:
    - Absorptive - (A6251-A6256), Contact dressing - (A6206-A6208), Foam (A6209-A6215) and Impregnated gauze - (A6222-A6233, A6266, A6456)
- Surgical dressings, that are separately reimbursed by Medicare, are self-applied by the patient in a home setting or in a skilled nursing facility after Medicare Part A benefits are exhausted. . Surgical dressings used in hospitals, hospital-based outpatient wound care departments, ambulatory surgery centers long term care hospitals, skilled nursing facilities during a Medicare Part A stay, and in qualified healthcare professionals' offices are not separately reimbursed by Medicare.

Recommendations:

1. All CTPs that meet Palmetto GBA's published clinical evidence criteria for coverage should be included as covered within this LCD and should be referred to as "cellular and/or tissue based products for wounds (CTPs)"

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

2. CTPs that have not yet met Palmetto's clinical coverage criteria should not be referred to as "wound dressings" and should not be listed in the LCD.

The Term "Skin Substitutes" Does Not Accurately Describe the CTP Technology

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.

As such, the Coalition recommends that Palmetto adopt the term "Cellular and/or tissue based products for wounds" ("CTPs") which accurately describe ,and is broad and inclusive of, both current and future technology. We respectfully point out that other organizations, contractors, and the wound care clinical community are adopting this verbiage. For instance, American Society of Testing and Materials (ASTM) has created a new draft guidance standard specifically using the CTP nomenclature. In addition, Cigna Government Services is utilizing the term "Cellular and/or Tissue Based Products for Wounds" as the title for its LCD.

Bibliography

The bibliography published included this draft LCD is incomplete and does not include the most recent sources available. As stated previously, there are products which are not covered under this policy that have studies and should be considered for coverage under this policy. Some of our member examples include: (and is certainly not limited to) BIOVANCE® (Alliqua BioMedical), ALLOSKIN®(Allosource), - AMNIOEXCEL® Membrane (DermaSciences), and DermACELL (LifeNet Health), just to name a few. We have requested that our members submit their studies to you directly as we know, based on your comments during the open meetings, that you have limited access to these studies.

In addition, we are aware that the Alliance of Wound Care Stakeholders included in their LCD comments a bibliography that was originally presented to CMS and that was recently updated. The Alliance supplied us with a copy of the updated bibliography, which we have attached for your review. We urge you to review this bibliography and utilize it to help make your coverage decisions.

Clinical Inaccuracies

The Coalition is a non-clinical, non-voting member of the Alliance of Wound Care Stakeholders (Alliance). We are aware that the Alliance is submitting comments on the clinical inconsistencies and inaccuracies in this draft LCD and submitted comments on the original draft LCD. We support both of their comments and request that Palmetto implement their recommendations prior to this LCD becoming final.

Conclusion

In summary, the Coalition recommends that:

1. Palmetto retain the current version of its draft LCD but consider making the final LCD reflect the suggestions and language that we have included in these comments.

2. Palmetto should only cover CTPs which have the clinical evidence that Palmetto GBA clearly defines in its final LCD. For example, we are in agreement with the statements made by the Palmetto GBA medical directors in the Richmond, Virginia public meeting, that one or more of the following types of well-designed clinical studies that are published in peer reviewed journals would be acceptable for coverage:
    1. randomized controlled clinical trial results,
    2. prospective case series
    3. retrospective studies
    4. studies using registry data.

3. Palmetto should attach brand-specific policy articles, such as the ones used in the NGS LCD "*Biologic Products for Wound Treatment and Surgical Interventions (L33391)"*, which are prescriptive for the products covered by Palmetto. The advantage to using these articles is that they will include the brand-specific covered indications, utilization guidelines, CPT® and HCPCS codes for the application of the products, HCPCS code(s) for the products, covered ICD-10-CM codes, and list of published clinical evidence that was used to determine positive coverage.

4. Palmetto should consider including sample language on pages 4-5 of these comments to clearly describe the type of clinical evidence that manufacturers must provide to gain positive coverage.

5. The LCD should list all the covered products that meet Palmetto GBA's published clinical evidence criteria and should use the nomenclature "cellular and/or tissue based products for wounds (CTPs)" when referring to the covered

products. The LCD should not refer to the CTPs that are not yet covered and should not list them in the LCD. Palmetto should include the updated bibliography provided by The Alliance of Wound Care Stakeholders in its final LCD.

6. Palmetto should review and adopt the Alliance of Wound Care Stakeholder's clinical comments prior to the finalization of the LCD.

We appreciate the opportunity to provide you with our comments on this important draft LCD. Should you have any questions or require any additional information, please do not hesitate to contact me.

Thank you for your consideration.

Sincerely,

Karen S. Ravitz, JD
Senior Policy Advisor