COALITION OF

Wound Care Manufacturers

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:

The Coalition of Wound Care Manufacturers ("Coalition") is submitting the following comments in response to the Draft Local Coverage Determination (LCD) for Application of Skin Substitute for Wounds, of Lower Extremities (DL36690). The Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of chronic wounds including cellular and/or tissue-based products for wounds (CTPs) that will be impacted by the policy. As such we have a particular interest in this draft LCD and are writing to express our concerns.

When the current LCD was issued, the Coalition complimented CGS as being a trendsetter, as your company was the first to recognize and adopt the CTP nomenclature as the title of, and within the body of the current policy. At that time, you understood that the term "cellular and/or tissue based products for wounds" more accurately reflected the technology for these products. The clinical community and scientific journals utilize the CTP nomenclature, and it has been approved by the ASTM (the international standard setting organization). As such, the Coalition is disappointed that CGS has decided to abandon utilizing this term in your LCD title. Why would CGS decide to go back and utilize incorrect terminology in describing the products that are subject to this policy? The term skin substitute is not scientifically or technically accurate and does not describe the technology for the products described in this policy. The Coalition will refer to "skin substitutes" as CTPs throughout our comment letter and we respectfully request that CGS continue to utilize the CTP terminology in the title of this LCD as well as within the body of the policy.

Our specific comments follow.

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Conflicting Language

The Coalitions' biggest concern is the conflicting language that is contained in this policy as it relates to the products identified in your policy for coverage. The two statements that conflict are:

*"**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**".*

And

*"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**. "*

The Coalition agrees with the first statement. This statement is accurate and represents the Q code products identified in your coverage policy. The 361 HCT/P products that meet the criteria established in 21 C.F.R. Part 1271 are regulated solely under §361 of the PHS Act (i.e., "361 HCT/Ps products") and are not required to be licensed, approved, or cleared prior to their introduction into interstate commerce. The Coalition appreciates that CGS has recognized this within the first statement and will equally consider these products for coverage.

However, we do not agree with the second statement. This statement is the source of confusion among the clinical community. Based on your language, all 361 HCT/P products are considered biologic dressings under this draft policy and therefore not separately reimbursed despite the first statement – that they will be equally considered. They can not be equally considered under this policy if they are a) not separately reimbursed and 2) considered wound dressings.

None of the 361 HCT/P products are wound dressings. They are all CTPs. Besides looking different, CTPs are very different than wound dressings. The products are stored differently, have different mechanisms of action, are affixed differently, are coded differently and have different properties including the fact that CTPs have biologic effect inherent in the tissue. The definition of a dressing – taken from the DMEMAC surgical dressing policy is: *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).*

Dressings are materials that cover and protect the wound against the environment without exerting any direct biological effect and are classified by CMS with an "A" HCPCS code. There are different types of dressings that fit under the surgical dressing benefit including but not limited to: Absorptive - (A6251-A6256), Contact dressing - (A6206-A6208), Foam - (A6209-A6215) and Impregnated gauze - (A6222-A6233, A6266, A6456)

CTPS on the other hand contain viable or non-viable cells and /or are derived from biologic tissue with intrinsic biological activity, are usually not removed from the wound, are uniquely utilized for their biological influence on the healing process by either their positive influence on the healing process without incorporation OR having the ability to stimulate or support healing through incorporation in whole or part into the regenerative issue. All of these products have been assigned a HCPCS Q code by CMS.

CTPs are materials made up of cells, extracellular matrix or a combination of both and can be classified into several types: they may be derived from human tissue (autologous or allogeneic), nonhuman tissue (xenographic), synthetic materials, or a composite of these materials. They 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. The various Acellular products can differ in a number of ways, including species source (human, bovine, porcine), tissue source (e.g., dermis, pericardium, intestinal mucosa), additives (e.g., antibiotics, surfactants), hydration (wet, freeze dried) and required preparation (multiple rinses, rehydration). Cellular products on the other hand contain living cells such as fibroblasts and keratinocytes within a matrix. The cells contained within the matrix may be autologous, allogeneic, or derived from other species (e.g., bovine, porcine).

CTPs may also be composed of dermal cells, epidermal cells, or a combination of dermal and epidermal cells and may provide growth factors to stimulate healing.

Regardless of their composition, CTPs are NOT wound dressings. It is simply scientifically incorrect to classify them in that manner. Furthermore, the 361 products will not be treated equally under this policy should CGS continue to utilize the statement, "*All listed products, unless they are specifically **FDA-labeled or cleared** for use in the types of wounds being treated".*

As such, the Coalition urges CGS to eliminate this language in the policy or at the very least revise the statement to read, "*All listed products, unless they are specifically **FDA-labeled or cleared** for use in the types of wounds being treated, **or are 361 designated product**s, will be considered to be biologic dressings and part of the relevant Evaluation and Management (E/M) service provided and not separately reimbursed".*

Coverage Guidance – FDA designations

Within the policy CGS has described the various pathways in which CTPs are regulated and identified 4 categories: PMA, 510K, HDE, and HCT/P. However, CGS failed to mention the 5th category: a biologic license application (BLA). Several CTP products do utilize this regulatory pathway. Should CGS decide to list the categories in which CTP products can be regulated by the FDA, the BLA should be added. A BLA is a request for permission to introduce, or deliver for introduction, a biologic product into interstate commerce not otherwise regulated by the FDA for interstate commerce.

Clinical Inaccuracies

The Coalition is a non-clinical, non-voting member of the Alliance of Wound Care Stakeholders (Alliance). The Alliance represents most of the major clinical specialty societies/organizations in wound care. Their clinical expertise in this area is second to none. We are aware that the Alliance is submitting comments on the clinical inconsistencies and inaccuracies in this draft policy and submitted comments on the draft LCD. We support their comments and request that CGS implement their recommendations prior to this policy becoming final.

CONCLUSION

The Coalition appreciates the opportunity to provide our comments. If you need more information or have any questions, please do not hesitate to contact me.

Sincerely,

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Coalition of Wound Care Manufacturers
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