

Coalition of Wound Care Manufacturers

**Open Public Meeting
Presentation to Palmetto GBA
On Draft Skin Substitute LCD
Richmond, Virginia**

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Who Is The Coalition of Wound Care Manufacturers

- ❖ Founded in 2000, Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds.
- ❖ Mission:
 - Serve as an advocacy organization for a regulatory, economic and legal climate that promotes patient access to wound care products and their corresponding services.
 - Impact regulatory, government and public affairs issues that affect wound care manufacturers.
 - Provide members with targeted advocacy, information, education and guidance to optimize success in the complex world of health care regulations.

Concerns With The Draft LCD

- ◆ Draft LCD is drastically different from the previous draft LCD without any explanation. Coverage would now be limited by covering only 11 products therefore eliminating their access for clinicians and Medicare beneficiaries
- ◆ Remaining products that are not covered in this draft policy are deemed to be wound dressings. None of these products are wound dressings
- ◆ Bibliography should be complete and updated

Concern #1: Draft LCD Deviates From Previous Draft LCD Without Any Transparency

- ◆ There is no transparency regarding why the draft policy was changed from a policy in which clinicians had the ability to choose the product they deemed to be appropriate for their patient based on reasonable and necessary versus this restrictive policy in which only 11 products are now available to them.
- ◆ How were products chosen for coverage under this policy? There are no coverage parameters identified.
- ◆ Limiting product choices for clinicians and patients when historically Palmetto has not had a published policy but based coverage on reasonable and necessary.

Concern #2: None of The Products in This Policy Are Wound Dressings

◆ Definition From the DMEMAC Surgical Dressing Policy:

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).

◆ Function and Coding of Dressings:

- ◆ Materials utilized for covering and protecting a wound
- ◆ Help shield the wound against the environment without exerting any direct biological effect
- ◆ Are classified by CMS with an “A” code

Examples of Dressings

- ◆ Absorptive
- ◆ Alginate
- ◆ Collagen
- ◆ Contact dressing
- ◆ Foam
- ◆ Hydrogel
- ◆ Hydrocolloid
- ◆ Gel
- ◆ Impregnated gauze

Concern #2: None of The Products in This Policy Are Wound Dressings (cont.)

◆ Cellular and/or Tissue Based Products for Wounds (CTP) -Technology, Coding and Function:

- ◆ Are classified by CMS with a “Q” code
- ◆ Contain viable or non-viable cells and /or are derived from biologic tissue with intrinsic biological activity
- ◆ Usually not removed from the wound
- ◆ Uniquely utilized for their biological influence on the healing process
- ◆ Positive influence on the healing process without incorporation OR have the ability to stimulate or support healing through incorporation in whole or part into the regenerative issue

CTP Examples

Autologous skin grafts, or autografts use skin from different parts of the individual's body.

Allografts which use skin or other human tissue from another human (e.g., consented human donor)

Xenografts which use skin from another species (e.g., porcine or bovine)

Bioengineered Skin / Cultured Epidermal Autografts (CEA) are autologous tissue derived from the patient's own skin cells grown or cultured from very small amounts of skin or hair follicle.

Allogeneic Acellular matrices derived from human tissue (fibroblasts, dermis or amniotic membrane)

Xenogenic Acellular matrices derived from xenogeneic collagen or tissue

Composite Matrices are derived from human keratinocytes and/or fibroblasts supported by a scaffold of synthetic mesh or xenogeneic collagen.

Comparison Between Wound Dressing and CTPs

| Distinguishing Factors | CTP | Wound Dressing |
|------------------------|--|---|
| Function | Positive influence on the healing process without incorporation or stimulates or supports healing through incorporation in whole or in part into the regenerative tissue | Covers and Protects the Wound |
| Biologic activity | Biologic effect is inherent in the tissue | No inherent biologic effect in the dressing |

(Continued)

Comparison Between Wound Dressing and CTPs

| Distinguishing Factors | CTP | Wound Dressing |
|--------------------------|--|---|
| How Applied to the Wound | Affixes by physician discretion. Required to utilize a CPT code (15271-15278) for clinician to apply it to the wound | Adheres by adhesive or tape. No CPT code utilized for application of the product. |
| Storage | May have special handling/storage. | Off the shelf |
| HCPCS Codes | CMS issues Q Codes | CMS issues A Codes |

Wound Dressings V. CTPs

Live Demonstration

The distinctions between wound dressings and cellular and/or tissue based product for wounds

Concern #3: Bibliography is Outdated and Limited

- ◆ Recommend a complete and updated bibliography be provided by Palmetto

Recommendations

- ◆ This LCD should be withdrawn
- ◆ The previous draft LCD should be reinstated after correcting clinical inaccuracies