

ALLIANCE OF WOUND CARE STAKEHOLDERS

*Palmetto GBA
Public Meeting*

*Draft LCD on Application of Skin
Substitutes (DL36466)*

October 13, 2015

ALLIANCE OF WOUND CARE STAKEHOLDERS

➤ Who is the Alliance?

- *A non-profit interprofessional 501(c)6 trade association of health care clinical and patient organizations*
- *Serves as an “umbrella” association for organizations whose members treat patients with wounds*
- *Organizations select specifically qualified members (possibly a board member) to represent them on a volunteer basis on the Alliance*

➤ Mission of the Alliance:

- *To promote quality care and access to wound care products and services for people with wounds. This is accomplished by focusing on compelling issues of commonality to the organizations in the reimbursement, government and public affairs affecting wound care.*

➤ Website:

- www.woundcarestakeholders.org

HOW CAN THE ALLIANCE HELP PALMETTO GBA?

- Serves as unbiased multidisciplinary knowledgeable clinical resource for information and as a collaborator
- Can address any wound care related subject matters
- Consist of physicians, surgeons (general, vascular and foot/ankle), podiatrists, physical therapists, nurses, dieticians
- Can help Palmetto GBA with:
 - Technical questions
 - Organizing educational seminars
 - Educating staff
- Happy to convene educational seminar on this issue as we did with CMS staff

CURRENT MEMBERS

CLINICAL ASSOCIATIONS

- Academy of Nutrition and Dietetics
- American Association of Nurse Practitioners
- American College of Foot & Ankle Surgeons
- American College of Hyperbaric Medicine
- American College of Phlebology
- American College of Wound Healing and Tissue Repair
- American Physical Therapy Association
- American Podiatric Medical Association
- American Professional Wound Care Association

CURRENT MEMBERS

CLINICAL ASSOCIATIONS (CONT.)

- American Venous Forum
- Association for the Advancement of Wound Care
- Dermatology Nurses Association
- National Association for Home Care and Hospice
- Society for Vascular Medicine
- Society for Vascular Surgery
- Undersea & Hyperbaric Medical Society
- Visiting Nurse Associations of America

FOUNDATIONS OF ALLIANCE WORKPLAN

- **Wound Care Research**
- **Wound Care Quality Measures**
- **Reimbursement Issues: Coverage, Coding and Payment**

PRESENTATION OVERVIEW

- **Issues with the Draft Policy**
 - Products are not wound dressings
 - Distinctions between wound dressings and CTPs
 - FDA and CTPs
 - Terminology does not adequately describe the technology
 - Rationale for new terminology of Cellular and/or Tissue based products for wounds (CTPs)
 - Clinical inaccuracies in the draft policy
 - References are dated and the policy should reflect current studies
- **Recommendation: Palmetto GBA should revert back to previous draft policy which allowed clinicians autonomy in choosing products based on medical necessity**
 - Lack of transparency in the complete reversal from the previous draft
 - Does not follow the trends of other A/B MACs in allowing clinical autonomy in choosing products – based on medical necessity (i.e., First Coast, Novitas)

CTPs ARE NOT WOUND COVERINGS/DRESSINGS

- Confusion by payers on use of the term “wound dressing” since FDA definition is different from CMS use of “surgical dressing” Alliance presented this to FDA staff on modernizing its 2006 guidance document
 - Currently 510(k) and PMA biological CTP products have been put into FDA product classifications indicating that they are “wound dressings.”
 - “Wound dressing” terminology used for these product categories is outdated and cannot represent the true nature of these products.
 - Many of the products are resorbed in the body, and some are temporary.
 - “Wound dressing” usually means inert temporary coverings.
 - Many payers have been confused with FDA labeling CTPs as “wound dressings”; payers thus believe they are topically applied protective covers and pay them as part of an office visit E&M service
 - CTP products are applied surgically, most with an associated debridement or excision prior to their application.

HOW CTPs ARE DIFFERENT FROM WOUND COVERINGS/DRESSINGS

- **Dressings –**
 - Any of various 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 “A” codes
- **Cellular and/or Tissue Based Products for wounds–**
 - Contain viable or non-viable cells and/or are derived from biological 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
 - Ability to stimulate or support healing through incorporation in whole or part into the regenerating tissue
 - Are classified by CMS with “Q” codes

REGULATORY STATUS

- **FDA classifies CTPs into three groups:**
 - **Biologics - Biologics Licensing Application (BLA) or Biosimilar application (§ 351(k) application)**
 - **Medical devices**
 - **Class II - Premarket notification (510(k))**
 - **Class III - Premarket approval (PMA)**
 - **Human cells, tissues, and cellular and tissue-based products (HCT/Ps) - FDA approval/clearance not required if no treatment-related claims made**
 - **361 - not subject to premarket review requirements as they are deemed to be safe and effective and meet the 4 requirements under the Public Health Service Part 1271.**
 - Is minimally manipulated
 - Intended for homologous use
 - Not combined with another article
 - Does not have systemic effect and is not dependent upon the metabolic activity of living cells for its primary function
 - Examples include (but not limited to):
 - » Biovance
 - » Dermacell
 - » Graftjacket *
 - » Theraskin *
 - **351 - Do not meet the requirements under the Public Health Service Part 1271 and therefore require a PMA or BLA**
 - Examples include (but are not limited to)
 - » Apligraf
 - » Dermagraft

REGULATORY STATUS

- **FDA classifies products based on:**
 - Principal mode of action
 - Example: A device does not achieve any of its primary intended purposes through chemical action within or on the body and is not dependent upon being metabolized for the achievement of any of its primary intended purposes.
 - Components of the product
 - Example: Device products that contain cells are assigned to Class III
 - Claims made about what the product does
 - Example: Class II device products are typically indicated for the “management” of wounds; whereas Class III device products are indicated for the “treatment” of wounds.
- **Recommendation:** All products for which CMS has issued a “Q” code should be CTPs and covered under this policy and should not be considered wound dressings regardless of their FDA regulatory pathway

ALLIANCE RECOMMENDS THAT PALMETTO GBA USES CTPs INSTEAD OF “SKIN SUBSTITUTES”

- Voted to adopt new name “Cellular and/or Tissue based products for wounds” (CTPs) to use instead of skin substitute in 2012
- Reason to change- clinically inaccurate term and impacted both coding and coverage criteria
- Right time-
 - AHRQ stated that these products were not “skin substitutes” since a true “skin substitute” would act like an autologous skin graft in adhering to the wound bed while providing the physiological and mechanical functions of normal skin.
 - CMS abandoned term when the Agency agreed that these products are not skin substitutes and instead issued Q codes for each individual product by its brand name.
- Process- fair and inclusive / a workgroup of scientists, clinical organizations, and business entities
- Reviewed 18 terms- needed to be broad and inclusive to include both present and future technology.

CRITERIA ALLIANCE WORKGROUP USED TO SELECT NEW NOMENCLATURE TO REPLACE “SKIN SUBSTITUTES”

- be based on science
- be inclusive of all products in marketplace today with eye towards what is in the “pipeline”
- be neutral in regards to FDA--- nothing that would be offensive and not allow manufacturers to get their products approved in the future if needed
- ensure that all products are eligible for Medicare coverage as drugs and biologicals consistent with their USP monographs
- easily understood by clinicians
- easily linked to the existing CPT codes for the application of the products

Winner- CTPs!

CLINICAL INACCURACIES WITH DRAFT (INCLUDING BUT LIMITED TO)

- One product and application per day
 - Issue- Patients have more than one wound that need to be treated. Language will preclude clinician from being able to treat more than one wound in a day on given patient when the patient may in fact 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”
- 2nd paragraph under coverage indications: Palmetto limits other etiologies of wounds/ulcers (omit atypicals)
- 3rd paragraph - when describing standard of care, there is no mention of edema management
- 4th paragraph- DFU are described as diabetic neuropathic ulcers which is not always accurate. Better language would be diabetic ulcers to keep it more generalized. (could be a neuroischemic etc ulcer).

CLINICAL INACCURACIES WITH DRAFT

- 4th paragraph- DFU are described as diabetic neuropathic ulcers which is not always accurate. Better language would be diabetic ulcers to keep it more generalized. (it could be a neuroischemic etc ulcer).
- Draft states that diabetic ulcers can be particularly difficult to heal and may require additional interventions? Why only DFU? – all chronic non healing wounds can be difficult to heal and may require additional interventions
- Page 3 of the draft, 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 reference. We believe that the whole paragraph should be rewritten.

CLINICAL INACCURACIES WITH DRAFT (CONT.)

- 2nd paragraph pg 3- Question the statement that CTPs have been shown to improve management of severe burns. 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- failed response is less than 30% closure from baseline? Which references validate that?
 - 4th bullet- conservative measures include.....
 - Change elimination of edema to reduction
 - Appropriate debridement of necrotic tissue/ should add nonviable/bioburden. It's not always just necrotic.

RECOMMENDATION

- **Palmetto GBA should revert back to previous draft policy which allowed clinicians autonomy in choosing products based on medical necessity**
 - Lack of transparency in the complete reversal from the previous draft
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CLINICAL PRACTICE: WHEN TO USE

- **Roles in wound healing**
 - Uniquely utilized for their biological influence on the healing process
 - Used to facilitate and orchestrate wound healing, particularly when the wound is not responding to standard wound care
 - Stimulate and augment the wound's intrinsic healing pathways
- **Medically necessary when wounds, for myriad reasons, fail to close or fail to progress through healing stages in a timely fashion, thereby becoming chronic, increasing complications and costs**
 - Direct costs of chronic wounds estimated at \$9.5 billion annually in United States¹

¹Bickers DR, et al. J Am Acad Dermatol. 2006;55(3):490–500. ²Steed DL, et al. Wound Rep Reg. 2006;14:680–692. ³Whitney J, et al. Wound Rep Reg. 2006;14:663–679. ⁴Robson MC, et al. Wound Rep Reg. 2006;14:649–662. ⁵International Consensus on Acellular Matrices for Chronic Wounds. Wounds International 2011. Available at: <http://www.woundsinternational.com/clinical-guidelines/acellular-matrices-for-the-treatment-of-wounds>.

CLINICAL PRACTICE: HOW OUR MEMBERS SELECT

- CTPs available to clinicians today represent the current therapeutic mainstay for patients with chronic wounds
- Selection among products
 - Based on specific evidence related to biological function and clinical efficacy in wound healing
 - Based on wound-related factors (eg, nature of the biological perturbations in the wound, location and type of wound)
 - Based on patient characteristics (eg, age, pre-existing co-morbidities)
 - Based on product characteristics (eg, size, application regimen)

Elements of Medical Decision Making

