

COMMENTS ON THE CLASSIFICATION OF WOUND CARE PRODUCTS WITH DRUGS

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ALLIANCE OF WOUND CARE STAKEHOLDERS

➤ Who is the Alliance?

- *A non-profit multidisciplinary trade association of physician specialty societies and clinical associations whose members treat patients with wounds*
- *Serves as an “umbrella” association for clinical organizations whose members treat patients with wounds*

➤ Mission of the Alliance:

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

CLINICAL ASSOCIATION MEMBERS

(Wound care is multi-disciplinary)

- 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 Diabetes Association® Interest Group on Foot Care
- American Physical Therapy Association
- American Podiatric Medical Association
- American Professional Wound Care Association
- American Venous Forum
- Association for the Advancement of Wound Care
- Dermatology Nurses Association
- National Association for Home Care and Hospice
- National Lymphedema Network
- Society for Vascular Medicine
- Society for Vascular Surgery
- Undersea & Hyperbaric Medical Society
- Visiting Nurses Association of America

FOUNDATIONS OF ALLIANCE WORKPLAN

- Wound Care Quality Measures
- Wound Care Research
- Regulatory Issues- Work with FDA
 - Updating 2006 Guidance for Industry-Developing Products for Treatment
 - Testify at Sept 12-13 meeting on Regulation of HCT/Ps
 - Home Care Issues
- Reimbursement Issues- Coverage, Coding and Payment
 - Submit Comments to Centers for Medicare and Medicaid Services and its Contractors
 - Serve as resource to CMS coverage, coding and payment staff for education about wound care

KEY POINTS TO CONSIDER

- Products in FRO category should be classified by FDA in either Class I or II, most remaining subject to 510 (k)
 - Wound dressings with drugs are used for the management of wounds not the treatment of wounds
 - Wound dressings with drugs have significant levels of clinical experience including clinical trial and literature in peer reviewed journals including safe and effective use
- Wound care patients often have co-morbidities
- Wound healing is complicated process and treating patients with chronic wounds is complex
- Chronic wounds may fail to heal and even when they do- 80% recurrence rate -little can be done to mitigate risk factors associated with their development

PRODUCTS IN FRO CATEGORY

- Products in FRO category should be classified by FDA in either Class I or II, most remaining subject to 510 (k)
 - Low to moderate risk
 - Have been in the marketplace for many years with a long history of safe and effective use
- Many diverse product groups with different indications for use- FDA may want to separate them out
 - Wound dressings with drugs are used for the MANAGEMENT not the treatment of wounds
- Effective controls- bench testing and animal studies to establish they are as safe and effective as those already in the market

TERMINOLOGY

- Antimicrobial agents are substances that kill or inhibit the growth of microorganisms. In many instances in which the antimicrobial acts outside the body, such as antimicrobial sterile drapes and gloves used in patient procedures, FDA does not treat the antimicrobial as a drug. FDA has regulated such products as devices rather than combination products. Today these products meet many of the general requirements for combination products.
- Antibiotics- FDA's definition of antibiotics is a subset of antimicrobials- often known as antimicrobial drugs, are drugs that fight infections caused by bacteria-
 - Antiseptics- Health care antiseptics are antimicrobial agents that are intended to reduce the number of micro-organisms on the skin.

COMPELLING INFORMATION ABOUT WOUND CARE

- Many different specialists who treat patients with chronic wounds whose contributions to care must be captured
- Wound care is a community who works hard for patients
 - Clinicians want what is best for their patients
 - Manufacturers develop products where the patient is their focus
- Wound care patients often have co-morbidities
 - Address chronic wounds- venous stasis, diabetic foot ulcers, pressure ulcers, arterial ulcers- all have different algorithms to manage the wounds
 - Occur patients with diabetes, peripheral artery disease, result of unique medical problems (vasculitis) or immunosuppression
 - Pressure ulcers- hospitalizations include pneumonia, urinary tract infections, congestive heart failure, etc.

COMPELLING INFORMATION ABOUT WOUND CARE (CONT.)

- Wound healing is a complicated process and treating patients with chronic wounds is complex
 - Process of wound healing- metabolic, structural, biochemical and patient factors in a unique way
 - Result of complex overlapping processes
 - Chronic wounds are dynamic, wound needs often change, requiring the order and combinations of treatments to be varied based upon frequent wound assessments and may be used anywhere along the wound healing cascade
 - Wound care products with drugs are only one of the products used to manage these chronic wounds; but they are an important tool for clinicians to use