COALITION OF Wound Care Manufacturers

Protecting and Advocating for CTPs

Use of cellular and tissue-based products for wounds (CTPs) is under threat from restrictive local coverage determinations, flawed reimbursement rates and regulatory scrutiny. A unified wound care manufacturer voice is needed to protect access to these important products. Threats we address include:

Reimbursement rates are set based on flawed, incomplete claims data

- The bundled/packaged payment for CTP products under the Hospital Outpatient Prospective Payment System (HOPPS) has been set artificially low, driven in part by flawed claims data analyzed by CMS to set price. Many hospitals fail to enter claims based on the total amount of square centimeters used. This has skewed the actual amount of CTPs used to treat Medicare beneficiaries, establishes incorrect thresholds, and thus has skewed reimbursement rates to a significantly lower level. Similarly, the payment methodology of grouping CTPs into two categories, high-cost and low-cost, ignores the differentiating evidence supporting the use of these products.
- As a result, hospitals can potentially lose money with some CTP products if reimbursement doesn't cover cost. This can cause health systems to make purchase changes if they are looking primarily for the lowest cost product rather than the best product for the wound being treated.
- Such decisions can significantly restrict the choices clinicians can make, impact treatment options being provided to patients, hurt manufacturers and hurt the overall wound care marketplace.

LCD utilization parameters for wound care treatments/services and documentation requirements are becoming increasingly burdensome

- Medicare Administrative Contractors (MACs) are putting utilization parameters in place and documentation requirements that are increasingly burdensome to clinicians.
- Of concern, some LCDs now include usage determinations that are inconsistent with products' instructions for use.
- These artificial limits can force clinicians to use CTPs in a way inconsistent with the product instructions.

Regulatory agencies don't fully understand the role of CTPs and are placing higher scrutiny on them

- Given the FDA's and CMS's continued use of the terms "skin substitute," the agencies seem to not fully understand what these products are, what they do and the evidence that supports them.
- Similarly, CTP coverage policies and draft guidance documents issued by the FDA illustrate a lack of knowledge on how these products have evolved and how they differ from wound dressings.
- Given the number of CTP products entering the marketplace, more scrutiny to the product sector is likely to flow from regulatory agencies.

Join the Coalition of Wound Care Manufacturers and have a voice to these issues:

It is essential that manufacturers speak with a unified voice about the value and use of CTPs in wound management. The Coalition has long been proactive in addressing regulatory and legislative issues that could impact coverage, coding and payment implications for CTPs. We:

- Convene a dedicated work group focused on CTP issues.
- Take an active role sharing analysis of draft CMS and A/B MAC policies and LCDs, collecting consensus inputs and submitting comments in a unified voice, as well as support member companies in addressing their own unique issues via comment.
- Keep members informed of emerging issues, relevant public meetings and regulatory/legislative activities that can impact CTPs, as well as host expert speakers to address key topics.

The Coalition functions as the respected and credible unified voice of wound care manufacturers to private/public payers and the government entities to ensure patient access to wound care products and services.

Membership provides the ability to identify, strategize, and take action on regulatory and legislative issues using the collective power of the Coalition.

Our 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.
- **Unite wound care manufacturers** to speak with one voice to regulatory agencies and legislative bodies and use the collective power to effect positive change in the wound care industry
- **Impact regulatory, legislative, and public affairs issues** that affect wound care manufacturers.
- **Position the Coalition of Wound Care Manufacturers as a highly visible, respected** and credible resource of industry information for the federal agencies that control or have influence on the coding, coverage and payment rules under Medicare and Medicaid for wound care products:
  - Congress
  - Centers for Medicare and Medicaid Services and its contractors, including: Durable Medical Equipment Medicare Administrative Contractor [DMEMAC] and A/B MAC Medical Directors; Pricing Data Analysis Contractor (PDAC), Center for Medicare and Medicaid Innovations (CMMI)
  - Food and Drug Administration (FDA)
  - State Medicaid Agencies, Agency for Healthcare Research and Quality (AHRQ), Office of Inspector General, Medicare Payment Advisory Commission (MEDPAC), Patient Centered Outcomes Research Institute (PCORI), U.S. Pharmacopeia (USP)
- **Provide members with targeted advocacy, information, education** and guidance to optimize success in the complex world of health care legislation and regulations.

The Value of Coalition Membership:

- **Allows you to sit at the table with other manufacturers** to dictate direction of the Coalition and our comments on substantive policy positions. Enhances individual member company's influence with the collective power of the Coalition to effect change.
- **Ensures you are up to date and fully briefed** on federal and state regulatory and legislative issues impacting wound care manufacturers with respect to Medicare and Medicaid coding, coverage and payment issues. Sends members updates on timely basis and alerts when to take action.
- **Provides expert guest speakers and opinion leaders** at meetings and on monthly calls to address hot and current topics impacting your business and health care delivery.
- **Enables access to key policy makers** by convening meetings with Members of Congress and their staff, senior staff at CMS and CMScontractors, DMEMAC and A/B MAC Medical Directors, PDAC and FDA. Provides members with access to key policy decision makers to address their own and their customers' specific regulatory problems.
- **Facilitates comment submission** by taking the lead in analyzing policies and drafting comments and solutions to solve coverage, coding and payment issues that adversely impact the Coalition's members and their customers. Supports member companies in development of their own standalone comments.
- **Serves as resource to members** in order to answer your specific policy questions. Provides business-critical information impacting members' products.

Learn more about Coalition membership. Contact the Coalition's Executive Director, Marcia Nusgart at marcia@woundcaremanufacturers.org or 301.802.1410