

ALLIANCE OF WOUND CARE STAKEHOLDERS 2013 ACCOMPLISHMENTS AND ACTIVITIES

Comments can be found at: <http://woundcarestakeholders.org/activities-a-accomplishments/official-comments>

ACCOMPLISHMENTS

- Worked with the U.S. Wound Care Registry to develop 12 new Physician Quality Reporting System (PQRS) wound care measures as submitted through the Qualified Clinical Data Registry process to CMS.
- Created and adopted the proposed Alliance terminology “Cellular and/or Tissue Based Products for Wounds” (CTPs) in place of clinically inaccurate term “skin substitutes” which was also included by A/B MACs in their LCDs (Cigna, Novitas Solutions) and by ASTM in its draft guidance document.
- Created unified voice of Alliance members to be proactive and quickly responsive to the release of the CMS Hospital Outpatient PPS proposed rule on the packaging of CTPs by meeting with CMS senior staff and Members of Congress.
- AHRQ adopted many of Alliance comments in final version of its technology assessment on CTPs
- Responded to CMS proposed rules on issues involving wound care by submitting three sets of comments to CMS: coverage with evidence development, inpatient prospective payment system and hospital outpatient prospective payment system.
- Submitted four sets of comments to CMS A/B Medicare Administrative Contractors on their draft wound care local coverage determination.
- Submitted two letters to Milliman Care Guideline’s Editor in chief and CEO to address inaccuracies in its guidelines based on faulty evidence review which impacted patients’ access to intermittent pneumatic compression devices since payers were adopting the guidelines in their coverage policies.

ACTIVITIES

➤ QUALITY MEASURES

- Recognizing the need for developing wound care quality measures, the Alliance performed the following activities:
 - Convene Alliance meeting on quality measures at SAWC spring
 - Attended National Quality Forum annual meeting and MAP Clinician workgroup meeting
 - Submitted two sets of quality measures to CMS on venous stasis (compression) and diabetic foot ulcers (offloading). Addressed on Alliance calls the need for testing of these measures and funding and prepared budgets with timelines of activities.
- Decided to work with the US Wound Care Registry as they self-nominate to CMS being a Qualified Clinical Data Registry and develop wound care quality measures in 2014 (De

➤ CELLULAR AND TISSUE BASED PRODUCTS FOR WOUNDS (CTPs)

Payment Issues-CTPs

Hospital Outpatient Prospective Payment System (HOPPs) and CTPs

- Created unified voice of Alliance members to be proactive and quickly responsive to the release of the HOPPs proposed rule as it impacted CTPs by doing the following:
 - Sending the proposed rule out to members and asking them for questions that they would like Alliance staff to submit to CMS for answers (July)
 - Hired attorney Larry Oday to review HOPPs rule and address implications and possible strategies on Alliance call (Aug)
 - Attended CMS APC meeting when packaging issues were discussed and advised members that the meeting was webcast for their own viewing (Aug)
 - Represented the wound care industry in meeting with Director John McInnes and his senior staff to address concerns; worked with attorney Paul Radensky to address legal argument; AAWCM to state financial issues and clinical associations to have representatives state the clinical arguments. Held multiple conference calls to determine strategy. CMS requested further information on legal arguments and financial issues. (Aug)
 - Reached out to other associations to determine their positions on issues (Aug)
 - Submitted comments to CMS (Sept)
 - Hired attorney Paul Radensky to review final rule on HOPPS and give guidance on Alliance call for advocacy strategy and next steps
- Educated Senator Casey's staff on Alliance position regarding his amendment to delay the HOPPs rule but include all CTPs instead of those who are PMA or BLA cleared by FDA (Dec)
 - Alerted members about amendment and asked them to call their Members of Congress to include all CTPs in the delay
 - Met with Senator Casey's staff to educate them on Alliance's position

Coverage Issues-CTPs

- Submitted four sets of comments on CTP draft LCDs:
 - First Coast (March)
 - Cigna Government Services (April)
 - Novitas Solutions (July, Nov.)
- Alliance follows up on its meeting with AHRQ and CMS staff (Hospital and Ambulatory Policy group, Chronic Care Policy Group and Coverage and Analysis Group) staffs by sending them the following information on CTPs:
 - Classification of CTPs in pictorial diagrams
 - Chart of classification of CTPs with Q codes
 - Bibliography of both RCTs and non-RCTs for CTPs
- AHRQ adopts many of Alliance comments in final version of its technology assessment

Additional Issues-CTPs

- Alliance votes positively to adopt new term “Cellular and/or Tissue Based Products for Wounds (CTP) in place of skin substitutes (March)
 - Due to our advocacy, Cigna Government Services adopts the updated term “Cellular and/or Tissue Based Products for Wounds (CTP) in place of “skin substitutes” in its final policy
 - Term being adopted and used in clinical journals (i.e. Kestrel wound care, Advances in Wound Care)
- Successfully advocated with ASTM F-4 committee to allow the creation of a separate guidance document for CTP

➤ **COVERAGE ISSUES- WOUND CARE**

- ***Three Sets of Comments Submitted to CMS***
 - Coverage with evidence development (January); Inpatient Prospective Payment System (June); Hospital Outpatient Prospective Payment (Sept)
- ***Milliman Care Guidelines (MCG) on Intermittent Pneumatic Compression***
 - Submitted two letters to MCG’s Editor in Chief and CEO to address inaccuracies in its guidelines which impacted patient’s access to these devices since payers were adopting the guidelines in their coverage policies. (July, Dec) The Alliance followed up with multiple phone calls and emails.
 - Organized Alliance clinical associations to also send letters of concern to MCG (American Physical Therapy Association, Society of Vascular Medicine, American Venous Forum)
 - The advocacy resulted in MCG convening a conference call with the American Venous Forum to correct this situation so that the 2014 set of published guidelines would be clinically accurate.
- ***NPWT***
 - Worked with manufacturers to submit reconsideration of NPWT coverage policy
 - Submitted information to RUC on behalf of business entities for disposable NPWT reimbursement

ADDITIONAL REGULATORY WOUND CARE ISSUES

- ***Face to Face Meetings for Physicians who Prescribe Durable Medical Equipment (DME)***
 - Alliance convened call with CMS staff Melanie Comb-Dyers to obtain clarification on the requirements for the new face-to-face exam requirements going into effect July 2013. This impacts any physician who prescribes DME for their patients. (May)
 - Alliance sends out summary of call to members on this issue (June).