

ALLIANCE OF WOUND CARE STAKEHOLDERS **2014 ACCOMPLISHMENTS AND ACTIVITIES**

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.
- Convened successful meeting of wound care researchers and industry representatives to identify concerns with the 2006 Wound Care guidance document and begin to form recommendations that will be further discussed in future meetings.
- Successfully delayed clinically inappropriate Durable Medical Equipment Medicare Administrative Carrier's (DMEMAC) Local Coverage Determination (LCD) on pneumatic compression devices thus allowing patients continuing to have access to them. This was accomplished through Alliance members creating an unified voice and being quickly responsive to reach out to CMS senior staff and DMEMAC medical directors to discuss the issue. Alliance clinical associations convened a conference call with the medical directors and submitted clinical evidence addressing policy inaccuracies to them and CMS staff. Hill meetings were also scheduled to educate Congressional staff about this issue.
- Created Cellular and/or Tissue Based Products for Wounds" (CTPs) guidance document for ASTM F-04 committee which was balloted.
- Helped to convince the DMEMAC Medical Directors to continue coverage and payment for honey impregnated dressings by submitting comments to their Request for Information on Medical Grade Honey as a Surgical Dressing Component
- Recognized that the A/B MACs (Novitas Solutions, Cigna) began to use the Alliance terminology "Cellular and/or Tissue Based Products for Wounds" (CTPs) in place of clinically inaccurate term "skin substitutes" in its LCDs and by ASTM in its draft guidance document.
- Due to Alliance's advocacy in addressing the clinical inaccuracies in the Milliman Care Guidelines (MCG) on Intermittent Pneumatic Compression with its Editor In Chief, the next edition (18th) in 2014 was corrected and more accurate. This will allow the payers who use the MCG for their coverage policies to have ones that are clinically correct and thus allow patient access to these products.
- Successful in convincing CMS to change QCDR requirements for outcomes measures in final Physician Fee Schedule rule based on our comments submitted to CMS on proposed rule. (Sept).
- Successful in having the A/B MACs adopt our comments for the following LCDs:
 - Novitas HBOT LCD policy was withdrawn based on Alliance comments. Novitas is willing to work with the Alliance to correct the policy.
 - NGS adopted Alliance's language and revised its LCD language regarding "failed response".

- Palmetto accepted Alliance's recommendations to add several additional ICD-9 codes to its debridement LCD and eliminated the quantification of the surface area, volume or dimensions of the viable tissue removed in the debridement procedure.
- Novitas adopted Alliance's CTP terminology and has a less restrictive coverage policy for CTPs (temporarily before the policy was put on hold for further review)

ACTIVITIES

➤ **QUALITY MEASURES**

- Recognizing the opportunity to develop new Physician Quality Reporting System (PQRS) wound care measures as submitted through the Qualified Clinical Data Registry process to CMS, the Alliance performed the following activities within 3 weeks:
 - Obtained the Alliance Board of Directors approval to move quickly on the initiative
 - Hired a former National Quality Forum senior staff to guide and educate the Alliance members on developing the quality measures
 - Reached out to both Alliance specialty societies and non-wound care associations to understand if and how they were developing quality measures
 - Ensured that the process was transparent by communicating effectively with the members to educate them on the opportunity and fully engaging them in the project. This was done by:
 - Sending 5 emails to the members outlining a series of 8 separate conference calls for member participation on the following subjects: diabetic foot ulcers, venous stasis ulcers, hyperbaric oxygen, pressure ulcers, wound bed preparation, lymphedema, advanced therapies and nutrition. The calls were successful in that they included participation of over 100 clinicians which included both Alliance organizations as well as those who had specific expertise in the subject matter.
 - Sending email to Alliance members after calls concluded to summarize the list of measures created, FAQs and next steps
 - Convened call with CMS QCDR senior staff to outline our plan for creating quality measures and educating them on wound care. CMS staff agreed to allow the Alliance to serve as a *de facto* specialty society for the wound care field to develop the measures.
 - Collaborated with the U.S Wound Registry (USWR) to develop 12 wound care measures which were submitted and adopted by CMS.
- Daniel Green, M.D., Medical Officer, CMS, Center for Clinical Standards and Quality (CCSQ), Division of Electronic and Clinician Quality (DECQ) spoke at Alliance's April meeting on the 2014 PQRS QCDR and answered questions.
- Reached out to Alliance clinical specialty associations to address implementation of the quality measures within their organizations.

➤ **FDA ISSUES**

2006 Wound Care Guidance Document on Wound Care

- FDA staff reaches out to Alliance staff to begin a series of conference calls to request Alliance's input on concerns and recommendations regarding the areas that need revision of the guidance document.

- April- Alliance members determined at its meeting that working with FDA on this issue was a priority
- Nov- Alliance convenes meeting of wound care researchers and industry representatives to identify concerns with the 2006 Wound Care guidance document and begin to form recommendations that will be further discussed in future meetings.

➤ **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:
 - Submitted comments to CMS on CY 2014 HOPPS Final Rule with Comment period. (Jan)
 - Submitted comments to CMS's Hospital Outpatient Panel (Feb)
 - Sent comments to CMS on CMS-1613-P 2015 HOPPS.(Sept)
 - Submitted comments to CMS on the Final HOPPS regulation with comment period (Dec)
- Educated Senator Isakson's staff with constituent Amniox Medical on Alliance's position regarding the HOPPs rule and to discuss the high/low cost thresholds (Jan)

Coverage Issues-CTPs

- Submitted two sets of comments on CTP draft LCDs:
 - First Coast (July)
 - Novitas (Nov.)
- Submitted clarification letter to NGS on L 26003- Biologic Products for Wound Treatment and Surgical Interventions regarding failed response
- Submitted reconsideration LCD requests to change "skin substitute" language to CTP to the following A/B MACs:
 - WPS (April)
 - Novitas, Cahaba (May)

Coding Issues-CTPs

- Marcia Nusgart spoke on behalf of the Alliance at May HCPCS Public meeting to support the CMS HCPCS Workgroup preliminary coding decision of not grouping CTPs into surgical dressing HCPCS codes and submitted comments to the HCPCS Workgroup on this issue.

Additional Issues-CTPs

- Created separate ASTM CTP guidance document and balloted it for the first time with the F-04 committee. Held numerous conference calls to create the document and address negative votes so as to re-ballot successfully in February 2015.

➤ **NPWT**

Coverage Issues-Disposable NPWT

- Advocated for change in Cigna coverage policy with its senior medical director to gain coverage for disposable NPWT. Compiled information from companies and wrote letter to Cigna (March- June 2014)

Payment Issues-Disposable NPWT

- Attended RUC meeting to support Alliance clinical associations (APMA, ASPS, ACS, AAOS) who advocated for RUC payment for practice expense new CPT codes for the procedure using disposable NPWT (97605, 97606, 976XX11, 976XX12). The Alliance sent them and to the RUC Committee invoice pricing for the devices to be used in the pricing of the codes. (Feb 2014)
- Worked with CMS to ensure that the price of the disposable NPWT was included in the RUC rate since it was not originally included in the practice expense by performing the following activities:
 - Hired antitrust attorney to collect and submit manufacturer invoice pricing with Alliance staff's help to CMS pricing staff in preparation for July meeting with them
 - Convened numerous conference calls and meetings to prepare for CMS meeting (11)
 - Met with CMS pricing staff to educate them on disposable NPWT and had antitrust attorney discuss the submitted pricing information with them (July)
 - At CMS's request for supplemental pricing information, antitrust attorney with Alliance staff's help collected and submitted to CMS complete data of current paid invoices in a designated time frame to ensure that the invoices were not "cherry-picked". (Aug)
 - Antitrust attorney and Alliance staff contacts CMS staff numerous times to ensure the Agency received the information and asks if any questions.
- CMS states in its final rule that the new CPT codes will use carrier pricing. (October)
- Submitted comments to CMS on APC reassignment from APC 0016 to APC 0015

AHRQ

- Submitted comments on AHRQ Draft TA on "*Negative Pressure Wound Care Technologies*" (July)

➤ **PNEUMATIC COMPRESSION DEVICES**

Durable Medical Equipment Medicare Administrative Contractors (DMEMAC) Local Coverage Determination (LCD) on Pneumatic Compression Devices

- Organized an Alliance pneumatic compression working group to develop legislative and regulatory strategies to address Sept 2014 DMEMAC release of a clinically inappropriate LCD that severely reduced patient access to necessary home treatment for patients who already have few effective treatment options.
- Submitted letter to senior CMS staff to advise them of the LCD's clinical, procedural and DMEMAC contractor issues and request a withdrawal of the LCD and met with staff to discuss. (Oct 2014)
- Reached out to Alliance clinical associations to educate them and advocate on this issue

- Convened conference call with DMEMAC medical directors and Alliance clinical associations to address clinical inaccuracies with policy.(Oct 9)
- Sent DMEMAC medical directors clinical concerns with the policy and included clinical studies not in original policy. Alliance clinical associations submitted additional clinical studies which were included in paper
- Hired lobbying organization to convene meetings with Congressional staff of committees of jurisdiction to educate them on this issue
- DMEMACs posted article on their website (October 16) delaying the implementation of LCD on November 1 2014 and that additional clinical information published since the release of the draft policy was being reviewed. No future effective date for the draft policy was available at that time. The current LCD and related PA will remain in effect.

Milliman Care Guidelines (MCG) on Intermittent Pneumatic Compression

- 2014- Due to Alliance's advocacy in addressing the clinical inaccuracies in the Milliman Care Guidelines (MCG) on Intermittent Pneumatic Compression with the Editor In Chief, the next edition (18th) in 2014 was corrected and more accurate. This will allow the payers who use the MCG for their coverage policies to have ones that are clinically correct and thus allow patient access to these products.

➤ Additional Coverage Issues- Wound Care

Seven Sets of Comments Submitted to CMS

- CY 2014 Hospital Outpatient Final Rule (Jan);
- Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items (July);
- Update to Home Health Agency PPS- Face to Face Requirement (CMS- 1611-P) (August);
- Hospital Outpatient Prospective Payment (Sept)
- Final Hospital Outpatient regulation with comment (Dec)
- CY 2015 Physician Fee Schedule (Sept); Final Physician Fee Schedule with comment (Dec);

Additional Comments Submitted to CMS Contractors

- August 2014- Alliance comments to Palmetto draft LCD on Debridement of Wounds (DL 35415)
- Cahaba Government Benefit Administrators®, LLC draft LCD regarding Ultrasound Therapy for Wounds (DL 35300) (Sept);

Hyperbaric Oxygen Issues

- March: Alliance submitted comments Novitas Solutions for Local Coverage Determination on Hyperbaric Oxygen Therapy
- June: Novitas LCD policy was withdrawn based on Alliance comments.
- July: Dr. Fife sent a letter to Novitas Medical Director Dr. Patterson requesting to help draft the Novitas HBO LCD.

Cochrane Collaboration Issues

- Alliance submits comments to Cochrane Collaboration regarding review of “Honey as a Topic Treatment for Wounds” in that it included a recommendation which had not been part of previous wound care Cochrane Reviews. This deviated from the intent of the Cochrane Review to only inform clinicians of the sufficiency of data for the use of particular product or procedure.

➤ **Coding Issues- Wound Care**

Honey As a Component in Surgical Dressings

- Submitted comments to DMEMAC medical directors regarding request for information regarding the use of honey as a component in surgical dressings (July).
- This support helped to resolve this issue in that the DMEMAC medical directors issued a directive that HCPCS coding for honey containing surgical dressings would continue as it has been in the past (i.e. HCPCS coding is based upon the underlying covered components.) (Sept)

➤ **Additional Regulatory Wound Care Issues**

United States Pharmacopoeia (USP) Meetings

- Marcia Nusgart and Karen Ravitz attend two USP meetings devoted to cells and tissues. The USP staff has stated that it would like to work more with the Alliance members.