



Alliance Advocacy Update: Caring About Wound Care

Summer 2015

Welcome to Alliance Advocacy Update, the Alliance of Wound Care Stakeholders' new quarterly update on our ongoing advocacy initiatives on behalf of our clinical association members to ensure access, coverage and payment to wound care procedures and technologies for patients and providers. Below is an update on some of our key areas of focus this past quarter of 2015 (Q2: April – June), as well as a look ahead on issues keeping us busy today and tomorrow. Please feel free to share this update within your organization.

Contents in this issue:

1. Summertime Update and Important Comments in Progress
2. Submitted Comments: Ensuring our Expert Perspective is Heard
3. Key Meetings: Building Relationships with In-Person Advocacy
4. Alliance News to Note

Summer Slow Down? We Think Not!

The “summer slowdown” memo did not reach the wound care advocacy community. In fact, this has been one of the busiest July’s on record! While the intention of this e-newsletter is to recap our activities over Q2 (April – June), summer has been so busy that we want to kick off this newsletter with a quick summary of the key issues we tackled in July. Then, keep reading below for Alliance successes, accomplishments and activities over the past quarter.

Of note, the proposed [Hospital Outpatient Prospective Payment System](#) (OPPS) and [Physician Fee Schedule](#) regulations issued in July, and we are currently collecting comments from our membership. While there are plenty of provisions that impact clinicians in the physician fee schedule, the Alliance will likely be focusing our comments on the provisions related to the qualified clinical data registry and its inclusion in the physician compare website as well as its expanded use to group practices. Within the OPSS, there are several wound care specific provisions on which the Alliance will be focusing attention, including: the proposal to consolidate and restructure the skin and debridement APCs into a single APC series, and reviewing the CY 2016 high/low cost threshold for CTPs which CMS has set at \$25 per cm² OR a per daily cost threshold of \$1050. The Alliance had circulated a topline summary to members when these regulations were published, and we are now preparing formal comments to submit. ***Do take time over these last few weeks of summer to send over your feedback so that we can incorporate your perspectives as we formulate Alliance comments.*** Comments are due Aug. 31 for OPSS and Sept. 8 for the physician fee schedule.

In July, we also:

- Met with **FDA staff** July 20 to share the Alliance's topline recommendations for the Agency's planned modernization of its 2006 "Guidance for Industry - Chronic Cutaneous Ulcer and Burn Wounds Developing Products for Wounds." The meeting was attended by more than 15 FDA staffers, representatives from Alliance clinical association members who perform clinical research (i.e., AAWC, APMA, SVM, APWCA), and members of the Coalition of Wound Care Manufacturers. This was the first in a series of planned meetings with the FDA on this guidance update.
- Attended the [Medicare Evidence Development and Coverage Advisory Committee \(MEDCAC\)](#) July 22 meeting examining the scientific evidence of interventions for lower extremity peripheral artery disease (PAD) and addressing areas where evidence gaps exist. Before the meeting, the Alliance convened conference calls with its member groups involved with PAD in order to represent a unified expert voice on key wound and vascular-relevant issues to highlight to the panel. Alliance member organizations who spoke included SVM, SVS, AAWC and clinicians advocating the medical necessity of arterial pumps. The Panel expressed moderate confidence regarding treatments of PAD. CMS staff stated that the Agency will address any changes in coverage within six to eight months.
- Sent a [letter](#) to Congress in support of the **Helping Ensure Life- and Limb-Saving Access to Podiatric Physicians (HELLPP) Act**, which helps ensure that Medicaid patients have access to podiatric care. Currently, access to care provided by a podiatrist is considered an optional benefit, not covered by all state plans. The bill will remedy this limitation to care.
- Submitted [comments to Novitas Solutions](#) addressing its draft local coverage determination (LCD) on hyperbaric oxygen therapy and comments to **Palmetto Government Benefits Administration**

addressing its draft LCD "Application of Skin Substitutes to Lower Extremity Chronic Non Healing Wounds"

Mark Your Calendars

- The Advisory Panel on Hospital Outpatient Prospective Payment System (HOPPS) meeting will be held Aug. 24-25 at CMS Headquarters in Baltimore, Md. This meeting can also be viewed as webcast. See more info here.
- Reminder: our in-person Alliance meeting at the Fall SAWC meeting in Las Vegas is currently scheduled for Sept. 26 at 11:00am PT. Please email Marcia Nusgart with your attendance plans.

Q2 Activities & Accomplishments (April-June)

Submitted Comments: Ensuring our Expert Perspective is Heard

It seems like ages ago, but the news dominating the early part of Q2 was, of course, the April signing into law of the "Medicare Access and CHIP Reauthorization Act of 2015" (MACRA), which reformed Medicare payment policy for physician services. Alliance advocacy continued

Key Meetings: Building Relationships with In-Person Advocacy

The Alliance prides itself on a broad network of strong relationships throughout the wound care universe, built and maintained by convening issue-driven meetings, attending hearings and conferences, visiting Congressional offices, presenting at conferences and more.

throughout Q2 via our submission of comments to key stakeholders:

- Comments to Medicare Administrative Contractors (MACs) and Pricing, Data Analysis and Coding contractor (PDAC):

°The Alliance submitted a [clarification-seeking letter](#) to Novitas in April regarding its local coverage determination (LCD) for **"Application of Bioengineered Skin Substitutes [CTPs] to the Lower Extremity for Chronic Non Healing Wounds."**

"The Alliance would like to applaud Novitas on utilizing the more correct term for skin substitutes, cellular and/or tissue based products for wounds (CTPs). While we appreciate that you are giving more discretion to clinicians to choose the product that they would like to use to treat their patients, there are areas in which we would like to seek clarification" including areas such as the ability of podiatrists to apply these products, the status of the 13 products that have HCPCS codes that are not listed in this policy, and coverage of these products to treat patients who have ulcers in other areas of the body.

°The Alliance submitted two letters- [one in April](#) and [another in May](#) regarding the January 2015 **DME MAC Correct Coding Article for Surgical Dressings Containing Non-Covered Components** and the subsequent decision by PDAC to no longer code surgical dressings containing

Alliance meetings this quarter included:

- Capitol Hill meetings:

Throughout the quarter, the Alliance has held many meetings with legislative staffers on the House Energy and Commerce – Health subcommittee, Senate HELP Committee and Senate Finance Committee to encourage inclusion of HCPCS coding reform in appropriate legislative vehicles. The strategy now is to create legislative language that can be used in Senate legislative vehicles which will be coordinated with the House’s 21st Century Cures bill.

- Symposium on Advanced Wound Care (SAWC):

Many of you attended the Alliance’s annual in-person meeting on Friday, May 1 at SAWC. In addition, we convened a meeting focused on recommended revisions to FDA’s 2006 wound care guidance document and met with editors at leading wound care publication. Watch our panel discussion - recorded with *Ostomy Wound Management* editor Barbara Zeiger live from SAWC - [here](#).

- ASTM

The Alliance’s important work with the international standards setting body ASTM to develop a new standard guide for Cellular and/or Tissue-based Products for wounds (CTPs) continues. Our work on the ASTM balloting initiative moved along in May, with a series of conference calls, feedback and updates in progress.

medical grade honey as covered. In June, the four DME MACs issued policy adjustments, confirming that coverage of multi-component dressings that contain medicinal honey will be based on the underlying covered components.

"Our overarching concern is the problematic co-mingling in this instance of a coverage and coding decision which, as we all know, are processes that should be made independently of each other. The process by which the January DMEMACs and PDAC decisions were made – were not independent or transparent.

°The Alliance submitted [comments](#) in May to First Coast Service Option's draft LCD on **Application of Skin Substitute Grafts for Treatment of DFU and VLU of Lower Extremities**. The Alliance's comments addressed issues such as a problematic definition of a chronic non-healing wound in the draft LCD, concern about allowable treatment timeframes, and discrepant guidance regarding the length of time for assessing a wound's failure to respond to treatment. In July, First Coast issued a final LCD that reflect several – but not all – of the Alliance's inputs. The LCD will be implemented starting Sept. 6.

"The Alliance believes that this policy addresses chronic non-healing wounds and while a majority of the chronic wounds may be DFU and VLU, there are other wound types that would be applicable under this policy. As such, we recommend that this policy should address chronic non healing wounds."

Currently, the standard guide is being balloted to the main committee where the voting will end in mid-August. We thank Dr. Chuck Drueck for his leadership on this issue and keeping it moving forward.

- European Wound Management Association (EWMA) meeting

Marcia shared Alliance regulatory successes at the May EWMA meeting in London via a presentation titled, "Collaboration between medical associations and industry" and via participation on a panel addressing "Where is wound care going? Threats and Opportunities."

- PCORI

In May, Dr. Diane Bild, a senior program officer at the Patient Centered Outcome Research Institute, served as a guest speaker on the Alliance's monthly call to share insights about clinical effectiveness research and answer questions from Alliance membership.

-Enhancing Alliance Visibility within Clinical Associations:

Marcia Nusgart represented the Alliance by attending the annual conferences of four member organizations this quarter, including the American Physical Therapy Association (June 3-6); Society for Vascular Medicine (June 11-13), Society for Vascular Surgery (June 17-20) and the American Podiatric Medical Association (July 23-26) and met with staff at the

offices of the American College of Foot and Ankle Surgeons.

The Alliance of Wound Care Stakeholders is an active association of physician and clinical organizations focused on promoting quality care and access to wound care procedures and technologies for patients with wounds through advocacy and educational outreach in the regulatory, legislative and public arenas.

The Alliance unites leading wound care experts to advocate on public policy issues that may create barriers to patients' access to treatments or care, with a focus on reimbursement, wound care research and wound care quality measures.

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