A Year of Success

2024 ANNUAL REPORT

ADVOCACY WITH IMPACT

Issue. Action. Impact.

ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY™

Providing a Collaborative, Unified Voice to Impact Wound Care Regulatory and Legislative Policies

A Message from our Executive Leadership

Dr. Matthew Garoufalis
Board Chair

Kara Couch
Board Vice Chair

Marcia Nusgart
CEO

Issue. Action. Impact.

These are words that guide our wound care advocacy work. Effective advocacy requires a deep and nuanced understanding of policy issues together with strategic, focused collaborative action to have impact. Our laser-focused advocacy requires persistence, patience and proactivity, and determination. Indeed, it takes downright doggedness to be the "wound care policy watch dog" protecting and defending wound care for the past 20+ years. Importantly, our tenaciousness pays off. Our impact in 2024 was extensive, with advocacy accomplishments that demonstrate the depth of our relationships with government agencies, the influence of collaborative action and a unified voice in shaping policies that protect and support quality wound care.

Wound care organizations and providers thrive when government regulations support fair reimbursement, appropriate coverage, and equitable patient access.

That is our focus.

Advocacy Success

Cellular and Tissue-based Products for Wounds (CTPs)

We protected quality clinical care.

Years of advocacy addressing local coverage determinations (LCDs) for CTP resulted in final policies issued in November 2024 that reflect substantive stakeholder input and remove arbitrary application limitations that had been included in prior drafts. The final LCD guiding use of CTPs in diabetic foot ulcers and venous leg ulcers now enable clinicians to have application flexibility and an extended episode of care to help heal the chronic wounds of their patients. The improvements made to the policy on the clinical care front illustrate the power of a unified voice to impact change. Importantly, our tenacious engagement in this area won't stop now that final versions have published. We immediately elevated concerns to CMS and the MACs and have put pressure on the Agency to more clearly specify the process and timeline by which new evidence can be submitted and reviewed for coverage, and to expand the number of covered products available for use treating DFU/VLU.

Advocacy Success

Blood-Derived Products

We attained reimbursement that better reflects the true cost of delivering care.

Advocacy to multiple MAC medical directors and CMS division heads resulted in the establishment of a national Medicare reimbursement rate for blood-derived products for use treating chronic diabetic wounds. Now set in the 2025 Medicare Physician Fee Schedule, the national rate replaces the inconsistent, inequitable contractor rates that caused access challenges in the physician office setting - as providers lost money when using autologous blood derived products to treat their patients. As a result of Alliance advocacy outreach and education, CMS not only established a national payment rate better reflecting the complexity, time, and costs associated with these products, but then increased the initially proposed rate to a higher rate in the final rule as a direct result of Alliance efforts.

Advocacy Success

Surgical Dressings

We fixed claims processing issues that were driving denials and impacting access.

When members of the Alliance's surgical dressings workgroup identified shared claim processing issues and compiled specific examples of inconsistent/inaccurate denials related to the maximum allowed quantities per patient/per month with multiple wounds, the Alliance alerted the DMEMAC medical directors. Our collection of denied claims provided impetus to the DMEMACs to review and adjust their claims processing to fix the issue that was resulting in denials. An additional outcome: the DMEMACs updated their surgical dressings policy article with language suggested by the Alliance to clarify modifier quantity limitations facilitating coverage and payment for surgical dressing application to a second wound.

These successes are a testament to the strength, power, and influence of having our collaborative work and unified voice, and they are just some of the many impressive advocacy initiatives detailed in this year's annual report. As you'll read, in 2024 we developed and submitted 32 comments, letters and oral testimonies to regulators and legislators, spanning a broad number of policies that impact wound care.

2024 Submitted Comments Weighing in with a United Voice on Policies Impacting Wound Care

26 to CMS & CMS Contractors	**3** to FDA	**2** to Congress	**1** to Private Payer
Policies addressed: →			
Physician Fee Schedule	Proposed New Classification of Antimicrobial Wound Dressings	21st Century Cures Act	Intravascular Ultrasound Policy Revision
Hospital Outpatient PPS	Guidance on Real-World Evidence for Medical Devices	CTP Coverage & Payment	
Home Health PPS	Tissue Reference Group Letters		
LCD on CTPs in DFU/VLU			
LCD on Non-Invasive Vascular Studies			
Non-Pressure Ulcers Episode-Based Cost Measure			
CAC Engagement			
CAC Review of Topical Oxygen Therapy			
MAC Consolidation			

Together, we make wound care better.

We're excited to share a detailed overview of our 2024 Alliance advocacy through this "Issue – Action - Impact" framework. We also want to recognize that the work we are doing and impact we are having is only possible because of the dedication and ongoing work of our staff, Board, and member representatives. Thank you for your collaboration and support. It is our active, engaged members that enable our impressive breadth of advocacy initiatives. We make wound care better and more accessible to patients and providers nationwide.

We can't do it without you, and as always, we are stronger together!

Matthew Garoufalis, DPM, FASPS, FACFAOM, CWS - Board Chair
Kara Couch, MS, CRNP, CWCN-AP, FAAWC - Board Vice Chair
Marcia Nusgart, R.Ph. - CEO

Executive Summary: 2024 Advocacy Highlights

- **Enabled wound care providers using CTPs to have application flexibility, an extended episode of care, and an expanded timeframe to implement the final CTP local coverage determinations** published in November by successfully advocating the Medicare Administrative Contractors to remove arbitrary application limitations and incorporate substantive stakeholder input in the final policies. The final policies included considerable improvements to the clinical practice limitations included in the proposed policies issued in April 2024 and now better protect quality patient care and evidence-based treatment.
- **Successfully encouraged CMS to establish a national payment rate for blood-derived products** in chronic diabetic wounds to better reflect the complexity, time, and costs associated with these products, then persuaded the Agency to increase the initially proposed rate in the draft policy to a higher rate in the final rule. These products are now no longer contractor priced and, as a result of Alliance advocacy, have a national, consistent payment rate that gives clinicians predictable reimbursement when treating patients.
- **Gained key "fixes" to surgical dressings claims processing issues that were impacting access.** Identified issues, compiled examples and educated DMEMAC medical directors about issues, mobilizing them to review and adjust claims processing system to fix inconsistent surgical dressings claim denials and make updates to address maximum allowed surgical dressing quantities per patient/per month with multiple wounds.
- **Achieved update to DMEMAC surgical dressings policy article** that was causing systematic denials and challenging access for patients with multiple wounds. Drafted by the Alliance and forwarded to the DMEMACs for consideration, the language published in the February 2024 policy article update clarifies surgical dressing modifier quantity limitations, facilitating coverage and payment for surgical dressing application to a second wound.
- **Led advocacy urging FDA to withdraw its proposal to reclassify hundreds of antimicrobial wound products** to class III, a policy shift that would result in the unnecessary removal of many important products from the market and challenge quality care. Convened meetings with FDA and submitted comments - along with many other organizations and practitioners - emphasizing the unintended impact of this proposed classification change.
- **Successfully escalated concerns with the episode-based cost measure being developed for non-pressure ulcers** via a series of letters, comments and conversations flagging flaws in the field testing and the many ways the measure did not accurately capture the data necessary for a fair, reliable measure. Following tenacious Alliance advocacy, CMS' Pre-Rulemaking Measure Review Clinician Recommendation Group did not reach consensus regarding the measure at its January 2025 meeting. As a result, the measure will not be considered for adoption until further work and testing is undertaken.
- **Urged CMS to enable payment for clinicians to measure and fit lymphedema compression garments** via an ongoing advocacy initiative of letters, comments and meetings to keep focus on this issue.
- **Gained HOPPS Panel support of the Alliance's recommendation to fix flawed total contact casting payment** with a separately payable APC code for TCC when performed on the same date of service as a debridement and/or the application of CTP. This would remove a barrier that inconveniences patients and providers by preventing these treatments from being performed on the same date.
- **Pursued update to DMEMAC LCD to establish coverage of topical oxygen therapy** for diabetic foot ulcer.
- **Proactively advanced CTP payment methodology recommendations focused on ASP pricing** as CMS continues to consider and vet its payment approach to these products across sites of care.
- **Maintained focus on the important role of real-world evidence in wound care research** and the importance of FDA/CMS dialogue to move forward.
- **Submitted 32 comments to regulators and legislators,** elevating the visibility, voice and influence of the wound care community in policy development.

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2024 Issues Tackled, Actions Taken & Advocacy Impacts

Surgical Dressings

Overview of Issues, Advocacy Actions and Impacts

The Alliance's collaborative relationship with the Durable Medical Equipment Medicare Administrative Contractor (DMEMAC) medical directors as a credible resource and unified voice for the wound care community resulted in successful 2024 advocacy results in the field of surgical dressings. Our advocacy started with the Alliance Surgical Dressing Workgroup identifying claims processing issues and then meeting with the DMEMAC medical directors on Jan. 23, 2024, to educate them and request their help in resolving the issues. We are pleased to say that all three were resolved in 2024! Here are the details:

1. Successfully educated the DMEMAC Medical Director to take action to review, address and fix inconsistent claim denials.

Issue: Members were receiving denial reason codes CO273 (payer has determined that a healthcare service or procedure is not covered or exceeds the allowed limits) or CO151 (payer believes the information submitted does not justify the number or frequency of services billed) for alginate or other fiber gelling dressings (HCPCS codes A6196, A6197, A6198) when a practitioner prescribed primary and secondary cover dressings that were assigned the same HCPCS code for the same wound. Although the local coverage policy states "Codes A6196, A6197 and A6198 may be used as either a primary and/or secondary dressing, as determined by the treating practitioner", allowing the combination of both dressings when reasonable and necessary, the DMEMAC claims processing system did not allow the coverage of the HCPCS past the maximum allowable, set at 30 units, on any one wound.

Alliance Action: With the collaboration of the Alliance's Surgical Dressing Workgroup members, the Alliance identified and compiled specific examples of these denials. The examples presented were from different jurisdictions, establishing with the medical directors the errors in denials were being seen across all MACs. The Alliance convened a meeting with the DMEMAC medical directors in January 2024 to elevate this issue and alert them to these claims processing issues and inconsistent denials.

SUCCESS

Advocacy Impact: With the examples provided and discussion with the DMEMAC Medical Directors, the Alliance successfully verified the concern and the error in the claim processing system. This error was not only causing concern for many of the members of the Alliance, but the patients they care for. The DMEMACs reviewed their internal process, resulting in an adjustment and reprogramming of the claims processing system to fix this issue.

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2. Successfully educated the DMEMAC Medical Director to take action to fix claims processing to address maximum allowed surgical dressing quantities, per patient, per month, with multiple wounds.

Issue: Alliance members identified a lack of alignment in claims processing with the HCPCS and modifiers when a category of dressing was used for multiple wounds (A1-A9 modifiers) on the same beneficiary in the same month. While the local coverage policies are written to be followed per wound, the process by which a claim is paid, the determination of maximum allowable by HCPCS, was not set up to take into consideration the total number of wounds associated with the order. This was creating false limitations per HCPCS, causing a lack of coverage for patients with multiple wounds.

Alliance Action: The Alliance met with DMEMAC Medical Directors and shared real-world examples, provided by members, illustrating that the modifiers were not programmed to correctly multiply the allowed dressings per month. This resulted in limiting the number of dressings allowed by product HCPCS code without considering the number of wounds. Thus, the denial code CO151 was being issued as a result.

SUCCESS

Advocacy Impact: The Alliance's advocacy prompted DMEMAC review of the errors and discussion of solutions. As a direct result, the DMEMACs modified the claims processing system to correctly calculate the allowed units per patient, per month, of each surgical dressing HCPCS code. By multiplying the correct units per month times the HCPCS modifier A1-A9 (or total number of wounds on which the product is utilized), CMS is able to determine allowable payment by wound without the need to circumvent arbitrary maximum caps per patient.

"The Alliance is a respected and clinical voice to regulators and policymakers, which helps support work at WOCN with the power of a collective voice."

-- Kelly Jaszarowski, Wound Ostomy and Continence Nurses Society

3. Successfully educated the DMEMACs to update the surgical dressings policy article to revise surgical dressing modifier quantity limitations.

Issue: The existing local coverage article included problematic application of a date of service specific modifier which caused systematic denials. If a practitioner ordered a 30-day supply of product for a patient with one wound, and then less than 30 days later the patient had a second wound, there were problems with the quantity modifier limitation. For that second wound, if the practitioner submitted a second claim for similar/same surgical dressings as the first wound, it would be denied under the current modifier structure due to the subsequent re-order exceeding the maximum allowable quantity over a specified time.

Alliance Action: The Alliance alerted DMEMAC Medical Directors to this issue, with specific examples. At the medical directors' follow-on request, the Alliance developed and submitted proposed policy revision language for consideration to address the issue. This language, now incorporated into the policy, includes an example of simplifying the process for clinicians and creating a more streamlined service for Part B surgical dressing billing.

SUCCESS

Advocacy Impact: Following Alliance input, the DMEMAC Medical Directors accepted the policy clarification language suggested by the Alliance and incorporated it in a joint surgical dressing policy article update published in February 2024, facilitating coverage and payment for surgical dressing application to the second wound.

> "Being an active member of the Alliance is a phenomenal way to get a vitally important message across about how we educate our colleagues, payers, and the government to empower change which focuses on patient outcomes."
>
> *--Dr. Mark Melin, American Board of Wound Medicine and Surgery*

CTPs:

Overview of Issues, Advocacy Actions and Impacts

The Alliance's long-time tenacious advocacy protecting access to Cellular and Tissue Based Products for Skin Wounds (CTPs) – supported by our long-standing role as a credible go-to resource to policy makers – helped to shape key provisions in local coverage determinations and their accompanying coding and billing articles, as well as policies that strategically remained "status quo" and without overhaul of CTP payment for the year ahead.

1. **Coverage: Enabled providers to have application flexibility, an extended episode of care, and an expanded implementation timeframe in the final CTP local coverage determinations (LCDs) by successfully advocating CMS' Medicare Administrative Contractors to remove arbitrary application limitations and incorporate substantive stakeholder input in the final policies.**

Issue: In April 2024, CMS Medicare Administrative Contractors (MACs) re-issued the LCDs with provisions that were inconsistent with clinical evidence and that jeopardized patient care.

Alliance Action: Following our successful advocacy in having the 2023 LCDs withdrawn, the Alliance quickly mobilized members and aligned stakeholders in April 2024 when all of the MACs covering all 50 states – instead of just 3 covering 15 states - issued revised draft LCDs on "Skin Substitute Grafts/ Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers" for comment. The Alliance:

- Convened numerous conversations with the Alliance CTP workgroup, as well as with many other stakeholders in the wound care space.
- Provided Alliance members the unique opportunity to gain first-hand insights from MAC leadership when First Coast Service Options medical director Dr. Anitra Graves spoke at the Alliance's meeting at Spring SAWC (May).
- Delivered 6 oral testimonies at the "listening sessions" for each of the MACs (May).
- Launched a call to action encouraging stakeholder submission of comments.
- Submitted comprehensive written comments and recommendations to each MAC (June) focused on the allowable number of applications, treatment duration, the need for an extended implementation timeframe, types of evidence for coverage, and the imperative for a predictable process for new evidence to be submitted for review to gain coverage.
- Engaged in ongoing discussions with senior CMS and MAC staff.

SUCCESS

Advocacy Impact: The MACs incorporated substantive input from the Alliance and other stakeholders, resulting in final coverage policies that enable providers to have application flexibility, an extended episode of care, and an expanded implementation timeframe. This is truly a testament to the strength, power, and influence of having a unified – and tenacious – voice for wound care advocacy.

A Closer Look

"Wins" for Clinical Care in the Final CTP LCDs

Increased number of covered applications: In a noted change that was in direct alignment with Alliance and other stakeholder recommendations, the MACs increased the covered application limit from 4 in the draft policy to 8 (supported by documentation + use of the KX modifier) in the final policy, now consistent with the supportive clinical evidence, treatment guidelines and current standard of care to promote wound healing.

Increased treatment duration: The "episode of care" treatment duration increased from 12 to 16 weeks.

Expanded number of products covered: The MACs responded to stakeholder requests to review new studies submitted over the comment period and ultimately added three products to the final "covered" lists, which now includes a total of 18 HCPCS codes – 13 codes (covering 20 products) for DFU only ("Group 2") and 5 codes (covering 6 products) for both DFU and VLU ("Group 3").

Expanded implementation period: The MACs took into account Alliance requests for an extended implementation date to allow for wound care providers across all sites of service to adjust their product selection, formularies, and documentation requirements. The implementation date of February 12, 2025, is 90 days from the date of final policy issuance, rather than the 45 days that is standard. [This was then postponed by CMS to April 13, 2025 following the Presidential transition and Executive Orders to pause for 60 days a variety of Federal policies that had been finalized but not yet implemented.]

These are considerable improvements to the limitations included in the proposed policies that issued for comment in April 2024.

While we did not get everything we recommended and realize there are many frustrated with the final policy's lengthy noncovered products list and lack of clarity on the process to submit new evidence to support coverage, ultimately the significant changes that the MACs made following stakeholder input illustrate the influence a unified advocacy voice can have to shape and influence policies and ensure they enable quality wound care.

Next Steps

ONGOING

Ongoing proactive advocacy to seek clarity, transparency and predictability

Upon issuance of the final policies, the Alliance immediately convened its CTP Workgroup to understand its impact and identified shared questions, concerns and areas in need of clarity. The Alliance then elevated concerns to CMS and the MACs focused on the policy's lack of a specific process or timeline by which new published scientific studies can be submitted and reviewed for coverage consideration. The likely next steps for many manufacturers of the 204 products on the noncovered list will be investing in studies to support the MACs new evidence standards for coverage. However, the LCDs' concluding section states only that "the intent is this policy will be reviewed every 12 months with updates to products/coverage as indicated." The Alliance strongly believes that a clearer process is needed to establish a predictable pathway and timeline for coverage consideration following submission of new evidence supporting existing products on the non-covered list, as well as for new products to be considered for coverage. The Alliance elevated this issue at the Dec. 10 MAC "Town Hall" and Dec. 20 listening session convened by CGS Administrators. Advocacy continues and the Alliance is seeking additional transparency from the MACs on these issues.

Ongoing dialogue with CMS and the MACs

As part of our ongoing advocacy, the Alliance convened a special member-only call January 30, 2025, with CGS Medical Director Dr. Meredith Loveless. Recognizing the diversity of Alliance members and our impact and reach across wound care, Dr. Loveless proactively offered to engage with our membership to answer questions regarding the CTP LCD as part of her MAC's educational outreach.

WORTH NOTING

Senior leaders from CMS and the MACs expressed appreciation for our engagement, recommendations, and the value we bring to the policy development process. In fact, they recently complimented the Alliance's dedicated work in this area and recognized that the changes and improvements would not have happened if we did not participate in the process as an advocate, educator and resource!

> "What the Alliance of Wound Care Stakeholders is doing is absolutely essential for the progress and success of wound care moving forward and I am so proud of the way they use evidence and our evidence-based guidelines to move forward."
>
> *--Laura Bolton, Association for the Advancement of Wound Care*

2. Payment: Gained HOPPS Panel endorsement of Alliance recommendations (again!) to correct flawed CTP payment structure that creates access barriers in outpatient setting.

Issue: Flaws in the current CTP payment methodology under the Hospital Outpatient Prospective Payment System (HOPPS) create barriers and impact patient access to these products in hospital outpatient departments. Policy "fix" can only be implemented via updates to the HOPPs rule, which the Alliance has been pursuing for years via recommendations to CMS' Advisory Panel on Hospital Outpatient Payment meeting and via submission of comments to the HOPPs rule each year.

Alliance Action: These have been outstanding issues for many years, and the Alliance has continued to put focus on them via testimony at CMS' Advisory Panel on Hospital Outpatient Payment meeting and in submitted comments to CMS' proposed CY 2025 HOPPS. Again in 2024, we presented policy recommendations to enable provider-based departments to (1) be reimbursed for an adequate amount of CTP products for larger wounds so that they do not need to absorb the cost themselves or refer patients out; (2) to equalize the payment for CTP application for wounds/ulcers of the same size no matter the anatomic location so that HOPDs receive consistent payment; and (3) to replace the current payment system for CTPs in this setting with a methodology based on average sales price (ASP) pricing.

ONGOING

Advocacy Impact: Successfully gained the endorsement, again - for the fourth year in a row - of the HOPPS Advisory Panel for the Alliance's recommendations. The Advisory Panel again included these policy recommendations in its report out to CMS from its August meeting. Despite this repeated endorsement, CMS did not adopt these recommendations in the proposed 2025 HOPPS rule. While frustrating, one upside of few changes from CMS is the maintenance of the status quo on CTP payment provisions in the HOPPS rule. While CMS stated it is still considering alternative payment models for CTPs in the outpatient setting, the Agency maintained status quo and did not use the HOPPS to move forward changes for 2025. This too is advocacy success!

> "The Alliance is an amazing group to marry industries and societies. It represents so many important topics. There is really no other body that assembles that type of talent and ability in such a proactive way."
>
> *--John Steinberg, DPM, Georgetown University School of Medicine*

3. Payment: Advanced CTP payment methodology recommendations.

Issue: In past rulemaking cycles, CMS has proposed bundling CTPs in the physician office setting by classifying CTPs as "incident to supplies." This was proposed in 2023 as part of the draft CY 2024 Medicare Physician Fee Schedule released for comment. Although CMS removed these provisions from the final CY 2024 Fee Schedule following an outpouring of concerns and comments from the Alliance and many other stakeholders, CMS has stated multiple times that realignment of CTP payment remains an area of interest.

Alliance Action: To address the ongoing interest of CMS in refining CTP payment, the Alliance reminded CMS of our continued opposition to packaged payment for CTPs as "incident to supplies" and focused advocacy on educating CMS policy makers about the benefits of an average selling price (ASP) reimbursement methodology for CTP products. The Alliance elevated these ASP pricing recommendations to senior staff in CMS Division of Practitioner Services Hospital and Ambulatory Policy Group in a "pre-rule making" letter submitted in January as policymakers embarked on CY2025 planning, as well as forwarded a letter to select Congressional committees with oversight of CMS. We then submitted more detailed CTP pricing recommendations to CMS in September as part of our comments to the draft CY 2025 Fee Schedule – articulating an ASP-based reimbursement methodology approach that ultimately could mitigate the concerns that are driving CMS to consider disruptive payment approaches that could limit patient access to needed care.

ONGOING

Advocacy Impact: Following the advocacy outcry from the previously proposed bundling of CTP products (2023) and the Alliance's ongoing dialogue with policymakers on this issue, CMS made no changes to the existing payment method for CTPs in physician offices in the final 2025 Medicare Physician Fee Schedule. The Alliance's persistent and proactive outreach on this topic and education about the benefits of an ASP-based approach will hopefully have influence if/when CPT payment methodologies are reconsidered in future Fee Schedule updates. Ongoing: The Alliance and our CTP workgroup remain in ongoing active dialogue with CMS on this issue.

II Blood Derived Products:

Overview of Issues, Advocacy Actions and Impacts

1. Successfully gained Physician Fee Schedule national reimbursement rates for blood-derived products to better reflect complexity, time, and costs.

Issue: Although there is a National Coverage Determination for use of autologous platelet rich plasma (PRP) and other blood-derived products for diabetic chronic wounds/ulcers, there was no equitable reimbursement rate across MAC jurisdictions. Each Medicare Administrative Contractor set pricing separately. The result was inconsistent pricing that failed to account for the complexity and costs of these unique products prepared from a patient's own blood. Inequitable reimbursement in turn caused issues with access in the physician office setting as providers lost money when using autologous blood derived products to treat their patients.

Alliance Action: Starting in January through March, the Alliance urged both the MACs and CMS to correct inadequate payment rate for autologous blood-derived products (G0465) via a series of letters, meetings and communiques. When no action was taken by the MACs, the Alliance and members of our Blood Derived Products Workgroup met twice with CMS' Hospital and Ambulatory Payment Group (February & April) to request that either the MACs revise the current fee schedules rates for these products, or that CMS set a nationwide reimbursement rate that reflects the cost of the product as well as the time required to evaluate a patient for an autologous blood-derived product for a chronic wound and to prepare/administer that product. In May, the Alliance and members of its Blood Derived Products Workgroup met with staff from Novitas and First Coast to discuss how they were determining payment for these products and provided expanded information for the MACs to use for pricing purposes. In July, the Alliance communicated with CMS' Deputy Director of the Hospital and Ambulatory Policy Group to discuss a solution to the disconnect between the Agency's implementation of a national coverage policy for blood-derived products but with inequitable payments that prevent use and hinder access.

SUCCESS

Advocacy Impact: In the CY 2025 Medicare Physician Fee Schedule CMS established a national payment rate for autologous platelet-rich plasma (PRP) or other blood-derived product for use in treating chronic diabetic wounds (HCPCS code G0465). These products will no longer be contractor priced beginning January 1, 2025, and now have a nationally published consistent and predictable payment rate under the Fee Schedule. The Alliance was also responsible for the nationally published rate being increased from the proposed to the final rule issuance (see next section).

2. Successfully gained increase to national reimbursement rate in final CY 2025 Physician Fee Schedule for blood-derived products to better reflect complexity, time, and costs.

Issue: The new national payment rate for autologous blood-derived products proposed in the 2025 Physician Fee Schedule was set at a level that is higher than the contractor pricing. However, many Alliance members believed it was still inadequate especially when used on patients with multiple wounds.

Alliance Action: The Alliance and its Blood Products Workgroup undertook a multi-prong advocacy initiative to seek an update to the proposed new national payment rate: (1) Engaged the input of coding experts to provide feedback on suggested codes and crosswalk options to submit to CMS in support of a methodology for higher payment; (2) Mobilized providers to submit comments to CMS – as well as to submit invoices showing costs – and share with the Agency how the inadequate payment rate impacts ability to provide care and offer blood product treatment to Medicare patients who could benefit; (3) Met in August with senior staff from CMS' Division of Practitioner Services to discuss considerations for national pricing including current costs of the products, professional time and effort, crosswalk codes as well as global periods, coding edits, and modifier use issue; (4) Elevated issue as part of September virtual meeting with senior staff at the Department of Health and Human Services, and (5) Submitted comments in September addressing the relevant provisions in the proposed CY 2025 Physician Fee Schedule and provided methodology recommendations.

SUCCESS

Advocacy Impact: CMS incorporated stakeholder input and increased the national payment rate in the final CY 2025 Fee Schedule. Under the new national pricing, the supply code in the non-facility setting is $770.83 (increased from the $678.57 originally proposed). In the non-facility setting, the national payment is $890.18 (debridement included). In the facility setting, the payment rate (professional fee) will be on par with the rate for cellular and tissue-based product (CTP, or skin substitute) applications. As many stakeholders believe that the final rate still fails to sufficiently cover the costs and time associated with the application of these products, advocacy will continue.

Next Steps

Since release of the final 2025 Fee Schedule, the Alliance has engaged with CMS on policy provisions that need clarity. The Alliance has sent CMS staff a letter requesting the Agency review, revise, and clarify its billing policies for multiple applications of an autologous blood-derived product when used to treat a large surface area wound and/or to treat multiple wounds on the same date of service or over the course of the patient's treatment period. Advocacy and engagement on this issue continues.

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3. Successfully worked with ASTM to update its F3209-24 standard to the new Standard Guide for Autologous Platelet-Rich Plasma, Platelet Gels and Whole Blood Gels for Use in Tissue Engineering and Cell Therapy.

Issue: The ASTM F3209 standard for Autologous Platelet-Rich Plasma for Use in Tissue Engineering and Cell Therapy WK 92343 needed to be updated to reflect the full range of current and future products in this category.

Alliance Action: Alliance members successfully worked with ASTM to expand the ASTM standard F3209 to include whole blood gels so a full range of current and future products in this category are covered under the standard. F3209 originally addressed platelet rich plasma (PRP) and platelet gels but did not address Whole Blood Gels. Alliance members helped to revise the standard, educated ASTM staff and members, gained their acceptance, and then presented it at the November ASTM meeting for adoption.

ONGOING

Advocacy Impact: As a result of Alliance members' proactive involvement, a new Standard Guide for Autologous Platelet-Rich Plasma, Platelet Gels and Whole Blood Gels for Use in Tissue Engineering and Cell Therapy (F3209-24) is due to be published imminently.

"We know our voice is louder when we share it with our inter-professional colleagues--physicians, surgeons, nurses, podiatrists, manufacturers, clinics—when we are all saying the same thing, fighting together to get our patients the care that they need. We know we are stronger when working together with the Alliance than apart."

--Renee Cordrey, American Physical Therapy Association

IV Antimicrobial Wound Dressings:

Overview of Issues, Advocacy Actions and Impacts

1. Led advocacy seeking withdrawal of FDA's proposed rule to reclassify antimicrobial wound products.

Issue: The Food and Drug Administration proposed two new rules for classification of certain unclassified wound dressings and liquid wound washes containing antimicrobials. The rules would categorize products with "a high level of antimicrobial resistance (AMR) concern" as class III medical devices (requiring Premarket Approvals/PMAs), and those with a "medium or low level of AMR concern" as class II (with special controls/510(k) notices). The FDA currently regulates these unclassified devices as devices requiring premarket notification with 510(k) requirements. The new classification would, the Alliance believes, result in the unnecessary withdrawal of many products from the market – and a likely secondary effect would be that clinicians turn to antibiotic pharmaceuticals, exacerbating the very resistance problems that FDA is trying to address through the proposed regulation.

Alliance Action: The Alliance played an impactful role educating the FDA and its Advisory Panel on this issue and stakeholder concerns back in 2016 when the FDA had convened an Advisory Panel to address this very topic. At that time, the Panel recommended that antimicrobial wound dressings should be classified as "Class II (with special controls)," enabling updated classification while protecting access and availability of antimicrobial wound care dressings for patients and providers. Following release of the proposed new policies in December 2023, the Alliance had quickly formed a member workgroup of regulatory experts to assess impacts and develop recommendations, met with FDA/CBER Office of Cellular Therapy and Human Tissue senior staff to voice concerns, educated and mobilized members and aligned stakeholders to submit comments to elevate concerns and request withdrawal of the policy for further vetting. The Alliance then submitted comprehensive comments requesting that FDA withdraw its current proposal, and if it desires to proceed, to publish a more detailed proposed rule with companion guidance that address the points raised in stakeholder comments. Additionally, several Alliance members have engaged with their Congressional representatives on this topic.

ONGOING

Advocacy Impact: Following our outreach and education, a range of organizations and practitioners submitted comments that aligned with our concerns and supported the request to withdraw and re-vet the proposed regulation. The Alliance also met with FDA staff in May at SAWC Spring to discuss our concerns once more and obtain any updates on the status of the proposed rule. As of the end of 2024, the FDA had taken no action to move the policy forward. The proposed policy has not been finalized and, assumedly, stakeholder input is still being considered. The Alliance remains in ongoing dialogue with policymakers and stakeholders on this issue.

V Lymphedema Compression:

Overview of Issues, Advocacy Actions and Impacts

1. Encouraged CMS to allow payment for clinicians to measure & fit lymphedema compression garments.

Issue: The Home Health Prospective Payment System CY 2024 Update implementing the Lymphedema Treatment Act mandated Medicare coverage for compression garments for patients with lymphedema but did not include any provisions for payment for medical providers and allied health professionals in the measuring, fitting, and training services associated with providing these items to patients. Instead, payment is made to the suppliers.

Alliance Action: Via comments, letters and conversations the Alliance urged CMS to include coding and payment provisions to ensure that qualified health professionals ("QHPs") can get reimbursed for the measuring, fitting, and training services they provide when furnishing patients with lymphedema compression treatment items. Most recently, the Alliance urged CMS in our comment to the CY 2025 Home Health PPS to reimburse QHPs.

ONGOING

Advocacy Impact: Policymakers are now much better educated about the work and services entailed in furnishing patients with lymphedema compression items. While CMS did not insert these recommended provisions into the CY 2025 Home Health PPS, Alliance education and advocacy on this issue will continue.

> "The Alliance brings together clinicians and providers of other services in a way that is unprecedented. With the Alliance, we can have open discussions on a variety of topics and work collaboratively to improve the care of our patients."
>
> *--Dr. Helen Gelly, Undersea and Hyperbaric Medical Society*

VI Topical Oxygen Therapy

Overview of Issues, Advocacy Actions and Impacts

1. Pursued update in oxygen and oxygen equipment LCD to establish coverage for topical oxygen therapy for use in diabetic foot ulcers.

Issue: The Durable Medical Equipment Medicare Administrative Contractors (DMEMACs) have received multiple reconsideration requests with evidence submissions to support revising the Oxygen and Oxygen Equipment LCD (L33797) to include language that Topical Oxygen Therapy (TOT) is reasonable and necessary for treating diabetic foot ulcers (DFUs). Yet for years no action had been taken despite new clinical evidence provided. When the DMEMACs finally convened a December 11, 2024, Contractor Advisory Committee (CAC) to discuss TOT, the meeting failed to follow appropriate processes nor allow for full discussion of evidence submitted for consideration.

Alliance Action: The Alliance had urged CMS to investigate why a reconsideration request submitted in 2021 to establish coverage criteria for TOT in DFU within the Oxygen and Oxygen Equipment LCD had not been addressed, despite newly published clinical evidence being provided. Elevated the issue in 2023 by submitting a letter to CMS inquiring about the Agency's lack of response and intended next steps. When the Agency finally scheduled a December 2024 Contractor Advisory Committee meeting to address this topic, the Alliance recommended clinicians who use topical oxygen to serve on the committee. Alliance members registered for the meeting with great anticipation, then were disappointed in its many procedural flaws. The Alliance quickly submitted a December letter to the DMEMAC medical directors and CMS alerting them to issues such as a start time delay leading to time constraints that prevented a full discussion of the new evidence base supporting TOT in DFU. The Alliance also flagged potentially improper voting procedures at the meeting that could have negatively impacted the final votes on key questions.

ONGOING

Advocacy Impact: The Alliance encouraged the DMEMACs to ignore or discount the results of this TOT CAC meeting due to its procedural flaws and failure to allow for full discussion of evidence. As this meeting was held in the last weeks of 2024, advocacy and ongoing discussions with CMS and the DMEMACs continue into 2025.

VII Total Contact Casting

Overview of Issues, Advocacy Actions and Impacts

1. Gained HOPPS Panel support to fix flawed total contact casting payment with a separate Ambulatory Payment Classification (APC).

Issue: Due to current inconsistencies in CMS policies, hospital outpatient departments are not getting paid separately for total contact casting (TCC) when provided on the same date of service as a debridement or CTP application. This discourages facilities from performing both services on the same day, despite the fact they are separate services that are appropriate to be performed and reported on the same day.

Alliance Action: The Alliance presented recommendations to fix flawed TCC payment policies at the August 2024 Advisory Panel on Hospital Outpatient Payment and gained the endorsement of the panel. Additionally, while TCC was not specifically included in the 2025 OPPS proposed draft, the Alliance opted to use the comment opportunity to elevate this issue and forwarded a recommendation for CMS to establish and pay a separate APC for the TCC when a debridement or CTP application is performed on the same date of service so that facilities can be paid, and patients can receive TCC care without the burden of needing additional appointments to get it. The Alliance also raised this issue with senior HHS staff.

ONGOING

Advocacy Impact: The Alliance gained the endorsement of CMS' Advisory Panel on Hospital Outpatient Payment on our recommendations to fix flaws in the National Correct Coding Initiatives by enabling payment for total contact casting as separately payable when performed on the same date of service as a debridement and/or the application of CTP. This policy update would remove barriers to TCC access in hospital outpatient departments and - by allowing for these standard of care treatments to be performed on the same date of service - would avoid patient inconvenience. In the final HOPPS rule, CMS acknowledged the Panel's recommendation but did not implement the suggested change. However, the Agency did recognize the issue and stated: "we will take commenters' suggestions into consideration for future rulemaking." The Alliance will continue to advocate and mobilize stakeholder comments on this issue.

VIII Episode-based cost measures for non-pressure ulcers

1. Provided wound care perspective on the episode-based cost measures for non-pressure ulcers included in the 2024 Measures Under Consideration list by CMS.

Issue: CMS contracted with Acumen, LLC to develop episode-based cost measures for potential use in the Merit-based Incentive Payment System (MIPS), including one for non-pressure ulcers. The goal of the measure is to inform clinicians of the cost of their beneficiary's care for which they are responsible. This also allows CMS to identify doctors whose spending on wound care patients is far outside the norm. As the measure will be considered for use in the MIPS cost performance category, it is important for it to be based on fair and correct criteria. However, initial field testing for the measure demonstrated concerning problems.

Alliance Action: When Acumen was forming workgroups to provide expert input into measure development, the Alliance identified and helped several clinicians submit their nomination – resulting in eight Alliance-vetted clinicians representing seven clinical associations appointed to the Clinician Expert Workgroup. When Acumen failed to incorporate inputs of Workgroup members and field tested a highly flawed measure, the Alliance:

- Flagged the many ways the measure did not accurately capture the data necessary. (March)
- Convened a meeting with Acumen to elevate real-world concerns with the field-testing results. (April)
- Escalated concerns – and the Alliance's ardent lack of support for the measure - as part of oral comments at the Pre-Rulemaking Measure Review (PRMR) Clinician Measures Listening Session. Offered to conduct a wound care educational session for Acumen to better inform its work on the measure. (December)
- Submitted comments to CMS and the Partnerships for Quality Measurement emphasizing the lack of support for the measure as proposed and recommending that it be withdrawn until further refinements are made and additional testing conducted. (December)

SUCCESS

Advocacy Impact: As of late 2024, no action had been taken on the cost measure, but a meeting of the Pre-Rulemaking Measure Review (PRMR) Clinician Recommendation Group was announced for January 22, 2025. At that meeting, discussion focused on concerns about the lack of any stakeholder support for the measure - especially the lack of support from the Clinician Expert Workgroup members – as well as issues with cost allocation. No consensus was reached by the Clinician Recommendation Group on whether or not to adopt this measure. The result of this lack of consensus: the measure will not be considered for adoption into MIPS until further work and testing is undertaken. The Alliance will continue to engage with CMS, Acumen and the Clinician Expert Workgroup on this issue.

IX Additional Advocacy Issues Addressed in 2024

21st Century Cures Act: In response to a Request for Information from Congress to collect stakeholder input, the Alliance submitted specific recommendations to strengthen the 21st Century Cures Act. With a unique wound care perspective, the Alliance focused on issues including: real world evidence, national and local coverage decision processes, local coding and billing article processes, the Coverage with Evidence Development paradigm, Contractor Advisory Committee engagement, the National Correct Coding Initiatives, and reconsideration request timelines.

Real-World Evidence: The Alliance submitted comments supporting the intentions of FDA's draft guidance "Use of Real-World Evidence (RWE) to Support Regulatory Decision-Making for Medical Devices," which would make use of real-world data and RWE for clinical trials and in expanding indications for use on already approved or cleared devices. We reminded the FDA that CMS and private payers do not accept this type of data as primary evidence for most products for coverage purposes. As such, even if the FDA permits RWE for regulatory decision making, unless CMS and commercial payers also accept real world data/evidence, manufacturers would need to provide one type of evidence for the FDA and another for payers for coverage and payment purposes. The Alliance encouraged the FDA to dialogue with CMS and offered to serve as a resource and convener so that dialogue focused on realistic and workable solutions can move forward.

Non-Invasive Vascular Studies LCD: The Alliance submitted comments to CGS Administrators proposed LCD "Non-Invasive Vascular Studies" (DL34045), flagging areas of the policy that are not reflective of current practice or standards of care.

Consolidation of Medicare Administrative Contractors jurisdictions: The Alliance responded to CMS' Request for Information (RFI) issued in September to obtain stakeholder feedback on the potential consolidation of four Medicare Administrative Contractors (MAC) jurisdictions into two jurisdictions, as well as to obtain feedback on extending MAC contracts to ten years. In its response, the Alliance emphasized the need for improved CMS oversight and transparency in MAC operations as well as provided feedback on issues spanning staffing and staff training, care disruption concerns, Contractor Advisory Committee (CAC) engagement, evidence evaluation processes, provider communications, prior authorization, appeals, reconsideration requests, and more.

Tissue Reference Group Letters: Submitted a letter to senior staff at FDA's Division of Human Tissue voicing concern that CMS and its MACs are using Tissue Reference Group (TRG) letters inappropriately for coverage purposes and using terminology/definitions that differ from FDA's, resulting in inconsistencies that may impact coding, coverage, and payment.

Podiatry Scope of Practice: Submitted letters to a number of State Senators in Mississippi supporting "Scope of Practice" legislation there to expand podiatric scope of practice to include ankle privileges to better meet the foot care needs of patients with diabetes in a state where the prevalence of diabetes is among the highest in the nation, and with it the increased risk of foot ulcers, infections, and lower limb amputations.

Year in Review:

2024 Submitted Comments to Regulators & Legislators

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32 Comments submitted in 2024

Submitted Comments

Weighing In with a United Wound Care Voice

11	5	3	2	10	1
to CMS	to CMS contractors	to FDA	to Congress	Oral testimonies	Other

Alliance Advocacy in Action

2024 Comments, Letters and Oral Testimonies:

1. Co-signed letter to Aetna addressing policies on Peripheral Atherectomy & Thrombectomy Devices, Intravascular Ultrasound (Jan.)
2. Letter to FDA Division of Human Tissue voicing concern that CMS/MACs are using the Tissue Reference Group (TRG) letters inappropriately for coverage purposes (Jan.)
3. Letter to MAC medical directors seeking consistent and equitable reimbursement rate for blood-derived products G0465 for diabetic chronic wounds/ulcer (Jan.)
4. Letter to CMS Hospital and Ambulatory Policy Group elevating the "mismatch" between the actual costs of blood-derived products (G0465) in wound care and the current Medicare payments (Feb.)
5. Comments to FDA Guidance on Real-World Evidence for Medical Devices (Feb.)
6. Comments to FDA Proposed Classification of Certain Wound Dressings (Feb.)
7. Pre-Rulemaking Letter to CMS re Physician Fee Schedule (March)
8. Co-signed Letter to CMS urging update to lymphedema compression garments payment policy (March)
9. Letter to Acumen re Non-Pressure Ulcers Episode-Based Cost Measure (March)

10-16. Oral Testimonies at seven MAC "Listening Sessions" on LCDs/LCAs for use of CTPs in DFU/VLU (May)

17. Comments & Recommendations to MACs to Improve LCDs on CTPs in diabetic foot & venous leg ulcers (June)
18. Letter to CMS Hospital and Ambulatory Policy Group and Division of Practitioner Services requesting establishment of appropriate pricing for blood-derived products (HCPCS code G0465) used to treat chronic wounds (July)
19. Letter to Congress on Strengthening the 21st Century Cures Act (Aug.)
20. Oral Testimony at CMS Advisory Panel on Hospital Outpatient Payment (Aug.)
21. Comments to Proposed 2025 Home Health Prospective Payment System Update (Aug.)
22. Comments to proposed 2025 Medicare Physician Fee Schedule (Sept.)
23. Comments to proposed 2025 Medicare Hospital Outpatient Prospective Payment System (OPPS) (Sept.)
24. Co-signed letter to CMS with the Contractor Advisory Committee (CAC) Engagement Coalition (Sept.)
25. Response to CMS Request for Information on Consolidation of MAC Jurisdictions (Oct.)
26. Letter to Congress providing update and perspective on the proposed LCDs for CTPs in DFU/VLU (Oct.)
27. Comments to CGS Administrators on Proposed "Non-Invasive Vascular Studies" LCD (Nov.)
28. Oral testimony at MAC Listening Sessions on the final CTP LCDs (Dec.)
29. Oral testimony to Acumen Panel on episode-based cost measures for non-pressure ulcers (Dec.)
30. Comments to CMS/PQM on Non-Pressure Ulcers Episode-Based Cost Measure (Dec.)
31. Letter to CMS seeking clarity on new national payment rate for autologous blood-derived products (Dec.)
32. Letter to DMEMAC Medical Directors on the December 2024 Contractor Advisory Committee on Topical Oxygen Therapy (Dec.)

Collaborations: Building Our Networks, Reach and Credibility

The Alliance participated in a number of collaborations to expand our network of aligned stakeholders and create new opportunities to collaboratively develop solutions to problematic health policies:

- AdvaMed
- Amputation Prevention Alliance
- AA Homecare Medical Supplies Council
- CAC Engagement/MAC Workgroup calls (led by APMA)
- Clinical Labor Coalition
- Hyperbaric Oxygen Stakeholder group
- Medical Device Manufacturers Association
- PAD Working Group
- US Medical Compression Alliance
- UHMS Partner Town Hall
- Wound Care Collaborative Community
- Wound Healing Foundation

Presentations: Growing Alliance Voice and Visibility

We attended and/or presented at conferences and public meetings:

Diabetic Limb Salvage Meeting
Washington DC (April 2024)
Presented with panel on FDA Proposed Rule "Classification of Certain Solid Wound Dressings; Wound Dressings Formulated as Gel Cream or Ointment; and Liquid Wound Washes"

Symposium on Advances in Wound Care (Spring SAWC)
Orlando (May 2024)
Presented: You Advocated for It, Tips to Implement It! (presented with Kathleen Schaum); Convened in-person Alliance meeting

European Wound Management Association (EWMA) Meeting
London (May 2024)
Presented: Importance of Advocacy in Wound Care: US and Europe

Wound Care Collaborative Community's "Driving Innovation Summit"
Grapevine, TX (May 2024)
Attended/Participated

MAC "Listening Sessions" on LCDs/LCAs for use of CTPs in DFU/VLU
Virtual (May 2024)
Provided oral testimony with Alliance feedback & recommendations to improve LCDs

American Board of Wound Care Foundation Wound Week 2024
Virtual (June 2024)
Presented: The Business of Wound Care - What Clinicians Should Understand About Wound Care Policy and Reimbursement Issues

CMS Advisory Panel on Hospital Outpatient Payment
Virtual (August 2024)
Presented for vote a series of recommendations to fix payment challenges for CTPs and total contact casting

American College of Wound Healing and Tissue Repair
Chicago (December 2024)
Presented: "Government and Regulatory Update"

DFCon / American Limb Preservation Society Meeting
Anaheim (November 2024)
Presented "Policy Issues Impacting You"; Convened in-person Alliance meeting

DMEMAC Carrier Advisory Committee on Topical Oxygen Therapy
Virtual (December 2024)
Attended as listener

Media Coverage: Showcasing Expertise & Thought Leadership

We expanded Alliance visibility, credibility and thought leadership via contributed articles to leading wound publications.

Advances in Wound Care

- Better Wound Care Begins With Better Evidence: Outcomes of the Wound Care Evidence Summit (March)

BioWorld MedTech

- US Medicare may tighten coverage for leg, foot ulcer treatments (April articles contains quote from Alliance)
- Attorney says wound dressings in 'dire circumstances' under FDA draft rule (April)

Journal of Wound Care

US Wound Care Advocacy and Patient Access: 2023 Impacts and 2024 Initiatives (March)

Today's Wound Clinic / Wound Care Learning Network / HMP Global Learning Network

- A Closer Look at Potential Changes in Wound Care in 2024 (Jan.)
- What Wound Care Advocacy Achieved in 2023 and Works Toward in 2024 (Feb.)
- A Closer Look at the CMS MACs' Recent Proposed Coverage Policies for CTPs (May)
- Policy Updates on Surgical Dressings, Wound Dressing Classifications, and More (May)
- How CMS 2025 Proposed Payment Updates Could Impact Wound Care (Oct.)
- CMS 2025 Final Payment Rules: Key Takeaways for Wound Care Providers (Nov.)

The Frank & Lizzie Show:

- Update from the Alliance – Impact of Wound Care Advocacy (June)
- Update from the Alliance – Overview of provisions in CMS' proposed 2025 Hospital Outpatient Payment update and Medicare Physician Fee Schedule that impact wound care (Aug)
- Update from the Alliance - Wound care provisions in the final 2025 Medicare payment rules (Nov)
- Update from the Alliance - Insights and takeaways on the final LCDs for CTPs in DFU/VLU (Dec)

Vein Specialist

- Advocating to Improve Wound Care: AVF and the Alliance of Wound Care Stakeholders (Sept.)

Wound Source

- What Wound Care Advocacy Achieved in 2023 and Works Toward in 2024 (Feb.)

Year in Review:

Alliance at 2024 Meetings and Conferences

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Growing Membership = Expanded Reach Across Wound Care Community

With evolving policy issues and increasing need for advocacy, interest in Alliance membership has grown significantly. In 2024, the Alliance added 18 new members (in blue) and closed the year with a record 80 members in total.

Clinical Association Members:

Academy of Nutrition and Dietetics
American Association of Nurse Practitioners
American Board of Wound Medicine & Surgery
American College of Foot & Ankle Surgeons
American College of Hyperbaric Medicine
American Diabetes Association® Amputation Prevention Alliance
American Physical Therapy Association
American Podiatric Medical Association
American Professional Wound Care Association
American Society of Plastic Surgeons
American Venous Forum
Amputee Coalition
Association for the Advancement of Wound Care
National Pressure Injury Advisory Panel
Post Acute Wound & Skin Integrity Council
Society for Vascular Medicine
Society for Vascular Nursing
Society for Vascular Surgery
Undersea & Hyperbaric Medical Society
Wound, Ostomy and Continence Nurses Society
Wound Healing Society

Non-Clinical Association Members:

ABWM Foundation
Coalition of Wound Care Manufacturers

Business Entity Members:

Acera Surgical
Acesso Biologics
Advanced Oxygen Therapy Inc.
Bio Compression Systems
BioStem Technologies
BioXtek
BioTissue
Convatec
Curitec
DermaRite Industries
Epiforge Technologies
ETS Wound Care
Flen Health
Gentell
Healogics
Human Regenerative Technologies
Integra LifeSciences
Kerecis
LifeNet Health
Medline Skin Health
Merakris Therapeutics
MIMEDX
MIMOSA Diagnostics
NATROX Wound Care
Open Wound Research
Organogenesis
PolyNovo
Prism Medical Products
Reapplix
RedDress Medical
RegenLab USA
RenovoDerm
Royal Wound-X
Sanara MedTech
Smith & Nephew
SpectralMD
Stability Biologics
Surgenex
Tides Medical
Urgo Medical North America

Provider Entity Members: (Clinical Provider Groups & Hospital Operated Wound Care Centers)

Heal Precisely
Indiana Foot & Ankle
LiveStrong Therapy
Omni Wound Physicians
Personic Health
Renovo Wound and Hyperbarics
Restore First Health
United Wound Healing
The Wound Pros
Wound Care & Hyperbaric Center - Piedmont Atlanta
Wyoming Wound Care

Professional Services Firms (Associate Membership):

The Frank and Lizzie Show
GR Consulting
Kathleen D. Schaum & Assoc. Inc.
MedTech Solutions Group
Shoreline Medical Administration
SmartTRAK

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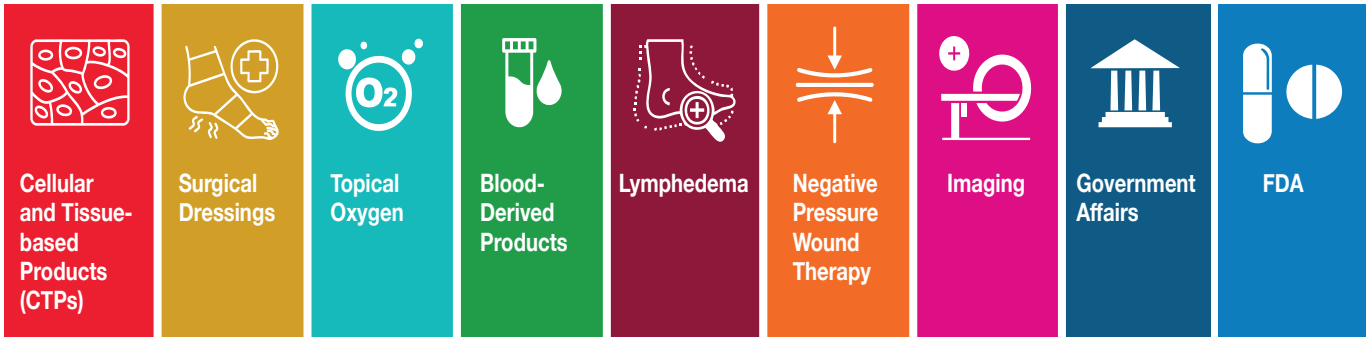
Collaborative Solution Building Around Shared Areas of Focus

As problematic coding, coverage and policy issues have continued to impact access, and as our role as a united voice for wound care has become increasingly critical, our areas of focus, membership, Board of Directors and Alliance Workgroups have all grown too. To proactively respond to the evolving needs of members and the growing range of emerging issues impacting wound care coding, coverage and payment, the Alliance has a range of Workgroups enabling solution building around shared areas of concern.

Alliance Workgroups include:



Workgroup participants play a critical role in identifying shared concerns and shaping action plans, policy recommendations and Alliance comments to policies.

> "The APMA has been working together with the Alliance in advocating for access and quality care for wound care patients, coding and reimbursement issues affecting the practice of wound care, and educating our legislators, government and private agencies on regulatory issues affecting the practice of wound care."
>
> *--Dr. Larry Santi, American Podiatric Medical Association*

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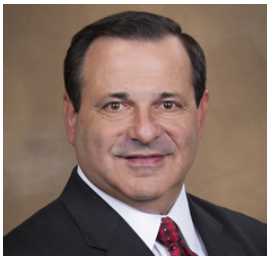
Board of Directors



Matthew Garoufalis, DPM, FASPS, FACFAOM, CWS

CHAIR

Chief Medical Officer, Advanced Oxygen Therapy Inc. (AOTI)

Past President, International Federation of Podiatrists

Past President, American Podiatric Medical Association

Kara Couch, MS, CRNP, CWCN-AP, FAAWC

VICE-CHAIR

Family Nurse Practitionaer and Certified Wound Specialist

Director, Wound Care Services, George Washington Univ. Hospital

David Alper, DPM

TREASURER

Board of Trustees, American Podiatry Medical Association

Leadership Board, American Diabetes Association

Board, Wound Care Collaborative Community

Michelle Cooper, MBA

SECRETARY

Executive Vice President and Chief Compliance Officer, CommonSpirit Health (retired)

Caroline Fife, MD, CWS, FUHM

Chief Medical Officer, Intellicure

Executive Director, U.S. Wound Registry

Medical Director, St. Luke's Wound Clinic

Co-editor, Today's Wound Clinic

Professor, Baylor College of Medicine

Julie Rhodovi, MBA, CWCA, LBBH

Chief Operating Officer, Tissue Health Plus

Board of Trustees, ABWM Foundation

Founding Member, Post-Acute Wound and Skin Integrity Council (PAWSIC)

Sreekumar Madassery, MD

Associate Professor of Vascular & Interventional Radiology, Rush University Medical Center (RUMC) and Rush Oak Park Hospital

Director, Advanced Vascular & Interventional Radiology Fellowship, RUMC

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About the Alliance

ALLIANCE OF WOUND CARE STAKEHOLDERS
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At the Intersection of Government, Health Policy & Wound Care, We Have a Seat at the Table.

Since its founding in 2002, the Alliance of Wound Care Stakeholders has served as the unified advocacy voice for the wound care community on regulatory and legislative policy issues. We elevate the visibility and influence of wound care by uniquely enabling the multi-disciplinary wound care community to collectively and collaboratively engage on issues of commonality, elevating the visibility and united voice of wound care to regulators and policy makers.

Our Mission:

Be the unified voice for the wound care community to ensure access to quality care for all patients with chronic wounds.

Our focus:

Advocate on policy issues that create barriers to patient access to necessary treatments or care, with a focus on coding, coverage and payment policies, quality measures and wound care research.

Our members:

The Alliance is a 501(c)(6) multidisciplinary association of physician specialty societies, clinical and patient associations, wound care provider groups, wound clinics, and business entities working collaboratively with CMS, FDA, and other federal agencies to inform policy, educate policymakers, ensure quality care, and protect access to products and services for patients with chronic wounds. As a united voice, we are stronger together to shape policy and create a regulatory and legislative environment that supports evidence-based clinical practice and innovation in wound care.