



ALLIANCE OF
**WOUND CARE
STAKEHOLDERS**
POWER THROUGH COLLECTIVE ADVOCACY™
★ CELEBRATING 20 YEARS ★

2022 A Year of Progress ANNUAL REPORT

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



ADVOCACY



EDUCATION



MEMBERSHIP



A Message From...

The Board of Directors

As we have done for the past 20 years, the Alliance of Wound Care Stakeholders enables the wound care community to elevate the unified voice of wound care to regulators, policymakers and legislators. Our proactive advocacy and collaborative initiatives to educate policymakers and payers had great impact in 2022.

Together, We Tenaciously Advocated for Improved Access to Care.

We joined voices with aligned stakeholders to engage Members of Congress on legislation directly impacting wound care, ultimately resulting in the Better Wound Care at Home Act and the Lymphedema Treatment Act being enacted into law in the final days of the year when they were included in the Consolidated Appropriations Act that President Biden signed into law on December 29, 2022!

In another huge advocacy win, we halted seismic changes to the way CTPs (“skin substitutes”) are coded and paid for in the 2023 Medicare Physician Fee Schedule. Proposed 2023 updates would have reclassified CTPs as “supplies incident to a physician service,” packaged payment into practice expenses, and created barriers to care that could lead to increased amputations and infections for patients with chronic non-healing wounds. Following a tremendous, unified effort by our Government Affairs Workgroup to galvanize Members of Congress, together with Alliance members who helped both craft our comments as well as submitted individual comments, we successfully convinced CMS to remove the proposed provisions until patient access issues could be further vetted with key stakeholders! CMS has already begun this process: the Agency convened a Town Hall in January 2023, at which Alliance members mobilized a strong showing.



Together, We Drove Clinically Accurate, Evidence-Based Wound Care Policies.

Via no less than nine submitted comments, letters and oral testimonies delivered in 2022, we were persistent in pursuit of revision/ withdrawal of coverage policies from four Medicare Administrative Contractors who released wound care LCDs containing clinically inaccurate language and/or restrictive, arbitrary utilization parameters not supported by evidence that would negatively impact patient care.

Together, We Addressed Wound Care Research and Coverage Challenges at our Wound Care Evidence Summit

We convened a critically needed conference that brought together payers, policymakers, researchers, physician specialty societies, patient and clinical associations, wound clinics and manufacturers to build mutual understanding to the question: **“What type and how much evidence do payers need to cover wound care products and procedures?”** The Wound Care Evidence Summit™ provided a rare and unique platform for a broad range of stakeholders to sit around the same table and collaborate to build consensus around issues ranging from development of coverage policies, clinical trial endpoints, the acceptance of real-world data and evidence, the current state of wound care research, clinical practice guidelines and more.



The Summit provided actionable knowledge, helped attendees prepare evidence to best meet payer and regulator needs, and facilitated an interdisciplinary network for future collaborations. Follow-up conversations with payers/regulators and development of next step action items continues.

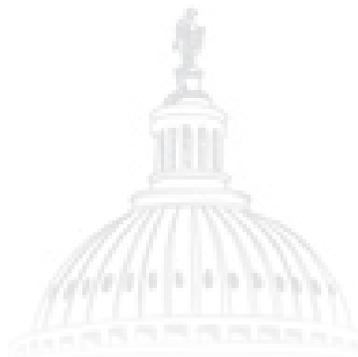
Together, We Make Wound Care Better.

We're excited to share a detailed overview of our 2022 Alliance advocacy, education and membership initiatives. We joyfully celebrate our 20th anniversary and 2022 successes while proactively preparing for a 2023 of continued change, challenge, and opportunity. We thank all our members for your collaboration. Your efforts enable the Alliance's astonishing breadth of activities and impacts across the past two decades. These achievements and accomplishments are YOUR achievement and accomplishments. We look forward to your continued support and engagement in 2023 and beyond.

Thank you.

Alliance 2022 Board of Directors

- Kara Couch**, MS, CRNP, CWCN-AP, FAWWC, Co-Chair Elect, Alliance of Wound Care Stakeholders
- Matthew Garoufalis**, DPM, FASPS, FACFAOM, CWS, Co-Chair, Alliance of Wound Care Stakeholders
- Caroline Fife**, MD, CWS, FUHM, Co-Chair Emeritus, Alliance of Wound Care Stakeholders
- Lee Rogers**, DPM, Board Member, Alliance of Wound Care Stakeholders
- Marcia Nusgart**, R.Ph., CEO, Alliance of Wound Care Stakeholders
- Karen Ravitz**, JD, Health Care Policy Advisor, Alliance of Wound Care Stakeholders



A Message from our CEO

Marcia Nusgart, RPh

We are honored to share our many accomplishments in 2022 - a year that marks not only impressive advocacy wins, but also the 20th anniversary of the founding of the Alliance.

Twenty years ago, I recognized that to effect change and effectively advocate with credibility and clout, there was a need to have a unified voice for wound care when speaking with regulatory agencies such as CMS, FDA and Congress. Since wound care is multidisciplinary and there are many physician and clinical associations whose members treat patients with wounds, it occurred to me that we did not know each other's positions on various important issues. So, if we would all go to CMS with conflicting positions, it would make it very easy for the Agency not to take any action until we had a united position. That realization led to action.

That action: **the creation of the Alliance for Wound Care Stakeholders.**

Our April 29, 2002, kick-off meeting in Baltimore started as an exploratory gathering. I invited about 25 different clinical organizations, medical specialty societies and manufacturers to attend to discuss and identify overlapping clinical, regulatory and legislative issues and shared challenges. As it turns out, it was the first time that such a broad base of healthcare professionals involved in wound care across diverse medical specialties had an opportunity to sit at the same table to discuss issues of mutual interest. That exploratory meeting became the launchpad for the cooperative efforts of the past 20 years.

Our inaugural policy issues those first years were access, coverage, reimbursement and education. These issues are still important today as the Alliance has served as the collective, credible, unified voice for wound care in working with CMS and its contractors and FDA. Over the years, we showcased this unified voice and our leadership organizing role spanning the 2005 CMS MEDCAC meetings on Usual Care of Chronic Wounds and 2009 Lymphedema to the 2023 CMS CTP Town Hall. We are proud of our work in wound care research from the 2012 "Consensus Principles for Wound Care Research" to our 2018 "An Economic Evaluation of the Impact, Cost and Medicare Policy Implications of Chronic Nonhealing Wounds" publication to our groundbreaking May 2022 Wound Care Evidence Summit.

We've been able to tackle the ever-expanding issues and challenges because we are fortunate to have such committed, talented and thoughtful members willing to devote the time and energy to advocate on behalf of wound care patients and providers. On behalf of the Alliance staff - Karen Ravitz, Shelley Ducker, Kristen Quinn, Gail Mutnik and myself - we are grateful to have had the opportunity to work with you over these past 20 years. We couldn't do it without you. Thank you for your support. We look forward to even more collaboration, engagement, active dialogue, and advocacy accomplishments in the future.

Here's to driving change and moving wound care forward for another 20 years!



Marcia Nusgart, RPh

ANNUAL REPORT 2022: EXECUTIVE SUMMARY



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

Shaping policy is an ongoing, long-term and collaborative effort. The Alliance testifies at meetings, submit public comments and engages in numerous dialogues to advocate, educate policymakers and influence wound care policy. Alliance members collaborate to improve coding, coverage and payment to help clinicians best serve their patients.

Our impact in 2022 has been extensive:

As a result of the Alliance's tenacious advocacy we:

- **Convinced CMS to delay and re-evaluate the problematic CTP provisions in the 2023 Physicians Fee Schedule Final Rule** which included: reclassifying all cellular and tissue-based products for wounds (CTPs, or skin substitutes) as "supplies incident to a physician service" and package payment into practice expenses as well as changes in coding and nomenclature. Following tenacious advocacy focused on the barriers to care this would create, these changes were NOT included in the final 2023 rule.
- **Combated restrictive, clinically inaccurate LCDs and LCAs:**
 - **Advocated for Novitas and First Coast Service Options (FCSO) to revise arbitrary utilization parameters** and other key provisions of their proposed Skin Substitutes for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers LCD/LCA that were not supported by evidence and that would negatively impact patient care. Elevated the issue by sending comments to the CEO of parent company Guidewell. In response, Guidewell's clinical team stated that due to our advocacy that when they release the Final LCDs/LCAs, there would be substantive changes.
 - **Pursued revision/withdrawal of CGS' proposed LCD/LCA on Skin Substitutes** for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers: flagged clinical inaccuracies and lack of supportive evidence.
- **Paved the way for Noridian's release of stalled claims.** Alliance advocacy prompted the MAC to publish an update reporting that for amniotic and/or placental derived products "claims that have been pending will be released in the upcoming days for processing."

- Obtained endorsement from CMS' Advisory Panel on Hospital Outpatient Payment** for the Alliance's recommendation to fix flawed/inadequate CTP payment policies by enabling provider-based departments to (1) to reimbursed for an adequate amount of CTP products for larger wounds and (2) to equalize the payment for CTP application for wounds/ulcers of the same size no matter the anatomic location. The Panel supported these, for the 2nd year in a row, elevated them to CMS for consideration.
- Brought about changes in the 2022 CMS NCCI Edit Manual which was the first step to allow** for reimbursement of the application of a total contact cast or compression therapy after a debridement or grafting procedure to be performed and reported for the same patient in the same anatomical region on the same day. The Alliance continues to meet and correspond with the NCCI contractor and CMS senior staff to delete the NCCI edits listed in the CPT Manual and CMS Manual Coding Instructions to mirror and reflect the guidance provided in its recently updated NCCI Policy Manual.

The Alliance built mutual understanding and a framework for solutions to the question: "What type and how much evidence do payers need to cover wound care products and procedures at the Wound Care Evidence Summit™?"

- Convened a critically needed and unique** two-day conference that brought together payers, policymakers, researchers, physician specialty societies, patient and clinical associations, wound clinics and manufacturers. Provided a unique platform for this broad range of stakeholders to discuss and build consensus around issues ranging from development of coverage policies, clinical trial endpoints, the acceptance of real-world data and evidence, the current state of wound care research and how clinical practice guidelines and research findings are being used by stakeholders to forward wound care.


**Wound Care
 Evidence Summit™**



As the go-to collaborative organization in wound care, the Alliance joined forces with aligned stakeholders in 2022 to impact change through the following efforts:

- **Succeeded in ensuring that two wound care legislative policy priorities-** the Better Wound Care at Home Act and the Lymphedema Treatment Act were included in H.R. 2617, the Consolidated Appropriations Act 2023 that President Biden signed into law on December 29, 2022.
- **Pressed CMS for greater transparency and uniformity** in development and implementation of coverage issues and the use of the Carrier Advisory Committees by meeting twice with CMS senior staff (Principal Deputy Administrator Jonathan Blum and Coverage staff) and co-signing letter with American Podiatric Medical Association and 18 additional physician specialty societies.
- **Supported the Academy of Nutrition and Dietetics' successful campaign for the inclusion of the Global Malnutrition Composite Score** in regulations by submitting comments to the Hospital Inpatient PPS rule, specifically supporting the inclusion of Global Malnutrition Composite Score (NQF #3592) in the proposed policy and recommending that CMS move forward with implementing the NQF #3592 Global Malnutrition Composite Score for the Hospital Inpatient Quality Reporting Program. **CMS included this measure in its IPPS Final Rule.**
- **Served as a key resource to the FDA as it planned its April Wound Healing Scientific Workshop** to shape the agenda, so it was synergistic with the Alliance's Evidence Summit.

The Alliance spoke at the meeting and provided two sets of comments to questions posed by the FDA.

- **In joint letters with the Clinical Labor Coalition, requested Congress' help to address the steep reductions in Medicare clinical labor payments** that started on January 1, 2022, and go through CY 2025 following CMS' update of the costs of clinical labor in the calculation of practice expense relative value units – an issue that impacts many wound care providers.
- **Partnered with 100+ clinician groups as part of the CF Coalition in letters urging Congress to take legislative action** to stop the 4.5% reduction to Medicare payment rates from being implemented on January 1, 2023, under the 2023 Physician Fee Schedule.
- **Served on the Wound Care Collaborative Community steering committee.**



The Alliance shaped policy development as we:

- **Urged Noridian to fix incorrect and outdated terminology in its Wound and Ulcer Care LCD;** submitted detailed chart of small but important changes (errors in HCPCS coding, CPT code descriptors, outdated language) that would not require reconsideration process but that would add accuracy and clarity.
- **Improved key CMS policymakers’ understanding of CTPs** via two meetings with CMS staff- a March session with 5 CMS directors and their staffs across 3 divisions of CMS to discuss how the inconsistent HCPCS code assignments for CTPs and synthetic CTPs has led to problematic issues in both the physician office setting and in hospital outpatient provider-based departments; a June educational seminar with six CMS directors/deputy directors and 18 senior staff to learn more about CTPs—the different types, clinical considerations on their use, and regulatory pathways.
- **Led the initiative for ASTM to update the CTP standard guide** (F3163-22) and its definitions used by payers for terminology purposes.

Submitted Comments: Weighing in with a United Wound Care Voice

Submission of comments to policies impacting wound care is a critical advocacy vehicle to be heard and on the record with regulators and legislators. Formal written comments, letters and oral testimonies are a core component of our advocacy work, supported and augmented by our in-person, phone and email dialogues.

Our 25 public comments in 2022 include:



Current Members & Membership Category Expansion

Clinical Association Members:

This membership category includes clinical, physician and patient associations or organizations that provide voluntary financial support or in-kind contribution to the Alliance. They have the power and authority to vote on the Alliance's work plan and on the Alliance's substantive policy positions.

[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® Interest](#)

[Group on Foot Care](#)

[American Physical Therapy Association](#)

[American Podiatric Medical Association](#)

[American Professional Wound Care Association](#)

[American Society of Plastic Surgeons](#)

[American Vein and Lymphatic Society](#)

[American Venous Forum](#)

[Amputee Coalition](#)

[Association for the Advancement of Wound Care](#)

[National Pressure Injury Advisory Panel](#)

[Society for Vascular Medicine](#)

[Society for Vascular Surgery](#)

[Undersea & Hyperbaric Medical Society](#)

[Wound, Ostomy & Continence Nurses Society](#)

[Wound Healing Society](#)

Non-Clinical Association Members:

This membership category includes non-clinical organizations that support the Alliance by providing comments and suggestions to the work plan and substantive policy positions. Non-clinical association members do not have voting rights but do provide financial support to the Alliance.

[ABWM Foundation](#)

[Coalition of Wound Care Manufacturers](#)



Current Members & Membership Category Expansion

Business Entity and Support Business Entity Members:

This membership category includes wound care business entities such as manufacturers, distributors, and suppliers, as well as support business entities such as wound center management companies and provider services that conduct wound care billing. These organizations have a compelling interest in the treatment of patients with wounds and provide financial support to the Alliance. They provide comments and suggestions to the work plan and in policy positions, but do not have voting rights.

[A3M Health Care](#)

[Acera Surgical](#)

[Advanced Oxygen Therapy Inc.](#)

[Bio Compression Systems Inc.](#)

[BioLab Sciences](#)

[BioTissue](#)

[Bioventus](#)

[E02 Concepts](#)

[ETS Wound Care](#)

[Geistlich Pharma North America](#)

[Healogics](#)

[Integra LifeSciences](#)

[Kathleen D. Schaum & Assoc. Inc.](#)

[Kerecis](#)

[Koya Medical](#)

[LifeNet Health](#)

[LymphaPress](#)

[Medline Skin Health](#)

[MedTech Solutions Group](#)

[MIMEDX](#)

[NATROX Wound Care](#)

[Organogenesis](#)

[Prism Medical Products](#)

[PolyNovo](#)

[Reaplix](#)

[RedDress Medical](#)

[Restorix Health](#)

[Sanara MedTech](#)

[Smith & Nephew](#)

[Tides Medical](#)

Current Members & Membership Category Expansion

NEW MEMBERSHIP CATEGORIES:

To expand its reach and in an effort to be more inclusive and responsive to the wound care community, the Alliance is adding three new membership categories: These categories join our existing categories: Clinical Associations / Physician Specialty Societies and Patient Associations; Non-Clinical Associations and Wound Care Business Entities or Support Business Entities. These additions will add knowledge, strength, and depth to the Alliance's advocacy mission.

- **Hospital Operated Wound Care Clinics:** This membership category includes hospital-based wound care clinics (WCC) and hospital systems operating one or more wound clinic.
- **Clinical Wound Care Provider Groups:** This membership category includes businesses providing direct face-to-face patient care (e.g., MDs, DPMs, NPs, RNs etc.)

[Renovo Wound and Hyperbarics](#)

[The Wound Pros](#)

- **Wound Care Business Entity Start-ups:** This membership category includes start-up or emerging companies with sales under \$1M and in business for less than 2 years.

[BioXtek, LLC](#)

[Merakris Therapeutics](#)

[Kent Imaging](#)

[Molecular Biologicals](#)

- **Professional Services Firms (Associate Membership):** This membership category includes professional service firms such as: law firms, research firms, health economics and policy consulting firms, market research, wound care publications, clinical trial companies and investment companies that support the wound care industry.

[GR Consulting](#)

[Ortho Spine Partners](#)

[SmartTRAK](#)

Welcome to our 16 new members who joined in 2022!

BioLab Sciences

BioXTek

EO2 Concepts

ETS Wound Care

GR Consulting

Kent Imaging

Koya Medical

Merakris Therapeutics

MiMedx

Molecular Biologicals

OrthoSpine Partners

PolyNovo

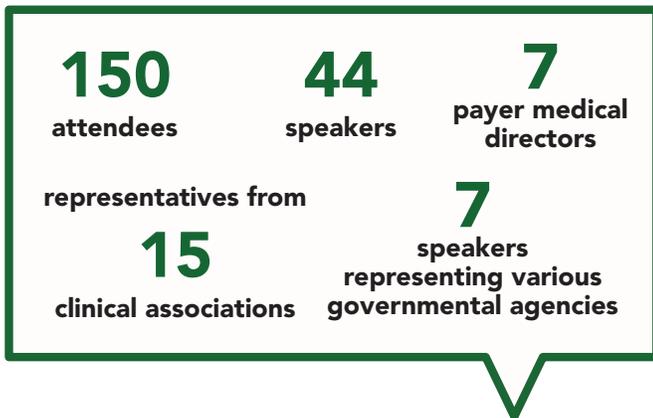
Reapplix

RedDress Medical

Renovo Wound and Hyperbarics

The Wound Pros

Wound Care Evidence Summit™



At the crossroads of advocacy, education, open communication and collaboration is the Alliance of Wound Care Stakeholder's inaugural Wound Care Evidence Summit.

The 2022 [Wound Care Evidence Summit](#) was an innovative two-day meeting of all stakeholder groups involved with wound care delivery including researchers, clinicians, manufacturers, payers and regulators.

Attendees explored the status of wound care research, answered the compelling questions that face stakeholders by defining the gaps, problems, limitations, and potential solutions, thereby contributing to a research base that met the needs of all involved parties.

Rarely do researchers, clinicians and manufacturers have an opportunity to discuss and collaborate in person with policy makers on clinical trial issues. Attendees and panelists ranged from **FDA, CMS, NIH, AHRQ** to representatives from companies who create the technology assessments and guidelines that commercial payers use to make coverage decisions. Payer medical directors from **Aetna, Anthem, CareFirst Blue Cross Blue Shield, CMS, Humana, Molina Healthcare of Texas and UnitedHealthcare** provided crucial perspectives.

This setting was critical to the Summit's success as a catalyst for **collaborative** activities in the future. Over the years, there have been increasing coverage restrictions stemming from the lack of shared clarity surrounding wound care evidence and the desires of payers and regulators to better understand the challenges of wound care research. Therefore, the Summit focus was to address the question:

What type and quantity of clinical evidence is required by payers in formulating positive coverage policies for products and procedures?



Presenting at Conferences About Coding/Coverage/Reimbursement Challenges and the Advocacy Work of the Alliance

A nationally and internationally recognized and respected reimbursement expert and advocate, Alliance CEO Marcia has spoken at conferences around the globe. In 2022 this included:

American College of Wound Healing and Tissue Repair (ACWHTR) Live! Conference

- Chicago, Illinois (November 2022)
- “Government Affairs Issues and Wound Care”

Association for the Advancement of Wound Care

- Salt Lake City, Utah (November 2022)
- “Washington and its Impact on Wound Care”

WHSI

- New York, New York (June 2022)
- “Challenges and Opportunities with Regulation and Policy in the Wound Care Industry”

Alliance Wound Care Evidence Summit

- Bethesda, Maryland (May 2022)
- Opening and Closing Remarks

FDA Wound Healing Workshop

- April 29, 2022, virtual
- “An Economic Evaluation of the Impact, Cost and Medicare Policy Implications of Chronic Non-Healing Wounds”

Symposium on Advanced Wound Care

- Phoenix Arizona (April 2022)
- “What Keeps Us Up at Night? Regulations Impacting Clinicians in Wound Care Centers and Private Practice”





2022: A Year of Progress

About the Alliance

WHO WE ARE AND WHAT WE DO

The Alliance of Wound Care Stakeholders is a 501(c)(6) nonprofit multidisciplinary trade association representing physician specialty societies, clinical and patient associations whose mission is to promote evidenced-based quality care and access to products and services for people with chronic wounds.

Through advocacy and educational outreach in the regulatory, legislative, and public arenas, the Alliance unites leading wound care organizations and experts to advocate on public policy issues that may create barriers to patient access to treatments or care. Our key focus areas are coding, coverage and payment; quality measures and wound care research.

Since its founding in 2002, the Alliance has enabled the wound care clinical community to collectively and collaboratively engage on issues of commonality, elevating the visibility and united voice of wound care providers to regulators and policy makers.

Celebrating 20 years in wound care advocacy!

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