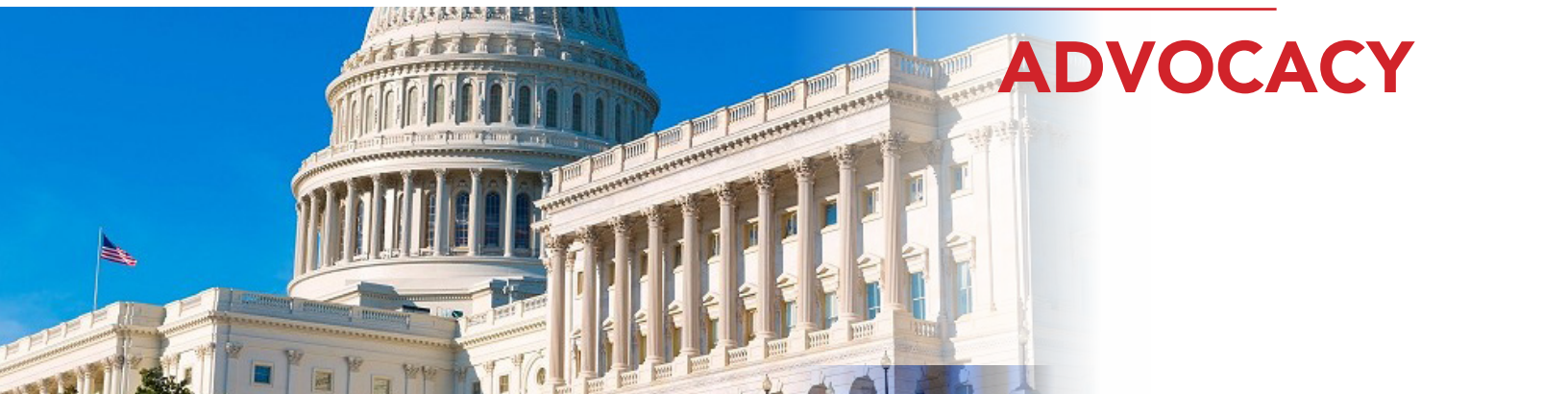




ALLIANCE OF  
**WOUND CARE  
STAKEHOLDERS**  
POWER THROUGH COLLECTIVE ADVOCACY™  
★ CELEBRATING 20 YEARS ★

# 2022 A Year of Progress ANNUAL REPORT

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



**ADVOCACY**



**EDUCATION**



**MEMBERSHIP**



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## 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**



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## A Year of Progress



# Advocacy

## CMS and CMS Contractor Advocacy: Activities and Accomplishments

### CMS POLICIES AND REGULATIONS

#### 1. Medicare Physician Fee Schedule

##### **Convinced CMS from Finalizing Problematic Provisions Regarding CTPs in CY 2023 Physician Fee Schedule Final Rule**

The Alliance initiated aggressive, proactive advocacy in response to seismic changes to the way CTPs would be coded and paid for. In the draft 2023 Physician Fee Schedule, CMS proposed 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 – a shift that the Alliance believed would create barriers to care that could ultimately lead to increased amputations and infections for patients with chronic non-healing wounds. In addition, CMS suggested changing the name “skin substitutes” to “wound care management products.” The Alliance submitted comments, activated members and individual clinicians to submit comments, and mobilized Members of Congress to send letters to CMS Administrator expressing concerns, through the work of the Alliance’s Government Affairs Workgroup.



**HUGE ADVOCACY  
WIN:**

Following tenacious advocacy with the Alliance urging CMS to remove or delay these highly problematic CTP provisions, they were NOT included in the final 2023 PFS, allowing the Agency time to review comments and hold a Town Hall meeting in January 2023 to further hear stakeholder concerns and gain insights into ways for CMS to move forward with a consistent payment approach between different sites of service. CMS may then issue for CY 2024 a proposed rule containing more details. (see additional details in CTP section, p.18)

## **Opposed payment cuts in the CY 2022 Physician Fee Schedule Proposed Rule**

In a series of co-signed letters, the Alliance urged Congress to address payment cuts in the CY 2022 Physician Fee Schedule to non-facility/office-based procedures.

- Collaborated with the Clinical Labor Coalition in letters and in our own submitted comments to marshal additional Congressional support to find a legislative fix (March). Co-signed with 20+ other Clinical Labor Coalition members a follow-on letter to Congress expressing concerns about the significant cuts in physician reimbursement and the repercussions to physician practices and their patients. The letter urged Congress to begin immediate deliberations to identify and advance policies to mitigate the forthcoming reimbursement cuts. (July)
- Opposed the cuts in the Clinical Labor Update in comments to the proposed 2023 Medicare Physician Fee Schedule, alerting CMS that the significant cuts in physician reimbursement undermine the long-term financial viability of physician practices and pose barriers for seniors to access critical treatments and procedures. (Sept.)
- Partnered with 100+ clinician groups collaborating together as the Conversion Factor (CF) Coalition on an advocacy campaign urging Congress take legislative action to stop the cuts (Nov.)



## 2. Hospital Outpatient Prospective Payment System (HOPPS)

### Advanced reform to the Hospital Outpatient Prospective Payment System CTP Payment Methodology to remove access barriers:

- Presented to CMS' Advisory Panel on Hospital Outpatient Payment and gained their support on policy updates to fix flawed/inadequate CTP payment policies and remove barriers to access. Obtained Panel endorsement of the Alliance's 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, 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.

## 3. Hospital Inpatient Prospective Payment System (IPPS)

### Supported member's advocacy efforts on global malnutrition composite score:

- In support of the Academy of Nutrition and Dietetics' campaign for the inclusion of the Global Malnutrition Composite Score in regulations, the Alliance submitted comments to the Hospital Inpatient PPS rule, specifically supporting the inclusion of Global Malnutrition Composite Score (NQF #3592) in the proposed policy and recommended that CMS move forward with implementing the NQF #3592 Global Malnutrition Composite Score for the Hospital Inpatient Quality Reporting Program. (June)



#### ADVOCACY WIN:

CMS included this measure in its 2023 IPPS Final Rule.

## 4. Home Health Prospective Payment System

### Submitted comments to gain clarity to provisions related to lymphedema.

The Alliance recommended that CMS the proposed reassignment of ICD-10 codes related to lymphedema to be moved to clinical group C as long as the providers are able to treat the patient, determine the types of services a patient receives and recommend the types of products being provided to patients, so they are not impacted by this reassignment. The Alliance also supported the assignment of diagnosis code Q82.0 (hereditary lymphedema) to circulatory 10 when listed as a secondary diagnosis code and recommended that CMS finalize the proposal. The Alliance also urged the Agency not to make many of its proposed cuts in payment to home health agencies, as their workload accelerated exponentially during the pandemic. The Alliance also highlighted the role home health plays in wound care.



### ADVOCACY WIN:

CMS agreed with the Alliance on the two lymphedema issues: it reassigned the ICD-10 codes related to lymphedema to be moved to clinical group C and assigned Q82.0 to circulatory 10. However, CMS did make significant cuts to home health care.

## 5. Healthcare Common Procedure Coding System (HCPCS) Issues

### Opposed proposed shift to "A" codes (supply codes) for CTPs

The Alliance adamantly opposed the shift to HCPCS "A" codes (supply codes) in the 2023 Medicare Physician Fee Schedule (see above). Strongly recommended that CMS continue to assign a Q code to CTPs when the requirements of the HCPCS application have been met and objected to CMS' renaming the term "skin substitutes" to "wound care management products."

## Pursued Consistency in HCPCS Coding for CTPs

Emphasized to CMS the inconsistencies of CTP HCPCS code assignments which led to the problematic OPFS and MPFS operational and administrative issues during a March meeting which the Alliance convened with 5 CMS directors across 3 divisions; summoned the Agency to bring consistency to coding for CTPs and correct the unintended payment impacts under current coding policies. Presented specific policy recommendations to address and fix issues.



**OUTCOME:** As a result of the March meeting, the Alliance was invited to lead a June seminar educating key CMS staffers about the different types of CTPs, their distinctions from surgical dressings, clinical considerations regarding use, selection and application and the policy challenges that most impact CTP use. Six CMS Directors/Deputy Directors and 18 senior staff attended from a range of divisions that oversee HCPCS coding, the physician fee schedule, hospital outpatient and ambulatory services, coverage, home health and more.

## Attended HCPCS Public Meetings, Shared Coding Decisions with Members

Shared with members CMS's preliminary coding decisions and agendas for the HCPCS Public Meetings. Attended virtual HCPCS Public Meetings and shared updates with members.

## 6. National Correct Coding Initiative (NCCI) Issues

### Advocated for Elimination of NCCI Edits to Allow for Debridement and Application of a CTP along with Compression to be Provided on the Same Day

In 2021, the Alliance submitted multiple letters and held numerous meetings with the National Correct Coding Initiative (NCCI) advocating for the deletion of edits made to the NCCI Policy Manual that prohibit the application of total contact cast or compression therapy after a debridement or skin grafting procedure in the same office/clinic visit. The 2022 manual was issued with these changes. However, the original edits remained in the edit tables and were listed in the CPT Manual or CMS Manual Coding Instructions, creating conflicting, confusing information that discourages clinicians from performing both services on the same limb, despite

the fact they are separate services that are appropriate to be performed and reported for the same patient in the same anatomical region on the same day.

Throughout 2022, the Alliance met or corresponded with NCCI contractor and CMS senior staff in many divisions (CMS' Program Integrity Group, Hospital and Ambulatory Policy Group and Audits and Vulnerabilities Group), requesting removal of the procedure-to-procedure edits or their guidance on how clinicians should correctly code and bill for these procedures on the same date of service and the same anatomical site. (see additional details in Compression section, p.29)

## 7. Additional CMS Policies & Issues

### **Focused Attention on Disparities in Chronic Wound Treatment Outcomes in Response to CMS Request for Information on Promoting Efficiency and Equity Within CMS Programs**

The Alliance submitted feedback to CMS' Request for Information seeking public input on accessing healthcare and related challenges, understanding provider experiences, advancing health equity and assessing the impact of waivers and flexibilities provided in response to the COVID-19 Public Health Emergency. Focused on healthcare disparities in the OUTCOME of chronic wounds which disproportionately affect minority populations and primarily affect persons with multiple comorbid conditions. Highlighted specific policy issues in the wound care space that negatively impact access to care and offered recommendations and policy fixes to address these issues. Addressing the Agency's request for input on COVID 19 PHE Waivers and Flexibilities, the Alliance also specifically provided a wound care perspective on areas including telehealth and remote patient monitoring.

## **Provided Wound Care Perspective on Development of a National Directory of Healthcare Providers & Services**

The Alliance provided comments to CMS' Request for Information; National Directory of Healthcare Providers & Services requesting that wound care and/or wound management services be identified within the directory. Expressed concern that CMS would only list providers with recognized specialties and reminded CMS of the many different specialties that treat patients with chronic wounds. Recommended a category within the directory for providers who treat chronic wounds.

## **CMS CONTRACTORS**

### **Medicare Administrative Contractors (MACs) Local Coverage Determinations (LCD) and Local Coverage Articles (LCA)**

**Advocated for Novitas and First Coast Service Options (FCSO) to revise arbitrary utilization parameters and other restrictive provisions** of their two proposed Skin Substitutes for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers LCD/LCA. Combated the restrictive, clinically inaccurate policies via advocacy initiatives for each contractor: providing oral testimony at two public meetings, submitting two sets of written comments, letters and emails focused on the multiple provisions within the policies, including the shift of 40+ products from the covered to non-covered list – that were not supported by evidence and that would negatively impact patient care. The Alliance recommended that with such problematic concerns that fundamentally severely impact patient care, we requested that FCSO and Novitas withdraw their draft LCDs and LCAs and instead create new ones that contain correct and up-to-date wound care terminology that are clinically sound and supported by current clinical evidence. We stated that this can be easily achieved by working with stakeholders such as the Alliance and FCSO Carrier Advisory Committee.

**Elevated issue by sending letters to the two MACs' parent company Guidewell and its CEO (Sept.).** In response, Guidewell's clinical team informed the Alliance that the final LCD/LCAs would be out in December and because of our advocacy, there would be substantive changes.



**OUTCOME:** Neither MAC's LCD/LCA have been finalized as of December 31, 2022.

### **Pursued revision/withdrawal of CGS LCD/LCA.**

Testified at CGS' October public meetings and submitted written comments voicing concerns with CGS' proposed Skin Substitutes for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers LCD/LCA that mimicked the flawed policies from Novitas and FCSO. Recommended that CGS pull the draft policies, then work with stakeholders and its Contractor Advisory Committee to craft a more clinically accurate policy that is based upon the most currently available evidence to mitigate any negative impact on patient care.



**OUTCOME:** CGS has not yet released its final LCD/LCA.

### **Requested that Noridian adopt Alliance's "non-substantive"**

**recommendations to Wound and Ulcer Care LCD. We initiated** numerous small but important updates and changes that would not require reconsideration process (errors in HCPCS coding, CPT code descriptors, outdated language).



**OUTCOME:** Noridian medical directors stated that they would review our information, but editorial changes were a low priority due to workload.

**Pressed for greater transparency and uniformity** in development and implementation of local and national coverage decisions and consistent use of Carrier Advisory Committees by meeting twice with the CMS senior staff (Principal Deputy Administrator Jonathan Blum and Coverage staff) and co-signing a letter with the American Podiatric Medical Association and 18 additional physician specialty societies.



**OUTCOME:** There will be additional meetings with CMS to address these issues.

## Advocacy to FDA, Capitol Hill, State Legislatures & Other Organizations

### FOOD AND DRUG ADMINISTRATION

#### Served as a key resource to the FDA as it planned its April Wound Healing Scientific Workshop

Worked closely with the FDA to serve as a resource in planning for its April [“Wound Healing Scientific Workshop,”](#) effectively positioning the event as synergistic with the Alliance’s Wound Care Evidence Summit meeting a month later. Many Alliance members not only participated in the meeting, but also served as speakers at the FDA Workshop, including board Co-Chair Dr. Caroline Fife and CEO Marcia Nusgart.

- Submitted detailed responses to the [questions posed](#) by the FDA as it sought feedback and input heading into its April Workshop. The Alliance provided responses to FDA’s questions for wound care providers, questions for product developers/researchers and questions specific to reimbursement (April). Invited Dr. Dev Verma, FDA Medical Officer, Division of Dermatology and Dentistry, Center for Drug Evaluation and Research (CDER) and organizer of the Workshop to provide an update on insights learned and next steps being considered as part of the Alliance’s May Wound Care Evidence Summit, enabling the meetings to build off each other’s activities.
- Built FDA support for real-world data/real-world evidence, primary and secondary clinical endpoints, mechanisms for modifying and expanding claims, funding of clinical trials by submitting additional comments after the Workshop that identified the consistent themes from both the FDA Wound Healing Workshop and the Wound Care Evidence Summit. Provided recommendations for the FDA to consider adopting to propel acceptance of real-world evidence.

#### Served on the steering committee of the Wound Care Collaborative Community.

## CONGRESSIONAL AND STATE ADVOCACY

**Collaborated with aligned stakeholders to help ensure 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.**

- The Alliance Government Affairs Work Group was instrumental in advocating for these initiatives to be included in this law. Considering the small size of the wound care industry compared to other health care sectors, this is an important win for the wound care industry to get two provisions included.
- The Lymphedema Treatment Act provides Medicare Part B coverage for compression garments for the treatment of lymphedema. This will allow patients whose wounds have healed to gain access to compression stockings; previously, Medicare required a debrided wound to cover these garments.
- The Better Wound Care at Home Act removes several CMS bureaucratic barriers making it a more desirable benefit for home health agencies to provide disposable negative pressure wound therapy.



## **Urged Congress to address payment cuts to non-facility/office-based procedures.**

- Collaborated with the Clinical Labor Coalition in letters and in our own submitted comments to gather additional Congressional support to find a legislative fix (March).
- Co-signed with 20+ other Clinical Labor Coalition members a follow-on letter to Congress expressing concerns about the significant cuts in physician reimbursement and the repercussions to physician practices and their patients. The letter urged Congress to begin immediate deliberations to identify and advance policies to mitigate the forthcoming reimbursement cuts. (July)

Joined 100+ medical societies and clinical associations as part of the Conversion Factor (CF) Coalition in co-signing a letter to Congress strongly urging Congressional action to prevent the 4.5% reduction to Medicare payment rates finalized in the 2023 Physician Fee Schedule and block them from implementation on Jan. 1, 2023. (Nov.)

## **ASTM**

**Led the effort to update the current ASTM Standard Guide for Categories and Terminology of CTPs (F3163-22)** and its definitions, which are important to keep updated as they are used by payers for terminology purposes.

## Product Category Advocacy Initiatives

### CELLULAR AND/OR TISSUE-BASED PRODUCTS FOR SKIN WOUNDS (CTPs)

With so many CTPs in the marketplace and CMS' intent to make payment methodology changes, this product category was a key focus of Alliance advocacy in 2022. Policy provisions impacting CPTs were in multiple 2022 proposed policies, including the Physician's Fee Schedule, Hospital Outpatient PPS and HCPCS coding decisions. The many advocacy activities of the Alliance, our CTP Workgroup and Government Affairs Workgroup to address payment and coding of CTPs are summarized below.

#### 1. Achieved a Significant Advocacy "Win" When We Successfully Halted Proposed Seismic Payment Changes, Protecting Access to CTPs in Physician Office Settings

**Stopped CMS from finalizing the CTP problematic coding, payment and terminology provisions in the CY 2023 Physician Fee Schedule Final Rule which, if implemented, would have created significant barriers to access in the physician office setting.**

The CY 2023 Physician Fee Schedule proposed rule recommended to reclassify all CTPs as "supplies incident to a physician service," and package payment for these "supplies" into the practice expense associated with that service. Under the proposed policy provision:

- CMS would no longer pay physician offices separately for CTPs under the traditional Average Sales Price +6% payment methodology.
- CTPs would be removed from the Medicare Part B pricing data file as pricing would now fall under the Physician Fee Schedule.
- CMS would discontinue all existing CTP products' Healthcare Common Procedure Coding System (HCPCS) "Q" codes (which are among the codes used to identify drugs and biologicals) All CTP products would instead be assigned HCPCS "A" codes (supply codes) and paid as "supplies incident to a physician service."

- CMS suggested changing the name “skin substitutes” to “wound care management products.”

## **Initiated aggressive, proactive advocacy.**

Convened a series of meetings with the Alliance’s CTP Workgroup to discuss issues, fixes and specific recommendations to reflect in comments. Convened Government Affairs Workgroup to identify opportunities to elevate issues to Congress and explore potential pathways for legislative fixes.

**Alerted CMS that the proposed payment policy shifts would not cover the costs to physician offices,** leaving many physicians unable to afford and provide these medically necessary advanced treatments to their patients in the absence of adequate reimbursement. The Alliance raised the alarm that this would result in barriers to care that could ultimately lead to increased infections and amputations. Urged CMS to remove or delay the proposed CTP provisions.

**Opposed the proposed shift to HCPCS “A” codes (supply codes)**, flagging to CMS that this policy shift ignored the therapeutic significance of CTPs and was not supported by any data, analysis or evidence. Recommended that CMS continue to assign Q codes to CTPs when the requirements of the HCPCS application have been met.

**Objected to CMS’ renaming the term “skin substitutes” to “wound care management products”** in the proposed 2023 Physician Fee Schedule. Alerted CMS that changing to the wound care management product nomenclature would actually cause more confusion in the industry than the CTP or skin substitute nomenclature that currently exists and would not provide the type of clarity that CMS is trying to achieve. Encouraged CMS to adopt the more clinically and technically accurate term “Cellular and/or Tissue-based Products for Skin Wounds” (CTPs) or “Cellular, Synthetic and/or Tissue-based Products” (CSTPs).

**Submitted Alliance comments, activated members and individual wound care clinicians** to submit comments. Mobilized Members of Congress to send letters to CMS Administrator expressing concerns, through the work of the Alliance’s Government Affairs Work Group.

**Issued press release and published by-lined articles** in wound care trade publications to draw attention to the issues.



**HUGE ADVOCACY  
WIN:**

Following tenacious advocacy with the Alliance urging CMS to remove or delay these highly problematic CTP provisions, they were NOT included in the final 2023 PFS so that the Agency could review comments and hold a Town Hall meeting in January 2023 to further hear stakeholder concerns and gain insights into ways for CMS to move forward with a consistent payment approach between different sites of service. CMS may then issue for CY 2024 a proposed rule containing more details.

## 2. Advocated for Novitas and First Coast Service Options to Revise Arbitrary Utilization Parameters and Other Restrictive Provisions in two sets of LCDs/LCAs

**Combatted Novitas and First Coast Service Options (FCSO)'s restrictive, clinically inaccurate** Skin Substitutes for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers proposed local coverage determinations (LCD) and local coverage articles (LCA) that were not supported by evidence and that would negatively impact patient care. The Alliance commented that with such problematic concerns that fundamentally and severely impacted patient care, we requested that FCSO and Novitas withdraw the draft LCDs and LCAs and instead create new versions that contained correct and up-to-date wound care terminology, were clinically sound and supported by current clinical evidence. We suggested that this can be easily achieved by working with stakeholders such as the Alliance and FCSO Carrier Advisory Committee.

**Testified twice at each Medicare Administrative Contractors' (MAC) public meetings (April and August) and submitted written comments** (May and Sept.) that objected to the shift of 40+ products from the covered to non-covered list, flagged numerous clinical inaccuracies and recommended that the MACs withdraw the draft LCD/LCAs and work with their Carrier Advisory Committees and stakeholders to craft more accurate policies.

**Elevated issue by sending letters to the two MACs' parent company Guidewell and its CEO.** In response, Guidewell's clinical team informed the Alliance that the final LCD/LCAs would be out in December and as a result of our advocacy, there would be substantive changes.



**OUTCOME:** Neither MAC's LCD/LCA has been finalized as of December 31, 2022.

### 3. Successfully Paved the Way for Noridian's Release of Stalled Claims

When the Alliance heard from members about suspensions of claims for amniotic skin substitute products or those with a "Q" code, we reached out to the Noridian medical directors to seek clarity on the rationale for the suspension.



#### ADVOCACY WIN:

As a result of our organized advocacy, in February, Noridian published an article on its website providing clarity regarding amniotic and/or placental derived products and reporting that "claims that have been pending will be released in the upcoming days for processing."

### 4. Sought to Fix Reimbursement Barriers in the Hospital Outpatient Setting Urged CMS to remove patient access barriers to CTPs in provider-based departments (PBDs) by correcting inadequacies in payments in the FY 2023 Hospital Outpatient Prospective Payment System proposed rule.

**Presented to and earned the endorsement of CMS' Advisory Panel on Hospital Outpatient Payment (HOP)** on two specific policy adjustment recommendations that would help correct flaws in CTP reimbursement and improve access to CTPs in provider-based departments (August):

**Recommendation 1:** Assign the existing CPT add-on codes (15272 and 15276; 15274 and 15278) to an appropriate APC group allowing for payment and issue an exception for the payment of CTP add-on codes. This would enable PBDs to be reimbursed for an adequate amount of CTP products for larger wounds (between 26 and 99 sq. cm and over 100 sq. cm) and addresses a key issue PBDs face: in the absence of add-on code payment, PBDs need to absorb the additional cost themselves or simply not offer CTPs for wounds of this size in this setting. Instead, patients may have to go to a hospital inpatient visit for this treatment, which is a more expensive setting.

**Recommendation 2:** Assign the application of skin substitute codes for wounds/ulcers on the feet to the same APC group as the application of skin substitutes for wounds/ulcers on the legs, making payment for the application of skin substitutes the same for wounds/ulcers of the same size no matter where they are on the body. This addresses the inconsistency that PBDs face as they must purchase and use the identical amount of product for wounds of the same size but are reimbursed at different levels depending on the anatomic location of the wound.



**OUTCOME:** The Panel approved, for the second consecutive year, these two recommendations and elevated them to CMS for consideration in its OPSS proposed rule.



## Submitted comments to proposed FY 2023 Hospital Outpatient Prospective Payment System (Sept.).

When the Alliance heard from members about suspensions of claims for amniotic skin substitute products or those with a “Q” code, we reached out to the Noridian medical directors to seek clarity on the rationale for the suspension.

- **Urged CMS to adopt the Alliance’s and HOP Panel’s recommendations** to correct reimbursement inadequacies.
- **Adamantly opposed CMS’ proposal to change HCPCS coding for CTPs from “Q” codes to “A” codes** (supply codes) – a cross-over issue from the Agency’s proposed 2023 Physician Fee Schedule that will also have significant impact in the hospital outpatient setting. Reiterated that HCPCS A codes are inappropriate because CTPs are not supplies, based upon both technological reasons and how they are used clinically.
- **Voiced disagreement with CMS’s proposal to rename “skin substitutes”** to the confusing and overly broad term “wound care management products.” Reiterated recommendations to instead adopt the more clinically accurate term– “Cellular and/or Tissue-based Products for Skin Wounds” (CTPs) or “Cellular, Synthetic and/or Tissue-based Products” (CSTPs).



**OUTCOME:** Despite the urging of the Alliance and CMS’ HOP Panel to use the HOPPS annual update opportunity to correct inadequacies in CTP payments that are causing barriers to care in Provider-Based Departments, the two policy fixes were not included in the final rule. Regarding issuance of A codes (supply codes), there was written discussion within the rule where CMS recognized that many CTP products being issued A codes are, in fact, biologicals and/or that several of the synthetic products also have biological components. Yet CMS is still moving forward in issuing HCPCS A codes to CTPs, ignoring the therapeutic significance of these products. The Alliance and other advocates have been fighting against this and will continue to dialogue with CMS on this matter. The shift from “skin substitutes” to “wound care management products” was not moved forward in the final rule. The Alliance remains in ongoing dialogue with the Agency on this issue as the Agency has made clear its intention to overhaul to its CTP payment methodology in future HOPPS rulemaking and indicated that they are still considering our recommendations.



## 5. Called on CMS to Bring Consistency to HCPCS Coding for CTPs & Synthetic CTPs

**Emphasized to CMS the unintended consequences of inconsistent HCPCS coding** for CTPs during a meeting that the Alliance convened with 5 CMS directors across 3 divisions. (March)

- Met with CMS directors and staff from the Division of Practitioner Services, the Division of Outpatient Care and Division of Coding and DRG (who have responsibility for the coding and payment of CTPs) 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.
- Alerted CMS to the unintended consequences in the physician's office and the hospital outpatient provider-based departments when CMS began assigning "A" and "C" codes instead of the traditional Q codes to skin substitutes.
- Presented six specific recommendations for CMS consideration to bring consistency to coding for CTPs and synthetic CTPs, supported by a 35-page chart of relevant HCPCS coding history along with HOPPS & Physician Fee Schedule policies to show how they impact each other and/or cause confusion. These recommendations included:
  - Immediately reassign unique HCPCS "Q" codes to all skin substitutes (including extracellular matrix, amniotic and synthetic skin substitutes): delete C1849 and A2001-A2013.
  - Immediately delete HCPCS code A4100 and instruct the physicians, PBDs, coders and billers to continue reporting new skin substitutes with HCPCS code Q4100.
  - Instruct all manufacturers of skin substitutes, including synthetic skin substitutes, to report their average sales price every quarter.

- Publish all reported skin substitute ASP prices on the Medicare Part B Drug Average Sales Price file so that the MACs know exactly how to pay for each brand.
- Provide clear instructions for submitting HCPCS code applications, including the types of skin substitutes that will qualify, and the materials that should be submitted with the application.
- Provide an opportunity for the Alliance to convene an educational session on skin substitutes.
- Called Alliance upon the Agency to bring consistency to coding for CTPs and synthetic CTPs and correct the unintended impacts being experienced under current coding policies. (March)



**OUTCOME:** CMS issued a document in which they placed all CTPs issued an A code into the low-cost payment bucket (except for Restrata) to reinforce that all CTPs should be treated the same. (April) However, there are still significant issues with the issuance of the A codes and the Alliance has escalated its focused advocacy in this area (see above). As an outgrowth of this meeting, CMS invited Alliance to lead an educational session on CTPs for CMS staff.

## 6. Improved CMS Policymakers' Understanding of CTPs Via an Educational Seminar

**The Alliance led an educational seminar customized for key CMS policymakers** who oversee policies guiding HCPCS coding, the physician fee schedule and hospital outpatient payments. (June) The seminar focused on the different types of CTPs (and how they differ from surgical dressings), the clinical considerations clinicians weigh when deciding about treatments and products and the regulatory pathways and policies that most impact them. Six CMS Directors/Deputy Directors and 18 senior staff attended from a range of divisions that oversee HCPCS coding, the physician fee schedule, hospital outpatient and ambulatory services, coverage, home health and hospice, data analysis and market-based pricing. (See Education section on p.34)



**OUTCOME:** CMS staff complimented the Alliance as being a resource for creating and implementing the educational session and stated that it was helpful to understand more about CTPs as they formulate their policies.

## 7. Fought Against Clinical Inaccuracies and Arbitrary Restrictions in LCDs

### **Pursued revision/withdrawal of Cigna Government Services (CGS) LCD/LCA.**

Testified at CGS' October public meetings and submitted written comments voicing concerns with CGS' proposed Skin Substitutes for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers LCD/LCA that mimicked the flawed policies from Novitas and FCSO. Recommended that CGS pull the draft policies, then work with stakeholders and its Contractor Advisory Committee to craft a more clinically accurate policy that is based on the most currently available evidence so that patient care will not be negatively impacted.



**OUTCOME:** CGS has not yet released its final LCD/LCA as of Dec. 31, 2022.

### **Urged Noridian to fix incorrect and outdated terminology in its Wound and Ulcer Care LCD**

The Alliance had spent a substantial amount of time in early 2021 developing comprehensive comments to Noridian's draft Wound and Ulcer Care LCD. When the final LCD issued in October 2021, the Alliance flagged concerns. In response, the MAC instructed the Alliance to submit a Reconsideration Request. However, the Alliance believes that many of our recommended changes (i.e., fixes to incorrect descriptions of CTP codes and outdated language) are "non-substantive," meaning that they are clarifying updates that do not change the policy itself and, therefore, can be incorporated without going through the reconsideration process. In early 2022, the Alliance submitted to Noridian a detailed chart of these small but important changes to show how the corrections would add accuracy and clarity to the LCD. (February)



**OUTCOME:** Noridian medical directors stated that they would review our information, but that editorial changes were a "low priority due to workload."

## 8. Updated Current ASTM Standard for CTPs

Led the effort to update the current ASTM Standard Guide for Categories and Terminology of CTPs (F3163-22) and its definitions, which are important to keep updated as they are used by payers for terminology purposes.

## 9. Advocated for Elimination of NCCI Edits to Allow for Debridement and Application of a CTP Along with Compression to be Provided on the Same Day

Following successful advocacy, the 2022 National Correct Coding Initiative (NCCI) deleted edits that had prohibited the application of total contact cast or compression therapy after a debridement or skin grafting procedure in the same office/clinic visit. The NCCI made these changes to the 2022 CMS NCCI Edit Manual (chapter 4, page 10) which provided the requested clarification that the bundling of CPT codes 20100-28899 and 29800-29999 is specific to a service in the Musculoskeletal System section of CPT and is not applicable to the treatment of wounds. However, the procedure-to-procedure edits listed in CPT Manual and CMS Manual Coding Instructions were not updated, creating conflicting, confusing information.

Throughout 2022, the Alliance met or corresponded with NCCI contractor and CMS senior staff in many divisions (CMS' Program Integrity Group, Hospital and Ambulatory Policy Group and Audits and Vulnerabilities Group), requesting removal of the procedure-to-procedure edits or CMS/NCCI guidance on how clinicians should correctly code and bill for these procedures on the same date of service and the same anatomical site. *(see additional details in NCCI section, p.11 and Compression section, p.29)*

## COMPRESSION

- 1. Joined forces with aligned stakeholders to ensure that the Lymphedema Treatment Act was included in H.R. 2617, the Consolidated Appropriations Act 2023 that President Biden signed into law on December 29, 2022.**

**The Alliance members, along with the Government Affairs Work Group** and other stakeholders, was instrumental in advocating for this initiative to be included in this law.

**The Lymphedema Treatment Act provides Medicare Part B coverage** for compression garments for the treatment of lymphedema. This will allow patients whose wounds have healed to have access to compression stockings; previously there needed to be a debrided wound for Medicare to cover these garments.

- 2. Advocated for Elimination of NCCI Edits to Allow for Debridement and Application of a CTP along with Compression to be Provided on the Same Day**

In both 2021 and 2022, a priority for the Alliance was to advocate to both CMS and the National Correct Coding Initiative (NCCI) contractor via a series of meetings and letters that there needed to be changes in the CMS NCCI Edit Manual and in the edit tables listed in the CPT Manual or CMS Manual Coding Instructions so as to allow clinicians to perform and report a debridement or application of a CTP as well as compression Total Contact Casting (TCC), Multi-layer Compression and Unna Boot paste casts) on a patient in the same anatomical area on the same day.

In 2022, due to the Alliance's advocacy, the NCCI made changes to the 2022 CMS NCCI Edit Manual (chapter 4, page 10) which provided the requested clarification that the bundling of CPT codes 20100-28899 and 29800-29999 is specific to a service in the Musculoskeletal System section of CPT and is not applicable to the treatment of wounds. While this was a good first step, the Agency still needed to delete the procedure-to-procedure edits listed in CPT Manual and CMS Manual Coding Instructions, to mirror and reflect the guidance provided in its NCCI Policy Manual and standard clinical practice.

Therefore, the focus in 2022 was to work with the NCCI contractor and CMS to remove the procedure-to-procedure edits or requested their guidance on how clinicians should correctly code and bill for these procedures on the same date of service and the same anatomical site. We met and corresponded on these issues with senior staff in many divisions of CMS: Program Integrity Group, Hospital and Ambulatory Policy Group, and Audits and Vulnerabilities Group. (see additional details in NCCI section, p.11)

- Convened a meeting with CMS senior staff to discuss the issue and the fixes needed. (Jan.)
- Submitted letter and a detailed table showing the specific corrections requested in order to have the newly updated language in the edit table be consistent with the Policy Manual. (April)
- Elevated the issue by submitting an email and following up with CMS Director of the Hospital and Ambulatory Policy Group Carol Blackford and Deputy Director Ryan Howe, apprising them of the issue, the lack of action and the barrier to care that remains. (April)
- Reached out to CMS' Division of Program Integrity, which has oversight of NCCI, and raised the issue to the Director of the Division's Audits and Vulnerabilities Group. (July)
- Traded emails with Dr. Pamela Villanyi with the Audits and Vulnerabilities Group who asked for claim ID numbers of cases that represent the concern. The Alliance stated that the issue is that "the modifier rules do not permit the use of modifier 59 to bypass the edits in question since the procedures are performed at the same anatomical site by the same practitioner during the same episode. Applying the 59 modifiers under these conditions is expressly prohibited in the modifier rules. For this reason, we cannot provide you with actual claims since providers are unable to submit such a claim." (Sept.)
- The Alliance continues to be in dialogue with CMS about this issue.

### 3. Submitted comments to CMS CY 2023 Home Health PPS Proposed Rule focused on gaining clarity to provisions related to lymphedema.

The Alliance recommended that CMS the proposed reassignment of ICD-10 codes related to lymphedema to be moved to clinical group C as long as the providers able to treat the patient, the types of services a patient receives and the types of products being provided to patients will not be impacted by this reassignment. The Alliance also supported the assignment of diagnosis code Q82.0 (hereditary lymphedema) to circulatory 10 when listed as a secondary diagnosis code and recommended that CMS finalize the proposal. (See CMS/Home Health PPS section on p.7,10)



#### ADVOCACY WIN:

CMS agreed with the Alliance on the two lymphedema issues: it did reassign the ICD-10 codes related to lymphedema to be moved to clinical group C and assigned Q82.0 to circulatory 10.

## NEGATIVE PRESSURE WOUND THERAPY: TRADITIONAL AND DISPOSABLE

**Mobilized the networks of the Alliance Government Affairs Workgroup; supported initiatives of aligned stakeholders to successfully ensure that the Better Wound Care at Home Act was included in H.R. 2617, the Consolidated Appropriations Act 2023 that President Biden signed into law on December 29, 2022.**

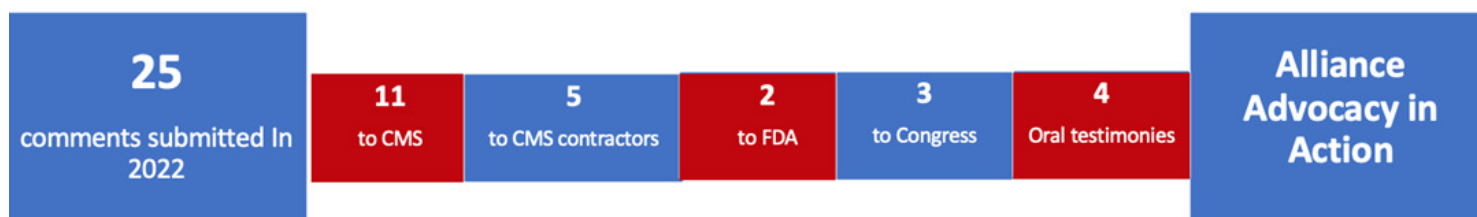
**The Alliance had signed on to letters of support for the Better Wound Care at Home Act** which removes several CMS bureaucratic barriers making it a more desirable benefit for home health agencies to provide disposable negative pressure wound therapy.

**Members of the Government Affairs Work Group were instrumental** in contacting Members of Congress and advocating for this initiative to be included in this law.



## 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:



### CMS

- Comments on CMS National Directory of Healthcare Providers & Services (Nov.)
- Response to RFI on Promoting Efficiency and Equity Within CMS Programs (Nov.)
- Comments to Proposed 2023 Hospital Outpatient Prospective Payment System (Sept.)
- Comments to Proposed 2023 Physician Fee Schedule (Sept.)
- Alliance CTP Educational Seminar for CME Directors and Senior Staff (June)
- CMS Home Health PPS (Aug.)
- Comments to 2023 Inpatient Prospective Payment System Proposed Rule (June)
- Letter to NCCI and CMS Urging Consideration of Requests for Edits (April)
- Presentation on Impact of Inconsistent HCPCS Coding for CTPs (March)

### MACS

- Comments to CGS draft LCD on Skin Substitutes for DFU/VLU (Nov.)
- Letter to Guidewell Urging Withdrawal

- of Novitas and FCSO Draft LCDs on Skin Substitutes for DFU/VLU (Sept.)
- Comments to Novitas and FCSO Draft LCD/LCA for Skin Substitutes for the Treatment of DFU/VLU (Sept.)
- Comments to Proposed 2023 Home Health PPS (Aug.)
- Comments to Novitas Draft LCD/LCA Skin Substitutes for Diabetic Foot Ulcers & Venous Leg Ulcers (May)
- Comments to FCSO Draft LCD/LCA on Skin Substitutes for Diabetic Foot Ulcers & Venous Leg Ulcers (May)
- Letter to Noridian on its Wound and Ulcer Care LCD/LCA (Feb.)
- Co-signed letter to CMS Urging Transparency & Uniformity in Setting Reimbursement for Products Used in Office-Based Settings (Jan.)

### ORAL TESTIMONY

- Oral Testimony at CGS Public Meeting on its Draft LCD on Skin Substitutes for DFU/VLU (Oct.)
- Oral Testimony on FCSO/Novitas Public Meetings on Draft LCD for Skin Substitutes

- for the Treatment of DFU/VLU (Aug.)
- Oral Comments on Novitas Draft LCD Skin Substitutes for the Treatment of DFU/VLU (April)
- Oral Comments Addressing FCSO Draft LCD on Skin Substitutes for Treatment of DFU/VLU (April)

### CONGRESS

- Letter to Congress to Prevent Cuts to Medicare Payments Rates (Dec.)
- Letter to Congress Regarding Cuts to Physician Reimbursement (July)
- Letter Requesting Congress' Help to Address the Steep Reductions in Medicare Payments (March)

### FDA

- Responses to Questions Posed by the FDA for its Wound Healing Workshop (April)
- Presentations at FDA Wound Healing Scientific Workshop (April)
- Follow Up Comments to the FDA Wound Healing Workshop (June)



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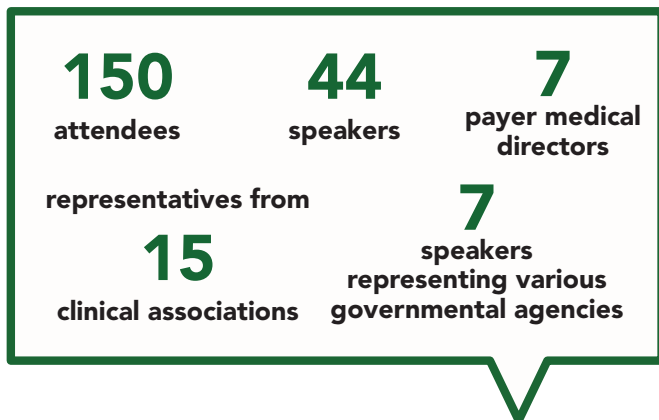
## A Year of Progress



# Education



## 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.

The 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, a 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?**





The Summit featured panels of payer medical directors discussing their perspectives on:

- **Current State of Wound Care Research, Clinical Practice Guidelines, HTAs and Utilization Review Guidelines**
- **Coverage Process Issues and Evidentiary Requirements**
- **FDA Issues and Real-World Evidence Opportunities**
- **Perspectives on Clinical Trial Design: Payers Perspectives and Possible Solutions.**

The conference provided a forum to collaborate and served as a catalyst to support a systematic implementation of policies, programs, and knowledge transfer approaches to improve the quality, effectiveness and safety of chronic wound care moving forward.



## Educational Seminars, Panels and Presentations

### Educating Policymakers at CMS

**The Alliance led a June educational seminar customized to key CMS policymakers** who oversee policies guiding HCPCS coding, the physician fee schedule and hospital outpatient payments. (June) The seminar focused on the different types of CTPs (and how they are different from surgical dressings), the clinical considerations clinicians weigh when deciding about treatments and products and the regulatory pathways and policies that most impact them.

**Six CMS Directors/Deputy Directors and 18 senior staff attended from a range of divisions that oversee HCPCS coding, the physician fee schedule, hospital outpatient and ambulatory services, coverage, home health and hospice, data analysis and market-based pricing:**

- Hospital and Ambulatory Policy Groups (Division of Practitioner Services, Division of Outpatient Care, Division of Ambulatory Services);
- Technology Coding and Pricing Group (Division of Coding and DRG; Division of Data Analysis and Market Based Pricing);
- Chronic Care Policy Group (Division of Home Health and Hospice);
- The Center for Clinical Standards and Quality (Coverage and Analysis Group).



## 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”



## Media Coverage

### Educating Readers via Outreach to Wound Care Trade Publications

The Alliance's proactive media outreach resulted in a series of by-lined articles published throughout the year in key wound care publications such as *Advances in Skin & Wound Care*, *Today's Wound Clinic*, *Wound Care Learning Network*, *Wound Management & Prevention* and others. These articles educate the wound care community about key issues and enhance Alliance visibility, credibility and thought leadership.



#### Advances in Skin & Wound Care

- [Coverage, Payment, and the Impact of Advocacy](#) (Jan.)

#### Today's Wound Clinic

- [Wound Care Community: Let's Make Our Voices Heard to Drive Payer and Regulator Acceptance of Real-World Evidence](#) (March)
- [Promoting Quality Care With the Alliance of Wound Care Stakeholders](#) (May)
- [Could Proposed Policy Changes in the 2023 Physician Fee Schedule Increase Amputations and Infections in Patients With Wounds?](#) (Sept.)
- [Remove Patient Access Barriers by Correcting Inadequacies in CTP Payments in the 2023 Hospital OPPS Proposed Rule](#) (Sept.)
- [2023 Medicare Physician Fee Schedule: Wound Care Wins, Challenges, and Opportunities](#) (Nov.)

#### Wound Management and Prevention

- [We Can Help Drive Acceptance of Real-World Evidence](#) (April)
- [Alliance of Wound Care Stakeholders Submits Comments on CTP Provisions](#) (Oct.)

#### Podiatry Today

- [CMS Releases 2023 Medicare Physician Fee Schedule](#) (Dec.)

#### Dermatology Times

- [CMS Looks to Make Changes on Codes for Skin Wounds](#) (Nov.)

#### WoundSource

- [Wound Care Evidence Summit to Gain Payer and Regulator Perspectives on Clinical Evidence and Coverage Challenges](#) (March)
- [Alliance Advocacy in Action](#) (April)





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★ CELEBRATING 20 YEARS ★

## A Year of Progress



## A Special Thank You to Our Members:

**Thanks to your participatory engagement and support over the past two decades,** the Alliance continues to enable and empowered leading wound care organizations and experts to come together to collectively advocate on public policy issues that challenge coding, coverage, payment, research, and/or patient access to wound treatments or care. We are small but mighty – a force to be reckoned with because we are stronger together! That’s because our greatest asset is our involved and engaged members. You each play a key role in enabling wound care to have a united voice to regulators and policy makers, to identify and elevate issues, to develop well-thought solutions to policy challenges, and to make impact. Thank you. We couldn’t do it without you.

**Here’s to our continued collaboration to drive change and move wound care forward!**



**Kristen Quinn, PT, DPT**  
Alliance Membership Director

## 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](#)

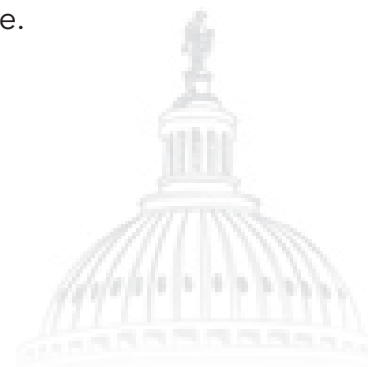


### Non-Clinical Association Members:

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](#)

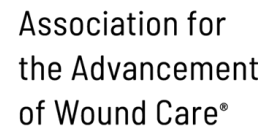
[Coalition of Wound Care Manufacturers](#)



# Membership

## Current Members & Membership Category Expansion

### Clinical Association Members:



### Non-Clinical Association Members:



## 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](#)

# Membership

## Current Members & Membership Category Expansion

### Business Entity and Support Business Entity Members:



## 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

# Membership

## Current Members & Membership Category Expansion

### Clinical Wound Care Provider Groups

RENOVO WOUND AND  
HYPERBARICS PLLC



### Professional Services Firms: Associate Membership





## 2022 Workgroups & Members:

**The CTP Workgroup** was formed to build consensus and action plans on how to best organize and deploy Alliance advocacy and individual member advocacy to address evolving issues surrounding CTPs.

<b>Chair: Bud Brame</b>	Donna Cartwright	Kristen Hedstrom	Pam McKeown
Alisha Oropallo	Doug Payne	Kurt Matheson	Peter Mikhail
Allan Staley	Emily Greenstein	Larry Santi	Rebecca Brown
Alyce Jones	George McNeely	Laura Shin	Robert Skerker
Andrew Amari	Jeffrey Lehrman	Laura Swoboda	Ryan Kerr
Antonio Montecalvo	Jennie Feight	Lee Rogers	Scott Reid
Benjamin Kimball	Joe Marchant	Lora Gillmore	Scott Swonger
Bill Tettelbach	Jolie Gischer	Lori Freedman	Shavondia Bell
Bob Maguire	Julie Orzali	Margaret Halstead	Tayo Clemons
Bruce Werber	Kara Couch	Maribel Henao	Tim Donovan
Caroline Fife	Karen Warner	Mark Olmstead	Timothy Hunter
Chris Broderick	Kate Gillard	Marshall Medley	Trish Dawidczyk
Christie Blakely	Kathy Schaum	Marion Snyder	Tyler Max
Colleen DeSantis	Kevin Combs	Michael Sinclair	
Dan Rinder	Kevin Kaboos	Michelle Guertin	

**The Government Affairs Workgroup** was formed to partner with our member organizations that have dedicated government affairs staff on legislative issues impacting the wound care community. The Alliance loaned its name to several sign-on letters as well as directly submitted letters to support (or oppose) legislative wound care initiatives.

Amy Law	Debra Swan	Kristen Hedstrom	Paul Seltman
Andrew Amari	Hunter Hall	Marion Snyder	Peter Rossi
Ben Wallner	Jeanne Blakenship	Margaret Halstead	PJ Andrus
Brenda Loft	Joe Haurani	Megan Marcinko	Robert White
Chris Rorick	John Martin	Michelle Kennedy	Samantha Helton
Colleen DeSantis	Julie Allen	Nic Mouawad	Timothy Hunter
Dave McNitt	Justin Elliott	Patrick Hermes	Wendy Chill
Deborah Williams	Kate Gillard	Patrick Bilbo	Yesenia Banks

**Special thanks to the individuals who contribute  
to our active workgroups!**

## Value of Alliance Membership

### Impacts policies to protect access to wound care products and services

Through advocacy and educational outreach in the regulatory, legislative and public arenas, the Alliance of Wound Care Stakeholders unites leading wound care experts to advocate on public policy issues that may create barriers to patient access to treatments or care. An umbrella organization that convenes the expertise of the full range of medical specialties involved in wound care, the Alliance provides a unique value proposition to members in that it:

- **Leverages the collective power** of its members to ensure that wound care has a strong voice and a seat at the regulatory table when policies are being developed and decisions that impact wound care are made.
- **Represents real-world clinical and technical expertise** on wound care issues, making the Alliance the champion on emerging issues of importance in wound care and positioning the Alliance as a recognized and respected go-to resource for regulatory agencies and other federal entities when addressing these issues.
- **Focuses exclusively on regulatory and legislative issues** impacting wound care coverage, payment, coding, FDA issues and quality measures.
- **Provides important access to regulatory and policy decision makers** via the strong network of federal and state regulatory and legislative contacts of Alliance leadership, staff and members.
- **Has the respect and recognition of regulatory and government agencies** following a proven track record of successful advocacy, led by an experienced and dynamic Executive Director who is passionate about ensuring patient access to and reimbursement of quality wound care.

## Value of Alliance Membership

### We achieve this by:

- **Communicating frequently with federal policymakers** regarding Alliance positions and needs when policies are in their formative stages to impact proposed or final policies.
- **Initiating and convening member meetings** with Members of Congress and their staffs, Centers for Medicare and Medicaid (CMS) senior level staff, their contractors DMEMAC and A/B MAC Medical Directors, PDAC and FDA.
- **Convening membership to develop and submit comments** to solve coverage, coding and payment issues and address quality issues that impact the Alliance's members.
- **Monitoring and analyzing issues affecting** quality, coverage, coding, and reimbursement impacting wound care clinical practice.
- **Serving as a resource** to members to answer and clarify specific policy questions immediately.
- **Updating members regularly**, alerting them to the anticipated impact and implications of new and draft policies, and advising them about when to take action.





## 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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