ALLIANCE OF

WOUND CARE STAKEHOLDERS

POWER THROUGH COLLECTIVE ADVOCACY™

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

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LETTER FROM ALLIANCE LEADERSHIP

MATTHEW GAROUFALIS, DPM
Co-Chair

CAROLINE E. FIFE, MD
Co-Chair

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Executive Director

After a year of challenge, change and opportunity, we offer a most important Thank You to our members on the front lines caring for patients while also carving out precious time from their already hectic schedules to participate on our calls, develop comments on regulatory changes, and support the Alliance's advocacy agenda. Your efforts led to the Alliance's astonishing successes in 2021, and for this, we are truly thankful.

The Alliance achieved great successes in many aspects of regulatory policy even amid this year's many challenges, which attests to the Alliance's **strength** and **agility**. This annual report reflects the depth of our membership collaboration, diligent advocacy, educational efforts, and extensive engagement with key government decision makers on behalf of the wound care community and its patients. You will see that in 2021 our unified voice was truly heard and heeded as we set the stage for our continued advocacy in 2022.

Collaboration is a core value of the Alliance, and we continued our mission of working with regulatory agencies, organizations and our member associations. Our executive summary lists our proud collaborations, including but not limited to: FDA staff, CMS contractors, Wound Care Collaborative Community, Clinical Labor Coalition and the Alliance for HCPCS Coding Reform. The creation of our new Government Affairs Work Group has allowed the Alliance to have additional new collaboration leading to a more prominent presence on Capitol Hill with the ability to support legislation of importance to wound care.

2021 brought exciting important changes to Alliance membership structure and addition of key personnel. The Alliance created three new membership categories in response to the need to have these voices heard within our association: (1) independently operated hospital wound care centers; (2) wound care business entity startups (having sales under $1 million and in business for fewer than two years); and (3) wound care professional service firms. These are all important components of the wound care community. In the new year, we will value their insights, support and participation, in addition to our current members. We hired Kelly Coates and Laura Kearney as Membership Directors and welcomed Gail Mutnik, MPA as our new Chief Operating Officer.

In 2021, we also welcomed many important new members: Acera Surgical, Amniox Medical, Coloplast, Kerecis, Medline Solutions Group, NATROX Wound Care, National Pressure Injury Advisory Panel (NPIAP), Organogenesis and Sanara MedTech.

2022 will be an important year for the Alliance. We will celebrate our 20th Anniversary and look forward to seeing you on May 19-20 at our important Wound Care Evidence Summit™ where leaders and payers will answer the question, "How much and what type of clinical evidence do payers need to cover wound care products and services?"

Your participation helps us achieve our mission of advancing wound care and improving coverage, coding and payment issues which benefits the patients we serve. The Alliance would not be where we are today without your continued involvement, and we are honored to share some of our incredible accomplishments this year with you, outlined in our executive summary and in the attached report.

Sincerely,

Caroline E. Fife, MD, and Matthew G. Garoufalis, DPM, Co-Chairs,
and Marcia Nusgart, RPh, Executive Director

ALLIANCE ACCOMPLISHMENTS 2021
EXECUTIVE SUMMARY

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

Shaping policy is an on-going, long-term, and collaborative effort with repeated public and private meetings and calls with CMS and its contractors, FDA, and other decision makers. Based on input from our front-line clinicians and experts, we present at meetings, submit numerous public comments and other correspondence to educate and influence wound care policy. Alliance staff and members work together to improve coding, coverage and payment to best help clinicians better serve their patients.

Our impact in 2021 has been extensive.

- **As a result of the Alliance's tenacious advocacy we:**
  - ✓ **Obtained a 9.6% increase for disposable negative pressure wound therapy (dNPWT**) instead of a 22% reduction in the physician office setting.
  - ✓ **Accomplished a National Correct Coding Initiative (NCCI) edit manual change** allowing for debridement and compression to be provided on the same day.
  - ✓ **Successfully convinced CMS to retract the proposed 2021 Physicians Fee Schedule provision** to bundle cellular and tissue-based products for wounds (CTPs, also known as skin substitutes) in the physician office setting.
  - ✓ **Created language, which was accepted and used by CMS, for an MLN Newsletter** article explaining why the new synthetic CPT "A" codes should be treated the same as all other CTPs, and how to correctly bill for them.
  - ✓ **Obtained a unanimous recommendation from the Advisory Panel on Hospital Outpatient Payment** to CMS, which prompted the Agency to begin reviewing recommendations for flawed CTP payment changes.
- **As the ultimate collaborative umbrella organization for wound care, the Alliance** continued to join forces with organizations and its members to impact change through the following efforts:
  - ✓ Collaborated with FDA staff to shape its agenda and speakers for its April 2022 wound healing workshop so it will be synergistic with the Alliance's Evidence Summit.
  - ✓ Became a charter member and serve on the steering committee of the Wound Care Collaborative Community.
  - ✓ Actively participated with the Clinical Labor Coalition to impact change on the significant physician payment cuts.
  - ✓ Led the Alliance for HCPCS Coding Reform's efforts to gain clarification from CMS on submitting new electronic HCPCS coding application and won more time for initial submission.
  - ✓ Partnered with a leading group of physicians to advocate to the DMEMACs for coverage of pneumatic compression devices to treat critical limb ischemia.
  - ✓ Spearheaded an ASTM workgroup to update CTP standard used by payers for terminology purposes.
  - ✓ Partnered with Alliance member associations to send letters of support on issues of importance to both organizations:
    - Academy of Nutrition and Dietetics to support Global Malnutrition Global Score.
    - American Podiatric Medical Association to update the Massachusetts Podiatry Act.

- ✓ Created a Government Affairs Work Group to partner with our member organizations that have dedicated government affairs staff on legislative issues impacting the wound care community. The Alliance has lent its name to several sign-on letters as well as directly submitted letters to support (or oppose) legislative wound care initiatives.

- **The Alliance shaped policy development as we:**

  - ✓ **Vocally opposed payment cuts** in the proposed CY2022 Physician Fee Schedule by collaborating with the Clinical Labor Coalition and submitting comments to impact change. As a result, the pay cuts were minimized. We will continue to address this in 2022.
  - ✓ **Championed CTP payment issues** by submitting hospital outpatient payment methodology recommendations to CMS.
  - ✓ **Served as a resource to CMS contractor Noridian medical directors** as they developed their wound care LCD.
  - ✓ **Called for transparency in CMS' and its contractors' implementation of the 21st Century Cures Act.**

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2021 Activities and Achievements

I. CMS and CMS Contractors Advocacy and Accomplishments

A. CMS Policies and Regulations Advocacy

1. Physician Fee Schedule

- **Opposed payment cuts in the proposed CY2022 Physician Fee Schedule**:
  The Alliance joined 23 other clinical associations in the Clinical Labor Coalition, which met with both the White House and Office of Management and Budget (OMB) staffs to oppose specific changes proposed in the Physician Fee Schedule. In these calls and through letters to CMS, the Coalition pointed out that these changes would be costly, shift procedures from the physician office to the hospital and decrease patient access to care. In the comments the Alliance submitted to CMS, it raised concerns about payment cuts to surgical procedures, physical therapy services, disposable negative pressure wound therapy and compression payment. (September/November). In December, Congress intervened and passed legislation that helped mitigate the physician payment cuts, however, it did not go far enough. There was success for dNPWT since instead of a decrease, CMS included an increase for dNPWT of 9.6% for the non-facility rate. The 2022 rate is $385.37 for 97607 and $380.33 for 97608. There was a slight decrease in the facility fee rate.

- **Convinced CMS not to bundle synthetic CTP payments in the physician office setting:**
  The Alliance submitted comments opposing proposed bundling of synthetic CTPs in the physician office setting in the CY2022 Physician Fee Schedule. As a result of our advocacy, CMS did not move forward with the bundling but rather now allows for synthetic CTPs to be contractor priced and billed as an add on code when they are applied in the physician office setting. (September/November)

- **Succeeded in our request to have CMS issue a "MLN Connects Newsletter" to educate contractors and providers on how to report new "A" codes for CTPs in the physician office, HOPD and ASC settings:**
  Recognizing that there may be confusion in reporting the newly released synthetic skin substitute and other skin substitute "A" codes in the physician office, ASCs and HOPDs, the Alliance created and submitted language for CMS to include in the "MLN Connects Newsletter," and requested that CMS publish this information expeditiously to defray any confusion by the Contractors. CMS published instructions for reporting "A" codes in the November 16, 2021, MLN Connects Newsletter, using language from the Alliance. (November/December).

2. Hospital Outpatient Prospective Payment System (HOPPS)

- **Advanced reform to the Hospital Outpatient Prospective Payment System CTP Payment Methodology:**
  - Prior to submitting comments to CMS regarding the proposed CY 2022 Hospital Outpatient Prospective Payment System (HOPPS) in September, the Alliance presented at the Advisory Panel on Hospital Outpatient Payment and gained their agreement on important Alliance issues. In a big win for the Alliance, the Panel unanimously approved two Alliance recommendations that would have corrected flaws in CMS' payment methodology that have negatively impacted reimbursement for CTPs and thus remove current barriers to access to these important wound care products. While CMS did not accept the recommendations at that time, it opened the door for further discussion with the Agency as was described in their response to our comments. **(**August/September)

- The Alliance proactively submitted recommendations to CMS on a new payment methodology prior to the proposed rule being issued. The letter resulted in CMS convening a call in April with Alliance members to gain further clarification. While ultimately CMS did not provide language in the final rule addressing a new payment methodology, they did state that the Agency would consider our recommendations in the future. (March/April)

3. Healthcare Common Procedure Coding System (HCPCS) Issues

- **Sought clarification from CMS on new coding and classification changes for CTPs:**
  The Alliance spearheaded the effort to gain clarity from CMS on its issuing "A" codes instead of the traditional "Q" codes for CTPs/skin substitutes. The Alliance submitted written comments to CMS' December HCPCS coding meeting requesting transparency. We asked that CMS publish guidance on the coding changes for CTPs, including defining the term "synthetic" and the rationale for CMS issuing "A" codes to all CTPs that have an FDA 510(k) clearance but are not necessarily synthetic skin substitutes. As part of our ongoing advocacy and relationships, we learned and passed along to members information that products with 510Ks would be considered devices and, therefore, would be required to go through the HCPCS code process as non-drug/non-biologicals and would receive "A" codes. (December)

- **Voiced support at CMS HCPCS public meetings for new HCPCS codes in pneumatic compression and CTPs:**
  Executive Director Marcia Nusgart spoke at two CMS HCPCS public meetings regarding preliminary coding decisions for CTPs and pneumatic compression devices and garments. (July/December)

- **Advocated for enhanced transparency in the HCPCS process:**
  As part of the Alliance's ongoing advocacy to make the HCPCS coding process more transparent, understandable and predictable, the Alliance submitted comments and recommendations to CMS' Medicare CY2021 DMEPOS/HCPCS Level II proposed rule that focused on code cycles, application re-submissions and other key areas to increase the speed of new products receiving codes so that patients have access to the latest products more quickly. (January)

- **Gained clarification from CMS on the process to submit new electronic HCPCS coding applications, and won more time for their submissions:**
  Four weeks before the September 20 deadline for submitting HCPCS Level II coding applications, CMS announced that it would require all applications go through its new online system, MEARIS. The Alliance met with CMS and their contractors to outline problematic issues since CMS did not create instructions for the completion of the new application. Just 24 hours later, the deadline for submitting HCPCS coding applications for drugs and biologicals (CTPs included) was extended to October 1, 2021. (September/October)

4. National Correct Coding Initiative (NCCI) Issues

- **Successfully achieved an update to the NCCI manual allowing for debridement and compression to be provided on the same day.**
  The Alliance submitted two letters to the National Correct Coding Initiative (NCCI) then met with 10 representatives from CMS and the NCCI to discuss the importance of eliminating specific NCCI edits made to the 2022 NCCI policy manual that prohibit the application of total contact cast or compression therapy after a debridement or grafting procedure in the same office/clinic visit. Removal of these edits allows clinicians to be paid appropriately. In December, the manual was issued with the changes the Alliance had requested, however, the correlating changes to the edits table were not made. The Alliance met with the Agency to notify them of the error and inconsistency and requested that the corresponding changes to the edits table be made retroactive to January 1, 2022. (June/October/December)

5. Medicare Coverage for Innovative Technology

- **Alliance urged CMS to quickly issue a new proposed rule for Medicare Coverage of Innovative Technologies (MCIT):**
  - The Alliance expressed extreme disappointment in CMS' decision to repeal the final Medicare Coverage of Innovative Technology (MCIT), which was poised to move FDA-approved, innovative technologies to market faster to help patients, and quickly propose a separate rule. (October)
  - At the same time, the Alliance recommended against the codification of "reasonable and necessary," as a definition already exists. The Alliance stated that a new codified standard would diminish Medicare Administrative Contractors' flexibility in deciding whether the item or service is "reasonable and necessary" for a specific beneficiary, thereby, decreasing access to needed care. (October)

6. Additional Issues

- **Promoted expanded use of PRP in wounds:**
  The Alliance recommended several changes to the National Coverage Decision (NCD) for Autologous Blood-Derived Products for Chronic Non-Healing Wounds, including the recommendation that CMS remove a policy provision that states that PRP would not be covered when used for the treatment of "chronic, non-healing, cutaneous wounds." The NCD was finalized, and an "MLN Matters Newsletter" and transmittal was released in November. (January)

- **Pursued a MIPS value pathway for wound care providers:**
  The Alliance, with the U.S. Wound Registry, convened a call with CMS staff to discuss the creation of a Merit-Based Incentive Payment System (MIPS) Value Pathway (MVP) for diabetic foot ulcers and other wound management issues to ensure that wound management practitioners have quality measures to report to CMS that are related to the specific wound care procedures they perform. (June)

- **Supported member's advocacy efforts on global malnutrition composite score:**
  The Alliance sent three letters in support of its member the Academy of Nutrition and Dietetics' campaign for the inclusion of the Global Malnutrition Composite Score in regulations: two to the National Quality Forum's Measures Application Partnership (MAP) and one to CMS for inclusion in the CY 2022 Hospital Inpatient Prospective Payment System (IPPS). (Spring and Summer 2021)

- **Advocated for transparency in the implementation processes of 21st Century Cures Act provisions**:
  The Alliance joined other medical specialty societies to sign on to a letter to CMS describing frustrations with the implementation of the 21st Century Cures Act, the lack of transparency regarding coverage policies and the impact that has had on the LCD process. (December)

B. CMS CONTRACTORS

Medicare Administrative Contractors (MACs) Local Coverage Determinations and Local Coverage Articles

- **Shaped Noridian's new Wound and Ulcer Care coverage policy:**
  As CMS contractor Noridian drafted its new wound care Local Coverage Determination/Local Coverage Article (LCD/LCA) in 2020 and 2021, the Alliance was a resource to the medical directors as they created the Contractor Advisory Committee (CAC) and developed the policy. We provided consultation and education to the medical directors, spoke at public meetings and submitted comprehensive recommendations through written comments. Released in November, the final policy, "Wound and Ulcer Care (LCD/LCA)," included some of the Alliance's recommendations. However, the Alliance identified clinical inaccuracies and incorrect terminology in the final policy and is continuing dialogue with the contractor to have them corrected. (Spring/November/December 2021)

- **Fought for coverage of pneumatic compression devices to treat CLI by DMEMACs:**
  The Alliance partnered with a leading group of physicians to advocate to the DMEMACs for coverage of pneumatic compression devices in the proposed LCD to treat critical limb ischemia. Despite extensive evidence to the contrary, the LCD states that the use of pneumatic compression devices for the treatment of critical limb ischemia (CLI) is not "reasonable and necessary" for purposes of Medicare reimbursement. The Alliance, leading clinicians and clinical associations attended the public meeting and submitted written comments to strongly disagree with this proposed decision. The final LCD has not been released. (November)

II. Advocacy to FDA, Capitol Hill, State Legislatures & Other Organizations

A. FOOD AND DRUG ADMINISTRATION

- **Applauded the FDA's support for real-world evidence (RWE) in decision making:**
  In its written comments, the Alliance commended the FDA's draft guidance for industry "Real-World Data: Assessing Electronic Health Records and Medical Claims Data to Support Regulatory Decision-Making for Drug and Biological Products." It also recommended that the Agency reference two articles in its guidance document to reinforce the value of RWE in wound care related decisions. (November)

- **Recommended actions to forward acceptance of real-world evidence:**
  Alliance Executive Director Marcia Nusgart educated the Wound Care Collaborative Community about the Alliance's work on supporting real-world evidence in wound care clinical research and outlined actions for moving this important issue forward. (May)

- **Collaborated with FDA staff to shape agenda and speakers for its April 2022 wound healing workshop so as to be synergistic with the Alliance Evidence Summit meeting.**

B. Congressional and State Advocacy

- **Advocated to Congress to Increase ASP for CTPs in Physician Offices**
  With a new mandatory ASP reporting requirement going into effect in 2022, the Alliance supported legislation to amend the 2021 Consolidated Appropriations Act through reconciliation to increase ASP for CTPs to ASP+15% (the current rate is ASP +6%).

- **Sought to remove cumbersome billing regulations in home health for dNPWT:**
  The Alliance submitted letters supporting the Better Wound Care at Home Act (S. 2363/H.R.2356), which addresses obstacles Home Health Agencies (HHAs) have faced when providing disposable negative pressure wound therapy devices (dNPWT) to Medicare beneficiaries. (August)

- **Encouraged comprehensive Medicare coverage for treatment of patients with lymphedema:**
  The Alliance submitted letters to Congress supporting the Lymphedema Treatment Act (S. 1315/H.R. 3630), legislation that would provide comprehensive Medicare coverage for the treatment of patients with lymphedema or for the prevention of venous stasis ulcers resulting from venous insufficiency. (August)

- **Brought our national clout to support Massachusetts podiatrists:**
  The Alliance sent a letter of support for Massachusetts' House Bill 2270/Senate Bill 1510 "An Act Relative to the Definition of Podiatry." This legislation would update the podiatric Practice Act in Massachusetts to allow podiatrists to treat the foot, ankle and lower leg.

C. ASTM

- **Led the effort to update the current ASTM standard for CTPs** to ensure its preservation by convening meetings of the workgroup.

III. COVID-19 Response Leadership

In 2020, the Alliance led the wound care community's rapid response to the COVID-19 Public Health Emergency and have a dedicated page on this topic on our website. In 2021, the Alliance continues these efforts, enabling members to respond quickly and effectively to new challenges as the Public Health Emergency evolves.

- Ensured that wound care was identified as "essential," enabling hospital administrators to keep wound care clinics open and provide care to their patients.

- Advocated for and achieved regulatory relief and flexibilities to ensure that policies reflected the on-the-ground realities of wound care clinicians and manufacturers amid the pandemic.

IV. Alliance Wound Care Evidence Summit™

You will not want to miss the Alliance's Wound Care Evidence Summit on May 19-20, 2022, in Bethesda, Maryland!

The Alliance created a critically needed and unique two-day conference to bring together medical directors from commercial payers, government policymakers, prominent researchers, representatives from physician specialty societies, patient and clinical associations, medical directors, wound clinics and manufacturers to address the question: **"What and how much evidence do payers need to cover wound care products and procedures?"**

Our goals include:

- Addressing the current state of wound care research and clinical trial design
- Exploring solutions to address the limitations in the wound care evidence-base
- Communicating with payer medical directors on the development of coverage policies and the use of clinical practice guidelines in coverage decision making
- Defining "next steps" to actualize solutions
- Participating in a uniquely intimate gathering of leading decisionmakers

Rarely do researchers, clinicians and manufacturers have an opportunity to discuss and collaborate in person with policy makers on clinical trial issues. These dialogues are the first step in understanding each person's point of view, leading to further collaboration in the future.

Originally scheduled for April 2020 and postponed due to COVID-19, the "Wound Care Evidence Summit" will provide a unique platform for this broad range of stakeholders to discuss development of clinical trials and coverage policies, explore the current state of wound care and wound care research, and address how clinical practice guidelines and research findings are being used by stakeholders.

We have an exciting agenda featuring **four** 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**

This is an important opportunity to hear from senior staff at these important agencies/organizations: FDA, CMS, NIH, AHRQ and from representatives from companies who create the technology assessments and guidelines that commercial payers use to make coverage decisions.

Learn more and register soon to secure your spot.

V. Product Category Advocacy Initiatives

SPECIAL FOCUS: Cellular and/or Tissue-Based Products for Skin Wounds (CTPs)

CTPs are a key focus area for the Alliance since their use is valued by both clinicians and wound care researchers as important in the treatment of chronic wounds. However, with so many CTPs in the marketplace and CMS' intent to make payment methodology changes, it was apparent in 2021 that there would be regulatory initiatives on which the Alliance would need to take action. Changes to HCPCS coding and payment for CTPs were front and center in three different CMS vehicles: the Physician's Fee Schedule, Hospital Outpatient PPS and HCPCS coding decisions.

The Alliance prepared for this early on by convening its CTP Workgroup to create and submit payment methodology recommendations to CMS which led to an April meeting with the Agency. In addition, the Alliance presented these recommendations to the HOPPS Advisory Panel which approved two of them. The Alliance worked with its CTP Workgroup to submit comments to these proposed rules and convened meetings with CMS staff to obtain clarity in HCPCS coding issues given the Agency's lack of transparency. (i.e., delay in issuing new codes, information needed to submit to CMS to obtain new code, issuing of "A" codes instead of "Q" codes) All the while, the Alliance was persistent in gathering information prior to the Agency publishing it and communicated with our members to keep them abreast of the many changes. We have outlined in detail below our many activities related to our advocacy on payment and coding of CTPs.

In 2022, we anticipate that CMS will continue to make changes to CTP coding and payment and the Alliance will working with our members and be there to advocate on their behalf on these important issues.

IN 2021, THE ALLIANCE:

1. Sought to Fix Reimbursement Barriers in the Hospital Outpatient Setting

- **In March, the Alliance proactively submitted recommendations regarding CTP payment methodology** for CMS to consider as it began development of proposed rules for CY 2022, since the Agency had previously placed the issue of reforming the CTP payment methodology in the HOPPS proposed/final rules and solicited feedback on three distinct payment systems: Episodic Payment, Single APC and a Comprehensive APC.

- **In April, Alliance leadership convened a call with the CMS staff** to discuss our recommendations and answer their questions. The Alliance subsequently submitted a follow-up communique responding in detail to CMS requests for specific information.

- **In August, the Alliance presented to the CMS' Advisory Panel on Hospital Outpatient Payment (HOPPS)** these two specific policy adjustment recommendations that would help correct flaws in CTP reimbursement and improve access to CTPs in provider-based departments (PBDs) regardless of a patient's wound size or location:

  - **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 unanimously approved these two recommendations which were elevated to CMS for consideration in its OPPS proposed rule.

- **In September, the Alliance submitted comments on CMS' proposed CY 2022 Hospital Outpatient Prospective Payment System** and urged CMS to adopt the Agency's Advisory Panel on Hospital Outpatient Payment recommendations.

Outcome: CMS did directly address, but not act on, both Alliance recommendations in the final rule. While the Agency stated that it does not believe that add-on codes are appropriate since there is already a bundled payment. CMS did state that:

- **Recommendation 1:** It will review the recommendation to place similar size wounds in the same APC regardless of anatomic location.
- **Recommendation 2:** It will review this more closely at a later date. This is the first time that CMS has directly indicated a willingness to review this issue – even if at a later date.

Ultimately, CMS did not include an overhaul to its CTP payment methodology in its CY 2022 HOPPS. The Alliance remains in ongoing dialogue with the Agency on this issue as the Agency has made clear its intention to address this matter in future rulemaking and indicated that they are still considering our recommendations

2. Advocated for Appropriate Coding and Payment for Synthetic CTPs

- **Voiced concern about the use of a new "C" code for synthetic CTPs** in comments to CMS' proposed CY2022 Hospital Outpatient Prospective Payment System. Recommended using "Q" codes instead, since all other CTPs are required to apply for and obtain a unique HCPCS "Q" code that is product and brand specific.

Outcome: In the final rule, CMS did address the Alliance's comment but only to explain why it believes these products need to have a separate code in this setting. The Alliance will continue to engage with CMS on this issue.

- **Emphasized the importance of a consistent payment system for synthetic resorbable skin substitutes** in physician offices so that the payment system would be the same as it is for all other skin substitutes in that setting. In the CY 2022 Physician Fee Schedule, CMS moved to change codes and establish bundling specifically for synthetic resorbable skin substitutes. The Alliance alerted CMS to the inappropriateness of bundling for these products as well as the confusion and administrative burden these changes would cause physician offices.

Outcome: The final CMS provisions largely followed Alliance recommendations. CMS:

- Did not finalize its proposal that synthetic resorbable skin substitutes provided in a physician's office be bundled, which is similar to hospital outpatient regulations.

- Did not finalize its proposal that synthetic resorbable skin substitutes be treated as "incident-to" supplies in the physician office.
- Did not move forward with its proposed requirement that ***all*** CTP products consult with the FDA Tissue Reference Group (TRG) prior to obtaining HCPCS codes.
- Did establish add on payment for synthetic skin substitutes.
- Did state in the rule that synthetic skin substitutes should be treated like other skin substitutes in the physician office setting despite receiving "A" code status. (*see below)*
- Noted that it plans to "further evaluate these components of products with an existing "Q" code for future rulemaking to, in a similar manner, address payment policies for all skin substitutes across settings in a consistent manner along with products discussed in this rule."

- **Sought clarifications from CMS and its HCPCS Work Group about the issuance of an "A" code instead of the traditional "Q" code** for a new synthetic skin substitute. The Alliance submitted comments to the December HCPCS coding meeting questioning this decision, requesting transparency on its rationale, and encouraging CMS to provide instruction to providers, billers, and the MACs so that they understand how the "A" code for skin substitutes should be billed and reimbursed in this case, as "A" codes are typically supply codes and bundled, therefore, not separately reimbursed.

- **Mobilized CMS to educate stakeholders about correct reporting for new CTP "A" Codes.** Since these code updates were going into effect on January 1, 2022, the Alliance quickly urged CMS to ensure that CTPs newly assigned "A" codes would be reported and paid for correctly in physician offices, ambulatory surgical centers, and HOPDs**.** The Alliance urged CMS to quickly provide education to their contractors on the accurate reporting of skin substitutes codes in these settings. To facilitate CMS action, the Alliance developed and submitted to CMS two draft "MLN Connect" articles that the Agency and its contractors could circulate:
  - An article informing stakeholders that effective January 1, 2022, CMS assigned HCPCS codes that begin with "A" to some skin substitutes in physicians' offices and providing instructions to billing departments on how to report when the skin substitutes assigned "A" codes are applied. The Alliance took this action as we believed there would be an access issue to these products since historically "A" codes are bundled as they are considered supplies.
  - An article informing stakeholders of the newly assigned HCPCS C1849 to synthetic skin substitutes and providing instructions to billing staff on how to report codes when synthetic skin substitutes assigned C1849 are applied in hospital outpatient departments.

  Both articles shared claims processing instructions for Part A/B MACs.

  Outcome: On November 16, 2021, CMS issued an "MLN Connect Newsletter" that included language from the Alliance.

3. Advocated for Transparency by CMS- on Delay of Issuing CTP HCPCS Codes and Clarifying of the Use of "A" Codes vs Q Codes for CTPs ("skin substitutes")

- **June**: **Sought to obtain clarity from CMS** on reasons the Agency was "deferring these applications to a subsequent coding cycle because the scope of the request necessitates that additional consideration be given before CMS reaches a final decision." **Convened call with CMS's Division of Coding and Diagnoses Related Groups Acting Director and Deputy Director** to better understand what the "additional considerations" were that CMS needed and any information that applicants could provide to CMS. The Agency said they needed more time to consider things and advised the Alliance to watch for information in the upcoming Proposed rules.

- **August: Persistent in obtaining answers from CMS on information that CTP manufacturers need to include in new HCPCS code applications** and how the Agency classifies them as biologicals or devices since the Agency has not been forthcoming on them. CMS replied to emails and stated that that products with 510Ks would be considered devices and, therefore, would be required to go through the HCPCS code process as non-drug/non-biologicals. In addition, the Agency was not requesting a letter from the FDA's TRG group for skin substitutes that have 510 (k) clearance.
- **July/December**: **Spoke at two CMS HCPCS public meetings regarding CTPs questioning delay in coding decisions and concerns with issuing "A" codes instead of "Q" codes** Executive Director Marcia Nusgart spoke at two CMS HCPCS public meetings in July and December regarding preliminary coding decisions for CTPs. In July, she addressed the Alliance's concerns regarding deferring the application to a subsequent coding cycle which impacts the commercialization of the product and hampers the ability for clinicians to use the product on their patients. In December, she agreed with the CMS HCPCS Workgroup to establish a new code but believed that it should be a "Q" code rather than an "A" codes since the product was not a "synthetic" skin substitute.

4. Advocated to Congress to Increase ASP for CTPs in Private Physician Offices

Supported legislation to amend the 2021 Consolidated Appropriations Act through reconciliation to ASP+15% for skin substitute products before new ASP reporting requirements under Part B go into effect in 2022. "This small change would allow skin substitute products to remain in private physician offices while retaining the new mandatory ASP reporting requirements," the Alliance informed the Senate Finance Committee via letter, noting that this in turn would have "a dramatic impact on minority and underserved communities, which disproportionally suffer from skin ulcers and other skin-related complications that require skin substitute products. Without this change, it is likely that these populations will see access to early treatment dwindle, leading to more amputations, more hospitalizations and poorer health outcomes." ASP is currently set at ASP+6%. (September)

5. Updated Current ASTM Standard for CTPs

Led the effort to update the current ASTM standard for CTPs to ensure its preservation by convening meetings of the workgroup.

6. Sought Fix to NCCI Edits that Create Burden for Patients, Providers

(see compression, below)

SPECIAL FOCUS: Compression

1. Sought Fix to NCCI Edits that Create Burden for Patients and Providers

Sought to remove the recent NCCI edits addressing Total Contact Casting (TCC), Multi-layer Compression, and Unna Boot paste casts that are inconsistent with peer-reviewed literature and inconsistent with appropriate allocation of resources to treat diabetic foot ulcers and venous ulcers. With the current edits in place, if a grafting or debridement procedure is clinically indicated for treatment of a wound, the CMS would deny payment for the application of the TCC or compression procedure during the same visit.

The Alliance informed the National Correct Coding Initiative (NCCI) contractor via a series of letters that its edits do not follow the standards for offloading and compression and necessitate scheduling two procedures on separate dates - a wasteful allocation of resources and more costly for both CMS and Medicare beneficiaries. (June, October)

Outcome: After much persistent advocacy, changes were made to the CMS NCCI Edit Manual in Chapter 4 on 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 Agency neglected to include the changes in the edit tables. The Alliance remains in active conversation with the NCCI contractor to ensure that the deletion of the edits is made so that there is no conflict between the manual and edit tables.

2. Fought for coverage of pneumatic compression devices to treat CLI by DMEMACs

The Alliance partnered with a leading group of physicians to advocate to the DMEMACs for coverage of pneumatic compression devices in the proposed LCD to treat critical limb ischemia. Despite extensive evidence to the contrary, the LCD states that the use of pneumatic compression devices for the treatment of critical limb ischemia (CLI) is not "reasonable and necessary" for purposes of Medicare reimbursement. The Alliance, leading clinicians and clinical associations attended the public meeting and submitted written comments to strongly disagree with this proposed decision. (November)

Outcome: The final LCD has not been released.

3. Opposed Cuts to Multi-Layer Compression Application

Opposed cuts for application of multi-layer compression that were proposed in the CY 2022 Physician Fee Schedule. The Alliance informed CMS: "A cut in the reimbursement for the application (which must be adequate to purchase the product and to pay the clinician) will make it cost prohibitive for physician offices to provide compression which benefits patients with the most common lower extremity malady, one that primarily affects Medicare beneficiaries. It may also lead to a reduced number of clinicians willing and able to provide this therapy or clinicians choosing a lower-priced, less-effective product that may not support appropriate therapeutic compression," the Alliance informed CMS.

Outcome: While our recommendation was not acted on, we are on the record with our concerns that these cuts could lead to a reduced number of clinicians willing to provide this therapy or clinicians choosing a lower-priced, less effective product that may not support appropriate therapeutic compression.

4. Supported new HCPCS codes for compression devices

Voiced support at CMS HCPCS public meetings for new HCPCS codes in pneumatic compression. Executive Director Marcia Nusgart spoke at two CMS HCPCS public meetings in July and December regarding preliminary coding decisions for compression devices and garments. She stated the Alliance's support for new technology in the marketplace by CMS issuing new HCPCS codes in their preliminary coding decisions and alerted the Agency that including disparate devices into the same HCPCS code would severely limit the ability of CMS and other interested parties to collect data and assess the utilization, cost, efficacy and clinical outcomes of these new devices.

Outcome: CMS issued new codes for the ones in July but have not issued the final coding decisions for those products in December.

5. Sought Appropriate Coverage in LCDs

When Medicare Administrative Contractor Noridian issued a draft wound care LCD that stated that the Unna Boot or application of a multi-layer compression system *"may be a useful adjunct to wound care management particularly with venous ulceration of the lower extremity,"* the Alliance educated the MAC via comments emphasizing that both are considered the Standard of Care and are primary treatments for patients with venous ulcers, as included in the language of the CMS approved quality measure on VLU compression.

SPECIAL FOCUS:
Negative Pressure Wound Therapy: Traditional & Disposable

1. Protected disposable negative pressure wound therapy (dNPWT) payment

Opposed the proposed reduction in payment of dNPWT CPT codes 97607 and 97608 by 22% when performed in physician office settings, as proposed in CMS' draft CY2022 Physician Fee Schedule. Informed CMS "if CMS moves forward with this decrease, its consequences will force services commonly performed in the physician office or home into the hospital setting, which will result in higher costs to the Medicare system."

Outcome: Success. Instead of a decrease, CMS included an increase for dNPWT of 9.6% for the non-facility rate. The 2022 rate is $385.37 for 97607 and $380.33 for 97608. There was a slight decrease in the facility fee rate.

2. Worked to remove cumbersome billing regulations

Submitted letters of support for the Better Wound Care at Home Act (S. 2363 / H.R.2356) that would improve access to dNPWT by streamlining billing for home health agencies (HHAs) onto the industry-standard claims form, eliminating burdensome time reporting requirements on home health nurses, and clarifying that payment to HHAs for disposable NPWT is for the device only.

Outcome: The bill is still under consideration in Congress.

VI. Media Coverage

Alliance Visibility: Articles in the Wound Care Trade Media

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 enhance Alliance visibility, credibility and thought leadership:

Advances in Skin & Wound Care

- Coverage, Payment, and the Impact of Advocacy (December)

Today's Wound Clinic

This influential trade publication is now featuring more CMS policy coverage updates on its site via a series of by-lined pieces from Alliance executive director Marcia Nusgart:

- Wound Clinics and Wound Care Advocacy: Advocating for Evidence-Based Coverage and Reimbursement (July)
- Will Proposed Wound Care Service Payment Reductions in 2022 Harm Wound Clinics? (October)
- Correct Inadequacies in CTP Payments and Remove Barriers to Access (September)
- Get Up To Speed With Wound Care Policy Updates (November)
- Changing Policy Through Advocacy: Elevating the Voice of Wound Care Providers for 20 Years (December)

Wound Care Learning Network (HMP)

- CMS' Advisory Panel on Hospital Outpatient Payment Unanimously Approves Alliance's Recommendations to Correct Inadequacies in CTP Payments, Remove Barriers to Access (September)

Wound Management and Prevention

- Alliance of Wound Care Stakeholders' Year in Review (January 2021)
- Advocating for the Wound Care Community (February)

Alliance Visibility: Virtual Presentations

Wound Care Learning Network (HMP)

- Presentation: **Impact of COVID-19 on Reimbursement and Governmental Policies,** Marcia Nusgart and Karen Ravitz joined Dr. Paul Kim on this virtual panel (May)

WHSI- Uniting Leaders Dedicated to Amputation Prevention

- Presentation: "Wound and Vascular Care in a Post-Covid World: Artificial Intelligence, Telemedicine & the Shifting Points of Care" (October)

VII. Membership Development

1. Alliance hires new staff

We welcomed Kelly Coates and Laura Kearney as Membership Directors. In addition to helping administer the Alliance's Wound Care Evidence Summit, Gail Mutnik, MPA has assumed responsibilities as the Alliance's Chief Operating Officer.

2. New membership categories

To expand its reach and in response to requests to join, the Alliance adding three new membership categories:

- Hospital Operated Wound Care Clinics
- Wound Care Business Entity Start-ups
- Professional Service Firms (i.e., 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.)

These additions will add knowledge, strength and depth to the Alliance's advocacy mission.

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.

3. The Alliance welcomed important new members in 2021:

ACERA SURGICAL
Revolutionizing Healing. Changing Lives.

amniox
A TissueTech Company

Coloplast

Kerecis®

MEDLINE

NATROX®
Oxygen Wound Therapy

NPIAP
NATIONAL PRESSURE INJURY ADVISORY PANEL

Organogenesis
Empowering Healing

Sanara MedTech
Evidence Based Healing

CURRENT ALLIANCE MEMBERSHIP

Clinical and Non-Clinical Association Members

Academy of Nutrition and Dietetics
AANP American Association of Nurse Practitioners
ABWM American Board of Wound Management CWCA® CWS® CWSP®
American College of Foot and Ankle Surgeons® Proven leaders. Lifelong learners. Changing lives.
American College of Hyperbaric Medicine Where Wound Healing Begins
American Diabetes Association.
APTA American Physical Therapy Association
apma Advancing foot and ankle medicine and surgery
APWCA American Professional Wound Care Association
American Society of Plastic Surgeons
American Vein & Lymphatic Society
American Venous Forum Promoting venous and lymphatic health
amputee coalition
AAWC
Coalition of Wound Care Manufacturer
National Lymphedema Network
NPIAP
Society for Vascular Medicine
SVS Society for Vascular Surgery
Undersea & Hyperbaric Medical Society Raising the quality of practice one member at a time
VNAA
Wound Healing Society
WOCN Wound, Ostomy, and Continence Nurses Society

Business Entity Members

3M Science. Applied to Life.™
ACERA SURGICAL Revolutionizing Healing. Changing Lives.
Advanced Oxygen Therapy Inc.
AMT
amniox A TissueTech Company
BIO COMPRESSION SYSTEMS INC. Number 1 in Compression Therapy
Coloplast
Geistlich Medical
Healogics The power to heal
INTEGRA MEDICAL
Kathleen D. Schaum & Assoc., Inc.
kerecis
LifeNet Health® Saving Lives. Restoring Health. Giving Hope.
lympha Press
MEDLINE
MedTech Solutions Group
MISONIX BETTER MATTERS
NATROX® Oxygen Wound Therapy
Organogenesis Empowering Healing
PRISM Home Medical Supply Specialists
Sanara MedTech Evidence Based Healing
SmithNephew
Tactile MEDICAL
tidesmedical.

Professional Services Firms

SmartTRAK®

VIII. Value of Membership in the Alliance of Wound Care Stakeholders

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.

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.

CONTACT US

To learn more about the Alliance of Wound Care Stakeholders,
contact Executive Director, Marcia Nusgart, Marcia@woundcarestakeholders.org .

For more information about joining the Alliance,
email us at membership@woundcarestakeholders.org

To sponsor the 2022 Wound Care Evidence Summit,
email evidencesummit@woundcarestakeholders.org

Participate in the Wound Care Evidence Summit
A multi-disciplinary meeting for payers, government agency policymakers, prominent researchers, wound care medical specialty societies, patient and clinical associations, wound care clinics and manufacturers, register **HERE**.

Follow us on LinkedIn

woundcarestakeholders.org