Following Tenacious Advocacy from the Wound Care Community, Medicare Administrative Contractors Withdraw Local Coverage Policy that Disrupted Care, Dramatically Restricted Access to CTPs (Skin Substitutes)

Sept. 28, 2023 – Bethesda, MD – Following tenacious collaborative advocacy from the Alliance of Wound Care Stakeholders and across the wound care community, Medicare Administrative Contractors (MACs) Novitas, First Coast Service Options (FCSO) and CGS Administrators today withdrew their local coverage determination (LCD) policies and local coverage articles (LCAs) that that would have dramatically restricted Medicare patients' access to cellular and tissue-based products for wounds (CTPs/"skin substitutes") – advanced wound care treatments that are instrumental to wound healing. The policies were scheduled to go into effect on Oct. 1st but have now been pulled.

"The LCD entitled, Skin Substitute Grafts/Cellular and/or Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers, will not become effective on 10/01/2023. A new Proposed LCD will be published for comment and presented at an Open Meeting in the near future," reads a document note placed at the top of each MACs' LCD web page on Sept. 28, 2023.

Released in August, the policies had removed coverage from 130 CTPs and capped the number of covered CTP applications to four, significantly limiting the number of applications allowed over a treatment episode without regard for wound healing progress or supportive clinical evidence. The implementation timeframe also raised care disruption concerns: less than 8 weeks transition had been provided from the Aug. 3 policy issuance to effective-date (initially Sept. 17, then extended to Oct. 1 to accommodate a technical "system update"). Yet, CTPs are a category of products with standard 12-week treatment plans – meaning that any wound patient who was in the middle of a CTP treatment plan could have had their care interrupted on Oct. 1st due to the coverage changes.

Elevating the Issue: Congressional Advocacy + Clinician "Call to Action"
The Alliance of Wound Care Stakeholders had initially elevated concerns with the coverage policies when they were issued as drafts in 2022. In the months that followed, the Alliance persistently submitted a series of written comments and oral testimonies that again and again flagged clinically incorrect information in the policies, arbitrary utilization parameters, and the lack of scientific evidence to support the changes proposed. When the LCDs/LCAs issued as "final" in August 2023 with few of these issues addressed, the Alliance directly communicated concerns to MAC medical directors and Centers for Medicare and Medicaid Services (CMS) leadership, then launched an Advocacy Action Center initiative to ensure that policymakers understood the real-world impact of these policies from the perspective of patients and clinicians. The "Call to Action" mobilized not just the Alliance's 20+ medical specialty society/clinical association members but also wound care provider groups, individual wound care providers and wound care patients to email MAC medical directors and CMS policymakers.

At the same time, several Alliance member organizations also engaged with Members of Congress, educated them on the issues and asked Congressional representatives to submit letters voicing concerns to CMS. Ultimately, multiple letters were sent to CMS, including a letter from a group of bipartisan members of Congress to CMS Administrator Chiquita Brooks-LaSure, writing:

"Stakeholders have stated that without access to those products that will be non-covered under the LCDs, it will be harder for providers in 15 states to provide appropriate wound care and avoid a decline in a patient's chronic wound condition that includes potentially having to amputate the patient's leg. We are further advised that this will adversely impact Medicare beneficiaries in particularly vulnerable populations such as African Americans,

Latinos, and other minorities, who are at higher risk for amputations from diabetes complications…We ask that you work with the MACs to rescind these [policies] as soon as possible."

Patient Access Protected
With the withdrawal of the policies, Medicare beneficiaries in these 15 impacted states under FCSO, CGS and Novitas A/B MAC jurisdictions – Arkansas, Colorado, Delaware, Florida, Kentucky, Louisiana, Maryland (select counties), Mississippi, New Jersey, New Mexico, Ohio, Oklahoma, Pennsylvania, Texas, Virginia (select counties), plus Washington DC and Puerto Rico – will now continue to have access to medically necessary CTPs. The MACs' previously existing LCDs on use of these products for DFU/VLU (that the 2023 update was supposed to supersede) will now remain in place. CMS has noted that a new, revised proposed LCD will be released for comment at some point in the near future, so our advocacy – and proactive education of policymakers – will continue.

"This was a collaborative effort across the wound care community and, with the withdrawal of the policies, our advocacy clearly had impact. The real winners here are Medicare beneficiaries with chronic wounds who now won't face disruptions to care or unnecessary restrictions to treatments that can support wound healing," said Marcia Nusgart, R.Ph., CEO of the Alliance of Wound Care Stakeholders.

The Alliance of Wound Care Stakeholders
The Alliance is a nonprofit multidisciplinary trade association of physician medical societies and clinical associations whose mission is to promote quality care and access to products and services for people with wounds through effective advocacy and educational outreach in the regulatory, legislative, and public arenas. With a key focus on coding, coverage and reimbursement, quality measures and wound care research, the Alliance elevates the visibility and united voice of wound care providers to regulators and policymakers. For more information, visit
www.woundcarestakeholders.org

# # #

Media Contact:
Shelley Ducker
shelley@woundcarestakeholders.org
202.255.0561