Proposed Policy Changes in the 2023 Physician Fee Schedule Could Increase the Amputations and Infections for Patients with Wounds, Alliance of Wound Care Stakeholders Tells CMS

Sweeping changes to the way cellular and/or tissue-based products for skin wounds (CTPs) are paid for and coded in the physician office will limit patient access

Sept 8, 2022 – Bethesda, MD – The Alliance of Wound Care Stakeholders alerted the Centers for Medicare and Medicaid Services (CMS) that changes to the way cellular and/or tissue-based products for skin wounds (CTPs, also known as "skin substitutes") are coded and paid for in the physician office under the proposed 2023 Physician Fee Schedule will create barriers to care that could ultimately lead to increased amputations and infections for patients with chronic non-healing wounds.

In comments submitted on Sept. 6, the Alliance urged CMS to delay implementation of the proposed CTP provisions from the final 2023 Physician Fee Schedule that will be published later this year, until patient access issues can be further studied and more detailed proposals are provided.

"Under the proposed 2023 policy, payments for CTPs and their application will simply not cover the costs to physician offices," said Marcia Nusgart, R.Ph., CEO of the Alliance of Wound Care Stakeholders. "Without adequate reimbursement, many physicians will no longer be able to afford to provide these medically necessary and successful advanced treatments to their patients. This would deprive patients these valuable treatment options which, in turn, could ultimately result in an increase in infections as well as amputations.

CTP Provisions and their Impacts
CMS' proposed policy **reclassifies** all CTPs as "supplies incident to a physician service," and **packages payment** for these "supplies" into the practice expense associated with that service. This means:

- 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."

The impacts are significant to wound care providers and patients:

Policy ignores the therapeutic significance of CTPs
Reclassifying CTP as "supplies" ignores the therapeutic significance of CTPs, emphasized the Alliance, noting that the Agency "has not offered any data, analysis, or evidence of any type that supports CMS's proposed position to now classify all CTPs as supplies incident to a physician service, packaged into the practice expense associated with that service, rather than their longstanding treatment as biological products." The Alliance adamantly opposed the proposed shift to "A" codes (supply codes) and strongly recommended that CMS continue to assign a Q code to CTPs when the requirements of the HCPCS application have been met.

Packaging payment for CTPs as "supplies" removes adequate payment, Limits patient access
Concerningly, packaging payment for CTPs as supplies then "strips the very payment mechanism that currently allows these advanced therapies to be provided" in the physician office. "Physicians will not be able to absorb the cost of purchasing CTPs by not receiving adequate payment to provide this advanced therapy. Mid-level providers will realize an even greater impact of this change, as they will only get reimbursed at 85% of the proposed packaged rate for physicians. This will result in a lack of access for patients who could benefit from receiving a CTP when provided in the physician office and as a result an increase in infections as well as amputations – both major and minor."

Policy creates access barrier at sites of service where outpatient facilities refer patients
Limited access in the physician office site of service is particularly concerning, as previous CMS policies have already created barriers to CTPs in Provider Based Departments (PBDs). In 2014, when CMS' Outpatient Prospective Payment System (OPPS) packaged payment for CTPs, there was no payment for the add-on codes that were included into the bundled rates so that the PBDs could purchase the sizes of CTPs necessary to apply to all wound sizes. This resulted in an OPPS payment system that fails to provide adequate payment for PBDs to purchase a sufficient amount of CTP products for large wounds between 26 and 99 sq. cm, and over 100 sq. cm. To avoid prohibitive costs and financial losses, many PBDs as a result have not been offering these treatments and more frequently refer these patients to physician's offices. "Outpatient facilities under the current prospective payment system are losing money on these larger wounds…Thus the steady shift/increase in the number of claims submitted in this physician office setting, largely due to physicians being able to treat larger and more complex wounds in the office and being reimbursed appropriately for their work," the Alliance wrote. With the proposed changes to the 2023 Fee Schedule, the physicians' office will also now face a reality in which Medicare payments for CTP products won't match their costs, resulting in the reduced ability to offer CTP treatments in this site of service as well. Without access to CTPs at the physicians' office, Medicare patients will either compromise their healing or have CTPs applied in a hospital operating room, which creates risks for patients and unintended and unnecessary cost burdens to CMS.

Policy change is at odds with CMS' priority to address amputations
In the FY2023 Physician Fee Schedule proposed rule, CMS expressly called out its concern with the number of amputations in diabetic patients and included a specific Request for Information seeking quality measures to address amputation avoidance. "CMS has specifically stated that 'amputation avoidance in diabetic patients is a priority clinical topic.'…Studies show that when advanced therapies such as CTPs are used on patients with diabetes there are lower incidence of minor and major amputations for patients with lower extremity diabetic ulcers. As such, it is particularly concerning that the Agency, in the same rule, proposes CTP policy changes that are likely to lead to more patients receiving amputations," wrote the Alliance, as part of its recommendation that CMS remove, or at least delay implementation of, the CTP changes until the impacts are more fully vetted.

The Alliance also objected to CMS' proposal to rename the term "skin substitutes" as "wound care management products" which the Alliance flagged as "misleading," "confusing" and "overly broad." See the Alliance's full comments submitted to CMS.

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About The Alliance of Wound Care Stakeholders
As the leading voice of wound care advocacy for the past 20 years, the Alliance unites leading wound care organizations and experts through advocacy and educational outreach in the regulatory, legislative and public arenas to advocate on public policy issues that may create barriers to patient access to treatments or care. With a key focus on coding, coverage and reimbursement, quality measures and wound care research, The Alliance has enabled the wound care clinical community to collaborate, elevating the visibility and united voice of wound care providers to regulators and policymakers. For more information visit www.woundcarestakeholders.org

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