



March 31, 2020

Ms. Tiffany Swygert
Director
Division of Outpatient Care
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Sent Electronically

Dear Ms. Swygert,

On behalf of the Alliance of Wound Care Stakeholders (“Alliance”), we are submitting recommendations regarding the payment methodology for cellular and/or tissue based products for skin wounds (CTPs) prior to CMS issuing proposed rulemaking for Calendar Year 2021. The Alliance is a nonprofit multidisciplinary trade association which represents not only physician specialty societies, clinical and patient associations but also wound care clinics and business entities (manufacturers, tissue banks/processors, and distributors). Our mission is to promote evidence-based quality care and access to products and services for people with chronic wounds (diabetic foot ulcers, venous stasis ulcers, pressure ulcers and arterial ulcers) through effective advocacy and educational outreach in the regulatory, legislative, and public arenas. This letter was written with the advice of all Alliance members. A list of our members can be found on our website: <http://www.woundcarestakeholders.org/about/members>.

General Information

As part of the CY 2014 OPPTS rulemaking process, CMS finalized a policy to package all drugs and biologicals that function as supplies when used in a surgical procedure. The current two-tier packaged payment methodology is not having the intended results of slowing cost growth; but instead has created the potential for 1) some entities to manipulate the reimbursement rate formula (mean unit cost [MUC] and per day cost [PDC]) by inflating product prices in an attempt to be classified as a high cost product, and 2) Provider Based Departments (PBDs) to only select high cost products which are more profitable. The Alliance applauds CMS for recognizing that the current payment system for these much needed products is in need of reform.

Over the past three years, CMS has proposed three payment methodologies that are still viable for consideration: Episodic Payment, Single APC, and APC (C-APC). We have provided below what the Alliance believes the definitions are for each of these payment methodologies, additional issues for CMS to consider, and when possible, offer our position. We would appreciate CMS’s consideration of this information and would welcome the opportunity to further discuss these ideas with the Agency in order to help move forward with implementing a new, sustainable payment methodology for CTPs.

Specific Information

As stated above, the Alliance is providing you with our definitions for each of the payment methodologies proposed by CMS in the hope that CMS will provide guidance on whether these definitions are consistent with what CMS is proposing. Once we come to an understanding of the definitions, we can better offer our specific recommendation.

Episodic Payment

In this payment methodology, the Alliance believes that CMS is ONLY referring to the episode in which the CTP and its application are being impacted. No other wound care services would be impacted. This payment methodology involves a lump-sum payment for a wound care episode in which a hospital receives a single bundled payment during a defined episode of care for all items and services related to the use of CTP products.

The Alliance has defined the episode of care payment methodology to include the CTP product(s) used and the related application procedures performed during a defined episode. The per episode payment would not include other means of treating wounds such as hyperbaric oxygen treatments or negative pressure wound therapy treatments, which would continue to be paid under policies applicable to those services. Likewise, payments to physicians for their professional services would remain paid separately under the physician fee schedule, as they would under a single APC approach and a C-APC payment methodology. We have further defined the episode to be triggered when the CTP product is first applied to the patient. Should a patient develop a new wound and require a CTP, the application of the CTP for the new wound would trigger a different episode for the new wound.

To date, CMS has not defined the duration of the episode but has provided some questions regarding whether the duration of the episode should be 12 weeks or 4 weeks (with the ability to extend the episode up to 12 weeks). While the Alliance recognizes that a 12-week episode is the optimal duration of the episode because it mirrors the Medicare Administrative Contractor (MAC) CTP coverage policies, the Alliance members unanimously believe that the 4 week duration is more appropriate (again, with the ability to extend the episode up to 12 weeks).

With an episode of care model, members are concerned that providers may use less product on a patient in order to ensure that their facility does not lose money in treating a patient with a CTP.

There are still questions and additional concerns that have been raised by our members which include the following:

- What if a patient has multiple wounds that are being treated on the same day? Does only 1 episode get triggered when the application of the CTP is provided on the first wound? From a CPT perspective, the sizes of the wounds are added together to get the total sq. cm. for the application by site if on the same anatomical sites using ICD-10 codes. There would need to be a mechanism for a modifier to indicate a separate episode on the same date of service such as modifier 25. Has CMS considered using modifiers to address this concern?
- How will payment be made for the outlier patient that will need to be treated past the 12 weeks under this model? Has CMS considered creating a modifier to be used to allow for additional payment?

Our members are generally supportive of this payment methodology but want to ensure that the definitions we provided are accurate. As such, we still need more information and clarity from the Agency.

Single APC

If CMS were to adopt a single APC approach for CTPs, we envision that it would occur through merging the procedure codes for high and low cost CTP application procedures.

The Alliance believes that CMS would accomplish this by first eliminating the C527X codes resulting in just the 1527X codes. CMS would then allocate the CTP application procedures to at least 2 APCs (linked to below/above 100 sq. cm. wounds) based upon differences in costs for larger vs. smaller wounds. Current claims data indicates that 15271 and 15275 single procedure claims account for approximately 90% of the utilization, and low cost CTP procedure codes (C5271 and C5275) account for the remainder. Because of this, we expect the geometric mean costs

for a single merged CTP APC would be somewhat close to current high-cost CTP procedure costs. Because we can only estimate these costs, we ask that CMS model geometric mean costs of a single CTP APC in its upcoming proposed rule, regardless of what payment reform is ultimately contemplated.

With a single APC approach for CTPs, the costs of the CTP application procedures would be based upon the relative utilization of the high vs. low cost products in those procedures and would adjust over time as utilization of the different CTP products may change based upon clinical appropriateness and provider preference.

Members have expressed concerns that this methodology would (1) not eliminate the current incentives which CMS is concerned, (2) create other incentives to use more CTPs or even those which have a larger number of applications, (3) have facilities gravitate towards the use of the least costly CTPs (4) not provide any differentiation on size of the wound for over and under 100 sq. cm., and (5) drive volume over value the same way that the current payment methodology does.

Additional questions for the Agency to consider with a single APC payment methodology include (but are not limited to) the following:

- How will the Agency pay for Medicare beneficiaries who have more than 1 wound/ulcer requiring a CTP under this model? Would each wound and each application trigger a payment? We presume the payment policy would be exactly the same as it is now, but we would like clarification.
- Would the Agency create multiple tiers for payment and how would those tiers be created?
- How will the Agency address those patients with very large wounds? The current system makes CTPs for large wounds cost-prohibitive and a single APC does not address this challenge. We presume that CMS would emply the current payment policy but would like clarification.

Some of our members support this methodology however, we still need more information and clarity from the Agency to make a more informed decision regarding this payment methodology.

C-APC

Based on historical perspective, the Alliance has defined a C-APC payment model to be all encompassing. The C-APC would not simply be for just CTPs but rather for all procedures and products related to wound care. As such, the Alliance believes that while the encounter would be triggered by the application of the CTP, CMS would package ALL items and services to treat the patient within that encounter for the 30 day cycle. The payment would include the product, the application of the CTP and, moving forward, would include all the items and services which are provided to the patient including but not limited to debridement, negative pressure wound therapy, and compression for the 30 day cycle.

Alliance members unanimously are opposed to a C-APC for CTPs. Wound care patients have many co-morbid conditions resulting in too many variables in care to effectively, and easily develop, implement and maintain a C-APC for wound care – or even just for CTPs. This type of system is complex and not easily implemented; thus, wound care does not lend itself well to this type of payment system.

Alliance members unanimously oppose the C-APC payment methodology proposed by CMS and recommend that CMS adopt a different payment methodology for CTPs and their application.

Conclusion

We appreciate your reviewing our definitions. We also would be interested in having a discussion with CMS to ensure that the definitions provided are in line with CMS thinking on these issues. This will help the Alliance in our

discussion with our membership to gain consensus to recommend to CMS the best payment methodology for CTPs. We believe that we are close to gaining that consensus and look forward to working with the Agency to move forward with a new payment methodology for CTPs with implementation beginning in 2022.

Thank you for your consideration.

Sincerely,

A handwritten signature in black ink that reads "Marcia Nusgart R.Ph." in a cursive script.

Marcia Nusgart R.Ph.
Executive Director

Cc: Mr. Josh McFeeters