Problems with the Cellular Tissue Product Policy

It's time for CMS to establish a fair and consistent LCD.

BY PAUL KESSELMAN, DPM

Since the April 2025 announcement concerning yet another postponement of the cellular tissue products (CTP) LCD, much has been published about this in both the lay and professional press. Those hailing and condemning the postponement have not been shy in alleging either problems with the policy or the need to immediately enact the proposed policy.

Even the *NY Times* got into the act with an article "Medicare Bleeds Billions on Pricy Bandages." Other articles and individuals are alleging the undue political influence of others whose interests are purely monetary. Manufacturers have filed lawsuits against CMS. Honest providers who have been successful with proposed "outlawed" products faced needing to switch to unfamiliar products. There are some wound care providers who have abused the status quo. *PM News* has posted many letters to the editor by some esteemed colleagues on this subject.

Writing this in early May, it is difficult to predict what the status of the "proposed" policy will be during the summer or fall. This month's column will review some of the contentious issues of the proposed policy. Some may be all too familiar to many, while others may appear somewhat new. Certainly, fixing these issues may resolve many of the allegations brought by both sides.

There is abuse of CTP by various types of wound care providers.

Before initiating this review, let's state a few irrefutable facts:

1) There is abuse of CTP by various types of wound care providers. This is not limited to podiatric physicians. MDs, DOs, and other qualified providers are also culpable.

2) A responsible policy is needed to curtail the unsustainable payments for application of CTP. The alleged $10 billion payment in 2024 is double that paid in 2023.

3) There have been successful six and seven figure recoupments for providers who don't provide the standard of wound care prior to resorting to using CTP.

4) Wound care business is BIG business, and with the diabetes pandemic showing no sign of slowing, diabetic foot ulcers will become more prevalent.

5) The CMS HCPCS coding committee over the past decade normally rejects 80% or more applications for new HCPCS codes. This is true for both biological and non-biological products. Yet, over that same period, a significant number of HCPCS applications for CTP have been approved. Thus the expo-

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nential increase from two products approximately twenty years ago to more than three hundred today.

6) Medicare mandates certain services prior to the introduction of CTP yet will not effectively cover some treatments. This must change to protect both patients and providers.

7) DFU and venous leg ulcers (VLU) are only one segment responsible for the $10B payment for CTP. Other types of wounds including all decubiti, surgical incisional dehiscent wounds are not covered by the proposed CTP. They too need to be reined in.

8) In most cases, patients should be provided with standard wound care for at least 30 days prior to resorting to advanced wound care. This includes debridement, surgical dressings, and addressing metabolic, nutritional, and metabolic issues.

9) Alternative technologies to CTP—including but not limited to wound vacs and debridement with low-frequency, non-thermal ultrasonic mist to topical oxygen—are also options which can be employed. The latter also are more expensive than SWC, but may be equally effective and in some cases less expensive than CTP.

10) HBO therapy is quite expensive and has a high time demand for patients.

Last-Minute Irresponsibility

Many share the disappointment that the CTP LCD proposed some time ago was pulled at the last minute.

This last-minute delay caused some chaos and confusion. Many providers are angry that they spent many hours needlessly re-learning how to dot the "I's" and cross the "T's" on new documentation requirements. Others felt angry at the disruption this could have caused to supply chains and inventory issues they faced. Still others who were successful with products no longer covered had to search for new CTP. This required them to abandon their use of products which were in their hands successful. All of these may appear to be relatively minor inconveniences, but they came from across the spectrum of wound care specialists.

Most would agree that if CMS was going to pull the CTP policy, waiting until the last moment was irresponsible, adding to the confusion and frustration of providers. This unfortunately is typical of CMS, pouring hundreds of millions of dollars into contracts, and creating widespread publicity of "drop dead" deadlines that are ultimately rescinded at the last minute. PECOS 2.0, a much-needed upgrade to provider enrollment, is one recent example where CMS spent $200M only to abandon this endeavor. Many are wondering how much CMS and the contractors have spent to this point on the CTP project. Additionally, many private concerns spent much of their resources on educating providers about the proposed LCD.

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Gray Areas

Many argued that the proposed policy documentation requirements were overly comprehensive. However, many of these requirements do make sense, while others may not go far enough. For example, deeming adequate vascularity either in the objective clinical examination or via a non-invasive vascular assessment makes perfect sense. Whether the assessment is performed by the physician applying the graft or by another specialist should not matter. These examinations should objectively meet the criteria of the non-invasive arterial vascular LCD. It makes sense to have this information documented, to preclude wasting thousands of dollars on graft materials on an ischemic patient. What the exact indices required, however, were left non-specific. Is one to conclude that an ABI is all that is required with the standard of normal vascularity being an ABI of 90%? Experience has taught that this benchmark alone is unreliable as a predictor of wound healing, particularly in diabetics. Doppler wave form analysis along with other microvascular assessment tools are needed. This would include any of the following but not limited to: wave form analysis of laser doppler, photo and pneumo-plethysomography, and/or infra-red spectroscopy. Any of these may be a better way to perform a microvascular assessment—hence documentation of vascularity without more specifics that many have declared to be insufficient.

Glycemic control was another gray area in the policy, perhaps requiring a more definite standard. Decades ago, Empire Blue Cross was one of the first to develop an LCD for CTP (then called skin substitutes). Their originally drafted policy stipulated an A1C of < 11 (approximately 270 BS). Some would call that irresponsible and they would be right. The proposed policy requires that glycemic control has been addressed. Which provider determines control and the targeted number was not provided. A more specific targeted number to protect providers against recoupment and to counter against allegations of malpractice against providers needs to be addressed. While gray in an LCD is often good, in this case, perhaps some other specific language regarding glycemic control may have been a better choice.

Some podiatry colleagues were against this, thinking that because of our limited licensure, this would lead to similar issues as with the therapeutic shoe program. But alas, this is not an issue, as other wound care specialists such as general, plastic, and vascular surgeons along with dermatologists and many other practitioners treating DFU also do not supervise glycemic control. This easily could be dealt with in a similar fashion to a pre-operative clearance as opposed to an attestation or certification. Thus, either a responsible A1C

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(< 8) or fructosamine level < 300) when A1C is unreliable, could be used as a gauge of adequate glycemic control. Glycemic optimization and nutritional counseling, whether in group or 1:1, needs to be easily available and affordable for our neediest patients.

Many providers complained that this new proposed policy required the provision of certain non-covered treatments. This is despite peer- reviewed studies supporting their efficacy. In essence, if these procedures were not provided, the provider could upon audit be liable for recoupment—specifically, off-loading, which is recommended even for standard wound care by the International Diabetes Working Group on Diabetic Foot (IDWG). The proposed CTP policy requires this, yet it either is not covered or for many patients is ostensibly inaccessible. This despite that many other private insurance and Medicaid plans do cover these devices. This includes:

A) CAM Boots or AFOs that are primarily used for off-loading foot ulcers are NOT covered in the AFO LCD. This rather inexpensive treatment needs the immediate attention of the medical directors of the DME MAC and must be corrected.

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B) Therapeutic Shoes are becoming increasingly difficult for patients to obtain because of the arduous hoops required by providers and the pre- and post-payment merciless audits. Thus, proper footwear that is covered by Medicare is simply not achievable for many patients to secure. In some locations across the country, a six-month wait to be fit is the norm and is also intolerable.

C) CROW boots are generally not indicated for most patients, except for a small subset of patients with Charcot, and come with a $2,000 price tag. Providing these sophisticated devices comes with many problems, even for patients for whom there is an indication.

D) A solution to A and C is the two or more "instant" crow boots personally submitted for PDAC validation, both of which were denied. This, because they are viewed as non-covered AFOs and thus denied under a new working HCPCS code as opposed to exploding the code L4631 into a pre-fabricated CROW boot.

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It is noteworthy that the IDWG has endorsed all these off-loading techniques, yet Medicare continues to deny coverage. Yet the proposed LCD for CTP requires off-loading. This punishes patients who cannot afford these valuable treatments and limits the providers' access to grafts. Some providers may only provide grafts to patients who properly off-load, while others who do provide CTP to patients who lack off-loading treatments may be subject to future recoupments. Ultimately this punishes whom the most? The patient simply cannot afford to self-pay.

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Further Difficulties

Turning one's attention to "D" above, we can see the ongoing conflict between the HCPCS committee, which has approved HCPCS codes for 300+ CTP, and the local Medicare carriers, which have limited coverage to less than 10% of those. Somehow the same studies providing sufficient efficacy to secure HCPCS approval for some CTP were deemed insufficient by the standards of the Medicare carriers. This has led to non-coverage for an astounding number of CTP approved by HCPCS. Equally confusing is that some of the same individuals reviewed the same materials in their dual roles as members of the HCPCS committee and their local MAC policy review team.

In performing a review a few years ago of all CTP currently on the market, it became very apparent that many of the products are similar to one another, with some almost identical. Many received HCPCS approval and either were never marketed or have had little market penetration. Yet, in this proposed ruling, some manufacturers' products were included in the proposed policy and other similar or identical products were not.

The policy initially proposed that only four CTP applications would be covered. After much discussion with APMA and other wound care stakeholders this was expanded to eight applications per episode of care, based on supportive documentation. This expansion was widely viewed as a victory by many wound care stakeholders. While an excellent idea, many patients do re-ulcerate for a variety of reasons, and still others will require more than eight applications. Is it the goal of the CTP policy to deny care to patients who continue to benefit and for whom we can delay or avoid proximal amputations? Will providers who provide more than eight applications in an episode of care, even if that total is from more than one location, be unduly targeted by MAC or RAC for recoupments? That remains to be seen, but it appears more likely than not that they will.

The proposed policy primarily addresses DFU and VLU. The latter has standard wound care requirements of nutritional optimization, elevation, and compression (dressing or PCD devices) for four weeks with failure to achieve significant closure. What is not addressed by this policy is the expenditures for wounds other than DFU or VLU. All types of decubiti (e.g., calcaneal, occipital, olecranon, etc.) lower and non-lower extremity surgical dehiscent wounds, burns, etc. are also not addressed. All of these need to be addressed if we are to achieve some control over the increasing costs of providing CTP.

Conclusions

Before another CTP policy is put out for comments, the local carrier medical directors and DME medical directors need to resolve the inconsistencies with requirements for coverage. Fixing these policies once and for all is necessary. Requiring the provision of off-loading yet deeming off-loading devices either inaccessible or non-covered services will doom CTP to all but those able to afford off-loading devices. Resolving the issues with ABI and vascular testing, glycemic, and nutritional optimization via better covered counseling also need to be addressed.

This country cannot afford to continue with the current spending on CTP. With much reluctance, perhaps it's time to implement a CTP prior authorization program. At a minimum, this should establish the need to prove: Patients have already received four weeks of standard wound care without substantial progress, have adequate vascularity, have appropriate glycemic control, are nutritionally optimized and perhaps have received formal nutritional counseling, and are non-smokers and/or have received smoking cessation counseling. Equally important, patients must have access to appropriate off-loading devices with CMS removing the current obstacles.

Last, HCPCS and the local MACs need to work together to come to an agreeable formula for approving efficacious products and discontinuing what some allege are significant inconsistencies. CMS, taxpayers, providers, and patients cannot continue to pay any further increase in the $10B currently spent on CTP. In fact, most will argue that number needs to be reduced to less than half, to the 2023 expenditures, in order to have a cost-effective responsible policy. Hence, every segment of this policy requires careful attention and needs to be fixed as soon as possible. PM

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