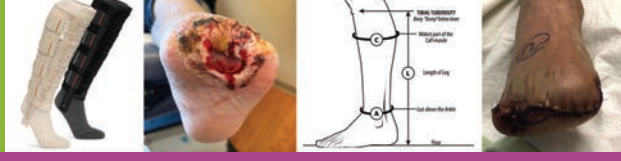

# An Update on the Latest Proposed LCD on CTPs

CMS's ultimate goal is to reduce costs.

**BY PAUL KESSELMAN, DPM**

There is significant turmoil in healthcare reimbursement policies when it comes to wound care due mostly to upcoming reimbursement changes for cellular tissue products (CTP). This article will attempt to present the challenges facing providers who utilize and for those manufacturing CTPs.

Last year, several (not all) of the Medicare Administrative Contractors (MAC) attempted to enact revolutionary changes which would have drastically affected CTP reimbursement. The policies of those carriers were pulled just prior to implementation with promises that a new Local Carrier Determination (LCD) and policy articles governing reimbursement for CTP would soon be forthcoming.

In the spring of 2024, all seven of the Medicare Contractors published an almost sixty-page proposed LCD on CTP and held hearings and welcomed comments on this new proposal. These hearings provided many opportunities for CTP manufacturers and wound care providers to air their opinions on the merits of the proposed policies.

The CTP LCD was in comment period until June 8, 2024, providing a good amount of time for providers and manufacturers to provide comments. The final LCD will not become effective for some time later this or next year. It is apparent from last year's resulting withdrawal of a new policy that CMS is intent on a unified national carrier strategy. The new proposed policy has culled the number of covered CTPs from over 200 to approximately fifteen and reduced the frequency of applications, based on unique episodes of care.

That leaves a huge number of products out of the reimbursement loop. One can assume that this does not sit well with those manufacturers or organizations representing them. It is anticipated that many left out of the reimbursement loop may choose to take (or have already taken) legal action against CMS and its contractors. Thus, it is feasible that changes with this LCD are still possible.

Many of the proposed changes center on the requirements stipulated by the 21st Century Cures Act. This mandates that evidence-based measures prove that a specific procedure, technique, or product is effective, with proof of effectiveness centered on well-conducted randomized controlled trials (RCTs). Anecdotal evidence is no longer by itself acceptable. Subtle changes in product ingredients have also resulted in some similar products being rejected and others included in the reimbursement pool.

The 21st Century Cures Act also changes the way the Carrier Advisory Committee (CAC) interacts with the Medicare contractors. Most have cited that the new processes as mandated by this law impede innovation, restrict policy change, and hinder access to care.

Furthermore, wound care providers will now need to concentrate more on the efficacy of the products they prescribe and/or order and not so much on the much-promised profitability promulgated by sales representatives. As one recent speaker at a well-attended wound care conference stated, "We are wound care providers and not cellular tissue salesman."

As has been learned from several recent client audits, CTPs have no doubt been abused by some practitioners. Many MACs have no policies at all due to the vast number of CTPs making these policies unmanageable. Most providers use CTPs as a last resort to prevent amputations and other more expensive procedures. The increased use of CTPs is offset by less reliance on more expensive and invasive procedures. The carriers need to be reminded that the primary intent of CTPs is to avoid the inherent risks associated with donor site complications and infections in the highest risk patients.

Much can be learned from two recently reviewed audits for several clients and the proposed CTP pol-

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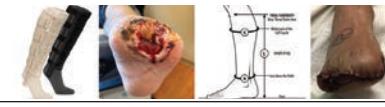

*LCD on CTPs* *(from page 69)*

icies. Providers are all too quick to rely on advanced wound care techniques, prior to exhausting standard wound care (SWC) techniques, which, given time, often work. That is, it is important to encourage patients to finish treatment and for providers to properly document the required four-week trial period using SWC

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treatments prior to advancing to more sophisticated treatments. SWC includes debridement, appropriate surgical dressings, elevation, off-loading, and infection and systemic management control of other medical and environmental factors.

1) There are also other novel wound care techniques and surgical dressings which afford more flexibility and are not subject to the CTP LCD. These include many surgical dressings, vaporous hyperoxia and/or low-frequency, non-contact ultrasound therapies, and autologous PRP devices, to name a few. All of these may be subject to their own LCD requirements with greater flexibility than that for the proposed CTP LCD.

2) Many providers choose a product based on their wholesale cost and reimbursement. That is, the cost and fee schedule and return on investment (net profit) have taken a front seat and placed science and healing rates in the rear. The LCD and recent uptake in audits have taken aim at this.

3) Carriers are attempting to jettison different policies and are eager to develop a clear and concise national policy which will be applied through all seven MAC.

4) The MACs have reduced the number of applications for any one episode of care. In some cases, this has reduced an infinite number of applications for some carriers to a mere four applications nationwide. This may lead to significant inaccessibility to care for patients responding to CTP applications, many of whom simply need more than four CTP applications to close their wounds. The episode of care may extend beyond the time of CTP treatment and could preclude further retreatment with CTP should the ulcer recur. The use of the KX modifier may provide some relief to allow both more treatments

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in a single episode of care or for recurrence within a 12-week or month period of care. The use of the KX modifier may also allow for bypassing an automatic front end audit and rejection. However, it will not preclude rejection on pre-payment or a TPE audit, nor will it prevent recoupment on a post-payment audit.

5) Jettisoning so many products at once with almost no grace period may lead to financial hardships for many manufacturers left with large useless inventories. It also may force providers and patients in the midst of therapy to switch to an unfamiliar product, and from one which is currently successful. Some additional grace period should be considered.

6) The four applications limit per unique episode of care seems to be arbitrary and not necessarily based on EBM. Perhaps the Medicare contractors need to afford some additional flexibility.

7) CMS is partially responsible for the large numbers of different CTPs. For the past five years, the HCPCS Common Work Group hearings on biologics have almost always approved new HCPCS codes with over-generous pricing set by PDAC. In the future, a more rigorous review at the HCPCS level may be more appropriate.

8) It is imperative that physicians document both the amount of CTP applied and wasted. The size of product applied must also be consistent with the wound size.

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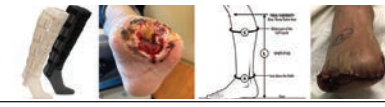

*LCD on CTPs* *(from page 70)*

The lot number and expiration date of the applied product must also be documented in the chart. The method by which the CTP was secured to the wound site (steristrips, sutures, etc.) must also be documented.

9) The LCD in its current form requires evidence of systemic management (e.g., DM management, vascular status etc. by a physician or non-physician practitioner). It is unclear whether the surgeon's note, if a non-MD/DO, will adequately address these issues. With respect to the vascular status, what is the ABI or TBI cutoff for adequate perfusion? Since most DFU-related wounds are related to small vessel disease, is it perhaps time to use other measures than ABIs, which are notoriously falsely elevated to determine if the wound is adequately perfused? If the ABI is lower than 0.65 but the micro-perfusion is adequate as measured by TCP02 or other acceptable micro-perfusion measures, then the CTP should be allowed.

10) The proposed LCD mentions systemic management of DM. What is the cutoff for A1C? Some endocrinologists have recently become more lenient with respect to A1C levels and perhaps the days of 6-7 being optimum are behind us and 7-7.5 are more acceptable. Thus, some specific reasonable range of A1C needs to be specified and not left ill-defined.

11) Most wound care professionals (MD/DO and DPM) are not likely managing systemic illnesses. The proposed LCD needs to be clarified, to allow a pre-op medical clearance or a recent note from the physician managing the patient's systemic condition to serve as proof of medical optimization. Wound care providers should not be required to seek an equivalency similar to the therapeutic shoe policy.

12) The proposed LCD stipulates that the chart documentation needs to support the medical necessity for a CTP as a skin replacement and not simply as a wound dressing or covering. This statement is notoriously one-sided to the advantage of the carrier's auditor. If a carrier is developing a reimbursement policy, the onus is on the carrier to define exactly what they consider as the criteria for medical necessity. This should be vetted during the comment and draft periods. To do otherwise sets up the possibility of endless debates between the clinical provider and the auditor as to what constitutes medical necessity. Why bother to have a policy that endorses an ongoing debate as to what constitutes medical necessity?

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13) The proposed LCD only addresses wounds related to diabetic foot and venous leg etiologies. It does not address wounds of a post-operative or traumatic nature. Nor does the proposed LCD address wounds related to any type of thermal injury (cold or heat), such as chemical or radiation-related burns.

The exact final version of the future CTP is unknown. However, it is apparent that the demographics for patients requiring chronic wound care services are exploding. With the current controversy over CTPs, a reasonable compromise by all interested parties is essential. Having reviewed the proposed policy, it's apparent that CMS and its contractor agents are seriously determined to rein in the costs of providing CTPs. However, it is imperative that CMS develop both a fiscally responsible and ethical medical CTP policy. The final version of the CTP policy must ensure that patients receive the care they need while simultaneously protecting the solvency of the Medicare Trust Fund. **PM**

**Dr. Kesselman** is board certified by ABFAS and ABMSP. He is a member of the Medicare Jurisdictional Council for the DME MACs' NSC and provider portal subcommittees. He is a noted expert on durable medical equipment (DME) and an expert for Codingline.com and many third-party payers. Dr. Kesselman is also a medical advisor and consultant to many medical manufacturers and compliance organizations.