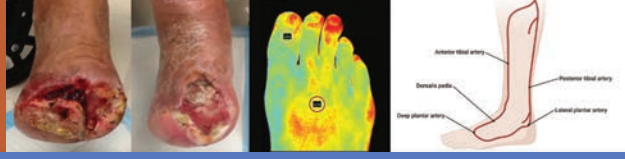

CTPs and the WISeR Model

It's important to be aware of these new wound care programs.

BY PAUL KESSELMAN, DPM

It is still possible that CMS may see fit to delay implementation of and make changes to the two policies to be discussed in this article. Some are part of the July 2025 announcement of the proposed 2026 Medicare Fee Schedule. As they are in the "proposed" Medicare fee schedule, they are still subject to change or delay.

The product category with the largest anticipated changes for wound care providers is undoubtedly cellular tissue products (CTP). Innumerable articles in the lay press have spotlighted the need for change. The professional press, email posts, lectures, webinars, and conferences on this subject have been dedicated to the need for change and the details of new policies coming for 2026. Suffice it to say, some of these changes are necessary to reduce the fraud and abuse that this category of service has experienced. The expansion in the number of reimbursable products and payments in the CTP category are unsustainable to the integrity of the Medicare Trust Fund. The remainder of this article will contain the facts as known at the time this article was written. However, because these policies are subject to further changes prior to implementation, it is imperative to stay abreast of CMS and your local MAC for further announcements on CTP policy.

CTP "NCD"

Currently, each local MAC has (or does not have) their own Cellular Tissue LCD and Policy Article (PA). These local policies are to be replaced by a proposed Nationwide policy, scheduled for implementation in January 2026. This National Coverage Determination (NCD) and Policy Article (PA) covering CTP dictates their coverage only for Diabetic Foot and Venous Leg Ulcers. Use of CTP for other wounds and indications (e.g., ischemic, post-surgical dehiscence, traumatic, radiation, or burns) will continue to be subject to medical necessity and are not covered under this new anticipated policy. It must be emphasized again that this new nationwide policy will only cover diabetic foot ulcers (DFU) and venous leg ulcers (VLU).

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The anticipated NCD and accompanying PA are extremely comprehensive. This article will cover the top ten requirements which must be thoroughly documented to ensure coverage for CTP application. It is imperative that the patient's medical chart doesn't just simply imply that the following ten services were performed. The chart must actually illustrate **ALL** the steps that were instituted, implemented, and/or performed:

1) Measurements. A baseline measurement of the wound in at least two dimensions is recommended. Three is better. The date and patient identifier should be present in the photo. Photos should be taken both pre- and post-debridement. This must be done on every date of service (DOS) for debridement or evaluation and management of a DFU or VLU.

2) Patients should be under care of an MD or DO if they are diabetic, and one should obtain copies of the MD/DO notes illustrating and not merely documenting that the patient's DM is optimized—i.e., copies of lab testing with control of A1C, glucose, etc. Think of obtaining a medical clearance note for diabetic patients.

3) The patient should have received conservative standard-of-wound care for no less than thirty days with documentation that there is little if any improvement in wound healing from the baseline. The measurements from day 1 as compared to day 30 (and all intervening DOSs) must be noted in the chart. Documenting the percentage of reduction from day 1 is also advised. Taking photos and measurement on the DOS on which you decide to proceed with CTP implementation and on the actual first and all future dates of implantation should also be done. All dates of debridement (and type of debridement) must be documented. The debridement portion of your note needs to read as an operative report. The percentage of wound closure or lack thereof should be documented from baseline on each date of CTP implantation.

4) Non-invasive arterial vascular testing needs to document sufficient blood flow for healing. These tests must meet with the LCD requirements for performing those tests and

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can be performed in-house or from an external source. Simply stating that the ABI is > 0.9 is insufficient. Proper wave form analysis must be performed and statements concerning the vascularity of the area surrounding the wound must be made.

5) Off-loading: If the wound is on a weight-bearing surface, there must be documentation that the patient is using an off-loading device, the exact device, and compliance with the device, and whether or not it is covered by Medicare should be referenced in the chart.

6) The patient's nutritional status must be reviewed and documented. There must be corroborating evidence (e.g., BMI, labs such as albumin, etc.). If the BMI is excessively high, evidence of both a goal of weight loss program discussion and implementation must be documented.

If the VLU is caused by some systemic disease (liver, renal, previous trauma to the leg, radiation, etc.), one should obtain medical documentation from the physician treating that systemic condition.

7) Rationale for use of specific CTP; amount used and size to reduce waste must be documented.

8) The amount of each CTP used and wasted must be reflected on the claim form and must match those in the chart. Doubling and folding of the CTP is not allowed. Only a single layer of product must be used. Stricter attention to the size of the wound while minimizing wastage is to be documented.

9) A method of securing the CTP to the wound must be documented (e.g., Steri-strips, sutures, etc.)

10) Despite the number of CTP available exceeding a few hundred, only a few select CTP are authorized to be reimbursed under the DFU and VLU policy. If you select a product not authorized by the policy, then you will not be reimbursed. The accepted products will be listed in the attached Policy Article.

In anticipation of either a pre- or post-payment audit, either on the initial date of CTP implantation or the date of the decision to implement CTP, a summary of all ten issues presented should be documented. This puts all the issues upfront and makes any review far less frustrating for the auditor.

For patients with venous leg ulcers, the above ten mostly apply with some variations:

1) Non-invasive venous (instead of, or in combination with arterial) leg testing should be performed. As with DFU, these tests can be performed in-house or referred

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out, but in both cases must comply with the LCD covering non-invasive venous leg testing. Wave form analysis must be performed in accordance with the LCD which illustrates the level of venous disease. Documentation of what steps are being utilized to optimize chronic venous insufficiency are necessary. Simply stating that the CVI is optimized is insufficient.

2) As opposed to off-loading, previous evidence of leg compression, rest, and elevation must be evident in the chart.

3) If the VLU is caused by some systemic disease (liver, renal, previous trauma to the leg, radiation, etc.), one should obtain medical documentation from the physician treating that systemic condition. This note should contain evidence and not merely state that the patient is optimized.

Other issues you should be aware of when providing CTP, irrespective of the etiology of the wound, include pricing, discounts, and rebates.

The allowed amount for CTP reimbursement is often complex. Currently, CTPs are priced based on average sale price (ASP), average manufacturing price (AMP), or invoice price. ASP are easily available via the CMS website. (To access that website, scan the QR code at right.) This is updated quarterly. Medicare has, however, decided as of January 2026 to instead list the specific reimbursement for each CTP covered under the policy. Since the proposed pricing structures are still subject to change, it is best to check the up-to-date ASP policy article and pricing structures in late December and early January for updates. This should be available on the APMA, CMS, and local MAC websites, as well as from your CTP vendor. Suffice it to say that the proposed policy still provides reasonable profitability, but it varies based both on the product and size. Some products and sizes will be far more affordable and yield a higher profit than others.

Discounts and Rebates

Currently, CTP pricing based on ASP allows for additional reimbursement of 9% over the ASP. However, if discounts and/or rebates provided to you from the manufacturer/distributor are not properly calculated into the fees charged to Medicare, they can be construed as violations of the Stark Anti-Incentive or the Anti-Kickback statutes.

If for any reason you are receiving discounts or rebates from a CTP manufacturer or distributor, it is best to consult with a healthcare attorney to ensure you are not in violation of any Stark or Anti-Kickback statutes.

Wasteful and Inappropriate Service Reduction (WISeR) Model

If the above stipulations are not enough, CMS this summer also proposed the Wasteful and Inappropriate Service Reduction Model (WISeR). This program has

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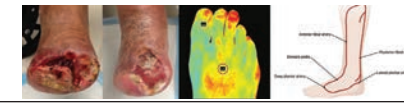

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as its main goal to reduce fraud and abuse for high-risk services and is to run from Jan 1, 2026—December 31, 2031.

A broad overview of the WISeR program is as follows:

CTP is one of the services mentioned in the original WISeR announcement. This program will be available in several MAC areas in a limited number of states (Arizona, New Jersey, Ohio, Oklahoma, Texas, and Washington). This pilot "voluntary" program will use AI and test a new prior authorization program vs. pre- or post-payment review of the claim. Those high-performing providers who participate and pass several prior authorizations may be issued a "Gold Card", exempting them from further prior authorizations or pre-or post-payment reviews.

Currently, WISeR is voluntary and only available in the above six states. CMS has already stated that the WISeR model may be expanded, even during its initial six-year period, to other services and other states, possibly usurping the NCD or LCD for various targeted services.

The impact of the WISeR program is clear. As with the DFU and VLU NCDs, it will require providers to provide thorough documentation, accurate coding (both diagnosis, CPT and HCPCS), and support strong clinical outcomes (wound closure faster than their peers).

The details of the WISeR program are as follows:

1) CMS has already started hiring companies with expertise to perform prior authorization and pre- and post-payment review of CTP claims for practices wishing to enroll in the WISeR program.

2) Model participants will receive a percentage of the savings associated with averted wasteful, inappropriate care as a result of their reviews. That percentage will be adjusted based on the participant's performance on measures related to the process, including provider experience. This very much sounds like Recovery Audit Contactor (RAC) which is paid as a "bounty hunter".

3) Providers and suppliers for people with Original Medicare in selected regions will have the choice of submitting a prior authorization request for the model's selected items and services or go through a post-service/pre-payment review.

4) Those that choose the prior authorization route may either submit the prior authorization request directly to the model participant or through their MAC that will forward the request to the model participant. Model participants will be held accountable for improving provider and supplier experience, which will be assessed by a survey of questions about the ease of the prior authorization process.

5) If providers or suppliers opt not to submit a request for an included service, their claim will be subject to medical review to ensure the delivered service met Medicare coverage, coding, and payment criteria prior to payment.

6) Providers and suppliers with demonstrated records of compliance may be exempt from the WISeR review process in the future. This exemption, or "gold card," would reduce administrative burden while allowing participants to focus their resources on providers and suppliers at higher risk of delivering unnecessary care.

The impact of the WISeR program is clear. As with the DFU and VLU NCDs, it will require providers to provide thorough documentation, accurate coding (both diagnosis, CPT and HCPCS), and support strong clinical outcomes (wound closure faster than their peers).

For more information on the WISeR program, including an instructional You Tube Video from CMS, go to: https://www.cms.gov/priorities/innovation/innovation-models/wiser. (To access that video, scan the QR code at right.)

It is important to note that Medicare Part C plan participants are not subject to either the proposed NCD or WISeR program. Each Medicare Part C plan has the right to develop its own LCD/PA. The Part C plan may, however, provide a narrower network of providers afforded the opportunity to perform CTP, reimburse less than Fee for Service Medicare, and delineate its own prior authorization program.

As a recent series of articles in the *NY Times* pointed out, the explosion in the use of CTP can by itself threaten the sustainability of the Medicare program. Doubling and tripling or more of CTP expenditures in the last few years must not be allowed to continue. However, as CTP is often limb- and lifesaving, reasonable limits need to be implemented, allowing patients continued access to providers willing to provide CTP in an ethical and affordable manner. As this is an evolving story, please stay tuned to the CMS and your local MAC website for CTP updates. **PM**

Dr. Kesselman is board certified by ABFAS and ABMSP. He is a member of the Medicare Jurisdictional Councils for the DME MACs and a member of the enrollment subcommittee. He is a noted expert on durable medical equipment (DME) and consultant for DME manufacturers worldwide. He is the owner of Park DPM and co-owner of PARE Compliance. He is also co-owner of www.thedoctorline.com, a new online forum for coding and reimbursement and was elected to the *PM* Podiatry Hall of Fame.