

Alliance Insights:
**Detailed Summary of Final Local Coverage Determinations, Coding & Billing
Articles for CTPs**

On November 14, 2024, all the Medicare Administrative Contractors (MACs) issued final Local Coverage Determinations and Coding and Billing Articles for “Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers.” This release was highly anticipated by the wound care community due to the significance and uncertainty surrounding proposed changes. The policies were issued as “future effective,” meaning that they are not going to be implemented in the standard 45-day time frame. Rather, the MACs are providing a 90-day implementation timeframe in consideration of the time needed for clinician practices, hospitals, wound care centers, and provider groups to adjust to the published changes. The policies will go into effect on **February 12, 2025**.

As a general matter, the Alliance submitted an extensive list of recommendations to the MACs, many of which were adopted within these final policies. The MACs did listen to stakeholder concerns and feedback across policy areas. However, there are still issues we believe require further clarification. We’ll be reaching out to our members to compile a list of questions and concerns, in order to obtain the clarification that we believe is still necessary, as well as continue to work with the MACs to ensure that there is a clear pathway for products to be covered in either the Group 2 (DFU) or Group 3 (DFU/VLU) list.

To aid you and your teams in understanding these policies and their requirements, we have compiled the most essential information into this summary below, addressing:

- Local Coverage Determination (LCD)
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We summarize what was finalized, what was updated in the final rule (**text in red** shows new language in the final rule not previously included in the draft), and areas of emphasis (**in bold**). We've also touched on areas where we still need to either gain clarification on or still try to change. Note: The information below is in order of the language appearance in the policy and not necessarily in order of importance.

It appears that all the LCDs and Billing and Coding Articles are the same, however, the Response to Comments are not. The Alliance is still reviewing all the Responses to Comments to gain additional insights into the decision making that went into the release of these finalized policies.

Alliance Insights: Local Coverage Determinations

These policies now allow for *“qualified providers”* instead of just physicians and nonphysician practitioner (NPPs) to be able to apply CTPs as long as all aspects of care are within the scope of practice for the provider and when performed by appropriately trained providers in the appropriate setting.

Covered Indications

This policy **ONLY applies to DFUs and VLUs**. No other wound type is addressed in this policy. When a patient with a DFU or a VLU have met all the criteria in this policy (and it is documented in their medical record) the application of a CTP will be considered medically necessary and reasonable.

According to this policy, a chronic wound is defined as: a DFU or VLU that has failed to respond to standard of care treatment after 4 weeks (28 days). Documentation must support the medical necessity for the use of a CTP. Documentation will be the key to success when using a CTP for your patients, so you will want to pay attention to and make sure your practice incorporates all the documentation requirements.

Documentation Requirements: DFU

The **requirements for a patient with a DFU** include the following (which we cannot emphasize enough, *needs to be documented in the patients' medical record*):

- The presence of a chronic, non-infected DFU having failed **to achieve at least 50% ulcer area reduction** with documented standard of care (SOC) treatment for a minimum of 4 weeks with documented compliance. SOC includes:
 - Comprehensive patient assessment (history, exam, **vascular assessment**) and diagnostic tests indicated as part of the implemented treatment plan.
 - Assessment of Type 1 or Type 2 diabetes and management history with attention to certain comorbidities (e.g., vascular disease, neuropathy, osteomyelitis), review of current blood glucose levels/hemoglobin A1c (HbA1c), diet and nutritional status, activity level, physical exam that

includes assessment of skin, ulcer, and **vascular perfusion**), and assessment of off-loading device or use of appropriate footwear.

- An implemented treatment plan to be continued throughout the course of treatment demonstrating **all** the following including:
 - Debridement as appropriate to a clean granular base.
 - Documented evidence of offloading for DFU.
 - Infection control with removal of foreign body or nidus of infection.
 - Management of exudate with maintenance of a moist environment (moist saline gauze, other classic dressings, bioactive dressing, etc.).
 - Documentation of smoking history, and counselling on the effect of smoking on wound healing. Treatment for smoking cessation and outcome of counselling, if applicable.
- The skin substitute graft/CTP is applied to an ulcer that has failed to heal or stalled in response to documented SOC treatment. Documentation of response requires measurements of the initial ulcer, pre-SOC ulcer measurements, weekly SOC ulcer measurements, post-completion SOC ulcer measurements following (at least) 4 weeks of SOC, ulcer measurements at initial placement of the skin substitute graft/CTP, and **before** each subsequent placement of the skin substitute graft/CTP.
- Failure to heal or stalled response despite SOC measures must have preceded the application for a minimum of 4 weeks and established SOC treatment must continue for the course of therapy.
- The medical record documentation must include the interventions having failed during prior ulcer evaluation and management. The record must include an updated medication history, review of pertinent medical problems diagnosed since the previous ulcer evaluation, and explanation of the planned skin replacement with choice of skin substitute graft/CTP product. The procedure risks and complications must also be reviewed and documented.
- The patient is under the care of a **qualified provider** for the treatment of the systemic disease process(es) etiologic for the condition (e.g., venous insufficiency, diabetes, neuropathy) and documented in the medical record.

Documentation Requirements: VLU

The **requirements for a patient with a VLU** include the following – which we cannot emphasize enough - *needs to be documented in the patients' medical record:*

- The presence of a chronic, non-infected VLU having failed to respond to documented SOC treatment (outlined below) for a minimum of 4 weeks with documented compliance. SOC includes:
 - Comprehensive patient assessment (history, exam, **vascular assessment**) and diagnostic tests indicated as part of the implemented treatment plan.

- Assessment of clinical history (that includes prior ulcers, **higher body mass index, history of pulmonary embolism or superficial/deep venous thrombosis, higher number of pregnancies, and physical inactivity**), **physical exam (edema, skin changes and vascular competence)**, evaluation of superficial or deep venous reflux, perforator incompetence, and chronic (or acute) venous thrombosis. The use of a firm strength compression garment (>20 mmHg) or multi-layered compressive dressings is an essential component of SOC for venous stasis ulcers.
- An implemented treatment plan to be continued throughout the course of treatment demonstrating all the following:
 - Debridement as appropriate to a clean granular base.
 - Documented evidence of some form of sustained compression dressings for VLU
 - Infection control with removal of foreign body or nidus of infection.
 - Management of exudate with maintenance of a moist environment (moist saline gauze, other classic dressings, bioactive dressing, etc.).
 - Documentation of smoking history, and counselling on the effect of smoking on wound healing. Treatment for smoking cessation and outcome of counselling, if applicable.
- The skin substitute graft/CTP is applied to an ulcer that has failed to heal or stalled in response to documented SOC treatment. Documentation of response requires measurements of the initial ulcer, pre-SOC ulcer measurements, weekly SOC ulcer measurements, post-completion SOC ulcer measurements following (at least) 4 weeks of SOC, ulcer measurements at initial placement of the skin substitute graft/CTP, and **before** each subsequent placement of the skin substitute graft/CTP. Failure to heal or stalled response despite SOC measures must have preceded the application for a minimum of 4 weeks and established SOC treatment must continue for the course of therapy.
- Continuous compression therapy for VLU must be documented for the episode of care. The medical record documentation must include the interventions having failed during prior ulcer evaluation and management. The record must include an updated medication history, review of pertinent medical problems diagnosed since the previous ulcer evaluation, and explanation of the planned skin replacement with choice of skin substitute graft/CTP product. The procedure risks and complications must also be reviewed and documented.
- The patient is under the care of a **qualified provider** for the treatment of the systemic disease process(es) etiologic for the condition (e.g., venous insufficiency, diabetes, neuropathy) and documented in the medical record.

Coverage requirements for CPT products

Products that are applied in sheet form, provide a scaffold, remain on the patient and “grow in place or allow a patients cells to grow” **AND** are supported by “**high certainty supporting evidence that demonstrates the product safety, effectiveness and positive clinical outcomes**” will be covered. **Substantial equivalence to predicate**

products does not allow sufficient evidence to support similarly cleared products and therefore products that do not have their own individual evidence will not be covered. Products in liquid or gel form are **not** covered.

Use, Application and Limitations

- The policy covers a maximum number of applications within an episode. **The number of applications is 8 over a 12-16 week period of time.** Greater than 8 applications in up to a 16 week period of time is considered not reasonable and necessary. The MACs stated that their claims data supports 4 applications so **any application over 4 will require additional documentation and a KX modifier must be used.** Please see the KX modifier information below in the LCA section below.
- The CTP must be applied in a single layer without overlay of product or adjacent skin in compliance with the correct labeling instructions.
- **The policy is now permitting use of CTPs over exposed muscle tendon or bone but only for products that have labeled indications for that use and only when there are no contraindications.**
- Repeat applications are not considered reasonable and necessary when previous applications were unsuccessful.
- Application of a CTP on an infected, ischemic or necrotic wound **will not be covered** as it is considered not reasonable and necessary.
- Application of a CTP on a patient with inadequate control of underlying conditions or exacerbating factors or other contraindications **will not be covered** as it is considered not reasonable and necessary.
 - Note: Uncontrolled diabetes used to be one of the examples provided, but the MACs **removed** that from the list of examples in the final policy.

Alliance Insights: Billing and Coding Article

The Billing and Coding Article provides further information on billing and coding requirements that must be followed to be reimbursed as well as all of the codes that are appropriate for billing under the policy. Information contained in it includes the following:

KX Modifier:

When using more than 4 applications of a CTP in a 12-16 week period of time you **MUST append a KX modifier beginning on the 5th application** (so if you are applying 5-8 applications of a CTP for any patient, the KX modifier is required). If there is no KX modifier provided beginning on the 5th application, the claims will be denied. If the KX modifier is abused, that may trigger a medical review audit (this means that the MACs do not think that all patients require more than 4 applications of a CTP so if you are using more than 4 on all your patients or a very high percentage of them, this may trigger a medical review audit).

When using the KX modifier, **additional documentation is also required.** Documentation must support medical necessity for the use of additional applications or time and include:

- Explanation of why extended time or additional applications is medically necessary for the patient.
- That the current treatment plan has resulted in wound healing and expectation that the wound will continue to heal with this plan. Documentation should include estimated time for extended treatment, number of additional applications anticipated, and plan of care if healing is not achieved as planned.
- What modifiable risk factors, such as diabetes optimization, are being approached to improve likelihood of healing.
- For venous leg ulcers, it is expected that appropriate consultation and management be obtained for the diagnosis and stabilization of any venous related disease.

Multiple Wounds:

The MACs added a new section to the Billing and Coding Article regarding when a patient has multiple wounds and how they expect providers to bill for these patients. According to the article,

- When multiple wounds are located on the same anatomic site, the surface area is to be added together and use the application code descriptor for the total surface area of the multiple wounds. For example, based on the code descriptor for code 15271 you would be providing the sum total of the size of trunk, arm and leg wounds combined. Based on the code descriptor for 15275 you would be providing the sum total of the size of face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands feet and/or multiple digit wounds combined.
- When multiple wounds are being treated that are **not** located on the same anatomic location, then the appropriate code should be used for the anatomic site for each date of service.
- Modifier 59 should not be used.
- Modifier 50 along with modifiers LT or RT are not required since “coding for CTP application is based on total surface area.”
 - **Note: These are standard CPT coding rules for application of CTP's as well as debridements.**

JW/JZ modifiers:

Providers are **required to document discarded CTPs** in the patient’s medical record **OR document that there was no product wastage**. The MACS are very clear as to the requirement of using either modifier JW (for discarded product) or JZ (no product was discarded) for each CTP application. Either way ONE OF THESE modifiers **must** be used.

For the JW modifier:

When using the JW modifier on the claim form the provider is acknowledging that there was some product that was wasted. Any amount wasted must be clearly documented in the patients’ medical record and include the date and time, amount of CTP discarded as well as the reason for the wastage.

The specific documentation requirements that must be included in the procedure notes in the patient's file includes **ALL** of the following:

- Date, time, and location of ulcer(s) treated.
- Name of skin substitute grafts/CTP and package size.
- Approximate amount of product unit used.
- Approximate amount of product unit discarded.
- Reason for the wastage (including the reason for using a package size larger than was necessary for the size of the ulcer, if applicable).
- Manufacturer's serial/lot/batch or other unit identification number of grafts/CTP material. When the manufacturer does not supply unit identification, the record must document such. The amount billed as wastage cannot exceed the price of the package.

For the JZ modifier:

The provider is providing an attestation that they did not waste any product – that **ALL** of the product was used. This modifier must be provided on the claim form if no product was wasted.

Products should not be folded in order not to be “wasted.” It is the intention of the MACs that the most appropriate size product is used for the wound being treated. *If a claim is submitted without either the JW or JZ modifier, the claim will be rejected.*

Documentation Requirements under the LCAs

Very specific requirements are provided throughout the LCD and LCA regarding the information that must be provided and maintained in the patients' records. As always, the documentation must be made available upon request, be legible (including the signature of the clinician providing care to the patient, support the use of the ICD-10 selected and the HCPCS code must describe the service performed. Additionally, documentation must include:

1. The circumstances regarding why the ulcer healing stalled with standard ulcer care treatment of greater than 4 weeks (28 days) and reference the specific interventions that have failed based on the prior ulcer evaluation.
2. An updated medication history, review of pertinent medical problems that may have arisen since the previous ulcer evaluation, and explanation of the planned “skin replacement therapy” with choice of skin substitute graft or CTP product. The procedure risks and complications must also be reviewed and documented.
3. That the criteria listed in the LCD has been met, as well as the appropriate diagnosis and response to treatment. Description of the ulcer(s) must be documented at baseline (prior to beginning standard of care treatment) relative to size, location, stage, duration, and presence of infection, in addition to the

type of standard of care treatment given and the response. This information must be updated in the medical record throughout the patient's treatment.

4. The response of the ulcer to treatment needs to be documented in the medical record at least once every 4 weeks. The ulcer description must also be documented pre- and post- treatment with the skin substitute grafts /CTP being used.
5. The reason(s) for any repeat application should be specifically addressed in the medical record, including whether the current treatment plan has resulted in wound healing and expectation that the wound will continue to heal with this plan.
6. Documentation should include estimated time for extended treatment, number of additional applications anticipated and plan of care if healing is not achieved as planned.
7. Documentation must include an assessment outlining the plan for skin replacement therapy and the choice of skin substitute grafts/CTP for the 12-to-16-week period as well as any anticipated repeat applications within the 12-to-16week period.
8. Documentation that modifiable risk factors, such as diabetes optimization, are being addressed to improve likelihood of healing. For venous leg ulcers, it is expected that appropriate management and consultation, if indicated, be obtained for the diagnosis and stabilization of any venous related disease.
9. An operative note must support the procedure (e.g., application of skin substitute grafts/CTPs to legs) for the relevant date of service (first application starts the 12-to 16-week episode of care) and include the reason for the procedure and a complete description of the procedure including product used (with identifying package label in the chart), and relevant findings.
10. Graphic evidence of ulcer size, depth, and characteristics of the ulcer or photo documentation of the ulcer at baseline and follow-up with measurements of wound including size and depth should be part of the medical record.
11. As stated above, wastage needs to be identified and the use of a JW or JZ modifier used. In the case of product wastage, any amount of wasted skin substitute grafts/CTP must be noted with the JW modifier and be clearly documented in the procedure note with ALL the following information (at a minimum):
 - Date, time, and location of ulcer(s) treated.
 - Name of skin substitute grafts/CTP and package size.
 - Approximate amount of product unit used.
 - Approximate amount of product unit discarded.
 - Reason for the wastage (including the reason for using a package size larger than was necessary for the size of the ulcer, if applicable).
 - Manufacturer's serial/lot/batch or other unit identification number of grafts/CTP material. When the manufacturer does not supply unit identification, the record must document such. The amount billed as wastage cannot exceed the price of the package.

12. The HCPCS code of the applicable skin substitute grafts/CTP and the units billed must be consistent with the medical record regarding wound description and size.
13. If more than 4 applications are necessary, as stated above, additional documentation along with the KX modifier is required. As documentation must support medical necessity for the use of additional applications or time, this includes the following:
 - Explanation of why extended time or additional applications is medically necessary for the specific patient.
 - That the current treatment plan has resulted in wound healing and expectation that the wound will continue to heal with this plan. Documentation should include estimated time for extended treatment, number of additional applications anticipated, and plan of care if healing is not achieved as planned.
 - What modifiable risk factors, such as diabetes optimization, are being approached to improve likelihood of healing.
 - For venous leg ulcers, it is expected that appropriate consultation and management be obtained for the diagnosis and stabilization of any venous related disease.

Getting Ready for Implementation: Key Take Aways for Providers

- This LCD is specifically for DFU and VLU. No other wound types are included in this policy. As such, the **reasonable and necessary** standard applies for the use of CTPs for other wound types. However, the MACs have all addressed this issue in their response to comments where they indicate that coverage for CTPs used on other wound types will be based on reasonable and necessary criteria on a case-by-case basis. However, as they also state in response to comment language, “coverage is based on a product or service being reasonable and necessary and this is demonstrated by evidence. Paying a service without sufficient (and published) evidence does not meet the definition of reasonable and necessary which is a requirement for the MACs.” ***So, it is unlikely that a product that does not have any evidence and is non-covered in this policy, will be covered when provided to a patient for different indications.***
- The total number of applications permitted is 8 in an episode (12-16 weeks). A provider can change the CTP being used within the episode, but a new application limitation will not be triggered with the application of the new CTP. Rather, if a CTP is changed mid treatment, there is still a total of 8 total applications permitted.
- When the policy goes into effect on February 12, 2025, the coverage and documentation parameters will be implemented. If a patient is on a product that is not covered, it will not be able to be used on February 12 or the claim if submitted will be denied.
- Similarly, if a patient has a CTP applied on or after February 12 and they already have reached 4 applications prior to February 12, the KX modifier must be used. In addition, the appropriate documentation must be in the patient file as discussed above, once 4 applications have been provided even if the patient began receiving applications prior to February 12.

- As stated, these policies go into effect on February 12, 2025. Until then, current policies are in effect and the coverage criteria listed in those policies govern. However, it would be wise for providers to get their systems ready for the new coverage parameters and documentation requirements prior to February 12 so they can go live with the new requirements beginning February 12, 2025.
- For all covered products, the HCPCS code must be reported with an “application of skin substitute code (15271-15278)” to be covered and reimbursed. Both codes are necessary. To reiterate, only sheet products are covered. Gels and liquid products are not.
- Please pay attention to the detailed documentation requirements in the summary above. Successful coverage and thus payment of CTPs relies on accurate documentation.

Submitting New Evidence For Consideration: The Need for Clarity & Ongoing Advocacy


- It is **unclear whether a manufacturer needs to file a reconsideration** request in order to have additional/new evidence reviewed for products currently not covered OR for new products to be considered for coverage. What is clear is that clarification is necessary from the MACs since the pathway to gain coverage is not transparent or timely. One MAC’s Response to Comments states in no uncertain terms that a reconsideration request is needed. Yet, in another, it says that “the MACs host open meetings several times a year, providing opportunities for stakeholders to present new evidence and discuss potential coverage updates.” They also state that “there are mechanisms in place to expedite the process when necessary, such as opening an LCD to comments for a new section only.” So, it is unclear and more information is needed. The Alliance will be further discussing this issue with our CTP workgroup and develop and advocacy strategy to address it.
- The timeline for review is way too long as the MACs state that “it is the intention of the MACs to review literature at least once every 12 months.” This is not a required action. This is another area that the Alliance will continue advocacy efforts and work with our CTP workgroup.
- It is uncertain if new evidence is submitted prior to February 12, 2025, whether the MACs will consider that evidence for possible coverage, and if deemed sufficient, add the product to the covered list. There is inconsistent information contained in the response to comments. The Alliance will seek clarification on this issue.
- Finally, from a process perspective, will manufacturers be required to submit new evidence to all of the MACs for review or whether submitting to one will be sufficient if the MACs will be reviewing the evidence together? Will it be possible for one MAC to accept evidence and make a determination to provide coverage in their jurisdiction or will all evidence be reviewed as part of the MAC CTP workgroup so either all will provide coverage, or none will?

These are some of the questions that we believe the MACs need to provide answers in their upcoming education sessions.

Next Steps

The MACs have stated that they will be holding various educational programs within their jurisdictions, including a multi-jurisdictional Town Hall meeting hosted by CGS on 12/10/2024 from 3:00-5:00 pm eastern time. During the meeting the MACs will discuss the Medicare policy and there will be an opportunity to speak at it.

Registration is required at:

<https://events.teams.microsoft.com/event/e01947e8-9a33-4d4f-8b94-6ff19f8f7cad@d560165e-85d7-436f-a978-c588cf12ebeb> 

Speakers are required to send a request to speak at it to: J15MRPolicy@cgsadmin.com

The Alliance will further discuss the LCD in our CTP work group, serve as a speaker at this Town Hall meeting, and will host a few webinars. So, stay tuned for more information on the webinars. In the meantime, the list of covered products and links to all the LCDs, LCAs and response to comments are provided below.

As always, if you have any comments or questions, please feel free to contact Karen Ravitz (karen@woundcarestakeholders.org or 301 807 5296).

Covered Products List

Covered Products: DFU

There are 13 codes (20 products) that are available for coverage under this policy that are specific to DFUs. These products are listed in the Group 2 covered product list and include the following:

A2019	Kerecis Omega 3 Marigen Shield
Q4105	Integra Dermal Regeneration Template (DRT) or Integra Omnigraft Dermal Regeneration Matrix
Q4107	GraftJacket
Q4110	Primatrix
Q4121	Theraskin
Q4122	Dermacell, Dermacell AWM or Dermacell AWM Porous
Q4128	Flex HD or Allopatch HD
Q4133	Grafix Prime, GrafixPL Prime, Stravix and StravixPL
Q4158	Kerecis Omega 3
Q4159	Affinity
Q4160	Nushield
Q4187	Epicord
Q4203	Derma-Gide

Covered Products: DFU and VLU

There are 5 codes (6 products) that are available for coverage under this policy that are indicated for both DFU and VLUs. These products are listed in the Group 3 covered product list and include:

Q4101	Apligraf
Q4102	Oasis Wound Matrix
Q4106	Dermagraft
Q4151	Amnioband or Guardian
Q4186	Epifix

Non-Covered Products

204 products are not covered under this policy as the MACs determined there was either no evidence to support the product or the evidence was not sufficient for coverage. Please see the final LCAs to review this list.

Links to Final LCDs, Coding and Billing Articles and Responses to Comment

- CGS: [Final Determination L39756](#); [Coding and Billing Article A59618](#); [Response to comments article A59941](#)
- First Coast: [Final Determination L36377](#); [Coding and Billing Article A57680](#); [Response to Comments Article A59824](#)
- NGS: [Final Determination L39828](#); [Coding and Billing Article A59712](#); [Response to Comments Article A59953](#)
- Noridian: [Final Determination L39760](#); [Coding and Billing Article A59626](#); [Response to Comments Article A59950](#)
- Noridian: [Final Determination L39764](#); [Coding and Billing Article A59628](#); [Response to Comments Article A59952](#)
- Novitas: [Final Determination L35041](#); [Coding and Billing Article A54117](#); [Response to Comments Article A59823](#)
- Palmetto: [Final Determination L39806](#); [Coding and Billing Article A59691](#); [Response to Comments Article A59945](#)
- WPS: [Final Determination L39865](#); [Coding and Billing Article A59740](#); [Response to Comments Article A59954](#)