North Carolina Foot and Ankle Society
2025 Winter Conference
Saturday, January 18, 2025
Update on the Application of Skin Substitutes/CTPs

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Presenter Disclosure

Michael G. Warshaw, DPM has no actual or potential conflict of interest in relation to this program

No off-label uses of any drugs or products will be discussed in this presentation

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Highlights

- The proposed requirement to perform an ankle-brachial index was modified to instead require a "vascular assessment."
- The proposed policy called for limiting the number of skin substitute applications per episode of care to four. APMA contested this limit, and the final policy allows a maximum of eight skin substitute graft/CTP applications within an episode of skin replacement therapy (defined as 12 to 16 weeks from the first application of a skin substitute graft/CTP) when there is documentation of progression of wound closure under the current treatment plan with documented medical necessity for additional applications.
- When more than four medically necessary applications are performed, the KX Modifier must be used to indicate the medical necessity of this number of applications.

Highlights

- **Skin substitute products/CTPs with labeled indications for use over exposed muscle, tendon, or bone will be allowed over exposed muscle, tendon, or bone in the absence of contraindications.**
- **When all criteria in the policy are met, skin substitute/CTP application will be allowed for chronic, non-infected diabetic foot ulcers that have failed to achieve at least 50 percent ulcer area reduction with the standard of care that is outlined in the policy for a minimum of four weeks with documented compliance.**
- **When all criteria in the policy are met, skin substitute/CTP application will be allowed for chronic, non-infected venous leg ulcers that have failed to respond to the standard of care that is outlined in the policy for a minimum of four weeks with documented compliance.**

Highlights

- The policy lists 17 brand name products that are "covered for diabetic foot ulcers."
- The policy lists five brand name products that are "covered for venous leg ulcers."
- The policy lists more than 100 brand name products that are considered to be "non-covered."

Covered Indications

1. 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 (outlined below) for a minimum of 4 weeks with documented compliance.
2. 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.
   For purposes of this LCD, SOC treatment includes:
   1. Comprehensive patient assessment (history, exam, vascular assessment) and diagnostic tests as indicated as part of the implemented treatment plan.
   2. For patients with a DFU: 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 devices or use of appropriate footwear.
   3. For patients with a VLU: assessment of clinical history (that includes prior ulcers, body mass index, history of pulmonary embolism or superficial/deep venous thrombosis, number of pregnancies, and physical inactivity), physical exam (edema, skin changes and vascular competence), evaluation of venous reflux, perforator incompetence, and venous thrombosis. The use of a firm strength compression garment (>20 mmHg) or multi-layered compressive dressing is an essential component of SOC for venous stasis ulcers.

3. An implemented treatment plan to be continued throughout the course of treatment demonstrating all the following:

1. **Debridement as appropriate to a clean granular base.**
2. **Documented evidence of offloading for DFUs.**
3. **Documented evidence of sustained compression dressings for VLUs.**
4. **Infection control with removal of foreign body or focus of infection.**
5. **Management of exudate with maintenance of a moist environment.**
6. **Documentation of smoking history, and counselling on the effect of smoking on wound healing. Treatment for smoking cessation and outcome of counselling (if applicable).**

4. The skin substitute graft/CTP is applied to an ulcer that has failed to heal or has stalled in response to documented SOC treatment. Documentation of response to treatment 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 treatment, 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 standard of care 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 VLUs must be documented for the episode of care.

5. 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. The procedure risks and complications must also be reviewed and documented.

6. 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 skin substitute grafts/CTPs

- **To qualify as a skin substitute graft/CTP the product must be:**

1. **A non-autologous human cellular or tissue product (e.g., dermal or epidermal, cellular and acellular, homograft or allograft), OR non-human cellular and tissue product (i.e., xenograft), OR biological product (synthetic or xenogeneic) applied as a sheet, allowing scaffold for skin growth, intended to remain on the recipient and grow in place or allow recipient's cells to grow into the implanted graft material**

AND

2. Supported by high-certainty evidence to demonstrate the product's safety, effectiveness, and positive clinical outcomes in the function as a graft for DFUs and/or VLUs.[4,10] Substantial equivalence to predicate products does not allow sufficient evidence to support similar cleared products.

3. Liquid or gel preparations are not considered grafts. Their fluidity does not allow graft placement and stabilization of the product on the wound.

The following are considered reasonable and necessary (per episode of care)

1. The maximum number of applications of a skin substitute graft/CTP within the episode of skin replacement therapy (defined as 12 to 16 weeks from the first application of a skin substitute graft/CTP) is 8 applications. The mean number of skin substitute graft/CTP applications associated with wound healing is 4; however, with documentation of progression of wound closure under the current treatment plan and medical necessity for additional applications, up to 8 applications may be allowed. Use of greater than 4 applications requires an attestation from the provider showing that requirements specified in the LCD have been met and the additional applications are medically necessary. In absence of this attestation, denial of the additional applications will occur. Please refer to the Billing and Coding article for instruction on reporting applications 5 to 8.

2. The usual episode of care for skin substitute grafts/CTP is 12 weeks; however, some wounds may take longer to heal therefore 16 weeks is allotted with documentation that includes progression of wound closure under current treatment plan.

3. The skin substitute graft/CTP must be used in an efficient manner utilizing the most appropriate size product available at the time of treatment.

   Excessive wastage (discarded amount) should be avoided by utilization of size appropriate packaging of the product consistent with the wound size. The graft must be applied in a single layer without overlay of product or adjacent skin in compliance with the correct label application techniques for the skin substitute graft/CTP.

4. Only skin substitute grafts/CTP with labeled indications for use over exposed muscle, tendon, or bone will be considered reasonable and necessary for those indications.

Limitations

- **The following are considered not reasonable and necessary:**

1. **Greater than 8 applications of a skin substitute graft/CTP within an episode of care (up to 16 weeks).**
2. **Repeat applications of skin substitute grafts/CTP when a previous application was unsuccessful. Unsuccessful treatment is defined as increase in size or depth of an ulcer, no measurable change from baseline, and no sign of improvement or indication that improvement is likely (such as granulation, epithelialization, or progress towards closure).**
3. **Application of skin substitute grafts/CTP in patients with inadequate control of underlying conditions or exacerbating factors, or other contraindications (e.g., active infection, progressive necrosis, active Charcot arthropathy of the ulcer extremity, active vasculitis, or ischemia).**

4. Use of surgical preparation services (e.g., debridement), with routine, simple, or repeat skin replacement surgery with a skin substitute graft/CTP.

5. All liquid or gel skin substitute products/CTP for ulcer care.

6. Placement of skin substitute grafts/CTP on an infected, ischemic, or necrotic wound bed.

Definitions

- **Autografts/tissue cultured autografts: Include the harvest or application of an autologous skin graft. These products are designed to avoid the challenges with autologous skin grafts in the treatment of chronic wounds, ulcers, or burns.**
- **Chronic Wound: A wound that is physiologically impaired due to a disruption of the wound healing cycle because of impaired angiogenesis, innervation, or cellular migration, or other deficits for 4 weeks or longer.**

- **Cellular and Tissue-Based Products (CTP) (also called skin substitute grafts): Include homologous human cellular and tissue products (e.g., dermal or epidermal, cellular and acellular, homograft or allograft), non-human cellular and tissue products (e.g., xenograft), and biological products (synthetic or xenogeneic) that form a sheet scaffolding for skin growth when applied in a sheet over an open wound or ulcer to augment closure or skin growth.**
- **There is a lack of clarity in the definition of skin substitute grafts. For the purpose of this policy, skin substitute grafts will align with the AMA CPT codebook[19] description of "non-human skin substitute grafts and biological products that form a sheet scaffolding for skin growth". This surface is not intended to be removed but grows into place or serves as a base for new skin to grow.**

- **Cellular, acellular, and matrix-like products (CAMPs): Cellular, acellular, and matrix-like products, also referred to as cellular/tissue products (CTP).**
- **Failed response: Increased size or depth, no change in baseline size or depth, no sign of improvement or indication that improvement is likely (such as granulation, epithelialization, or progress towards closing).**
- **Healed ulcer (completed healing): 100 percent re-epithelialization without drainage or dressing noted on 2 occasions at least 2 weeks apart.**

- **Scaffolding: A support, delivery vehicle, or matrix for facilitating the migration, binding, or transport of cells or bioactive molecules used to replace, repair, or regenerate tissues.**
- **Stalled Wound: An ulcer that has entered a non-healing or intransigent phase.**
- **Standard of Care (SOC): In this policy refers to a Best Practice recommendation and it is not to be interpreted as the legal definition of SOC for either diabetic foot ulcers or venous leg ulcers.**
- **Wound dressing or coverings: Applications applied to wounds as a selective barrier to clean, cover, and protect wounds from the surrounding environment to promote optimal environment for wound healing.**

Covered Products for DFUs

- Affinity
- AmnioBand, guardian
- Apligraf
- DermACELL, awm, porous
- Derma-Gide
- Dermagraft
- Epicord
- Epifix

- FlexHD or AllopatchHD
- Grafix stravix prime pl
- GraftJacket
- Integra or Omniograft dermal regeneration template
- Kerecis Omega3/ Kerecis omega3, MariGen shield
- NuShield
- Oasis wound matrix
- PriMatrix
- Theraskin

Covered Products for VLUs

- AmnioBand, guardian
- Apligraf
- Dermagraft
- Epifix
- Oasis wound matrix

For Part B Claims

- **Loop 2400 or SV101-7 for the 5010A1 837P**
  Box 19 for paper claim
- **The name of the product, size, and the amount used must appear in the Documentation Field.**
- **If the charge matches the actual invoice cost, note "Actual Invoice Cost" in the Documentation Field. You are not required to submit invoice information with the claim; however, it must be available if requested.**

- **The name of the product, size, and the amount used must appear in the Documentation Field.**
- **If the charge matches the actual invoice cost, note "Actual Invoice Cost" in the Documentation Field. You are not required to submit invoice information with the claim; however, it must be available if requested.**
- **The appropriate CPT or HCPCS application code must be reported on the same claim as the skin substitute graft/CTP HCPCS code. The claim will be returned to provider or rejected if the application code and skin substitute graft/CTP code are not submitted on the same claim. When the skin substitute graft/CTP HCPCS code is denied, the related application code will also be to be denied.**

Utilization Parameters

- **A maximum of 8 skin substitute grafts/CTP applications per ulcer will be allowed for the episode of skin replacement surgery (defined as 12 to 16 weeks from the first application of a skin substitute grafts/CTP). Product change within the episode of skin replacement surgery may be appropriate. When more than one specific product is used during the 12-to-16-week period, it is expected that the total number of applications or treatments will still not exceed 8.**

Modifier -KX

- **Modifier -KX must be used as an attestation by the practitioner and/or provider of the service that documentation is on file verifying that the patient meets the requirements for additional applications of skin substitute grafts/CTPs. Consistent with the LCD, more than 4 applications of a skin substitute grafts/CTP in a 12-to-16-week period must be appended with a -KX modifier. Failure to apply the -KX modifier for applications greater than 4 will result in claim denial. Aberrant use of the -KX modifier may trigger focused medical review.**

- **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 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.**

JW Modifier

- **Code product using 2 lines**
  - **Units of CTP used: Q code X units**
  - **Units of CTP discarded: Q code X units - JW mod**

- **Line 1 + Line 2 = Total CTP product**

Example

- **A 6 sq. cm. piece of CTP is used to cover a 5 sq. cm. foot ulcer**

- **15275**
- **Q4160 5 units - KX**
- **Q4160 1 unit – JW - KX**

JZ Modifier

- **Effective date July 1, 2023**
- **JW and JZ Modifier Billing Guidelines**
  - **JZ Modifier is a HCPCS Level II modifier reported on a claim to attest that no amount of CTP was discarded and is eligible for payment**
  - **To submit claims for a waste-required claim, submit two complete claim lines.**
    - **Claim line #1:**
    - **HCPCS Level II code for CTP applied**
    - **No modifier appended**
    - **Number of units of CTP applied**
    - **Calculated submitted price for ONLY the amount of CTP applied**

    - **Claim line #2**
    - **HCPCS Level II code for CTP wasted**
    - **JW modifier appended to HCPCS Level II code to indicate CTP wasted**
    - **Number of units of CTP wasted**
    - **Calculated submitted price for ONLY the amount of CTP wasted**

JZ Modifier

- **To submit claims for a non-discarded claim, submit one complete claim line.**
  - **HCPCS Level II code for CTP applied**
  - **JZ modifier to indicate no waste of CTP**
  - **Number of units of CTP applied**
  - **Calculated submitted price for the amount of CTP applied**

Documentation Requirements

1. All documentation must be maintained in the patient's medical record and made available to the contractor upon request.
2. Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service[s]). The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient.
3. The submitted medical record must support the use of the selected ICD-10-CM code(s). The submitted CPT/HCPCS code must describe the service performed.

4. The medical record documentation must specifically address the circumstances regarding why the ulcer healing has stalled with standard ulcer care treatment of greater than 4 weeks and reference the specific interventions that have failed based on the prior ulcer evaluation. The record must include 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.

- **5. The medical record must clearly document 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. It is expected that the response of the ulcer to treatment will 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. The reason(s) for any repeat application should be specifically addressed in the medical record, whether 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.**

6. 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-16-week period.

7. Documentation that modifiable risk factors, such as diabetes optimization, are being addressed to improve likelihood of healing must be included in the medical record. 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.

8. An operative note must support the procedure (e.g., application of skin substitute grafts/CTPs to legs) for the relevant DOS (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.

9. 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.

10. Any amount of wasted skin substitute grafts/CTP must be clearly documented in the procedure note with ALL the following information (at a minimum):

1. **Date, time, and location of ulcer(s) treated.**
2. **Name of skin substitute grafts/CTP and package size:**
3. **Approximate amount of product unit used.**
4. **Approximate amount of product unit discarded.**
5. **Reason for the wastage (including the reason for using a package size larger than was necessary for the size of the ulcer, if applicable).**
6. **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.**

11. 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.

Codes for the Application of CTPs

CPT 15271

- **Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area**

CPT 15272

- **Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)**

- **Add-on code**

Example

- **CTP to 78 sq cm of leg**

- **CPT 15271 X 1 unit**
- **CPT 15272 X 3 units**

CPT 15273

- **Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children**

CPT 15274

- **Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)**

- **Add-on code**

CPT 15275

- **Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area**

CPT 15276

- **Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)**

- **Add-on code**

CPT 15277

- **Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children**

CPT 15278

- **Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)**

- **Add-on code**

Site Preparation Codes

Preparation Codes

- **Surgical preparation codes 15002-15005 for skin replacement surgery describe the initial services related to preparing a clean and viable wound surface for placement of a skin substitute graft or for negative pressure wound therapy.**

- **Check LCD!**

CPT 15002

- **Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, trunk, arms, legs; first 100 sq cm or 1% of body area of infants and children**

CPT 15003

- **Add-on code**

- **Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, trunk, arms, legs; each additional 100 sq cm, or part thereof, or each additional 1% of body area of infants and children (List separately in addition to code for primary procedure) (add-on code)**

Example

- **Prepare 250 sq cm of leg**

- **CPT 15002**
- **CPT 15003 X 2 units**

CPT 15004

- **Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet and/or multiple digits; first 100 sq cm or 1% of body area of infants and children**

CPT 15005

- **Add-on code**

- **Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet and/or multiple digits; each additional 100 sq cm, or part thereof, or each additional 1% of body area of infants and children (List separately in addition to code for primary procedure) (add-on code)**

ISSUE!

- **The number one CPT code used by podiatrists for the application of a skin substitute is:**

- **<u>CPT 15275</u> (application of skin substitute graft to, for example, foot or toe(s)). This code is based on a wound size (after cleansing, prepping, and/or debriding) maximum of 100 sq cm. Specifically, this code is to be used for application of a skin substitute graft to a wound surface area size of 0 to 25 sq cm (first 25 sq cm within the maximum wound size grouping up to 100 sq cm).**

- **When you download and read the LCDs for the Application of Bioenginered Skin Substitutes it clearly states that you CANNOT bill for the preparation of the skin site and the application of the skin substitute on the same date of service.**

- **What is one to do?**

Solution!

- **Why not bring the patient in prior to the application of the skin substitute to ensure that the site is prepped correctly in order to appropriately have the skin substitute applied?**
- **Perhaps the day before, the week before.**

Problem!

- **The number one CPT code that podiatrists use for the preparation of the site is:**

15004 Surgical preparation or creation of recipient site by excision of open wounds, burn eschar or scar (including subcutaneous tissues), or incisional release of scar contracture, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet and/or multiple digits; first 100 sq cm or 1% of body area of infants and children

Is this what you are really performing?

- **Read the words, not the numbers**
- **15004 reimburses approximately 400.00 National average**
- **CPT codes 15002-15005 should NOT regularly be used for the removal of nonviable tissue/debris in chronic wounds. These CPT codes are for excision of open wounds, burn eschar, or scar (including subcutaneous tissue), or incisional release of scar contracture. These surgical sites will probably heal by secondary intention or perhaps even tertiary intention. CPT 11042-11047 and CPT codes 97597-97598 are more appropriate to be used for the removal of nonviable tissue/debris in chronic wounds.**

Questions?

Thank You So Much!