



Novitas Medicare Policy Primer

Medicare Jurisdiction (JL and JH)

AR, CO, LA, MS, NM, OK, TX, DC, DE, MD, NJ, & PA—Counties of Arlington and Fairfax in Virginia and the city of Alexandria in Virginia

Application of Bioengineered Skin Substitutes to Lower Extremity Chronic Non-Healing Wounds—#L35041

Indications

- Therefore, all products with FDA clearance/approval or designated 361 HCT/P exemption used in accordance with that product's individualized application guidelines will be equally considered for the purpose of this LCD and may be considered reasonable and necessary.
- Presence of neuropathic diabetic foot ulcer(s) having failed to respond to documented conservative wound-care measures of greater than four weeks, during which the patient is compliant with recommendations, and without evidence of underlying osteomyelitis or nidus of infection.
- Presence of a venous stasis ulcer for at least 3 months but unresponsive to appropriate wound care for at least 30 days with documented compliance.
- Presence of a full-thickness skin loss ulcer that is the result of abscess, injury, or trauma that has failed to respond to appropriate control of infection, foreign body, tumor resection, or other disease process for a period of 4 weeks or longer.
- Response from Apligraf reconsideration letter from Novitas JH June 2015 “ Novitas only requires 1 month of compliant wound therapy prior to placement on a venous stasis (VSU), though it is suggested that the wounds be present for at least 3 months; this is not a requirement for placement. It is standard therapy for all ulcers for 30 days and would not need to meet medical necessity requirements.”
- Medicare covers application of skin substitutes to Ulcers or Wounds with Failed Response that are:
 - Partial- or full-thickness ulcers, not involving tendon, muscle, joint capsule, or exhibiting exposed bone or sinus tracts, with a clean granular base;
 - Skin deficit at least 1.0 cm² in size;
 - Clean and free of necrotic debris or exudate;
 - Have adequate circulation/oxygenation to support tissue growth/wound healing as evidenced by physical examination (e.g., Ankle-Brachial Index (ABI) of no less than 0.60, toe pressure > 30mm Hg);



- For diabetic foot ulcers, the patient's medical record reflects a diagnosis of Type 1 or Type 2 Diabetes and also reflects medical management for this condition.

Limitations

- Skin substitute grafts will be allowed for the episode of wound care in compliance with FDA guidelines for the specific product (see utilization guidelines) not to exceed 10 applications or treatments. In situations where more than one specific product is used, it is expected that the number of applications or treatments will still not exceed 10.
- Simultaneous use of more than one product for the episode of wound is not covered. Product change within the episode of wound is allowed, not to exceed the 10 application limit per wound per 12 week period of care.
- Treatment of any chronic skin wound will typically last no more than twelve (12) weeks.
- Repeat or alternative applications of skin substitute grafts are not considered medically reasonable and necessary when a previous full course of applications was unsuccessful. Unsuccessful treatment is defined as increase in size or depth of an ulcer or no change in baseline size or depth and no sign of improvement or indication that improvement is likely (such as granulation, epithelialization, or progress towards closing) for a period of 4 weeks past start of therapy.
- Retreatment of healed ulcers, those showing greater than 75% size reduction and smaller than .5 sq.cm, is not considered medically reasonable and necessary.
- Skin substitute grafts are contraindicated and are not considered reasonable and necessary in patients with inadequate control of underlying conditions or exacerbating factors (e.g., uncontrolled diabetes, active infection, and active Charcot arthropathy of the ulcer extremity, vasculitis, or continued tobacco smoking without physician attempt to effect smoking cessation).
- Repeat use of surgical preparation services (CPT codes 15002, 15003, 15004, and 15005) in conjunction with skin substitute application codes will be considered not reasonable and necessary. It is expected that each wound will require the use of appropriate wound preparation code at least once at initiation of care prior to placement of the skin substitute graft.
- Re-treatment within one (1) year of any given course of skin substitute treatment for a venous stasis ulcer or (diabetic) neuropathic foot ulcer is considered treatment failure and does not meet reasonable and necessary criteria for re-treatment of that ulcer with a skin substitute procedure.

Documentation

- 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.
- 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.
- Medical record documentation must support the medical necessity of the services as directed in this policy.
- The documentation must support that the service was performed and must be included in the patient's medical record. This information is normally found in the history and physical, office/progress notes, hospital notes, and/or procedure report.
- The medical record must clearly show that the criteria listed under the "Indications and Limitations of Coverage and/or Medical Necessity" sections have been met, as well as, the appropriate diagnosis and response to treatment.
- A description of the wound(s) must be documented at baseline (prior to beginning conservative treatment) relative to size, location, stage, duration, and presence of infection, in addition to type of treatment given and response.
- Wound description must also be documented pre and post treatment with the skin substitute graft being used.
- If obvious signs of worsening or lack of treatment response is noted, continuing treatment with the skin substitute would not be considered medically reasonable and necessary without documentation of a reasonable rationale for doing so.
- Documentation of smoking history, and that the patient has received counseling on the effects of smoking on surgical outcomes and treatment for smoking cessation (if applicable) as well as outcome of counselling must be in the medical record.
- The amount of utilized and wasted skin substitute must be clearly documented in the procedure note.

Coding

HCPCS Codes:

- **Q4101:** Apligraf, per square centimeter
- **Q4106:** Dermagraft, per square centimeter
- **Q4172:** PuraPly, PuraPly Antimicrobial per square centimeter
- **Q4159:** Affinity, per square centimeter
- **Q4160:** NuShield, per square centimeter

Disclaimer: This document is for informational purposes only. Use of this information does not guarantee coverage or payment for these services by Medicare or other payors. Physicians and other providers should use independent judgment when selecting codes that most appropriately describe the services provided to a patient. Physicians and hospitals are solely responsible for compliance with Medicare and other payors' laws, rules, and requirements. For the full LCD, please refer to www.CMS.gov

JW Modifier:

Effective January 1, 2017 in Physician Office Setting (Place of service 11): Claims for discarded drug or biological amount not administered to any patient shall be submitted using the JW modifier. This modifier, billed on a separate line, will provide payment for the amount of discarded drug or biological. Providers must document the discarded drugs or biologicals in patient's medical record.

CPT Codes:

Application Codes for Leg, Arm or Trunk:

- **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
- **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)
- **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
- **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 (List separately in addition to code for primary procedure)

Application Codes for Foot, Face, Scalp, etc.:

- **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
- **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)
- **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
- **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 (List separately in addition to code for primary procedure)

Novitas Medicare Sample Model Documentation

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Pre-Treatment

1. Duration of ulcer: _____ weeks
2. Exact location of ulcer
3. Describe adequate treatment of the underlying disease process contributing to the ulcer.
4. Diagnosis of patient

Treatment

5. Document measurement of ulcer (width and length or circumference and depth) immediately prior to application of the skin substitute _____ sq cm
6. Document whether this is an initial application of skin substitute or a reapplication.
7. For skin substitute reapplications, document that applications have been successful (e.g. decrease in size or depth, increase in granulation tissue).
8. Document the wound dressing changes and the standard conservative measures accompanying the wound treatment with the skin substitute.
9. Document how the wound site was prepared, and how the skin substitute was fixated on the wound.
10. Product Wastage Documentation Requirements:
 - Date and time
 - Location of ulcer
 - Approximate amount of product unit used
 - Approximate amount of product unit discarded
 - Reason for the wastage
 - Manufacture's serial/lot/batch number

Modifiers

JW: Skin substitute not applied to wound, wastage

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