Indications

- 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.
- Response from reconsideration letter from Novitas JH June 2015 “Novitas only requires 1 month of compliant wound therapy prior to placement on a venous stasis ulcer (VSU), though it is suggested that the wound 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 need to meet medical necessity requirements”.
- Chronic Wounds are defined as wounds that do not respond to standard wound treatment for at least a 30 day period during organized comprehensive conservative therapy.

Ulcers or Wounds with Failed Response to appropriate therapy are:

- Partial- and/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);
- Wound healing is impaired by the systemic use of tobacco. Therefore, ideally patients who have smoked will have ceased smoking or have refrained from systemic tobacco intake for at least 4 weeks during conservative wound care and prior to planned bioengineered skin replacement therapy.
- 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;
- Documentation (in the pre-service record) specifically addressing circumstances as to why the wound has failed to respond to standard wound care treatment of greater than 4 weeks and must reference specific interventions that have failed. Such record should include updated medication history, review of pertinent medical problems that may have occurred since the previous wound evaluation, and explanation of the planned skin replacement surgery with choice of skin substitute graft product. The procedure risks and complications should also be reviewed and documented.
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 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.)

- 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.

- Separately billed repeated use of the skin substitute after 12 weeks for a single wound or episode is non-covered. Alternative or additional skin substitute products used within the 12 week initial wound episode are similarly non-covered when the sum of applications of all Skin Substitutes is greater than ten (10) for a single wound.
Documentation

- All documentation must be maintained in the patient’s medical record and made available to the contractor upon request.
- 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-9-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.
- The documentation must support the need for skin substitute application and the product used.
- 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 counseling must be in the medical record.
- The amount of utilized and wasted skin substitute must be clearly documented in the procedure note with the following minimum information:
  - Date, time and location of ulcer treated;
  - Name of skin substitute and how product supplied;
  - Amount of product unit used;
  - Amount of product unit discarded;
  - Reason for the wastage;
  - Manufacturer’s serial/lot/batch or other unit identification number of graft material.
  - When manufacturer does not supply unit identification, record must document such.

Coding

CPT/HCPCS

- Q4101: Apligraf, per square centimeter


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.

**Application Codes for Leg**

- **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**

- **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)

1 Source: www.cms.gov 2 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. 3 CPT © American Medical Association. All Rights Reserved.
### 2017 Novitas Medicare Apligraf® Sample UB-04 Claim Form

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**Patient Information**

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**Diagnosis Code**

Jane Smith
111 Maple Avenue
Anytown, NJ 00000

**Application**

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**Notes**

- Apligraf is supplied in 44 sq cm. Apligraf is FDA approved for single use only.
- 15271 and 15272 should be used based on the size of the wound. For example, a LEG wound measuring 40 sq cm, would be billed using 15271 (first 25 sq cm or less) and 15272 (each additional 25 sq cm or part thereof).
- Enter appropriate revenue codes for all services provided. Revenue code 636 should be used when billing for Apligraf.
- All dates should be in eight digit format.
- Medicare A987654X
- Smith, Jane

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**Page 1 of 1**

**Creation Date**

**TOTALS**

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**Diagnosis Code**

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### Diagnosis Codes

15271 and 15272 should be used based on the size of the wound. For example, a LEG wound measuring 40 sq cm, would be billed using 15271 (first 25 sq cm or less) and 15272 (each additional 25 sq cm or part thereof).
Diagnosis Codes

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<td>40 sq cm of the product was used on the wound. 4 sq cm of product was discarded and documented as wastage and therefore billed with a JW Modifier.</td>
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15271 and 15272 should be used based on the size of the wound. For example, a LEG wound measuring 40 sq cm, would be billed using 15271 (first 25 sq cm or less) and 15272 (each additional 25 sq cm or part thereof).

Apligraf® is supplied in 44 sq cm. Apligraf is FDA approved for single use only.
Pretreatment:
1. For DFU - Document 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.
2. For VSU - Document presence of a venous stasis ulcer for at least 1 month but unresponsive to appropriate wound care for at least 30 days with documented compliance.
3. Document the exact location of each ulcer treated and include in the medical record
4. Diagnosis of patient
5. Document the extent of site preparation procedures, including the medical necessity of and performance of site preparation
6. Document that wound is clean and free of infection
7. For DFU - Document appropriate non-weight bearing and/or off-loading pressure
8. For VSU - Document compression therapy provided with documented diligent use of multilayer dressings, compression stockings of > 20mmHg pressure, or pneumatic compression

Treatment:
9. Document measurement of ulcer (width and length or circumference and depth) immediately prior to application of Apligraf ___________________________ sq cm
10. Document location, stage and duration
11. Document whether this is an initial application of Apligraf or a reapplication. (Per FDA-approved labeling no more than 5 applications per ulcer is permitted)
12. For Apligraf reapplications, document whether prior applications have been successful

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. LCDs are updated by Medicare and Medicare contractors on a regular basis. Physicians and other providers should regularly refer to the applicable Medicare local coverage determinations (LCDs) for complete information on medical necessity documentation requirements. Physicians, providers and hospitals are solely responsible for compliance with Medicare and other payors' laws, rules, and requirements.
13. Document whether wound treatment with Apligraf is accompanied by appropriate adjunctive wound care measures (e.g. dressing changes during healing, off-loading, compressive dressings)

14. 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 counseling must be in the medical record.

Modifiers:

**JW**- Skin substitute not applied to wound, wastage.

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

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