### Indications
- VSU³ ulcers that have failed to respond to documented conservative measures of greater than 4 weeks in duration.
- DFU⁴ ulcers of greater than 3 weeks in duration which extend through the dermis but without tendon, muscle, capsule or bone exposure.

### Limitations
- Application is limited to physicians (M.D, D.O., D.P.M., and NNP (non-physician practitioner) who are skilled in wound care management.
- The patient must have adequate circulation/oxygenation to support tissue growth/wound healing as evidenced by physical examination (presence of acceptable peripheral pulses and/or Doppler toe signals and/or ankle-brachial index (ABI) of no less than 0.65 in the limb undergoing the procedure).  
- Managed wounds should be clean and free of infection and are of reasonable size (at least 1.0 cm²)
- A single application of DET for any particular ulcer is usually all that is required to affect wound healing in those wounds that are likely to be helped by this therapy. Treatment with Apligraf® is usually expected to last no more than twelve (12) weeks and to involve a maximum of five Apligraf® applications for any ulcer that initially qualifies for treatment. The use of more than five applications for the same ulcer is not considered reasonable and necessary and will not be reimbursed.
- Re-application of Apligraf® more frequently than once per week for the same ulcer is not considered reasonable and necessary and will not be reimbursed.
- Re-application of Apligraf® where initial application has resulted in no decrease in size or depth or increase in granulation tissue, epithelialization, or progress towards closing, will be denied as not reasonable and necessary and will not be reimbursed.
- Re-treatment within one year following the last successful application with DET is not considered reasonable and necessary, and will not be reimbursed.
- Re-treatment of an ulcer following the unsuccessful treatment where it consisted of two failed Apligraf® applications is not considered reasonable and necessary, and will not be reimbursed.

### Documentation
- The medical record documentation supporting medical necessity should be legible, maintained in the patient’s medical record, and made available to Medicare upon request.
- The medical record documentation must confirm and support that all requirements set forth in the “Indications” section of this policy (and applicable article) have been satisfied with regards to the clinical characteristics of the ulcer, the presence of qualifying or disqualifying conditions, and the duration and intensity of pre-treatment conservative/conventional management.
Documentation of response or lack thereof, requires measurement of the ulcer at baseline and following cessation of conservative or conventional management and must be included in the medical record. Documentation should also include measurement of the ulcer immediately prior to the placement of skin substitutes/replacements. A “failed response” is defined as an ulcer that has increased in size or depth, or for which there has been no change in baseline size or depth and no sign of improvement or indication that improvement is likely, such as granulation, epithelialization or progress toward closing.

The medical record must document that wound treatments with skin substitutes/replacements are accompanied by appropriate wound dressing changes during the healing period and by appropriate compressive dressings during follow-up, including, for neuropathic diabetic foot ulcers, appropriate steps to off-load wound pressure during the follow-up.

Rationale for the selection of a biological product for surgical interventions in repair of anatomic defects or reconstruction work must be documented in the medical record and submitted to Medicare upon request.

The patient’s medical record must contain documentation that fully supports the medical necessity for services included within this coverage article. (See “Indications and Limitations of Coverage.”) This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures.

### Product Wastage Documentation Requirements

Although a reasonable amount of product wastage is permitted, an exact amount of the tissue used per application should be documented in the patient’s medical record with:

- Date and time.
- Amount of product used.
- Amount of product wasted.
- The reason for the wastage.

### Coding

#### CPT/HCPCS

- **Q4101**: Apligraf, per square centimeter, (when Apligraf is used in accordance with the below definition it should be billed with the JC modifier, as well as site modifier RT or LT.)

### 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)

Modifiers effective 01/01/2009 (as per CMS Change Request #6315)

- **JC**: Skin substitute used as a graft.
- **JD**: Skin substitute not used as a graft.

The JC and JD modifiers should be used when billing for skin substitutes. The difference between them is whether the skin substitute is used as a graft or as a skin covering. The definition of a skin graft for this purpose is whether the skin substitute is implanted into the wound to be incorporated in the healing of the wound. If the skin substitute is used to cover a wound, to protect it from contamination or fluid loss, then it is not a graft, but a dressing.
**2015 National Government Services Medicare Apligraf® Sample UB-04 Claim Form**

<table>
<thead>
<tr>
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<th>B.</th>
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<td>Smith, Jane</td>
<td>111 Maple Avenue</td>
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<td>15272 RT or LT</td>
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</table>

Apligraf is supplied in 44 units.

15271 and 15272 should be used based on the size of the wound. For example, a LEG wound measuring 30 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.

**Diagnosis Code**

All dates should be in eight digit format.
### Diagnosis Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
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Model Documentation Form for National Government Services for Apligraf®

Pretreatment:

1. Duration of ulcer

______________________________________ weeks

2. For VSU - Documented conservative measures of greater than four (4) weeks in duration, that have at minimum included regular dressing changes, debridement of necrotic tissue and standard therapeutic compression. A "failed response" is defined as an ulcer that has increased in size or depth, or for which there has been 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. Documentation of response, or lack thereof, requires measurement of the ulcer at baseline, following cessation of conservative or conventional management. Documentation should also include measurement of the ulcer immediately prior to the placement of Apligraf®.

3. Document adequate treatment of the underlying disease process contributing to the ulcer

4. Exact location of ulcer (site modifier RT or LT must be reported to indicate right-side or left-side)

5. Diagnosis of patient

6. Document that wound is free of infection, redness, drainage, underlying osteomyelitis, surrounding cellulitis, tunnels and tracts, eschar or any necrotic material

7. The patient must have adequate circulation/oxygenation to support tissue growth/wound healing as evidenced by physical examination (presence of acceptable peripheral pulses and/or Doppler toe signals and/or ankle-brachial index (ABI) of no less than 0.65 in the limb undergoing the procedure);

8. For DFU, document ulcer extends through the dermis but without tendon, muscle, capsule or bone exposure.

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Treatment:

9. Document measurement of ulcer (width and length or circumference and depth) immediately prior to application of Apligraf _______sq cm

10. Document whether this is an initial application of Apligraf or a reapplication.

11. Document the wound dressing changes and the standard conservative measures (i.e. use of pressure-reducing footwear, non-weight bearing regiment, debridement of necrotic and callused tissue, saline moistened dressings, dressing changes) accompanying the wound treatment with Apligraf.

12. Document how the wound site was prepared, and how Apligraf was fixated on the wound

13. The patient must be competent and/or have the support system required to participate in follow-up care associated with treatment of the wound with Apligraf

14. Product Wastage Documentation Requirements:

15. Date and Time:

16. Location of ulcer:

17. Approximate amount of product unit used:

18. Approximate amount of product unit discarded:

19. Reason for the wastage:

20. Manufacture’s serial/lot/batch number

Modifiers:

JC – Skin substitute used as a graft (use for Apligraf)

JD – Skin substitute not used as a graft

The JC and JD modifiers should be used when billing for skin substitutes. The difference between them is whether the skin substitute is used as a graft or as a skin covering. The definition of a skin graft for this purpose is whether the skin substitute is implanted into the wound to be incorporated in the healing of the wound. If the skin substitute is used to cover a wound, to protect it from contamination or fluid loss, then it is not a graft, but a dressing.

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