Summary of Package Insert\(^1\) for Apligraf\(^\circ\)®  
For States with Non-Published Policies – NGS

### Indications
- Non-infected partial and full-thickness skin ulcers due to VSU\(^2\) of greater than 1 month duration and which have not adequately responded to conventional ulcer therapy.
- Full-thickness neuropathic DFU\(^3\) of greater than 3 weeks duration which have not adequately responded to conventional ulcer therapy and which extend through the dermis but without tendon, muscle, capsule or bone exposure.

### Limitations
- The safety and effectiveness of Apligraf have not been established for patients receiving greater than 5 device applications.

### Coding
**CPT/HCPCS\(^1,4\)**
- Q4101: Apligraf, per square centimeter
- JW Modifier: Effective January 1, 2017- In the Physician Office Setting, POS 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.

**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
<table>
<thead>
<tr>
<th>sq cm or less wound surface area</th>
</tr>
</thead>
<tbody>
<tr>
<td>• <strong>15276</strong>: 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)</td>
</tr>
<tr>
<td>• <strong>15277</strong>: 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</td>
</tr>
<tr>
<td>• <strong>15278</strong>: 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)</td>
</tr>
</tbody>
</table>

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1 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. 2 VSU = Venous Stasis Ulcer. 3 DFU = Diabetic Foot Ulcer. 4 CPT © American Medical Association. All Rights Reserved.
Jane Smith
111 Maple Avenue
Anytown, NJ 00000

Apligraf is supplied in 44 sq cm. Apligraf is FDA approved for single use only.

Enter appropriate revenue codes for all services provided. Revenue code 636 should be used when billing for Apligraf.

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).

Please refer to “Codes Commonly Used when Billing for Apligraf” for appropriate diagnosis codes and your specific payer’s requirements.
**Apligraf**

Sample CMS-1500 Claim Form

Physician Services in an Outpatient Setting

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### Health Insurance Claim Form

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MEDICARE</strong></td>
<td>Medicare #</td>
</tr>
<tr>
<td><strong>MEDICAID</strong></td>
<td>Medicaid #</td>
</tr>
<tr>
<td><strong>CHAMPUS</strong></td>
<td>(Sponsor's SSN (if applicable))</td>
</tr>
<tr>
<td><strong>CHAMPVA</strong></td>
<td>(VA File #)</td>
</tr>
<tr>
<td><strong>GROUP HEALTH PLAN</strong></td>
<td>(SSN or ID)</td>
</tr>
<tr>
<td><strong>HEALTH PLAN</strong></td>
<td>(SSN or ID)</td>
</tr>
<tr>
<td><strong>FECA RUL LONG</strong></td>
<td>(ID)</td>
</tr>
<tr>
<td><strong>INSURED'S I.D. NUMBER</strong></td>
<td>123-45-6789A</td>
</tr>
</tbody>
</table>

**Patient Information**

- **Name:** Smith, Jane
- **Address:** 123 Any Street, Anytown, NY 00000
- **Telephone:** (973) 555-1234
- **SSN:** 123-45-6789

**Insurance Information**

- **Company:** Medicare/No Formal Policy

**Diagnosis**

- **Condition:** Illness (First symptom) or Injury (Accident) or Pregnancy (MP)
- **I.D. Number of Referring Physician:**

**Procedure**

1. **CPT/HCPCS:**
   - **Procedure Code:** 15271
   - **Date of Service:** 01/01/17
   - **Description:**

2. **CPT/HCPCS:**
   - **Procedure Code:** 15272
   - **Date of Service:** 01/01/17
   - **Description:**

**Other Information**

- **Code:**
  - **Remarks:**
    - **Remarks:** Please refer to "Codes Commonly Used when Billing for Apligraf" for appropriate diagnosis codes and your specific payer's requirements.

**Notes:**

- **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®
Sample CMS-1500 Claim Form
Physician Services in an Office Setting

2017 NGS Medicare / No Formal Policy

HEALTH INSURANCE CLAIM FORM

1. MEDICARE (Medicaid) OR CHAMPUS (CHAMPVA)
   - Medicare # (Medicaid #) (Sponsor's SSN) (VA File)
   X

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)
   - Smith, Jane

3. PATIENT'S BIRTH DATE
   - 12/13/35 M

4. INSURED'S NAME (Last Name, First Name, Middle Initial)
   - Smith, Jane

5. PATIENT'S ADDRESS (No., Street)
   - 123 Any Street

6. PATIENT'S RELATIONSHIP TO INSURED
   - Spouse

7. INSURED'S ADDRESS (No., Street)
   - 123 Any Street

8. CITY
   - Anytown

9. STATE
   - NY

10. INSURED'S POLICY GROUP OR FEDERAL NUMBER
    - 123-45-6789A

11. INSURED'S DATE OF BIRTH
    - MM DD YY

12. INSURED'S SEX
    - M

13. IS PATIENT'S CONDITION RELATED TO:

14. EMPLOYMENT? (CURRENT OR PREVIOUS)
    - X

15. AUTO ACCIDENT? (PLACE OF OCCURRENCE)
    - YES

16. EMPLOYER'S NAME OR SCHOOL NAME
    -全

17. OTHER ACCIDENT?
    - YES

18. INSURANCE PLAN NUMBER OR PROGRAM NAME
    -全

19. RESERVED FOR LOCAL USE

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

SIGNATURE ON FILE

DATE

SIGNED

DIAGNOSIS OR NATURE OF ILLNESS OR INJURY
RELATE ITEMS 13, 14 OR 4 TO ITEM 24E BY LINE

1. XXX XX

2. XXX XX

DATE(S) OF SERVICE

PLACE OF SERVICE

PROCEDURES, SERVICES, OR SUPPLIES

DIAGNOSIS CODE

$ CHARGES

DAYS OR UNITS

FAMILY PLAN EMG COB

RESERVED FOR LOCAL USE

1. 01-01-17 01-01-17 11
   - Q4101
   - 40
   - 1

2. 01-01-17 01-01-17 11
   - Q4101 JW
   - 4
   - 1

3. 01-01-17 01-01-17 11
   - 15271
   - 1

4. 01-01-17 01-01-17 11
   - 15272

5. 01-01-17 01-01-17 11

6. 01-01-17 01-01-17 11

7. 01-01-17 01-01-17 11

8. 01-01-17 01-01-17 11

9. 01-01-17 01-01-17 11

10. 01-01-17 01-01-17 11

11. 01-01-17 01-01-17 11

12. 01-01-17 01-01-17 11

13. 01-01-17 01-01-17 11

14. 01-01-17 01-01-17 11

15. 01-01-17 01-01-17 11

16. 01-01-17 01-01-17 11

17. 01-01-17 01-01-17 11

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24. 01-01-17 01-01-17 11

25. 01-01-17 01-01-17 11

26. 01-01-17 01-01-17 11

27. 01-01-17 01-01-17 11

28. 01-01-17 01-01-17 11

29. 01-01-17 01-01-17 11

30. 01-01-17 01-01-17 11

31. SIGNATURE OF PROVIDER

32. MEDICARE RESUBMISSION CODE

33. PRIOR AUTHORIZATION NUMBER

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.

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).
Model Documentation Form
for National Government Services / Summary of Package Insert for Apligraf

Pretreatment:
1. Duration of ulcer (DFU: 3 weeks, VSU: greater than 1 month)
   __________________________ weeks
2. Document failure to respond to conservative measures (a failed response is defined as an ulcer that has increased in size or depth and no indication that improvement is likely e.g., epithelial in growth and progression towards closure)
3. Document measurement of the ulcer at baseline, following cessation of conservative management.
4. Describe adequate treatment of the underlying disease process contributing to the ulcer
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. For DFU, document current HbA1C reading (HbA1C should not exceed 12%)
8. Document adequate arterial blood supply as evidenced by an ABI of 0.65 or greater

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. (Apligraf is limited to 5 applications per ulcer)
11. For Apligraf reapplications, document that applications have been successful (e.g. decrease in size or depth, increase in granulation tissue)
12. Document the wound dressing changes and the standard conservative measures accompanying the wound treatment with Apligraf
13. Document how the wound site was prepared, and how Apligraf was fixated on the wound.

**Product Wastage Documentation Requirements:**

14. Date and Time:

15. Location of ulcer:

16. Approximate amount of product unit used:

17. Approximate amount of product unit discarded:

18. Reason for the wastage:

19. Manufacture’s serial/lot/batch number

**Modifiers:**

JW- Skin substitute not applied to wound, wastage.

The JW modifier is only applied to the amount of drug or biological that is discarded.

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.