Apligraf
add life to healing

Cigna Carrier Part B Policy Primer[1,2]

ID | LCD# 22127 | Effective Date: 1/1/12

Indications

- VSU[3] of partial or full thickness, present greater than 4 to 6 weeks duration and has failed to respond to documented conservative measures.
- Neuropathic DFU[4] of of full thickness, greater than 3 weeks' duration that have failed to respond to conventional ulcer treatment which extend through the dermis but without tendon, muscle, capsule or bone exposure.

Limitations

- Use of Apligraf is limited to 3 separate applications to a given ulcer.
- For VSU there should be no fewer than 4 weeks between applications.
- **VSU:** If after 6-8 weeks and 2 applications, a 50% or greater improvement is noted and documented, then reapplication of a 3rd skin substitute will be considered for coverage. If no significant improvement has occurred further skin substitute will not be reimbursed.
- **Neuropathic DFU:** If after 3 applications if satisfactory healing progress is not noted, other treatment modalities should be considered as reapplication of the skin substitute is not recommended and will not be reimbursed.
- Apligraf allowed when adequate treatment of the underlying disease process(es) contributing to the ulcer; e.g.: diabetes or hypertension, is provided and documented in conjunction with treatment.
- Only for ulcers that are free of infection, redness, drainage, underlying osteomyelitis, surround cellulitis, sinus tracts or tunnels, eschar or any necrotic material that could interfere with the adherence of metabolically active skin substitutes and wound healing.
- For both VSU and DFU, patient must have adequate arterial blood supply as evidenced by either a readily palpable dorsal pedal pulse (2+) or ankle-brachial index (ABI) of 0.65 or greater in limb undergoing the procedure.
- Retreatment of the same ulcer within one year following the last successful DET application is not considered reasonable and necessary, and will not be reimbursed.

Documentation

- Documentation supporting the medical necessity of the service must be submitted with each claim.
- Documentation of response or lack thereof, requires measurement of the ulcer at baseline and at cessation of conservative or conventional management. Documentation should also include measurement of the ulcer immediately prior to the placement of DET substitute.
- Documentation must be available to Medicare upon request.
- Documentation should include the skin substitute used including the number of units when applicable.
- The use of more than three applications of a skin substitute is rarely medically necessary. Any applications beyond the norm will require extensive documentation of a clear and unique justification for the additional procedure as this is exceeding the usual norms of medical care.

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Cigna Carrier Part B Policy Primer[1,2] (continued)

Coding

CPT/HCPCS[5]

- **Q4101:** Apligraf, per square centimeter
  JC modifier must be billed in conjunction with Q4101

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 therof (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 therof (List separately in addition to code for primary procedure)

ICD-9-CM

- **VSU:** 454.0, 454.2, 459.31, 459.33
- **DFU:** 250.80-250.83, 707.12-707.15

1 Source: www.cms.com **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** VSU = Venous Stasis Ulcer. **4** DFU = Diabetic Foot Ulcer. **5** CPT © American Medical Association. All Rights Reserved.

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Cigna Medicare

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Sample CMS-1500 Claim Form

Physician Services in an Outpatient Setting

APPROVED OMB-0938-0008

CARRIER

PICA

HEALTH INSURANCE CLAIM FORM

PICA

1. MEDICARE [X] (Medicare #) MEDICAID [ ] (Medicaid #) CHAMPUS [ ] (Sponsor's SSN) CHAMPVA [ ] (VA File #) GROUP HEALTH PLAN [ ] (SSN or ID) FECA BLK LUNG [ ] (SSN) OTHER [ ] (ID)

1a. INSURED'S I.D. NUMBER (FOR PROGRAM IN ITEM 1): 123-45-6789A

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

3. PATIENT'S BIRTH DATE MM DD YY: 12 13 35 SEX M [ ] F [X]

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

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

6. PATIENT RELATIONSHIP TO INSURED: Self [X] Spouse [ ] Child [ ] Other [ ]

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

CITY: ANYTOWN STATE: NJ

8. PATIENT STATUS: Single [ ] Married [X] Other [ ]

Employed [ ] Full-Time Student [ ] Part-Time Student [ ]

CITY: ANYTOWN STATE: NJ

ZIP CODE: 00000 TELEPHONE (Include Area Code): (973) 555-1234

ZIP CODE: 00000 TELEPHONE (INCLUDE AREA CODE): (973) 555-1234

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

a. OTHER INSURED'S POLICY OR GROUP NUMBER

b. OTHER INSURED'S DATE OF BIRTH MM DD YY SEX M [ ] F [ ]

c. EMPLOYER'S NAME OR SCHOOL NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10. IS PATIENT'S CONDITION RELATED TO:

a. EMPLOYMENT? (CURRENT OR PREVIOUS) [ ] YES [X] NO

b. AUTO ACCIDENT? [ ] YES [X] NO PLACE (State)

c. OTHER ACCIDENT? [ ] YES [X] NO

10d. RESERVED FOR LOCAL USE

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. INSURED'S DATE OF BIRTH MM DD YY SEX M [ ] F [ ]

b. EMPLOYER'S NAME OR SCHOOL NAME

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? [ ] YES [ ] NO *If yes*, return to and complete item 9 a-d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED SIGNATURE ON FILE DATE

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED

PATIENT AND INSURED INFORMATION

14. DATE OF CURRENT: MM DD YY ILLNESS (First symptom) OR INJURY (Accident) OR PREGNANCY(LMP)

15. IF PATIENT HAS HAD SAME OR SIMILAR ILLNESS. GIVE FIRST DATE MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION FROM MM DD YY TO MM DD YY

17. NAME OF REFERRING PHYSICIAN OR OTHER SOURCE

17a. I.D. NUMBER OF REFERRING PHYSICIAN

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM MM DD YY TO MM DD YY

19. RESERVED FOR LOCAL USE

20. OUTSIDE LAB? [ ] YES [ ] NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY. (RELATE ITEMS 1,2,3 OR 4 TO ITEM 24E BY LINE)

1. XXX . XX

2. XXX . XX

VSU: 454.0, 454.2, 459.31, 459.33
DFU: 250.80-250.83, 707.12-707.15

22. MEDICAID RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24.	A: DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B: Place of Service	C: Type of Service	D: PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E: DIAGNOSIS CODE	F: $ CHARGES	G: DAYS OR UNITS	H: EPSDT Family Plan	I: EMG	J: COB	K: RESERVED FOR LOCAL USE
1	01 01 12	01 01 12	22		15271								
2	01 01 12	01 01 12	22		15272								
3													
4													
5													
6													

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 (additional 25 sq cm or part thereof).

25. FEDERAL TAX I.D. NUMBER SSN EIN: 01-2345678 [ ] [ ]

26. PATIENT'S ACCOUNT NO.: 012345678

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) [ ] YES [ ] NO

28. TOTAL CHARGE: $ XXX

29. AMOUNT PAID: $

30. BALANCE DUE: $

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

SIGNED DATE

32. NAME AND ADDRESS OF FACILITY WHERE SERVICES WERE RENDERED (If other than home or office)

33. PHYSICIAN'S, SUPPLIER'S BILLING NAME, ADDRESS, ZIP CODE & PHONE #

PIN# GRP#

PHYSICIAN OR SUPPLIER INFORMATION

(APPROVED BY AMA COUNCIL ON MEDICAL SERVICE 8/88) ***PLEASE PRINT OR TYPE*** FORM CMS-1500 (12-90), FORM RRB-1500, FORM OWCP-1500

Cigna Medicare

Apligraf®

Sample CMS-1500 Claim Form

Physician Services in an Office Setting

PLEASE DO NOT STAPLE IN THIS AREA

APPROVED OMB-0938-0008

CARRIER

PICA

HEALTH INSURANCE CLAIM FORM

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CITY: ANYTOWN STATE: NJ

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ZIP CODE: 00000 TELEPHONE (Include Area Code): (973) 555-1234

ZIP CODE: 00000 TELEPHONE (INCLUDE AREA CODE): (973) 555-1234

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (CURRENT OR PREVIOUS) [ ] YES [X] NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M [ ] F [ ]

b. OTHER INSURED'S DATE OF BIRTH MM DD YY SEX M [ ] F [ ]

b. AUTO ACCIDENT? [ ] YES [X] NO PLACE (State)

b. EMPLOYER'S NAME OR SCHOOL NAME

c. EMPLOYER'S NAME OR SCHOOL NAME

c. OTHER ACCIDENT? [ ] YES [X] NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. RESERVED FOR LOCAL USE

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? [ ] YES [ ] NO *If yes*, return to and complete item 9 a-d.

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13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

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DFU: 250.80-250.83, 707.12-707.15

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3	01	01	12	01	01	12	11		15272								
4																	
5																	
6																	

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 (additional 25 sq cm or part thereof).

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33. PHYSICIAN'S, SUPPLIER'S BILLING NAME, ADDRESS, ZIP CODE & PHONE #

PIN# GRP#

PHYSICIAN OR SUPPLIER INFORMATION

Apligraf

Model Documentation Form for Cigna

Pretreatment:

1. Duration of ulcer (**DFU:** 3 weeks, **VSU**: 4 to 6 weeks)
   ________________________weeks

2. Document that the ulcer has been treated with intensive conventional non surgical therapy for a minimum for 4-6 weeks and has shown at least a 28% reduction in size but less than a 60% reduction

3. Document all treatment modalities utilized in the past

4. Document failure to respond to conservative measures (a failed response is defined as an ulcer that has increased in size or depth, no change in baseline size or depth, and no sign of improvement, such as granulation, epitheliazation or progress towards closing).

5. Document measurement of the ulcer at baseline, following cessation of conservative management.

6. Document that adequate treatment of the underlying disease states have been and continue to be treated appropriately based on current national standards of care and that pertinent diseases are controlled

7. Document the exact location of the ulcer

8. Diagnosis of patient and date of onset:
   VSU: 454.0, 454.2, 459.31, 459.33
   DFU: 250.80-250.83, 707.12-707.15

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

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10. For DFU, document current HbA1C reading (HbA1C should not exceed 12%).

11. Document adequate arterial blood supply as evidenced by an ABI of 0.65 or greater, or dorsal pedal pulse of 2+

Treatment:

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

13. Document whether this is an initial application of Apligraf or a reapplication. (Cigna limits Apligraf to 3 applications per ulcer. For VSU, generally 2 applications of the skin substitute are indicated. However, if after 6 to 8 weeks of compression treatment, and 2 applications of the skin substitute, a 50 percent or greater improvement is noted and documented, then application of a third skin substitute will be considered for coverage)

14. For Apligraf reapplications, document that applications have been successful (e.g. decrease in size or depth, increase in granulation tissue)

15. Document the standard conservative measures (e.g. use of pressure-reducing footwear, non-weight bearing regiment, debridement of necrotic and callused tissue or any other wound care methods) that were used in conjunction with the Apligraf application.

16. Document whether the patient is competent and/or has the support system required to participate in follow-up care associated with treatment of the wound with Apligraf.

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

Modifiers:

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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Apligraf

ICD-9 CM Codes commonly used when billing for Apligraf[1]

454.0 Varicose veins of lower extremities, with ulcer
454.1 Varicose veins of lower extremities, with inflammation
454.2 Varicose veins of lower extremities, with ulcer and inflammation
459.11 Postphlebitic syndrome with ulcer
459.13 Postphlebitic syndrome with ulcer and inflammation
459.31 Chronic venous hypertension with ulcer
459.33 Chronic venous hypertension with ulcer and inflammation
459.81 Other specified disorders of circulatory system, venous (peripheral) insufficiency, unspecified

707.10 Ulcer of lower limb, unspecified
707.11 Ulcer of thigh
707.12 Ulcer of calf
707.13 Ulcer of ankle
707.14 Ulcer of heel and midfoot (Plantar surface of midfoot)
707.15 Ulcer of other part of foot (Toes)
707.19 Ulcer of other part of lower limb
707.8 Chronic ulcer of other specified sites

249.00 Secondary diabetes mellitus without mention of complication, not stated as uncontrolled, or unspecified
249.01 Secondary diabetes mellitus without mention of complication, uncontrolled
249.10 Secondary diabetes mellitus with ketoacidosis, not stated as uncontrolled, or unspecified
249.11 Secondary diabetes mellitus with ketoacidosis, uncontrolled
249.20 Secondary diabetes mellitus with hyperosmolarity, not stated as uncontrolled, or unspecified
249.21 Secondary diabetes mellitus with hyperosmolarity, uncontrolled
249.30 Secondary diabetes mellitus with other coma, not stated as uncontrolled, or unspecified
249.31 Secondary diabetes mellitus with other coma, uncontrolled

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249.40 Secondary diabetes mellitus with renal manifestations, not stated as uncontrolled, or unspecified

249.41 Secondary diabetes mellitus with renal manifestations, uncontrolled

249.50 Secondary diabetes mellitus with ophthalmic manifestations, not stated as uncontrolled, or unspecified

249.51 Secondary diabetes mellitus with ophthalmic manifestations, uncontrolled

249.60 Secondary diabetes mellitus with neurological manifestations, not stated as uncontrolled, or unspecified

249.61 Secondary diabetes mellitus with neurological manifestations, uncontrolled

249.70 Secondary diabetes mellitus with peripheral circulatory disorders, not stated as uncontrolled, or unspecified

249.71 Secondary diabetes mellitus with peripheral circulatory disorders, uncontrolled

249.80 Secondary diabetes mellitus with other specified manifestations, not stated as uncontrolled, or unspecified

249.81 Secondary diabetes mellitus with other specified manifestations, uncontrolled

249.90 Secondary diabetes mellitus with unspecified complication, not stated as uncontrolled, or unspecified

249.91 Secondary diabetes mellitus with unspecified complication, uncontrolled

250.60 Diabetes With Neurological Manifestations, Type II Or Unspecified Type, not stated as uncontrolled

250.61 Diabetes With Neurological Manifestations, Type I (Juvenile Type), not stated as uncontrolled

250.62 Diabetes With Neurological Manifestations, Type II Or Unspecified Type, uncontrolled

250.63 Diabetes With Neurological Manifestations, Type I (Juvenile Type), uncontrolled

250.70 Diabetes With Peripheral Circulatory Disorders, Type II Or Unspecified type, not stated as uncontrolled

250.71 Diabetes With Peripheral Circulatory Disorders, Type I (Juvenile Type), not stated as uncontrolled

250.72 Diabetes With Peripheral Circulatory Disorders, Type II Or Unspecified type, uncontrolled

250.73 Diabetes With Peripheral Circulatory Disorders, Type I (Juvenile Type), uncontrolled

250.80 Diabetes with other specified manifestations, type II or unspecified type, not stated as uncontrolled

250.81 Diabetes with other specified manifestations, type I, not stated as uncontrolled

250.82 Diabetes with other specified manifestations, type II or unspecified type, uncontrolled

250.83 Diabetes with other specified manifestations, type I, uncontrolled

[1] This brief summary is provided for consideration only. All codes provided herein are for information purposes only and shall not be construed as a statement, promise, or guarantee that these codes are accurate or reimbursement will be received. Coding requirements are subject to change at any time, therefore check with your local payer regularly to verify prior authorization requirements.

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