

Pinnacle FI Part A and Part B Article Primer^{1,2}

Part A: AR, MS & LA | Part B: AR & LA | Effective Date: 1/1/12

Indications

- Provided in accordance with the material's FDA approved package label. (It is the responsibility of the provider to know this information. Use off-label will be subject to denial and potential recoupment of money.)
- Applied to partial or full thickness wounds (according to each products FDA label) not involving tendon, muscle, joint capsule or exhibiting exposed bone or sinus tract.
- Applied to wounds that have demonstrated a failed or had insufficient response to no fewer than four weeks of conservative wound-care measure when applied to chronic wounds
- Applied to wounds reasonably expected to heal and not applied to wounds demonstrating such hostile host environment that destruction of the substitute is highly likely.
- Applied to wounds that are clean and free of infection.
- Applied to wounds of reasonable size given the clinical circumstances. Medicare would not expect routine use of these products in treating small wounds, (See definition of small wound below.), unless documentation clearly demonstrated the wound to be refractory to conservative treatment (or is only improving to this size with a prior application of these products). Medicare recognizes neuropathic foot ulcers may be small with deep tunneling which may require these products. The intent of this coverage statement is to let providers know small (but refractory) ulcers may be reviewed intensely for medical necessity.
- Applied only to wound with adequate circulation/oxygenation to support tissue growth/wound healing as evidenced by physical examination with presence of acceptable peripheral pulses and/or Doppler toe signals and/or ankle-brachial index (ABI) of no less than 0.65.

Limitations

- Q4101 (Apligraf) no more than 5 applications
- However, it would be expected that all wounds would not need the maximum allowed products used. Consistent use of the maximum allowed will be subject to review.
- There should be no fewer than two (2) weeks between applications for venous stasis ulcers and there should be no fewer than three (3) weeks between applications for neuropathic diabetic foot ulcers, except when more frequent applications are either a part of the FDA product specific labeling instructions or are clearly supported by medical record documentation of medically reasonable and necessary indication.
- For venous stasis ulcer, two (2) applications of the bioengineered products skin are indicated unless FDA product specific labeling provides for additional applications. If after twelve (12) weeks of compression treatment and the appropriate number of applications of the skin substitutes a 50% or greater improvement is noted and documented, then one or more subsequent re-applications of the skin substitutes will be considered for Medicare coverage. Otherwise, reapplication of the skin substitute is not recommended and other treatment modalities should be considered.
- Repeat applications of skin substitutes/replacements are not indicated when applications heretofore were unsuccessful.
- Retreatment of healed ulcers or ulcers for which an initial course of treatment with skin substitutes was unsuccessful is not indicated.

Continued on next page >

<h2>Documentation</h2>	<ul style="list-style-type: none"> ■ The medical records must clearly show that the criteria in “Indications and Limitation of Coverage and/or Medical Necessity” have been met. ■ The medical records must clearly document that conservative pretreatment wound management has been tried and failed to induce healing. ■ There must be a documented plan of care with documented goals and documented provider follow-up present in the patient’s medical records. Wound healing must be medically reasonable expectation based on the clinical circumstances documented. ■ Documentation of the progress of the wound’s response to treatment must be made for each service billed. At a minimum this must include current wound size, wound depth, presence and extent of or absence of obvious signs of infection, presence and extent of or absence of necrotic, devitalized or non-viable tissue, or other material in the wound that is expected to inhibit healing or promote adjacent tissue breakdown ■ The medical records must document wound treatment is accompanied by appropriate wound dressing during the healing period and by appropriate compressive therapy for foot ulcer(s) and appropriate steps to off load wound pressure during follow-up. Adequate patient compliance must be clearly ascertained and documented during such treatment.
<h2>Coding</h2>	<p>CPT/HCPCS⁵</p> <ul style="list-style-type: none"> ■ Q4101: Apligraf, per square centimeter <p>Application Codes for Leg</p> <ul style="list-style-type: none"> ■ 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) <p>Application Codes for Foot</p> <ul style="list-style-type: none"> ■ 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) <p>ICD-9-CM</p> <ul style="list-style-type: none"> ■ 250.80-250.83, 440.23, 454.0, 454.2, 459.11, 459.31, 459.33, 707.10-707.19 <p>For coding neuropathic diabetic ulcers, two codes are necessary. Code the causal condition (250.80 + range) as primary diagnosis and ulcer (707.10 + range) as the secondary diagnosis.</p>

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.

2012 Pinnacle | Apligraf® Sample UB-04 Claim Form

1 Anytown Hospital 123 Medical Drive Anytown, NJ 00000		2		3a PAT. CNTL # b. MED. REC. # HIC 012345678A		4 TYPE OF BILL 131	
5 FED. TAX NO. 01-2345678		6 STATEMENT COVERS PERIOD FROM 01012012		7 THROUGH 01012012			

8 PATIENT NAME a Smith, Jane		9 PATIENT ADDRESS a 111 Maple Avenue						c NJ		d 00000		e	
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10 BIRTHDATE 01011935		11 SEX F		12 DATE			13 HR			14 TYPE			15 SRC			16 DHR			17 STAT			18			19			20			21			22			23			24			25			26			27			28			29 ACDT STATE			30		
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31 OCCURRENCE CODE DATE		32 OCCURRENCE CODE DATE		33 OCCURRENCE CODE DATE		34 OCCURRENCE CODE DATE		35 OCCURRENCE CODE DATE		36 OCCURRENCE SPAN FROM THROUGH		37 OCCURRENCE SPAN FROM THROUGH	
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All dates should be in eight digit format.

Jane Smith
111 Maple Avenue
Anytown, NJ 00000

38		39 VALUE CODES CODE AMOUNT		40 VALUE CODES CODE AMOUNT		41 VALUE CODES CODE AMOUNT	
a		b		c		d	

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
1 636	Apligraf	Q4101	01012012	44	XXX:XX		
2 360	Application, first 25 sq cm	15271	01012012	1	XXX:XX		
3 360	Application, each additional 25 sq cm	15272	01012012	1	XXX:XX		

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 30 sq cm, would be billed using 15271 (first 25 sq cm or less) and 15272 (additional 25 sq cm or part thereof).

Apligraf is supplied in 44 units.

PAGE ____ OF ____		CREATION DATE		TOTALS →	
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50 PAYER NAME A Medicare		51 HEALTH PLAN ID A987654X		52 REL. INFO		53 ASG. BEN.		54 PRIOR PAYMENTS		55 EST. AMOUNT DUE		56 NPI 57 OTHER PRV ID	
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58 INSURED'S NAME A Smith, Jane		59 P.REL.		60 INSURED'S UNIQUE ID		61 GROUP NAME		62 INSURANCE GROUP NO.	
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63 TREATMENT AUTHORIZATION CODES		64 DOCUMENT CONTROL NUMBER		65 EMPLOYER NAME	
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250.80-250.83, 440.23, 454.0, 454.2, 459.11, 459.31, 459.33, 707.10-707.19

66 DX XXX:XX		68	
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69 ADMIT DX		70 PATIENT REASON DX		71 PPS CODE		72 EQI		73	
74 PRINCIPAL PROCEDURE CODE DATE		a. OTHER PROCEDURE CODE DATE		b. OTHER PROCEDURE CODE DATE		75		76 ATTENDING NPI QUAL	
c. OTHER PROCEDURE CODE DATE		d. OTHER PROCEDURE CODE DATE		e. OTHER PROCEDURE CODE DATE		77 OPERATING NPI QUAL		78 OTHER NPI QUAL	
79 OTHER NPI QUAL		79 OTHER NPI QUAL		79 OTHER NPI QUAL		79 OTHER NPI QUAL		79 OTHER NPI QUAL	

80 REMARKS		81CC a		81CC b		81CC c		81CC d	
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Apligraf®

APPROVED OMB-0938-0008

PLEASE DO NOT STAPLE IN THIS AREA



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

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

HEALTH INSURANCE CLAIM FORM

1. MEDICARE (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

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 Spouse Child Other

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

CITY **ANYTOWN** STATE **NJ**

8. PATIENT STATUS Single Married Other

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)

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 NO

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

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

b. AUTO ACCIDENT? YES NO PLACE (State)

c. EMPLOYER'S NAME OR SCHOOL NAME

c. OTHER ACCIDENT? YES NO

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.

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.

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 **SIGNATURE ON FILE** DATE

SIGNED

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)

22. MEDICAID RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

250.80-250.83, 440.23, 454.0, 454.2, 459.11, 459.31, 459.33, 707.10-707.19

24.	A		B		C	D	E	F	G	H	I	J	K	
	DATE(S) OF SERVICE From MM DD YY	To MM DD YY	Place of Service	Type of Service										PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS MODIFIER
1	01	01	12	01	01	12	11							44
2	01	01	12	01	01	12	11							
3	01	01	12	01	01	12	11							
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).

25. FEDERAL TAX I.D. NUMBER **01-2345678** SSN EIN

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.)

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 #

SIGNED DATE

PIN# GRP#

Model Documentation Form for Pinnacle

Pretreatment:

1. Duration of pre treatment conservative /conventional management (by you or the predecessor physician)
_____ weeks
2. Exact location of ulcer (for DFU, plantar, medial or lateral area of the foot)
3. Duration of ulcer (VLU - greater than 1 month for; DFU - greater than 3 weeks)
4. Diagnosis of patient
440.23, 454.0, 454.2, 459.11, 459.31, 459.33, 707.10-707.19, 250.80-250.83
5. Document size of the ulcer (depth, width and length or circumference) at initial presentation
6. Document lack of response to conservative therapy. Include size of the ulcer (depth, width and length or circumference) following cessation of conservative therapy.
7. Document treatment of underlying diseases
8. Document that the wound is free of infection
9. Document applied to partial or full thickness wounds not involving tendon, muscle, joint capsule or exhibiting exposed bone or sinus tract.
10. Document plan of care
11. For DFU, document appropriate steps to off-load pressure during treatment
12. Document adequate circulation /oxygenation to support growth (presence of acceptable peripheral pulses or Doppler toe signals or ABI of no less than 0.65)

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Treatment:

13. Document measurement of ulcer (width and length or circumference and depth) immediately prior to application of Apligraf _____sq cm
14. Document whether this is an initial application of Apligraf or a reapplication. (Per Pinnacle, no more than 5 applications of Apligraf per ulcer is permitted)
15. For Apligraf VSU reapplications, (two (2) applications of the bioengineered products skin are indicated unless FDA product specific labeling provides for additional applications) document- If after twelve (12) weeks of compression treatment and the appropriate number of applications of the skin substitutes a 50% or greater improvement is noted and documented, then one or more subsequent re-applications of the skin substitutes will be considered for Medicare coverage.
16. Document how Apligraf was fixated on the wound

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ICD-9 CM Codes commonly used when billing for Apligraf¹

- 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

Continued on next page >

- 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.