



Summary of Package Insert¹

For States with Non-Published Policies

Indications	<ul style="list-style-type: none">■ Non-infected partial and full-thickness skin ulcers due to VSU² of greater than 1 month duration and which have not adequately responded to conventional ulcer therapy.■ Full-thickness neuropathic DFU³ 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	<ul style="list-style-type: none">■ The safety and effectiveness of Apligraf have not been established for patients receiving greater than 5 device applications.■ No timeframe between applications/except for 10 day global.
Coding	CPT/HCPCS^{1,4} <ul style="list-style-type: none">■ 15340: Application, first 25 sq cm of wound size■ 15341: Application, each additional 25 sq cm of wound size■ Q4101: Apligraf, per square centimeter <i>For Palmetto GBA, JC modifier must be billed in conjunction with Q4101 along with JW modifier for wastage</i>

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.

No Formal Policy—PI | Apligraf® Sample UB-04 Claim Form

* Anytown Hospital 123 Medical Drive Anytown, NJ 00000		HIC 012345678A		TYPE OF BILL 131	
PATIENT NAME Smith, Jane		PATIENT ADDRESS 111 Maple Avenue Anytown NJ 00000		FEDERAL TAX ID NO 01-2345678	
BIRTH DATE 01011935		OCCURRENCE DATE 01012009		OCCURRENCE PERIOD 01012009	
Jane Smith 111 Maple Avenue Anytown, NJ 00000		VALUE CODES AMOUNT			
636 Apligraf		Q4101		01012010 44	
360 Application, first 25 sq cm		15340		01012010 1	
360 Application, each additional 25 sq cm		15341		01012010 1	
TOTALS		XXXXX XXXXX XXXXX			
PAYER NAME Medicare		HEALTH PLAN ID A987654X		TOTAL DUE XXXXX	
INSURED NAME Smith, Jane		GROUP NAME			
TREATMENT AUTHORIZATION CODE		DOCUMENT CONTROL NUMBER		EMPLOYER NAME	
ICD-9-CM CODE XXX.XX		ICD-9-CM CODE			
ADDITIONAL PROCEDURE CODE DATE		OTHER PROCEDURE CODE DATE		ATTENDING PHYSICIAN LAST FIRST	
OTHER PROCEDURE CODE DATE		OTHER PROCEDURE CODE DATE		OPERATING PHYSICIAN LAST FIRST	
OTHER PROCEDURE CODE DATE		OTHER PROCEDURE CODE DATE		OTHER PHYSICIAN LAST FIRST	
OTHER PROCEDURE CODE DATE		OTHER PROCEDURE CODE DATE		OTHER PHYSICIAN LAST FIRST	

All dates should be in eight digit format.

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

CPT 15340 and 15341 should be used based on the size of the wound. For example, a wound measuring 30 sq cm, would be billed using 15340 (first 25 sq cm) and 15341 (additional 25 sq cm or part thereof).

Apligraf is supplied in 44 units.

Please refer to "Codes Commonly Used when Billing for Apligraf" for appropriate ICD-9-CM diagnosis codes and your specific payer's requirements.

No Formal Policy—PI

PLEASE DO NOT STAPLE IN THIS AREA



Apligraf®
Sample CMS-1500 Claim Form
Physician Services in an Outpatient Setting

APPROVED CMS-0020-0008

CARRIER
PATIENT AND INSURED INFORMATION
PHYSICIAN OR SUPPLIER INFORMATION

HEALTH INSURANCE CLAIM FORM																			
1. MEDICARE <input type="checkbox"/> MEDICAID <input type="checkbox"/> CHAMPUS <input type="checkbox"/> CHAMPVA <input type="checkbox"/> GROUP HEALTH PLAN <input type="checkbox"/> FICA BLK LUNG <input type="checkbox"/> OTHER <input type="checkbox"/>					1a. INSURED'S I.D. NUMBER (FOR PROGRAM IN ITEM 1)														
X (Medicare #) (Medicaid #) (Sponsor's ID#) (VA File #)					123-45-6789A														
2. PATIENT'S NAME (Last Name, First Name, Middle Initial)					3. PATIENT'S BIRTH DATE		SEX		4. INSURED'S NAME (Last Name, First Name, Middle Initial)										
Smith, Jane					MM DD YY 12 13 35		M <input type="checkbox"/> F <input checked="" type="checkbox"/>		Smith, Jane										
5. PATIENT'S ADDRESS (No., Street)					6. PATIENT RELATIONSHIP TO INSURED			7. INSURED'S ADDRESS (No., Street)											
123 Any Street					Self <input checked="" type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other <input type="checkbox"/>			123 Any Street											
CITY			STATE		8. PATIENT STATUS			CITY		STATE									
ANYTOWN			NJ		Single <input type="checkbox"/> Married <input checked="" type="checkbox"/> Other <input type="checkbox"/>			ANYTOWN		NJ									
ZIP CODE		TELEPHONE (Include Area Code)			Employed <input type="checkbox"/> Full-Time <input type="checkbox"/> Part-Time <input type="checkbox"/>		ZIP CODE		TELEPHONE (INCLUDE AREA CODE)										
00000		(973) 555-1234			Student <input type="checkbox"/>		00000		(973) 555-1234										
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)					10. IS PATIENT'S CONDITION RELATED TO:														
a. OTHER INSURED'S POLICY OR GROUP NUMBER					a. EMPLOYMENT? (CURRENT OR PREVIOUS)														
b. OTHER INSURED'S DATE OF BIRTH					b. AUTO ACCIDENT? PLACE (State)														
c. EMPLOYER'S NAME OR SCHOOL NAME					c. OTHER ACCIDENT?														
d. INSURANCE PLAN NAME OR PROGRAM NAME					10c. RESERVED FOR LOCAL USE														
11. INSURED'S POLICY GROUP OR FICA NUMBER					d. IS THERE ANOTHER HEALTH BENEFIT PLAN?														
12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE					13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE														
SIGNED SIGNATURE ON FILE DATE					SIGNED														
14. DATE OF CURRENT ILLNESS (First symptom) OR INJURY (Accident) OR PREGNANCY (LMP)			15. IF PATIENT HAS HAD SAME OR SIMILAR ILLNESS: GIVE FIRST DATE			16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION													
MM DD YY			MM DD YY			FROM MM DD YY TO MM DD YY													
17. NAME OF REFERRING PHYSICIAN OR OTHER SOURCE					17a. I.D. NUMBER OF REFERRING PHYSICIAN														
19. RESERVED FOR LOCAL USE					20. OUTSIDE LAB? \$ 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.														
1. XXX XX					23. PRIOR AUTHORIZATION NUMBER														
2. XXX XX																			
24. A. DATE(S) OF SERVICE						B. PLACE OF SERVICE		C. TYPE OF SERVICE		D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) (For govt. claims, see back)		E. DIAGNOSIS (ICD-9-CM)		F. SOURCE		G. DAYS EPBDT OR (Family) CMC COL		H. RESERVED FOR LOCAL USE	
MM DD YY MM DD YY						Service		Service		CPT/HCPCS MODIFIER		ICD-9-CM							
01 01 10 01 01 10						22				15340									
01 01 10 01 01 10						22				15341									
25. FEDERAL TAX I.D. NUMBER					BBN EIN		26. PATIENT'S ACCOUNT NO.			27. ACCEPT ASSIGNMENT? (For govt. claims, see back)		28. TOTAL CHARGE		29. AMOUNT PAID		30. BALANCE DUE			
01-2345678							012345678			YES <input type="checkbox"/> NO <input type="checkbox"/>		\$ XXX		\$		\$			
31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREE 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#				

Please refer to "Codes Commonly Used when Billing for Apligraf" for appropriate ICD-9-CM diagnosis codes and your specific payer's requirements.

CPT 15340 and 15341 should be used based on the size of the wound. For example, a wound measuring 30 sq cm, would be billed using 15340 (first 25 sq cm) and 15341 (additional 25 sq cm or part thereof).

No Formal Policy—PI

PLEASE DO NOT STAPLE IN THIS AREA



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

APPROVED CMS-0028-0008

CARRIER
PATIENT AND INSURED INFORMATION
PHYSICIAN OR SUPPLIER INFORMATION

HEALTH INSURANCE CLAIM FORM																					
1. MEDICARE <input type="checkbox"/> MEDICAID <input type="checkbox"/> CHAMPUS <input type="checkbox"/> CHAMPVA <input type="checkbox"/> GROUP HEALTH PLAN <input type="checkbox"/> FICA BLK LUNG <input type="checkbox"/> OTHER <input type="checkbox"/>					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 M <input type="checkbox"/> F <input checked="" type="checkbox"/>																
5. PATIENT'S ADDRESS (No., Street) 123 Any Street					6. PATIENT RELATIONSHIP TO INSURED Self <input checked="" type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other <input type="checkbox"/>																
7. INSURED'S ADDRESS (No., Street) 123 Any Street					8. PATIENT STATUS Single <input type="checkbox"/> Married <input checked="" type="checkbox"/> Other <input type="checkbox"/>																
CITY ANYTOWN STATE NJ					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: a. EMPLOYMENT? (CURRENT OR PREVIOUS) YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> b. AUTO ACCIDENT? PLACE (State) YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> c. OTHER ACCIDENT? YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>																
4. OTHER INSURED'S POLICY OR GROUP NUMBER					11. INSURED'S POLICY GROUP OR FICA NUMBER																
b. OTHER INSURED'S DATE OF BIRTH MM DD YY M <input type="checkbox"/> F <input type="checkbox"/>					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																
c. EMPLOYER'S NAME OR SCHOOL NAME					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																
d. INSURANCE PLAN NAME OR PROGRAM NAME					14. DATE OF CURRENT: ILLNESS (First symptom) OR INJURY (Accident) OR PREGNANCY (LMP) MM DD YY																
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					15. IF PATIENT HAS HAD SAME OR SIMILAR ILLNESS: GIVE FIRST DATE MM DD YY																
14. DATE OF CURRENT: ILLNESS (First symptom) OR INJURY (Accident) OR PREGNANCY (LMP) 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																
19. RESERVED FOR LOCAL USE					18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM MM DD YY TO MM DD YY																
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY. (RELATE ITEMS 1, 2, 3 OR 4 TO ITEM 24E BY LINE)					20. OUTSIDE LAB? \$ CHARGES YES <input type="checkbox"/> NO <input type="checkbox"/>																
1. XXX XX					22. MEDICAID RESUBMISSION CODE ORIGINAL REF. NO.																
2. XXX XX					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 EPBD Family Plan		I EMB		J COB		K RESERVED FOR LOCAL USE	
01 01 10 01 01 10		11		Q4101						44											
01 01 10 01 01 10		11		15340																	
01 01 10 01 01 10		11		15341																	
25. FEDERAL TAX I.D. NUMBER 01-2345678 BBN EIN					26. PATIENT'S ACCOUNT NO. 012345678					27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES <input type="checkbox"/> NO <input type="checkbox"/>					28. TOTAL CHARGE \$ XXX						
29. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREE OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)					30. NAME AND ADDRESS OF FACILITY WHERE SERVICES WERE RENDERED (if other than home or office)					29. AMOUNT PAID \$					30. BALANCE DUE \$						
31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREE 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 #											

Please refer to "Codes Commonly Used when Billing for Apligraf" for appropriate ICD-9-CM diagnosis codes and your specific payer's requirements.

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CPT 15340 and 15341 should be used based on the size of the wound. For example, a wound measuring 30 sq cm, would be billed using 15340 (first 25 sq cm) and 15341 (additional 25 sq cm or part thereof).



Model Documentation Form for No Formal Policy / Summary of Package Insert

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
VSU: 454.0, 454.1, 454.2, 459.11, 459.13, 459.31, 459.33, 459.81
DFU: 707.10-707.15, 707.19, 249.00-249.01, 249.10-249.11, 249.20-249.21, 249.30-249.31, 249.40-249.41, 249.50-254.951, 249.60-249.61, 249.70-249.71, 249.80-249.81, 250.60-250.63, 250.70-250.73, 250.80-250.83
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

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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

Wound Size	CPT 15340	CPT 15341
< 25 sq cm	x1	-
26-50 sq cm	x1	x1
51-75 sq cm	x1	x2
76-100 sq cm	x1	x3
> 100 sq cm	x1	Continue based on 25 sq cm or part thereof

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

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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** Postphlebotic syndrome with ulcer
- 459.13** Postphlebotic 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.