



Noridian Policy Primer^{1,2}

MAC A: AZ, MT, ND, SD, UT & WY | MAC B: AZ, MT, ND, SD, UT & WY | LCD# L24409 | Effective Date: 1/01/2010 | Jurisdiction 3 MAC
Legacy Part A: AK, ID, MN, OR & WA | Legacy Part B: AK, OR & WA

Indications	<ul style="list-style-type: none">■ VSU³ of greater than 3 month duration that have failed to respond to documented conservative treatment of greater than 2 months.■ DFU⁴ of greater than 4 weeks duration that have failed to respond to documented conservative treatment of greater than 1 month.
Limitations	<ul style="list-style-type: none">■ Use of Apligraf is limited to 3 separate applications to any given ulcer, or more only when utilized with adherence to specific FDA labeling instructions and criteria.■ 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 indications.■ Treatment of any ulcer will typically last approximately twelve (12) weeks.■ For VSU's, two (2) applications of the skin substitute are indicated. If after twelve (12) weeks of compression treatment, and two (2) applications of the skin substitute, a 50 percent or greater improvement is noted and documented, then re-application of a third skin substitute will be considered for coverage. Otherwise, re-application of the skin substitute is not recommended and other treatment modalities should be considered.■ For neuropathic DFU's, if after nine (9) weeks of treatment, and three (3) applications of the skin substitute, satisfactory healing progress is not noted, then reapplication of the skin substitute is not recommended and other treatment modalities should be considered.■ Re-treatment for any single ulcer within one year is not covered.
Documentation	<ul style="list-style-type: none">■ The ulcer must be free of infection and underlying osteomyelitis.■ Documentation must be provided that these conditions have been successfully treated, resolved, prior to instituting skin substitute treatment.■ Treatment for the underlying disease must be provided and documented.■ For DFUs, steps must be taken to off-load pressure during treatment and documented in the patient's medical record.■ Measurement must be taken of the initial ulcer, after cessation of conservative management and the size at beginning of Apligraf treatment.

Continued on next page >

Noridian Policy Primer^{1,2} (continued)

Coding

CPT/HCPCS⁵

- **15340:** Tissue cultured allogeneic skin substitute; first 25 sq cm or less
- **15341:** Tissue cultured allogeneic skin substitute; ea. additional 25 sq cm
- **Q4101:** Apligraf, per square centimeter

ICD-9-CM

- **VSU:** 454.0, 454.2

Or you may bill:

- **VSU (Primary):** 707.10-707.15, 707.19
- **VSU (Secondary):** 459.81
- **DFU (Primary):** 707.10-707.15*, 707.19*
- **DFU (Secondary):** 249.00-249.01, 249.10-249.11, 249.20-249.21, 249.30-249.31, 249.40-249.41, 249.50-249.51, 249.60-249.61, 249.70-249.71, 249.80-249.81, 249.90-249.91, 250.60-250.63, 250.70-250.73, 250.80-250.83*

*When billing for ulcers caused by diabetes, the provider must use both a code from the diabetes range and a code from the ulcer of lower limb range (707.10-707.15, 707.19).

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.

Noridian Medicare 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 THROUGH 01012009	

** OCCURRENCE DATE 01011935		** OCCURRENCE DATE 01012009		** OCCURRENCE PERIOD THROUGH 01012009	
** OCCURRENCE DATE 01011935		** OCCURRENCE DATE 01012009		** OCCURRENCE PERIOD THROUGH 01012009	
** OCCURRENCE DATE 01011935		** OCCURRENCE DATE 01012009		** OCCURRENCE PERIOD THROUGH 01012009	

All dates should be in eight digit format.

Jane Smith
 111 Maple Avenue
 Anytown, NJ 00000

43 REVENUE CODE	43 DESCRIPTION	44 HICPC (ICD-9-CM) HICPC CODE	45 SERVICE DATE	46 QUANTITY	47 TOTAL CHARGE	48 UNITS
636	Apligraf	Q4101	01012010	44	XXX.XX	
360	Application, first 25 sq cm	15340	01012010	1	XXX.XX	
360	Application, each additional 25 sq cm	15341	01012010	1	XXX.XX	

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.

** PAYER NAME Medicare		** HEALTH PLAN ID A987654X		** PRIOR PERIODS 01012009		** EST. AMOUNT DUE XXX.XX	
** INSURED NAME Smith, Jane		** REL. INSURED NUMBER ID 01012009		** GROUP NAME Medicare		** ORGANIZATION GROUP NO. 01012009	

VSU: 454.0, 454.2 Or you may bill: VSU (Primary): 707.10-707.15, 707.19; VSU (Secondary): 459.81
DFU (Primary): 707.10-707.15*, 707.19*; DFU (Secondary): 249.00-249.01, 249.10-249.11, 249.20-249.21, 249.30-249.31, 249.40-249.41, 249.50-249.51, 249.60-249.61, 249.70-249.71, 249.80-249.81, 249.90-249.91, 250.60-250.63, 250.70-250.73, 250.80-250.83*
 *When billing for ulcers caused by diabetes, the provider must use both a code from the diabetes range and a code from the ulcer of lower limb range (707.10-707.15, 707.19).

** ADMIT DX XXX.XX		** REVISION INDEX 01012009		** OTHER PROCEDURE DATE 01012009		** OTHER PROCEDURE DATE 01012009	
** OTHER PROCEDURE DATE 01012009		** OTHER PROCEDURE DATE 01012009		** OTHER PROCEDURE DATE 01012009		** OTHER PROCEDURE DATE 01012009	

PLEASE DO NOT STAPLE IN THIS AREA



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

APPROVED CMS-0928-0008

CARRIER
PATIENT AND INSURED INFORMATION
PHYSICIAN OR SUPPLIER INFORMATION

HEALTH INSURANCE CLAIM FORM													
1. MEDICARE <input checked="" type="checkbox"/> (Medicare #) <input type="checkbox"/> MEDICAID <input type="checkbox"/> (Medicaid #) <input type="checkbox"/> CHAMPUS <input type="checkbox"/> (Sponsor's ID#) <input type="checkbox"/> CHAMPVA <input type="checkbox"/> (VA File #) <input type="checkbox"/> GROUP HEALTH PLAN <input type="checkbox"/> (ID# or ID) <input type="checkbox"/> FICA BLK LUNG <input type="checkbox"/> (ID) <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			SEX M <input type="checkbox"/> F <input checked="" type="checkbox"/>			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 <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							
CITY ANYTOWN		STATE NJ	8. PATIENT STATUS Single <input type="checkbox"/> Married <input checked="" type="checkbox"/> Other <input type="checkbox"/>			CITY ANYTOWN		STATE NJ					
ZIP CODE 00000		TELEPHONE (Include Area Code) (973) 555-1234	Employed <input type="checkbox"/> Full-Time <input type="checkbox"/> Part-Time <input type="checkbox"/> Student <input type="checkbox"/>			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) <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			11. INSURED'S POLICY GROUP OR FICA NUMBER							
4. OTHER INSURED'S POLICY OR GROUP NUMBER			b. AUTO ACCIDENT? PLACE (State) <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			4. INSURED'S DATE OF BIRTH MM DD YY			SEX M <input type="checkbox"/> F <input type="checkbox"/>				
b. OTHER INSURED'S DATE OF BIRTH MM DD YY			c. OTHER ACCIDENT? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			b. EMPLOYER'S NAME OR SCHOOL NAME							
c. EMPLOYER'S NAME OR SCHOOL NAME			10c. RESERVED FOR LOCAL USE			c. INSURANCE PLAN NAME OR PROGRAM NAME							
d. INSURANCE PLAN NAME OR PROGRAM NAME						d. IS THERE ANOTHER HEALTH BENEFIT PLAN? <input type="checkbox"/> YES <input type="checkbox"/> NO <i>If yes, return to and complete item 9 a-d.</i>							
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.						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						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. ID. NUMBER OF REFERRING PHYSICIAN			18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM MM DD YY TO MM DD YY							
19. RESERVED FOR LOCAL USE													
21. DIAGNOSIS OR NATURE 1. XXX XX 2. XXX XX													
<p>VSU: 454.0, 454.2 Or you may bill: VSU (Primary): 707.10-707.15, 707.19; VSU (Secondary): 459.81 DFU (Primary): 707.10-707.15*, 707.19*; DFU (Secondary): 249.00-249.01, 249.10-249.11, 249.20-249.21, 249.30-249.31, 249.40-249.41, 249.50-249.51, 249.60-249.61, 249.70-249.71, 249.80-249.81, 249.90-249.91, 250.60-250.63, 250.70-250.73, 250.80-250.83*</p> <p>*When billing for ulcers caused by diabetes, the provider must use both a code from the diabetes range and a code from the ulcer of lower limb range (707.10-707.15, 707.19).</p>													
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 DAVE OR UNITS	H ERBUD Family Plan	I EMB	J COB	K RESERVED FOR LOCAL USE
01 01 10 01 01 10 11		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		BBN EIN	26. PATIENT'S ACCOUNT NO.			27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO		28. TOTAL CHARGE \$ XXX	28. AMOUNT PND \$	30. BALANCE DUE \$			
01-2345678			012345678			<input type="checkbox"/> YES <input type="checkbox"/> NO							
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# GR#							

Apligraf is supplied in 44 units.

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 Noridian

Pretreatment:

1. Duration of pre treatment conservative/conventional management (by you or the predecessor physician)
_____ months
2. Document exact location of ulcer
3. Diagnosis of Patient:
VSU: 454.0, 454.2, or
VSU (Primary): 707.10-707.15, 707.19 **VSU (Secondary):** 459.81
DFU (Primary): 707.10-707.15, 707.19 **DFU (Secondary):** 249.00-249.01, 249.10-249.11, 249.20-249.21, 249.30-249.31, 249.40-249.41, 249.50-249.51, 249.60-249.61, 249.70-249.71, 249.80-249.81, 249.90-249.91, 250.60-250.63, 250.70-250.73, 250.80-250.83
4. Document failure to respond to conservative measures (VSU -2 months duration and DFU -1 month), including appropriate off-load pressure during treatment.
5. Document measurement of the initial ulcer size, size following cessation of conservative management, and size at the beginning of skin substitute treatment.
6. Document adequate treatment of the underlying disease process contributing to the ulcer.
7. Document that wound is free of infection and underlying osteomyelitis.

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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. Information based on LCD# L24409

Treatment:

8. 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

9. Document whether this is an initial application of Apligraf or a reapplication. (Per FDA-approved labeling no more than 5 applications per ulcer is permitted. Noridian's LCD for Apligraf states use of Apligraf is limited to 3 separate applications to any given ulcer, or more only when utilized with adherence to specific FDA labeling instructions and criteria).
10. For reapplications, document time between applications (There should be no fewer than two (2) weeks between applications for VSU and there should be no fewer than three (3) weeks between applications for DFU, 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 indications).
11. Document whether 50 percent or greater improvement was noted (For VSU's, two (2) applications of the skin substitute are indicated. If after twelve (12) weeks of compression treatment, and two (2) applications of the skin substitute, a 50 percent or greater improvement is noted and documented, then re-application of a third skin substitute will be considered for coverage. Otherwise, reapplication of the skin substitute is not recommended, and other treatment modalities should be considered. For neuropathic DFU's, if after nine (9) weeks of treatment, and three (3) applications of the skin substitute, satisfactory healing progress is not noted, then reapplication of the skin substitute is not recommended and other treatment modalities should be considered.).
12. For Apligraf reapplications, document whether prior applications have been successful /satisfactory healing progress noted.
13. Document whether wound treatment is accompanied by appropriate wound dressing during the healing period and by appropriate compressive therapy and appropriate steps to off-load wound pressure.
14. Document patient compliance
15. Document how Apligraf was fixated on the wound
16. Document that all labeling instructions have been followed

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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

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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.