Apligraf®
add life to healing

Summary of Package Insert[1]

For States with Non-Published Policies

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

For Palmetto GBA, JC modifier must be billed in conjunction with Q4101 along with JW modifier for wastage

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)

For Palmetto GBA, JC modifier must be billed in conjunction with codes above

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.

Organogenesis inc.
LIVING TECHNOLOGY

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2012 No Formal Policy—Palmetto | Apligraf® Sample UB-04 Claim Form

Provider (1): Anytown Hospital, 123 Medical Drive, Anytown, NJ 00000

3a PAT. CNTL #: HIC 012345678A

4 TYPE OF BILL: 131

5 FED. TAX NO.: 01-2345678

6 STATEMENT COVERS PERIOD: FROM 01012012 THROUGH 01012012

8 PATIENT NAME: Smith, Jane

9 PATIENT ADDRESS: 111 Maple Avenue, Anytown, NJ 00000

10 BIRTHDATE: 01011935 **11 SEX:** F

All dates should be in eight digit format.

38: Jane Smith, 111 Maple Avenue, Anytown, NJ 00000

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES
636	Apligraf	Q4101 JC	01012012	30	XXX XX	
	Apligraf product wastage	Q4101 JC JW		14		
360	Application, first 25 sq cm	15271 JC	01012012	1	XXX XX	
360	Application, each additional 25 sq cm	15272 JC	01012012	1	XXX XX	

PAGE ____ OF ____ CREATION DATE TOTALS

Apligraf is supplied in 44 sq cm and is for single use. This example is for a 30 sq cm wound with 14 sq cm coded for wastage with the JW modifier.

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). JC modifier must be used.

50 PAYER NAME: Medicare **51 HEALTH PLAN ID:** A987654X

58 INSURED'S NAME: Smith, Jane

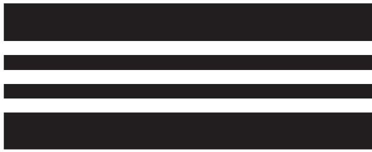
66 DX: XXX.XX

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

UB-04 CMS-1450 APPROVED OMB NO. 0938-0997 NUBC™ National Uniform Billing Committee

THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF.

PLEASE DO NOT STAPLE IN THIS AREA



Apligraf®

Sample CMS-1500 Claim Form

Physician Services in an Outpatient Setting

APPROVED OMB-0938-0008

CARRIER

PICA

HEALTH INSURANCE CLAIM FORM

PICA

PATIENT AND INSURED INFORMATION

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)

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.

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

PHYSICIAN OR SUPPLIER 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

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

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	JC							
2	01 01 12	01 01 12	22		15272	JC							
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 #

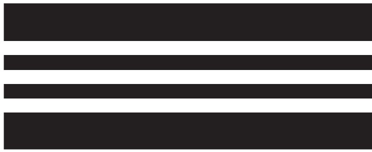
PIN# GRP#

(APPROVED BY AMA COUNCIL ON MEDICAL SERVICE 8/88)

PLEASE PRINT OR TYPE

FORM CMS-1500 (12-90), FORM RRB-1500, FORM OWCP-1500

PLEASE DO NOT STAPLE IN THIS AREA



Apligraf®

Sample CMS-1500 Claim Form

Physician Services in an Office Setting

APPROVED OMB-0938-0008

PICA

HEALTH INSURANCE CLAIM FORM

PICA

CARRIER

PATIENT AND INSURED INFORMATION

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)*

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

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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)

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.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

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SIGNED: SIGNATURE ON FILE — DATE

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SIGNED

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

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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

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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.	J.	K. RESERVED FOR LOCAL USE
1	01 01 12	01 01 12	11		Q4101	JC			30				
2	01 01 12	01 01 12	11		Q4101	JC JW			14				
3	01 01 12	01 01 12	11		15271	JC							
4	01 01 12	01 01 12	11		15272	JC							
5													
6													

Apligraf is supplied in 44 sq cm and is for single use. This example is for a 30 sq cm wound with 14 sq cm coded for wastage with the JW modifier.

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#

Apligraf®

Model Documentation Form for Palmetto

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, 249.50-249.51, 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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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.

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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

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

Modifiers:

JC – Skin substitute used as a graft (use for Apligraf)

JD – Skin substitute not used as a graft

The JC and JD modifiers should be used when billing for skin substitutes. The difference between 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.

Product Wastage Documentation Requirements:

14. Date:

15. Time:

16. Location of ulcer:

17. Approximate amount of product unit used:

18. Approximate amount of product unit discarded:

19. Reason for the wastage:

20. Manufacture's serial/lot/batch number

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Wastage example of 30sq cm wound that was treated with Apligraf (Apligraf is supplied in 44 sq cm)

Q4101 - 30units

Q4101 JW - 14 units

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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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