

Table of Contents

1.0 Description of the Procedure, Product, or Service..... 1
1.1 Definitions 1

2.0 Eligibility Requirements 1
2.1 Provisions..... 1
2.1.1 General..... 1
2.1.2 Specific 1
2.2 Special Provisions..... 2
2.2.1 EPSDT Special Provision: Exception to Policy Limitations for a Medicaid
Beneficiary under 21 Years of Age 2
2.2.2 EPSDT does not apply to NCHC beneficiaries 3
2.2.3 Health Choice Special Provision for a Health Choice Beneficiary age 6 through
18 years of age 3

3.0 When the Procedure, Product, or Service Is Covered..... 3
3.1 General Criteria Covered 3
3.2 Specific Criteria Covered..... 3
3.2.1 Specific criteria covered by both Medicaid and NCHC 3
3.2.1.1 Apligraf for Venous Stasis Ulcers (VSU)..... 3
3.2.1.2 Apligraf for Neuropathic Diabetic Foot Ulcers (DFU)..... 4
3.2.1.3 Dermagraft for Full-Thickness Diabetic Foot Ulcers 4
3.2.1.4 Integra 5
3.2.1.5 AlloDerm 5
3.2.1.6 TheraSkin® for Venous Stasis Ulcers 5
3.2.1.7 TheraSkin® for Diabetic Foot Ulcers..... 6
3.2.2 Medicaid Additional Criteria Covered..... 6
3.2.3 NCHC Additional Criteria Covered 6

4.0 When the Procedure, Product, or Service Is Not Covered..... 6
4.1 General Criteria Not Covered 6
4.2 Specific Criteria Not Covered..... 7
4.2.1 Specific Criteria Not Covered by both Medicaid and NCHC..... 7
4.2.2 Medicaid Additional Criteria Not Covered..... 7
4.2.3 NCHC Additional Criteria Not Covered..... 7

5.0 Requirements for and Limitations on Coverage 8
5.1 Prior Approval 8
5.2 Prior Approval Requirements 8
5.2.1 General..... 8
5.2.2 Specific 8
5.3 Limitations or Requirements..... 8

6.0 Providers Eligible to Bill for the Procedure, Product, or Service 8
6.1 Provider Qualifications and Occupational Licensing Entity Regulations..... 8
6.2 Provider Certifications 9

7.0	Additional Requirements	9
7.1	Compliance	9
7.2	Documentation.....	9
8.0	Policy Implementation/Revision Information.....	9
Attachment A:	Claims-Related Information	11
A.	Claim Type	11
B.	International Classification of Diseases, Tenth Revisions, Clinical Modification (ICD-10- CM) and Procedural Coding System (PCS).....	11
C.	Code(s).....	15
D.	Modifiers.....	16
E.	Billing Units.....	16
F.	Place of Service	16
G.	Co-payments	16
H.	Reimbursement	16

1.0 Description of the Procedure, Product, or Service

Skin substitutes are used to treat chronic wounds, burns, and rare skin conditions. These products promote the growth of new skin or serve as a temporary cover until other grafts can be placed. Skin substitutes consist of a dermal layer, epidermal layer, or both, that are embedded into a cellular matrix forming the skin substitute.

Skin substitutes have emerged as a potential alternative to skin grafting in cases of refractory, non-healing skin ulcers and burns. Various manufacturers produce skin substitutes, including Apligraf, Integra, TheraSkin[®], and Dermagraft.

1.1 Definitions

None Apply.

2.0 Eligibility Requirements

2.1 Provisions

2.1.1 General

(The term “General” found throughout this policy applies to all Medicaid and NCHC policies)

- a. An eligible beneficiary shall be enrolled in either:
 1. the NC Medicaid Program (*Medicaid is NC Medicaid program, unless context clearly indicates otherwise*); or
 2. the NC Health Choice (*NCHC is NC Health Choice program, unless context clearly indicates otherwise*) Program on the date of service and shall meet the criteria in **Section 3.0 of this policy**.
- b. Provider(s) shall verify each Medicaid or NCHC beneficiary’s eligibility each time a service is rendered.
- c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.
- d. Following is only one of the eligibility and other requirements for participation in the NCHC Program under GS 108A-70.21(a): Children must be between the ages of 6 through 18.

2.1.2 Specific

(The term “Specific” found throughout this policy only applies to this policy)

- a. **Medicaid**
None Apply.
- b. **NCHC**
None Apply.

2.2 Special Provisions

2.2.1 EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

a. 42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiary under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination** (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product or procedure:

1. that is unsafe, ineffective, or experimental or investigational.
2. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

b. EPSDT and Prior Approval Requirements

1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
2. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *NCTracks Provider Claims and Billing*

Assistance Guide, and on the EPSDT provider page. The Web addresses are specified below.

NCTracks Provider Claims and Billing Assistance Guide:

<https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html>

EPSDT provider page: <http://www.ncdhhs.gov/dma/epsdt/>

2.2.2 EPSDT does not apply to NCHC beneficiaries

2.2.3 Health Choice Special Provision for a Health Choice Beneficiary age 6 through 18 years of age

The Division of Medical Assistance (DMA) shall deny the claim for coverage for a NCHC beneficiary who does not meet the criteria within **Section 3.0** of this policy. Only services included under the NCHC State Plan and the DMA clinical coverage policies, service definitions, or billing codes are covered for a NCHC beneficiary.

3.0 When the Procedure, Product, or Service Is Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

3.1 General Criteria Covered

Medicaid and NCHC shall cover the procedure, product, or service related to this policy when medically necessary, and:

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the beneficiary's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available statewide; and
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the beneficiary, the beneficiary's caretaker, or the provider.

3.2 Specific Criteria Covered

3.2.1 Specific criteria covered by both Medicaid and NCHC

Medicaid and NCHC shall cover skin substitutes for:

3.2.1.1 Apligraf for Venous Stasis Ulcers (VSU)

Apligraf is covered when all of the following conditions are met in the treatment of venous stasis ulcers and documented in the beneficiary's health record:

- a. Ulcers are of more than one months' duration;
- b. Ulcers are partial or full thickness;
- c. Measurement of the initial ulcer size, the ulcer size following cessation of conservative management, and the size at the beginning of skin substitute treatment;

- d. Ulcers have failed to respond to documented conservative measures used for more than four weeks duration (failed to decrease the ulcer by 50%); and
- e. The ulcer must be free of infection and underlying osteomyelitis, and treatment of the underlying disease must be provided and documented in conjunction with skin substitute treatment.

3.2.1.2 **Apligraf for Neuropathic Diabetic Foot Ulcers (DFU)**

Apligraf is covered when all of the following conditions are met in the treatment of neuropathic diabetic foot ulcers and documented in the beneficiary's health record:

- a. Full thickness ulcers of greater than three weeks' in duration, which extend through the dermis but without tendon, muscle, capsule or bone exposure;
- b. Measurement of the initial ulcer size, the ulcer size following cessation of conservative management, and the size at the beginning of skin substitute treatment;
- c. Ulcers have failed to respond to documented conservative measures used for more than four weeks' duration (failed to decrease the ulcer by 50%);
- d. Appropriate steps to off-load pressure during treatment are being taken; and
- e. The ulcer must be free of infection and underlying osteomyelitis, and treatment of the underlying disease must be provided and documented in conjunction with skin substitute treatment.

3.2.1.3 **Dermagraft for Full-Thickness Diabetic Foot Ulcers**

Dermagraft is covered for the treatment of full-thickness diabetic foot ulcers when all of the following conditions are met:

- a. The ulcer has persisted for six weeks or longer;
- b. The ulcer extends through the dermis, but without tendon, muscle, joint capsule, or bone exposure;
- c. The beneficiary has adequate arterial blood supply to the foot;
- d. The beneficiary has a primary diagnosis of foot ulcer and a secondary diagnosis of diabetes with other specified manifestations. (Refer to **Attachment A Section B** for specific diagnostic codes that are covered under this policy);
- e. Ulcers are located on foot or toes and are free of infection, (increased exudates, odor, swelling, heat, pain, tenderness, purulent discharge), underlying osteomyelitis, surrounding cellulitis, sinus tracts, eschar, or any necrotic material that would interfere with adherence of a living skin equivalent and wound healing;
- f. Beneficiary's current Glycated hemoglobin(**HbA1c**)does not exceed 12%; and
- g. Dermagraft is used in conjunction with standard wound care regimens.

3.2.1.4 Integra

The application of Integra is covered when indicated for either of the following:

- a. Postexcisional treatment of life-threatening full-thickness or deep partial-thickness thermal injuries where sufficient autograft is not available at the time of excision or not desirable due to the physiological condition of the beneficiary; or
- b. Repair of scar contractures when other therapies have failed or when donor sites for repair are not sufficient or desirable due to the physiological condition of the beneficiary.

3.2.1.5 AlloDerm

The application of AlloDerm is covered when indicated for either of the following:

- a. Skin grafting: AlloDerm is often used in conjunction with a split-thickness skin graft. AlloDerm is laid down first and is then covered by a thin split-thickness autograft. Both the application of AlloDerm and the split-thickness autograft are coded separately; or
- b. Plastic surgeries on various soft tissue defects, including abdominal wall reconstruction, breast reconstruction post-mastectomy, and tympanoplasty. Although reconstructive procedures require prior approval, the application of AlloDerm does not.

3.2.1.6 TheraSkin® for Venous Stasis Ulcers

TheraSkin® is covered in the treatment of lower extremity ulcers which extend through the dermis with or without tendon, muscle, joint capsule or bone exposure when the following conditions are met:

- a. Ulcers have demonstrated a failed or insufficient response to no fewer than four weeks of conservative wound-care measures including at minimum regular dressing changes, debridement of necrotic tissue and standard therapeutic compression;
 1. A "failed response" is defined as an ulcer that has increased in size or depth, or for which there has been no change in baseline size or depth and no sign of improvement or indication that improvement is likely, such as granulation, epithelialization, or progress towards closing.
- b. Documentation of response, or lack thereof, requires measurement of the ulcer at baseline, following cessation of conservative or conventional management. Documentation should also include measurement of the ulcer immediately prior to the placement of TheraSkin®.
- c. Ulcers are free of infection, (increased exudates, odor, swelling, heat, pain, tenderness, purulent discharge), underlying osteomyelitis, surrounding cellulitis, sinus tracts, eschar, or any necrotic material that would interfere with adherence of a living skin equivalent and wound healing; and
- d. Ulcers are partial or full-thickness.

3.2.1.7 TheraSkin® for Diabetic Foot Ulcers

TheraSkin® is covered for the treatment of full-thickness diabetic foot ulcers when all of the following conditions are met:

- a. The ulcer has persisted for greater than three weeks duration;
- b. The ulcer extends through the dermis, with or without tendon, muscle, joint capsule, or bone exposure;
- c. The beneficiary has adequate arterial blood supply to the foot;
- d. The beneficiary has a primary diagnosis of foot ulcer and a secondary diagnosis of diabetes with other specified manifestations. (Refer to **Attachment A Section B** for specific diagnostic codes that are covered under this policy);
- e. Ulcers are located on foot or toes and are free of infection, (increased exudates, odor, swelling, heat, pain, tenderness, purulent discharge), underlying osteomyelitis, surrounding cellulitis, sinus tracts, eschar, or any necrotic material that would interfere with adherence of a living skin equivalent and wound healing;
- f. Beneficiary's current **HbA1c** does not exceed 12%; and
- g. TheraSkin® is used in conjunction with standard wound care regimens.

3.2.2 Medicaid Additional Criteria Covered

None Apply.

3.2.3 NCHC Additional Criteria Covered

None Apply.

4.0 When the Procedure, Product, or Service Is Not Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

4.1 General Criteria Not Covered

Medicaid and NCHC shall not cover the procedure, product, or service related to this policy when:

- a. the beneficiary does not meet the eligibility requirements listed in **Section 2.0**;
- b. the beneficiary does not meet the criteria listed in **Section 3.0**;
- c. the procedure, product, or service duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental, investigational, or part of a clinical trial.

4.2 Specific Criteria Not Covered

4.2.1 Specific Criteria Not Covered by both Medicaid and NCHC

Medicaid and NCHC shall not cover skin substitute for these diagnoses and conditions:

- a. Infected ulcers;
- b. Wounds or ulcers that are progressing toward closure with traditional wound care dressings and treatment
- c. Eschar, or any necrotic material
- d. Ulcers with sinus tracts or tunnels;
- e. Underlying osteomyelitis;
- f. Surrounding cellulitis;
- g. Beneficiaries with known hypersensitivity to bovine products, bovine collagen and chondroitin materials;
- h. Arterial disease with an ankle brachial index (ABI) (systolic ankle blood pressure over the systolic brachial blood pressure) of less than .65 in the case of venous stasis ulcers, or a lack of pedal pulses in the case of neuropathic diabetic foot ulcers;
- i. Uncontrolled diabetes (for purposes of this policy, controlled diabetes is based on documentation in the health record);
- j. Active Charcot's arthropathy of the ulcer extremity;
- k. Vasculitis;
- l. Uncontrolled rheumatoid arthritis, rheumatoid ulcers, or both;
- m. Other uncontrolled collagen vascular diseases;
- n. Beneficiaries who are under treatment with high-dose corticosteroids or immunosuppressants; or
- o. Beneficiaries who have undergone radiation, chemotherapy, or both within the month immediately preceding proposed skin substitute treatment

4.2.2 Medicaid Additional Criteria Not Covered

None Apply.

4.2.3 NCHC Additional Criteria Not Covered

- a. In addition to the specific criteria not covered in **Subsection 4.2.1** of this policy, NCHC shall not cover...
- b. NCGS § 108A-70.21(b) "Except as otherwise provided for eligibility, fees, deductibles, copayments, and other cost sharing charges, health benefits coverage provided to children eligible under the Program shall be equivalent to coverage provided for dependents under North Carolina Medicaid Program except for the following:
 1. No services for long-term care.
 2. No nonemergency medical transportation.
 3. No EPSDT.
 4. Dental services shall be provided on a restricted basis in accordance with criteria adopted by the Department to implement this subsection."

5.0 Requirements for and Limitations on Coverage

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

5.1 Prior Approval

Medicaid and NCHC shall not require prior approval for Skin Substitutes.

5.2 Prior Approval Requirements

5.2.1 General

The provider(s) shall submit to the, Department of Health and Human Services (DHHS) Utilization Review Contractor the following:

- a. the prior approval request;
- b. all health records and any other records that support the beneficiary has met the specific criteria in **Subsection 3.2** of this policy; and

5.2.2 Specific

None Apply.

5.3 Limitations or Requirements

- a. Apligraf is limited to 88 units within 365 calendar days with no more than five applications per ulcer.
- b. Dermagraft is limited to 304 units every 12 weeks. When reasonable healing progress is noted, re-application may continue to a maximum of eight applications in 12 weeks.
- c. TheraSkin[®] is limited to eight applications per ulcer, though more than three applications of TheraSkin[®] to a single wound are usually unnecessary. Each application is limited to 80 units/day, to a maximum of 640 units every 12 weeks. Re-application of TheraSkin[®] within one week for the same ulcer is not allowed. Re-application of TheraSkin[®] is not allowed for the same ulcer if satisfactory and reasonable healing progress is not noted after 12 weeks of therapy.
- d. Integra coverage is limited to the application of a quantity of material that closely approximates the size of the wound. The number of units billed, must closely correlate with the wound size. The maximum daily allowable units are 60.

6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services related to this policy, providers shall

- a. meet Medicaid or NCHC qualifications for participation;
- b. be currently Medicaid - enrolled; and
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

6.1 Provider Qualifications and Occupational Licensing Entity Regulations

None Apply.

6.2 Provider Certifications

None Apply.

7.0 Additional Requirements

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

7.1 Compliance

Provider(s) shall comply with the following in effect at the time the service is rendered:

- a. All applicable agreements, federal, state and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements;
- b. All DMA's clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or fiscal contractor(s);
- c. The safety and effectiveness of specific skin substitutes approved by the US Food and Drug Administration (FDA) have been established. Provider(s) shall use FDA approved Skin Products when used within the scope of the FDA indications.; and
- d. Human tissue products are subject to the rules and regulations of banked human tissue by the American Association of Tissue Banks (AATB). The FDA has classified TheraSkin® as banked human tissue and is therefore subject to the rules and regulations of banked human tissue by the American Association of Tissue Banks (AATB).. The Center for Biologics Evaluation and Research (CBER) regulates Human Cell & Tissue Products (HCT/Ps) in accordance with 21 CFR Part 1270 and 1271—Human cells, tissues, and cellular and tissue-based products at:
<http://www.ecfr.gov/>

7.2 Documentation

The health record must show that criteria described in **Section 3.0** and the limitations set forth in **Section 5.0** have been met and must document that wound treatment by this method is accompanied by appropriate:

- a. wound dressing during the healing period;
- b. compressive dressings during follow-up; and
- c. steps to off-load wound pressure during follow-up (for neuropathic diabetic foot ulcers).

8.0 Policy Implementation/Revision Information

Original Effective Date: November 1, 2000

Revision Information:

Date	Section Revised	Change
04/01/2007	All sections and attachment(s)	Implementation of coverage for the application of Integra

Date	Section Revised	Change
05/01/2007	Attachment A	Added UB-04 as an accepted claim form
05/01/2009	All sections and attachment(s)	Updated to DMA's current standard language.
05/01/2009 (eff. 01/01/2009)	Attachment A	HCPCS code update: Q4101 replaced J7340 and Q4106 replaced J7342.
07/01/2010	All sections and attachment(s)	Policy Conversion: Implementation of Session Law 2009-451, Section 10.32 "NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY."
03/01/2012	All sections and attachment(s)	To be equivalent where applicable to NC DMA's Clinical Coverage Policy # 1S-4 under Session Law 2011-145, § 10.41.(b)
03/12/2012	All sections and attachment(s)	Technical changes to merge Medicaid and NCHC current coverage into one policy.
01/04/2013	Subsection 3.3	Item "e." deleted word "redness"
01/04/2013	Attachment A	Code changes for 2012 CPT update
01/04/2013	Subsection 3.3 and Attachment A	Incorrect policy was posted. Policy amended to incorporate the changes listed above in Subsections 3.3 and Attachment A.
01/04/2013	All sections and attachment(s)	Replaced "recipient" with "beneficiary."
07/01/2013	Section 1.0, Subsections 3.4 and 5.2, Attachment A	Implementation of coverage for TheraSkin Updated code descriptions,
07/01/2013	Section 1.0, and throughout	Changed title from Bioengineered skin to-Skin substitutes
07/01/2013	Sections 3.0 through 5.2	Changed formatting of sections 3 through 5
07/01/2013	Subsections 3.2.6 & 3.2.7	Added TheraSkin [®] criteria
07/01/2013	Subsection 4.2	Updated
07/01/2013	Subsection 5.3 a b & c	Added limitations
07/01/2013	Subsections 5.3 & 5.4	Deleted
07/01/2013	Subsection 7.1	Updated to reflect TheraSkin [®] compliance
07/01/2013	Attachment A	Added ICD-9 codes for TheraSkin [®] updated HCPCS Procedure Codes and added TheraSkin [®] where applicable
10/01/2015	All Sections and Attachments	Updated policy template language and added ICD-10 codes to comply with federally mandated 10/1/2015 implementation where applicable.

Attachment A: Claims-Related Information

Provider(s) shall comply with the, *NCTracks Provider Claims and Billing Assistance Guide*, Medicaid bulletins, fee schedules, DMA's clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid and NCHC:

A. Claim Type

Professional (CMS-1500/837P transaction)

B. International Classification of Diseases, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS)

Provider(s) shall report the ICD-10-CM and Procedural Coding System (PCS) to the highest level of specificity that supports medical necessity. Provider(s) shall use the current ICD-10 edition and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for code description, as it is no longer documented in the policy.

Apligraf			
ICD-10-CM Code(s)			
E10.40	I70.432	I83.202	L97.411
E10.41	I70.433	I83.203	L97.412
E10.42	I70.434	I83.204	L97.413
E10.43	I70.435	I83.205	L97.414
E10.44	I70.438	I83.208	L97.419
E10.49	I70.439	I83.209	L97.421
E10.610	I70.442	I83.212	L97.422
E10.618	I70.443	I83.213	L97.423
E10.620	I70.444	I83.214	L97.424
E10.621	I70.445	I83.215	L97.429
E10.622	I70.448	I83.218	L97.501
E10.628	I70.449	I83.219	L97.502
E10.69	I70.532	I83.222	L97.503
E10.8	I70.533	I83.223	L97.504
E11.40	I70.534	I83.224	L97.509
E11.41	I70.535	I83.225	L97.511
E11.42	I70.538	I83.228	L97.512
E11.43	I70.539	I83.229	L97.513
E11.44	I70.542	L97.201	L97.514
E11.49	I70.543	L97.202	L97.519
E11.610	I70.544	L97.203	L97.521
E11.618	I70.545	L97.204	L97.522
E11.620	I70.548	L97.209	L97.523
E11.621	I70.549	L97.211	L97.524
E11.622	I70.632	L97.212	L97.529
E11.628	I70.633	L97.213	L97.801
E11.69	I70.634	L97.214	L97.802
E11.8	I70.635	L97.219	L97.803
E13.40	I70.638	L97.221	L97.804

E13.41	I70.639	L97.222	L97.809
E13.42	I70.642	I83.229	L97.811
E13.43	I70.643	L97.201	L97.812
E13.44	I70.644	L97.202	L97.813
E13.49	I70.645	L97.203	L97.814
E13.610	I70.648	L97.204	L97.819
E13.618	I70.649	L97.209	L97.821
E13.620	I70.732	L97.211	L97.822
E13.621	I70.733	L97.212	L97.823
E13.622	I70.734	L97.213	L97.824
E13.628	I70.735	L97.214	L97.829
E13.69	I70.738	L97.219	L97.901
E13.8	I70.739	L97.221	L97.902
I70.232	I70.742	L97.222	L97.903
I70.233	I70.743	L97.223	L97.904
I70.234	I70.744	L97.224	L97.909
I70.235	I70.745	L97.229	L97.911
I70.238	I70.748	L97.301	L97.912
I70.239	I70.749	L97.302	L97.913
I70.242	I83.002	L97.303	L97.914
I70.243	I83.003	L97.304	L97.919
I70.244	I83.004	L97.309	L97.921
I70.245	I83.005	L97.311	L97.922
I70.248	I83.008	L97.312	L7.923
I70.249	I83.009	L97.313	L97.924
I70.332	I83.012	L97.314	L97.929
I70.333	I83.013	L97.319	
I70.334	I83.014	L97.321	
I70.335	I83.015	L97.322	
I70.338	I83.018	L97.323	
I70.339	I83.019	L97.324	
I70.342	I83.022	L97.329	
I70.343	I83.023	L97.401	
I70.344	I83.024	L97.402	
I70.345	I83.025	L97.403	
I70.348	I83.028	L97.404	
I70.349	I83.029	L97.409	

Dermagraft			
ICD-10-CM Code(s)			
E10.40	E11.622	I70.344	L97.412
E10.41	E11.628	I70.345	L97.413
E10.42	E11.69	I70.434	L97.414
E10.43	E11.8	I70.435	L97.419
E10.44	E13.40	I70.444	L97.421
E10.49	E13.41	I70.445	L97.422
E10.610	E13.42	I70.534	L97.423
E10.618	E13.43	I70.535	L97.424
E10.620	E13.44	I70.544	L97.429
E10.621	E13.49	I70.545	L97.501
E10.622	E13.610	I70.634	L97.502
E10.628	E13.618	I70.635	L97.503
E10.69	E13.620	I70.644	L97.504
E10.8	E13.621	I70.645	L97.509
E11.40	E13.622	I70.734	L97.511
E11.41	E13.628	I70.735	L97.512
E11.42	E13.69	I70.744	L97.513
E11.43	E13.8	I70.745	L97.514
E11.44	I70.234	L97.401	L97.519
E11.49	I70.235	L97.402	L97.521
E11.610	I70.244	L97.403	L97.522
E11.618	I70.245	L97.404	L97.523
E11.620	I70.334	L97.409	L97.524
E11.621	I70.335	L97.411	L97.529

Theraskin			
ICD-10-CM Code(s)			
E08.40	E13.620	I70.748	L97.311
E08.41	E13.621	I70.749	L97.312
E08.42	E13.622	I83.002	L97.313
E08.43	E13.628	I83.003	L97.314
E08.44	E13.69	I83.004	L97.319
E08.49	E13.8	I83.005	L97.321
E08.51	I70.232	I83.008	L97.322
E08.52	I70.233	I83.009	L97.323
E08.59	I70.234	I83.012	L97.324
E08.610	I70.235	I83.013	L97.329
E08.618	I70.238	I83.014	L97.401
E08.620	I70.239	I83.015	L97.402
E08.621	I70.242	I83.018	L97.403
E08.622	I70.243	I83.019	L97.404
E08.628	I70.244	I83.022	L97.409
E08.69	I70.245	I83.023	L97.411

E09.40	I70.248	I83.024	L97.412
E09.41	I70.249	I83.025	L97.413
E09.42	I70.332	I83.028	L97.414
E09.43	I70.333	I83.029	L97.419
E09.44	I70.334	I83.202	L97.421
E09.49	I70.335	I83.203	L97.422
E09.51	I70.338	I83.204	L97.423
E09.52	I70.339	I83.205	L97.424
E09.59	I70.342	I83.208	L97.429
E09.610	I70.343	I83.209	L97.501
E09.618	I70.344	I83.212	L97.502
E09.620	I70.345	I83.213	L97.503
E09.621	I70.348	I83.214	L97.504
E09.622	I70.349	I83.215	L97.509
E09.628	I70.432	I83.218	L97.511
E09.69	I70.433	I83.219	L97.512
E10.40	I70.434	I83.222	L97.513
E10.41	I70.435	I83.223	L97.514
E10.42	I70.438	I83.224	L97.519
E10.43	I70.439	I83.225	L97.521
E10.44	I70.442	I83.228	L97.522
E10.49	I70.443	I83.229	L97.523
E10.51	I70.444	I87.011	L97.524
E10.52	I70.445	I87.012	L97.529
E10.59	I70.448	I87.013	L97.801
E10.618	I70.449	I87.019	L97.802
E10.620	I70.532	I87.031	L97.803
E10.621	I70.533	I87.032	L97.804
E10.622	I70.534	I87.033	L97.809
E10.628	I70.535	I87.039	L97.811
E10.69	I70.538	I87.2	L97.812
E10.8	I70.539	I87.311	L97.813
E11.40	I70.542	I87.312	L97.814
E11.41	I70.543	I87.313	L97.819
E11.42	I70.544	I87.319	L97.821
E11.43	I70.545	I87.331	L97.822
E11.44	I70.548	I87.332	L97.823
E11.49	I70.549	I87.333	L97.824
E11.51	I70.632	I87.339	L97.829
E11.52	I70.633	I87.9	L97.901
E11.59	I70.634	L97.201	L97.902
E11.610	I70.635	L97.202	L97.903
E11.618	I70.638	L97.203	L97.904
E11.620	I70.639	L97.204	L97.909
E11.621	I70.642	L97.209	L97.911
E11.622	I70.643	L97.211	L97.912
E11.628	I70.644	L97.212	L97.913
E11.69	I70.645	L97.213	L97.914
E11.8	I70.648	L97.214	L97.919

E13.40	I70.649	L97.219	L97.921
E13.41	I70.732	L97.221	L97.922
E13.42	I70.733	L97.222	L97.923
E13.43	I70.734	L97.223	L97.924
E13.44	I70.735	L97.224	L97.929
E13.49	I70.738	L97.229	
E13.51	I70.739	L97.301	
E13.52	I70.742	L97.302	
E13.59	I70.743	L97.303	
E13.610	I70.744	L97.304	
E13.618	I70.745	L97.309	

C. Code(s)

Provider(s) shall report the most specific billing code that accurately and completely describes the procedure, product or service provided. Provider(s) shall use the Current Procedural Terminology (CPT), Health Care Procedure Coding System (HCPCS), and UB-04 Data Specifications Manual (for a complete listing of valid revenue codes) and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for the code description, as it is no longer documented in the policy.

If no such specific CPT or HCPCS code exists, then the provider(s) shall report the procedure, product or service using the appropriate unlisted procedure or service code.

Apligraf, Dermagraft and TheraSkin® must be billed in conjunction with codes that describe application of the tissue and preparation of the site. For burn treatments, reimbursement for physician services is limited to the application of the product.

1. HCPCS Procedure Code

- Q4101 - Apligraf
- Q4106 - Dermagraft
- Q4121- TheraSkin®

2. CPT Procedure Codes

15002 through 15005 may be used to bill for the site preparation. Bill on the CMS-1500 form using HCPCS procedure code listed above.

Unlisted Procedure or Service

CPT: The provider(s) shall refer to and comply with the Instructions for Use of the CPT Codebook, Unlisted Procedure or Service, and Special Report as documented in the current CPT in effect at the time of service.

HCPCS: The provider(s) shall refer to and comply with the Instructions For Use of HCPCS National Level II codes, Unlisted Procedure or Service and Special Report as documented in the current HCPCS edition in effect at the time of service.

D. Modifiers

Provider(s) shall follow applicable modifier guidelines.

E. Billing Units

Provider(s) shall report the appropriate procedure code(s) used which determines the billing unit(s).

One unit equals 1 square centimeter (sq cm).

Code		
15002	+15272	15277
+15003	15273	+15278
15004	+15274	Q4101
+15005	15275	Q4106
15271	+15276	Q4121

F. Place of Service

Place of service for Dermagraft, Apligraf and TheraSkin® is limited to inpatient, outpatient hospital, and office. Place of service for Integra and Alloderm is limited to inpatient and outpatient hospital.

G. Co-payments

For Medicaid refer to Medicaid State Plan, Attachment 4.18-A, page 1, located at <http://www.ncdhhs.gov/dma/plan/sp.pdf>.

For NCHC refer to G.S. 108A-70.21(d), located at http://www.ncleg.net/EnactedLegislation/Statutes/HTML/BySection/Chapter_108A/GS_108A-70.21.html

H. Reimbursement

Provider(s) shall bill their usual and customary charges.

For a schedule of rates, see: <http://www.ncdhhs.gov/dma/fee/>