To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your PHP.

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Related Clinical Coverage Policies
Refer to https://medicaid.ncdhhs.gov/ for the related coverage policies listed below:

1.0 Description of the Procedure, Product, or Service

Skin substitutes are used to treat chronic wounds, burns, rare skin conditions, trauma, ischemia, or other neurological impairments; over 90% of the lesions are related to venous stasis disease and diabetic neuropathy. These products promote the growth of new skin or serve as a temporary cover until other grafts can be placed.

The addition of Skin Substitutes, Cellular or Tissue Based Products (CTPs) to certain wounds may afford a healing advantage over dressings and conservative treatments when these options appear insufficient to affect complete healing. There are currently a wide variety of bioengineered products available for soft tissue coverage to affect closure. These products may be derived from human tissue (allogeneic or autologous), non-human tissue (xenogeneic), synthetic sources or a combination of any or all these types of materials. However, without the component of the recipient's own distinct epithelium and cellular skin elements, permanent skin replacement or coverage by graft cannot be accomplished.

1.1 Definitions

1.1.1 Diabetic Foot Ulcer (DFU)

A diabetic foot ulcer is a non-healing or poorly healing full-thickness wound, through the dermis, below the ankle, in a beneficiary with diabetes. DFUs are categorized as being purely neuropathic, purely ischemic or neuroischemic (mixed). The most common sites for a DFU are the plantar surface of the foot (metatarsal heads and midfoot), and toes (dorsal interphalangeal joints or distal tip).

1.1.2 Venous Stasis Ulcer (VSU)

A venous stasis ulcer is a shallow wound that develops on the lower leg when the leg veins fail to return blood back toward the heart normally - a condition known as venous insufficiency. A venous stasis ulcer may also be referred to as a varicose ulcer or stasis leg ulcer.

1.1.3 Conservative Management

Conservative management is the appropriate standard treatment for a chronic lower extremity ulcer or skin loss. This organized comprehensive conservative wound therapy regimen primarily includes infection and edema control, mechanical offloading, mechanical compression or limb elevation, debridement of necrotic or infected tissue, and management of existing medical issues. Maintenance of a therapeutic environment with appropriate dressings to prevent further trauma facilitates the development of healthy granulation tissue and encourages re-epithelization.

1.1.4 Chronic Wound

A chronic wound is defined as a wound that does not respond to standard wound treatment for at least a 30-day period during conservative management, as defined in **Subsection 1.1.3.**

1.1.5 Failed Response

A failed response is when an ulcer or skin deficit that has failed to respond to documented conservative management, as defined in **Subsection 1.1.3,** has increased in size or depth, or has not changed in baseline size or depth and has no indication that improvement is likely (such as granulation, epithelialization or progress towards closing).

2.0 Eligibility Requirements

2.1 Provisions

2.1.1 General

(*The term "General" found throughout this policy applies to all Medicaid policies*)

a. An eligible beneficiary shall be enrolled in the NC Medicaid Program *(Medicaid is NC Medicaid program, unless context clearly indicates otherwise*).
b. Provider(s) shall verify each Medicaid 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.

2.1.2 Specific

(***The term "Specific" found throughout this policy only applies to this policy***)

a. Medicaid
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: https://medicaid.ncdhhs.gov/

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 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 Medicaid

Medicaid considers skin substitutes to be clinically proven and, therefore, medically necessary for treatment of chronic wounds in beneficiaries who meet **ALL OF** the following criteria for their diagnosis:

a. Refer to **Subsection 7.3** for health record documentation requirements.
b. Refer to **Attachment B** for medically necessary skin substitutes and clinical indications.

3.2.1.1 Application of Skin Substitutes for the Treatment of Diabetic Foot Ulcers (DFUs)

a. The beneficiary has a primary diagnosis of foot ulcer and a secondary diagnosis of Type 1 or 2 diabetes mellitus with a glycated hemoglobin (HbA1c) of less than 12 percent;
b. The ulcers have failed to respond to documented conservative management used for more than four weeks duration (failed to decrease the ulcer by 50 percent);
c. Appropriate steps to off-load pressure during treatment are being taken;
d. The ulcer must be free of infection (increased exudates, odor, swelling, heat, pain, tenderness, purulent discharge) and underlying osteomyelitis, **and** treatment of the underlying disease must be provided and documented in conjunction with skin substitute treatment; and
e. The treated foot has an adequate blood supply as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of greater than or equal to 0.70.

3.2.1.2 Application of Skin Substitutes for the Treatment of Venous Stasis Ulcers (VSUs)

a. Measurement of the initial ulcer size, the ulcer size following cessation of conservative management, and the size at the beginning of skin substitute treatment;
b. The ulcer has failed to respond to documented conservative management used for more than four weeks duration (failed to decrease the ulcer by 50 percent);

c. The ulcer must be free of infection (increased exudates, odor, swelling, heat, pain, tenderness, purulent discharge) and underlying osteomyelitis, and treatment of the underlying disease must be provided and documented in conjunction with the skin substitute treatment; and

d. The treated foot has an adequate blood supply as evidenced by either the presence of a palpable pedal pulse or an ankle-brachial index (ABI) of greater than or equal to 0.70.

3.2.1.3 Application of Skin Substitutes for the Treatment of Thermal Injuries

Medicaid shall cover the application of skin substitutes when indicated for either **ONE** of the following:

a. Post-excisional 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.

3.2.2 Medicaid 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 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 Medicaid

Medicaid shall not cover skin substitutes for any ONE of the following 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. A beneficiary 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 0.70 or a lack of pedal pulses;
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. A beneficiary who is under treatment with high-dose corticosteroids or immunosuppressants;
o. A beneficiary who has undergone radiation, chemotherapy, or both within the month immediately preceding proposed skin substitute treatment;
p. EpiFix® for wounds that probe to the bone or are infected; or
q. Dermagraft® for the treatment of dystrophic epidermolysis bullosa.

4.2.2 Medicaid Additional Criteria Not Covered

None Apply.

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 shall not require prior approval for Skin Substitutes.

5.2 Prior Approval Requirements

5.2.1 General

None Apply.

5.2.2 Specific

None Apply.

5.2.3 Limitations or Requirements

a. Apligraf is limited to 176 units within 180 calendar days, with no more than four applications per ulcer.

b. GrafixPrime is limited to one application per calendar week, for a maximum of 12 weeks per ulcer.
c. GrafixCore is limited to one application per calendar week, for a maximum of 12 weeks per ulcer.
d. Amnioband is limited to one application per seven calendar days, for a maximum of 12 weeks per ulcer.
e. Dermagraft ®is limited to 304 units within 12 weeks, with no more than 8 applications per ulcer.
f. Allopatch is limited to one application per seven calendar days for a maximum of 12 weeks per ulcer.
g. TheraSkin® is limited to eight applications per ulcer. Each application is limited to 80 units per 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.
h. 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.
i. EpiFix® is limited to ten applications per ulcer; the initial application, then additional applications may be applied at a minimum of one-week intervals, for up to a maximum of four applications in 12 weeks, when there is evidence of wound healing.

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 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; and

b. All NC Medicaid'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).

7.2 US Food and Drug Administration (FDA) Approvals

a. 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 intended use and indications; and

b. 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®, GrafixCore, and GrafixPrime 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) according to 21 CFR Part 1270 Human tissue Intended for transplantation, and 1271 Human cells, tissues, and cellular and tissue-based products at: **http://www.ecfr.gov/**

7.3 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. date, time and location of ulcer treated;

b. name of skin substitute and how product supplied;

c. amount of product used;

d. wound dressing during the healing period;

e. compressive dressings during follow-up; and

f. 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
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.

Date	Section Revised	Change
11/01/2017	Section 1.1	Added definitions.
11/01/2017	Section 3.2.1.1	Updated coverage text to include an ABI of greater than or equal to 0.70.
11/01/2017	Section 3.2.1.2	Updated coverage text to include an ABI of greater than or equal to 0.70.
11/01/2017	Section 3.2.1.5	Updated coverage text to include an ABI of greater than or equal to 0.70.
11/01/2017	Section 3.2.1.6.a	Added EpiFix® coverage for venous stasis ulcers.
11/01/2017	Section 3.2.1.6.b	Added EpiFix® coverage for diabetic foot ulcers.
11/01/2017	Section 4.2.1	Added non-coverage text for ABI less than 0.70, non-coverage text for EpiFix® and Dermagraft®.
11/01/2017	Subsection 5.2.1	Removed Prior Approval: General text and replaced with None Apply.
11/01/2017	Subsection 5.3e	Added limitations for EpiFix®.
11/01/2017	Subsection 7.2	Subsection created from 7.1
11/01/2017	Subsection 7.3	Additional documentation requirements added.
11/01/2017	Attachment A Section B	Removed ICD 10 code tables for Apligraf®, Dermagraft® and TheraSkin®.
11/01/2017	Attachment A Section C.1.	Added CPT code for EpiFix®, AlloDerm® and Integra®.
11/01/2017	Attachment A Section C. 2.	Added codes 15271-15278 used to bill the applications.
11/01/2017	Attachment A Section E	Added CPT codes Q4104, Q4116, Q4131 to the table.
11/01/2017	Attachment A Section F	Added place of service for EpiFix®.
11/14/2017	All Sections and Attachments	Amended policy posted 11/14/2017 with an effective date of 11/01/2017
01/01/2019	Attachment A Section C. 1.	Deleted Q4131 EpiFix® and replaced with Q4186 - EpiFix®.
01/01/2019	Attachment A Section E	End dated Q4131 and replaced with Q4186 as per 2019 CPT update.
03/15/2019	Table of Contents	Added, “To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after November 1, 2019, please contact your PHP.”
03/15/2019	All Sections and Attachments	Updated policy template language.
12/31/2019	Table of Contents	Updated policy template language, “To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your PHP.”
12/31/2019	Attachment A	Added, “Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines”.
6/15/2021	Section 1.0	Removed “immobility” from Description of the

Date	Section Revised	Change
		Procedure, Product, or Service
6/15/2021	Section 1.1.2	Added the phrase "A venous stasis ulcer may also be referred to as a varicose ulcer or stasis leg ulcer."
6/15/2021	Section 1.1.3	Updated the definition of "conservative management" to include the phrase "organized comprehensive conservative wound therapy regimen"
6/15/2021	Section 1.1.4	Updated the definition of "chronic wound" to include the phrase "conservative management"
6/15/2021	Section 1.1.5	Updated the definition of "failed response" to include the phrase "conservative management"
6/15/2021	Section 3.2.1	Added the phrases "Refer to Subsection 7.3 for health record documentation requirements" and "Refer to Attachment A for medically necessary skin substitutes and clinical indications." Removed the phrase "and documented in the beneficiary health record". Replaced all instances of the phrase "standard wound care regimens" with the phrase "conservative management". Removed all of the product-specific coverage from this section and moved it to a table in Attachment A.
6/15/2021	Section 3.2.1.1	Added the section "Application of Skin Substitutes for the Treatment of Diabetic Foot Ulcers (DFUs)"
6/15/2021	Section 3.2.1.2	Added the section "Application of Skin Substitutes for the Treatment of Venous Stasis Ulcers (VSUs)"
6/15/2021	Section 3.2.1.3	Added the section "Application of Skin Substitutes for the Treatment of Thermal Injuries"
6/15/2021	Section 5.2.3	Corrected limit restrictions for Apligraf® from 88 units every 365 calendar days to 176 units every 180 calendar days
6/15/2021	Section 5.2.3	Added GrafixCore, GrafixPrime, Amnioband, and Allopatch application limits to the policy. Updated the Epifix application limit from five to ten applications.
6/15/2021	Section 7.2	Updated description of the sources for clarity and added the products Grafix Core and Grafix Prime
6/15/2021	Section 7.3	Added requirements for measurement of ulcer
6/15/2021	Attachment A Section C	Added HCPCS codes for GrafixCore, GrafixPrime, Amnioband, and Allopatch
6/15/2021	Attachment A Section E	Added GrafixCore, GrafixPrime, Amnioband, and Allopatch to the billing codes
6/15/2021	Attachment A Section F	Added GrafixCore, GrafixPrime, Amnioband, and Allopatch to the list of products covered inpatient, outpatient, and in office
6/15/2021	Attachment B Section I	Added New Attachment Section chart of "Medically Necessary Skin Substitutes and Clinical Indications"
06/01/2023	All Sections and Attachments	Updated policy template language due to North Carolina Health Choice Program's move to Medicaid. Policy posted 6/1/2023 with an effective date of 4/1/2023.

Attachment A: Claims-Related Information

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

A. Claim Type

Professional (CMS-1500/837P transaction)

Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.

B. International Classification of Diseases and Related Health Problems, 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.

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®, Integra®, AlloDerm®, EpiFix®, Amnioband®, GrafixPrime®, GrafixCore®, Allopatch®, 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 ®
Q4104 - Integra®
Q4106 - Dermagraft®
Q4116 - AlloDerm®
Q4121 - TheraSkin®
Q4186 - EpiFix®
Q4151 -Amnioband®
Q4133 -GrafixPrime®
Q4132 -GrafixCore®
Q4128 – Allopatch®

2. **CPT Procedure Codes**

15002 through 15005 are used to bill for the site preparation and 15271 through 15278 are used to bill application. 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	15273	Q4101
15003	15274	Q4104
15004	15275	Q4106
15005	15276	Q4116
15271	15277	Q4121
15272	15278	Q4186
		Q4151
		Q4133
		Q4132
		Q4128

F. Place of Service

Place of service for Dermagraft® Apligraf®, EpiFix®, TheraSkin®, GrafixCore®, GrafixPrime®, Allopatch® and Amnioband® 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:
https://medicaid.ncdhhs.gov/meetings-notices/medicaid-state-plan-public-notices

H. Reimbursement

Provider(s) shall bill their usual and customary charges.
For a schedule of rates, refer to: https://medicaid.ncdhhs.gov/

Attachment B: Medically Necessary Skin Substitutes and Clinical Indications

Product	Diabetic Foot Ulcers (DFUs)	Venous Stasis Ulcers (VSUs)	Thermal Burns	Other Indications/Additional Information
Apligraf®	✓	✓		• Full thickness DFUs must be greater than three weeks in duration, which extend through the dermis but **without** tendon, muscle, capsule or bone exposure • Duration of VSU must be greater than four weeks
Dermagraft®	✓			• Full thickness DFUs must be greater than six weeks in duration, which extend through the dermis but **without** tendon, muscle, capsule or bone exposure
Integra®			✓	
AlloDerm®				• 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 allowed separately; **or** • Plastic surgeries on various soft tissue defects, such as abdominal wall reconstruction, breast reconstruction post-mastectomy, and tympanoplasty. Although reconstructive procedures require prior approval, the application of AlloDerm does not require prior approval.
TheraSkin®	✓	✓		• Full thickness DFUs must be greater than three weeks in duration, which extend through the dermis **with or without** tendon, muscle, capsule or bone exposure • Partial or full-thickness VSU which extends through the dermis with or without tendon, muscle, joint capsule or bone exposure

EpiFix®	✓	✓		• Full thickness DFUs must be greater than three weeks in duration, which extend through the dermis **with or without** tendon, muscle, capsule or bone exposure • Partial or full-thickness VSU which extends through the dermis, **with or without** tendon, muscle, joint capsule or bone exposure
GrafixCore	✓			• Full thickness DFUs must be greater than three weeks in duration, which extend through the dermis **with or without** tendon, muscle, capsule or bone exposure
GrafixPrime	✓			• Full thickness DFUs must be greater than three weeks in duration, which extend through the dermis **with or without** tendon, muscle, capsule or bone exposure
Amnioband	✓			• Full thickness DFUs must be greater than three weeks in duration, which extend through the dermis **with or without** tendon, muscle, capsule or bone exposure
Allopatch	✓			• Full thickness DFUs must be greater than three weeks in duration, which extend through the dermis **with or without** tendon, muscle, capsule or bone exposure