# Clinical Policy: Skin Substitutes

Reference Number: WNC.CP.222
Last Review Date: 02/2025

Coding Implications
Revision Log

**See** Important Reminder **at the end of this policy for important regulatory and legal information.**

**Note:** When state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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## Description[1]

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.

WellCare of North Carolina may consider the cost-effectiveness of alternative skin substitute products based on FDA labeling when determining which products will be covered.

## Definitions

***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).

***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.

***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.

***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 above, in **Conservative Management.**

***Failed Response***
A failed response is when an ulcer or skin deficit that has failed to respond to documented conservative management, as defined above, in **Conservative Management,** 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).

## Policy/Criteria[1]

**I.** WellCare of North Carolina® considers skin substitutes to be clinically proven and, therefore, medically necessary for treatment of chronic wounds in members who meet **ALL OF** the following criteria for their diagnosis:
1. Refer to Criteria V. for health record documentation requirements.
2. Refer to Table I, below, for medically necessary skin substitutes and clinical indications.

**A. Application of Skin Substitutes for the Treatment of *Diabetic Foot Ulcers (DFUs)***
1. The member has a primary diagnosis of a foot ulcer and a secondary diagnosis of Type 1 or 2 diabetes mellitus with a glycated hemoglobin (HbA1c) of less than 12 percent;
2. The ulcers have failed to respond to documented conservative management used for more than four weeks duration (failed to decrease the ulcer by 50 %)
3. Appropriate steps to off-load pressure during treatment are being taken;
4. 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**
5. 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.

**B. Application of Skin Substitutes for the Treatment of *Venous Stasis Ulcers (VSUs)***
1. Measurement of the initial ulcer size, the ulcer size following cessation of conservative management, and the size at the beginning of skin substitute treatment;
2. The ulcer has failed to respond to documented conservative management used for more than four weeks duration (failed to decrease the ulcer by 50 %);
3. 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**

4. 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.

***C. Application of Skin Substitutes for the Treatment of Thermal Injuries, ONE of the following:***

1. 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 member; **OR**
2. 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 member.

## II. 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.

**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/.

## III.

WellCare of North Carolina® **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, untreated, or active osteomyelitis;
**F.** Surrounding cellulitis;
**G.** A member with known hypersensitivity to materials in the skin substitute (example bovine products, bovine collagen, chondroitin or fish);
**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 member who is under treatment with high-dose corticosteroids (> 60 mg Prednisone per day or equivalent) or immunosuppressants;
**O.** A member 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.

## IV. Additional 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 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 (1) 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
**J.** Kerecis® is limited to one application per calendar week, for a maximum of 12 weeks per ulcer.

## V. Documentation

**A.** The health record must show that criteria described in Criteria I and the limitations set forth in Criteria IV, have been met and must document that wound treatment by this method is accompanied by appropriate:
1. Date, time and location of ulcer treated;
2. Name of skin substitute and how product supplied;
3. Amount of product used;
4. Amount of product unit discarded and the reason for the wastage;

5. Wound dressing during the healing period;
6. Compressive dressings during follow-up; and
7. Steps to off-load wound pressure during follow-up (for neuropathic diabetic foot ulcers).

**Table 1: Medically Necessary Skin Substitutes and Clinical Indications**

| Product | Diabetic Foot Ulcers (DFU) | Venous Stasis Ulcers (VSU) | Thermal Burns | Other Indications/Additional Information |
|---|---|---|---|---|
| **Apligraf®** | **X** | **X** | | • Full thickness DFUs must be greater than three weeks induration, which extend through the dermis but **without** tendon, muscle, joint capsule or bone exposure.<br>• Duration of VSU must be greater than four weeks. |
| **Dermagraft** | **X** | | | • Full thickness DFUs must be greater than six weeks in duration, which extend through the dermis but **without** tendon, muscle, joint capsule or bone exposure. |
| **Integra®** | | | **X** | |
| **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**<br>• 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. |

| Product | Diabetic Foot Ulcers (DFU) | Venous Stasis Ulcers (VSU) | Thermal Burns | Other Indications/Additional Information |
|---|---|---|---|---|
| **TheraSkin®** | **X** | **X** | | • Full thickness DFUs must be greater than three weeks in duration, which extend through the dermis **with or without** tendon, muscle, joint capsule or bone exposure.<br>• Partial or full-thickness VSU which extends through the dermis with or without tendon, muscle, joint capsule or bone exposure. |
| **EpiFix®** | **X** | **X** | | • Full thickness DFUs must be greater than three weeks in duration, which extend through the dermis **with or without** tendon, muscle, joint capsule or bone exposure.<br>• Partial or full-thickness VSU which extends through the dermis, **with or without** tendon, muscle, joint capsule or bone exposure. |
| **GrafixCore®** | **X** | | | • Full thickness DFUs must be greater than three weeks in duration, which extend through the dermis with or without tendon, muscle, joint capsule or bone exposure. |
| **GrafixPrime®** | **X** | | | • Full thickness DFUs must be greater than three weeks in duration, which extend through the dermis with or without tendon, muscle, joint capsule or bone exposure. |
| **Amnioband®** | **X** | | | • Full thickness DFUs must be greater than three weeks in duration, which extend through the dermis with or without tendon, muscle, joint capsule or bone exposure. |
| **Allopatch®** | **X** | | | • Full thickness DFUs must be greater than three weeks in duration, which extend through the dermis with or without tendon, muscle, joint capsule or bone exposure. |

| Product | Diabetic Foot Ulcers (DFU) | Venous Stasis Ulcers (VSU) | Thermal Burns | Other Indications/Additional Information |
|---|---|---|---|---|
| **Kerecis®** | **X** | **X** | **X** | • Partial or full thickness DFUs must be greater than four weeks in duration, which extends through the dermis **with or without** tendon, muscle, joint capsule or bone exposure.<br>• Partial or full-thickness VSU must be greater than 4 weeks in duration, which extends through the dermis, **with or without** tendon, muscle, joint capsule or bone exposure. |

## Background[1]

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 the graft cannot be accomplished.

## Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2025, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

| CPT®* Codes | Description |
|---|---|
| 15002 | Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, trunk, arms, legs; first 100 sq cm or 1% of body area of infants and children |

| CPT®* Codes | Description |
|---|---|
| 15003 | Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, trunk, arms, legs; each additional 100 sq cm, or part thereof, or each additional 1% of body area of infants and children |
| 15004 | Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet and/or multiple digits; first 100 sq cm or 1% of body area of infants and children |
| 15005 | Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet and/or multiple digits; each additional 100 sq cm, or part thereof, or each additional 1% of body area of infants and children |
| 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 |
| 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, or 1% of body area of infants and children |
| 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 thereof, or each additional 1% of body area of infants and children, or part thereof; |
| 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; |
| 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, or 1% of body area of infants and children |
| 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 thereof, or each additional 1% of body area of infants and children, or part thereof; |

***Note:*** *15002 through 15005 are used to bill for the site preparation and 15271 through 15278 are used to bill application*

| HCPCS ®* Codes | Description |
|---|---|
| Q4101 | Apligraf® per sq cm |
| Q4104 | Integra®bilayer matrix wound dressing (BMWD), per sq cm |
| Q4106 | Dermagraft®per sq cm |
| Q4116 | AlloDerm®per sq cm |
| Q4121 | TheraSkin®per sq cm |
| Q4128 | AllopatchHD® per sq cm |
| Q4132 | Grafix Core®, per sq cm |
| Q4133 | Grafix PRIME®, per sq cm |
| Q4151 | AmnioBand®, per sq cm |
| Q4158 | Kerecis®, per sq cm |
| Q4186 | Epifix®per sq cm |

***Note:*** *Apligraf®, Dermagraft®, Integra®, AlloDerm®, EpiFix®, Amnioband®, GrafixPrime®, GrafixCore®, Allopatch®, TheraSkin®, and Kerecis®, 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.*

***Note:***
***Place of service*** *for Dermagraft®, Apligraf®, EpiFix®, TheraSkin®, GrafixCore®, GrafixPrime®, Allopatch®, Amnioband®, and Kerecis® is limited to inpatient, outpatient hospital, and office.*

***Place of service*** *for Integra® and AlloDerm® is limited to inpatient and outpatient hospital.*

| Reviews, Revisions, and Approvals | Reviewed Date | Approval Date |
|---|---|---|
| Original Approval date. | 04/21 | 06/21 |
| Removed “immobility” from Description. Removed all of the product-specific coverage. Added the following sections: “Application of Skin Substitutes for the Treatment of Diabetic Foot Ulcers (DFUs),” “Application of Skin Substitutes for the Treatment of Venous Stasis Ulcers (VSUs),” and “Application of Skin Substitutes for the Treatment of Thermal Injuries.” Added FDA Approval information. Added “Medically Necessary Skin Substitutes and Clinical Indications” table. Added "untreated, or active" osteomyelitis. Added definition of high dose corticosteroids. Corrected limit restrictions for Apligraf from 88 units every 365 calendar days to 176 units every 180 calendar days. Added GrafixCore, GrafixPrime, Amnioband, and Allopatch application limits to the policy. Updated the Epifix | 07/21 | 08/21 |

| Reviews, Revisions, and Approvals | Reviewed Date | Approval Date |
|---|---|---|
| application limit from five to ten applications. Added Documentation requirements. Added HCPCS codes for GrafixCore, GrafixPrime, Amnioband, and Allopatch. | | |
| Reviewed CPT and HCPCS codes. | 06/22 | 08/22 |
| Annual Review. NCHC verbiage removed from NC Guidance Verbiage. | 05/23 | 05/23 |
| Annual Review. Removed ICD-10 code table. | 05/24 | 05/24 |
| Annual Review. Removed "Medicaid and clinical health choice," verbiage from References. Added Definitions Criteria I. changed verbiage to "WellCare of North Carolina®, 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: 1. "Refer to Criteria V. for health record documentation requirements," And 2. "Refer to Table I, below, for medically necessary skin substitutes and clinical indications." Added title for Criteria II and separated A. and B. from above. Added Title to Table 1, and Added "joint" prior to the word "capsule" throughout. Criteria III.G. Added fish as an example of a material that could cause an allergy or hypersensitivity. Criteria IV.J. Added "Kerecis®, is limited to one application per calendar week, for a maximum of 12 weeks per ulcer." And added to Table 1 and HCPCS. Criteria V.A.4. Added "amount of product unit discarded and the reason for the wastage to required documentation." Under CPT box added "15002 through 15005 are used to bill for the site preparation and 15271 through 15278 are used to bill application." Under HCPCS box added "Note: Apligraf®, Dermagraft®, Integra®, AlloDerm®, EpiFix®, Amnioband®, GrafixPrime®, GrafixCore®, Allopatch®, TheraSkin®, and Kerecis® 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." **And Note:** Place of service for Dermagraft®, Apligraf®, EpiFix®, TheraSkin®, GrafixCore®, GrafixPrime®, Allopatch®, and Amnioband®, and Kerecis®, is limited to inpatient, outpatient hospital, and office. Place of service for Integra®, and AlloDerm®, is limited to inpatient and outpatient hospital. | 02/25 | 02/25 |

## References

1. State of North Carolina Medicaid Clinical Coverage Policy No: 1G-2 Skin Substitutes. Program Specific Clinical Coverage Policies | NC Medicaid (ncdhhs.gov). Published June 1, 2023. Accessed January 4, 2025.

## North Carolina Guidance

*Eligibility Requirements*

a. An eligible 02ficiary 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.

*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 practitioner).

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.

**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/

*Provider(s) Eligible to Bill for the Procedure, Product, or Service*
To be eligible to bill for the procedure, product, or service related to this policy, the provider(s) shall:

a. meet Medicaid qualifications for participation;
b. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; 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.

*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).

*Claims-Related Information*
Provider(s) shall comply with the NC Tracks 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 - as applicable to the service provided:
   Professional (CMS-1500/837P transaction)
   Institutional (UB-04/837I 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.

*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 - Providers shall follow applicable modifier guidelines.
e. Billing Units - Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).
f. Co-payments -
   For Medicaid refer to Medicaid State Plan:
   https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan

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

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.