BioTissue® Surgical

2022 Reimbursement Resource Guide

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Disclaimer: The guidance contained in this document, dated January 2022, is provided for informational purposes only and represents no statement, promise, or guarantee by TissueTech Inc or its operating subsidiaries including BioTissue Inc and Amniox Medical Inc (collectively TissueTech) concerning reimbursement, payment, charges. Similarly, all CPT codes and HCPCS codes are supplied for informational purposes only and represent no statement, promise, or guarantee by TissueTech that these code selections will be appropriate for a given service or that reimbursement will be made to the provider. This Guide is not intended to increase or maximize reimbursement by a Payer. TissueTech strongly recommends that you consult your individual Payer Organization regarding its relative and current reimbursement policies. For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full package insert.

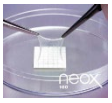
Procedure coding should be based upon medical necessity, procedures and supplies provided to the patient. Coding and reimbursement information is provided for educational purposes and does not assure coverage of the specific item or service in each case. TissueTech, Inc. and The Pinnacle Health Group make no guarantee of coverage or reimbursement of fees. These payment rates are nationally unadjusted average amounts and do not account for differences in payment due to geographic variation. Contact your local Medicare Administrative Contractor (MAC) or CMS for specific information as payment rates listed are subject to change. To the extent that you submit cost information to Medicare, Medicaid, or any other reimbursement program to support claims for services or items, you are obligated to accurately report the actual price paid for such items, including any subsequent adjustments. CPT five-digit numeric codes, descriptions, and numeric modifiers only are Copyright AMA.

Summary

BioTissue Allograft HCPCS (Supply) codes

Neox® and Clarix® wound allografts are reported with either of two HCPCS codes. The code selection depends on the allograft selected:

Q4148 – Neox® Cord 1K, Neox® Cord RT, or Clarix® 1K, per sq cm



Q4156 – Neox® 100 or Clarix® 100, per sq cm

Coverage for the use of amniotic membrane derived skin substitutes varies by payer, contract, and the patient's plan. The Medicare average payments included in this document serve as a guide to general reimbursement.

Importance of documentation

Many payers are silent regarding coverage and have no published policies. When there is no policy in place, coverage and medical necessity are determined on a case-by-case basis at the time of claim submission. For this reason, it is important to document the medical necessity in the patient's record, especially conservative care treatments that have been tried and failed.

Provider offices remain responsible for correct performance, coding, billing, and documenting medical necessity. See pages 8 and 13, for additional documentation information.

Need answers to questions?

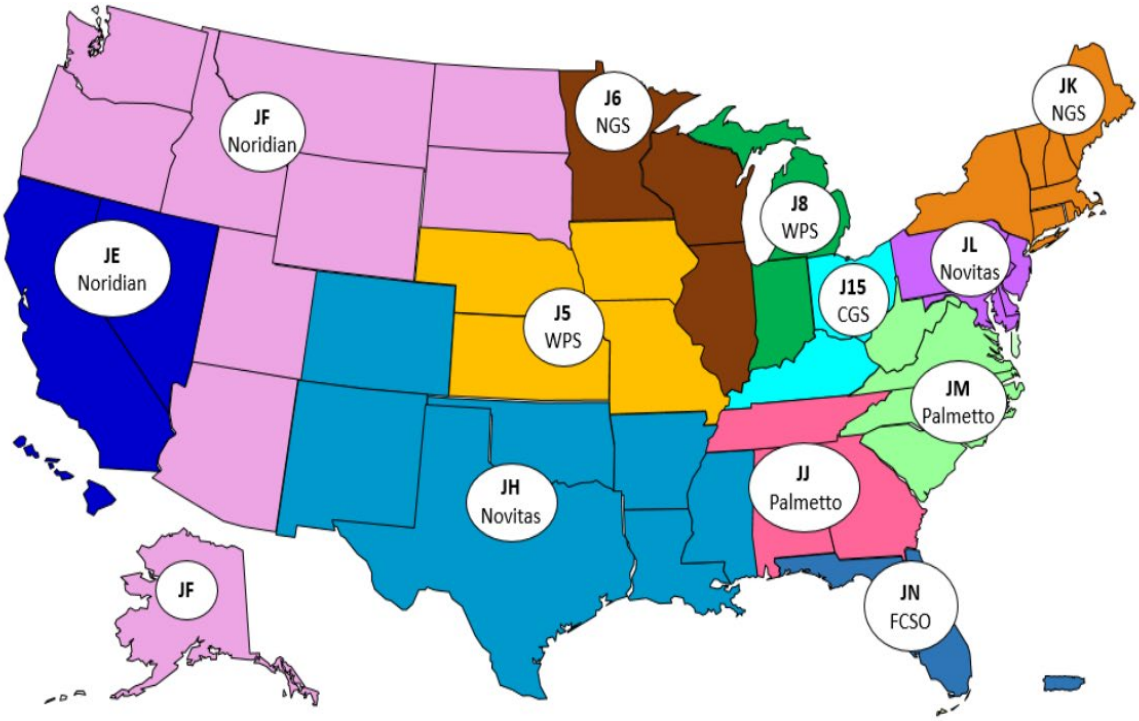
The Pinnacle Health Group can help with benefit verification or billing issues for Neox and/or Clarix wound allografts. Reach out to their team of reimbursement professionals, Monday through Friday, 8:30 AM – 6:00 PM ET to help resolve common reimbursement and billing issues. Their contact information is below:

THE PINNACLE HEALTH GROUP

Contact The Pinnacle Health Group

Email: biotissuesurgical@thepinnaclehealthgroup.com
Phone: 866-369-9290
Fax: 877-499-2986
Hours: Monday to Friday: 8:30 AM – 6:00 PM ET

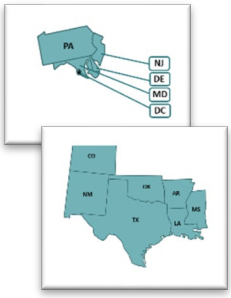
Medicare Administrative Contractor (MAC) Jurisdictions
(As of June 2021)



Medicare Skin Substitute Coverage LCDs (By Jurisdiction)

There are no National Coverage Determinations (NCD) for the use of skin substitutes and each jurisdiction will determine coverage on a case-by-case basis, based on medical necessity. It is important that providers document patient necessity thoroughly within the patient's chart.

Medicare Administrative Contractors (MACs) that have published Local Coverage Determinations (LCD) are as follows:



Novitas JL: DE, DC, MD. NJ, PA &
JH: AR, CO, LA, MS, NM, OK, TX,
Indian Health, & Veteran Affairs:

LCD 35041

CGS – J15: KY & OH:

LCD L36690

First Coast FSCO – JN: FL

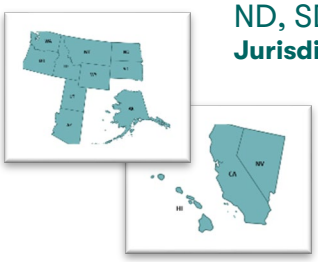
LCD 36377

Medicare Jurisdiction without Coverage LCDs

The following MAC jurisdictions do not have published Skin Substitute Coverage LCDs. Whether or not there is an LCD in place, be advised that Medicare only covers services that are reasonable and necessary. So those guidelines which dictate acceptable medical practice from other sources (peer reviewed literature, professional society protocols, etc.), would serve as potential sources of "reasonable and necessary" indications and practices in the event of an audit. Provider offices remain responsible for correct performance, coding, billing, and medical necessity under Medicare.

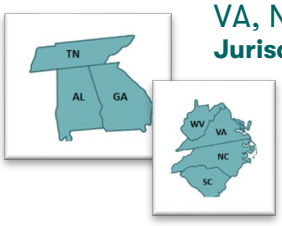
The MAC jurisdictions below do not have LCDs. For additional jurisdiction-specific information, go to that MAC by clicking on the corresponding map or text box to be taken to the jurisdiction landing page. Additional information can be obtained on the specific Jurisdiction page.

Noridian JE: CA, HI, NV **& JF:** AK, AZ, ID, MT, ND, SD, OR, UT, WA, & WY



Jurisdiction E – Part B - JE Part B - Noridian (noridianmedicare.com)
Jurisdiction F - Part B - JF Part B - Noridian (noridianmedicare.com)

Palmetto GBA JJ & JM – TN, AL, GA, W VA, VA, NC, & SC



Jurisdiction J - Part B – Palmetto
Jurisdiction M - Part B (palmettogba.com)

NGS J6: IL, MN, & WI,
& JK – ME, VT, NH, MA, RI CT, NY
Jurisdiction J6 & JK – NGS Medicare

(Select "Part B" and specific state in the "Access NGSMedicare" selection box.)

WPS J5 & J8: NE, KS, IA, MO, MI, & IN
Jurisdictions J5 & J8 - WPS Government Health Administrators Home

(Select specific jurisdiction in the blue bar at the top of the landing page.)

Common Coverage Themes for Skin Substitutes

While LCDs will vary somewhat from MAC to MAC, there are some common coverage themes throughout each of the skin substitute application LCDs. These may provide general guidelines for providers practicing in jurisdictions that are silent regarding coverage. Following these guidelines does not guarantee coverage or payment but does provide a strong basis upon which to support medical necessity. Always follow the requirements of your local MAC.

These common themes were compiled from existing Medicare LCDs

Medicare coverage for wound care on a continuing basis, for a single wound, in an individual patient, is contingent upon evidence documented in the patient's medical record, that the wound is improving in response to the wound care being provided. Since it is neither reasonable nor medically necessary to continue a given type of wound care in the absence of wound improvement, it is expected that the wound's response to treatment will be documented in the medical record at least once every 30 days for each episode of wound treatment and made available to the contractor upon request.

- Documentation of response requires measurements of the initial ulcer, measurements at the completion of at least four weeks of appropriate wound care and measurements immediately prior to placement and with each subsequent placement of the human cells, tissues, and cellular and tissue-based product or H/CTP.

Patient Criteria

- Conservative/appropriate treatment failure – 30-day trial and documentation
  - Control of edema, venous hypertension, or lymphedema.
  - Control of any infection.
  - Elimination of underlying cellulitis, osteomyelitis, foreign body, or malignant process.
  - Debridement of necrotic tissue or foreign body.
  - For DFUs, appropriate non-weight bearing and/or off-loading pressure.
  - For VSUs, compression therapy.
  - Provision of wound environment to promote healing.
  - Protection from trauma and contaminants.

- Failed response to treatment of wound
  - Increased in size or depth.
  - Has not changed in baseline size or depth.
    - Be sure to measure and document!
  - No indication that improvement is likely.
    - Granulation, epithelialization, or progress towards healing.

- Adequate oxygenation
  - Ankle-Brachial Index (ABI) ≥60-65mm.
  - Toe pressure >30mm.

- Wound is free of infection and underlying osteomyelitis.

- No involvement of tendon, muscle, joint capsule or exhibiting exposed bone or sinus tracts unless labeling states otherwise.

- For DFUs, medical record must reflect:
  - Diagnosis of Type 1 or Type 2 Diabetes: and
  - Under medical management.
  - Failed to respond to documented conservative wound-care measures of greater than four weeks, during which the patient is compliant with recommendations, and without evidence of underlying osteomyelitis or nidus of infection.

- Presence of a VSU for at least 3 months but unresponsive to appropriate wound care for at least 30 days with documented compliance.

- Presence of a full thickness skin loss ulcer that is the result of abscess, injury or trauma that has failed to respond to appropriate control of infection, foreign body, tumor resection, or other disease process for a period of 4 weeks or longer.

- Non-smoker or refrained for 4-6 weeks or received counseling on effects of smoking on surgical outcomes and treatment for smoking cessation.

- Under care of a physician or non-physician practitioner (NPP).
    - Not a non-advanced practice nurse, therapist, or medical assistant.

Treatment Limitations

- Skin substitute application typically limited to 10 applications.
- Treatment should not exceed 12 weeks.
- Improvement should be observed by 4 weeks.
- Retreatment of a healed ulcer within 1 year is considered a treatment failure and not covered.

Treatment Documentation:

- Wound measurements throughout treatment.
    - Size/measurement/location/stage/duration/evidence of infection).

- Skin Substitute Application.
    - Op Note: pre- and post-operative diagnoses, surgeon name, anesthesia, reason for procedure, surgical description, product affixed to wound.

- Date, time, and location of treated ulcer or treated area.

- Name of product, how product supplied, amount used and discarded (if applicable), reason for waste. Manufacturer's serial/lot/batch, other unit I.D. # of graft. Document if not supplied.

Post-Treatment Documentation

- Response to treatment for each episode. Evidence of improvement with each application.

- If wound worsens/lack of treatment response, reason for continuing treatment.

BioTissue Surgical

BioTissue Reimbursement Hotline **866-369-9290**
Email: **biotissuesurgical@thepinnaclehealthgroup.com**

2022 Medicare Physician and Facility Coding & Reimbursement Guide
Neox® 1K, Neox® 100, and Neox® RT

Neox 1K, Neox RT, Neox 100, are human amniotic membrane products derived from placenta or umbilical cord tissue. The biological integrity of the amniotic membrane is maintained through a proprietary CryoTek® process. These products are registered with the U.S. Food and Drug Administration (FDA) as Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P) under Section 361 of the Public Health Service (PHS) Act.

The Neox product line is indicated for use as a wound covering for dermal ulcers and defects.

Product line		
Neox 1K	Neox RT	Neox 100
Neox 1K Cryopreserved umbilical cord derived allograft	Neox RT Terminally sterilized umbilical cord derived allograft	Neox 100 Cryopreserved amniotic membrane allograft

Allograft				
HCPCS	Descriptor	Non-Facility MPFS		
Q4148	Neox® Cord 1K, Neox® Cord RT, or Clarix® Cord 1K, per square centimeter	Based on Invoice or WAC		
Q4156	Neox® 100 or Clarix® 100, per square centimeter	Based on Invoice or WAC		
HCPCS	Descriptor	Inpatient	HOPPS	ASC
Q4148	Neox® Cord 1K, Neox® Cord RT, or Clarix® Cord 1K, per square centimeter	N/A	Packaged	Packaged
Q4156	Neox® 100 or Clarix® 100, per square centimeter	N/A	Packaged	Packaged

Skin Substitute Application Procedure Codes

Physician Fee Schedule – Facility and Non-Facility Settings (CY 2022)				
CPT Code	Code Description	RVU	Physician Non-Facility	Physician Facility
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	1.50	$159.88	$85.13
+15272	each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)	0.33	$25.95	$18.00
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	3.50	$327.72	$201.41
+15274	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 (List separately in addition to code for primary procedure)	0.80	$86.86	$46.37
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	1.83	$164.38	$94.82
+15276	each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)	0.50	$33.57	$25.95
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	4.00	$359.56	$229.44
+15278	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 (List separately in addition to code for primary procedure)	1.00	$100.36	$57.79

Skin Substitute Application Procedure Codes –

Facility Reimbursement – Hospital Outpatient Department and Ambulatory Surgical Center Settings (CY 2022)						
CPT Code	Code Description	APC	Status Indicator OPPS (SI)	Hospital Outpatient	Payment Indicator ASC	Ambulatory Surgical Center
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	5054	T	$1,749.26	G2	$887.09
+15272	each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)	N/A	N	$0	N1	$0
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	5055	T	$3,596.22	G2	$1,823.73
+15274	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 (List separately in addition to code for primary procedure)	N/A	N	$0	N1	$0
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	5054	T	$1,749.26	G2	$887.09
+15276	each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)	N/A	N	$0	N1	$0
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	5054	T	$1,749.26	G2	$887.09
+15278	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 (List separately in addition to code for primary procedure)	N/A	N	$0	N1	$0

OPPS Status Indicator - **T** = Significant Procedure, Multiple Reduction Applies
N = Items and Services Packaged into APC Rates

ASC Status Indicator – **N1** = Packaged service/item; no separate payment made
G2 = Non-office based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight.

+ = Add-on code

***Modifier 58 should be used if an autograft or another skin substitute is applied as part of a staged procedure applied during a different surgical encounter after the initial placement of the skin substitute.

Revenue Code	
Revenue Code	Descriptor
636	Pharmacy Extension 025X-Drug Requiring Detailed Coding

Inpatient Facility Reimbursement		
DRG	Descriptor	Payment
463	Wound Debridement and Skin Graft Except Hand for Musculoskeletal System and Connective Tissue Disorders with MCC	$34,977.92
464	Wound Debridement and Skin Graft Except Hand for Musculoskeletal System and Connective Tissue Disorders with CC	$19,382.68
465	Wound Debridement and Skin Graft Except Hand for Musculoskeletal System and Connective Tissue Disorders without CC/MCC	$12,011.02
573	Skin graft for Skin Ulcer or Cellulitis with MCC	$36,077.35
574	Skin graft for Skin Ulcer or Cellulitis with CC	$21,145.15
575	Skin graft for Skin Ulcer or Cellulitis without CC/MCC	$11,484.10

Notes:

- The payment rates specified in this document are Centers for Medicare & Medicaid Services (CMS) national unadjusted averages. Actual payment rates will vary based on geographic adjustments and are updated quarterly. Commercial payment rates will vary per contract.
- By Report – For CPT codes that have not been assigned RVUs (e.g., miscellaneous codes), there is no national payment rate. Providers must provide detailed operative notes describing the service provided. If there is an existing service with an established CPT code that involves similar work, that CPT code may be provided as a suggested crosswalk for payment purposes.
- If required, please utilize appropriate modifiers with Neox® 1K, Neox® RT and Neox® 100 products.
- JC - Skin substitute used as a graft,
- JW - Portion of skin substitute discarded (required for ALL MACS as of January 1, 2017).
- For drugs and biologicals not included in the ASP Medicare Part B Drug Pricing File, payment is based on WAC or invoice pricing.
- CY 2022 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; (CMS-1751-F); Addendum B. All MPFS Fee Schedules calculated using CF of $34.6062 effective January 1, 2022.
- Current Procedural Terminology (CPT®) is a registered trademark of the American Medical Association.

Available Sizes & Billing Quantities		
Catalogue Number	Size – cm^2	Billing Quantity*
NEOX 1K (Q4148)		
NX-10-2010	2.0 X 1.0	2
NX-10-1515	1.5 X 1.5	3
NX-10-2020	2.0 X 2.0	4
NX-10-3020	3.0 X 2.0	6
NX-10-2525	2.5 X 2.5	7
NX-10-3030	3.0 X 3.0	9
NX-10-4030	4.0 X 4.0	12
NX-10-6030	6.0 X 3.0	18
NX-10-8030	8.0 X 3.0	24
NEOX RT (Q4148)		
NX-UR-2010	2.0 X 1.0	2
NX-UR-2020	2.0 X 2.0	4
NX-UR-3020	3.0 X 2.0	6
NX-UR-3030	3.0 X 3.0	9
NX-UR-4030	4.0 X 3.0	12
NX-UR-6030	6.0 X 3.0	18
NX-UR-8030	8.0 X 3.0	24
NEOX 100 (Q4156)		
NX-02-2020	2.0 X 2.0	4
NX-02-3030	3.0 X 3.0	9
NX-02-4040	4.0 X 4.0	16
NX-02-7070	7.0 X 7.0	49

*Rounded up to the nearest whole number.

Examples of Wound Care Documentation

Source: JE Part B - Noridian (noridianmedicare.com)

Documentation may include:

- ☐ Practitioner, nurse, and ancillary progress notes
- ☐ Records of conservative measures trialed for treatment of service provided
- ☐ Wound care notes
- ☐ Wound measurements prior to treatment
- ☐ Treatment of any infection
- ☐ Prior skin substitute graft application notes
- ☐ Beneficiary name and date of service on all documentation
- ☐ Documentation as required in LCD or NCD
- ☐ Any additional documentation to support the reasonable necessity of the service(s) performed
- ☐ Advance Beneficiary Notice (If applicable)
- ☐ Signature log or signature attestation for any missing or illegible signatures within the medical record (all personnel providing services)
- ☐ Signature attestation and credentials of all personnel providing services
- ☐ If an electronic health record is utilized, include your facility's process of how the electronic signature is created. Include an example of how the electronic signature displays once signed by the physician

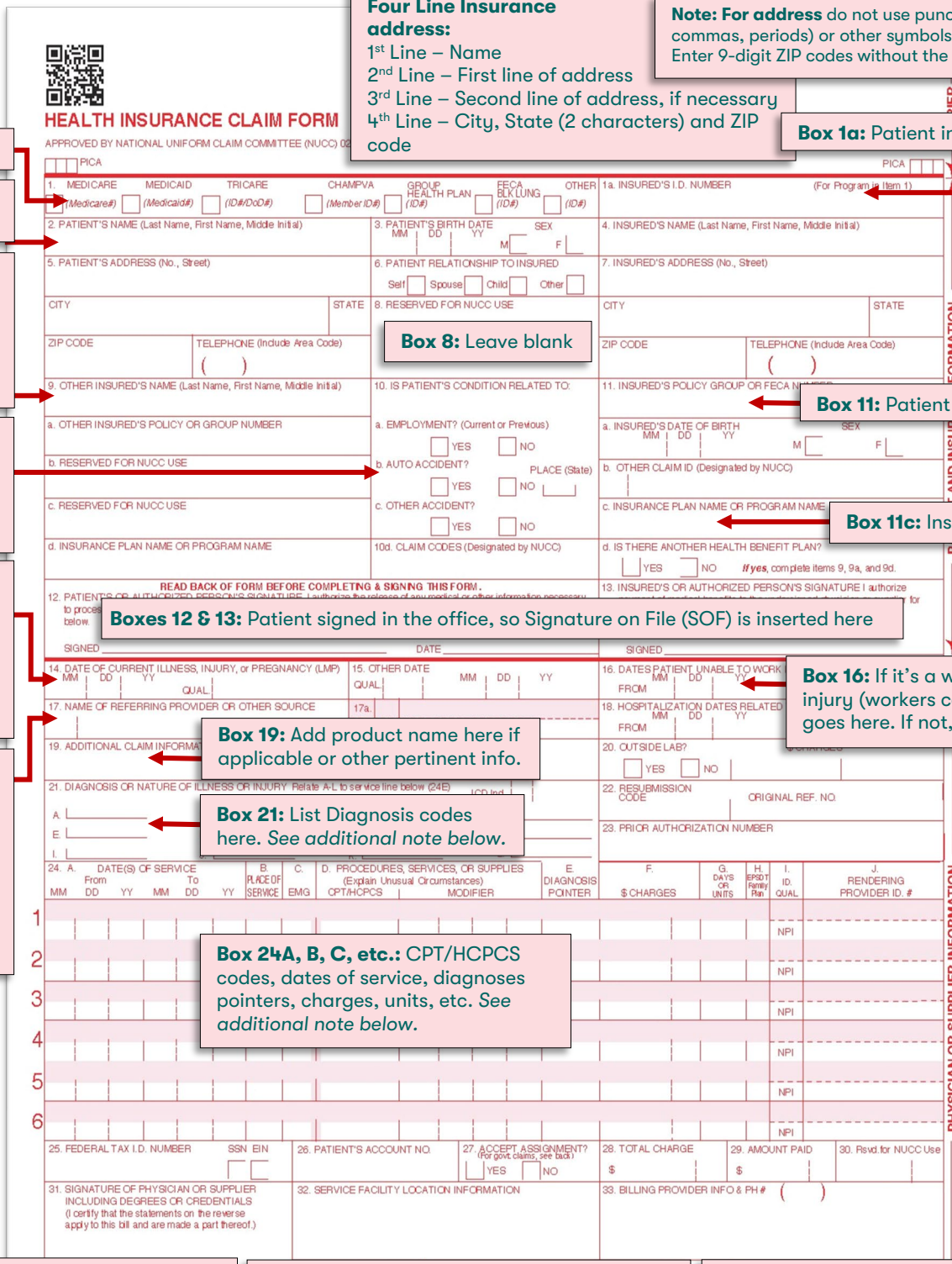
Medicare Documentation Requirements

Source: cms.gov

1. All documentation must be maintained in the patient's medical record and made available to the contractor upon request.
2. Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service[s]). The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient.
3. Medical record documentation must support the medical necessity of the services as stated in this policy.
4. The documentation must support that the service was performed and must be included in the patient's medical record. This information is normally found in the history and physical, office/progress notes, hospital notes, and/or procedure report.
5. The medical record must clearly show that the criteria listed under the Covered Indications and Limitations sections have been met, as well as the appropriate diagnosis and response to treatment.
6. The documentation must support the need for skin substitute application and the product used.
7. A description of the wound(s) must be documented at baseline (prior to beginning conservative treatment) relative to size, location, stage, duration, and presence of infection, in addition to type of treatment given and response.
    - This information must be updated in the medical record throughout treatment.
    - Wound description must also be documented pre and post treatment with the skin substitute graft being used.
    - If obvious signs of worsening or lack of treatment response is noted, continuing treatment with the skin substitute would not be considered medically reasonable and necessary without documentation of a reasonable rationale for doing so.
8. Documentation of smoking history, and that the patient has received counseling on the effects of smoking on surgical outcomes and treatment for smoking cessation (if applicable) as well as outcome of counselling must be in the medical record.
9. The amount of utilized and wasted skin substitute must be clearly documented in the procedure note with the following minimum information:
    - Date, time, and location of ulcer treated;
    - Name of skin substitute and how product supplied;
    - Amount of product unit used;
    - Amount of product unit discarded;
    - Reason for the wastage;
    - Manufacturer's serial/lot/batch or other unit identification number of graft material. When manufacturer does not supply unit identification, record must document such.

Sample CMS-1500 Claim form

NOTE: Dates must be in 6- or 8-digit format. (MM/DD/YY or MM/DD/CCYY)



Four Line Insurance address:
1st Line – Name
2nd Line – First line of address
3rd Line – Second line of address, if necessary
4th Line – City, State (2 characters) and ZIP code

Note: For address do not use punctuation (i.e., commas, periods) or other symbols in the address. Enter 9-digit ZIP codes without the hyphen.

Box 1: Select payer

Box 1a: Patient insurance ID #

Boxes 2-7: Patient / Guarantor info

Boxes 9- 9d: Patient 's other insurance info (if applicable) is listed here. **Leave 9b and 9c blank.**

Box 8: Leave blank

Box 10: Answer questions regarding injury, or accident. **Completion of 10a-c is required.**

Box 11: Patient ins. GROUP#

Box 11c: Insurance name

Boxes 14 & 15: Insert dates if the visit is related to current illness or injury. Pregnancy is probably not applicable.

Boxes 12 & 13: Patient signed in the office, so Signature on File (SOF) is inserted here

Box 16: If it's a work-related injury (workers comp) info goes here. If not, leave blank.

Box 17: If there is a referring provider, insert their name here. If no referring provider, doctor seeing patient that day goes here.
Box 17b: NPI of MD listed in Box 17.

Box 19: Add product name here if applicable or other pertinent info.

Box 21: List Diagnosis codes here. *See additional note below.*

Box 24A, B, C, etc.: CPT/HCPCS codes, dates of service, diagnoses pointers, charges, units, etc. *See additional note below.*

Box 21D: IMPORTANT INFO Regarding diagnosis code sequence: If you include multiple diagnosis codes on a single claim, place them in order according to significance. (The first-listed (i.e., primary) code being the one that most strongly supports the medical necessity of your services.)

Box 24D: IMPORTANT INFO Regarding CPT code sequence: Sequencing CPT Codes is crucial to appropriate claims submission and appropriate reimbursement. When reporting claims with multiple CPT codes, sequence the codes from highest to lowest relative value.

Box 24D, cont.: IMPORTANT INFO Regarding modifier sequence: The general order of sequencing modifiers is (1) pricing (2) payment (3) location. Location modifiers, in all coding situations, are coded "last".

SOURCE: National Uniform Claim Committee. https://www.nucc.org/images/stories/PDF/1500_claim_form_instruction_manual_2021_07-v9.pdf and https://www.novitas-solutions.com/webcenter/portal/MedicareJH/pagebyid?contentId=00103783

BioTissue Surgical

Complete and fax to Pinnacle: **215-369-9198** or **877-499-2986**
Email to **BV@thepinnaclehealthgroup.com**

Service Request Form

Requested service: ☐ Prior Authorization ☐ Prior Authorization Appeal ☐ Claim Denial / Appeal

Provider Information

Name of Rendering Physician:		
Physician NPI:	Physician TIN:	Medicare PTAN:
Place of Service: ☐ Physician Office ☐ Ambulatory Surgical Center ☐ Hospital Inpatient ☐ Hospital Outpatient ☐ Other (Specify)		
Practice/Facility Name:		
Address:		
Facility NPI:	Facility TIN:	BioTissue Representative:
Anticipated Procedure Date:	Contact Person:	Contact Phone:
Contact Email Address:	Contact Fax:	

PATIENT INFORMATION

Patient Name:		
Address:	City:	
State:	Zip code:	Gender:
DOB:	Home Phone:	Cell Phone:
Primary Ins:	Ins ID#	Group#
Ins. Phone:	Subscriber Name:	Subscriber DOB:
Secondary Ins:	Ins ID#	Group#
Ins. Phone:	Subscriber Name:	Subscriber DOB:

Clinical/Procedure Information

	ICD-10 Diagnosis Code(s)	CPT/Procedure Code(s)	HCPCS/Product/Supply Code(s)
Primary			
Secondary			

Products to be utilized:
(Wound) ☐ NEOX®1K™ *(Q4148)* ☐ NEOX®RT *(Q4148)* ☐ NEOX®100 *(Q4156)* ☐ NEOX® FLO *(Q4155)*

(Surgical Use) ☐ CLARIX®1K (Q4148) ☐ CLARIX®100 (Q4156) ☐ CLARIX® FLO *(Q4155)*

Number of Grafts:	Size of Graft:	Milligrams to be used (if applicable):

Do you have a Business Associate Agreement on file? ☐ **Yes** ☐ **No** If no, patient consent is required and must be included

Required Documentation

Please attach all supporting clinical documentation (e.g., plan of care, previous conservative care progress notes, and lab reports, etc.) To obtain a prior authorization or pre-determination.

PUBLISHED CLINICAL EVIDENCE

This information can be used with any Letter of Medical Necessity, Appeal, Prior Authorization request, etc.

Neox® 1K is a cryopreserved human amniotic membrane product derived from donated umbilical cord tissue following healthy live birth. Neox® 1K has been used successfully for many years and was developed to treat complex wounds and is the only amniotic tissue that has been widely studied in complex ulcers that extend to the bone, tendon, or joint capsule. Further, Neox® 1K is the only amniotic membrane product that has been reviewed and studied in complex ulcers with osteomyelitis. I have included three published articles for Neox® 1K and one article for a biologic product that is being developed from the same tissue platform.

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31 patients presenting with 33 complex foot ulcers with a confirmed histopathological diagnosis of osteomyelitis treated by the same surgeon at a single wound care center by the following treatment regimen: sharp debridement, resection of infected bone, when necessary, open cortex, antibiotics, and application of cryopreserved umbilical cord (Neox 1K).

The average ulcer size was 15.6 ± 17.7 cm2 (0.4–73.95 cm2). Overall, 26 out of the 33 wounds achieved complete closure (78.8 percent). Five patients were lost to follow-up and one patient expired during the course of treatment, not believed to be treatment related. Of the remaining 27 wounds in patients not lost to follow-up, 26 achieved complete healing with an average time to healing of 16 weeks and an average of 1.24 applications of cUC.

Raphael A. **A single-centre, retrospective study of cryopreserved umbilical cord/amniotic membrane tissue for the treatment of diabetic foot ulcers.** https://pubmed.ncbi.nlm.nih.gov/29027852/

In this study 32 wounds in 29 patients were treated with Neox 1K for diabetic foot ulcers. The average initial wound area for all wounds was 10.6 ± 2.15 cm2.

Of the 32 wounds, 28 achieved complete epithelialization for an overall healing rate of 87.5 percent. Average time to wound closure was 13.8 ± 1.95 weeks with a median of nine weeks. The average number of graft applications was 1.68 grafts.

Raphael A, Gonzales J. **Use of cryopreserved umbilical cord with negative pressure wound therapy for complex diabetic ulcers with osteomyelitis.** J Wound Care. 2017 Oct 1;26(Sup10):S38-S44. doi: 10.12968/jowc.2017.26.Sup10.S38. https://www.ncbi.nlm.nih.gov/pubmed/28976835

In this study, investigators reported on 14 wounds in 13 patients, with an average initial wound area of 33.2 ± 21.7 cm2 and wound volume of 52 ±26.2 cm3 received Neox 1K and NPWT.

All achieved complete re-epithelialization with an average time to closure of 24.0 ± 10.9 weeks, using between two to five cUC applications. No adverse events were noted and none of the wounds required limb amputation during the follow-up of 24 months for each patient.

Marston WA, Lantis JC, 2nd, Wu SC, et al. An open-label trial of cryopreserved human umbilical cord in the treatment of complex diabetic foot ulcers complicated by osteomyelitis. Wound Repair and Regeneration: The Official Publication of the Wound Healing Society [and] the European Tissue Repair Society 2019.

This study examined prospective results from TissueTech's Phase 2 trial under and Investigational New Drug trial to support a Biologics Licensing Application (BLA) for TTAX01. TTAX01 is aseptically processed in compliance with both current Good Tissue Practices and "351" Good Manufacturing Practices based upon the same technology platform as Neox 1K reiterating the wound closure experiences seen with Neox 1K in this population.

In this study, investigators prospectively treated 32 complex diabetic foot ulcers with confirmed active osteomyelitis. Initial closure occurred in 18 of 32 (56 percent) wounds, with 16 (50 percent) of these having confirmed closure in 16 weeks with a median of one-product application. Cases with biopsy confirmed osteomyelitis (n = 20) showed initial closure in 12 (60 percent) wounds and confirmed closure in ten (50 percent) wounds. Four of the five ulcers presenting as recurrences experienced confirmed closure. Mean overall time to healing was 12.8 ± 4.3 weeks. Mean wound area reduction from baseline was 91 percent for all wounds.

A second Phase 2 trial reporting 52-Week follow-up results, accepted for publication in Wound Repair and Regeneration, show a total closure rate of 78.1% at 52 weeks, with most ulcers completely closing by Week 28.

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This follow-up study evaluated one-year outcomes associated with the patients reported in Marston 2019. The complete healing rate at 1 year was 86.20%. Overall, the study found TTAX01 to be safe in long-term follow-up and associated with both a low rate of major amputation and a higher-than-expected rate of healing.

Sample Letter of Medical Necessity

For Neox® 1K

Please include physician letterhead on appeal letters and letters of medical necessity

DATE

[Payer Contact]
[Title]
[Address]
[City, State, Zip]

Re: [Patient Name]
[Patient Member ID]

Dear [Payer Contact]:

On behalf of my patient, [INSERT PATIENT NAME], I am submitting this letter of medical necessity for Neox® 1K (HCPCS: Q4148). This product is routinely used in the hospital to treat complex ulcers of the lower extremity, but the product is listed as not covered under your insurance plan's medical coverage policy for amniotic membrane products.

Given the severity of my high-risk patient's complex ulcer, I am respectfully requesting **prior authorization** approval to use Neox 1K for them, to allow me to aggressively treat them and help prevent hospitalization and more complex surgical treatment of the ulcer. In my medical judgement, Neox 1K is the most appropriate next step treatment for this patient. Using Neox 1K will allow me to treat my patient in clinic, instead of a more costly place of service. Additionally, since the graft is designed to stay on the wound for four weeks or more, I can follow-up with the patient via telehealth visits. Using other wound products would require the patient to return to clinic weekly, for graft replacement.

Below, I have included information regarding my patient, published clinical evidence supporting Neox 1K for this patient, and my clinical rationale for selecting Neox 1K.

PATIENT HISTORY

[INSERT Patient History, Including Diagnoses and Previous Failed Treatment Modalities]

[INSERT Patient comorbidities that put the patient at particular risk for ulcer-related complications and COVID-19-related complications]

[AS APPROPRIATE AND OBSERVED – INSERT Rationale for Using Neox 1K For This Patient, Including COVID-19 Hospital Restrictions, Ability to Leave the Neox 1K Graft on the Ulcer For 4 or More Weeks Without Replacement, Ability to Treat the Complex Ulcer with a Single Graft, etc.]

[AS APPROPRIATE AND OBSERVED – Discuss Previous Use of Neox 1K in Similar Cases and Discuss the Outcomes. Explain Why These Outcomes Are Relevant to this Patient]

[AS APPROPRIATE AND OBSERVED – Is There a Particular Need for Neox 1K as it Relates to Hospital Access Problems or Practice Restrictions Related to COVID-19?]

PUBLISHED CLINICAL EVIDENCE

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   31 patients presenting with 33 complex foot ulcers with a confirmed histopathological diagnosis of osteomyelitis treated by the same surgeon at a single wound care center by the following treatment regimen: sharp debridement, resection of infected bone, when necessary, open cortex, antibiotics, and application of cryopreserved umbilical cord (Neox 1K).

   The average ulcer size was 15.6 ± 17.7 cm2 (0.4–73.95 cm2). Overall, 26 out of the 33 wounds achieved complete closure (78.8 percent). Five patients were lost to follow-up and one patient expired during the course of treatment, not believed to be treatment related. Of the remaining 27 wounds in patients not lost to follow-up, 26 achieved complete healing with an average time to healing of 16 weeks and an average of 1.24 applications of cUC.

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   Of the 32 wounds, 28 achieved complete epithelialization for an overall healing rate of 87.5 percent. Average time to wound closure was 13.8 ± 1.95 weeks with a median of nine weeks. The average number of graft applications was 1.68 grafts.

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Given the current health crisis and concurrent need to address this serious medical condition I ask that you allow me to use Neox 1K for this patient so that I can avoid possible hospital admission of this patient.

Thank you for your time reviewing this information as well as your consideration.

Sincerely,

[Doctor Name]
[Title/Specialty]
[Email address]

Sample Appeal Letter

For Neox® 1K

Please include physician letterhead on appeal letters and letters of medical necessity

DATE

[Payer Contact]
[Title]
[Address]
[City, State, Zip]

Re: [Patient Name]
[Patient Member ID]
[DOS]

Dear [Payer Contact]:

On behalf of my patient, [INSERT PATIENT NAME], I am submitting this appeal for coverage of Neox® 1K (HCPCS: Q4148) that was denied by [INSERT PAYER NAME]. This product is routinely used in the hospital to treat complex ulcers of the lower extremity. Given the severity of this high-risk patient's complex ulcer, I used Neox 1K for this patient, to allow me to aggressively treat them and help prevent hospitalization and more complex surgical treatment of the ulcer. In my medical judgement, Neox 1K was the most appropriate next step treatment for this patient. Using Neox 1K allowed me to treat my patient in clinic, instead of a more costly place of service. Additionally, since the graft is designed to stay on the wound for four weeks or more, I can follow-up with the patient via telehealth visits. Using other wound products would have required the patient to return to clinic weekly, for graft replacement.

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After reviewing the enclosed information illustrating your member's need for Neox 1K, I ask that you promptly authorize payment for this claim. If you have any questions, please reach out to my office at the contact information below.

Thank you for your time reviewing this information as well as your consideration.

Sincerely,

[Doctor Name]
[Title/Specialty]
[Email address]

Where to go for Assistance?

The Pinnacle Health Group

BioTissue has enlisted **The Pinnacle Health Group** to assist with Reimbursement Support. Pinnacle provides help via a Hotline or can be accessed via email. Their team of credentialed professional coders can provide support to physicians and facilities and answer many reimbursement questions. They can provide:

- Coding guidance for BioTissue products
- Coverage criteria for specific payers
- Claim appeals and underpayment support
- Benefit verification and prior authorization requests
- Reimbursement and guidance documents
- Coding guide
- Letter of Medical Necessity
- Appeal Templates

Contact The Pinnacle Health Group

Email: biotissuesurgical@thepinnaclehealthgroup.com
Phone: 866-369-9290
Fax: 877-499-2986
Hours: Monday to Friday: 8:30 AM – 6:00 PM ET