BioTissue® Surgical

Reimbursement Resource Guide

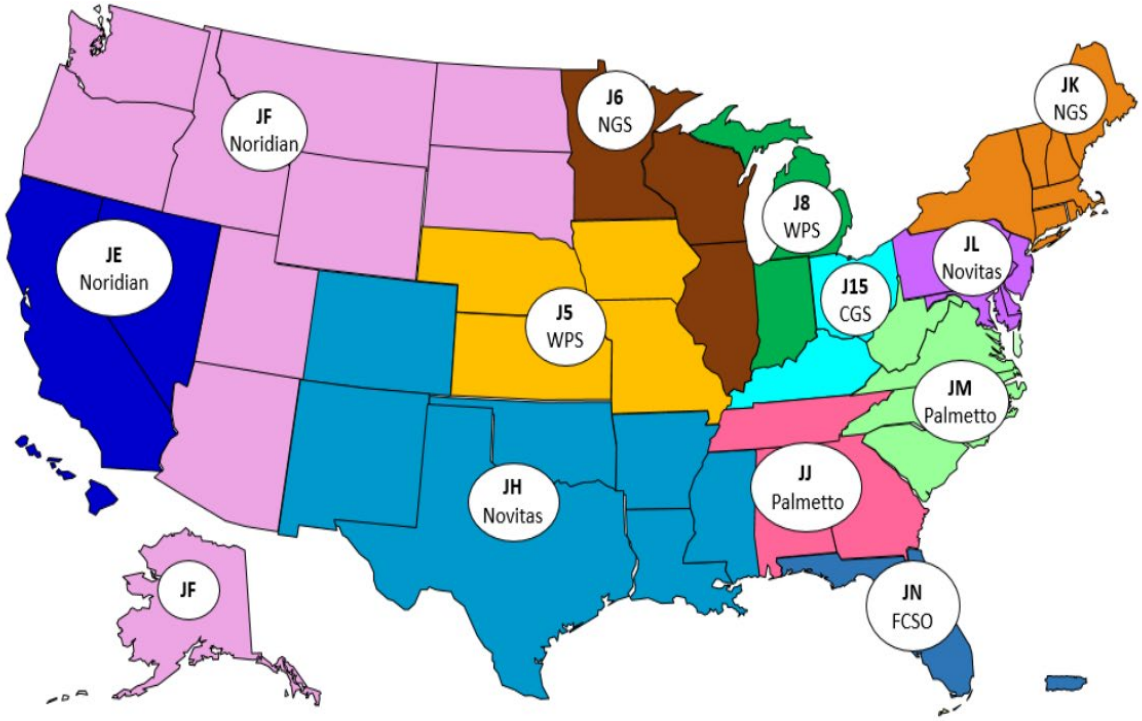
Neox®

WOUND CARE

January 2024
US-NX-0013

Table of Contents – Reimbursement Resource Guide

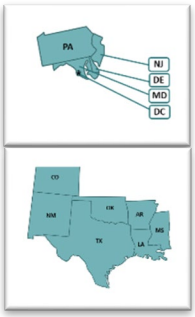
Medicare Administrative Contractor (MAC) Jurisdictions
(As of November 2023)



Medicare Jurisdictions with Skin Substitute Coverage LCDs

There are no National Coverage Determinations (NCD), **however four MACs listed below have Local Coverage Determinations (LCDs) for the use of skin substitutes.** Jurisdictions without an LCD 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.

Coding information can be found in the Articles accompanying the LCDs. **Always check applicable Medicare Local Coverage Determinations (LCDs) and accompanying Articles to identify specific requirements.**



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

LINK TO CURRENT LCD L35041

LINK TO CURRENT ARTICLE A54117

CGS J15: KY & OH

LINK TO CURRENT LCD L36690
LINK TO CURRENT ARTICLE A56696

First Coast FSCO JN: FL

LINK TO CURRENT LCD L36377
LINK TO CURRENT ARTICLE A57680

Medicare Jurisdictions without Coverage LCDs

The following MAC jurisdictions do not have published Skin Substitute Coverage LCDs. Jurisdictions without an LCD 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. 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

Noridian JF: AK, AZ, ID, MT, ND, SD, OR, UT, WA, & WY

Palmetto GBA JJ: – TN, AL, & GA

Palmetto GBA JM: W VA, VA, NC, & SC

NGS J6: IL, MN, & WI

NGS JK – ME, VT, NH, MA, RI CT, & NY

WPS J5: NE, KS, IA, & MO

WPS J8: MI, & IN

BioTissue Surgical

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

2024 BioTissue Wound Coding Sheets – Neox®
Neox® 1K, Neox® RT, and Neox® 100

Neox 1K, Neox RT and Neox 100, are Human Amniotic Membrane Allografts derived from Human Birth Tissue. The biological integrity of the Amniotic Membrane is maintained through a proprietary CryoTek® Cryopreservation 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 to create a protective environment for wound healing to occur.

Product line		
Neox 1K	Neox RT	Neox 100
Neox 1K Cryopreserved ultra-thick human amniotic membrane allograft derived from umbilical cord	Neox RT Sterile hydrated, ultra-thick, human amniotic membrane allograft derived from umbilical cord	Neox 100 Cryopreserved human amniotic membrane allograft

Allograft				
HCPCS	Descriptor	Non-Facility MPFS		
Q4148	Neox 1K, Neox RT, or Clarix 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	OPPS	ASC
Q4148	Neox 1K, Neox RT, or Clarix 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 2024)					
CPT Code	Code Description	Non-Facility		Facility	
		RVUs	MPFS	RVUs	MPFS
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	4.63	$151.59	2.50	$81.85
+15272	each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)	0.74	$24.23	0.50	$16.37
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	9.26	$303.17	5.80	$189.89
+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)	2.43	$79.56	1.32	$43.22
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	4.77	$156.17	2.77	$90.69
+15276	each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)	0.97	$31.76	0.74	$24.23
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	10.22	$334.60	6.61	$216.41
+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)	2.84	$92.98	1.65	$54.02

Skin Substitute Application Procedure Codes – OPPS & ASC

Facility Reimbursement – Hospital Outpatient Department and Ambulatory Surgical Center Settings (CY 2024)						
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	$1,739.33	G2	$945.99
+15272	each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)	N/A	N	Packaged	N1	Packaged
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	$3,421.82	G2	$1,861.08
+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	Packaged	N1	Packaged
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	$1,739.33	P3	$90.05
+15276	each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)	N/A	N	Packaged	N1	Packaged
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	$1,739.33	G2	$945.99
+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	Packaged	N1	Packaged

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	$39,654.96
464	Wound Debridement and Skin Graft Except Hand for Musculoskeletal System and Connective Tissue Disorders with CC	$21,014.60
465	Wound Debridement and Skin Graft Except Hand for Musculoskeletal System and Connective Tissue Disorders without CC/MCC	$13,098.59
573	Skin graft for Skin Ulcer or Cellulitis with MCC	$43,536.65
574	Skin graft for Skin Ulcer or Cellulitis with CC	$23,846.05
575	Skin graft for Skin Ulcer or Cellulitis without CC/MCC	$14,325.27

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 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; (CMS-1786-FC); Addendum B. All MPFS Fee Schedules calculated using CF of $32.74 effective January 1, 2024.
- 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 3.0	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.

HCPCS Q CODES

Neox wound allografts are reported with either of two HCPCS Q Codes. The code selection depends on the allograft selected

Q4148 – Neox 1K, Neox 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 payor, contract, and the patient's plan.

Examples of Wound Care Documentation

Importance of documentation

Many payors 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.

Providers remain responsible for correct performance, coding, billing, and documenting medical necessity.

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

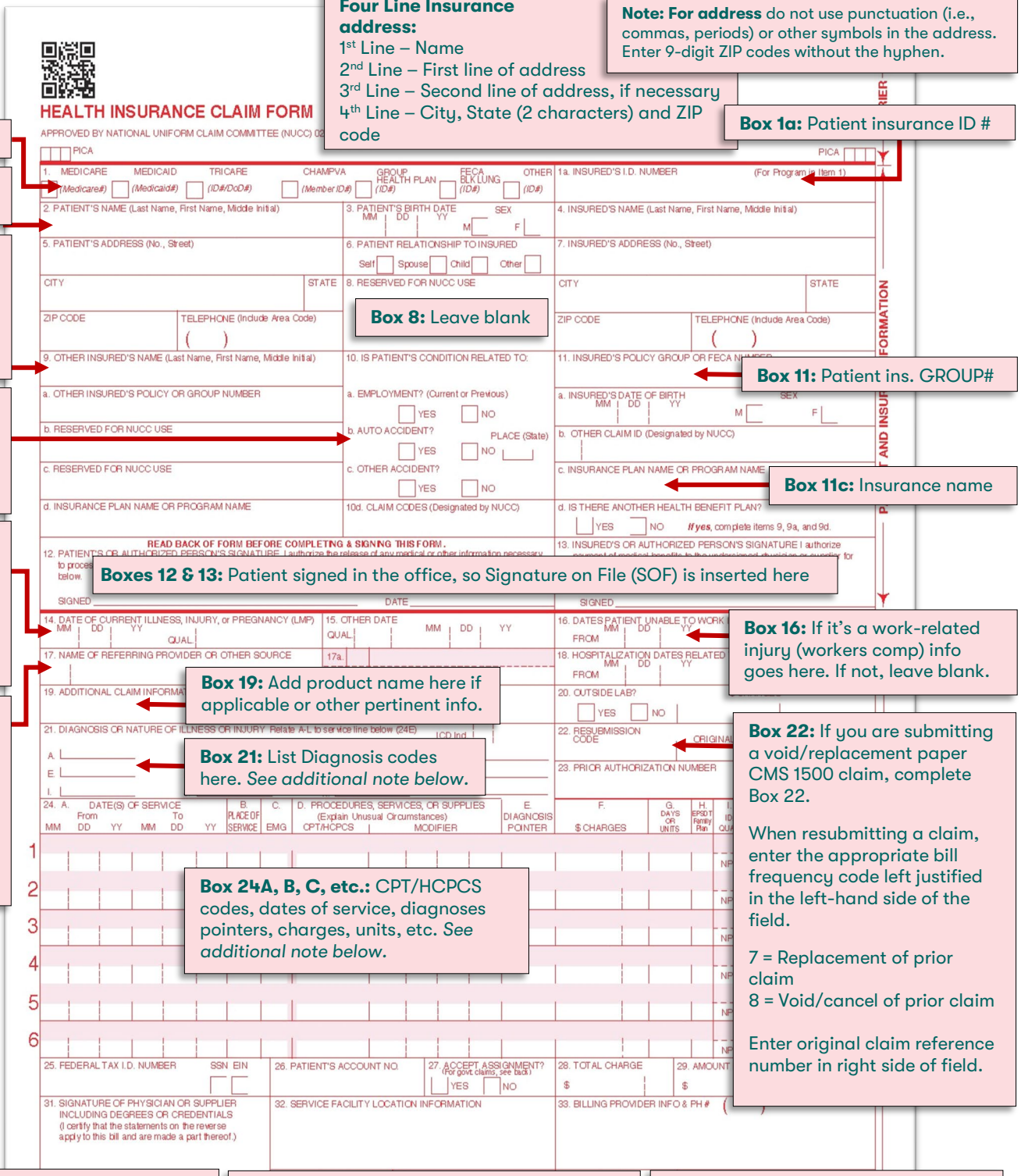
Medicare Documentation Requirements

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 payor

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 11: Patient ins. GROUP#

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

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 22: If you are submitting a void/replacement paper CMS 1500 claim, complete Box 22.

When resubmitting a claim, enter the appropriate bill frequency code left justified in the left-hand side of the field.

7 = Replacement of prior claim
8 = Void/cancel of prior claim

Enter original claim reference number in right side of field.

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: **BV@thepinnaclehealthgroup.com**

Service Request Form for BioTissue Product

SERVICE: ☐ Prior Authorization (PA) ☐ Pre-Determination (PD) ☐ PA / PD 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:

☐ Neox® 1K *(Q4148)* ☐ Neox® RT *(Q4148)* ☐ Neox® 100 *(Q4156)*

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® is a Cryopreserved Human Amniotic Membrane Allograft derived from donated birth tissue following healthy live birth. Neox 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 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 and one article for a biologic product that is being developed from the same tissue platform.

Caputo W, Vaquero C, Monterosa A, Monterosa P, Johnson E, Beggs D, Fahoury GJ. **A retrospective study of cryopreserved umbilical cord as an adjunctive therapy to promote the healing of chronic, complex foot ulcers with underlying osteomyelitis.** *Wound Repair Regen.* 2016 Sep;24(5):885-893. doi: 10.1111/wrr.12456. https://www.ncbi.nlm.nih.gov/pubmed/27312890

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 cm^2 (0.4–73.95 cm^2). 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 cm^2.

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 9-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 cm^2 and wound volume of 52 ±26.2 cm^3 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.

Sample Letter of Medical Necessity Template

For Neox® 1K, Neox RT®, and Neox® 100

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

DATE

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

Re: [Patient Name]
[Patient Member ID]

Dear [Payor Contact]:

On behalf of my patient, [INSERT PATIENT NAME], I am submitting this letter of medical necessity for [Neox® 1K or Neox RT®] (HCPCS: Q4148). This product is routinely used 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 or Neox RT] 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 or Neox RT] is the most appropriate next step treatment for this patient. Using [Neox 1K or Neox RT] 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 4-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 or Neox RT] for this patient, and my clinical rationale for selecting [Neox 1K or Neox RT].

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

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

Neox is a Cryopreserved Human Amniotic Membrane Allograft derived from 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 allograft 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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   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 cm^2.

   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 9-weeks. The average number of graft applications was 1.68 grafts.

3. 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 cm^2 and wound volume of 52 ±26.2 cm^3 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.

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 Template

For Neox® 1K, Neox® RT, and Neox® 100

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

DATE

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

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

Dear [Payor Contact]:

On behalf of my patient, [INSERT PATIENT NAME], I am submitting this appeal for coverage of [Neox 1K or Neox RT] (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 or Neox RT] 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 or Neox RT] was the most appropriate next step treatment for this patient. Using [Neox 1K or Neox RT] 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 4-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.

Please review the included information regarding my patient, published clinical evidence supporting [Neox 1K or Neox RT] for this patient, and my clinical rationale for selecting [Neox 1K or Neox RT].

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

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

Neox is a Cryopreserved Human Amniotic Membrane Allograft derived from Umbilical Cord Tissue following healthy live birth. The Neox product line is indicated for use as a wound covering to create a protective environment for wound healing to occur. 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 Allograft 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.

1. Caputo W, Vaquero C, Monterosa A, Monterosa P, Johnson E, Beggs D, Fahoury GJ. **A retrospective study of cryopreserved umbilical cord as an adjunctive therapy to promote the healing of chronic, complex foot ulcers with underlying osteomyelitis.** *Wound Repair Regen.* 2016 Sep;24(5):885-893. doi: 10.1111/wrr.12456. https://www.ncbi.nlm.nih.gov/pubmed/27312890

   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 cm^2 (0.4–73.95 cm^2). 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.

2. 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 cm^2.

   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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   In this study, investigators reported on 14 wounds in 13 patients, with an average initial wound area of 33.2 ± 21.7 cm^2 and wound volume of 52 ±26.2 cm^3 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.

After reviewing the enclosed information illustrating your members' 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 Reimbursement 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 payors
- Claim appeals and underpayment support
- Benefit verification and prior authorization requests
- Reimbursement and guidance documents
- Coding guide
- Letter of Medical Necessity
- Appeal Templates

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