BioTissue® Surgical

Reimbursement Resource Guide

Clarix®

FOOT & ANKLE

January 2026
US-CL-0008

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

Table of Contents:

Coverage for the use of Amniotic Membrane-derived skin substitutes varies by payor, contract, and the patient's plan.

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.

Need Answers to Reimbursement Questions?

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

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 EST

2026 BioTissue® Surgical Coding Sheets - Foot & Ankle

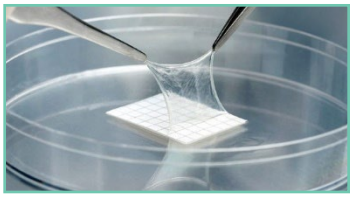
Clarix® 1K & Clarix® 100

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

Clarix 1K and Clarix 100 are cryopreserved human amniotic membrane products derived from birth tissue. The biological integrity of the Amniotic Membrane and Umbilical Cord is maintained through a proprietary cryopreservation process, called CryoTek®.

Clarix® 1K

Cryopreserved Ultra-Thick Amniotic Membrane Allograft derived from Human Umbilical Cord.



Clarix® 100

Cryopreserved Human Amniotic Membrane Allograft

Allograft				
HCPCS	Descriptor	Physician Facility	OPPS	ASC
Q4148	Clarix 1K or Clarix 100, per square centimeter	N/A	Packaged	Packaged
Q4156	Neox 100 or Clarix 100, per square centimeter	N/A	Packaged	Packaged

Implantation of Allograft - Report in Addition to Primary Surgical Procedure				
CPT	Descriptor	Physician Facility	OPPS	ASC
+15777	Implantation of biologic implant (e.g., acellular dermal matrix) for soft tissue reinforcement (e.g., breast, trunk) (List separately in addition to code for primary procedure)	$182.37	Packaged	Packaged
17999	Unlisted Procedure, skin, mucous membrane, and subcutaneous tissue	By Report	Packaged*	N/A
20999	Unlisted procedure, musculoskeletal system, general	By Report	Packaged**	N/A
27899	Unlisted procedure, leg, or ankle	By Report	Packaged**	N/A
28899	Unlisted procedure, foot, or toes	By Report	Packaged**	N/A

*CPT 17999 has a "Q1" status indicator in the OPPS. Procedures assigned a Q1 status indicator are packaged if reported on the same claim as a HCPCS code with a status indicator of "S," "T," or "V;" otherwise, it is paid separately.
**Placement of Clarix is typically done in conjunction with another orthopedic procedure that has been assigned a J1 status which triggers all other procedures appearing on the same claim to be packaged (i.e., there will be no separate payment).

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

Clarix®

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

Common Lower Extremity Procedures				
CPT	Descriptor	Physician Facility	OPPS	ASC
TENDON PROCEDURES				
27650	Repair, primary, open or percutaneous, ruptured Achilles tendon	$624.26	$7,413.38	$4,682.29
27652	Repair, primary, open or percutaneous, ruptured Achilles tendon; with graft (includes obtaining graft)	$616.91	$7,413.38	$4,914.65
27654	Repair, secondary, Achilles tendon, with or without graft	$676.37	$7,413.38	$4,714.43
27658	Repair flexor tendon, leg, primary, without graft	$357.06	$3,342.87	$1,644.87
27659	Repair flexor tendon, leg, secondary with or without graft, each tendon	$446.57	$7,413.38	$3,695.53
27665	Repair, extensor tendon leg; secondary, with or without graft, each tendon	$399.47	$7,413.38	$4,836.35
27675	Repair dislocating peroneal tendons; without fibular osteotomy	$468.95	$3,342.87	$1,644.87
27676	Repair dislocating peroneal tendons; with fibular osteotomy	$574.50	$7,413.38	$3,695.53
27680	Tenolysis, flexor or extensor tendon, leg and/or ankle; multiple tendons (through separate incision(s))	$408.49	$3,342.87	$1,644.87
27681	Tenolysis, flexor or extensor tendon, leg and/or ankle; multiple tendons (through separate incision(s))	$489.99	$3,342.87	$1,644.87
27685	Lengthening or shortening of tendon, leg or ankle; single tendon (separate procedure)	$443.56	$3,342.87	$1,644.87
27686	Lengthening or shortening of tendon, leg or ankle; multiple tendons (through same incision), each	$503.02	$3,342.87	$1,644.87
27690	Transfer or transplant of single tendon (with muscle redirection or rerouting); superficial (e.g., anterior tibial extensors into midfoot)	$608.23	$7,413.38	$3,695.53
27691	Transfer or transplant of single tendon (with muscle redirection or rerouting); deep (e.g., anterior tibial or posterior through interosseous space, flexor or digitorum longus, flexor halluxes longus, or peroneal tendon to midfoot or hindfoot)	$702.42	$7,413.38	$3,695.53
ARTHROPLASTY PROCEDURES				
27700	Arthroplasty, ankle	$669.35	$7,413.38	$5,124.73
27702	Arthroplasty, ankle; with implant (total ankle)	$885.46	$27,721.73	$21,837.31
27703	Arthroplasty, ankle; revision, total ankle	$1,017.73	$17,913.59	$14,025.67
FRACTURE, ARTHRODESIS, AND RECONSTRUCTION PROCEDURES				
27766	Open treatment of medial malleolus fracture, includes internal fixation, when performed	$579.84	$7,413.38	$3,695.53
27769	Open treatment of posterior malleolus fracture, includes internal fixation, when performed	$675.70	$7,413.38	$4,682.29
27792	Open treatment of distal fibular fracture (lateral malleolus), includes internal fixation, when performed	$607.90	$7,413.38	$4,813.11
27814	Open treatment of bimalleolar ankle fracture (e.g., lateral, and medial malleoli, or lateral and posterior malleoli, or medial and posterior malleoli), includes internal fixation, when performed	$714.78	$7,413.38	$4,843.35
27822	Open treatment of trimalleolar ankle fracture, includes internal fixation, when performed, medial and/or lateral malleolus; without fixation of posterior lip	$826.67	$7,413.38	$4,821.39
27823	Open treatment of trimalleolar ankle fracture, includes internal fixation, when performed, medial and/or lateral malleolus; with fixation of posterior lip	$923.20	$7,413.38	$4,829.98
27826	Open treatment of fracture of weight bearing articular surface/portion of distal tibia (e.g., pilon or tibial plafond), with internal fixation, when performed; of fibula only	$812.98	$7,413.38	$4,682.29
27827	Open treatment of fracture of weight bearing articular surface/portion of distal tibia (e.g., pilon or tibial plafond), with internal fixation, when performed; of tibia only	$1,053.46	$13,116.76	$8,938.36

Clarix

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

Common Lower Extremity Procedures, *continued*				
CPT	Descriptor	Physician Facility	OPPS	ASC
FRACTURE, ARTHRODESIS, AND RECONSTRUCTION PROCEDURES, *continued*				
27828	Open treatment of fracture of weight bearing articular surface/portion of distal tibia (e.g., pilon or tibial plafond), with internal fixation, when performed; of both tibia and fibula	$1,230.16	$13,116.76	$9,196.24
27829	Open treatment of distal tibiofibular joint (syndesmosis) disruption, includes internal fixation, when performed	$673.03	$7,413.38	$4,876.77
27870	Arthrodesis, ankle, open	$927.88	$13,116.76	$9,693.82
27871	Arthrodesis, tibiofibular joint, proximal or distal	$647.31	$13,116.76	$9,492.21
28035	Release, tarsal tunnel (posterior tibial nerve decompression)	$343.70	$1,995.02	$948.66
28238	Reconstruction (advancement), posterior tibial tendon with excision of accessory tarsal navicular bone (e.g., Kidney type procedure)	$459.26	$7,413.38	$3,695.53
28289	Hallux rigidus correction with cheilectomy, debridement and capsular release of the first metatarsophalangeal	$438.89	$3,342.87	$1,644.87
28296	Hallux valgus correction with metatarsal osteotomy (e.g., Mitchell, Chevron, or concentric type procedure	$484.31	$3,342.87	$1,644.87
28299	Hallux valgus correction by double osteotomy	$563.47	$7,413.38	$4,751.04
28306	Osteotomy, with or without lengthening, shortening or angular correction, metatarsal; first metatarsal	$385.78	$7,413.38	$3,695.53
28308	Osteotomy, with or without lengthening, shortening or angular correction, metatarsal; other than first metatarsal, each	$371.75	$3,342.87	$1,644.87
28415	Open treatment of calcaneal fracture, includes internal fixation, when performed	$1,048.79	$7,413.38	$4,871.04
28420	Open treatment of calcaneal fracture, includes internal fixation, when performed; with primary iliac or other autogenous bone graft (includes obtaining graft)	$1,209.11	$13,116.76	$8,879.17
28445	Open treatment of talus fracture, includes internal fixation, when performed	$976.31	$7,413.38	$4,701.39
28465	Open treatment of tarsal bone fracture (except talus and calcaneus), includes internal fixation, when performed, each	$619.59	$7,413.38	$4,671.46
28485	Open treatment of metatarsal fracture, includes internal fixation, when performed, each	$542.43	$7,413.38	$4,755.18
28505	Open treatment of fracture, great toe, phalanx, or phalanges, includes internal fixation, when performed	$470.28	$3,342.87	$1,644.87
28525	Open treatment of fracture, phalanx, or phalanges, other than great toe, includes internal fixation, when performed, each	$386.11	$3,342.87	$1,644.87
28531	Open treatment of sesamoid fracture, with or without internal fixation	$174.69	$7,413.38	$4,682.29
28555	Open treatment of tarsal bone dislocation, includes internal fixation, when performed	$612.24	$7,413.38	$5,297.57
28585	Open treatment of talotarsal joint dislocation, includes internal fixation, when performed	$675.70	$7,413.38	$5,290.57
28615	Open treatment of tarsometatarsal joint dislocation, includes internal fixation, when performed	$793.61	$7,413.38	$4,682.29
28645	Open treatment of metatarsophalangeal joint dislocation, includes internal fixation, when performed	$461.60	$3,342.87	$1,644.87
28675	Open treatment of interphalangeal joint dislocation, when performed	$394.13	$3,342.87	$1,644.87
28705	Arthrodesis; pantalar	$1,106.57	$17,913.59	$13,461.22
28715	Arthrodesis; triple	$883.79	$13,116.76	$9,510.96
28725	Arthrodesis, subtalar	$729.48	$13,116.76	$9,367.96
28730	Arthrodesis, midtarsal or tarsometatarsal, multiple or transverse	$678.37	$13,116.76	$10,044.89
28735	Arthrodesis, midtarsal or tarsometatarsal, multiple or transverse; with osteotomy (e.g., flatfoot correction)	$728.81	$13,116.76	$10,232.44

Common Lower Extremity Procedures, *continued*				
CPT	Descriptor	Physician Facility	OPPS	ASC
FRACTURE, ARTHRODESIS, AND RECONSTRUCTION PROCEDURES, *continued*				
28737	Arthrodesis, with tendon lengthening and advancement, midtarsal, tarsal navicular cuneiform (e.g., Miller type procedure)	$631.95	$13,116.76	$9,646.35
28740	Arthrodesis, midtarsal or tarsometatarsal, single joint	$577.50	$7,413.38	$5,216.09
28750	Arthrodesis, great toe; metatarsophalangeal joint	$536.75	$7,413.38	$5,187.12
28755	Arthrodesis, great toe; interphalangeal joint	$467.28	$7,413.38	$3,695.53
28760	Arthrodesis, with extensor hallucis longus transfer to first metatarsal neck, great toe, interphalangeal joint (e.g., Jones type procedure)	$537.09	$7,413.38	$4,705.52

Note: In the OPPS, CMS has assigned all the CPT codes listed above a "J1" status indicator; as such, payment for all covered Part B services reported on the claim are packaged with the primary service for the claim, except services with OPPS SI=F, G, H, L and U.

Imaging				
CPT	Descriptor	Physician Facility	OPPS	ASC
73620	Radiologic examination, foot; 2 views	$7.68	$88.91/Packaged*	Packaged
73630	Radiologic examination, foot; complete, minimum 3 views	$8.02	$88.91/Packaged*	Packaged
73650	Radiologic examination, calcaneus, minimum 2 views	$7.68	$88.91/Packaged*	Packaged
76881	Ultrasound, extremity, nonvascular, real time with image documentation; complete	$42.75	$106.81	Packaged
76882	Ultrasound, extremity, nonvascular, real time with image documentation, limited; anatomic specific	$32.06	$106.81	Packaged

*Assigned a "Q1" status indicator. Procedures assigned a Q1 status indicator are packed if reported on the same claim as a HCPPCS code with a status indicator of "S," "T," or "V;" otherwise, it is paid separately.

Inpatient		
DRG	Descriptor	Payment*
500	Soft Tissue Procedures with MCC	$23,029.49
501	Soft Tissue Procedures with CC	$12,720.50
502	Soft tissue procedure w/o CC/MCC	$9,793.79
503	Foot Procedures with MCC	$20,310.16
504	Foot Procedures with CC	$13,601.72
505	Foot Procedures without CC/MCC	$13,045.78
515	Other Musculoskeletal System and Connective Tissue O.R. Procedures with MCC	$23,190.31
516	Other Musculoskeletal System and Connective Tissue O.R. Procedures with CC	$15,121.84
517	Other Musculoskeletal System and Connective Tissue O.R. Procedures w/o CC/MCC	$11,182.20
562	Fracture, sprain, strain and dislocation except femur, hip, pelvis & thigh with MCC	$10,367.93
563	Fracture, sprain, strain & dislocation except femur, hip, pelvis & thigh w/o MCC	$6,516.34
907	Other OR Procedures for Injuries with MCC	$27,937.66
908	Other OR Procedures for Injuries with CC	$14,518.59
909	Other OR Procedures for Injuries w/o MCC/CC	$9,552.20

*Payment amounts rounded.

Clarix®

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

Notes & References:

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 by contract.

CY 2026 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; and Final CY 2026 Payment Rates (CMS-1834-FC); Addendum B and ASC Addenda.

CY 2026 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; (CMS-1832-F); Addendum B. All MPFS Fee Schedules calculated using CF of $33.4009 effective Jan. 1, 2026.

DRG values were calculated using a base labor + non-labor rate of $6,752.61 and Capital Standard Payment of $524.15. The base payment rate assumes the hospital submitted quality data and is a user of EHR. The weighted rate used the 10% Cap Applied. A hospital's base payment rate will change if the hospital does not meet either or both measures. Calculations were based on data provided in FY 2026 IPPS Final Rule (Tables 1B, 1D, and Table 5).

Current Procedural Terminology (CPT®) is a registered trademark of the American Medical Association.

Disclaimer: The guidance contained in this document, dated January 1, 2026, is provided for informational purposes only and represents no statement, promise, or guarantee by BioTissue® Holdings Inc or its operating subsidiaries including BioTissue® Ocular Inc. and BioTissue® Surgical Inc. (collectively "BioTissue") concerning reimbursement, payment and charges. Similarly, all CPT codes and HCPCS codes are supplied for informational purposes only and represent no statement, promise, or guarantee by BioTissue 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 Payor. BioTissue strongly recommends that you consult your individual Payor Organization regarding its relative and current reimbursement policies. For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full Product 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. BioTissue 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 the 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.

www.biotissue.com/surgical
7300 Corporate Center Drive, Suite 700, Miami, FL 33126 | 888.296.8858

BioTissue Surgical

BioTissue Surgical products are authorized under the regulations of the U.S. Food and Drug Administration (FDA) governing the manufacture and distribution of Human Tissue Products. They are marketed as structural tissue products for homologous use and are used by physicians as barriers, wound coverings, conduits, and/or cushions in the treatment of their patients.

Clarix

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

Sample Form CMS-1450/UB-04

The CMS-1450 form, also known as UB-04 form, is approved by the Centers for Medicare & Medicaid Services (CMS) and the National Uniform Billing Committee for facility and ancillary paper billing.

- Areas highlighted in Yellow are **Required.**
- Areas highlighted in Blue are **Situational/ Required, if applicable/ Optional.**

For complete instructions on preparing the CMS-1450/UB-04, please go to the following link: [Medicare Claims Processing Manual Crosswalk (cms.gov)]

SOURCE: [Medicare Claims Processing Manual Crosswalk (cms.gov)]

Clarix

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

Appeal Resources - Sample Letter Templates

Physician's Sample Appeal Letter:

This is a general template and must be tailored to the patient's specific situation and demonstrate sufficient medical necessity for the service, procedure, or therapy involved.

Insurance Company Name
Insurance Company Address
Insurance Company City, State ZIP

Re: Patient's Name
Insurance
Group/Policy Numbers
Subscriber ID Number

Dear [name of contact person at insurance company],

It is my understanding that [patient's name] has received a denial for [name of procedure] because the procedure is [state specific reason for the denial i.e., not considered medically necessary, experimental, etc.].

As you know, [patient's name] has been under my care since [date] for the treatment of [state diagnosis]. [Give a brief medical history emphasizing the most recent events that directly influence your decision to recommend the denied therapy.]

For this reason, I am writing to provide you with information regarding [name of procedure/treatment]. [Give a brief, yet specific description of the procedure/treatment and why you believe it should be approved].

I have also included a list of several Journal articles supporting the use of [name of procedure/treatment] for [patient's name] [patient's diagnosis].

Based on the information included, I ask that you reconsider your previous decision to deny and authorize prompt payment of their claim. Should you have any questions, please do not hesitate to call me at [insert phone number].

Sincerely,
Your Name
Your Street Address
Email address
Phone Number
Fax Number
Cell Phone Number

Enclosures:
Statement of Medical Necessity if requested.
Journal or peer-reviewed literature/bibliography supporting the service in question.

Clarix

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

Patient's Sample Appeal Letter Template: (Addressing Medical Necessity):

Insurance Company Name
Insurance Company Address
Insurance Company City, State ZIP

Re: Request for reconsideration of coverage denial.
Your Name
Insurance
Group/Policy Numbers
Subscriber ID Number

Dear [name of representative] or Claims Review Department,

After consulting with my physician, [doctor's name], I have decided to appeal your decision to deny coverage of [his/her] recommended treatment plan for [enter the name of type of surgery or treatment your doctor has recommended that was denied by your insurance company].

Your letter dated [date of denial letter] stated that "[quote the exact reasons for denial from the letter]."
On [date], Dr. [name] diagnosed me with [diagnosis]. [If you have obtained any other medical opinions that confirm this diagnosis, list those physicians, also. List any diagnostic test, such as an MRI, x-ray, or CT scan, that was used by your doctor to reach this diagnosis]. This serious medical condition has [describe how your medical condition has affected the quality of your everyday life, the level of pain and disability you are experiencing, your ability to work and any other effects]. Since [date], I have tried various other treatments for my condition. These treatments include: [list treatments, surgeries, non-surgical therapies, and medications].

I am greatly encouraged that my doctor believes I am a good candidate for [name of surgery or treatment that was denied coverage]. [He/she] also believes I will have significant relief from [name what the treatment will do for you, such as relieve pain] after the [name of surgery or treatment that was denied coverage] and will be able to eventually discontinue [list therapies, medications, and other medical treatment your insurer is currently paying for]. Please read Dr. [name]'s Letter of Medical Necessity which is included in this packet. In this letter, Dr. [name] describes my medical history, diagnosis and the rationale used in determining that I should have [name of surgery or treatment that was denied coverage]. This surgery has been [pick appropriate descriptions: approved by the FDA, proven to be safe and effective, proven to have an extremely low complication or re-admission rate, considered a covered treatment by Medicaid, Medicare, and the following private payors: (name insurers)].

I am confident in Dr. [name]'s experience in performing (recommending) this [surgery/treatment.] [He/she] is [doctor's credentials, such as board certification in a given specialty field of medicine, any professional titles such as medical director, any special training in this specific procedure] and has performed this procedure since [date] in more than [number] surgeries. Please contact Dr. [name] or me if you need more information about the efficacy, safety, and effectiveness of the [name of surgery or treatment that was denied coverage]. For your information, I have attached peer review studies, clinical studies and articles from scientific journals regarding this procedure.

I look forward to hearing from you by [date that is within the insurance policy's guidelines]. My contact information is listed below.

Sincerely,

Your Name
Your Street Address, E-mail Address, Phone Number, Fax Number, Cell Phone Number

cc: Doctors' names
Employer name if applicable
Enclosures: [List everything in your appeals packet]
Include a Statement of Medical Necessity from your medical provider.

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

Appeal Support - Clarix® 100 & Clarix® 1K Bibliography:

Orthopedics & Musculoskeletal:

Kiehna, Erin Nicole MD. 415 Cryopreserved Human Umbilical Cord in the Treatment of Pediatric Tethered Cord Syndrome. *Journal of Neurosurgery* 70 (Supplement_1):p 126, April 2024. | DOI: 10.1227/neu.0000000000002809_415

Newcomb, N, Nammour, M, Desai, et al. Revision Carpal Tunnel Release with Umbilical Cord Allograft: A Four-Year Retrospective Cohort Study. *Ochsner Journal*. 2023; Jan.

DeMill, SL, Granata, JD, McAlister, JE, et al. Safety analysis of cryopreserved amniotic membrane/umbilical cord tissue in foot and ankle surgery: a consecutive case series of 124 patients. *Surgical Technology International*. 2014;25:257-61.

Ellington, JK, Ferguson, CM. The use of amniotic membrane/umbilical cord in first metatarsophalangeal joint cheilectomy: a comparative bilateral case study. *Surgical Technology International*. 2014;25:63-7.

Warner, M, Lasyone, L. An open-label, single-center, retrospective study of cryopreserved amniotic membrane and umbilical cord tissue as an adjunct for foot and ankle surgery. *Surgical Technology International*. 2014;25:251-5.

Covell, DJ, Cohen, B, Ellington, JK, et al. The Use of Cryo-Preserved Umbilical Cord Plus Amniotic Membrane Tissues in the Resection of Tarsal Coalition. *Foot & Ankle Orthopaedics*. 2016;1:2473011416S00311.

Anderson, DG, Popov, V, Raines, AL, et al. Cryopreserved amniotic membrane improves clinical outcomes following microdiscectomy. *Clinical Spine Surgery*. 2017;30:413-8.

Jones, DG, Williams, GK, Duru, N. Achilles tendon tear repair with adjunctive use of cryopreserved umbilical cord: A case report. *Journal of Muscle Health*. 2018;2(1):1011.

Bemenderfer, T, Anderson, R, Odum, et al. Effects of Cryopreserved Amniotic Membrane Allograft on Total Ankle Arthroplasty Wound Healing. *Foot & Ankle Orthopaedics*. 2017; Sep 11;2(3):2473011417S000027.

Bemenderfer, TB, Anderson, RB, Odum, SM, et al. Effects of cryopreserved amniotic membrane-umbilical cord allograft on total ankle arthroplasty wound healing. *The Journal of Foot and Ankle Surgery: The Official Publication of the American College of Foot and Ankle Surgeons*. 2019;58:97-102.

Stewart, C M. The Use of Cryopreserved Umbilical Cord in Open Reduction and Internal Fixation of Calcaneus Fractures. SunKrist *J Trauma Emerg Med Acute Care*. 2019;4(1):1-8.

Godshaw, B., Wong, M., Ojard, C, et al. Acute Traumatic Tear of the Gluteus Medius and Gluteus Minimus in a Marathon Runner. *Ochsner Journal* 2019;19(4): 405-409.

Penner, M, Younger, A, Wing, K, et al. Arthroscopic Repair of Talar Osteochondral Defects With Umbilical Cord Allograft: A Prospective, Single-Center, Pilot Study. *Foot & Ankle Spec*. 2020;:1938640020910953.

Galli, SH, Ferguson, CM, Davis, WH, et al. Cheilectomy with or without Cryopreserved Amniotic Membrane-Umbilical Cord Allograft for Hallux Rigidus: A Prospective Randomized Controlled Trial. *Foot & Ankle Orthopaedics*. 2020;5(2):2473011420S00004.

Heintzman, S, Ferguson, C, Davis, WH, et al. Cheilectomy With or Without Cryopreserved Umbilical Cord for Hallux Rigidus: A Prospective Randomized Controlled Trial. *Foot & Ankle Orthop*. 2019;4(4):2473011419S00207.

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

Urology:

Corse T, Ahmed M, Dayan L, Zaifman J, Degen M, Munver R, Stifelman M. PD27-09 Preliminary Findings of a Prospective Randomized Controlled Pilot Study Evaluating the Recovery of Potency and Continence Following Robotic Prostatectomy With and Without Umbilical Cord Allograft. *Journal of Urology*. 2022 May;207(Supplement 5):e497.

Ferretti M, Lovallo G, Stifelman M and Ahmed M. V9-09 Robot-assisted Laparoscopic Management of Inflatable Penile Prosthesis Reservoir Migration into Bladder with Utilization of Cryopreserved Amniotic Membrane and Umbilical Tissue. *Journal of Urology*. 2017; 197: e1059-e.

Stites J, Tsui J, Degen M, et al. Initial Experience with a Bioregenerative Matrix on Erectile Function Following Nerve- Sparing Robot-Assisted Laparoscopic Radical Prostatectomy. World Congress of Endourology. 2018: Paris, France.

Ahmed M, Esposito M and Lovallo G. A single- center, retrospective review of robot-assisted laparoscopic prostatectomy with and without cryopreserved umbilical cord allograft in improving continence recovery. *Journal of Robotic Surgery*. 2019

Cheng N, Velazquez N, Desroches BR, Munver R. Bioregenerative Umbilical Cord Amniotic Membrane Allograft Ureteral Wrap During Robot-Assisted Ureterolysis. *Journal of Endourology* Case Reports. 2020 Dec 1;6(4):431-4.

Drescher M, Russell JR, Billah MS, Ahmed M. MP20-14 Clinical Outcomes Of Robotic Ureteral Reconstruction With Adjunctive Ultra-Thick Amniotic Membrane. *Journal of Urology*. 2025;213(5S):e698.

Spina Bifida:

Patel, SK, et al. Effect of allograft patch closure on incidence of spinal inclusion cyst formation following open fetal myelomeningocele repair. *Journal of Neurosurgery: Pediatrics 1* (aop). 2023:1-8.

Papanna R, Fletcher S, Moise KJ, Jr., Mann LK and Tseng SC. Cryopreserved human umbilical cord for in utero myeloschisis repair. *Obstetrics and Gynecology*. 2016; 128:325-30.

Calle S, Papanna R, Hughes K, Aein A, Riascos R, Johnson A, Tsao K, Moise Jr KJ, Fletcher S, Patel R. Prenatal and Postnatal Imaging Findings After Fetal Repair of Spinal Dysraphisms Using Cryopreserved Human Umbilical Cord Patch: A Case Series of 4 Patients. *Journal of Computer Assisted Tomography*. 2020 Nov 1;44(6):998-1007.

Trauma Reconstruction:

Assi PE, Hunzicker A, Jones J, Pemberton J, Golinko MS. An Ode to Gillies and Millard:"The Ten Commandments Applied to Self-Inflicted Head and Neck Gunshot Wounds". FACE. 2021 Dec 14:27325016211064344

Other:

Goez JC, Kilfoil RL, Wang CA, Sax Z, Arif F. A Novel Use of Umbilical Perinatal Graft in Subungual Exostosis Resection. Journal of the American Podiatric Medical Association. 2020 Jul 1;110(4).

Blaney, J. C. (2024). Use of cryopreserved, ultra-thick amniotic membrane allograft for colorectal and intestinal anastomoses. International Journal of Gastrointestinal Intervention, 13(1), 11-15.

Zwayne, N., & Boos, K. (2024). 61. Guidewires and Amnion Tissue Grafts: A Novel Approach for Surgical Management of Distal Vaginal Agenesis. Journal of Pediatric and Adolescent Gynecology, 37(2), 266.

Clarix®

BioTissue Reimbursement Hotline: **866-369-9290**
Email Address: **biotissuesurgical@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:
☐ Clarix® 1K *(Q4148)* ☐ Clarix® 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.

Clarix®

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

Reimbursement Assistance Resource:

Have additional reimbursement questions?

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

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 EST

Tips When Requesting/Submitting Prior Authorization Requests (PAs)

Requesting Prior Authorization	If you contact the payor, requesting prior authorization and the payor states, “PA not necessary” or “No PA required” ask that they verify that the selected code is a covered, payable code.
If the PA is denied, identify the reason	Contact the payor for clarification regarding the denial. Reach out to Pinnacle for assistance with the appeal.