

Reimbursement Resource Guide



FOOT & ANKLE

Table of contents

2024 Surgical Coding Sheets – Foot & Ankle	3
Sample Form CMS-1450 / UB-04	8
Appeal Resources - Sample Letter Templates	9-10
Appeal Support - Clarix 100 and Clarix 1K Bibliography	11
Reimbursement Assistance – The Pinnacle Health Group Service Request Form	12
Reimbursement Assistance – The Pinnacle Health Group contact information	13

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 ET to help resolve common reimbursement and billing issues. Their contact information is below:



Email: biotissuesurgical@thepinnaclehealthgroup.com

Phone: <u>866-369-9290</u> Fax: 877-499-2986

Hours: Monday to Friday: 8:30 AM - 6:00 PM ET



2024 BioTissue Surgical Coding Sheets – Foot & Ankle

Clarix 1K & Clarix 100

BioTissue Reimbursement Hotline: 866-369-9290

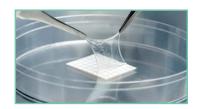
Email Address: biotissuesurgical@thepinnaclehealthgroup.com

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





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





Cryopreserved Human Amniotic Membrane Allograft

Allograft					
HCPCS	Descriptor	Physician Facility	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	

	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)	\$208.55	Packaged	Packaged			
17999	Unlisted Procedure, skin, mucous membrane, and subcutaneous tissue By Report \$190.94/Packaged*						
20999	Unlisted procedure, musculoskeletal system, general	By Report	\$224.92**	N/A			
27899	Unlisted procedure, leg, or ankle	By Report	\$207.01**	N/A			
28899	Unlisted procedure, foot, or toes	By Report	\$207.01**	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					

Disclaimer: The guidance contained in this document, dated January 2024, 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, 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, varnings, precautions, and adverse reactions, please reference full package insert.



BioTissue Reimbursement Hotline: 866-369-9290

Email Address: biotissuesurgical@thepinnaclehealthgroup.com

Commo	n Lower Extremity Procedures			
CPT	Descriptor	Physician Facility	OPPS	ASC
TENDO	N PROCEDURES			
27650	Repair, primary, open or percutaneous, ruptured Achilles tendon	\$652.84	\$6,823.42	\$3,393.01
27652	Repair, primary, open or percutaneous, ruptured Achilles tendon; with graft (includes obtaining graft)	\$665.28	\$6,823.42	\$4,458.07
27654	Repair, secondary, Achilles tendon, with or without graft	\$710.13	\$6,823.42	\$4,275.11
27658	Repair flexor tendon, leg, primary, without graft	\$368.00	\$3,087.24	\$1,518.96
27659	Repair flexor tendon, leg, secondary with or without graft, each tendon	\$469.82	\$6,823.42	\$3,393.01
27665	Repair, extensor tendon leg; secondary, with or without graft, each tendon	\$423.00	\$6,823.42	\$4,423.64
27675	Repair dislocating peroneal tendons; without fibular osteotomy	\$492.74	\$3,087.24	\$1,518.96
27676	Repair dislocating peroneal tendons; with fibular osteotomy	\$605.69	\$6,823.42	\$3,393.01
27680	Tenolysis, flexor or extensor tendon, leg and/or ankle; multiple tendons (through separate incision(s))	\$419.07	\$3,087.24	\$1,518.96
27681	Tenolysis, flexor or extensor tendon, leg and/or ankle; multiple tendons (through separate incision(s))	\$505.51	\$3,087.24	\$1,518.96
27685	Lengthening or shortening of tendon, leg or ankle; single tendon (separate procedure)	\$463.93	\$3,087.24	\$1,518.96
27686	Lengthening or shortening of tendon, leg or ankle; multiple tendons (through same incision), each	\$529.08	\$3,087.24	\$1,518.96
27690	Transfer or transplant of single tendon (with muscle redirection or rerouting); superficial (e.g., anterior tibial extensors into midfoot)	\$633.19	\$6,823.42	\$3,393.01
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)	\$737.30	\$6,823.42	\$3,393.01
ARTHRO	PLASTY PROCEDURES		,	
27700	Arthroplasty, ankle	\$644.00	\$6,823.42	\$5,190.49
27702	Arthroplasty, ankle; with implant (total ankle)	\$950.77	\$17,774.76	N/A
27703	Arthroplasty, ankle; revision, total ankle	\$1,095.81	Inpatient Only	N/A
FRACTU	RE, ARTHRODESIS, AND RECONSTRUCTION PROCEDURES			
27766	Open treatment of medial malleolus fracture, includes internal fixation, when performed	\$603.07	\$6,823.42	\$3,393.01
27769	Open treatment of posterior malleolus fracture, includes internal fixation, when performed	\$721.92	\$6,823.42	\$3,393.01
27792	Open treatment of distal fibular fracture (lateral malleolus), includes internal fixation, when performed	\$642.36	\$6,823.42	\$4,345.95
27814	Open treatment of bimalleolar ankle fracture (e.g., lateral, and medial malleoli, or		\$6,823.42	\$4,385.22
27822	Open treatment of trimalleolar ankle fracture, includes internal fixation, when performed, medial and/or lateral malleolus; without fixation of posterior lip	\$866.96	\$6,823.42	\$4,415.38
27823	Open treatment of trimalleolar ankle fracture, includes internal fixation, when performed, medial and/or lateral malleolus; with fixation of posterior lip	\$975.98	\$6,823.42	\$4,387.50
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	\$782.49	\$6,823.42	\$4,441.85
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	\$1,109.56	\$12,552.87	\$8,755.39

Disclaimer: The guidance contained in this document, dated January 2024, 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, 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 package insert.



	Common Lower Extremity Procedures, con	tinued		
СРТ	Descriptor	Physician Facility	OPPS	ASC
FRACTUR	E, 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	\$1,311.24	\$12,552.87	\$8,661.07
27829	Open treatment of distal tibiofibular joint (syndesmosis) disruption, includes internal fixation, when performed	\$703.26	\$6,823.42	\$4,551.97
27870	Arthrodesis, ankle, open	\$996.28	\$12,552.87	\$9,300.00
27871	Arthrodesis, tibiofibular joint, proximal or distal	\$686.89	\$12,552.87	\$8,195.51
28035	Release, tarsal tunnel (posterior tibial nerve decompression)	\$355.88	\$1,841.54	\$897.79
28238	Reconstruction (advancement), posterior tibial tendon with excision of accessory tarsal navicular bone (e.g., Kidney type procedure)	\$484.22	\$6,823.42	\$3,393.01
28289	Hallux rigidus correction with cheilectomy, debridement and capsular release of the first metatarsophalangeal	\$457.71	\$3,087.24	\$1,518.96
28296	Hallux valgus correction with metatarsal osteotomy (e.g., Mitchell, Chevron, or concentric type procedure	\$508.45	\$3,087.24	\$1,518.96
28299	Hallux valgus correction by double osteotomy	\$589.65	\$6,823.42	\$4,333.72
28306	Osteotomy, with or without lengthening, shortening or angular correction, metatarsal; first metatarsal	\$404.67	\$6,823.42	\$3,393.01
28308	Osteotomy, with or without lengthening, shortening or angular correction, metatarsal; other than first metatarsal, each	\$385.68	\$3,087.24	\$1,518.96
28415	Open treatment of calcaneal fracture, includes internal fixation, when performed	\$1,108.90	\$6,823.42	\$4,479.69
28420	Open treatment of calcaneal fracture, includes internal fixation, when performed; with primary iliac or other autogenous bone graft (includes obtaining graft)		\$12,552.87	\$8,668.71
28445	Open treatment of talus fracture, includes internal fixation, when performed		\$6,823.42	\$4,442.42
28465	Open treatment of tarsal bone fracture (except talus and calcaneus), includes internal fixation, when performed, each		\$6,823.42	\$4,256.32
28485	Open treatment of metatarsal fracture, includes internal fixation, when performed, each	\$561.16	\$6,823.42	\$4,386.36
28505	Open treatment of fracture, great toe, phalanx, or phalanges, includes internal fixation, when performed	\$492.74	\$3,087.24	\$1,518.96
28525	Open treatment of fracture, phalanx, or phalanges, other than great toe, includes internal fixation, when performed, each	\$405.65	\$3,087.24	\$1,518.96
28531	Open treatment of sesamoid fracture, with or without internal fixation	\$180.72	\$6,823.42	\$3,393.01
28555	Open treatment of tarsal bone dislocation, includes internal fixation, when performed	\$658.07	\$6,823.42	\$4,404.29
28585	Open treatment of talotarsal joint dislocation, includes internal fixation, when performed	\$700.96	\$6,823.42	\$4,782.45
28615	Open treatment of tarsometatarsal joint dislocation, includes internal fixation, when performed	\$823.08	\$6,823.42	\$4,342.54
28645	Open treatment of metatarsophalangeal joint dislocation, includes internal fixation, when performed	\$483.57	\$3,087.24	\$1,518.96
28675	Open treatment of interphalangeal joint dislocation, when performed	\$412.20	\$3,087.24	\$1,518.96
28705	Arthrodesis; pantalar	\$1,202.21	\$17,774.76	\$12,699.07
28715	Arthrodesis; triple	\$929.49	\$12,552.87	\$9,821.71
28725	Arthrodesis, subtalar	\$771.35	\$12,552.87	\$9,005.07
28730	Arthrodesis, midtarsal or tarsometatarsal, multiple or transverse	\$717.99	\$12,552.87	\$9,594.93
28735	Arthrodesis, midtarsal or tarsometatarsal, multiple or transverse; with osteotomy (e.g., flatfoot correction)	\$767.10	\$12,552.87	\$9,495.71



	Common Lower Extremity Procedures, continued					
CPT	Descriptor Physician Facility OPPS					
FRACTUR	FRACTURE, ARTHRODESIS, AND RECONSTRUCTION PROCEDURES, continued					
28737	Arthrodesis, with tendon lengthening and advancement, midtarsal, tarsal navicular-cuneiform (e.g., Miller type procedure)	\$683.94	\$12,552.87	\$9,745.39		
28740	Arthrodesis, midtarsal or tarsometatarsal, single joint	\$610.60	\$6,823.42	\$4,891.14		
28750	Arthrodesis, great toe; metatarsophalangeal joint	\$570.66	\$6,823.42	\$4,745.74		
28755	Arthrodesis, great toe; interphalangeal joint	\$332.31	\$6,823.42	\$3,393.01		
28760	Arthrodesis, with extensor hallucis longus transfer to first metatarsal neck, great toe, interphalangeal joint (e.g., Jones type procedure)	\$566.73	\$6,823.42	\$4,275.11		

Note: In the OPPS, CMS has assigned all of 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	\$7.20	\$86.67/Packaged*	Packaged		
73630	Radiologic examination, foot; complete, minimum 3 views	\$7.86	\$86.67/Packaged*	Packaged		
73650	Radiologic examination, calcaneus, minimum 2 views \$7.53 \$86.67/Packaged* Pac					
76881	Ultrasound, extremity, nonvascular, real time with image documentation; complete	\$41.91	\$104.87	\$10.48		
76882	Ultrasound, extremity, nonvascular, real time with image documentation, limited; anatomic specific	\$31.76	\$104.87	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	\$22,704.79	
501	Soft Tissue Procedures with CC	\$12,152.68	
502	Soft tissue procedure w/o CC/MCC	\$9,681.11	
503	Foot Procedures with MCC	\$18,777.59	
504	Foot Procedures with CC	\$12,092.46	
505	Foot Procedures without CC/MCC	\$11,942.63	
515	Other Musculoskeletal System and Connective Tissue O.R. Procedures with MCC	\$22,135.56	
516	Other Musculoskeletal System and Connective Tissue O.R. Procedures with CC	\$14,288.87	
517	Other Musculoskeletal System and Connective Tissue O.R. Procedures w/o CC/MCC	\$10,463.19	
562	Fracture, sprain, strain and dislocation except femur, hip, pelvis & thigh with MCC	\$10,647.33	
563	Fracture, sprain, strain & dislocation except femur, hip, pelvis & thigh w/o MCC	\$6,270.63	
907	Other OR Procedures for Injuries with MCC	\$26,042.45	
908	Other OR Procedures for Injuries with CC	\$14,031.91	
909	Other OR Procedures for Injuries w/o MCC/CC	\$9,496.27	



Email Address: 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 per contract.

CY 2024 Changes to Hospital Outpatient Prospective Payment and Ambulatory Payment Systems – Final Rule with Comment and Final CY 2024 Payment Rates (CMS 1786-FC); Addendum B and ASC Addenda.

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.

DRG values were calculated using a base rate of \$6,497.77 and Capital Standard Payment of \$503.83. The base payment rate assumes the hospital submitted quality data and is a user of EHR. A hospital's base payment rate will change if the hospital does not meet either or both of these measures. Calculations were based on data provided in FY 2024 IPPS Final Rule (Tables 1B, 1D, and 5).

 $Current \, Procedural \, Terminology \, (CPT@) \, is \, a \, registered \, trademark \, of \, the \, American \, Medical \, Association.$

Disclaimer: The guidance contained in this document, dated January 2024, 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, 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 package insert.

www.biotissue.com/surgical

7300 Corporate Center Drive, Suite 700, Miami, FL 33126 | 888.296.8858 © 2024 BioTissue Holdings Inc. All rights reserved | US-CL-0008



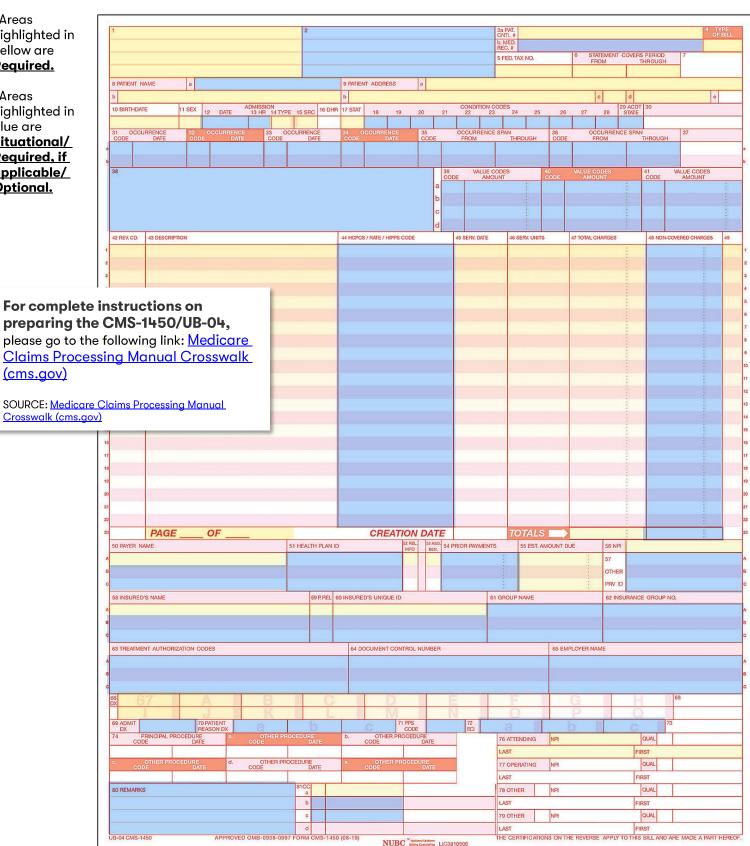


Sample Form CMS-1450 / UB-04

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.

highlighted in Yellow are Required.

➤ Areas highlighted in Blue are Situational/ Required, if applicable/ Optional.





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.



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.



Appeal Support - Clarix® 100 and Clarix® 1K Bibliography

Orthopedics and Musculoskeletal Pain

Newcomb N, Nammour M, Desai B, Vaughan L, Sisco-Wise L. Revision Carpal Tunnel Release with Umbilical Cord Allograft: A Four-Year Retrospective Cohort Study. Ochsner Journal. 2023 Jan.

Patel, S.K., 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.

DeMill SL, Granata, J.D., McAlister, J.E., Berlet, G.C., Hyer, C.F. 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 and 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 and 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, Jones CP, Davis WH and Anderson RB. 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 and O'Connell J. Cryopreserved amniotic membrane improves clinical outcomes following microdiscectomy. Clinical Spine Surgery. 2017; 30: 413-8.

Jones D, Jr GKW and Duru N. Achilles tendon tear repair with adjunctive use of cryopreserved umbilical cord: A case report. Journal of Muscle Health. 2018; 2.

Bemenderfer T, Anderson R, Odum S, Davis WH. 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 and Davis WH. 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. 2019. The Use of Cryopreserved Umbilical Cord in Open Reduction and Internal Fixation of Calcaneus Fractures. SunKrist Journal of Trauma, Emergency Medicine and Acute Care.

Godshaw, B., Wong, M., Ojard, C., Williams, G., Suri, M., & Jones, D. (2019). Acute Traumatic Tear of the Gluteus Medius and Gluteus Minimus in a Marathon Runner. *Ochsner Journal*, 19(4), 405-409.

Penner M, Younger A, Wing K, Cresswell M, Veljkovic A. Arthroscopic Repair of Talar Osteochondral Defects With Umbilical Cord Allograft: A Prospective, Single-Center, Pilot Study. Foot & Ankle Specialist. 2020 Mar 14:1938640020910953.

Galli SH, Ferguson CM, Davis WH, Anderson RB, Cohen BE, Jones CP, Odum SM, Ellington JK. Cheilectomy with or without Cryopreserved Amniotic Membrane-Umbilical Cord Allograft for Hallux Rigidus: A Prospective Randomized Controlled Trial. Foot & Ankle Orthopaedics. 2020 Jul 2;5(2):2473011420S00004.

Heintzman S, Ferguson C, Davis WH, Anderson RB, Cohen BE, Jones CP, Odum SM, Ellington JK. Cheilectomy With or Without Cryopreserved Umbilical Cord for Hallux Rigidus: A Prospective Randomized Controlled Trial. Foot & Ankle Orthopaedics. 2019 Oct 16;4(4):2473011419S00207. Same as Heintzman 2021



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								
				PROVIDE	RINFORMATION			
Name of Rei	ndering Physicio	an:						
Physician N	기:	Р	Physic	cian TIN:			Medicare PTAN:	
Place of Service: Physician Office Ambulatory Surgical Center Hospital Inpatient Hospital Outpatient Outpatient								
Practice/Fa	cility Name:							
Address:								
Facility NPI:		F	acilit	y TIN:			BioTissue Representative:	
Anticipated	Procedure Date	e: C	Conto	act Person:			Contact Phone:	
Contact Em	ail Address:	· ·			Contact Fax:			
				PATIENT	INFORMATION			
Patient Nam	ie:							
Address:			City:					
State:		Zip code:	de:		Ge	Gender:		
DOB:		Home Ph	Phone:		Се	Cell Phone:		
Primary Ins:		Ins ID#	#		Gr	Group#		
Ins. Phone:		Subscribe	riber Name:		Su	Subscriber DOB:		
Secondary I	ns:	Ins ID#	†		Gr	Group#		
Ins. Phone:		Subscribe	iber Name:		Su	Subscriber DOB:		
			C	CLINICAL/PROC	CEDURE INFORMAT	ΓΙΟΝ		
	ICD-10 Diagno	sis Code(s	s Code(s) CPT/Procedu		re Code(s)		HCPCS/Product/Supply Code(s)	
Primary								
Secondary								
Products to be utilized: □ Clarix®1K™ (Q4148) □ Clarix®100 (Q4156)								
Number of Grafts: Size of		Size of G	Graft:		Mil	lligrams 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 att	ach all supportin				plan of care, previ		conservative care progress notes, and lab letermination.	



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 ET to help resolve common reimbursement and billing issues. Their contact information is below:



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

Requesting / Submitting Prior Authorization Requests (PAs)

Requesting Prior Authorization	Contact Pinnacle, or 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. Also requesting a predetermination is suggested.
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.