Anthem

Medical Policy

Subject: Percutaneous Ultrasonic Ablation of Soft Tissue
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Description/Scope

This document addresses the use of percutaneous ultrasonic ablation (emulsification) of soft tissue for the treatment of any condition.

Note: Please see the following related documents for additional information:

- SURG.00045 Extracorporeal Shock Wave Therapy
- SURG.00088 Coblation® Therapies for Musculoskeletal Conditions
- SURG.00100 Cryoablation for Plantar Fasciitis and Plantar Fibroma

Note: This document does not address the use of high intensity focused ultrasound (HIFU) ablation for any indication. For information regarding HIFU ablation, please see the following documents:

- CG-MED-81 Ultrasound Ablation for Oncologic Indications
- MED.00057 MRI Guided High Intensity Focused Ultrasound Ablation for Non-Oncologic Indications

Position Statement

Investigational and Not Medically Necessary:

Percutaneous ultrasonic ablation of soft tissue is considered**investigational and not medically necessary** for the treatment of **any** condition, including, but not limited to **any** of the following musculoskeletal conditions:

A. Achilles tendinosis; **or**
B. Lateral or medial elbow tendinosis;**or**
C. Patellar tendinosis; **or**
D. Recalcitrant plantar fasciitis; **or**
E. Rotator cuff or shoulder tendinosis.

Rationale

Percutaneous ultrasonic ablation is a minimally invasive surgical procedure proposed for use in the fragmentation, emulsification, and aspiration of soft tissue associated with any condition, including chronic or degenerative conditions of the musculoskeletal system involving fascia or tendons of the ankle, foot, elbow, hip, knee, shoulder, or wrist.

Barnes and colleagues (2015) reported a case series of 19 individuals treated with percutaneous ultrasonic ablation for chronic elbow tendinosis. Individuals with greater than 6 months of conservative management for chronic medial (n=7) or lateral (n=12) elbow tendinosis were offered the percutaneous ultrasonic ablation procedure as one of several treatment options. All individuals were evaluated using visual analog scale (VAS) pain score (range, 0-10; lower score is “better”), the Quick Disabilities of the Arm, Shoulder and Hand (Q-DASH) 11-item score (range 0-100; lower score is “better”), and the Mayo Elbow Performance Score (MEPS, range, 0-100; higher score is “better”) on the day of treatment and at 6 weeks posttreatment. Additional VAS, Q-DASH, and MEPS scores were obtained by mail responses from participants at 3, 6, and 12 months after treatment. The mean VAS pain scores were reported as significantly improved from baseline (VAS, 6.4) compared to 6 weeks (VAS, 2.6), 3 months (VAS, 0.9), 6 months (VAS, 1.7), and 12 months (VAS, 0.7) after treatment ($p<0.0001$). The majority of improvement in VAS pain score was reported during the first 3 months postprocedure, with VAS scores improving significantly between pretreatment and 6 weeks posttreatment and between 6 and 12 weeks posttreatment; thereafter, VAS scores remained statistically unchanged (that is, between 3 months and 12 months posttreatment). Improvement in Q-DASH scores and MEPS values were similar when compared to VAS scores at pre- and posttreatment measurements ($p<0.0001$). No procedure-related complications occurred during the 12-month follow-up period. Limitations of this case series include lack of a control group, participant-reported outcomes (by mail) at 3, 6, and 12 months after treatment, and lack of direct comparisons to other interventions used in the treatment of chronic lateral or medial elbow tendinopathy.

Koh and colleagues (2013) reported on the safety, tolerability, and efficacy of percutaneous ultrasonic ablation of degenerative tendon tissue using a percutaneous ultrasonic ablation procedure in an open-label case series of 20 individuals who failed nonoperative therapy for a minimum of 3 months for recalcitrant lateral elbow tendinopathy. Outcome parameters included procedure- and device-related complications, VAS pain scores, DASH scores at 1, 3, 6, and 12 months, radiological documentation in the form of postprocedural ultrasound assessment of the elbow at 3 and 6 months, and patient satisfaction indicators. There were no reported procedure- or device-related adverse events. A significant improvement in the median VAS score occurred from baseline to 1 week postprocedure (5.5 to 3.3; $p<0.001$), with further improvement at 3, 6, and 12 months from baseline (from 2.0 to 1.0 to 0.50, respectively; $p=0.003$ and 0.023). Significant improvements in both DASH-Compulsory (from 21.7 to 11.3; $p=0.001$) and DASH-Work scores (from 25.0 to 6.3; $p=0.012$) occurred by 1 month. The DASH-Compulsory score improved significantly from 3 to 6 months (from 8.6 to 4.6; $p=0.003$), and both the DASH-Compulsory and DASH-Work scores were sustained by 12 months. A total of 19 of 20 participants (95%) expressed satisfaction with the procedure at 6 months: 9 participants were very satisfied, 10 participants were somewhat satisfied, and 1 participant was neutral. By 6 months, ultrasonography findings identified reduced tendon thickness in 19 of 20 participants (95%), resolved (n=10) or reduced (n=7) hypervascularity in 17 participants, and reduced hypoechoic lesions in 18 participants. Limitations of this case series include lack of a control group and lack of blinding to treatment. The authors noted that “it is well recognized that elbow tendinopathy is a self-limiting condition and can also be subject to placebo effects of perceived therapeutic procedures.”

Seng and colleagues (2016) reported on 3-year outcomes of percutaneous ultrasonic ablation for recalcitrant lateral elbow tendinopathy. All 20 participants from the Koh case series (2013) were reassessed at 36 months after the procedure in all outcome parameters. Sustained improvement was reported in VAS pain scores (pain relief) and DASH-Work scores, and further reduction was reported in DASH-Compulsory scores to a median of 0 ± 0.644 with a significant decrease on repeated measures ($p=0.008$). At 36 months, all 20 participants exhibited reduction in tendon thickness, 17 of 20 participants (94.4%) achieved complete resolution of

hypervascularity, and 4 of 20 participants (20%) had complete resolution of hypoechoic lesions.

Subjects from the 2013 Koh study were reassessed again at a median of 90 months (range 86-102 months). The study published by Ang and colleagues (2021) reported on 19 subjects from the original cohort using the VAS and DASH scoring systems. Satisfaction was 100% with 6 subjects satisfied and 13 subjects very satisfied. Compared with scores at 6 months and 36 months, there were no reported differences in VAS and DASH scores at 90 months. Ultrasounds of the affected elbow were also performed along with information about subsequent procedures that could have been relevant to treatment of recurrent elbow tendinopathy. A total of 16 participants had ultrasound evaluation which revealed reduction of tendon hypervascularity, tendon thickness, and hypoechoic lesions. None of the participants required secondary intervention. There were no reported adverse outcomes. While the results of the 90 month follow-up appear to be efficacious, the study is not without limitations including lack of a control group for comparison with other interventions. It should also be noted that DASH scores are not specific to the elbow, in which case degenerative conditions of the shoulder or hand may have influenced results.

In an industry-sponsored case series, Patel (2015) provided a detailed description of a percutaneous ultrasonic ablation system to partially release plantar fascia lesions in 12 subjects (mean duration of symptoms, 19 months) who failed conservative care including physical therapy, casting, injections, and other invasive procedures such as endoscopic partial release for refractory plantar fasciitis. Of the 12 subjects, 4 subjects were previously treated with an open or endoscopic partial release with no improvement in symptoms. Pre- and postoperative subjective and objective health outcomes were evaluated using the American Orthopaedic Foot and Ankle Society (AOFAS) Scoring Scale to measure pain, function, and alignment (total score, 100 points). Subjects had a mean preoperative AOFAS score of 30 (range, 17-46) and a mean postoperative score of 88 (range, 25-92). A total of 11 subjects reported resolution of symptoms, that is, no activity restricted by plantar fascia pain, by the 3-month postoperative visit. Pain relief was documented as occurring between 5 weeks and 13 weeks after treatment. There were no postoperative infections or wound complications. Limitations of this case series are single-surgeon experience, lack of a control group, and short-term outcomes.

Sanchez and colleagues (2017) reported on complications similar to those following Achilles tendon surgery in 6 subjects treated with percutaneous ultrasonic ablation for chronic Achilles tendinosis or heel pain. Four of the 6 subjects were active sports participants (including, cycling, ultra distance running, or marathon runners). Complications following percutaneous ultrasonic ablation included longitudinal and transverse tearing of the tendon, deep vein thrombosis, sudden onset of popping in the surgical area with searing pain (6 weeks postoperative), and sudden, sharp pain with chronic tearing. The authors expressed concerns with the efficacy and safety of the procedure for Achilles tendinosis, stating that percutaneous ultrasonic ablation with ultrasound visualization should allow the surgeon to visualize the pathologic portion of the Achilles tendon. However, “in reality, ultrasound scanning delivers a 2-dimensional image of a 3-dimensional structure. This leaves surgeons with 1 of 2 scenarios: removing too much healthy tendon or failing to remove all the pathologic tendon.” Another concern with the procedure (and as observed in the study subjects) is that the pistoning motion of the cutting handpiece may penetrate healthy tendon due to inadequate visualization provided by the ultrasound probe. Transverse cuts could be seen, in addition to the longitudinal, chronic tearing of the Achilles tendon, leading to “stagnation of symptoms or worsening of the Achilles tendinosis. The healing potential and vascularity of the Achilles tendon are baseline concerns with Achilles tendon pathologic entities, in general, and the use of [percutaneous ultrasonic tenotomy] can potentially increase this risk.” The authors concluded that “because of the severe lack of published data backing up its use, we would recommend against the use of [percutaneous ultrasonic tenotomy] to treat Achilles tendon issues or, at the least, consider its use similar to that of surgery.” Nonsurgical interventions should be tried before surgical intervention, including physical therapy, foot orthoses, heel cushions, and eccentric strengthening.

In 2018, Chimenti and colleagues published a retrospective chart review with the aim to evaluate individuals’ self-reported pain (AOFAS pain scale), quality of life [Physical Component Summary (PCS) and the Mental Component Summary (MCS) subscales of the Short-Form 12-Item Survey], function, and satisfaction in relation to percutaneous ultrasonic tenotomy, and to examine complications with the procedure. A chart review of all percutaneous ultrasonic tenotomy procedures performed between September 2013 and May 2017 yielded 34 individuals with 40 procedures. Primary outcomes were assessed before the tenotomy procedure, at a short-term follow-up (6 or 12 weeks), and at a long-term follow-up (median, 1.7 years; interquartile range, 11–36 months). The evaluators found significant decreases in pain levels reported at both short-term (n=23; $p<0.01$) and long-term follow-up (n=17; $p=0.01$) in comparison to baseline pain levels. There was a significant improvement in the quality of life PCS component at the short-term follow-up (n=23; $p=0.03$), but not in the MCS component (n=23; $p=0.96$). “At the short-term follow-up, 11 of 21 (n=7 at 6 weeks; n=14 at 12 weeks) had resumed normal activity, and 14/14 had resumed work (n=11 at 6 weeks, n=3 at 12 weeks)” (Chimenti, 2018). Also at the short-term follow-up, 70% of individuals were either “very satisfied” or “satisfied” with the outcomes of the procedure. There was one complication in 1 individual, which was a superficial skin infection. While this study showed some significant findings, there were several limitations, including a retrospective design and missing baseline and follow-up data.

In a 2021 retrospective review by Altahawi and colleagues, the authors compared the outcomes of individuals who had percutaneous ultrasonic tenotomy to individuals who had surgical tenotomy. There were 23 participants who underwent percutaneous ultrasonic tenotomy and 10 participants who had surgical tenotomy who agreed to participate in the study. Post-procedure outcomes were assessed by the Q-DASH and Oxford elbow scores (OES) at 2 weeks, 3 to 6 months, and 12 months. Participants in the percutaneous ultrasonic tenotomy group had Q-DASH mean preprocedural score of 56. The mean 2 week score was 49, mean 3 to 6 month score was 21, and mean 12 month score was 12. Participants in the surgical tenotomy group had a mean Q-DASH preprocedural score of 56. Mean score at 2 weeks was 58, mean score at 3 to 6 months was 16, and mean score at 12 months was 10. The OES showed no significant differences between the two treatment groups from baseline to 12 months post procedure. This study has limitations which include the retrospective design. Larger prospective studies are necessary to compare efficacy of percutaneous ultrasonic tenotomy with surgical techniques and show improved net health outcomes.

Another retrospective review published in 2021 by Chalian and colleagues reports on the efficacy of ultrasound-guided percutaneous needle tenotomy for lateral epicondylitis. There were 37 subjects with refractory lateral epicondylitis included in the study. Severity of tendinopathy was broken down into mild (n=1), moderate (n=23),and severe (n=13). The first post-operative follow-up was at 90 days and 4/37 participants were excluded due to decision to proceed with surgical debridement. Following the ultrasound-guided percutaneous needle tenotomy, there were no reported tendon ruptures, post-procedural infections, significant bleeding, or other complications. The total follow-up duration was 531 ± 393 days with an average third follow-up duration of 34.5 months. Prior to the procedure, pain and functional assessment of the affected limb was assessed using Patient-Rated Tennis Elbow Evaluation (PRTEE) and DASH questionnaires. Pre-procedure PRTEE pain score, function score, total score and DASH scores were 28.7 ± 11.1, 28.1 ± 11.1, 56.8 ± 21.4, and 56.2 ± 26.8, respectively. At the first follow-up (average follow-up duration of 8.5 months), the scores were 11.5 ± 10.9, 8.1 ± 9.9, 19.6 ± 20.4, and 16.3 ± 18.8, respectively. At the second follow-up (average 15 months) with 20 subjects available, scores were 8.0 ± 10.7, 4.6 ± 6.9, 12.2 ± 17.3, and 11.0 ± 15.4, respectively. At the third follow-up (average 34.5 months) with 8 subjects available, scores were 9.9 ± 12.7, 7.1 ± 11.5, 17 ± 23.9, and 14.5 ± 20.1, respectively. The study is limited by the lack of a control group, comparison to other alternative interventions for refractory lateral epicondylitis, the retrospective design, and is subject to recall bias based on use of participant-reported outcomes.

A 2021 systematic review by Vajapey and colleagues reported on seven studies for percutaneous ultrasonic tenotomy in the treatment of tendinopathy. There were five studies which addressed elbow tendinopathies, one study addressed Achilles

tendinopathy, and one study addressed plantar fasciitis. All studies were case series (four prospective and three retrospective). Average follow-up ranged from 10-36 months. Participant population ranged from 7-34. Efficacy of treatment was most commonly determined using these various methods: VAS score, the American Shoulder and Elbow Surgeons score, DASH score, MEPS score, 12-Item Short Form Health Survey (SF-12), and the AOFAS scores. Of the five studies addressing elbow tendinopathy, the overall VAS and DASH scores improved compared to baseline. In the plantar fasciitis study, 11/12 participants noted complete pain relief 12 months following percutaneous ultrasonic tenotomy. There were no reported adverse events and mean AOFAS score improved from baseline. In the Achilles tendinopathy study, 4/34 participants reported no pain at long-term follow-up (11-36 months), 13 noted mild pain, 2 had moderate pain, 1 had severe pain. The rest of the participants were lost to follow-up. SF-12 showed some improvement in the physical component, but no improvement in the mental component. There was one reported complication of surgical site infection. The authors note “Further, higher quality studies are necessary to accurately assess the comparative effectiveness of this treatment modality.”

The American Medical Society for Sports Medicine (AMSSM) published a position statement on the use of interventional musculoskeletal ultrasound in sports medicine (Finnoff, 2015). Ultrasound-guided surgical techniques, such as percutaneous ultrasonic ablation of soft tissue that use specialized devices, are described as “third-generation techniques” for musculoskeletal conditions, and will likely “be adopted” in the near future.

There is currently a lack of evidence in the peer-reviewed medical literature in the form of randomized, double-blind controlled trials demonstrating improved net health outcomes of percutaneous ultrasonic ablation of soft tissue using minimally invasive devices for the treatment of any condition, including, but not limited to chronic conditions of the musculoskeletal system (for example, fasciopathy or tendinopathy).

In summary, while short-term results from a limited number of small case series report early positive outcomes in reduction of pain and improvement in physical function, further investigation is needed to determine if percutaneous ultrasonic ablation can sustain functional improvement and eliminate or reduce pain in individuals with chronic or recalcitrant conditions of the soft tissue. Well-designed prospective, randomized controlled trials comparing percutaneous ultrasonic ablation to standard treatments are needed to determine if spontaneous improvement without the procedure can be excluded and if a durable treatment effect can be established over placebo.

Background/Overview

Description of the Conditions
Soft tissue conditions of the musculoskeletal system include, but are not limited to, acutely inflamed or chronic conditions of the fascia or tendons. Treatment of these conditions, particularly tendinopathies, is dependent on confirmation of the distinct diagnosis of tendinitis versus tendinosis. Tendinitis is described as an acutely inflamed and swollen tendon without microscopic tendon damage. In contrast, tendinosis is a clinically damaged tendon with disorganized fibers and a hard, thickened, scarred and rubbery appearance. The underlying cause of tendinosis is degeneration. Tendinosis is chronic and occurs in the Achilles tendon, extensor tendon of the elbow (tennis elbow), gluteal tendons on the outside of the hip, the patellar tendon, and the rotator cuff tendons of the shoulder. Standard treatment for tendinosis may include rest, non-steroidal anti-inflammatory drugs, braces, splints and straps, physical therapy, or injection therapy.

The plantar fascia is a wide ligament-like structure that covers the bottom of the foot, extending from the heel bone to the base of the toes. This band of thick tissue protects the bottom of the heel bone and acts like a shock absorber for the bottom of the foot. In many individuals, the plantar fascia may become irritated, causing a condition called plantar fasciitis. This is the most common cause of heel pain. The cause of this condition is not entirely clear, but is associated with or due to repetitive trauma. It is common in several sub-groups of people, including runners and other athletes, people who have jobs that require a fair amount of walking or standing (especially if it is done on a hard surface), and in some cases it is seen in people who have put on weight, including through pregnancy. Most people who have plantar fasciitis recover with conservative treatments with use of pain relievers (such as, ibuprofen or naproxen to ease pain and inflammation), physical therapy (stretching and strengthening exercises), night splints, and over-the-counter orthotics (such as, heel cups, cushions, or custom-fitted arch supports). Approximately 75% of individuals recover after 6 months and up to 98% after 12 months. In cases where plantar fasciitis is chronic and resistant to conservative treatments, surgical intervention may be indicated to treat the fibrous tissue that develops at the plantar fascia attachment resulting from long-standing inflammation.

Description of the Technology
Percutaneous ultrasonic surgical devices debride and ablate (remove) the degenerative soft tissue under local anesthetic. A stab incision creates an entry site for the blunt tip of the device. The device is advanced under sonographic guidance into the lesion where it is activated using a foot pedal to irrigate, fragment, emulsify and aspirate the involved soft tissue lesion(s). The device may need to be redirected to cover the entire area of the lesion (as identified by ultrasound) until the degenerative tissue is completely treated. Following the procedure, wound closure is accomplished using a sterile dressing. Postprocedural activity restrictions and the need for a conservative rehabilitation program depend on the site being treated and the extent of the preoperative condition. The procedure is reported as being performed in the physician’s office or an ambulatory surgery setting (Barnes, 2015; Peck, 2016).

Several devices have received U.S. Food and Drug Administration (FDA) 510(k) clearance for percutaneous ultrasonic ablation. In March 2013, the TX1 Tissue Removal System (Tenex Health, Inc., Lake Forest, CA) received 510(k) clearance (K123640) as “an ultrasonic surgical aspirator” to emulsify and remove soft tissue. In March 2016, the Tenex Health TX® System (K153299) (Tenex Health, Inc., Lake Forest, CA) received 510(k) clearance as substantially equivalent to the predicate device, the TX1 Tissue Removal System. Both systems are intended for use with a TX2 MicroTip in “surgical procedures where fragmentation, emulsification, and aspiration of soft tissue are desirable.” The FDA 510(k) clearance regulates these devices as “unclassified”; in addition, the FDA’s *Indications for Use Statement* for each device does not specifically describe their intended use in surgical procedures involving partial or complete surgical cutting (transection) or division of fascia (fasciotomy) or tendons (tenotomy) (FDA, 2016). Another example is the Sonopet iQ Ultrasonic Aspirator System® (K190070) (Stryker Instruments, Kalamazoo, MI), which received 510(k) clearance on April 11, 2019 (FDA, 2019).

Definitions

Tendinitis (or tendonitis): An acutely inflamed swollen tendon that does not have microscopic tendon damage. Tendinitis results from chronic inflammation of the tendon when it is overloaded with a tensile force that is too heavy and/or too sudden.

Tendinosis: A chronically damaged tendon with disorganized fibers and a hard, thickened, scarred and rubbery appearance. The underlying cause in tendinosis is a degeneration of the tendon’s collagen in response to chronic overuse, such as with repetitive strain injury.

Tendon: A tough cord or band of dense fibrous tissue that connects a muscle to some part of a bone.

Tenotomy: The surgical cutting or division of a tendon for relief of a deformity caused by congenital or acquired shortening of a muscle, as in clubfoot or strabismus.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
For the following procedure codes; or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT

17999	Unlisted procedure, skin, mucous membrane and subcutaneous tissue [when specified as percutaneous ultrasound ablation of subcutaneous tissue]
20999	Unlisted procedure, musculoskeletal system, general [when specified as percutaneous ultrasonic ablation of soft tissue] Note: if a tenotomy or fasciotomy code is used to represent percutaneous ultrasonic ablation, the procedure is considered investigational and not medically necessary.

ICD-10 Diagnosis

All diagnoses

References

Peer Reviewed Publications:

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4. Chalian M, Nacey NC, Rawat U, et al. Ultrasound-guided percutaneous needle tenotomy using Tenex system for refractory lateral epicondylitis; short and long-term effectiveness and contributing factors. Skeletal Radiol. 2021; 50(10):2049-2057.
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9. Sanchez PJ, Grady JF, Saxena A. Percutaneous ultrasonic tenotomy for Achilles tendinopathy is a surgical procedure with similar complications. J Foot Ankle Surg. 2017; 56(5):982-984.
10. Seng C, Mohan PC, Koh SB, et al. Ultrasonic percutaneous tenotomy for recalcitrant lateral elbow tendinopathy: sustainability and sonographic progression at 3 years. Am J Sports Med. 2016; 44(2):504-510.
11. Vajapey S, Ghenbot S, Baria MR, et al. Utility of percutaneous ultrasonic tenotomy for tendinopathies: a systematic review. Sports Health. 2021; 13(3):258-264.

Government Agency, Medical Society, and Other Authoritative Publications:

1. Finnoff JT, Hall MM, Adams E, et al. American Medical Society for Sports Medicine position statement: interventional musculoskeletal ultrasound in sports medicine. Clin J Sport Med. 2015; 25(1):6-22.
2. U.S. Food and Drug Administration (FDA). 510(k) Premarket Notification Database. Sonopet iQ Ultrasonic Aspirator System Device Summary. No. K190070. Rockville, MD: FDA. April 2019. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf19/K190070.pdf. Accessed on December 20, 2023.
3. U.S. Food and Drug Administration (FDA). 510(k) Premarket Notification Database. Tenex Health TX System Device Summary. No. K153299. Rockville, MD: FDA. March 2016. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K153299. Accessed on December 20, 2023.

Websites for Additional Information

1. American Academy of Orthopaedic Surgeons (AAOS). OrthoInfo. Plantar fasciitis and bone spurs. August 2022. Available at: http://orthoinfo.aaos.org/topic.cfm?topic=A00149. Accessed on December 20, 2023.
2. American Academy of Orthopaedic Surgeons (AAOS). OrthoInfo. Tennis elbow (Lateral epicondylitis). August 2020. Available at: https://orthoinfo.aaos.org/en/diseases--conditions/tennis-elbow-lateral-epicondylitis/. Accessed on December 20, 2023.
3. National Library of Medicine (NLM). Medline Plus: Foot injuries and disorders. September 2021. Available at: http://www.nlm.nih.gov/medlineplus/footinjuriesanddisorders.html. Accessed on December 20, 2023.

Index

Sonopet iQ Ultrasonic Aspirator System
Tenex Health TX System
TX1 Tissue Removal System

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	02/15/2024	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised Rationale and References sections.
Reviewed	02/16/2023	MPTAC review. Updated References section.
Reviewed	02/17/2022	MPTAC review. Updated Description/Scope, Rationale, Background/Overview and References sections.
Reviewed	02/11/2021	MPTAC review. Updated Rationale, References, and Websites for Additional Information sections.
Reviewed	02/20/2020	MPTAC review. Updated Description/Scope, Rationale, References, Websites for Additional Information, and Index sections.
Reviewed	03/21/2019	MPTAC review. Updated Rationale, References, and Websites for Additional Information sections.
Reviewed	05/03/2018	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” Updated Rationale, References, and Websites for Additional Information.
New	05/04/2017	MPTAC review. Initial document development.

Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member’s contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.