Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 1/1/25**
(See policy history boxes for previous effective dates)

Title: Percutaneous Ultrasonic Ablation as Treatment of Chronic Pain due to Tendonitis and Fasciitis (Tenex Health TX®)

Description/Background

Tendinopathy is the breakdown of collagen in a tendon, what connects muscles to bones. This breakdown causes pain, burning sensation, reduced flexibility, and decreased range of motion. Tendinopathy is most common in the following tendons: Achilles, rotator cuff, patellar, and hamstring. It is most often caused by repetitive, minor impact on the affected tendon. It is common in workers performing repetitive tasks, athletes and active individuals. Changes noted with tendinopathy are primarily seen in the structure of the tendon due to scarring and/or a failed response to healing.

Initial symptom relief includes avoiding activities that aggravate the problem and modification of task performance that exacerbated the issue. Other treatment options include resting of the injured area, icing of the area, and use of anti-inflammatory medications. Additional therapeutic options include physical therapy and corticosteroid injection. Fasciotomy and tenotomy are surgical procedures performed when all other conservative measures fail to relieve the pain.

The Tenex Health TX System (Tenex Health TX®)—previously known as focused aspiration of soft tissue (FAST)—is a minimally invasive device proposed as an alternative to conventional surgery for the treatment of chronic tendon pain. It incorporates ultrasound imaging to determine the location of degenerated tendon tissue. A skin incision is made under local anesthesia and a MicroTip Needle of the Tenex device is then inserted into the damaged tissue. Using ultrasound guidance, the therapeutic probe vibrates rapidly to break up the damaged tissue, which is then suctioned out. This tendon ablation procedure is known by several terms, including percutaneous ultrasonic tenotomy, percutaneous needle tenotomy, percutaneous ablation, and percutaneous fasciotomy. The procedure is performed in an outpatient setting, and it takes approximately 15 minutes. The incision is closed with an adhesive bandage. Physical therapy may be recommended after the procedure.

Regulatory Status

The Tenex Health TX System was cleared on March 3, 2016, through the U.S. Food and Drug Administration (FDA) Premarket Notification Process. K153299 was predicated on a previous submission (K123640) known as the TX1 Tissue Removal System (also by Tenex Health), cleared on March 20, 2013. Modifications to the Tenex TX System, which include a TXP MicroTip, were cleared on August 15, 2018. This modification (K181367) expanded the indications for the system to include wound debridement. All of the Tenex systems are assigned product code LFL.

Medical Policy Statement

The use of the Tenex Health TX® procedure is considered experimental/investigational when used to treat tendon pain regardless of the anatomical location. There is insufficient published evidence to assess the safety and/or impact on health outcomes or patient management of the Tenex Health TX® procedure for treatment of tendon pain.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

27299 27599

Note: Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.

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 degenerative or chronic conditions of the musculoskeletal system involving fascia or tendons of the ankle, elbow, foot, hip, knee, shoulder, or wrist.

In 2015, Barnes et. al reported a case series of 19 patients with medial (7) or lateral (12) elbow tendinopathy who had failed conservative management. [1] All patients were treated with percutaneous ultrasonic tenotomy of the elbow using the TX1 device by a single operator. Visual analog scale (VAS) for pain, the 11-item version of the Disabilities of the Arm, Shoulder, and Hand (Quick DASH) index, and the Mayo Elbow Performance Score (MEPS) were assessed by an independent observer before treatment and at 6 weeks, 3 months, 6 months, and 12 months after treatment. Average VAS scores were significantly improved from 6.4 to2.6 at 6 weeks and were 0.7 at 12 months ($p<.0001$). Similar improvement occurred with the Quick DASH (pretreatment, 44.1; 12 months, 8.6, $p<.0001$) and MEPS (pretreatment, 59.1; 12 months, 83.4; $p<.0001$). The authors acknowledged several study limitations including a small number of subjects, no control group, does not provide insight regarding the therapeutic mechanism of the TX1 treatment, and that future prospective comparative investigations are warranted. Two of the authors (Barnes DE and Smith J) also disclosed a financial relationship with Tenex Health which is related to the subject of the study.

In 2015, Patel reported a case series in which patients with plantar fasciitis were allowed either to continue with noninvasive treatment or to undergo focal aspiration and partial fasciotomy with an ultrasonic probe (TX1). [2] Study inclusion criteria were plantar fasciitis symptoms lasting 12 months or longer. Twelve patients with refractory plantar fasciitis lasting a mean of 19 months chose the procedure. They all had failed conservative care, including physical therapy, casting, shock wave therapy, and invasive procedures such as injections and endoscopic plantar releases. Four of the 12 had undergone an open or endoscopic partial release at a different institution but had experienced no improvement symptoms. American Orthopaedic Foot and Ankle Society (AOFAS) scores were obtained before and after surgery. Follow-up consisted of clinic visits 2 weeks after surgery and monthly thereafter. The 12 patients had a mean preoperative AOFAS score of 30 (range,17-46) and a mean postoperative score of 88 (range, 25-92). By the 3 month postoperative visit, symptoms were resolved in 11 patients (no activity restricted by plantar fascia pain). On physical examination, 11 patients had no palpable tenderness at the site of preoperative pain. Pain relief was documented as having occurred between 5 and 13 weeks after treatment. One patient had bilateral procedures. One foot was treated, pain resolved by the 3-month postoperative visit, and the patient asked for the other foot to be treated. Three months after the procedure, patient had minimal non-activity-restricting pain. The author concluded that more studies are needed to further validate the safety and efficacy of this treatment modality. The author also reported that he is a member of the medical advisory board of Tenex Health, which developed the tissue removal system used in the study.

In 2017, Sanchez et. al. 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.[3] 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 2021 Vajapey et.al. reported on seven studies for percutaneous ultrasonic tenotomy in the treatment of tendinopathy.[4] 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 concluded further; higher quality studies are necessary to accurately assess the comparative effectiveness of this treatment modality.

In 2021, Altahawi et. al. in a retrospective review compared the outcomes of individuals who had percutaneous ultrasonic tenotomy to individuals who had surgical tenotomy.[5] 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.

Summary of Evidence

Based on the current available published evidence, the safety and efficacy of the TX1 device in the treatment of pain caused by various tendinopathies/tendinitis and fasciitis is limited, further investigation is needed to determine if percutaneous ultrasonic ablation can sustain functional improvement and eliminate or reduce pain in individuals with tendon pain. Well-designed prospective, randomized controlled trials comparing percutaneous ultrasonic ablation to standard treatments (open surgical tenotomy) are needed to determine if spontaneous improvement without the procedure can be excluded and if a durable treatment effect can be established over placebo. There is insufficient published evidence to assess the safety and/or impact on health outcomes or patient management of the Tenex Health TX® Procedure for treatment of tendon pain. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Clinical trials that might influence this review are listed in Table 1.

NCT No.	Trial Name	Planned Enrollment	Completion Date
Withdrawn Lack of funding			
NCT04384809	Platelet Rich Plasma Injection vs Percutaneous Tenotomy for Common Extensor Tendinopathy	Not yet recruiting	May 2022
Ongoing			
NCT05622279	Percutaneous Needle Tenotomy Associated With Platelet-rich Plasma Injection Platelet-rich Plasma in the Treatment of Refractory Plantar Fasciitis: a Pilot Study of the Effect on Pain and Tolerance (ANTILOPE)	19	May 2025 (Recruiting)

NCT: national clinical trial

Government Regulations

National:

No National Coverage Decision on this procedure.

Local:

No Local Coverage Decision on this procedure.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

Extracorporeal Shock Wave Therapy for Treatment of Plantar Fasciitis and Other Musculoskeletal Disorders

References

1. Barnes D.E., Beckley J.M., Smith J, Percutaneous ultrasonic tenotomy for chronic elbow tendinosis Journal of Shoulder and Elbow Surgery. 24 (1) (pp 67-73), 2015.
2. Patel MM. A novel treatment for refractory plantar fasciitis, Am J Orthopaedics (Belle Mead NJ). 2015 Mar;44(3):107-10. PMID: 25750942.
3. Sanchez, PJ, Grady JF, Saxena, Percutaneous Ultrasonic Tenotomy for Achilles Tendinopathy is a Surgical Procedure with Similar complications, J Foot Ankle Surg. 2017 Sep - Oct;56(5):982-984. doi: 10.1053/j.jfas.2017.06.015
4. 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
5. Altahawi F, Li X, Demarest B, Forney MC. Percutaneous ultrasonic tenotomy with the TX-1 device versus surgical tenotomy for the treatment of common extensor tendinosis. Skeletal Radiol. 2021; 50(1):115-124.
6. U.S. FDA 510(k) approval for the TENEX HEALTH TX SYSTEM (k153299). March 3, 2016 Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K153299

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through July, 2024, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
1/1/24	10/25/23		Joint policy established Vendor: N/A (ky)
1/1/25	10/15/24		Routine maintenance. Removed codes 17999 and 20999 from JUMP policy and replaced with codes 27299 and 27599. Codes 27299 and 27599 are managed by TurningPoint (TP) and are both on TP's policy. Vendor: TP (ky)

Next Review Date: 4th Qtr, 2025

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN:	Revised:
BCBSM:	Revised:

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: PERCUTANEOUS ULTRASONIC ABLATION AS TREATMENT OF CHRONIC PAIN DUE TO TENDONITIS AND FASCIITIS (TENEX HEALTH TX®)

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered.
BCNA (Medicare Advantage)	See government section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- Duplicate (back-up) equipment is not a covered benefit.