

## Radiofrequency Coblation Tenotomy and Percutaneous Ultrasonic Tenotomy for Musculoskeletal Conditions

**Policy # 00916**

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*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

*Note: Decompression of the Intervertebral Disc Using Laser Energy (Laser Discectomy) or Radiofrequency Coblation (Nucleoplasty) is addressed separately in medical policy 00087.*

### Services Are Considered Investigational

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers radiofrequency coblation tenotomy (e.g., using TOPAZ<sup>®</sup> EZ Microdebrider Coblation<sup>®</sup> Wand)‡ as a treatment for musculoskeletal conditions, including but not limited to the following conditions, to be **investigational**.\*

- Plantar fasciitis; **OR**
- Lateral epicondylitis; **OR**
- Wrist tendinopathy; **OR**
- Shoulder or rotator cuff tendinopathy; **OR**
- Achilles tendinopathy; **OR**
- Patellar tendinopathy.

Based on review of available data, the Company considers percutaneous ultrasonic tenotomy and fasciotomy (e.g., Tenex percutaneous ultrasonic ablation procedure) as a treatment for musculoskeletal conditions, including but not limited to the following conditions, to be **investigational**.\*

- Plantar fasciitis; **OR**
- Lateral epicondylitis; **OR**
- Wrist tendinopathy; **OR**
- Shoulder or rotator cuff tendinopathy; **OR**
- Achilles tendinopathy; **OR**
- Patellar tendinopathy.

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## **Background/Overview**

### **Radiofrequency Coblation**

Radiofrequency (RF) coblation uses bipolar low-frequency energy in an electrically conductive fluid (e.g., saline) to generate a high-density plasma field around the energy source. This creates a low-temperature field of ionizing particles that break organic bonds within the target tissue. Coblation technology is used in a variety of surgical procedures, particularly related to otolaryngology and orthopedics. The proposed advantage of coblation is that the procedure provides for controlled and highly localized ablation, resulting in minimal damage to surrounding tissue. Radiofrequency coblation was also found to exhibit several properties that may make it an attractive option for addressing the underlying pathophysiology of chronic tendinopathies, namely increased angiogenesis, reduction of inflammatory responses, and increased expression of growth factors. Radiofrequency coblation surgical wands are utilized by orthopedic surgeons in minimally invasive arthroscopic procedures to facilitate soft tissue debridement, subacromial decompression, meniscal removal and sculpting, or tendon debridement.

### **Percutaneous ultrasonic ablation**

Percutaneous ultrasonic tenotomy (PUT) 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.

The Tenex Health TX System (Tenex Health TX<sup>®</sup>)‡—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.

### **Tendinopathy**

Tendinopathy is a clinical pain syndrome characterized by tendon thickening due to proliferation and chronic irritation of neovascular repair tissue with a history of repetitive tendon loading. This condition commonly results from overuse and has a high incidence rate in athletes and laborers. Clinical history should clarify predisposing training or activity and assess the level of functioning. Biomechanical abnormalities during activity should be identified and corrected. Standard treatment may, therefore, consist of biomechanical modification, activity modification, physical therapy (eg, heavy load resistance training), and nonsteroidal anti-inflammatory medication. For chronic tendinopathies, glucocorticoids should only be used in select cases (eg, rotator cuff tendinopathy).



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Surgical consultation following 6 months of a well-designed physical therapy program with adjunct medical treatments can be considered if there is no improvement in pain or function. Validated and reliable functional assessment scores should be utilized by the clinician to grade symptoms and assess patient function. Examples of suitable scales include the Victoria Institute of Sport Assessment for Achilles tendinopathy. Surgical approaches may involve incisions to the paratendon and removal of adhesions and degenerate tissue. Longitudinal incisions may be made in the tendon to promote a repair response. This latter strategy has also been delivered via minimally invasive arthroscopic approaches. These approaches may also address the debridement of the neovascular supply to the tendon surface. Collectively, a prolonged recovery duration to accommodate tendon healing may be required with these interventions.

### **Plantar Fasciitis**

Plantar fasciitis is a musculoskeletal condition characterized by pain in the plantar region of the foot that worsens upon initiation of walking and with local point tenderness elicited during a clinical examination. Radiographic and ultrasonographic studies are not typically indicated for primary diagnosis but may be useful in ruling out alternative causes and visualizing the thickening of the plantar fascia. Initial standard therapy may consist of stretching exercises, orthotics, activity and lifestyle modification, nonsteroidal anti-inflammatory drugs, splints or casts, and glucocorticoid injections. The vast majority of patients improve without surgery. Surgery is generally considered a last line of therapy and is reserved for individuals who do not respond to at least 6 to 12 months of initial, nonsurgical therapy. Surgical approaches include variations of open or endoscopic, partial or complete, plantar fascia release, which may or may not include calcaneal spur resection, excision of abnormal tissue, and nerve decompression. The use of RF microtenotomy during open or percutaneous surgery has been explored alone or in combination with plantar fasciotomy.

Plantar fasciitis is one of the most common causes of foot and heel pain in adults. It is estimated to be responsible for approximately 1 million patient medical visits per year in the U.S. The peak incidence of the condition in the general population occurs between ages 40 and 60. There is a higher incidence rate among runners with a younger age of onset. The etiology of plantar fasciitis is poorly understood and may be multifactorial in nature. Contributing risk factors may include obesity, prolonged standing or activity, flat feet, and reduced ankle dorsiflexion. Plantar fasciitis has been reported in association with fluoride use for the treatment of osteoporosis. Differential sources of foot and heel pain may include Achilles tendinopathy, stress fractures due to osteoporosis, rheumatoid arthritis, peripheral neuropathies associated with diabetes, extrinsic factors (eg, inappropriate footwear), aging, and structural disorders.

### **Lateral Epicondylitis**

Lateral epicondylitis, also known as tennis elbow, represents chronic tendinosis of the myotendinous group of the lateral epicondyle characterized by pain and disability. The incidence in the general population may approach 1% to 3%. Risk factors include smoking, obesity, forceful activity, and repetitive activity for at least 2 hours daily. Lateral epicondylitis is characterized by injury to the



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extensor carpi radialis brevis or extensor digitorum communis muscles. The condition is diagnosed through findings of localized tenderness and pain with clinical examination. Initial conservative management includes modification of activity and biomechanics, counterforce bracing or splinting, nonsteroidal anti-inflammatory drugs, and physical therapy. Surgical referral is typically reserved for patients with severe symptoms that do not improve despite compliance with an appropriately designed physical therapy program for at least 6 months.

## **FDA or Other Governmental Regulatory Approval**

### **U.S. Food and Drug Administration (FDA)**

In 2014, the TOPAZ<sup>®</sup> EZ Microdebrider Coblation<sup>®</sup> Wand with Integrated Finger Switch, an electro-surgical cutting and coagulation device (ArthroCare Corporation, K140521), was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process, on the basis of an earlier predicate device (ArthroCare Topaz Wand, K080282, 2008). The surgical wands are indicated for debridement, resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in arthroscopic and orthopedic procedures, including fasciotomy, synovectomy, tenotomy, and capsulotomy of the foot and tenotomy of the knee, wrist, elbow, ankle, shoulder, and rotator cuff. FDA product code: GEI.

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.

Tenex 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<sup>®</sup> (K190070) (Stryker Instruments, Kalamazoo, MI), which received 510(k) clearance on April 11, 2019 (FDA, 2019).

## **Rationale/Source**

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.



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Radiofrequency (RF) coblation is being evaluated for the treatment of plantar fasciitis, lateral epicondylitis, and various musculoskeletal tendinopathies. When utilized for tenotomy, bipolar RF energy is directed into the tendon to generate a controlled, low-temperature field of ionizing particles that break organic bonds, ablating or debriding target tissue with the goal of relieving pain and restoring function.

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.

### Summary of Evidence

For individuals with plantar fasciitis who receive radiofrequency (RF) coblation tenotomy, the evidence includes nonrandomized, comparative cohort studies, a systematic review of these studies, and case series. Relevant outcomes are symptoms, functional outcomes, quality of life (QOL), medication use, and treatment-related morbidity. The trials reported improved pain and functional scores over 3 to 12 months, with improved outcomes with open versus percutaneous approaches. However, open RF coblation microtenotomy was associated with a higher incidence of postoperative persistent pain (9.1%) compared to endoscopic plantar fasciotomy (0%) in 1 study, with a separate study reporting a complication rate of 33% when both interventions were used in combination. A higher number of postoperative pain recurrences at 6 and 12 months were also reported with open RF coblation microtenotomy compared to endoscopic plantar fasciotomy. The durability of this intervention is unknown as no studies have reported long-term outcomes beyond 12 months. Studies are limited by small sample sizes, heterogeneity in surgical technique (open, percutaneous, endoscopic), missing data and/or inappropriate exclusions, lack of randomization, unclear blinding practices for patient outcome assessments, and poor statistical reporting. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with lateral epicondylitis who receive RF coblation tenotomy, the evidence includes small randomized controlled trials (RCTs). Relevant outcomes are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. The trials compared RF microtenotomy to open or arthroscopic elbow release surgery. Clinically meaningful improvements in pain and functional scores were noted for all treatment arms, with no significant differences between groups through 1 to 7 years of follow-up. For disability assessments in 1 study, open release surgery met the threshold for a clinically meaningful improvement over RF microtenotomy at 1 year, though this mean difference was not statistically significant. Studies were generally underpowered or demonstrated inconsistent delivery and unclear blinding of outcome assessments and inappropriate handling of missing or crossover data. No studies featuring RF coblation tenotomy for the treatment of wrist tendinopathy were identified. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.



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For individuals with Achilles tendinopathy who receive RF coblation tenotomy, the evidence includes small, single-blind RCTs. Relevant outcomes are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. One trial did not demonstrate an added benefit for RF microdebridement compared to surgical decompression. Pain and functional outcomes improved in both groups but were not statistically different at a 6 month follow-up. The study was limited by a control group that showed significantly less severe symptom scores at baseline that did not fully meet the 2 point threshold for a clinically meaningful difference in pain score reduction. The other small RCT demonstrated potential benefits in pain and quality of life for RF microtenotomy (ArthroCare) compared with physical therapy at 2 years. But, conclusions cannot be drawn based on these findings due to numerous notable study limitations. Larger, adequately controlled studies with longer follow-up durations are lacking. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with shoulder or rotator cuff tendinopathy who receive RF coblation tenotomy, the evidence includes small RCTs. Relevant outcomes are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. Trials did not demonstrate an added benefit for RF microdebridement compared to arthroscopic subacromial decompression surgery. Pain and functional outcomes improved in both groups but were not statistically different through 1 to 2 years of follow-up. Neither study prespecified a clinically meaningful difference in outcome measures nor were harms assessed throughout their course. The loss to follow-up in 1 study was 18.7%. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with patellar tendinopathy who receive RF coblation tenotomy, the evidence includes 1 small RCT. Relevant outcomes are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. The trial did not demonstrate an added benefit for RF microdebridement compared to mechanical debridement in patients with chondral lesions and patellar tendinopathy. The study lacked reporting with validated pain measures over time and reported a higher incidence of crepitus in patients undergoing RF microdebridement. Furthermore, the study only enrolled female participants, limiting the broader applicability of these findings. Larger studies with validated pain and functional outcome measures are required to adequately assess the technology. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with various tendinopathies who receive percutaneous ultrasonic tenotomy (PUT) ablation, the evidence includes case series, retrospective reviews, and a systematic review. Relevant outcomes are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. The 2021 systematic review included seven studies, all uncontrolled prospective and retrospective case series consisting of level 4 evidence. Five studies involved the treatment of elbow tendinopathy (76 patients) and 1 each the management of Achilles tendinopathy (34 patients) and plantar fasciitis (12 patients), with average follow-up of 10-36 months. Several major limitations





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were noted, including very limited data, small sample sizes, sparse information on patient-reported outcomes, and short follow-up duration. The quality of evidence in the available literature did not allow a robust statistical analysis and authors concluded that further higher quality studies are necessary to accurately assess the comparative effectiveness of this treatment modality.

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. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

### **Supplemental Information**

#### **Practice Guidelines and Position Statements**

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information’ if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

#### **American College of Foot and Ankle Surgeons**

In 2017, the American College of Foot and Ankle Surgeons published a clinical consensus statement on the diagnosis and treatment of adult acquired infracalcaneal heel pain based upon the best available evidence in the literature. The panel determined that the following statement was uncertain – that is – neither appropriate nor inappropriate:

- “Other surgical techniques (eg, ultrasonic debridement using a microtip device, cryosurgery, and bipolar radiofrequency ablation) are safe and effective options for chronic, refractory plantar fasciitis.”

#### **American Medical Society for Sports Medicine**

In 2015, the American Medical Society for Sports Medicine (AMSSM) published a position statement on the use of interventional musculoskeletal ultrasound in sports medicine. 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. It is also noted that “in the author's opinion, many new procedures require guidance in order to perform the procedure safely and effectively”.



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### American College of Occupational and Environmental Medicine

In 2013, the American College of Occupational and Environmental Medicine updated their treatment guidelines for lateral epicondylitis as a result of a systematic review of the literature. Surgery is recommended for cases inadequately responsive to multiple evidence-based treatments (Level of Evidence: I, insufficient evidence). Microtenotomy is also recommended (Level of Evidence: C, limited evidence base).

### U.S. Preventive Services Task Force Recommendations

No U.S. Preventive Services Task Force recommendations for the use of radiofrequency coblation tenotomy have been identified.

### Medicare National Coverage

The Centers for Medicare & Medicaid Services have determined that thermal intradiscal procedures, including percutaneous (or plasma) disc decompression or coblation, are not reasonable and necessary for the treatment of low back pain. Therefore, thermal intradiscal procedures, which include procedures that “employ the use of a radiofrequency energy source or electrothermal energy to apply or create heat and/or disruption within the disc for the treatment of low back pain, are noncovered.”

However, the Centers for Medicare & Medicaid Services have not published a national coverage decision on radiofrequency coblation tenotomy for the musculoskeletal conditions addressed in this evidence review. In the absence of a national coverage determination, coverage determinations are left to the discretion of local Medicare carriers.

### Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 1.

**Table 1. Summary of Key Trials**

<b>NCT No.</b>	<b>Trial Name</b>	<b>Planned Enrollment</b>	<b>Completion Date</b>
<i>Ongoing</i>			
NCT03854682	Surgical or Non-surgical Treatment of Plantar Fasciitis - A Randomized Clinical Trial	70	Jun 2025 (recruiting)
<i>Unpublished</i>			
NCT02304952	Eccentric Exercise or Radiofrequent Microtenotomy as Treatment of Chronic Lateral Epicondylalgia - a Randomized Controlled Trial	100	Sep 2018 (unknown)





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NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT02275689	Alternative Treatment of Rotator Cuff Tendinopathy	34	Dec 2016 (completed)
NCT00534781 <sup>a</sup>	Radiofrequency-based Plasma Microdebridement Compared to Surgical Microdebridement for Treating Achilles Tendinosis: A Prospective, Randomized, Controlled Multi-Center Study	60	Sep 2010 (completed)
NCT00189592 <sup>a</sup>	Plantar Fasciosis Treatment Using Coblation <sup>®†</sup> Prospective, Double-Blind, Randomized Controlled Study	45	Jun 2008 (completed)

NCT: national clinical trial.

<sup>a</sup> Denotes industry-sponsored or cosponsored trial.

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02/06/2025 Medical Policy Committee review

02/12/2025 Medical Policy Implementation Committee approval. New policy.



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## **Coding**

*The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)†, copyright 2024 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.*

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	17999, 20999, 23405, 23406, 23929, 24357, 24999, 27299, 27599, 27605, 27606, 27899, 28899, 29999
HCPCS	N/A
ICD-10 Diagnosis	M67811-M67819, M67831-M67839, M722, M7650-M7652, M7660-M7662, M7710-M7712

\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or



## Radiofrequency Coblation Tenotomy and Percutaneous Ultrasonic Tenotomy for Musculoskeletal Conditions

Policy # 00916

Original Effective Date: 03/01/2025

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- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
1. Consultation with technology evaluation center(s);
  2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
  3. Reference to federal regulations.

‡ Indicated trademarks are the registered trademarks of their respective owners.

**NOTICE:** If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

**NOTICE:** 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.

