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## Percutaneous Ultrasonic Ablation for Tendinopathy

MEDICAL POLICY NUMBER: 248

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**INSTRUCTIONS FOR USE:** Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

**SCOPE:** Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

## PLAN PRODUCT AND BENEFIT APPLICATION

Commercial

Medicaid/OHP\*

Medicare\*\*

### \*Medicaid/OHP Members

*Oregon:* Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

### \*\*Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered “**not medically necessary**” for Medicare members.

## COVERAGE CRITERIA

- I. Percutaneous ultrasonic ablation for the treatment of tendinopathy (e.g. Tenex Health TX® System) is considered **investigational and not covered**.

Link to [Evidence Summary](#)

## POLICY CROSS REFERENCES

None

The full Company portfolio of current Medical Policies is available online and can be [accessed here](#).

## POLICY GUIDELINES

### BACKGROUND

#### Tendinopathy

Tendinopathy is the breakdown of collagen in a tendon, what connects muscles to bones.<sup>1</sup> 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.

Tendinopathy is most often due to overuse or sudden stress on a tendon. Aging and decreased muscle tone can also lead to the development of tendinopathy. Treatment of tendinopathy usually starts with

rest, as well as ice, compress, and elevation. Physical therapy is also used to help rebuild strength and stimulate tendon healing. Surgery, tenotomy, is a last-line treatment in severe cases of tendinopathy.

### **Percutaneous Ultrasonic Ablation (i.e., Tenex Health TX System)**

Percutaneous ultrasonic ablation using the Tenex Health TX System is intended as an alternative to conventional surgical techniques for the treatment of tendinopathy.<sup>2</sup> Tenex is an ultrasonic surgical instrument that breaks up hard and soft tissue. First, the TX System is used to visualize and identify the damaged tendon's exact location via ultrasound imaging. The MicroTip needle of the Tenex device is then inserted under local anesthetic at the location of the damaged tissue. The ultrasonic treatment is then activated to break down and remove the damaged tissue. This minimally invasive, ultrasonic technique is purported to keep the surrounding tissue healthy and unharmed. The procedure can be performed on an outpatient basis, and recovery is estimated at four to six weeks.

## **REGULATORY STATUS**

### **U.S. FOOD AND DRUG ADMINISTRATION (FDA)**

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

FDA granted 510(k) marketing clearance to for the Tenex Health TX System on March 3, 2016 (510(k) Number: K153299).<sup>3</sup> Indications for use:

*"The Tenex Health TX System is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft tissue are desirable, including General Surgery, Orthopedic Surgery, Laparoscopic Surgery and Plastic and Reconstructive Surgery."<sup>3</sup>*

## **CLINICAL EVIDENCE AND LITERATURE REVIEW**

### **EVIDENCE REVIEW**

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of percutaneous ultrasonic ablation (i.e., Tenex Health TX System) as a treatment of tendinopathy. Below is a summary of the available evidence identified through September 2022.

#### **Systematic Reviews**

- In 2021, Hayes reviewed the use of the Tenex Health TX System to treat Achilles tendinopathy,<sup>4</sup> elbow tendinopathy,<sup>5</sup> and tendinopathy.<sup>6</sup> Levels of support for the Tenex System in the treatment of these indications was either minimal or unclear, with studies to date suffering from small sample sizes, lack of long-term follow-up, lack of randomized comparator groups and lack of standardized treatment parameters.

- In 2021, the ECRI Institute conducted a systematic evidence review to evaluate the Tenex Health TX System (Tenex Health, Inc.) for Treating Chronic Tendinopathy.<sup>2</sup> The review identified six small studies (one retrospective nonrandomized study and five case series), encompassing 163 patients, evaluating Tenex for the treatment of tendinopathy. All studies were determined to be at a high risk of bias. Two prospective case series (n=20, n=19) and one retrospective study (n=62) evaluated Tenex for the treatment of elbow tendinopathy. Both reported improved visual analog scale pain scores and Disabilities of the Arm, Shoulder, and Hand scores at 1-to-3-year follow-up. Two of the three studies also reported that over 80% of patients were satisfied with the treatment and less than 20% required additional treatment. The nonrandomized retrospective study reported similar outcomes for pain relieve and function with Tenex compared to platelet-rich plasma injections.

In regards to lower-limb tendinopathies, one retrospective case series (n=34) reported reduction in moderate to severe pain from 68% to 15% in patients with Achilles tendinopathy. Two prospective case series reported recovery to full function in 10/16 patients after Tenex treatment for patellar tendonitis. Additionally, 12/13 patients reported complete pain resolution after plantar fascia treatment. The ECRI review concluded “(f)indings are at very high risk of bias from 3 or more of the following: lack of control group, randomization, and blinding; small sample size; retrospective design; and/or single center focus. The studies also reported subjective outcome measures (i.e., pain), which is why control groups, randomization, and blinding are needed to reduce bias.”<sup>2</sup> The ECRI Evidence Bar™ was determined to be “inconclusive” because of “too few data”.<sup>2</sup>

- In 2020, Vajapey and colleagues conducted a systematic review assessing the utility of percutaneous ultrasonic tenotomy (PUT) for tendinopathies.<sup>7</sup> Outcomes of interest included pain relief, patient-reported outcomes and complication rates. In total, 7 case series met the inclusion criteria and quality measures—5 studies involving the treatment of elbow tendinopathy and 1 study each involving the management of Achilles tendinopathy and plantar fasciitis (n= 142). Follow-up ranged from 1 year to 3 years. PUT resulted in decreased pain/disability scores and improved functional outcome scores for chronic elbow tendinopathy and plantar fasciitis. Results for Achilles tendinopathy showed modest improvement in the short term, but long-term data are lacking. Authors concluded that additional, high-quality studies are needed to accurately assesses the long-term efficacy of PUT for the treatment of tendinopathies.

## **CLINICAL PRACTICE GUIDELINES**

No clinical practice guidelines were identified which address percutaneous ultrasonic ablation for tendinopathy.

## **EVIDENCE SUMMARY**

There is insufficient high-quality, published evidence to evaluate the safety, efficacy, and clinical utility of percutaneous ultrasonic ablation for tendinopathy. Larger, higher-quality studies (i.e., randomized controlled trials with long-term follow-up) are required to validate the findings of the current body of literature. Additional studies should also compare percutaneous ultrasonic ablation with other established surgical treatments of tendinopathy.

## BILLING GUIDELINES AND CODING

There is no specific code for percutaneous ultrasonic tenotomy. This service should be billed with an unlisted code (e.g., 17999, 20999).

However, if any of the following codes for tenotomy or fasciotomy are billed for percutaneous ultrasonic ablation, the code is considered investigational and is not covered:

23405	27006	28008
23046	27306	28060
24357	27307	28230
27000	27605	28234-52
27005		

CODES*		
CPT	17999	Unlisted procedure, skin, mucous membrane and subcutaneous tissue
	20999	Unlisted procedure, musculoskeletal system, general
HCPCS	None	

### \*Coding Notes:

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- See the non-covered and prior authorization lists on the Company [Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website](#) for additional information.
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as “medically unlikely edits” (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

## REFERENCES

1. Morrison W. Healthline: Understanding Tendinopathy. <https://www.healthline.com/health/tendinopathy>. Published 2018. Accessed 10/8/2022.
2. ECRI Institute. ECRI Institute: Tenex Health TX System (Tenex Health, Inc.) for Treating Chronic Tendinopathy. <https://www.ecri.org/components/ProductBriefs/Pages/13597.aspx?tab=1>. Published 2013 (Updated 2021). Accessed 10/8/2022.
3. U.S. Food and Drug Administration. 510(k) Premarket Notification: Tenex Health TX System (Product Code: LFL). <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>. Published 2021. Accessed 10/8/2022.

4. Hayes Inc. Tenex (Tenex Health TX) Percutaneous Ultrasonic Tenotomy System to Treat Achilles Tendinopathy. <https://evidence.hayesinc.com/report/eer.tenotomyachilles5220>. Published 2021. Accessed 10/8/2022.
5. Hayes Inc. Percutaneous Ultrasonic Tenotomy (Tenex Health TX) for Treatment of Elbow Tendinopathy. <https://evidence.hayesinc.com/report/eer.tenotomyelbow5219>. Published 2022. Accessed 10/8/2022.
6. Hayes Inc. Percutaneous Ultrasonic Tenotomy (Tenex Health TX) for Treatment of Tendinopathy. <https://evidence.hayesinc.com/report/hss.tenexhealth2605>. Published 2021 (archived 2022). Accessed 10/8/2022.
7. Vajapey S, Ghenbot S, Baria MR, Magnussen RA, Vasileff WK. Utility of Percutaneous Ultrasonic Tenotomy for Tendinopathies: A Systematic Review. *Sports Health*. 2021;13(3):258-264.

## POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.