MEDICAL POLICY	Percutaneous Ultrasonic Ablation for Tendinopathy
Effective Date: 12/1/2021  12/1/2021 Medical Officer Date	Medical Policy Number: 248 Medical Policy Committee Approved Date: 10/19; 11/2020; 11/2021

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

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").

APPLIES TO:

All lines of business

BENEFIT APPLICATION

Medicaid 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.

POLICY CRITERIA

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

Link to Policy Summary

BILLING GUIDELINES

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:

24357	23405	28060
27306	23406	28230
27307	28008	28234-52

27605
27000
27005
27006

CPT/HCPCS CODES

All Lines of Business	
Note: If a tenotomy of fasciotomy code is used to represent percutaneous ultrasonic ablation, the code is considered investigational and is not covered.	
Unlisted Codes All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then it will be **denied as not covered.**	
17999	Unlisted procedure, skin, mucous membrane and subcutaneous tissue
20999	Unlisted procedure, musculoskeletal system, general

DESCRIPTION

Tendinopathy

Tendinopathy is the breakdown of collagen in a tendon, what connects muscles to bones.[1] 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.[2] 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.

REVIEW OF EVIDENCE

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 2021.

Systematic Reviews

- In 2021, the ECRI Institute conducted a systematic evidence review to evaluate the Tenex Health TX System (Tenex Health, Inc.) for Treating Chronic Tendinopathy.[2] 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."[2] The ECRI Evidence Bar™ was determined to be "inconclusive" because of "too few data".[2]

- In 2020, Vajapey and colleagues conducted a systematic review assessing the utility of percutaneous ultrasonic tenotomy (PUT) for tendinopathies.[3] 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.

CENTERS FOR MEDICARE & MEDICAID

As of 10/6/2021, no specific Medicare coverage policy or guidance (e.g., manual, national coverage determination [NCD], local coverage determination [LCD] article [LCA], etc.) was identified which addresses percutaneous ultrasonic ablation for tendinopathy. In the absence of a NCD, LCD, or other Medicare policy, Medicare guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an objective, evidence-based process, based on authoritative evidence. *(Medicare IOM Pub. No. 100-16, Ch. 4, §90.5)*

Therefore, this Company coverage review will be applied for medical necessity decision-making. Under Medicare, only medically reasonable and necessary services are covered (*Title XVIII of the Social Security Act, §1862(a)(1)(A)*). Procedures, devices, or other medical technologies which lack scientific evidence regarding safety and efficacy because they are investigational or experimental are considered **"not medically reasonable or necessary"** to treat illness or injury under Medicare. *(Medicare IOM Pub. No. 100-04, Ch. 23, §30 A)*

POLICY 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.

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 Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days' notice of policy changes that are restrictive in nature.

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.

REGULATORY STATUS

U.S. Food and Drug Administration (FDA)

FDA granted 510(k) marketing clearance to for the Tenex Health TX System on March 3, 2016 (510(k) Number: K153299).[4] 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."*[4]

Mental Health Parity Statement

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.

REFERENCES

1. Morrison W. Healthline: Understanding Tendinopathy. https://www.healthline.com/health/tendinopathy. Published 2018. Accessed 10/6/2021.
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 10/6/2021.
3. 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
4. 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 10/6/2021.