KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Focused Aspiration of Scar Tissue (FAST)

- Tenex
- Tenex Health TX System (Tenex Microtip, X1 MicroTip, TX2 Microtip, TXB MicroTip) for the Treatment of Tendinopathies

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of a NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "***Focused Aspiration of Scar Tissue (FAST)***" for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies for tendonitis and soft tissue injuries.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Tenex Health TX™ is used for the treatment of tendonitis and soft tissue injuries. This procedure — Fasciotomy and Surgical Tenotomy (may also be referred to as Focused Aspiration of Scar Tissue FAST) – is a minimally invasive, non-surgical approach for eliminating scar tissue, the source of chronic tendon pain. FAST is a minimally invasive treatment designed to remove tendon scar tissue, allowing patients to return to their athletics and active lifestyles. The Tenex system is a surgical instrument that uses ultrasonic energy to perform a percutaneous tenotomy and fasciotomy. It is intended to precisely cut and remove disease and damaged tissue that leads to natural tendon and soft-tissue function.

Hayes Review

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Hayes, Inc. Hayes Health Technology Brief. Tenex Health TX Procedure (Tenex Health) for Treatment of Tendon Pain. Lansdale, PA: Hayes Inc.; 9/2015

Medical Technology Assessment Committee (MTAC)

Tenex Health TX System (Tenex Microtip, X1 MicroTip, TX2 Microtip, TXB MicroTip) for the Treatment of Tendinopathies

BACKGROUND

Tendons are fibrous connective tissues that attach muscles to other body parts, usually bones. They play an important role in the movement by transmitting the contraction force produced by the muscles to the bone they hold. Tendons are anatomically designed to withstand extensive mechanical loading but are prone to injury through a variety of biomechanical and biological mechanisms Tendon disorders have become very common among athletic and non-athletic population and account for a considerable proportion of activity-related diseases of the musculoskeletal system. Different terms have been used to describe tendon pathology including tendinitis, tendinosis, paratendonitis, and tendinopathy. Currently, tendinopathy has become the accepted term to describe a spectrum of changes that occur in damaged and/or diseased tendons. Common tendinopathies include plantar fasciitis, Achilles tendinopathy, medial and lateral elbow epicondylitis, rotator cuff tendinopathy, and others. These are mainly characterized by pain, reduced exercise tolerance, and decreased function (Ahmad 2020, Scott 2015, Steinmann 2020).

Tendinopathy is primarily a diagnosis of clinical suspicion and can be difficult to diagnose. Imaging can be normal in pathological tendon, and asymptomatic tendon can be histologically pathological. It is thus reported that the clinical presentation and prognosis of tendinopathy can be very individualized and require detailed assessment of the extent or nature of pathology and risk factors to diagnose and manage the condition. Treatment of tendinopathy should promote repair and remodeling rather than further injury/inflammation. However, it is reported that there is no good clinical outcome measure for tendon remodeling as there is often a discrepancy between clinical improvement and structural improvement measured with clinical imaging (Ahmad 2020, Scott, 2015).

The first line treatment for a diagnosed tendinopathy consists of conservative measures such as rest and activity modification to allow the tendon to heal, bracing, and individualized rehabilitation exercises to stimulate the cellular activity and increase the blood flow in the tendon. Pharmacological therapies such as non-steroidal anti-inflammatory drugs (NSAIDs) and corticosteroids may have short-term effect on reducing pain but could have negative or equivocal long-term effect. The majority of individuals will respond to conservative therapy; however, in some patients the tendinopathy is refractory (recalcitrant) to conservative therapy. Corticosteroid injections are commonly used in cases refractory to conservative therapy but have unproven efficacy, can delay healing, and may be associated with potential harms to the tendons (Ahmad 2020, Mattie 2017).

Currently, there is no universally accepted therapeutic modality for recalcitrant tendinopathies. Several non-pharmacological invasive or minimally invasive therapies have been introduced to practice or are being investigated such as laser therapy, shock-wave therapy, therapeutic ultrasound, and thermal modalities (cryotherapy and hyperthermia), platelet rich plasma (PRP) injection, stem cell therapy and others. Many of these therapies were found to have no effect, have only a short-term effect on improving symptoms and /or result in long-term damage to the tendon. Some investigators have advocated re-injuring the tendon through treatments such as intra-tendinous needling and injections, and aggressive soft tissue therapy. These approaches may improve the patient's symptoms in the short-term but could result in long-term damage to the tendon (Mattie 2017, Scott 2015, Stover 2019).

Surgery is often considered as a last option for patients with persistent pain and disability after exhausting all appropriate nonoperative options. Surgery involves the excision of degenerative tendon portions, removal of adhesions, decompression, and/or creation of multiple longitudinal tenotomies. It is reported that ideally surgical treatment of chronic tendinopathy should involve micro-resection of specific regions demonstrating mucoid degenerative tissue. However, traditional surgical techniques are based on gross and not microscopic appearance. Over the years the surgical procedures have evolved from open techniques to more minimally invasive approaches using arthroscopy, or through percutaneous incisions under ultrasound guidance. It is

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reported however, that there is insufficient evidence from high quality RCTs to determine the effectiveness of surgical interventions for the treatment of tendinopathies (Koh 2013, Ma 2020).

Ultrasound-guided percutaneous tenotomy (UGPT) (also known as percutaneous ultrasonic tenotomy [PUT]) is a relatively recent option introduced for the treatment of multiple types of tendinopathy. The therapy is based on the assumption that the removal of the pathological tissues would convert the chronic degenerative process into an acute process that introduces inflammatory growth factors and promotes tendon healing. UGPT combines ultrasound visualization with a small cutting handpiece to allow debridement of the pathological tendon tissue. It is reported however, that ultrasound scanning delivers a 2-dimensional image for a 3-D structure which may result in either failing to remove all the pathologic tissue or removing too much of the healthy tissue. In addition, the pistoning motion of the cutting handpiece can penetrate healthy tendons due to the inadequate visualization provided by the ultrasound probe (Sanchez 2017).

Tenex procedure is an ultrasound-guided percutaneous tenotomy performed with the assistance of proprietary device "TX Tissue Removal System" (Tenex Health; Lake Forest, CA). It uses both diagnostic and therapeutic ultrasound and is intended for ablating, emulsifying and removing diseased or pathologic musculoskeletal tissue to treat chronic tendon and soft-tissue injuries. The Tenex Health TX System is an ultrasonic surgical aspirator that fragments, emulsifies, and removes soft tissue. The system consists of a console, ultrasonic handpiece, inflation cuff and a foot pedal. The console provides control over the user functions including irrigation, aspiration, and ultrasonic fragmentation/emulsification. It has a large, color LCD and employs a touchscreen with a graphical user interface for selection of required settings. The console also houses the irrigation valve, the irrigation pump, and the aspiration pump. The ultrasonic handpiece has a double lumen to allow for concomitant aspiration and irrigation of emulsified tendon tissue. It connects to the console for power, as well as for delivering irrigation fluid directly to the surgical site and for aspirating emulsified tissue by way of integrated tubing set. The handpiece and tubing are single use disposable components of the system. Irrigation fluid is delivered under pressure to the surgical site by operation of an air pump residing in the console. The foot pedal is used to control each of the functions (irrigation, aspiration, ultrasonic fragmentation/emulsification) of the system (FDA website, Batista 2018).

The Tenex procedure is performed in an outpatient setting under sterile condition with local anesthesia and no sedation. A pre-procedure ultrasound is performed to identify the location and extent of the pathology. A small incision (approximately 5 mm) is then made in line with the tendon fiber to allow the introduction of the TX cutting device while limiting any iatrogenic damage to the tendon. The TX ultrasonic cutting device a needle-like point (the TX Micro Tip) is inserted into the area and high-frequency vibrations cuts and debrides the damaged scar tissue and intra-tendinous calcifications that were identified by the pre-procedural ultrasound. Once debridement is complete the skin incision is closed with adhesive bandage, an occlusive film and a compression sleeve. Post procedure protocol limits movement according to the tendon treated. (Chimenti 2019).

Sanchez, et al (2017) reported that that percutaneous ultrasound-guided tenotomy using Tenex device is a surgical procedure associated with complications similar to those of surgery including tendon tear, re-rupture, deep vein thrombosis, and worsening of healing.

10/12/2020: MTAC REVIEW

Evidence Conclusion:

There is insufficient published evidence from well-conducted randomized or non-randomized prospective observational studies to determine the safety and efficacy of Tenex Health TX system for the management of recalcitrant tendinopathies.

Low- to very low strength of evidence suggest that the intervention may lead to some improvement in pain and /or function when compared to baseline symptoms.

Articles:

The literature search did not identify any randomized controlled trials or prospective comparative study that compared the safety and efficacy of percutaneous ultrasound tenotomy, using Tenex Health TX tissue removal system versus a sham therapy or any other intervention used for the treatment of tendinopathy refractory to conservative therapy. The limited published literature consisted of small observational studies and case series the majority of which were retrospective with data obtained from chart reviews.

The use of Tenex Health TX System (Tenex Microtip, X1 MicroTip, TX2 Microtip, TXB MicroTip) for the Treatment of Tendinopathies does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

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Applicable Codes

Considered not medically necessary:

CPT® Codes	Description
23405	Tenotomy, shoulder area; single tendon
23406	Tenotomy, shoulder area; multiple tendons through same incision
24357	Tenotomy, elbow, lateral or medial (e.g., epicondylitis, tennis elbow, golfer's elbow); percutaneous
27000	Tenotomy, adductor of hip, percutaneous (separate procedure)
27306	Tenotomy, percutaneous, single tendon (separate procedure)
27307	Tenotomy, percutaneous, adductor or hamstring; multiple tendons
27605	Tenotomy, percutaneous, Achilles tendon (separate procedure); local anesthesia

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
04/04/2017	04/04/2017[MPC], 04/02/2019[MPC], 04/07/2020[MPC], 04/06/2021[MPC], 04/05/2022[MPC], 04/04/2023[MPC]	12/02/2022

[MPC] Medical Policy Committee

Revision History	Description
02/14/2019	Updated criteria set to publish
12/01/2020	Added MTAC report for Tenex Health TX System (Tenex Microtip, X1 MicroTip, TX2 Microtip, TXB MicroTip) for the Treatment of Tendinopathies. MPC approved to retain non-coverage policy. Included additional CPT codes for percutaneous tenotomy for review. Requires 60-day notice, effective date of additional codes 05/01/2021.
12/02/2022	Removed codes 28008 and 28060 fasciotomy codes as they are not applicable to this procedure.

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