

Percutaneous Tenotomy for Epicondylitis

Policy Number: **M20140710001**
Effective Date: **9/1/2014**
Sponsoring Department: **Health Care Services**
Impacted Department(s): **Health Care Services**

Type of Policy: ☒ Internal ☒ External

Data Classification: ☐ Confidential ☐ Restricted ☒ Public

Applies to (Line of Business):

- ☐ Corporate (All)
☒ State Products, if yes which plan(s): ☒ MediSource; ☒ MediSource Connect; ☒ Child Health Plus ☒ Essential Plan
☒ Medicare, if yes, which plan(s): ☒ MAPD; ☐ PDP; ☒ ISNP; ☒ CSNP
☒ Commercial, if yes, which type: ☒ Large Group; ☒ Small Group; ☒ Individual
☒ Self-Funded Services *(Refer to specific Summary Plan Descriptions (SPDs) to determine any pre-authorization or pre-certification requirements and coverage limitations. In the event of any conflict between this policy and the SPD of a Self-Funded Plan, the SPD shall supersede the policy.)*

Excluded Products within the Selected Lines of Business (LOB)

N/A

Applicable to Vendors? Yes ☐ No ☒

Purpose and Applicability:

To set forth the criteria for percutaneous tenotomy for epicondylitis.

Policy:

Commercial, Self-Funded and Medicare Advantage:

Percutaneous tenotomy utilizing needle fenestration is considered medically necessary for epicondylitis.

Percutaneous tenotomy utilizing the TX1 Tissue Removal System is considered experimental/investigational as there is insufficient published evidence to assess the safety and/or impact on health outcomes or patient management.

MediSource, MediSource Connect, Child Health Plus, and Essential Plan:

MediSource, Child Health Plus and Essential Plan cover percutaneous tenotomy utilizing the Commercial and Self-Funded criteria above.

Background:

According to the Food and Drug Administration (FDA), the TX I Tissue Removal System is approved 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.

Ultrasound-guided percutaneous needle tenotomy with needle fenestration involves using a needle under ultrasound guidance to fenestrate tendinotic tissue, break up calcifications and if needed abrade the surface of underlying bone. The mechanism of action is unclear.

The Tenex Health TX procedure is performed as an outpatient procedure using a local anesthetic. No stitches are required, as only a tiny incision is needed for the insertion of the TX MicroTip. Post-procedure, wound closure requires adhesive strips, occlusive dressing with a compression bandage applied. There is limited evidence available pertaining specifically to the Tenex procedure. No randomized controlled trials (RCTs) were located, therefore the Tenex procedure will be considered experimental/investigational.

An evaluation of the peer-reviewed scientific literature, including but not limited to subscription materials, has provided Independent Health the basis for its medical necessity coverage outlined above.

Pre-Authorization Required? Yes ☐ No ☒

Pre-authorization is not required at the present time. Criteria above will be utilized upon retro-review.

Definitions

Percutaneous Tenotomy using the TX1 Tissue Removal System, also known as FAST (fasciotomy and surgical tenotomy) technique, uses real-time ultrasound to detect the tendinopathic area within the tendon and ultrasonographically direct the surgical tool through a 4-mm incision to debride and remove the diseased tissue.

References

Related Policies, Processes and Other Documents

N/A

Non-Regulatory references

Barnes DE. Ultrasonic energy in tendon treatment. Operative Techniques in Orthopaedics. 23 (2) (pp 78-83), 2013.

Buchbinder R, Green SE, Struijs P. Tennis elbow. BMJ Clin Evid. 2008 May 28;2008.

Hayes, Inc. Evolving Evidence Review. Percutaneous Ultrasonic Tenotomy (Tenex Health TX) for Treatment of Elbow Tendinopathy. Lansdale, PA: January 2022.

Hegmann KT, Hoffman HE, Belcourt RM, et al.; American College of Occupational and Environmental Medicine. ACOEM practice guidelines: elbow disorders. J Occup Environ Med. 2013 Nov;55(11):1365-74.

Jayanthi, N. Epicondylitis (tennis and golf elbow). In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on October 30, 2023.)

McShane JM, Nazarian LN, Harwood MI. Sonographically guided percutaneous needle tenotomy for treatment of common extensor tendinosis in the elbow. J Ultrasound Med. 2006 Oct;25(10):1281-9.

Regulatory References

Center for Devices and Radiological Health (CDRH). K101561. TX1 Tissue Removal System [Substantially equivalent (SE)] June 2, 2010. Food and Drug Administration [website]. Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf10/K101561.pdf Accessed November 18, 2024

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New York State Department of Health [web site]. New York State Medicaid Program Physician Procedure Codes Section 5 Surgery April 2023. Available at: <https://www.emedny.org/ProviderManuals/Physician/PDFS/Physician%20Procedure%20Codes%20Sect5.pdf> Accessed November 18, 2024

This policy contains medical necessity criteria that apply for this service. Please note that payment for the services covered is subject to eligibility criteria, contract exclusions and the limitations noted in the member's contract at the time the services are rendered.

Version Control

Signature / Approval on File? Yes ☒ No ☐

Restricted

Revision Date	Owner	Notes
1/1/2025	Health Care Services	Reviewed
1/1/2024	Health Care Services	Revised
1/1/2023	Health Care Services	Reviewed
1/1/2022	Health Care Services	Reviewed
1/1/2021	Health Care Services	Reviewed
2/1/2020	Medical Management	Revised
3/1/2019	Medical Management	Revised
3/1/2018	Medical Management	Revised
3/1/2017	Medical Management	Revised
3/1/2016	Medical Management	Revised
9/1/2014	Medical Management	Revised