Prior Authorization Review Panel MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review. Policies submitted without this form will not be considered for review.

Plan: Keystone First	Submission Date: 6/26/2023
Policy Number: ccp.1370	Effective Date: 5/2018
	Revision Date: June 1, 2023
Policy Name: Neuroablation for chronic foot pain	
Type of Submission – Check all that apply:	
New Policy x Revised Policy* Annual Review – No Revisions Statewide PDL	
*All revisions to the policy <u>must</u> be highlighted using track changes throughout the document.	
Please provide any clarifying information for the policy below:	
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Name of Authorized Individual (Please type or print):	Signature of Authorized Individual:
Manni Sethi, MD, MBA, CHCQM	Manni Settri



Neuroablation for chronic foot pain

Clinical Policy ID: CCP.1370

Recent review date: 6/2023

Next review date: 10/2024

Policy contains: Achilles tendinosis; intermetatarsal nerve entrapment; plantar fasciitis; thermal ablation or

chemo-ablation.

Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First's clinical policies are not guarantees of payment.

Coverage policy

Thermal ablation or chemoablation for chronic foot pain is investigational/not clinically proven and, therefore, not medically necessary.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

Standard of care for each diagnosis (e.g., analgesia medications, physical therapy, orthoses, surgery).

Background

Foot pain is a common complaint and includes diverse neurogenic and musculoskeletal causes, which often present with similar symptoms. The specific anatomic location of the pain (the forefoot, midfoot, and hindfoot) can often guide diagnosis and treatment (American Orthopaedic Foot and Ankle Society, 2023).

The treatment algorithm for most chronically painful soft tissue conditions of the foot begins with conservative therapies (e.g., anti-inflammatory medications, off-loading, changes in footwear, orthoses, and self-care) and progresses to more invasive options. Prescribed options such as corticosteroid injections and physical therapy may relieve pain and improve mobility. When conservative treatment fails, surgery (e.g., decompression, release, or resection) may be indicated (Agyekum, 2015). Percutaneous techniques, such as platelet-rich plasma, extracorporeal shock wave therapy, and neuroablation have emerged as potential treatment options for chronic foot pain (Smith, 2017).

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Neuroablation is designed to destroy neural tissue. In current practice, the goal of neuroablation is to temporarily interrupt rather than permanently destroy the nerve impulse or pathway, thus preventing the pain signal from traveling to the brain (Association of Extremity Nerve Surgeons, 2014). Neuroablation can be administered during open surgery or percutaneously with ultrasound, computed tomography, or magnetic resonance imaging guidance. The most common neuroablative techniques apply extreme heat (radiofrequency), cold (cryotherapy), or chemicals (e.g., ethanol) to denervate tissue.

The advantages of neuroablative techniques over surgery are minimal invasiveness, low associated morbidity, and repeatability should the pain recur. However, these methods damage tissue in a relatively blind manner without absolute control and may not permanently resolve symptoms (Association of Extremity Nerve Surgeons, 2014).

Findings

We found no systematic reviews, meta-analyses, or economic analyses for this policy. We included three evidence-based guidelines or consensus statements (American College of Foot and Ankle Surgeons, 2009; Association of Extremity Nerve Surgeons, 2014; National Institute for Health and Care Excellence, 2015). The evidence base consists of mostly retrospective case series of short-term duration (six months or less) and few comparative studies by which to compare the effectiveness of neuroablative techniques to surgical procedures considered the current standard of care. We included four individual studies that provided comparative or longer-term outcome data to further inform this policy (Cozzarelli, 2010; Landsman, 2013; Perini, 2016; Wei, 2017).

The limitations in the evidence are those inherent to non-comparative, non-randomized, retrospective, and insufficiently powered studies. The literature provides low quality evidence of the safety and efficacy of radiofrequency ablation, cryoablation, and chemoablation (alcohol) for treating intermetatarsal nerve entrapment (also referred to as Morton's neuroma) (Perini, 2016), plantar fasciitis (Cozzarelli, 2010; Landsman, 2013), and Achilles tendinosis (Wei, 2017). These procedures appear safe and efficacious in the short-term with durable results in some instances, but the optimal patient selection criteria or ablative protocol cannot be determined.

Evidence-based recommendations are conflicting on the value neuroablation especially for patients with intermetatarsal nerve entrapment, as professional societies attempt to balance the lack of quality evidence with increasing interest in minimally invasive neuroablative approaches to treat chronic foot pain (American College of Foot and Ankle Surgeons, 2009; Association of Extremity Nerve Surgeons, 2014; National Institute for Health and Care Excellence, 2015). At this time, neuroablation cannot be recommended as a primary treatment option for any etiology of chronic foot pain.

In 2019, we added one systematic review (Santos, 2018) of sclerosing alcohol injections for intermetatarsal neuromas, the results of which are consistent with prior findings. No policy changes are necessary. The policy ID was changed from CP# 14.02.14 to CCP.1317.

In 2020, we added the results of three systematic reviews of treatments for Morton's neuroma (Lu, 2021; Matthews, 2019; Thomson, 2019) that expose the lack of high-quality evidence comparing the effectiveness of available treatment options, including neurolytic methods. The American Academy of Orthopaedic Surgeons' (2022) website discusses only nonsurgical options (changes in footwear or orthoses), corticosteroid injections, and surgery as treatment alternatives. The findings are consistent with previous findings, and no policy changes are warranted.

In 2021, we replaced one systematic review with its update (Thomson, 2020, update of 2019) of non-surgical treatment for Morton's neuroma, including neuroablative techniques. The results are consistent with previous findings, and no policy changes are warranted.

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In 2022, we added small reviews of persons with Morton's neuroma of the foot treated with ultrasound-guided radiofrequency ablation; large improvements in pain resolution were reported (Masala, 2018; Shah, 2019).

In 2023, we added a review of 261 patients (378 feet) that showed radiofrequency ablation for chronic persistent plantar fasciitis improved functioning (P < .001) between pre-procedure and final follow-up 8-24 months later (Kurtoglu, 2022). We also added a review that found ultrasound-guided alcohol injections for Morton's neuroma were cost-effective compared to placebo, as an alternative to surgical neurectomy (Ross, 2022).

References

On March 13, 2023, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were "Ablation technique" (MeSH), "Metatarsalgia" (MeSH), "Peripheral nerves" (MeSH), "neuroablation," "radiofrequency ablation," "cryoablation," "plantar," and "foot." We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

Agyekum EK, Ma K. Heel pain: A systematic review. *Chin J Traumatol.* 2015;18(3):164-169. Doi: 10.1016/j.cjtee.2015.03.002.

American Academy of Orthopaedic Surgeons. Ortholnfo. Diseases & Conditions. Morton's neuroma. https://orthoinfo.aaos.org/en/diseases--conditions/mortons-neuroma. Last reviewed July 2022.

American College of Foot and Ankle Surgeons. Clinical Practice Guideline Forefoot Disorders Panel, Thomas JL, Blitch EL, et al. Diagnosis and treatment of forefoot disorders. Section 3. Morton's intermetatarsal neuroma. *J Foot Ankle Surg.* 2009;48(2):251-256. Doi: 10.1053/j.jfas.2008.12.005.

American Orthopaedic Foot and Ankle Society. FootCareMD. Conditions and treatments. https://footcaremd.org/conditions-treatments#conditions. Published 2023.

Association of Extremity Nerve Surgeons. Clinical Practice Guidelines. Edition 1. https://www.aens.us/images/aens/AENS%20Guidelines%20-%20Final.pdf. Published November 2014.

Cozzarelli J, Sollitto RJ, Thapar J, Caponigro J. A 12-year long-term retrospective analysis of the use of radiofrequency nerve ablation for the treatment of neurogenic heel pain. *Foot Ankle Spec.* 2010;3(6):338-346. Doi: 10.1177/1938640010379048.

Kurtoglu A, Kochai A, Inanmaz ME, et al. Effectiveness of radiofrequency ablation for treatment of plantar fasciitis. *Medicine (Baltimore)*. 2022;101(12):e29142. Doi: 10.1097/MD.0000000000029142.

Landsman AS, Catanese DJ, Wiener SN, Richie DH, Jr., Hanft JR. A prospective, randomized, double-blinded study with crossover to determine the efficacy of radio-frequency nerve ablation for the treatment of heel pain. *J Am Podiatr Med Assoc.* 2013;103(1):8-15. Doi: 10.7547/10300008.

Lu VM, Puffer RC, Everson MC, et al. Treating Morton's neuroma by injection, neurolysis, or neurectomy: A systematic review and meta-analysis of pain and satisfaction outcomes. *Acta Neurochir (Wien)*. 2021;163(2):531-543. Doi: 10.1007/s00701-020-04241-9.

Masala S, Cuzzolino A, Morini M, Raguso M, Fiori R. Ultrasound-guided percutaneous radiofrequency for the treatment of Morton's neuroma. *Cardiovasc Intervent Radiol.* 2018;41(1):137-144. Doi: 10.1007/s00270-017-1786-y.

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Matthews BG, Hurn SE, Harding MP, Henry RA, Ware RS. The effectiveness of non-surgical interventions for common plantar digital compressive neuropathy (Morton's neuroma): A systematic review and meta-analysis. *J Foot Ankle Res.* 2019;12:12. Doi: 10.1186/s13047-019-0320-7.

National Institute for Health and Care Excellence. Radiofrequency ablation for symptomatic interdigital (Morton's) neuroma. Interventional procedures guidance [IPG539]. https://www.nice.org.uk/guidance/ipg539/chapter/1-Recommendations. Published December 16, 2015.

Perini L, Perini C, Tagliapietra M, et al. Percutaneous alcohol injection under sonographic guidance in Morton's neuroma: Follow-up in 220 treated lesions. *Radiol Med.* 2016;121(7):597-604. Doi: 10.1007/s11547-016-0622-9.

Ross AB, Jacobs A, Williams KL, Bour RK, Gyftopoulos S. Ultrasound-guided injection treatments versus surgical neurectomy for Morton Neuroma: A cost-effectiveness analysis. *AJR Am J Roentgenol*. 2022;218(2):234-240. Doi: 10.2214/AJR.21.26419.

Santos D, Morrison G, Coda A. Sclerosing alcohol injections for the management of intermetatarsal neuromas: A systematic review. *Foot (Edinb)*. 2018;35:36-47. Doi: 10.1016/j.foot.2017.12.003.

Shah R, Ahmad M, Hanu-Cernat D, Choudhary S. Ultrasound-guided radiofrequency ablation for treatment of Morton's neuroma: Initial experience. *Clin Radiol.* 2019;74(10):815.e9-815.e13. Doi: 10.1016/j.crad.2019.07.002.

Smith WB, Melton W, Davies J. Midsubstance tendinopathy, percutaneous techniques (platelet-rich plasma, extracorporeal shock wave therapy, prolotherapy, radiofrequency ablation). *Clin Podiatr Med Surg.* 2017;34(2):161-174. Doi: 10.1016/j.cpm.2016.10.005.

Thomson L, Aujla RS, Divall P, Bhatia M. Non-surgical treatments for Morton's neuroma: A systematic review. *Foot Ankle Surg.* 2020;26(7):736-743. Doi: 10.1016/j.fas.2019.09.009.

Wei M, Liu Y, Li Z, Wang Z. Comparison of clinical efficacy among endoscopy-assisted radio-frequency ablation, extracorporeal shockwaves, and eccentric exercises in treatment of insertional Achilles tendinosis. *J Am Podiatr Med Assoc.* 2017;107(1):11-16. Doi: 10.7547/14-146.

Policy updates

3/2018: initial review date and clinical policy effective date: 5/2018

5/2019: Policy references updated. Policy ID changed.

6/2020: Policy references updated.

6/2021: Policy references updated.

6/2022: Policy references updated.

6/2023: Policy references updated.

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