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MEDICAL POLICY – 7.01.147

Minimally Invasive Ablation Procedures for Morton and Other Peripheral Neuromas

BCBSA Ref. Policy:	7.01.147	
Effective Date:	Sept. 1, 2023	RELATED MEDICAL POLICIES:
Last Revised:	Aug. 7, 2023	None
Replaces:	N/A	

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Introduction

Peripheral nerves are the nerves that connect the brain and spinal cord to the body. When a peripheral nerve is injured, a neuroma can form at the area of injury. A neuroma is a thickening or growth composed of nerve tissue. Morton's neuroma is a thickening of nerve tissue usually between the third and fourth toes. It can cause sharp, burning pain in the ball of the foot, a stinging sensation, or a feeling of numbness. There are a number of options to treat neuromas. Newer techniques involve trying to destroy the neuroma by using extreme cold or heat. Both of these techniques are investigational when used to try to treat Morton's neuroma or other peripheral neuromas. More studies are needed to find out if these techniques are effective.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Procedure	Investigational
Ablation procedures to treat peripheral neuromas	**Minimally invasive ablation procedures, including intralesional alcohol injection, radiofrequency ablation and cryoablation, are considered investigational for the treatment of Morton and other peripheral neuromas.**

Coding

Code	Description
CPT	
64632	Destruction by neurolytic agent; plantar common digital nerve.
64640	Destruction by neurolytic agent; other peripheral nerve or branch.

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Related Information

N/A

Evidence Review

Description

Morton neuroma is a common and painful compression neuropathy of the dorsal foot that is also referred to as intermetatarsal neuroma, interdigital neuroma, interdigital neuritis, and Morton metatarsalgia. Morton neuroma has been treated with conservative measures (pads, orthotics, drugs) or surgery. Minimally invasive procedures, including intralesional alcohol injection, radiofrequency ablation (RFA) and cryoablation, have been investigated as alternatives to open surgery. These methods have also been used to treat other peripheral neuromas.

Background

Neuroma

A neuroma is a pathology of a peripheral nerve that develops as part of a normal reparative process. Neuromas may develop after nerve injury or result from chronic irritation, pressure, stretch, poor repair of nerve lesions or previous neuromas, laceration, crush injury, or blunt trauma.[1] Neuromas typically appear 6 to 10 weeks after trauma, with most presenting within 1 to 12 months after injury or surgery. They may gradually enlarge over 2 to 3 years and may or may not be painful. Pain from a neuroma may be secondary to traction on the nerve by scar tissue, compression of the sensitive nerve endings by adjacent soft tissues, ischemia of the nervous tissue, or ectopic foci of ion channels that elicit neuropathic pain. Individuals may describe the pain as low-intensity dull pain or intense paroxysmal burning pain, often triggered by external stimuli such as touch or temperature. Neuroma formation has been implicated as a contributor of neuropathic pain in residual limb pain, postthoracotomy, postmastectomy, and postherniorrhaphy pain syndromes. Neuromas may coexist with phantom pain or can predispose to it.

Morton Neuroma

Morton neuroma is a common and painful compression neuropathy of the common digital nerve of the foot that may also be referred to as interdigital neuroma, interdigital neuritis, and interdigital or Morton metatarsalgia.[1,2,3] It is histologically characterized by perineural fibrosis, endoneurial edema, axonal degeneration, and local vascular proliferation. Thus, some investigators do not consider Morton neuroma to be a true neuroma; instead, they consider it to be an entrapment neuropathy occurring secondary to compression of the common digital nerve under the overlying transverse metatarsal ligament. Morton neuroma appears 10-fold more often in women than in men, with an average age at presentation of around 50 years.[4]

The pain associated with Morton neuroma is usually throbbing, burning, or shooting, and localized to the plantar aspect of the foot. It is typically located between the 3rd and 4th metatarsal heads, although it may appear in other proximal locations.[1,2] The pain may radiate to the toes and can be associated with paresthesia. The pain can be severe, and the condition may become debilitating to the extent that individuals are apprehensive about walking or touching their foot to the ground. It is aggravated by walking in shoes with a narrow toe box or high

heels that cause excessive pronation and excessive forefoot pressure; removal of tight shoes typically relieves the pain.

Diagnosis

Although a host of imaging methods are used to diagnose Morton neuroma, including plain radiographs, magnetic resonance imaging, and ultrasonography, objective findings are unique to this condition and are primarily used to establish a clinical diagnosis.[1] Thus, an individual's toes often show splaying or divergence. Individuals may describe the feeling of a "lump" on the foot bottom or a feeling of walking on a rolled-up or wrinkled sock. Clinical examination with medial and lateral compression may reproduce the painful symptoms with a palpable "click" on interspace compression (Mulder sign).[5]

Treatment

Management of individuals diagnosed with Morton neuroma typically starts with conservative approaches, such as the use of metatarsal pads in shoes and orthotic devices that alter supination and pronation of the affected foot.[3] These approaches try to reduce pressure and irritation of the affected nerve. They may provide relief, but do not alter the underlying pathology. There is scant evidence to support the effectiveness or comparative effectiveness of these practices.[2,6,7] In a case series, Bennett et al (1995) evaluated a 3-stage protocol of "stepped care" through which private practice patients (N=115) advanced from stage I (education plus footwear modifications, and a metatarsal pad) to stage II (steroid injections with local anesthetic or local anesthetic alone), and into stage III (surgical resection) if stages I and II were not relieved within three months.[8] Overall, 97 (85%) of 115 patients believed that pain had been reduced with the treatment program. However, 24 (21%) patients eventually required surgical excision of the nerve, and 23 (96%) of them had satisfactory results.

Minimally Invasive Ablation Procedures

Several minimally invasive procedures to treat refractory Morton and other peripheral neuromas are aimed at in situ destruction of the pathology, including intralesional alcohol injection, RFA and cryoablation (also known as cryoneurolysis, cryolysis, and cryoanalgesia).[2]

Dehydrated ethanol has been shown to inhibit nerve function in vitro, has high affinity for nerve tissue, and causes direct damage to nerve cells via dehydration, cell necrosis, and precipitation

of protoplasm, leading to neuritis and a pattern of Wallerian degeneration.[2] Technically, ethanol is a sclerosant that causes chemical neurolysis of the nerve pathology but is considered an ablative procedure for this policy. The use of ultrasound guidance during this procedure has been shown to increase surgical accuracy, improve outcomes, and shorten procedure duration. RFA uses heat generated by an electrode that conducts electromagnetic energy into a tissue or lesion to denature proteins and destroy cells. RFA is used to ablate a wide range of tissues or lesions, including osteoid osteoma; cardiovascular system pathologies; cervical pain syndromes; liver, lung, and other cancers; and varicosities. [9,10,11,12,13,14,15,16,17,18,19,20] Cryoablation uses coolant to chill a cryoprobe to temperatures below -75°C, which when inserted into a lesion, freezes and kills the tissue. It has been used to treat Morton neuroma, other chronic nerve pain syndromes, and conditions for which RFA has been used.[21,22,23,24,25,26,27,28]

This policy primarily focuses on evidence for the use of intralesional alcohol injection, RFA and cryoablation on painful neuromas, with emphasis on Morton neuroma and the comparative effectiveness of these less invasive therapies with open surgical resection of the nerve pathology.

Summary of Evidence

For individuals who have Morton neuroma who receive intralesional alcohol injection(s), the evidence includes retrospective case series. Relevant outcomes are symptoms, functional outcomes, and treatment-related morbidity. The body of evidence is limited, consisting of case series reporting on the treatment response of individuals with refractory Morton neuroma. The available case series have generally reported that some individuals experience pain relief and express satisfaction with the procedure. Some evidence has suggested that surgery after failed cases of alcohol injections is more complex and challenging than in untreated individuals due to the presence of fibrosis. There is a lack of controlled trials comparing alcohol injections with alternative therapies, and there are no controlled studies comparing outcomes for alcohol injections with those for surgery in surgical candidates. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have Morton neuroma who receive RFA, the evidence includes case series. Relevant outcomes are symptoms, functional outcomes, and treatment-related morbidity. Four case series identified reported outcomes for RFA to treat Morton neuroma. The body of evidence is highly heterogeneous regarding RFA protocols, descriptions of prior conservative management, patient characteristics, follow-up durations, outcome measures, and reporting of outcomes. Variable proportions of individuals require surgery after RFA, making the benefit of

RFA for avoiding more invasive treatment uncertain. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have Morton neuroma who receive cryoablation, the evidence includes case series. Relevant outcomes are symptoms, functional outcomes, and treatment-related morbidity. Only two retrospective case series on the use of cryoablation to treat peripheral nerve pain were identified in a literature review. The case series were heterogeneous regarding cryoablation protocols and length of follow-up. Outcome measures did not provide information on functional end points. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have peripheral neuroma(s) other than Morton neuroma who receive ablation, no published literature was identified. Relevant outcomes are symptoms, functional outcomes, and treatment-related morbidity. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

A currently ongoing and unpublished trials that might influence this review is listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05501262	Comparative Effectiveness of Cryoablation Using the ICE-Seed Cryoablation Needle With Steroid and Lidocaine Versus Steroid and Lidocaine Alone for Treatment of Morton's Neuroma	32	Dec 2023
Unpublished			
NCT02838758	A 3-Arm Randomized Controlled Study Comparing Ultrasound-Guided Cryoablation, Ultrasound-Guided Perineural Lidocaine, and Ultrasound-Guided Perineural Saline to Treat Intrametatarsal Neuroma	66 (actual enrollment: 10)	Jun 2018*

NCT: national clinical trial. *As of May 2021, no results posted.

Clinical Input From Physician Specialty Societies and Academic Medical Centers

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2015 Input

In response to requests, input was received from two specialty societies and five academic medical centers while this policy was under review in 2015. Input was consistent that the use of alcohol injections to treat Morton neuroma is investigational.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a U.S. professional society, an international society with U.S. representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

Association of Extremity Nerve Surgeons

The Association of Extremity Nerve Surgeons issued practice guidelines (2020)[42] which drew the following conclusions:

- We do not recommend ablation in the primary treatment of Intermetatarsal Nerve Entrapment (Morton's Neuroma).
    - Alcohol injections: The literature regarding alcohol injections is equivocal. There may be some short-term positive effect, but long-term effect is poor for this therapy. Some of

the literature recommends using 30% alcohol solution to get effective results. However, new research has shown the use of 30% alcohol does not create any measurable change in the histology of nerve tissue. There is also a moderate risk of necrosis of surrounding tissues. As a general rule, we do not advocate the use of alcohol injections.

- Radiofrequency ablation: Radiofrequency ablation has use in the lower extremity, but must be done with caution as this procedure has the potential for thermal necrosis of the adjacent tissues. Judicious use of fluoroscopy and other visualization techniques is advised while utilizing radiofrequency ablation...further research in this technique is needed.
- Cryoablation: Cryoablation (cryotherapy) should be used with extreme caution, as the amount of literature in the lower extremity is limited. If cryotherapy is used, it should ideally be performed with an open technique rather than percutaneously for optimal results.

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

Alcohol injection for Morton neuroma is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration (FDA).

Although RFA probes and generators and cryoablation equipment have been cleared for marketing by the FDA through the 510(k) process, none appear to be specifically indicated for the treatment of Morton neuroma or any other specific peripheral neuroma.

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History

Date	Comments
08/01/18	New policy, approved July 10, 2018, effective November 2, 2018. Policy created with literature review through April 2018. Minimally invasive ablation procedures (eg, radiofrequency ablation and cryoablation) are considered investigational for the treatment of peripheral neuromas.
09/01/19	Annual Review, approved August 22, 2019. Policy updated with literature review through April 2019; no references added; Policy statement unchanged.
09/01/20	Annual Review, approved August 4, 2020. Policy updated with literature review through April, 2020; no references added; Policy statement unchanged.
09/01/21	Annual Review, approved August 3, 2021. Policy updated with literature review through May 12, 2021; one reference added and 2020 guideline added; Policy statement unchanged.
09/01/22	Annual Review, approved August 8, 2022. Policy merged with 2.01.97 and updated with literature review through April 26, 2022; no references added. Intralesional alcohol ablation added to investigational policy statement. Policy title changed from "Ablation Procedures for Peripheral Neuromas" to "Minimally Invasive Ablation Procedures for Morton and Other Peripheral Neuromas."
09/01/23	Annual Review, approved August 7, 2023. Policy updated with literature review through May 8, 2023; no references added. Policy statement unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.

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PAKDAAR: Nu saritaem ti Ilocano, ti serbisyo para ti baddang ti lengguahe nga awanan bayadna, ket sidadaan para kenyam. Awagan ti 800-607-0546 (TTY: 711).

УВАГА! Якщо ви розмовляєте українською мовою, ви можете звернутися до безкоштовної служби мовної підтримки. Телефонуйте за номером 800-607-0546 (телетайп: 711).

ប្រយ័ត្ន៖ បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតឈ្នួល គឺអាចមានសំរាប់បំរើអ្នក។ ចូរ ទូរស័ព្ទ 800-607-0546 (TTY: 711)។

ማስታወሻ: የሚናገሩት ቋንቋ ኣማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያግዝዎት ተዘጋጀተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 800-607-0546 (መስማት ለተሳናቸው፡ 711).

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 800-607-0546 (TTY: 711).

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 800-607-0546 (رقم هاتف الصم والبكم: 711).

ਧਿਆਨ ਦਿਓ: ਜੇ ਤੁਸੀਂ ਪੰਜਾਬੀ ਬੋਲਦੇ ਹੋ, ਤਾਂ ਭਾਸ਼ਾ ਵਿੱਚ ਸਹਾਇਤਾ ਸੇਵਾ ਤੁਹਾਡੇ ਲਈ ਮੁਫਤ ਉਪਲਬਧ ਹੈ। 800-607-0546 (TTY: 711) 'ਤੇ ਕਾਲ ਕਰੋ।

เรียน: ถ้าคุณพูดภาษาไทยคุณสามารถใช้บริการช่วยเหลือทางภาษาได้ฟรี โทร 800-607-0546 (TTY: 711).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 800-607-0546 (TTY: 711).

UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 800-607-0546 (TTY: 711).

ATANSYON: Si w pale Kreyòl Ayisyen, gen sèvis èd pou lang ki disponib gratis pou ou. Rele 800-607-0546 (TTY: 711).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 800-607-0546 (ATS : 711).

ATENÇÃO: Se fala português, encontram-se disponíveis serviços linguísticos, grátis. Ligue para 800-607-0546 (TTY: 711).

ATTENZIONE: In caso la lingua parlata sia l'italiano, sono disponibili servizi di assistenza linguistica gratuiti. Chiamare il numero 800-607-0546 (TTY: 711).

توجه: اگر به زبان فارسی گفتگو می کنید، تسهیلات زبانی بصورت رایگان برای شما فراهم می باشد. با 800-607-0546 (TTY: 711) تماس بگیرید.