

MEDICAL POLICY

POLICY TITLE	MINIMALLY INVASIVE ABLATION PROCEDURES FOR MORTON AND OTHER PERIPHERAL NEUROMAS
POLICY NUMBER	MP 2.084

CLINICAL BENEFIT	<input type="checkbox"/> MINIMIZE SAFETY RISK OR CONCERN. <input checked="" type="checkbox"/> MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. <input type="checkbox"/> ASSURE APPROPRIATE LEVEL OF CARE. <input type="checkbox"/> ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. <input type="checkbox"/> ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. <input type="checkbox"/> ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	1/1/2025

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I. POLICY

Minimally invasive ablation procedures, including intralesional alcohol injection, radiofrequency ablation (RFA), and cryoablation are considered **investigational** for treatment of Morton and other peripheral neuromas. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-references:

MP- 2.034 Extracorporeal Shock Wave Treatment for Plantar Fasciitis and Other Musculoskeletal Conditions
MP- 2.376 Ablation of Peripheral Nerves to Treat Pain
MP- 5.049 Facet Joint Denervation

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross please see additional information below, and subject to benefit variations as discussed in Section VI below.

FEP PPO:

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at:
<https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies> .

III. DESCRIPTION/BACKGROUND

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Neuroma

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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. 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. Patients 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, post-thoracotomy, postmastectomy, and post-herniorrhaphy 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. 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.

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. 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 patients 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 diagnosis 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, a patient's toes often show splaying or divergence. Patients 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).

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Treatment

Management of patients 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. 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. In one case series (1995), investigators 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 3 months. 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, radiofrequency ablation (RFA) and cryoablation (also known as cryoneurolysis, cryolysis, and cryoanalgesia).

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. Technically, ethanol is a sclerosant that causes chemical neurolysis of the nerve pathology but is considered an ablative procedure for this evidence review. 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. 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.

This review 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..

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).

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

IV. RATIONALE

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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 patients with refractory Morton neuroma. The available series have generally reported that some patients 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 patients 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 radiofrequency ablation (RFA), the evidence includes case series. Relevant outcomes are symptoms, functional outcomes, and treatment-related morbidity. Three case series identified reported outcomes for RFA to treat Morton neuroma. The body of evidence is highly heterogeneous regarding RFA protocols, prior conservative management, patient characteristics, follow-up durations, outcome measures, and reporting of outcomes. Variable proportions of patients require surgery after RFA, making the benefit of RFA for avoiding more invasive treatment uncertain. The evidence is insufficient to determine the effects of the technology on 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 our 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 the effects of the technology on health outcome.

For individuals who have peripheral neuroma(s) other than Morton neuroma who receive ablation, the evidence is very limited: no published literature was identified. Relevant outcomes are symptoms, functional outcomes, and treatment-related morbidity. The evidence is insufficient to determine the effects of the technology on health outcome.

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V. DEFINITIONS

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NEUROMA is the formal term for any type of tumor comprised of nerve cells. Classification is made with respect to the specific portion of the nerve involved. For example, ganglionated neuroma is a neuroma composed of true nerve cells.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross' medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Minimally invasive ablation procedures, radiofrequency ablation (RFA), and cryoablation, are considered investigational for treatment of peripheral neuromas; therefore, not covered:

Procedure Codes							
64624	64632	64640	0440T	0441T	0442T		

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MP 2.084	06/18/2021 Consensus Review. No change to policy statement. References updated. Coding reviewed.
	10/18/2022 Minor Review. Updated title and policy statement to include Morton neuroma. Policy statement update to also include alcohol injections. Coding Reviewed. References updated.
	08/11/2023 Consensus Review. Updated references. Added procedure code 0440T.
	01/19/2024 Administrative Update. Clinical benefit added.
	08/05/2024 Consensus Review. Updated background and references. Added 0442T to coding table.

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