

## Corporate Medical Policy

### Ablation Procedures for Peripheral Neuromas and Peripheral Nerves

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#### Description of Procedure or Service

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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 injury to a nerve or as a result of chronic irritation, pressure, stretch, poor repair of nerve lesions or previous neuromas, laceration, crush injury, or blunt trauma. Neuromas typically appear about 6 to 10 weeks after trauma with most presenting within 1 to 12 months after injury or surgery. They may gradually enlarge over a period of 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 a 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. They may coexist with phantom pain or can predispose to it.

#### Morton Neuroma

Morton intermetatarsal neuroma is a common and painful compression neuropathy of the common digital nerve of the foot that may be referred to by other names, including 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 that occurs secondary to compression of the common digital nerve under the overlying transverse metatarsal ligament. The incidence and prevalence of Morton neuroma are not clear, but it 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 a throbbing, burning, or shooting pain that is 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.

Although a host of imaging methods may be used to aid diagnosis of 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. Thus, a patient's toes often show splaying or divergence. Patients may describe the feeling of a "lump" on the foot

# Ablation Procedures for Peripheral Neuromas and Peripheral Nerves

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).

## **Treatment of Morton Neuroma**

Management of patients with a diagnosis of Morton neuroma typically proceeds through a pathway that 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 are aimed at reducing pressure and irritation of the affected nerve. They may provide some relief, but do not alter the underlying pathology. There is scant evidence to support the effectiveness or comparative effectiveness of these practices.

Historically, surgical intervention is considered the definitive therapy. The most common procedure is open excision of the interdigital nerve pathology through a dorsal or plantar approach. A second procedure, referred to as nerve decompression with neurolysis or translocation of the affected part of the interdigital nerve has been used to treat Morton neuroma.

A third approach that has been investigated to treat refractory Morton neuroma involves several minimally invasive procedures aimed at in situ destruction of the pathology: intralesional alcohol injections, radiofrequency ablation (RFA), and cryoablation (also known as cryoneurolysis, cryolysis, or 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 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 has been used to ablate a wide range of disparate tissues or lesions that include osteoid osteoma, cardiovascular system pathologies, cervical pain syndromes, liver, lung and other cancers, and varicosities. Cryoablation uses a coolant to chill a cryoprobe to temperatures below -75 degrees Celsius, which when inserted into a lesion freezes and kills the tissue that is treated. It has been used to treat Morton neuroma and other chronic nerve pain syndromes as well as many other conditions in which RFA has been used.

## **Plantar Fasciitis**

Plantar fasciitis is a common cause of foot pain in adults, characterized by deep pain in the plantar aspect of the heel, particularly on arising from bed. While the pain may subside with activity, in some patients the pain may persist, impairing activities of daily living. On physical examination, firm pressure will elicit a tender spot over the medial tubercle of the calcaneus. The exact etiology of plantar fasciitis is unclear, although repetitive injury is suspected. Heel spurs are a common associated finding, although it has never been proven that heel spurs cause the pain. Asymptomatic heel spurs can be found in up to 10% of the population. Most cases of plantar fasciitis are treated with conservative therapy, including rest or minimization of running and jumping, heel cups, and nonsteroidal anti-inflammatory drugs. Local steroid injection may also be used. Improvement may take up to 1 year in some cases.

## **Knee Osteoarthritis**

Knee osteoarthritis (OA) is common, costly, and often the cause of substantial disability. Among U.S. adults, the most common causes of disability are arthritis and rheumatic disorders. Treatment for OA of the knee aims to alleviate pain and improve function. However, most treatments do not modify the natural history or progression of OA and are not considered curative. Nonsurgical modalities used include exercise; weight loss; various supportive devices;

# Ablation Procedures for Peripheral Neuromas and Peripheral Nerves

acetaminophen or non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen; nutritional supplements (glucosamine, chondroitin); and intra-articular viscosupplements. Corticosteroid injection may be considered when relief from NSAIDs is insufficient or the patient is at risk from gastrointestinal adverse effects. If symptom relief is inadequate with conservative measures, invasive treatments may be considered. Operative treatments for symptomatic OA of the knee include arthroscopic lavage and cartilage débridement, osteotomy, and, ultimately, total joint arthroplasty. Surgical procedures intended to repair or restore articular cartilage in the knee (eg, abrasion arthroplasty, microfracture techniques, autologous chondrocyte implantation) are appropriate only for younger patients with focal cartilage defects secondary to injury and are not addressed in this policy.

## **Nerve Radiofrequency Ablation**

Nerve radiofrequency ablation (RFA) is a minimally invasive method that involves use of heat and coagulation necrosis to destroy tissue. A needle electrode is inserted through the skin and then into the tissue to be ablated. A high-frequency electrical current is applied to the target tissue. A small sphere of tissue is coagulated around the needle by the heat generated. It is theorized that the thermal lesioning of the nerve destroys peripheral sensory nerve endings, resulting in the alleviation of pain. Cooled radiofrequency (RF) treatment is a variation of nerve RFA using a special device that applies more energy at the desired location without excessive heat diffusing beyond the area, causing less tissue injury away from the nerve. The goal of ablating the nerve is the same.

For the indications assessed in this policy, nerve RFA should be distinguished from RF energy applied to areas other than the nerve to cause tissue damage. Some patients have been treated for plantar fasciitis with a fasciotomy procedure using a RF device. This procedure does not ablate a specific nerve.

Nerve RFA is also distinguished from pulsed RF treatment, which has been investigated as a treatment for different types of pain. The mechanism of action of pulsed RF treatment is uncertain, but it is thought not to destroy the nerve. If it does produce some degree of nerve destruction, it is thought to cause less damage than standard RFA. Some studies refer to pulsed RF treatment as ablation.

## **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.

Although RFA probes and generators and cryoablation equipment have received FDA 510(k) marketing clearance, none appear to be specifically indicated for treatment for Morton neuroma or any other specific peripheral neuroma.

**\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

## **Policy**

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**Minimally invasive ablation procedures, including radiofrequency ablation, cryoablation and alcohol injections are considered investigational for treatment of peripheral neuromas. BCBSNC does not provide coverage for investigational services or procedures.**

**Radiofrequency ablation of peripheral nerves to treat pain associated with plantar fasciitis or knee osteoarthritis is considered investigational. BCBSNC does not provide coverage for investigational services or procedures.**

# Ablation Procedures for Peripheral Neuromas and Peripheral Nerves

## Benefits Application

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This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

## When ablation procedures for peripheral neuromas and peripheral nerves are covered

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Not applicable.

## When ablation procedures for peripheral neuromas and peripheral nerves are not covered

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Minimally invasive ablation procedures, including RFA, cryoablation and alcohol injections, are considered investigational for treatment of peripheral neuromas.

Radiofrequency ablation of peripheral nerves to treat pain associated with plantar fasciitis or knee osteoarthritis is considered investigational.

## Policy Guidelines

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The overall body of evidence evaluating the efficacy of minimally invasive ablation techniques is weak, consisting of case series reporting on outcomes following ablative treatment. There are no controlled studies to compare outcomes with those of surgery in patients who all are surgical candidates.

For individuals who have Morton neuroma who receive intralesional alcohol injection(s), the evidence includes retrospective case series. Relevant outcomes are symptoms, resource utilization, and treatment-related morbidity. The body of evidence is limited, consisting of case series reporting on 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. However, relief is not universally achieved. Some evidence has suggested that surgery after alcohol injections in failed cases 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 to alternative therapies and there are no controlled studies comparing outcomes for alcohol injections to those for surgery in patients who all are surgical candidates. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have Morton neuroma who receive RFA, the evidence includes case series. Relevant outcomes are symptoms, functional outcomes, and treatment-related morbidity. Three case series have reported outcomes of RFA to treat Morton neuroma. The body of evidence is highly heterogeneous in terms of RFA protocols, prior conservative management, patient characteristics, follow-up durations, outcome measures, and reporting of outcomes. The available evidence is also limited by variable proportions of patients requiring surgery after RFA. The evidence is insufficient to determine the effects of the technology on health outcomes.

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 the literature review. The case series were heterogeneous regarding cryoablation protocols and length of follow-up. Outcome measures did not provide information on functional

# Ablation Procedures for Peripheral Neuromas and Peripheral Nerves

end points. The evidence is insufficient to determine the effects of the technology on health outcomes.

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 outcomes.

For individuals who have plantar fasciitis who receive radiofrequency ablation of the peripheral nerves, the evidence includes case series studies and a randomized controlled trial (RCT). Relevant outcomes include symptoms and functional outcomes. The case series generally have small sample sizes, and many have methodologic deficiencies such as retrospective assessment of pain. The single RCT evaluated only 17 patients, and randomized outcomes were only assessed out to 4 weeks post-treatment. Although the studies report that radiofrequency ablation reduced heel pain, the quality of the evidence was poor. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have knee osteoarthritis who receive radiofrequency ablation of the peripheral nerves, the evidence includes case series studies and one RCT. Relevant outcomes include symptoms and functional outcomes. The method of radiofrequency treatment varied between studies. Some case series showed improvement in symptoms with treatment. The single randomized trial had a small sample size of 38 and assessed outcomes out to 12 weeks. Although this trial showed improvement in pain at 12 weeks, these results are insufficient to draw conclusions about treatment efficacy. The evidence is insufficient to determine the effects of the technology on health outcomes.

## **Billing/Coding/Physician Documentation Information**

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcsnc.com](http://www.bcsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable codes: 64632, 64640*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

## **Scientific Background and Reference Sources**

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BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.147, 12/11/14

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.97, 4/23/15

Specialty Matched Consultant Advisory Panel – 2/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.154, 1/14/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.147, 6/16/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.97, 6/16/2016

Specialty Matched Consultant Advisory Panel – 2/2017

# Ablation Procedures for Peripheral Neuromas and Peripheral Nerves

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.147, 6/8/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.97, 6/8/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.154, 9/14/2017

Specialty Matched Consultant Advisory Panel – 2/2018

## **Policy Implementation/Update Information**

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- 10/1/15 New policy issued. Ablation procedures of any type for treatment of all peripheral neuromas are considered investigational. Policy noticed 10/1/15 for policy effective date 12/30/15. (sk)
  
- 4/1/16 Specialty Matched Consultant Advisory Panel review 2/24/2016. (sk)
  
- 5/31/16 Reference added. Description section updated. Policy Guidelines updated. Radiofrequency ablation of peripheral nerves to treat pain associated with plantar fasciitis or knee osteoarthritis is considered investigational. Policy noticed 5/31/2016 for effective date 8/30/2016. (sk)
  
- 3/31/17 References added. Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 2/22/2017. (sk)
  
- 7/28/17 References added. Policy Guidelines updated. (sk)
  
- 1/12/18 Reference added. (sk)
  
- 4/27/18 Specialty Matched Consultant Advisory Panel review 2/28/2018. (sk)

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.