Ablation Procedures for Peripheral Neuromas and Peripheral Nerves

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.
Ablation Procedures for Peripheral Neuromas and Peripheral Nerves

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 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 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

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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; 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.

**Occipital Neuralgia**

Occipital neuralgia is a specific type of headache that is located on one side of the upper neck, back of the head, and behind the ears, and sometimes extending to the scalp, forehead, and behind the eyes. The pain, which may be piercing, throbbing, or electric-shock-like, follows the course of the greater and lesser occipital nerves. Occipital neuralgia is believed to occur due to pressure or irritation to the occipital nerves, which may result from injury, entrapment by tight muscles, or inflammation. Treatment may include massage and rest, muscle relaxants, nerve blocks, and injection of steroids directly into the affected area.

**Cervicogenic Headache**

Cervicogenic headache is a headache that is secondary to a disorder of the cervical spine. The pain may be referred from facet joints, intervertebral discs, or soft tissue. The pain is constant rather than throbbing, and may be aggravated by movements of the neck or pressure to certain areas on the neck. The first 3 cervical spinal nerves can refer pain to the head. The C1 suboccipital nerve innervates the atlanto-occipital joint; the C2 spinal nerve and the C3 dorsal ramus have close proximity to and innervate the C2-C3 facet joint. The C2-3 facet joint is the most frequent source of a cervicogenic headache. A diagnosis of a cervicogenic headache may be confirmed by an anesthetic block of the lateral atlanto-axial joint, the C2-3 facet joint, or the C3-4 facet joint. Treatment may include nerve blocks, physical therapy, and exercise.

**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...
Ablation Procedures for Peripheral Neuromas and Peripheral Nerves

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.

Cryoneurolysis

Cryoneurolysis is being investigated to alleviate pain in knee osteoarthritis and to manage pain following total knee arthroplasty. Temperatures of -20° to -100°C applied to a nerve cause Wallerian (anterograde axonal) degeneration, with disruption of nerve structure and conduction but maintenance of the perineural and epineural elements of the nerve bundle. Wallerian degeneration allows complete regeneration and recovery of nerve function in about 3 to 5 months. The iovera® cryoablation system is a portable handheld device that applies percutaneous and targeted delivery of cold to superficial peripheral nerves.

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.

In 2005, the SInergy® (Kimberly-Clark/Baylis), a water-cooled single-use probe, was cleared by FDA, listing the Baylis Pain Management Probe as a predicate device. The intended use is with an RF generator to create RF lesions in nervous tissue.

In 2011, NeuroTherm® NT 2000 (NeuroTherm) was cleared for marketing by FDA through the 510(k) process. FDA determined that this device was substantially equivalent to existing devices for use in lesioning neural tissue. Existing predicate devices included the NeuroTherm NT 1000, Stryker Multi-Gen, and Cosman G4 RF Generator.

In 2013, the Cryo-Touch IV (iovera®; Myoscience) was cleared for marketing by FDA through the 510(k) process. Predicate devices were the Cryo-Touch II and Cryo-Touch III.

In 2017, the COOLIEF Cooled Radiofrequency Probe (Avanos, previously known as Halyard Health) was cleared for marketing by the FDA through the 510(k) process to be used in conjunction with a radiofrequency generator to create lesions in nervous tissue (K163461). "The device is also indicated for creating radiofrequency lesions of the genicular nerves for the management of moderate to severe knee pain of more than 6 months with conservative therapy, including medication, in patients with radiologicallyConfirmed osteoarthritis (grade 2-4) and a positive response (> 50% reduction in pain) to a diagnostic genicular nerve block."

***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.
Ablation Procedures for Peripheral Neuromas and Peripheral Nerves

Policy

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, knee osteoarthritis, occipital neuralgia, or cervicogenic headache is considered investigational. BCBSNC does not provide coverage for investigational services or procedures.

Cryoneurolysis of peripheral nerves to treat pain associated with knee osteoarthritis or total knee arthroplasty is considered investigational. BCBSNC does not provide coverage for investigational services or procedures.

Ablation of peripheral nerves to treat pain is considered investigational in all other conditions, with the exception of facet joint pain. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

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

Not applicable.

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

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, knee osteoarthritis, occipital neuralgia, or cervicogenic headache is considered investigational.

Cryoneurolysis of peripheral nerves to treat pain associated with knee osteoarthritis or total knee arthroplasty is considered investigational.

Ablation of peripheral nerves to treat pain is considered investigational in all other conditions, with the exception of facet joint pain.

Policy Guidelines

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.
Ablation Procedures for Peripheral Neuromas and Peripheral Nerves

For individuals who have Morton neuroma who receive intraläsional 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 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 cryoaablation, the evidence includes case series. Relevant outcomes are symptoms, functional outcomes, and treatment-related morbidity. Only two retrospective case series on the use of cryoaablation to treat peripheral nerve pain were identified in the literature review. The case series were heterogeneous regarding cryoaablation 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 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 two randomized controlled trials (RCT). Relevant outcomes include symptoms, functional outcomes, and quality of life. The case series generally have small sample sizes, and many have methodologic deficiencies such as retrospective assessment of pain. One RCT evaluated only 17 patients, and randomized outcomes were only assessed out to 4 weeks post-treatment. A second RCT evaluated 36 patients out to 12 weeks. To be more confident in the efficacy of this treatment, controlled trials with larger samples and longer follow-up would be necessary. 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 two randomized controlled trials (RCTs) with a total of 211 patients with 6-month follow-up and observational studies with 12 months of follow-up. Relevant outcomes include symptoms, functional outcomes, and quality of life. Knee OA is a common disorder in older adults. RFA of the genicular nerves has the potential to alleviate pain and improve function in this population, and might also delay or eliminate the need for TKA. The larger of the RCTs compared cooled RFA to active control of steroid injection and utilized genicular nerve blocks to select patients for the study. At one month after treatment, pain scores on an 11-point numeric rating scale differed by 0.9 points, a variance that was statistically significant but of marginal clinical significance. The subjective outcome measures may also have...
Ablation Procedures for Peripheral Neuromas and Peripheral Nerves

been influenced by the novelty of the treatment in this unblinded study. By three months after treatment, pain scores had increased in the steroid group, while pain scores in the RFA group remained low throughout the 6-month follow-up. The durability of this treatment approach to one year has been evaluated in a follow-up to the RCT, a retrospective study, and a small (n=25) independent prospective study. In both of the industry-sponsored publications, 65% of the patients treated with cooled RFA reported a greater than 50% reduction in pain scores at 12 months. In an independent and prospective observational study, about one-third continued to show a response at one year after RFA of the genicular nerves. The second RCT used stimulation to identify the genicular nerves, rather than genicular nerve blocks with an anesthetic. None of the studies were blinded, which may have biased the subjective outcome measures. It should be noted that the anatomy of the genicular nerves is variable, and the best method for their identification has not been determined. Study in a larger number of patients, preferably in blinded studies with active control and follow-up longer than 12 months, is needed to determine the benefits and potential harms of this treatment. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have knee osteoarthritis or total knee arthroplasty who receive cryoneurolysis of peripheral nerves, the evidence includes an RCT with 180 patients and a retrospective comparative study. Relevant outcomes include symptoms, functional outcomes, and quality of life. Cryoneurolysis in patients with knee osteoarthritis resulted in a greater decrease in Western Ontario McMaster Universities Osteoarthritis Index (WOMAC) pain score, WOMAC total score, and visual analog scale score at 30 days compared with sham-treated controls. However, subsequent measurements showed no significant benefit of cryoneurolysis on WOMAC score at 60 days or visual analog scale scores at 60 or 90 days. Perioperative cryoneurolysis was shown in a retrospective comparison to reduce the length of stay and opioid use in patients undergoing total knee arthroplasty. These results need to be confirmed in an RCT. Several technical issues including the optimal number of applications for each nerve, the duration of treatment, and the duration of thawing before moving the cannula have not been resolved. The most effective method for determining probe insertion location (eg, ultrasound-guided or based on anatomic landmarks) also need to be established. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have occipital neuralgia or cervicogenic headache who receive RFA of peripheral nerves, the evidence includes systematic reviews. Relevant outcomes are symptoms, functional outcomes, and quality of life. No RCTs of RFA for chronic occipital neuralgia have been identified. Three RCTs of RFA for a cervicogenic headache have been published, none of which were high quality. Pain is a subjective, patient-reported measure that is particularly susceptible to placebo effect. Randomized trials with sham or active-controls are needed to evaluate the efficacy of this treatment. The evidence is insufficient to determine the effects of the technology on health outcomes.

Billing/Coding/Physician Documentation Information

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.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 64454, 64624, 64632, 64640
Ablation Procedures for Peripheral Neuromas and Peripheral Nerves

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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Policy Implementation/Update Information

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<tr>
<td>10/1/15</td>
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<td>4/1/16</td>
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Ablation Procedures for Peripheral Neuromas and Peripheral Nerves

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)


7/28/17  References added. Policy Guidelines updated. (sk)

1/12/18  Reference added. (sk)


1/14/20  CPT codes 64454 and 64624 added to Billing/Coding section. (sk)


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.