



Louisiana

Ablation Procedures for Peripheral Neuromas

Policy # 00574

Original Effective Date: 10/18/2017

Current Effective Date: 10/17/2018

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers minimally invasive ablation procedures, radiofrequency ablation (RFA), and cryoablation for the treatment of peripheral neuromas to be **investigational**.*

Background/Overview

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. 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 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 also be referred to as interdigital neuroma, interdigital neuritis, and interdigital or Morton metatarsalgia. Morton neuroma is usually associated with a throbbing, burning, or shooting pain 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. 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.

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

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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

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 1 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.

Ablation Techniques

Several minimally invasive procedures to treat refractory Morton neuroma are aimed at in situ destruction of the pathology: RFA and cryoablation (also known as cryoneurolysis, cryolysis, cryoanalgesia). 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 a 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 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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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

Centers for Medicare and Medicaid Services (CMS)

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

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Rationale/Source

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Clinical Context and Therapy Purpose

The purpose of peripheral nerve ablation (ie, RFA or cryoablation) in patients who have peripheral neuromas is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Do minimally invasive ablation procedures improve health outcomes in patients with peripheral neuromas?

The following PICOTS were used to select literature to inform this review.

Patients

The relevant population of interest is patients with peripheral neuromas, with emphasis on Morton neuroma.

Interventions

The therapies being considered are RFA and cryoablation for painful neuromas.

Comparators

The following practice is currently being used to make decisions about the treatment of peripheral neuromas: open surgical resection of the nerve pathology.

Outcomes

The general outcomes of interest are pain, typically measured with a visual analog score (VAS), ability to walk, and adverse events related to ablation procedures.

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Louisiana

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Policy # 00574

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Timing

The timing ranges from hours for the immediate effect of treatment, to months to assess recurrence of treatment.

Setting

The setting may include pain clinics or other specialist care centers that have the equipment to perform RFA or cryoablation.

RADIOFREQUENCY ABLATION FOR MORTON NEUROMA

Three case series were identified reporting outcomes with RFA for treating Morton neuroma.

Genon et al (2010) reported on a retrospective review of a single center's experience with RFA to treat Morton neuroma according to a clinical algorithm that proceeds from nonoperative interventions to RFA and to open neurectomy if initial approaches failed. Thirty-seven patients who had failed conservative management (not described) and had symptoms for at least 12 months in duration were treated with RFA using a NeuroTherm NT1000 (NeuroTherm) radiofrequency generator. At an average follow-up of 11 months (range, 3-21 months), among the 37 patients (38 neuromas) treated, 7 (19%) reported complete relief of symptoms, 21 (58%) reported partial relief, and 10 (27%) reported no relief. Among those with no relief, 8 (22%) of patients had an open surgical revision, with 6 of 8 reporting complete relief, 3 reporting partial relief, and 1 was unchanged. No complications due to RFA were reported.

Moore et al (2012) reported on a second retrospective series of RFA management of Morton neuroma. This series included 29 patients (22 women; age range, 23-73 years) who had not responded to conservative management (primarily steroid and alcohol injections) over 1 to 2 months. Patients were treated with RFA (Smith & Nephew) under monitored anesthesia using an electrode inserted dorsally with fluoroscopic guidance. Among the 29 patients, 24 (83%) expressed complete relief of symptoms 1 month after RFA; none reported more pain. The remaining 5 (17%) had minimal to no relief. Of them, one had an open revision, and the others had no additional treatment or were lost to follow-up. One patient reported recurrence 9 months following RFA, and another had superficial cellulitis that responded to antibiotic therapy. All patients returned to normal shoe gear and activities within 2 days of RFA.

Chuter et al (2013) reported on a third retrospective series of RFA to treat Morton neuroma. This series included 25 patients (21 women) with a mean age of 55 years (range, 33-73 years) who had mean symptom duration of 3.8 years (range, 6 months to 15 years). All failed conservative management. Before RFA, patients had an average pain score of 6.0 (range, 3.0-9.0) on a 10-point VAS. Four weeks after RFA, the average VAS pain score was 1.7 (range, 0-8.0; $p < 0.001$), an average symptom improvement of 76%. The only complication reported involved a patient who experienced irritation of the posterior tibial nerve following the procedure. Three (10%) patients proceeded to open surgical excision within 6 months of RFA due to incomplete pain relief or recurrence.

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Section Summary: Radiofrequency Ablation for Morton Neuroma

Three case series have reported outcomes of RFA to treat Morton neuroma. The body of evidence is highly heterogeneous regarding RFA protocols used, prior conservative management, patient characteristics, follow-up durations, outcome measures, and the reporting of outcomes (eg, using denominators of “feet,” “neuromas,” or “patients,” which required conversion to “patients”). Although favorable outcomes were achieved in substantial proportions in each study, the outcome measures were unclear as to their clinical meaning, except the VAS used in the Chuter report. Furthermore, in all 3 series, a variable proportion of patients required further surgical excision, making the value of prior RFA uncertain.

CRYOABLATION FOR MORTON NEUROMA

Two retrospective case series on the use of cryoablation to treat peripheral nerve pain have been identified. One case series by Friedman et al (2012) reported on a series of patients who had undergone sonographically guided cryoneurolysis. Among a cohort of 20 patients, 5 had Morton neuroma (all women; mean age, 55 years). Cryotherapy was administered with a Frigitonics CE 2000 (Cooper Surgical) device using nitrous oxide coolant. A cryoprobe was inserted into the Morton neuroma, and the probe temperature was decreased to -75°C and left in place until a continuous series of ice balls was created (one or two 3-minute cycles of cooling). Patients were scheduled for follow-up at 4 to 6 weeks. However, actual follow-up varied due to patient discretion. Among the 5 Morton neuroma patients, 3 had “marked relief,” 1 had “moderate relief,” and 1 had no relief, at a mean follow-up of 14 weeks (range, 6 weeks to 14 months). Complications of cryoablation were not reported.

The second case series, by Cazzato et al (2016), retrospectively described 20 patients (24 lesions) with Morton neuroma who underwent magnetic resonance–guided cryoablation. All patients were previously treated with ultrasound-guided corticosteroid injections and had not reported relief. While positioned in the magnetic resonance unit, a cryoprobe (Ice-Seed; Galil Medical) was inserted into the center of the lesion. A single freezing cycle of 150 seconds was performed. Mean procedural time was 41 minutes (range, 35-60 minutes). Patients were followed with a telephone survey. The number of months between procedure and last follow-up ranged from 1 to 50 months. Results were reported by lesion, with data available for 18 of the 24 lesions treated. Patients with 14 (78%) of the 18 lesions were “completely satisfied,” 17% were “satisfied with minor reservations,” and 6% were “satisfied with major reservations.” Mean local pain score was 3.0 on a 0-to-10 VAS. Post-VAS scores were not available.

Section Summary: Cryoablation for Morton Neuroma

Two retrospective case series have investigated cryoablation to treat Morton neuroma. The body of evidence is heterogeneous regarding cryoablation protocols used, prior conservative management, and length of follow-up. Although large proportions of patients reported satisfaction with the procedure in both studies, daily functioning did not clearly improve after the procedure. The weaknesses in the body of evidence preclude conclusions on the efficacy of cryoablation for Morton neuroma.

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OTHER PAINFUL NEUROMAS

The literature review for this update did not identify any controlled studies on the use of ablative techniques to treat painful peripheral neuromas other than Morton neuroma. Two recent review articles reported little evidence for any other sites.

Section Summary: Other Painful Neuromas

The current literature base on the use of ablative techniques for peripheral neuromas other than Morton neuroma provides insufficient data on which to form conclusions about treatment efficacy.

SUMMARY OF EVIDENCE

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 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 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 2 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 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.

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Louisiana

Ablation Procedures for Peripheral Neuromas

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10/05/2017 Medical Policy Committee review

10/18/2017 Medical Policy Implementation Committee approval. New policy.

10/04/2018 Medical Policy Committee review

10/17/2018 Medical Policy Implementation Committee approval. No change to coverage.

Next Scheduled Review Date: 10/2019

Coding

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Code Type	Code
CPT	64632, 64640
HCPCS	No codes
ICD-10 Diagnosis	G57.60-G57.63

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- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
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