

## Medical Policy



### Title: Alcohol Injection Therapy for Morton's Neuroma

#### Professional

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Populations	Interventions	Comparators	Outcomes
Individuals: • With Morton's neuroma	Interventions of interest are: • Intralesional alcohol injection(s)	Comparators of interest are: • Conservative therapy (eg, rest, metatarsal supports) • Surgical excision	Relevant outcomes include: • Symptoms • Resource utilization • Treatment-related morbidity

### DESCRIPTION

Morton's neuroma is a common and painful compression neuropathy of the dorsal foot that may be referred to by other names, including intermetatarsal neuroma, interdigital neuroma, interdigital neuritis, and Morton's metatarsalgia. Historically, Morton's neuroma has been treated with conservative measures, surgery, or minimally invasive procedures.

Alcohol injection is a minimally invasive alternative to open surgery to treat Morton's neuroma. Alcohol causes chemical neurolysis through dehydration, necrosis and precipitation of the treated area, ultimately destroying the lesion after multiple injections.

### **OBJECTIVE**

The objective of this policy is to determine whether the use of alcohol injections improves the net health outcome in individuals with Morton's neuroma compared with surgery or other conservative therapy.

### **BACKGROUND**

#### **Neuroma**

A neuroma is a growth or tumor consisting of nerve tissue that develops as part of a normal reparative process following nerve injury. 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.<sup>1</sup> 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's Neuroma

Morton's 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's metatarsalgia.<sup>1-3</sup> It is histologically characterized by perineural fibrosis, endoneurial edema, axonal degeneration and local vascular proliferation. Thus, some investigators do not consider Morton's 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's 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.<sup>4</sup>

The pain associated with Morton's 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 close-by locations.<sup>1,2</sup> 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 and anxious 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 may be used to aid diagnosis of Morton's 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.<sup>1</sup> 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).<sup>5</sup>

### Treatment

Management of patients with a diagnosis of Morton's 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.<sup>3</sup> 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.<sup>2,6,7</sup> In 1 case series, 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), into stage III (surgical resection) if stages I and II did not bring relief within 3 months.<sup>8</sup> Overall, 97 of 115 patients (85%) believed that they had improved with the treatment program. However, twenty-four patients (21%) eventually required surgical excision of the nerve and 23 of those (96%) had satisfactory results.

*Ablation Techniques:* Alternative approaches to treat refractory Morton's neuroma involves several minimally invasive procedures aimed at in situ destruction of the pathology, including intralesional alcohol injections.<sup>2</sup> 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.

## **REGULATORY STATUS**

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

**POLICY****A. Clinical Indications for Percutaneous Alcohol (4-29% solution) Nerve Sclerosing (PANS) Injections**

PANS injections are considered **medically necessary** for treatment of Morton's neuroma when all of the following conservative therapies, performed within 6 months of the initiation of PANS, have been attempted and have been documented as having failed:

1. Change in shoe types that are reported to result in neuroma-like symptoms
2. Change or limitation in activities that are reported to result in neuroma-like symptoms
3. Use of metatarsal pads (placed proximal to the metatarsal heads) to reduce pressure on the nerve by "spreading the metatarsals"
4. Cortisone injections administered 2 (minimum) to 3 times in a 6 week period (unless documented to be otherwise contraindicated)

PANS injections are expected to be performed according to the following protocol:

1. Two injections (CPT 64455 administered at 5-10 day intervals)  
Note: If the patient is unable to tolerate a second injection, PANS treatment would be terminated.
2. If there is a clinically significant positive response - symptoms reduced - reported and documented after 2 injections, up to 5 additional (or less if the patient reports elimination of neuroma symptoms) injections at 5-10 day intervals may be administered if symptoms persist.
3. If, however, two consecutive PANS injections fail to achieve continued and clinically significant symptom improvement, subsequent PANS injections would be considered not medically necessary and not reimbursed. Documentation failing to report interval status improvements prior to the administration of the next injection will be considered to be evidence of a lack of symptom improvement.

**B. Clinical Indications for Percutaneous Alcohol (30-100% solution) Nerve Destruction (PAND) Injections**

PAND injections (CPT 64632) are considered **medically necessary** for treatment of Morton's neuroma when all of the following conservative therapies, performed within 6 months of the initiation of PAND, have been attempted and have been documented as having failed:

1. Change in shoe types that are reported to result in neuroma-like symptoms
2. Change or limitation in activities that are reported to result in neuroma-like symptoms
3. Use of metatarsal pads (placed proximal to the metatarsal heads) to reduce pressure on the nerve by "spreading the metatarsals"
4. Cortisone injections administered 2 (minimum) to 3 times in a 6 week period (unless documented to be otherwise contraindicated)

5. A minimum of 2 percutaneous alcohol nerve sclerosing injections with no significant clinical improvement documented. Initiation of PAND injections would not be appropriate if PANS injections are not tolerated

PAND injections are expected to be performed according to the following protocol:

1. Ultrasonic or fluoroscopic imaging guidance (hard copy clear images must be recorded and available, upon request, for review)  
NOTE: The imaging guidance needle placement is considered part of the injection global fee and not separately reimbursed.
2. If there is a clinically significant positive response - symptoms reduced - reported and documented after 2 injections, up to 3 additional (or less if the patient reports elimination of neuroma symptoms) injections at 14 day intervals may be administered.
3. If, however, two consecutive PAND injections fail to achieve continued and clinically significant symptom improvement, subsequent PAND injections would be considered not medically necessary and not reimbursed. Documentation failing to report interval status improvements prior to the administration of the next injection will be considered to be evidence of a lack of symptom improvement.

- C. PANS injections and PAND injections are considered **not medically necessary** when the above indications are not met.

### Policy Guidelines

1. The medical record must adequately describe the patient's clinical state (history, physical findings, laboratory and other tests), eg, identification of the problem including diagnosis, precipitating events, quantity and quality of pain, test results, response to previous conservative treatment, as well as any other pertinent evaluation and management elements of the history, examination, and medical decision making.
2. The medical record must contain documentation indicating the reason for the procedure, the concentration of the alcohol solution injected, and a description of the procedure performed – including whether imaging guidance was used.
3. When a specific neuroma is injected, it will be considered one injection service regardless of the number of injections administered at that specific anatomical location on a single date of service.
4. The medical necessity for injections of more than two sites at one session is considered uncommon. Performance and submitting claims for such injections are likely to result in a request for medical records that must clearly document the medical necessity of these additional injections.
5. Failure of percutaneous alcohol nerve sclerosing (PANS) injections to achieve long term elimination or clinically significant reduction in symptoms precludes the medical necessity for repeated or continued PANS injections.

6. Failure of percutaneous alcohol nerve destruction (PAND) injections to achieve long term elimination or clinically significant reduction in symptoms precludes the medical necessity for repeated or continued PAND injections.
7. Payment for all substances injected is included in the amount paid for the injection and not separately reimbursable.

## **RATIONALE**

This policy is based on a literature review of MEDLINE. The most recent update with literature review covered the period through April 9, 2018.

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 a 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.

## **Intralesional Alcohol Injections for Morton's Neuroma**

### **Clinical Context and Therapy Purpose**

The purpose of intralesional alcohol injection therapy for patients who have Morton's neuroma 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: Does use of alcohol injections improve health outcomes for patients with Morton's neuroma compared with conservative therapy or surgery?

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

### **Patients**

The relevant population of interest is individuals with Morton's neuroma.

### **Interventions**

The therapy being considered is an intralesional injection of alcohol.

Comparators

The following therapies are currently being used: conservative therapy (eg, rest, metatarsal supports) and surgical excision.

Outcomes

The general outcomes of interest are reduction in pain, improvement in function, and patient satisfaction.

Timing

Intralesional injection of alcohol causes neurolysis of the affected nerve tissue. Patients are followed within 1 to 2 weeks after an injection to determine pain reduction and patient satisfaction. Additional injections may occur in subsequent 1 to 2 months to achieve the level of desired pain reduction for the patient.

Setting

Morton's neuroma is treated by podiatrists and orthopedists in an outpatient setting.

Case Series

No randomized controlled trials or nonrandomized interventional trials were identified. Several published case series have used alcohol injections to treat Morton's neuroma. Summaries of these series appear in Table 1.

Treatment in all the case series consisted of injections of alcohol combined with an anesthetic (eg, lidocaine or bupivacaine). Injections were repeated at 2-week intervals, if symptoms persisted. On average, across studies, each patient received approximately 4 injections. Ultrasound guidance was used in all of the series described in Table 1. Outcomes were patient-reported and consisted of various measures of pain and satisfaction.

The largest series identified was reported by Pasquali et al (2015), who described a retrospective 2-center case series of 508 patients who received ultrasound-guided alcohol injection from 2001 to 2012 for Morton's neuroma.<sup>9</sup> Eligible patients presented with 2nd or 3rd web space symptoms and had failed 3 months of conservative treatment with insoles and nonsteroidal anti-inflammatory drugs. Patients were injected with a 50% alcohol plus mepivacaine solution, with a mean of 3 injections (range, 1-4 injections) per neuroma. Pain at the Morton's neuroma site was assessed on a visual analog scale (VAS) ranging from 0 to 10, by local adverse reactions at 1 week postprocedure (0=no reaction; 1=minimal swelling, pain, redness; 2=significant swelling, pain redness), and patient-reported satisfaction. Pain scores improved from a mean preinjection VAS score of 8.7 to a mean postinjection score of 3.6 at 1 year (change in VAS score,  $p<0.001$ ). At 1 year postinjection, 74.5% of patients were completely satisfied with the procedure. Fifty (9.3%) feet eventually required operative excision.

**Table 1.** Case Series of Intralesional Alcohol Injections for Morton's Neuroma

Study	N	Treatment	Mean FU, mo	Results	Surgical FU, n (%)
Perini et al (2016) <sup>10</sup>	220	Alcohol, lidocaine	19	<ul style="list-style-type: none"> <li>• Median NRS pain score improved from 9 to 3</li> <li>• 88.6% reported reductions in limitations of everyday activities</li> <li>• Reduction in neuropathic pain (100% to 45%)</li> <li>• No change in nociceptive pain (47% to 53%)</li> </ul>	14 (6)

Study	N	Treatment	Mean FU, mo	Results	Surgical FU, n (%)
Pasquali et al (2015) <sup>9</sup>	508	Alcohol, mepivacaine	12	<ul style="list-style-type: none"> <li>• Mean VAS pain score improved from 8.7 to 3.6</li> <li>• 74.5% completely satisfied</li> </ul>	50 (9)
Musson et al (2012) <sup>11</sup>	75	Alcohol, bupivacaine	14	<ul style="list-style-type: none"> <li>• Mean VAS pain score improved from 8.5 to 4.2</li> <li>• 32% complete symptom relief; 33% partial relief; 35% no relief</li> </ul>	17 (20)
Hughes et al (2007) <sup>12</sup>	101	Alcohol, bupivacaine	12	<ul style="list-style-type: none"> <li>• Mean VAS pain score improved from 8 to 0</li> <li>• 84% "essentially pain free"; 8% "mild/moderate pain"; 8% "no difference"</li> </ul>	3 (3)
Fanucci et al (2004) <sup>13</sup>	40	Alcohol, carbocaine	10	<ul style="list-style-type: none"> <li>• 21 completely satisfied; 9 satisfied with minor complications; 6 satisfied with major complications; 4 dissatisfied</li> </ul>	4 (10)

FU: follow-up; NRS: numeric rating scale; VAS: visual analog scale.

Morgan et al (2014)<sup>14</sup> reported on a systematic review that included the studies above published through February 2012 plus another by Dockery (1999)<sup>15</sup> and compared the need for subsequent surgery after alcohol injections for Morton's neuroma with or without ultrasound guidance. Reviewers concluded that use of ultrasound guidance for alcohol injections to treat Morton's neuroma could reduce the need for subsequent surgery better than unguided treatments.

### SUMMARY OF EVIDENCE

For individuals who have Morton's 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 the treatment response of patients with refractory Morton's 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 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.

### CLINICAL INPUT RECEIVED FROM PHYSICIAN SPECIALTY SOCIETIES AND ACADEMIC MEDICAL CENTERS

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.

In response to requests, input was received from 5 academic medical centers and 2 specialty societies while this policy was under review in 2015. Input was consistent that the use of alcohol injections to treat Morton's neuroma is investigational.

### PRACTICE GUIDELINES AND POSITION STATEMENTS

#### American College of Foot and Ankle Surgeons

The American College of Foot and Ankle Surgeons released a clinical practice guideline (now referred to as a clinical consensus statement) in 2009 on the diagnosis and treatment of forefoot disorders.<sup>3</sup> The consensus statement reports that 3 to 7 dilute alcohol injections of 4% alcohol

injected at 5 to 10 day intervals has been associated with an 89% success rate with 82% of patients achieving complete relief of symptoms. The statement's pathway for treatment of intermetatarsal space neuroma lists decompression, excision, and cryogenic neuroablation under surgical management options.

#### Association of Extremity Nerve Surgeons

The Association of Extremity Nerve Surgeons issued 2014 Clinical Practice Guidelines<sup>16</sup> in which they make the following conclusions regarding 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, there is not enough data to support the use of alcohol. As a general rule, we do not advocate the use of alcohol injections"

#### **U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS**

Not applicable.

#### **ONGOING AND UNPUBLISHED CLINICAL TRIALS**

A search of ClinicalTrials.gov in May 2018 did not identify any ongoing or unpublished trials that would likely influence this policy.

#### **CODING**

**The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.**

#### CPT/HCPCS

For Percutaneous Alcohol Nerve Sclerosing (PANS) injections:

64455 Injection(s), anesthetic agent and/or steroid, plantar common digital nerve(s) (eg, Morton's neuroma)

For Percutaneous Alcohol Nerve Destruction (PAND) injections (Morton's neuroma):

64632 Destruction by neurolytic agent; plantar common digital nerve

#### ICD-10 Diagnoses

G57.61 Lesion of plantar nerve, right lower limb  
 G57.62 Lesion of plantar nerve, left lower limb  
 G57.63 Lesion of plantar nerve, bilateral lower limbs

#### **REVISIONS**

06-03-2011	Policy added to the bcbsks.com web site.
04-26-2013	Policy reviewed.
	In Coding section: <ul style="list-style-type: none"> <li>▪ Added ICD-10 diagnoses codes. <i>(Effective October 1, 2014)</i></li> </ul>

	Updated Reference section.
05-26-2015	In Coding section: <ul style="list-style-type: none"> <li>▪ Updated effective date of ICD-10 diagnosis codes to October 1, 2015.</li> </ul>
08-04-2016	Updated Description section.
	Updated Rationale section.
	Updated References section.
10-01-2016	In Coding section: <ul style="list-style-type: none"> <li>▪ Added ICD-10 code effective 10-01-2016: G57.63</li> </ul>
07-11-2017	Updated Description section.
	Updated Rationale section.
	Updated References section.
08-15-2018	Updated Description section.
	Updated Rationale section.
	In Coding section: <ul style="list-style-type: none"> <li>▪ Removed ICD-9 codes.</li> </ul>
	Updated References section.

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### Other References

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