MEDICAL POLICY

POLICY TITLE	ABLATION PROCEDURES FOR PERIPHERAL NEUROMAS
POLICY NUMBER	MP-2.084

Original Issue Date (Created):	**12/1/2011**
Most Recent Review Date (Revised):	**6/7/2018**
Effective Date:	**8/1/2018**

I. POLICY

Minimally invasive ablation procedures, radiofrequency ablation (RFA), and cryoablation, are considered **investigational** for treatment of peripheral neuromas. There is insufficient evidence to support a 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-2.018 Foot Care Services

II. PRODUCT VARIATIONS

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This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

FEP PPO - Refer to FEP Medical Policy Manual MP-7.01.147, Ablation Procedures for Peripheral Neuromas. 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 pathology of 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.[1] 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.[1-3] 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.[4]

Diagnosis of Morton Neuroma

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).[5]

Treatment of Morton Neuroma

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.[3] 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.[2,6,7] 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.[8] 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.

Surgical Techniques

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. Although this second approach uses smaller incisions and seems to have more rapid recovery than open excision, it is reported to be a more demanding surgical procedure that requires specialist training and equipment and is less common in practice.[2] No randomized controlled trials have been reported comparing the effectiveness of different management approaches for Morton neuroma.

A 2004 Cochrane systematic review found evidence insufficient to assess the effectiveness of surgical and nonsurgical interventions for Morton neuroma.[7] A 2013 literature review summarized the results of surgical excision studies that included 250 patients.[2] In general, these series were poorly reported and highly heterogeneous, used disparate outcome measures, had short follow-up periods (average, 2-10 years), and could not be directly compared. In the only prospective comparative study (1997) of surgical methods, the dorsal approach resulted in earlier weight bearing (mean, 16 days vs 23 days, respectively) and return to work (mean, 22 days vs 37 days, respectively) compared with a plantar approach in 52 cases at an average follow-up of 3 years.[9] Painful scars were more common with the plantar approach (n=5) than with the dorsal approach (n=2), with only 1 patient in each group experiencing symptom recurrence. Other case series of primary neurectomy have shown reductions in pain in 50% to 100% of patients, with self-reported satisfaction rates ranging from 52% to 86%, at mean follow-up of 24 to 126 months.[2] Common complications included paresthesia (range, 51%-82%), scar tenderness or hypersensitivity (range, 6%-32%), and wound infection (range, 1.4%-9.7%).

Long-term outcomes of surgical resection were reported in 2 additional series that involved a total of 159 cases refractory to conservative management. One 2010 series (N=78) reported a mean follow-up of 4.6 years (range, 0.8-8.1 years).[10] With a dorsal approach, 82% of patients with long-standing symptoms (mean duration, 33 months) reported excellent or good results, 10% had a fair result with restriction of activities or pain, while 8% had no improvement postsurgery. Complications included wound infections in 8 cases that resolved with antibiotics, 5 with persistent hypersensitive scars,

and 4 developing local keloid formations. Eight (10%) cases required revision due to neuroma recurrence at a mean of 2 years after index surgery. The second long-term series (N=81), published in 2013, reported a mean follow-up of 15.3 years (range, 10-20 years).[11] With a mostly dorsal approach (97% of cases), outcomes were reported as excellent in 45%, good in 32%, and fair in 15%; 8% reported poor results postsurgery and were referred for revision. Paresthesia in the supplying area of the resected nerve was reported in 72% of cases, while normal sensation was reported in 26%. Other surgical complications were not reported in this series.

Ablation Techniques

Several minimally invasive procedures to treat refractory Morton neuroma are aimed at in situ destruction of the pathology: radiofrequency ablation (RFA) and cryoablation (also known as cryoneurolysis, cryolysis, cryoanalgesia).[2] 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.[12-23] 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.[24-31]

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.

Regulatory Status

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 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 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 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 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.

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 contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's 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. Capital BlueCross 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:

CPT Codes ®							
64632	64640	0441T					

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IX. REFERENCES

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X. POLICY HISTORY

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MP-2.084	**CAC 7/26/11** New policy. No previous policy statements regarding this treatment. Standard FEP variation in place.
	7/24/13 Admin coding review complete
	CAC 9/24/13 Consensus. No change to policy statements. References reviewed and updated.
	CAC 9/30/14 Consensus review. References updated. Rationale added. No changes to the policy statements.
	CAC 9/29/15 Minor review. BCBSA adopted. Changed **"**Stereotactic radiofrequency thermal lesioning, or radiofrequency nerve ablation" to "Minimally invasive ablation procedures, radiofrequency ablation (RFA), and cryoablation". Changed "for treatment of foot conditions" to "treatment of peripheral neuromas". Changed title to Ablation Procedures for Peripheral Neuromas. Formerly Radiofrequency Thermal Lesioning for Treatment of Foot Conditions. Revised rationale and references. Coding reviewed.
	CAC 7/26/16 Consensus review. No change to policy statements. Background, rationale and references reviewed. Coding updated.
	10/24/16 Administrative Update Variation reformatting
	CAC 9/26/17 Consensus review. Policy statement unchanged. Medicare variation added d/t difference in denial reason. Description/Background, Rationale and Reference sections updated. Coding Reviewed.
	1/1/18 Admin Update: Medicare variations removed from Commercial Policies.
	6/7/18 Consensus. No change to policy statements. References reviewed. Condensed rationale.

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