



Louisiana

Radiofrequency Ablation of Peripheral Nerves to Treat Pain

Policy # 00503

Original Effective Date: 05/18/2016

Current Effective Date: 05/16/2018

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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 radiofrequency ablation (RFA) of peripheral nerves to treat pain associated with plantar fasciitis or knee osteoarthritis (OA) to be **investigational**.*

Background/Overview

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 persists and can impede 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 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 nonsteroidal anti-inflammatory drugs, such as ibuprofen; nutritional supplements (glucosamine, chondroitin); and intra-articular viscosupplements. Corticosteroid injection may be considered when relief from nonsteroidal anti-inflammatory drugs is insufficient, or the patient is at risk of 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 (e.g., 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 evidence review.

NERVE RADIOFREQUENCY ABLATION

Nerve RFA is a minimally invasive method that involves the 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-

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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 evidence review, 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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

A number of RF generators and probes have been cleared for marketing by the U.S. FDA through the 510(k) process. In 2005, the SIenergy^{®†} (Kimberly-Clark/Baylis, Irving, TX), 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 a RF generator to create RF lesions in nervous tissue. FDA product code: GXD.

In September 2011, NeuroTherm^{®†} NT 2000 (NeuroTherm, Wilmington, MA) 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.

Centers for Medicare and Medicaid Services (CMS)

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

Rationale/Source

This review includes indications for heel pain due to plantar fasciitis and knee pain due to OA. RFA of other peripheral nerves is not addressed herein.

Because of the variable natural history of plantar fasciitis and knee OA and the subjective nature of the outcome measures, randomized controlled trials (RCTs) are needed to determine whether outcomes are improved with interventions for pain. Trials should include a homogenous population of patients with a defined clinical condition, use standardized outcome measures when possible, and define a priori the clinically significant magnitude of response.

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The most clinically relevant outcome measures for pain treatments are measures of pain severity and functional limitations. Pain is a subjective, patient-reported measure. Therefore, pain outcomes require quantifiable pre- and posttreatment measures. Pain is most commonly measured with a visual analog scale (VAS). Quantifiable pre- and posttreatment measures of functional status are also used, such as 12-Item Short-Form Health Survey (SF-12) and SF-36.

PLANTAR FASCIITIS

Several case series and an RCT were identified that evaluated RFA for the treatment of chronic heel pain. In all studies, RF treatment used constant RF application with the intent to ablate the nerve endings. Some studies used a specific pretreatment test to select subjects in whom pretrial testing was hypothesized to predict trial treatment success. For example, Erken et al (2014) performed trial injections of local anesthetic at a specific location. Patients who responded were considered eligible for treatment. In a study by Cione et al (2009), a sensory conduction threshold test was performed. Patients with abnormal results were eligible for treatment. In some studies, the procedure required the patient to be conscious and respond to the sensation of electrical stimuli to locate the proper site for ablation. In other studies, the patient was under general anesthesia, and the ablation site was determined by other means.

Landsman et al (2013) reported the only randomized study of RFA. Seventeen patients were enrolled in a double-blind crossover trial, with crossover to the alternative treatment at 4 weeks. Patients must have failed at least 3 prior types of treatments, have had pain for more than 3 months, and rated pain at least 6 on a 0-to-10 VAS. The sham treatment consisted of all aspects of the actual RFA procedure, which included stimulation of sensory nerves in an awake patient, except for the delivery of RF energy at the final step. Outcomes assessed weekly were a pain VAS reported at the first step in the morning, average pain level, and peak pain level.

In a graphic presentation of results, patient pain levels for all 3 outcomes decreased after RFA but showed minimal change after sham. At 4 weeks, change in first-step pain was 5.00 in the RF group vs 1.33 in the sham group ($p=0.30$), change in average pain was 4.06 in the RF group vs 0.8 in the sham group ($p=0.047$), and change in peak pain was 5.33 in the RF group vs 1.80 in the sham group ($p=0.048$). After patients crossed over from sham to RFA, there was a steep drop in all pain outcomes. The maximum follow-up assessment was at 16 weeks and appears to show similar pain levels throughout the follow-up period.

The largest case series with the longest follow-up is by Cozzarelli et al (2010). This study reported on 12-year follow-up of 82 patients who had undergone RFA for heel pain. Patients had undergone RFA between 1994 and 1995 and had been interviewed at 5, 10, and 12 years postprocedure. Baseline pain levels before the procedure were recalled retrospectively at the time of the follow-up interviews. Of 99 patients potentially eligible to be interviewed, the study evaluated 82 patients. The results are presented without statistical testing. It appears that 73 of 82 patients reported being pain-free at 12 years. Of the pain-free patients, they rated their preprocedure pain at a mean of 7.1 on a 0-to-10 pain VAS.

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Cione et al (discussed above) reported on a retrospective case series of 75 patients treated with RFA. Patients who underwent RFA between 2000 and 2003 were surveyed in 2004 to assess preprocedure and current pain status. In this study, the actual number of treated patients is unknown, and preprocedure pain status was assessed only at the follow-up survey. Median preprocedure pain VAS was 9 (range, 2-10) and the postprocedure pain VAS was 1 (range, 0-8; $p < 0.001$).

Erken et al (discussed above) reported on 2-year follow-up of 36 feet in 29 patients who underwent RFA for heel pain. All patients had heel pain for at least 6 months and had failed at least 2 conservative treatments. Outcomes assessed included a pain VAS and the American Orthopedic Foot and Ankle Society Scale (AOFAS) scores assessed at baseline, 1 month, 1 year, and 2 years. Average VAS scores of patients were 9.2 before treatment, 1.2 at 1 month, 1.5 at 1 year, and 1.5 at 2 years. In addition, 85.7% of the patients rated their treatment as successful or very successful at 1- and 2-year follow-ups. The mean AOFAS scores (score range, 1-100) in 20 patients were 66.9 before treatment, 95.2 at 1 month, 93 at 1 year, and 93.3 at 2 years. Discomfort after the procedure in some patients resolved within 3 months.

Liden et al (2009) published a retrospective case series of 22 patients treated with RF nerve ablation. Patients had heel pain for at least 6 months and had failed at least 2 conservative treatments. The outcome measure used was a pain VAS. The mean pain VAS decreased from 8.12 to 3.26 1 week after treatment. At a mean follow-up duration of 8 months, pain VAS scores decreased to 1.5, 2.0, and 2.1 at 1 month, 3 months, and 6 months postprocedure. Adverse events noted were minor and transient in most cases. One adverse event was called persistent poststatic dyskinesia, which probably represents nonresponse to treatment.

Section Summary: Plantar Fasciitis

Case series and a randomized, double-blind trial have shown consistent sensory nerve improvement in pain after RFA for patients with heel pain due to plantar fasciitis. However, several case series have methodologic weaknesses. In two of the case series, all pain assessments were performed retrospectively, including pretreatment pain assessment. The single randomized trial enrolled few subjects and, due to crossover at 4 weeks, randomized comparisons only evaluate outcomes to 4 weeks. To be more confident in the efficacy of this treatment, studies with larger samples and longer follow-up would be necessary. The safety of the procedure cannot be fully evaluated in the small samples studied so far.

KNEE OSTEOARTHRITIS

Four studies of RFA for knee OA pain were identified. Two studies were case series, one was a nonrandomized study that compared outcomes against nerve block, and one was a randomized, double-blind trial.

In the only RCT, Choi et al (2011) investigated RFA of the genicular nerve compared with a sham procedure in 38 patients with chronic knee pain who had not responded to other treatments. Before randomization into the study, patients underwent diagnostic genicular nerve blocks with local anesthetic. If patients experienced a decrease in numeric pain scale scores of at least 50% for more than 24 hours, they underwent RFA or a sham procedure. Outcome measures included a pain VAS, Oxford Knee Score, and a

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global assessment. The Oxford Knee Score is scaled between 12 and 60, with 12 representing the best outcome. At 1, 4, and 12 weeks, pain scores in the RF group decreased from 78 to 40 (visual estimation). The control group decreased significantly at 1 week, but then returned to baseline at 4 and 12 weeks. Ten participants in the RF group achieved at least 50% reduction in knee pain at 12 weeks vs 0 in the control group. No participants reported any adverse events during the follow-up period.

Ikeuchi et al (2011) evaluated RFA compared with local nerve block in a nonrandomized study of patients with refractory anteromedial knee pain. Based on date of treatment, patients received either RFA of the sensory nerves to the medial knee or a nerve block using local anesthetic. Outcome measures included the Western Ontario McMaster Universities Osteoarthritis index (WOMAC) score, pain VAS, and patient global assessment. WOMAC scores were lower in the RF group (worse function) throughout the trial including the baseline period, and showed no benefit of treatment. Pain VAS showed a group by time interaction consistent with a treatment benefit of RFA, but there was no statistically significant difference in pain VAS score at 6 months. There was no significant difference in patients' global assessment ($p=0.126$). The only adverse effect mentioned was hypoesthesia, which occurred only in RF patients, and remitted within two-to-six weeks.

The 2 case studies identified were very small. In one, Bellini et al (2015) treated 9 patients with chronic knee pain using cooled RFA of the genicular nerve. Patients had previously not responded to physical therapy, analgesics, hyaluronic acid, or steroid injections. They were not candidates for invasive treatments due to comorbidities. Outcome measures included a pain VAS and WOMAC scores. VAS scores improved from a baseline mean of 8 to 2, 2.3, 2.1, and 2.2 at 1, 3, 6, and 12 months after treatment, respectively. WOMAC scores improved from a baseline mean of 88 to 20, 22, 21, and 20 at the same assessment intervals. All posttreatment means were statistically significant compared with baseline. No adverse events of treatment were mentioned.

Section Summary: Knee Osteoarthritis

The evidence of RFA for knee pain consists of 2 case series, a nonrandomized comparison, and an RCT. The treatments given differ slightly across studies and may not be comparable. One used cooled RFA, another study treated a single nerve, and the other treated only nerves associated with anteromedial knee pain. The most rigorous study evaluated 38 patients and observed outcomes over a 12-week follow-up period. To be more confident in the efficacy of this treatment, studies with large samples and longer follow-up would be necessary. The safety of the procedure cannot be fully evaluated in the small samples studied so far.

SUMMARY OF EVIDENCE

For individuals who have plantar fasciitis who receive RFA of the peripheral nerves, the evidence includes case series studies and a randomized controlled trial. 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 randomized controlled trial only evaluated 17 patients, and randomized outcomes were only assessed out to 4 weeks posttreatment. Although the studies reported

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that RFA 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 OA who receive RFA of the peripheral nerves, the evidence includes case series and a randomized controlled trial. Relevant outcomes include symptoms and functional outcomes. The method of RF treatment varied between studies. Some case series showed improvement in symptoms with treatment. The single randomized trial had a small sample size (N=38) and assessed outcomes out to 12 weeks. Although this trial showed reductions in pain at 12 weeks, these results do not support any conclusions about treatment efficacy. The evidence is insufficient to determine the effects of the technology on health outcomes.

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Policy History

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05/05/2016 Medical Policy Committee review

05/18/2016 Medical Policy Implementation Committee approval. New policy.

11/01/2016 Coding update

01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes

05/04/2017 Medical Policy Committee review

05/17/2017 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

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05/03/2018 Medical Policy Committee review
 05/16/2018 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
 Next Scheduled Review Date: 05/2019

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Code Type	Code
CPT	64450, 64640
HCPCS	No codes
ICD-10 Diagnosis	M17.0-M17.9, M72.2

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