Introduction

Radiofrequency ablation (RFA) is a procedure that has been proven to treat certain kinds of pain in specific areas of the body. A radio wave produces an electrical current, which then heats up and destroys a small area of nerves. The nerves are unable to send pain signals to the brain. RFA has been tried as a way to limit or stop pain in feet caused by plantar fasciitis and in the knees caused by wear-and-tear arthritis. The studies looking at RFA in these areas only studied a few dozen people. They also followed the patients for only a few weeks after treatment. There is not enough information from clinical studies to be certain that this works for foot and knee pain. For this reason, RFA is considered investigational (unproven) when used in these areas.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
Service | Investigational
---|---
Radiofrequency ablation of peripheral nerves | Radiofrequency ablation of peripheral nerves to treat nerve pain, including but not limited to pain associated with plantar fasciitis or knee osteoarthritis, is considered investigational.

### Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>64640</td>
<td>Destruction by neurolytic agent; other peripheral nerve or branch</td>
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<tr>
<td>64999</td>
<td>Unlisted procedure, nervous system</td>
</tr>
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</table>

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### Related Information

N/A

### Evidence Review

#### Description

Radiofrequency ablation of nerves has been proposed as a treatment for several different types of pain. It has been used to treat a number of clinical pain syndromes such as trigeminal neuralgia, cervical and lumbar pain, and headache syndromes.
Background

**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**

Knee osteoarthritis is common, costly, and a cause of substantial disability. Among U.S. adults, the most common causes of disability are arthritis and rheumatic disorders. Treatment for osteoarthritis of the knee aims to alleviate pain and improve function. However, most treatments do not modify the natural history or progression of osteoarthritis and are not considered curative. Nonsurgical modalities that are used include exercise; weight loss; various supportive devices; acetaminophen or nonsteroidal anti-inflammatory drugs (NSAIDs), 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 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 evidence review.
**Nerve Radiofrequency Ablation**

Nerve radiofrequency ablation (RFA) is a minimally invasive method that involves the use of heat and coagulation necrosis to destroy nerve tissue. A needle electrode is inserted through the skin and into the tissue around the nerve to be ablated. A high-frequency electrical current is applied to the target tissue which heats the nerve, causing coagulation necrosis and destruction of the nerve. 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.\(^1\) 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.

**Summary of Evidence**

For individuals who have plantar fasciitis who receive radiofrequency ablation 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 evaluated only 17 patients, and randomized outcomes could only be assessed out to 4 weeks posttreatment. Although the studies report that radiofrequency ablation reduces heel pain, the quality of the evidence is poor. 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 case series and a randomized controlled trial. Relevant outcomes include symptoms and functional outcomes. The method of radiofrequency 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 improvement 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.

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this review are listed in **Table 1**.

**Table 1. Summary of Key Trials**

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>NCT02294864</td>
<td>A Controlled Comparison of Pulsed Radiofrequency Vs Physical Therapy on Treating Chronic Knee Osteoarthritis</td>
<td>50</td>
<td>Apr 2017 (ongoing)</td>
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<tr>
<td>NCT02260869</td>
<td>Efficacy of Cooled and Monopolar Radiofrequency Ablation of the Geniculate Nerves for the Treatment of Chronic Osteoarthritic Knee Pain</td>
<td>102</td>
<td>July 2018</td>
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<tr>
<td><strong>Unpublished</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02242513</td>
<td>Ultrasound-guided Pulsed Radiofrequency for Plantar Fasciitis</td>
<td>36</td>
<td>July 2016 (completed)</td>
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<tr>
<td>NCT02343003a</td>
<td>Nerve Ablation by Cooled Radiofrequency Compared to Corticosteroid Injection for Management of Knee Pain</td>
<td>144</td>
<td>Mar 2017 (completed)</td>
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</table>

NCT: national clinical trial  
NR: not reported

**Practice Guidelines and Position Statements**

The American College of Foot and Ankle Surgeons issued a guideline on the treatment of heel pain in 2010. Bipolar radiofrequency is listed as a third tier option for patients who have failed other treatments. It was given a grade C recommendation, meaning that this treatment option is supported by either conflicting or level IV (expert opinion) evidence.
Medicare National Coverage

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

Regulatory Status

A number of radiofrequency (RF) generators and probes have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. In 2005, the SiEnergy® (Kimberly Clark/Baylis, Irving, TX), a water-cooled single-use probe, was cleared by the 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 the FDA through the 510(k) process. The 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.

References


**History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
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<tr>
<td>07/01/16</td>
<td>New Policy, approved June 14, 2016. Radiofrequency ablation of peripheral nerves to treat nerve is considered investigational.</td>
</tr>
<tr>
<td>11/01/17</td>
<td>Annual Review, approved October 19, 2017. Policy updated with literature review through July 20, 2017; no references added. Policy statement clarified; added “including but not limited to”.</td>
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</tbody>
</table>

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Illoko (Illocano):
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