MEDICAL POLICY – 7.01.565

Ablation of Peripheral Nerves to Treat Pain

BCBSA Ref. Policy: 7.01.154

Effective Date: Dec. 1, 2019
Last Revised: Jan. 1, 2020
Replaces: 7.01.154

RELATED MEDICAL POLICIES:
7.01.147 Ablation Procedures for Peripheral Neuromas
7.01.563 Ablative Treatments for Occipital Neuralgia, Chronic Headaches, and Atypical Facial Pain
7.01.564 Pulsed Radiofrequency

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

Peripheral nerves are the nerves that connect the brain and spinal cord to the body. Nerves transmit sensation, including pain. Newer techniques to try to treat pain arising from the peripheral nerves involve trying to destroy a small part of the nerve. The goal is to try to interrupt pain signals. All techniques to destroy parts of the peripheral nerve, including using devices that create heat or extreme cold and devices that combine heat and cooled water are investigational. That means they need more study to see if they are effective.

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.

Policy Coverage Criteria
### Service

<table>
<thead>
<tr>
<th>Ablative procedures of the peripheral nerves</th>
</tr>
</thead>
</table>

Ablative procedures of peripheral nerves to treat pain, including but not limited to pain associated with plantar fasciitis or knee osteoarthritis, are considered investigational. Ablative procedures include, but are not limited to the following:

- Cooled radiofrequency ablation (eg, COOLIEF)
- Cryoneuroloysis (cryoablation, cryotherapy, cryoanalgesia)
- Radiofrequency ablation (RFA)

### Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td></td>
</tr>
<tr>
<td>0441T</td>
<td>Ablation, percutaneous, cryoablation, includes imaging guidance; lower extremity distal/peripheral nerve</td>
</tr>
<tr>
<td>64624</td>
<td>Destruction by neurolytic agent, genicular nerve branches including imaging guidance, when performed (new code effective 1/1/20)</td>
</tr>
<tr>
<td>64640</td>
<td>Destruction by neurolytic agent; other peripheral nerve or branch</td>
</tr>
<tr>
<td>64999</td>
<td>Unlisted procedure, nervous system</td>
</tr>
</tbody>
</table>

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### Related Information

N/A

### Evidence Review
Description

Radiofrequency ablation (RFA) and cryoneurolysis of nerves have been proposed as a treatments for several different types of pain. RFA has been used to treat a number of clinical pain syndromes such as trigeminal neuralgia as well as cervical and lumbar pain. This medical policy evaluates the application of RFA, and cryoneurolysis in peripheral sites distant from the spine.

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.

Treatment

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. Cryoneurolysis uses cold (freezing) for the treatment of plantar fasciitis for those who have failed prior conservative therapy. The most important aspect of this treatment modality is locating the exact area of heel pain. The target area for the tip of the cryoprobe is the area where there is the greatest pain. The cryoneurolysis procedure provides ablation of the divisional branches of the medial calcaneal nerve medially and the branches of the lateral calcaneal nerve laterally. Ablative procedures to include radiofrequency ablation and cryoneurolysis (cryoablation, cryoanalgesia, cryotherapy) have been proposed as an alternative for the treatment of chronic heel pain associated with plantar fasciitis.
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

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 total joint arthroplasty.

When an individual exhibits knee pain, the pain signals can be generated from the peripheral nerves innervating the knee. The nerves supplying the knee are called the genicular nerves, comprising the articular branches of the obturator, femoral, saphenous, common peroneal, and tibial nerves. An ablative procedure such as radiofrequency ablation, cryoneurolysis and chemical neurolysis of any of these genicular nerves may be performed to restore function and alleviate knee pain as an alternative therapy. These ablative procedures have been proposed as an alternative when other measures have not effectively managed the treatment of chronic knee pain.

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 and 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 water-cooled probe that applies more energy at the desired
location without excessive heat diffusing beyond the area, causing less tissue damage away from the nerve (see Table 1). The goal of ablating the nerve is the same.

Nerve RFA is also distinguished from pulsed RF treatment, which has been investigated 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.

For the indications assessed in this medical policy, 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 an RF device. This procedure does not ablate a specific nerve.

### Table 1. Types of Radiofrequency Ablation

<table>
<thead>
<tr>
<th>Type</th>
<th>Procedure</th>
<th>Tissue Temperature</th>
<th>Key Differences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard RFA</td>
<td>Electrode tip provides thermal energy for 90 – 130 seconds</td>
<td>70 – 90()()C</td>
<td>Longer lasting but with more adjacent thermal tissue injury and limitation in size and shape of lesion.</td>
</tr>
<tr>
<td>Pulsed RFA</td>
<td>Non-ablative - provides 20 ms pulses every 30 seconds</td>
<td>42()()C</td>
<td>Limits tissue damage but results in incomplete and transient pain relief</td>
</tr>
<tr>
<td>Cooled RFA</td>
<td>Water circulates through RF electrode to cool the tip</td>
<td>60()()C</td>
<td>Larger lesion with limited thermal injury to tissue. Less complete and shorter durability than standard RFA</td>
</tr>
</tbody>
</table>

RF: radiofrequency; RFA: radiofrequency ablation
Adapted from Oladeji et al (2019)\(^2\)

**Cooled Radiofrequency (C-RFA)**

Cooled radiofrequency is a minimally invasive method in which a radiofrequency generator transmits a small current of thermal radiofrequency energy through an insulated, water-cooled, electrode or probe placed within tissue to target the sensory nerves responsible for sending pain signals. Coolief™ (Avanos previously known as Haylard Health) circulates water through the device while heating nervous tissue to create a larger treatment area than conventional radiofrequency is able to treat. “This combination of ionic heating, produced by the friction of
charged water molecules, and cooling deactivates the nerves responsible for sending pain signals to the brain by targeting the pain-transmitting nerves without excessive heating, leading to pain relief.”25 Coolief™ is performed in an outpatient setting.

Cryoneurololysis

Cryoneurololysis also referred to as cryoablation, cryotherapy or cryoanalgesia temporarily blocks nerve conduction along peripheral pathways using a small probe to freeze the target nerve and treat a variety of painful conditions. Cryoneurolysis treatments that use nitrous oxide (boiling point of -88.5⁰C) as the coolant are reversible. Nerves treated in this temperature range experience a disruption of the axon, with Wallerian degeneration occurring distal to the site of injury. The axon and myelin sheath are affected, but the connective tissues remain intact. The axon can regenerate along the nerve path, usually at the rate of 1-2 mm per day. Thus, the nerve basically dies as it freezes, which stops the pain signals from transmitting. However, over time the nerve regrows, which may mean recurrence of the pain. Cryoneurolysis differs from cryoablation in that cryoablation treatments use liquid nitrogen (boiling point of -195.8⁰C) as the coolant. Treatments of the nerve in this temperature range are irreversible as the nerves experience a disruption of both the axon and the endoneurium connective tissue layer. These treatments are being investigated to alleviate pain in knee OA and to manage pain following total knee arthroplasty. The iovera® cryoablation system is a portable handheld device that applies percutaneous and targeted delivery of cold to superficial peripheral nerves.

Summary of Evidence

For individuals who have plantar fasciitis who receive radiofrequency ablation (RFA) of peripheral nerves for the treatment of chronic heel pain associated with plantar fasciitis, the evidence includes two randomized controlled trials (RCTs). The relevant outcomes include symptoms and functional outcomes, and quality of life (QOL). One of the randomized trials only evaluated 17 patients, and assessment of randomized outcomes was limited to 4 weeks posttreatment. A second RCT evaluated 36 patients out to 12 weeks. The case series generally had small sample sizes, and many had methodologic deficiencies such as retrospective assessment of pain. To be more confident in the efficacy of this treatment, controlled trials with larger samples and longer follow-up would be necessary. The evidence is insufficient to determine the effects of the technology on health outcomes.
For individuals who have knee osteoarthritis (OA) who receive radiofrequency ablation (RFA) of peripheral nerves, such as the genicular nerves, comprising the articular branches of the obturator, femoral, saphenous, common peroneal, and tibial nerves, the evidence includes 2 RCTs with a total of 211 patients with a 6-month follow-up and observational studies with 12 months of follow-up. The relevant outcomes include symptoms, functional outcomes, and quality of life (QOL). Knee OA is a common disorder in older adults. RFA of the genicular nerves has the potential to alleviate pain and improve function in this population, and might also delay or eliminate the need for TKA. To date, the evidence on RFA for knee pain includes 2 RCTs with a total of 211 patients with a 6-month follow-up and prospective observational studies with 12 months of follow-up. The larger of the RCTs compared C-RFA to active control of steroid injection and utilized genicular nerve blocks to select patients for the study. At 1 month after treatment, pain scores on an 11-point numeric rating score (NRS) differed by less than 1 point, a finding that was statistically significant but of marginal clinical significance. By three months after treatment pain scores had increased in the steroid group, consistent with the known durability of the treatment. Pain scores in the RFA group remained low in patients who remained in the study. Durability of this treatment approach to 1 year has been evaluated in a follow-up to the RCT, a retrospective study, and a small (n=25) independent prospective study. In both of the industry-sponsored publications, 65% of the patients treated with C-RFA reported a greater than 50% reduction in pain scores at 12 months. In an independent and prospective observational study, about one-third continued to show a response at one year after RFA of the genicular nerves. The second RCT used stimulation to identify the genicular nerves, rather than genicular nerve blocks with an anesthetic. None of the studies were blinded, which may have biased the subjective outcome measures. It should be noted that the anatomy of the genicular nerves is variable, and the best method for their identification has not been determined. Study in a larger number of patients, preferably in blinded studies with active control and follow-up longer than 12 months, is needed to determine the benefits and potential harms of this treatment. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have knee osteoarthritis who received cooled radiofrequency, some studies may have shown promising results, however, there were concerns about procedural protocols, study quality, small study sizes and patient follow-up which limit the applicability of any specific study to clinical practice. Further randomized clinical trials (RCTs) are needed to determine the efficacy of cooled radiofrequency to include studies with larger sample sizes, longer follow up periods and double-blinding to establish the overall effectiveness of these procedures and to compare their outcomes against one another. The evidence is insufficient to determine the effects of this technology on net health outcomes.
For individuals who have knee osteoarthritis or total knee arthroplasty (TKA) who received cryoneurolysis (cryoablation, cryoanalgesia, cryotherapy) of peripheral nerves, the evidence includes an RCT with 180 patients and a retrospective comparative study. The relevant outcomes include symptoms, functional outcomes, and QOL. Cryoneurolysis in patients with knee OA resulted in a greater decrease in the Western Ontario McMaster Universities Osteoarthritis Index (WOMAC) pain score, WOMAC total score, and visual analog scale (VAS) score at 30 days compared with sham-treated controls. However, subsequent measurements showed no significant benefit of cryoneurolysis on WOMAC score at 60 days or VAS scores at 60 or 90 days. Perioperative cryoneurolysis was shown in a retrospective comparison to reduce the length of stay and opioid use in patients undergoing TKA. These results need to be confirmed in an RCT. Several technical issues including the optimal number of applications for each nerve, the duration of treatment, and the duration of thawing before moving the cannula have not been resolved. The most effective method for determining probe insertion location (eg, ultrasound-guided or based on anatomic landmarks) also need to be established. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Ongoing and Unpublished Clinical Trials**

Some currently ongoing and unpublished trials that might influence this review are listed in **Table 2**.

**Table 2. Summary of Key Trials**

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td>A Randomized Controlled Study to Compare Efficacy of Continuous Versus Pulsed Radiofrequency Treatment of Genicular Nerves to Alleviate Pain and Improve Functional Impairment in Patients With Advanced Osteoarthritis of the Knee</td>
<td>188</td>
<td>Aug 2019</td>
</tr>
<tr>
<td>NCT03628482</td>
<td>A Prospective, Multi-center, Randomized, Clinical Trial Evaluating the Safety and Effectiveness of Using COOLIEF™ Cooled Radiofrequency Probe to Create Lesions of the Genicular Nerves and Comparing a Single Injection of Hyaluronic Acid in the Management of Knee Pain</td>
<td>168</td>
<td>Oct 2019</td>
</tr>
<tr>
<td>NCT03381248</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT No.</td>
<td>Trial Name</td>
<td>Planned Enrollment</td>
<td>Completion Date</td>
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<tr>
<td>-------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>--------------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>NCT02925442</td>
<td>Comparison Between Cooled (C-RFA) and Standard (t-RFA) Radiofrequency Ablation, and Control for Pain Management Following Unilateral Knee Arthroplasty: A Double-Blinded, Parallel-Grouped, Placebo-Controlled Randomized Clinical Trial</td>
<td>150</td>
<td>Feb 2020</td>
</tr>
<tr>
<td>NCT02915120</td>
<td>Ultrasound-Guided Pulsed Radiofrequency Of The Genicular Nerves In The Treatment Of Patients With Osteoarthritis Knee Pain: Randomized, Double-Blind, Placebo-Controlled Trial</td>
<td>142</td>
<td>Dec 2020</td>
</tr>
<tr>
<td></td>
<td><strong>Unpublished</strong></td>
<td></td>
<td></td>
</tr>
<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 (unknown)</td>
</tr>
<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>78</td>
<td>Jun 2019 (completed)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial  
NR: not reported

Practice Guidelines and Position Statements

*The American College of Foot and Ankle Surgeons*

The American College of Foot and Ankle Surgeons (2018) issued consensus guidelines on the treatment of acquired infracalcaneal heel pain.¹¹ The safety and efficacy of bipolar radiofrequency were listed as uncertain (neither appropriate nor inappropriate).

Medicare National Coverage

There is no national coverage determination.

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 SInergy®
(Kimberly-Clark/Baylis), 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 within an RF generator to create RF lesions in nervous tissue. FDA product code: GXD.

In 2011, NeuroTherm® NT 2000 (NeuroTherm) 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.

In 2013, the Cryo-Touch IV (iovera®; Myoscience) was cleared for marketing by the FDA through the 510(k) process (K123516). Predicate devices were the Cryo-Touch II (K102021) and Cryo-Touch III (K120415).

In 2017, the COOLIEF Cooled Radiofrequency Probe (Avanos, previously known as Halyard Health) was cleared for marketing by the FDA through the 510(k) process to be used in conjunction with a radiofrequency generator to create lesions in nervous tissue (K163461). “The device is also indicated for creating radiofrequency lesions of the genicular nerves for the management of moderate to severe knee pain of more than 6 months with conservative therapy, including medication, in patients with radiologically-confirmed osteoarthritis (grade 2-4) and a positive response (> 50% reduction in pain) to a diagnostic genicular nerve block.” FDA Product Code: GXI

References


19. iovera° system (Myoscience, Inc)

20. COGUIF (Halyard Health, Inc)


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>08/01/18</td>
<td>New policy, approved July 10, 2018. This policy is replacing policy 7.01.154. Policy created with literature review through June 2018. Ablative procedures of peripheral</td>
</tr>
</tbody>
</table>
nerves to treat pain for all indications, including but not limited to pain associated with plantar fasciitis or knee osteoarthritis, is considered investigational for the following treatments: cooled radiofrequency ablation (such as, but not limited to COOLIEF), cryoneurolysis (cryoablation, cryotherapy, cryoanalgesia), or radiofrequency ablation (RFA).

12/01/19
Annual Review, approved November 6, 2019. Policy updated with literature review through July 2019; references added. Title changed to “Ablation of Peripheral Nerves to Treat Pain” from “Ablative Procedures of Peripheral Nerves to Treat Pain”. Policy statements unchanged except for minor edits only.

01/01/20
Coding update, added CPT code 64624 (new code effective 1/1/20).

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