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.
### Service

<table>
<thead>
<tr>
<th>Service</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiofrequency ablation of peripheral nerves</td>
<td>Radiofrequency ablation of peripheral nerves to treat pain associated with knee osteoarthritis or plantar fasciitis is considered investigational.</td>
</tr>
<tr>
<td></td>
<td>Radiofrequency ablation of peripheral nerves to treat pain associated with occipital neuralgia or cervicogenic headache is considered investigational.</td>
</tr>
<tr>
<td>Cryoneurolysis of peripheral nerves</td>
<td>Cryoneurolysis of peripheral nerves to treat pain associated with knee osteoarthritis or total knee arthroplasty is considered investigational.</td>
</tr>
<tr>
<td></td>
<td>Cryoneurolysis of peripheral nerves to treat pain associated with occipital neuralgia or cervicogenic headache is considered investigational.</td>
</tr>
<tr>
<td>Ablation of peripheral nerves</td>
<td>Ablation of peripheral nerves to treat pain is considered investigational in all other conditions, including but not limited to the following: (with the exception of facet joint pain (see Related Policies)</td>
</tr>
<tr>
<td></td>
<td>• Intercostal neuralgia.</td>
</tr>
</tbody>
</table>

### Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<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>64620</td>
<td>Destruction by neurolytic agent, intercostal nerve</td>
</tr>
<tr>
<td>64624</td>
<td>Destruction by neurolytic agent, genicular nerve branches including imaging guidance, when performed</td>
</tr>
<tr>
<td>64640</td>
<td>Destruction by neurolytic agent; other peripheral nerve or branch</td>
</tr>
</tbody>
</table>

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Radiofrequency ablation (RFA) and cryoneurolysis of nerves have been proposed as 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 policy evaluates the application of RFA and cryoneurolysis in peripheral sites distant from the spine.

Background

Knee Osteoarthritis

Knee osteoarthritis (OA) is common, and often the cause of substantial disability. Prevalence increases with age, from about 24% among those 60 to 64 years of age to as high as 40% in those 70 to 74 years of age. Knee osteoarthritis is characterized by pain upon initiation of movement or walking. As osteoarthritis progresses, the pain becomes continuous and joint functionality is severely impaired.

Treatment

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 (e.g., 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 individual is at risk of gastrointestinal adverse events. If symptom relief is
inadequate with conservative measures, invasive treatments may be considered. Total knee arthroplasty is an operative treatment for symptomatic OA of the knee.

**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 individuals 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 a 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 one year in some cases.

**Occipital Neuralgia**

Occipital neuralgia is a specific type of headache that is located on one side of the upper neck, back of the head, and behind the ears, and sometimes extending to the scalp, forehead, and behind the eyes. The pain, which may be piercing, throbbing, or electric-shock-like, follows the course of the greater and lesser occipital nerves. Occipital neuralgia is believed to occur due to pressure or irritation to the occipital nerves, which may result from injury, entrapment by tight muscles, or inflammation.

**Treatment**

Treatment may include massage and rest, muscle relaxants, nerve blocks, and injection of steroids directly into the affected area.
Cervicogenic Headache

Cervicogenic headache is a headache that is secondary to a disorder of the cervical spine. The pain may be referred from facet joints, intervertebral discs, or soft tissue. The pain is constant rather than throbbing and may be aggravated by movements of the neck or pressure to certain areas on the neck. The first three cervical spinal nerves can refer pain to the head. The C1 suboccipital nerve innervates the atlanto-occipital joint; the C2 spinal nerve and the C3 dorsal ramus have close proximity to and innervate the C2-C3 facet joint. The C2-3 facet joint is the most frequent source of a cervicogenic headache. A diagnosis of a cervicogenic headache may be confirmed by an anesthetic block of the lateral atlanto-axial joint, the C2-3 facet joint, or the C3-4 facet joint.

Treatment

Treatment may include nerve blocks, physical therapy, and exercise.

Intercostal Neuralgia

Intercostal neuralgia is a neuropathic pain involving the intercostal nerves and manifests as sharp, shooting, tingling, or burning pain in the thorax affecting the chest wall and upper trunk. Intercostal nerves are peripheral nerves that are below the ribs and so pain may worsen with deep inspiration. Intercostal neuralgia is usually caused by some type of irritation, inflammation, or entrapment of the intercostal nerves which may be due to trauma, thoracotomy surgery, or a viral infection, such as shingles.

Treatment

Topical medications such as capsaicin cream or lidocaine gels may provide temporary relief. Systemic medications such as gabapentin may be tried as well as an intercostal nerve block if relief is not obtained by the oral or topical medications. Radiofrequency ablation (pulsed or non-pulsed) has been proposed as a treatment option.
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 into the tissue 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 RFA 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.

RFA is also distinguished from pulsed radiofrequency (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. It does produce some degree of nerve destruction but 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 policy, nerve RFA should be distinguished from RF energy applied to areas other than the nerve to cause tissue damage. Some individuals 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 term pain relief 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 shorter duration of 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. Longer term pain relief.</td>
</tr>
</tbody>
</table>

RF: radiofrequency; RFA: radiofrequency ablation; Adapted from Oladeji et al (2019)
Cryoneurolysis

Cryoneurolysis is being investigated to alleviate pain. Temperatures of -20° to -100°C applied to a nerve cause Wallerian (anterograde axonal) degeneration, with disruption of nerve structure and conduction but maintenance of the perineural and epineural elements of the nerve bundle. Wallerian degeneration allows complete regeneration and recovery of nerve function in about three to five months. 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 knee OA who receive RFA of peripheral nerves, the evidence includes systematic reviews of RCTs, RCTs with 24 to 200 individuals (including 4 with a minimum of 6-month follow-up), and prospective observational studies with 12 to 24 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. At this time, there is high heterogeneity in methods and comparators. The 2 multi-center trials conducted in the U.S. used anesthetic nerve block under fluoroscopic guidance and compared efficacy of cooled RFA to either steroid injection or hyaluronic acid injection. Both studies reported a responder rate of approximately 70% at 6 months, which was significantly greater than the control conditions. Given that OA of the knee is a common condition; study in a larger number of individuals, preferably blinded with active and sham controls and follow-up of at least 12 months, is needed to determine the benefits and potential harms of this treatment. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have knee OA or TKA who receive cryoneurolysis of peripheral nerves, the evidence includes an RCT with 180 individuals and a retrospective comparative study. The relevant outcomes include symptoms, functional outcomes, and QOL. Cryoneurolysis in individuals with knee OA resulted in a greater decrease in WOMAC pain score, WOMAC total score, and 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 individuals 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 (e.g., ultrasound-guided or based on anatomic landmarks) also need to be established. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have plantar fasciitis who receive RFA of peripheral nerves, the evidence includes two RCTs. The relevant outcomes include symptoms, functional outcomes, and QOL. One of the randomized trials only evaluated 17 individuals, and assessment of randomized outcomes was limited to four weeks posttreatment. A second RCT evaluated 36 individuals out to 12 weeks. Both trials found RFA associated with pain reduction, but 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 that the technology results in an improvement in the net health outcome.

For individuals who have occipital neuralgia or cervicogenic headache who receive RFA or cryoneurolysis of peripheral nerves, the evidence includes RCTs and systematic reviews of RCTs. The relevant outcomes are symptoms, functional outcomes, and quality of life. No RCTs of RFA for chronic occipital neuralgia have been identified. Three RCTs of RFA for a cervicogenic headache have been published, none of which were high quality. Pain is a subjective, individual-reported measure that is particularly susceptible to a placebo effect. Randomized trials with sham or active controls are needed to evaluate the efficacy of this treatment. One controlled trial found a temporary benefit of cryoneurolysis for cervicogenic headache, but the effect was not significantly better than injection of corticosteroid and local anesthetic. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have intercostal neuralgia who receive RFA or cryoneurolysis of intercostal nerves, the evidence includes prospective case series/case reports. Most cases are limited by small sample size and short-term follow-up. While some studies demonstrated reduced pain with cryoneurolysis, the studies were limited as well by small sample size and short-term follow-up. Randomized controlled trials with larger sample sizes and longer follow-up are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

**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></td>
<td></td>
<td></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>Jul 2022</td>
</tr>
<tr>
<td>NCT03774121</td>
<td>Cryoneurolysis for the Management of Chronic Pain in Patients With Knee Osteoarthritis; A Randomized Controlled Study</td>
<td>90</td>
<td>Mar 2023</td>
</tr>
<tr>
<td><strong>Unpublished</strong></td>
<td></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 (terminated due to finances)</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>NCT03818022</td>
<td>Effectiveness of Preoperative Cryoneurolysis (Iovera) for Postoperative Pain Control in Total Knee Arthroplasty</td>
<td>100</td>
<td>Dec 2020 (unknown)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial. * Industry sponsored or partially sponsored.

### Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a U.S. professional society, an international society with U.S. representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that...
are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

**American Academy of Orthopaedic Surgeons et al**

In 2021, the American Academy of Orthopaedic Surgeons published a clinical practice guideline, endorsed by the American Association of Hip and Knee Surgeons and the American Physical Therapy Association, on management of osteoarthritis (OA) of the knee.\(^{17}\) The guideline did not specifically address RFA or cryoneurolysis, but did include a guideline statement on denervation therapy that included various ablation techniques (e.g., RFA, cryoneurolysis, thermal ablation and chemical ablation). The guideline stated, "denervation therapy may reduce pain and improve function in patients with symptomatic osteoarthritis of the knee" (strength of recommendation: limited).

**American College of Rheumatology and Arthritis Foundation**

The 2019 guidelines from the American College of Rheumatology and the Arthritis Foundation gave a conditional recommendation for radiofrequency ablation for the treatment of knee osteoarthritis.\(^{31}\) The recommendation was based on evidence of a potential analgesic benefit, but the studies used heterogeneous techniques and there was a lack of long-term safety data.

**The American College of Foot and Ankle Surgeons**

The American College of Foot and Ankle Surgeons (2018) issued consensus guidelines on the diagnosis and treatment of acquired infracalcaneal heel pain.\(^{32}\) The safety and efficacy of bipolar radiofrequency were listed as uncertain (neither appropriate nor inappropriate).

**American Society of Pain and Neuroscience**

The American Society of Pain and Neuroscience (2021) issued consensus guidelines using U.S. Preventive Services Task Force (USPSTF) grading criteria on the use of RFA to treat various pain conditions.\(^{33}\) The guidelines stated that genicular RFA may be used for the treatment of osteoarthritis-related and post-surgical knee joint pain (Grade B), and may be selectively offered
for the treatment of occipital neuralgia pain when greater or lesser nerves have been identified as the etiology of pain via diagnostic blocks (Grade C).

**Medicare National Coverage**

There is no national coverage determination.

**Regulatory Status**

A number of RF generators and probes for the peripheral nervous system have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. Some examples are listed in Table 3.

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). One of the indications is specifically 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 individuals with radiologically-confirmed osteoarthritis (grade 2-4) and a positive response (> 50% reduction in pain) to a diagnostic genicular nerve block."

**Table 3. Radiofrequency and Cryoneurolysis Devices**

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Clearance</th>
<th>Date</th>
<th>FDA Product Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>SInergy®/Bayless Pain Management Probe</td>
<td>Kimberly-Clark/Baylis</td>
<td>K053082</td>
<td>2005</td>
<td>GXD</td>
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<tr>
<td>NeuroTherm® NT 2000</td>
<td>NeuroTherm</td>
<td>K111576</td>
<td>2011</td>
<td>GXD</td>
</tr>
<tr>
<td>iovera</td>
<td>Pacira (formerly Myoscience)</td>
<td>K133453</td>
<td>2014</td>
<td>GXH</td>
</tr>
<tr>
<td>COOLIEF Cooled Radiofrequency Kit</td>
<td>Avanos (Halyard Health)</td>
<td>K163236</td>
<td>2016</td>
<td>GXI</td>
</tr>
<tr>
<td>COOLIEF® Cooled RF Probe</td>
<td>Avanos (Halyard Health)</td>
<td>K163461</td>
<td>2017</td>
<td>GXI</td>
</tr>
<tr>
<td>Device</td>
<td>Manufacturer</td>
<td>Clearance</td>
<td>Date</td>
<td>FDA Product Code</td>
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</tr>
<tr>
<td>Rulo(TM) Radiofrequency Lesion Probe</td>
<td>Epimed International</td>
<td>K190256</td>
<td>2019</td>
<td>GXI</td>
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References


History

<table>
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<th>Date</th>
<th>Comments</th>
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<tbody>
<tr>
<td>08/01/20</td>
<td>New policy, approved July 14, 2020. Policy replaces 7.01.565. Policy statements remain unchanged; CPT codes 0441T, 64624, &amp; 64999 removed.</td>
<td></td>
</tr>
<tr>
<td>12/01/20</td>
<td>Interim Review, approved November 3, 2020. Policy updated with literature review through July, 2020; references added. Cryoneurolysis was added to the investigational statement on occipital neuralgia or cervicogenic headache, other statements unchanged. Added CPT codes 64624 and 0441T.</td>
<td></td>
</tr>
<tr>
<td>12/01/22</td>
<td>Annual Review, approved November 7, 2022. Policy updated with literature review through July 14, 2022; references added. Minor editorial refinements to policy statements; intent unchanged. Changed the wording from &quot;patient&quot; to &quot;individual&quot; throughout the policy for standardization.</td>
<td></td>
</tr>
</tbody>
</table>

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