Description/Background

NERVE RADIOFREQUENCY ABLATION
Nerve radiofrequency ablation (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-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.

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.
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.

OSTEOARTHRITIS (Knee and Hip)
Knee and hip osteoarthritis 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
Treatment for osteoarthritis 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 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 osteoarthritis 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.

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 3 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.

Coolief Radiofrequency
Coolief is a cooled RF device currently being used for RFA of peripheral nerves of the back, hip and knee. Cooled RF devices generate heat using radio waves and are often used for RF denervation (RFD) in nerve tissue. The radio waves are delivered to the targeted nerves via needles inserted through the skin. Sterile water pumped through the device circulates and cools the RF probe, allowing treatment of an area larger than conventional RFD. The tip of the needle heats the surrounding tissue.

Regulatory Status
A number of 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, 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.

Medical Policy Statement
Radiofrequency ablation of peripheral nerves to treat pain (e.g., plantar fasciitis, occipital neuralgia, cervicogenic headache, osteoarthritis, etc.) including Coolief Cooled RF is experimental/investigational. It has not been scientifically demonstrated to improve patient clinical outcomes.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)
N/A

CPT/HCPCS Level II Codes (Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)

Established codes:
N/A
Other codes (investigational, not medically necessary, etc.): 64640*

*This code is not covered when used for the procedures discussed within this policy.

Note: Code(s) may not be covered by all contracts or certificates. Please consult customer or provider inquiry resources at BCBSM or BCN to verify coverage.

Rationale

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

PLANTAR FASCIITIS

Clinical Context and Therapy Purpose
The purpose of RFA in patients who have plantar fasciitis is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of RFA improve the net health outcome in patients with plantar fasciitis?

The following PICOTS were used to select literature to inform this review.

Patients
The relevant population of interest is patients with plantar fasciitis.

Interventions
The therapy being considered is RFA.
Comparators
The following therapy is currently being used to make decisions about treating plantar fasciitis: conservative management, which may include corticosteroid injection.

Outcomes
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 using a VAS. Quantifiable pre- and posttreatment measures of functional status are also used, such as the American Orthopedic Foot and Ankle Society (AOFAS) ankle-hindfoot score. The AOFAS ankle-hindfoot scores range from 0 to 100, with up to 40 points for pain, 50 points for functional aspects, and 10 points for alignment. A high score indicates a better outcome.

Because of the variable natural history of plantar fasciitis and the subjective nature of the outcome measures, 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.

Timing
The time for follow-up is within days to determine procedural success and at least 6 months to a year to evaluated durability.

Setting
RFA would be administered in an outpatient setting, typically pain clinics.

Randomized Controlled Trials
Two double-blind sham-controlled randomized trials have assessed RFA for the treatment of chronic heel pain (see Table 1). Wu et al (2017) randomized 36 patients to ultrasound-guided pulsed radiofrequency of the posterior tibial nerve. First step pain, average pain, and the AOFAS ankle-hindfoot score were assessed at baseline and at 1, 4, 8, and 12 weeks. Scores at 12 weeks are shown in Table 2. Changes in VAS score in the sham group were modest (<1 on a 10-point VAS) and of short duration (statistically significant at weeks 1 and 4, but not weeks 8 and 12). The AOFAS ankle-hindfoot score was 60.55 at baseline and 60.05 at 12 weeks in the sham group. In the RFA group, VAS scores at weeks 1, 4, 8, and 12 were all significantly lower than baseline (p<0.001), and the AOFAS ankle-hindfoot score increased from 55.5 to 87.6 (p<0.001). The improvements in pain and function were greater in the RFA group than in the control group (p<0.001 for all measures).

Landsman et al (2013) reported the only randomized study of RFA. Crossover to the alternative treatment was allowed at 4 weeks. Outcomes assessed weekly were a pain VAS score reported at the first step in the morning, average pain level, and peak pain level (see Table 2). In a graphic presentation of results, patient pain levels for all 3 outcomes decreased after RFA but showed minimal change after sham. 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 appeared to show similar pain levels throughout the follow-up period.
Table 1. Summary of Key RCT Characteristics

<table>
<thead>
<tr>
<th>Study</th>
<th>Countries</th>
<th>Sites</th>
<th>Dates</th>
<th>Participants</th>
<th>Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wu et al (2017)¹</td>
<td>Taiwan</td>
<td>1</td>
<td>2014-2016</td>
<td>36 patients (40 feet) with recalcitrant plantar fasciitis</td>
<td>Ultrasound-guided pulsed RF stimulation of the posterior tibial nerve</td>
</tr>
<tr>
<td>Landsman et al (2013)²</td>
<td>U.S.</td>
<td>Multicenter</td>
<td>NR</td>
<td>17 patients failed at least 3 prior types of treatments, pain for &gt;3 mo, and VAS score ≥5</td>
<td>RFA procedure, including stimulation of sensory nerves in an awake patient</td>
</tr>
</tbody>
</table>

NR: not reported; RCT: randomized controlled trial; RF: radiofrequency; RFA: radiofrequency ablation; VAS: visual analog scale.

Table 2. Summary of Key RCT Results

<table>
<thead>
<tr>
<th>Study</th>
<th>First Step Pain on VAS Score</th>
<th>Average VAS Pain Score</th>
<th>AOFAS Ankle-Hindfoot Score</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>At 12 Weeks</td>
<td>At 12 Weeks</td>
<td></td>
</tr>
<tr>
<td>Wu et al (2017)¹</td>
<td>36</td>
<td>36</td>
<td>36</td>
</tr>
<tr>
<td>RFA (SD)</td>
<td>1.79 (1.62)</td>
<td>1.54 (1.26)</td>
<td>87.60 (9.12)</td>
</tr>
<tr>
<td>Sham (SD)</td>
<td>6.13 (1.75)</td>
<td>6.09 (1.70)</td>
<td>60.05 (11.38)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Change At 4 Weeks</th>
<th>Change Score</th>
<th>Change in Peak Pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>17</td>
<td>17</td>
</tr>
<tr>
<td>RFA</td>
<td>5.0</td>
<td>4.06</td>
</tr>
<tr>
<td>Sham</td>
<td>1.33</td>
<td>0.8</td>
</tr>
<tr>
<td>p</td>
<td>0.30</td>
<td>0.047</td>
</tr>
</tbody>
</table>

AOFAS: American Orthopedic Foot and Ankle Society; RCT: randomized controlled trial; RF: radiofrequency; RFA: radiofrequency ablation; VAS: visual analog scale.

Tables 3 and 4 display notable gaps identified in each study.
Table 3. Relevance Gaps

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Outcomes</th>
<th>Follow-Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wu et al (2017)¹</td>
<td>3. Study did not report a minimum VAS for inclusion criteria</td>
<td>1. Targeted nerve not clearly defined</td>
<td>1. Crossover allowed at 4 wk</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

VAS: visual analog score.

¹Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

²Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.

³Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.


⁵Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 4. Study Design and Conduct Gaps

<table>
<thead>
<tr>
<th>Study</th>
<th>Allocation</th>
<th>Blinding</th>
<th>Selective Reporting</th>
<th>Follow-Up</th>
<th>Power</th>
<th>Statistical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wu et al (2017)¹</td>
<td>3. Crossovers at 4 wks prevented longer term assessments</td>
<td>1. Power calculations not reported</td>
<td>3. Confidence intervals not reported</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Landsman et al (2013)²</td>
<td>3. Crossovers at 4 wks prevented longer term assessments</td>
<td>1. Power calculations not reported</td>
<td>3. Confidence intervals not reported</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.


⁴Follow-Up key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).

⁵Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

⁶Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

The largest case series with the longest follow-up is by Cozzarelli et al (2010).³ 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 post procedure. 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.

Cione et al (2009) reported on a retrospective case series of 75 patients treated with RFA.⁴ 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; \( p<0.001 \)).

**Section Summary: Plantar Fasciitis**

Two randomized, double-blind trials and several case series have shown consistent sensory nerve reductions in pain after RFA for patients with heel pain due to plantar fasciitis. However, several case series had methodologic weaknesses. In two of them, all pain assessments were performed retrospectively, including pretreatment pain assessment. The 2 randomized trials enrolled a few subjects. Due to crossover at 4 weeks in one of the trials, the randomized comparison only evaluated 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.

**RADIOFREQUENCY ABLATION [including cooled RF] For OSTEOARTHRITIS (Knee, Hip)**

**Clinical Context and Therapy Purpose**

The purpose of RFA in patients who have knee osteoarthritis is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of RFA improve the net health outcome in patients with knee osteoarthritis?

The following **PICOTS** were used to select literature to inform this review.

**Patients**
The relevant population of interest is patients with knee osteoarthritis.

**Interventions**
The therapy being considered is RFA.

**Comparators**
The following therapy is currently being used to make decisions treating osteoarthritis: conservative management, which may include analgesics, physical therapy, or corticosteroid injection.

**Outcomes**
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) or numeric rating scale (NRS). The Oxford Knee Score is scaled between 12 and 60, with 12 representing the best outcome. Quantifiable pre- and post-treatment measures of functional status are also used, such as 12-Item Short-Form Health Survey (SF-12) and SF-36. The Western Ontario McMaster Universities Osteoarthritis Index (WOMAC) is also frequently used to evaluate function due to osteoarthritis.

Because of the variable natural history of osteoarthritis and the subjective nature of the outcome measures, 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.

Timing
The time for follow-up is within days to determine procedural success and at least 6 months to 1 year to evaluate durability.

Setting
RFA would be administered in an outpatient setting, typically pain clinics.

Randomized Controlled Trials
Davis et al (2018) reported on a multicenter randomized trial comparing RFA with corticosteroid injection in 151 patients who had chronic (>6 months) knee pain unresponsive to conservative therapy (see Table 1). At 1 month after treatment, both groups showed a reduction in pain, with a 0.9-point difference on an 11-point NRS (see Table 2). By 3 months after treatment, pain scores had increased in the steroid group, while pain scores in the RFA group remained low throughout the 6-month follow-up. At the 6-month follow-up, 74.1% of patients in the RFA group were considered responders (≥50% decrease in the NRS), compared with 16.2% of patients treated with steroid injections (p<0.001). Follow-up is continuing to assess the durability of this more resource-intensive treatment approach.

Table 5. Summary of Key RCT Characteristics

<table>
<thead>
<tr>
<th>Study</th>
<th>Countries</th>
<th>Sites</th>
<th>Participants</th>
<th>Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Davis et al (2018)</td>
<td>U.S.</td>
<td>11</td>
<td>151 patients with chronic (&gt;6 mo) knee pain unresponsive to conservative therapy; pain score ≥6; OA grades 2-4; Oxford Knee Score of ≤35; a positive diagnostic genicular nerve block&lt;sup&gt;a&lt;/sup&gt;</td>
<td>76 patients treated with cooled RFA under fluoroscopic guidance</td>
</tr>
</tbody>
</table>

OA: osteoarthritis; RCT: randomized controlled trial; RFA: radiofrequency ablation.
<sup>a</sup> At least 50% reduction in numeric rating scale for pain with anesthetic injection to the superomedial and inferomedial branches of the saphenous nerve and the superolateral branch of the femoral nerve.

Table 6. Summary of Key RCT Results

<table>
<thead>
<tr>
<th>Study</th>
<th>Mean NRS Pain Scores (SD)</th>
<th>Responders at 6 Months, %&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Mean Oxford Knee Score at 6 Months (SD)</th>
<th>Global Perceived Effect at 6 Months, %</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>At 1 Month</td>
<td>At 3 Months</td>
<td>At 6 Months</td>
<td></td>
</tr>
<tr>
<td>Davis et al (2018)&lt;sup&gt;5&lt;/sup&gt;</td>
<td>136</td>
<td>132</td>
<td>126</td>
<td>126</td>
</tr>
<tr>
<td>RFA</td>
<td>3.0 (2.3)</td>
<td>2.8 (2.2)</td>
<td>2.5 (2.3)</td>
<td>74.1</td>
</tr>
<tr>
<td>Steroid</td>
<td>3.9 (2.2)</td>
<td>5.2 (2.0)</td>
<td>5.9 (2.2)</td>
<td>16.2</td>
</tr>
<tr>
<td>p</td>
<td>0.025</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

SD: standard deviation; NRS: numeric rating scale; RCT: randomized controlled trial.<br><sup>a</sup> Greater than 50% reduction in the NRS.
The purpose of the gaps tables (see Tables 7 and 8) is to display notable gaps identified in each study. This information is synthesized as a summary of the body of evidence following each table and provides the conclusions on the sufficiency of the evidence supporting the position statement.

Table 7. Relevance Gaps

<table>
<thead>
<tr>
<th>Study</th>
<th>Population(^a)</th>
<th>Intervention(^b)</th>
<th>Comparator(^c)</th>
<th>Outcomes(^d)</th>
<th>Follow-Up(^e)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Davis et al (2018)(^5)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1. Follow-up &gt;6 mo is needed to evaluate durability of the procedure</td>
</tr>
</tbody>
</table>

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

RFA: radiofrequency ablation.

\(^a\) Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

\(^b\) Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.

\(^c\) Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

\(^d\) Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported.

\(^e\) Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 8. Study Design and Conduct Gaps

<table>
<thead>
<tr>
<th>Study</th>
<th>Allocation(^a)</th>
<th>Blinding(^b)</th>
<th>Selective Reporting(^d)</th>
<th>Data Completeness(^e)</th>
<th>Power(^d)</th>
<th>Statistical(^f)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Davis et al (2018)(^5)</td>
<td></td>
<td></td>
<td></td>
<td>1. Unequal loss to follow-up in both groups</td>
<td></td>
<td>2. The study used Wilcoxon signed-rank sum test rather than a repeated-measures test</td>
</tr>
</tbody>
</table>

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

RFA: radiofrequency ablation.


\(^b\) Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.

\(^c\) Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

\(^d\) Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).

\(^e\) Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

\(^f\) Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

**Observational Studies**

Observational studies can provide information on durability that is not available from RCTs. Follow-up to 12 months was reported in a prospective study of 25 patients (see Tables 5 and 6).\(^6\) The response rate was 88% at 1 month after treatment, decreasing to 64% at 6 months and 32% at 12 months.
Table 5. Summary of Key Case Series Characteristics

<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Participants</th>
<th>Treatment Delivery</th>
<th>Follow-Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Santana Pineda et al (2017)⁶</td>
<td>E.U.</td>
<td>25 patients with grade III-IV knee osteoarthritis (n=24) or after total knee arthroplasty (n=1) and intractable pain with VAS ≥5 for &gt;6 mo</td>
<td>RFA of superior medial, superior lateral, and inferior medical genicular nerves with electrode tips placed on periosteal areas and guided by ultrasound and neurostimulation</td>
<td>12 mo</td>
</tr>
</tbody>
</table>

RFA: radiofrequency ablation; VAS: visual analog scale.

Table 6. Summary of Key Case Series Results

<table>
<thead>
<tr>
<th>Study</th>
<th>Treatment</th>
<th>Proportion With ≥50% Improvement in VAS, n/N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Santana Pineda et al (2017)⁶</td>
<td>RFA of genicular nerves</td>
<td>At 1 Month: 22/25 (88)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>At 6 Months: 16/25 (64)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>At 12 Months: 8/25 (32)</td>
</tr>
</tbody>
</table>

VAS: visual analog scale.

Section Summary: Osteoarthritis (Knee, Hip)

The evidence on RFA for knee pain includes an RCT with over 100 patients that compared RFA with steroid injection. At 1 month after treatment, pain scores on an 11-point NRS differed by 0.9 points, a variance that was statistically significant but of marginal clinical significance. The subjective outcome measures might also have been influenced by the novelty of the treatment in this unblinded study. By 3 months after treatment, pain scores had increased in the steroid group, consistent with the known durability of treatment. Pain scores in the RFA group remained low throughout the 6-month follow-up. Follow-up is continuing to assess the durability of this treatment approach. In an observational study of 25 patients, about one-third continued to show a response at 1 year after RFA of the genicular nerves.

Occipital Neuralgia and Cervicogenic Headache

Clinical Context and Therapy Purpose

The purpose of RFA in patients who have occipital neuralgia or a cervicogenic headache is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of RFA improve the net health outcome in patients with occipital neuralgia or a cervicogenic headache?

The following PICOTS were used to select literature to inform this review.

Patients

The relevant population of interest is patients with occipital neuralgia or a cervicogenic headache.
Interventions
The therapy being considered is RFA. RFA involves the percutaneous insertion of a catheter that is directed toward the nerve of interest. RFA can be used to ablate the nerve by thermal lesioning.

Comparators
The following therapy is currently being used to make decisions about treating occipital neuralgia or a cervicogenic headache: conservative management.

Outcomes
The most clinically relevant outcome measures for pain treatments are measures of pain severity and functional limitations. Pain is most commonly measured with a VAS or RNS. Quantifiable pre- and posttreatment measures of functional status are also used, such as SF-12 and SF-36.

Timing
The time for follow-up is within days to determine the procedural success and months to years to evaluate durability.

Setting
RFA would be administered in an outpatient setting, typically pain clinics.

Systematic Reviews
Grandhi et al (2018) conducted a systematic review of RFA for the treatment of a cervicogenic headache. Ten studies met selection criteria, including 3 RCTs, 3 prospective studies, and 4 retrospective studies. There were no high-quality RCTs. Two of the RCTs evaluated RFA of the facet joints and failed to find a benefit of RFA. The third RCT compared RFA with steroid injection of the greater occipital nerve, finding no difference between the groups in the short term, but a longer duration of pain control in the RFA group.

A systematic review by Ducic et al (2014) did not identify any RCTs assessing RFA for chronic occipital neuralgia. Reviewers identified 3 case series (total N=131 patients) on pulsed RF treatment. Success rates in these series ranged from 51% to 100%, with an overall success rate of 55%. Follow-up ranged from 3 to 10 months.

Section Summary: RFA for Occipital Neuralgia and Cervicogenic Headache
No RCTs of RFA for chronic occipital neuralgia have been identified. A systematic review identified 3 RCTs of RFA for a cervicogenic headache, none of which were high quality. Pain is a subjective, patient-reported measure that is particularly susceptible to placebo effect. Trials with sham or active controls are needed to evaluate the efficacy of this treatment.

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 only evaluated 17 patients, and randomized outcomes were only assessed out to 4 weeks posttreatment. Although the studies reported
that radiofrequency ablation 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 or hip 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 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.

For individuals who have occipital neuralgia or cervicogenic headache who receive RFA of peripheral nerves, the evidence includes systematic reviews. 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, patient-reported measure that is particularly susceptible to placebo effect. Randomized trials with sham or active-controls are needed to evaluate the efficacy of this treatment. 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 7.

**Table 7. 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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<tbody>
<tr>
<td></td>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
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<tr>
<td>NCT03628482a</td>
<td>A randomized controlled study to compare efficacy of continuous vs. 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>Nov 2018</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 osteoarthritis of the knee</td>
<td>102</td>
<td>July 2019</td>
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<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 in treating chronic knee osteoarthritis</td>
<td>50</td>
<td>Apr 2017 (ongoing)</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

*a Denotes manufacturer sponsored or cosponsored trial*
SUPPLEMENTAL INFORMATION

PRACTICE GUIDELINES AND POSITION STATEMENTS

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

American Society of Interventional Pain Physicians (ASIPP)
ASIPP addresses radiofrequency neurotomy for lumbar and sacroiliac joint interventions. However, ASIPP does not have guidelines addressing radiofrequency ablation techniques for peripheral nerve pain.

Government Regulations
National:
No NCD available for this service.

Local:
No LCD available for this service.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Radiofrequency Ablation of Misc Solid Tumors
- Radiofrequency Ablation of Primary or Metastatic Liver Tumors
- Spinal Surgery: Percutaneous Intradicinal Electrothermal (IDET) Annuloplasty, Radiofrequency Annuloplasty, and Biacuplasty
- Spinal Surgery: Percutaneous Disc Decompression Using Laser Energy or Radiofrequency Coplation

References


The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through February 2019, the date the research was completed.
Joint BCBSM/BCN Medical Policy History

<table>
<thead>
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<th>BCBSM Signature Date</th>
<th>BCN Signature Date</th>
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<td>7/1/18</td>
<td>4/17/18</td>
<td>4/17/18</td>
<td>Joint policy established</td>
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<tr>
<td>7/1/19</td>
<td>4/16/19</td>
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<td>Added Occipital Neuralgia and Cervicogenic Headache to MPS as E/I. Updated rationale, added reference 7 &amp; 8.</td>
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Next Review Date: 2nd Qtr, 2020

Pre-Consolidation Medical Policy History

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<td>Revised:</td>
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<td>BCBSM:</td>
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BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: RADIOFREQUENCY ABLATION OF PERIPHERAL NERVES TO TREAT PAIN
INCLUDING COOLIEF COOLED RF

I. Coverage Determination:

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<th>Plan Type</th>
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<tr>
<td>(includes Self-Funded groups unless otherwise specified)</td>
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<tr>
<td>BCNA (Medicare Advantage)</td>
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<tr>
<td>BCN65 (Medicare Complementary)</td>
<td>Not covered</td>
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</table>

II. Administrative Guidelines:
N/A