



Louisiana

Ablation of Peripheral Nerves to Treat Pain

Policy # 00503

Original Effective Date: 05/18/2016

Current Effective Date: 05/10/2021

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Facet Radiofrequency Denervation is addressed separately in medical policy 00199.

Note: Spinal Cord Stimulation is addressed separately in medical policy 00260.

Note: Sacroiliac Joint Fusion is addressed separately in medical policy 00558.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers radiofrequency ablation (RFA) of peripheral nerves to treat pain associated with knee osteoarthritis (OA) or plantar fasciitis to be **investigational**.*

Based on review of available data, the Company considers cryoneurolysis of peripheral nerves to treat pain associated with knee osteoarthritis (OA) or total knee arthroplasty to be **investigational**.*

Based on review of available data, the Company considers radiofrequency ablation (RFA) or cryoneurolysis of peripheral nerves to treat pain associated with occipital neuralgia or cervicogenic headache to be **investigational**.*

Based on review of available data, the Company considers diagnostic block performed before planned ablation to be **investigational**.*

Based on review of available data, the Company considers ablation of peripheral nerves to treat pain in all other conditions, with the exception of facet joint pain (see medical policy 00199) to be **investigational**.*

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Background/Overview

Knee Osteoarthritis

Knee OA is common, 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 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 (eg, 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 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 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 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 1 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

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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.

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 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 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

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the nerve. If it does produce some degree of nerve destruction but is thought to cause less damage than standard RFA. Some studies refer to pulsed RF treatment as ablation.

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 an RF device. This procedure does not ablate a specific nerve.

Table 1. Types of Radiofrequency Ablation

Type	Procedure	Tissue Temperature	Key Differences
Standard RFA	Electrode tip provides thermal energy for 90 – 130 seconds	70 – 90° C	Longer term pain relief but with more adjacent thermal tissue injury and limitation in size and shape of lesion.
Pulsed RFA	Non-ablative - provides 20 ms pulses every 30 seconds	42° C	Limits tissue damage but results in shorter duration of pain relief
Cooled RFA	Water circulates through RF electrode to cool the tip	60° C	Larger lesion with limited thermal injury to tissue. Longer term pain relief.

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 3 to 5 months. The iovera cryoablation system is a portable handheld device that applies percutaneous and targeted delivery of cold to superficial peripheral nerves.



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FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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 2.

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 patients with radiologically-confirmed osteoarthritis (grade 2-4) and a positive response ($\geq 50\%$ reduction in pain) to a diagnostic genicular nerve block."

Table 2. Radiofrequency and Cryoneurolysis Devices

Device	Manufacturer	Clearance	Date	FDA Product Code
SInergy [®] ‡/Bayless Pain Management Probe	Kimberly-Clark/Baylis	K053082	2005	GXD
NeuroTherm [®] ‡ NT 2000	NeuroTherm	K111576	2011	GXD
iovera	Myoscience	K133453	2014	GXH
COOLIEF Cooled Radiofrequency Kit	Avanos, previously known as Halyard Health	K163236	2016	GXI
Rulo(TM) Radiofrequency Lesion Probe	Epimed International	K190256	2019	GXI

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Rationale/Source

Description

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 review evaluates the application of RFA and cryoneurolysis in peripheral sites distant from the spine.

Summary of Evidence

For individuals who have knee osteoarthritis (OA) who receive RFA of peripheral 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. 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 3 RCTs with 6-month follow-up and prospective observational studies with 12 to 24 months of follow-up. One of the larger RCTs compared cooled 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 NRS differed by less than 1 point, a finding that was statistically significant but of marginal clinical significance. By 3 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. Another RCT compared cooled RFA with injection of hyaluronic acid, which has questionable efficacy. At this time, results have been reported in the control group only for the patients who had crossed over to RFA. The durability of this treatment approach at 12 to 24 months has been evaluated in a follow-up to an 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 cooled 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 1 year after RFA of the genicular nerves. One of the RCTs 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

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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 OA or TKA who receive cryoneurolysis of peripheral nerves, the evidence includes an RCT with 180 patients and a retrospective comparative study. Relevant outcomes include symptoms, functional outcomes, and QOL. Cryoneurolysis in patients 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 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.

For individuals who have plantar fasciitis who receive RFA of peripheral nerves, the evidence includes two RCTs. Relevant outcomes include symptoms, functional outcomes, and QOL. One of the randomized trials only evaluated 17 patients, and assessment of randomized outcomes was limited to 4 weeks post-treatment. 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 occipital neuralgia or cervicogenic headache who receive RFA or cryoneurolysis of peripheral nerves, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are symptoms, functional outcomes, and QOL. 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 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

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of corticosteroid and local anesthetic. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information

Practice Guidelines and Position Statements

American College of Rheumatology and Arthritis Foundation

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. 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.

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. The safety and efficacy of bipolar radiofrequency were listed as uncertain (neither appropriate nor inappropriate).

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

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

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 3.

Table 3. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			

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NCT03381248 ^a	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	177	Aug 2020
NCT03818022	Effectiveness of Preoperative Cryoneurolysis (Iovera) for Postoperative Pain Control in Total Knee Arthroplasty	100	Dec 2020
NCT02915120	Ultrasound-Guided Pulsed Radiofrequency Of The Genicular Nerves In The Treatment Of Patients With Osteoarthritis Knee Pain: Randomized, Double-Blind, Placebo-Controlled Trial	142	Dec 2020
NCT03774121	Cryoneurolysis for the Management of Chronic Pain in Patients With Knee Osteoarthritis; A Randomized Controlled Study	90	Dec 2021
NCT04145011 ^a	A Prospective, Multi-center, Randomized, Single Blind Clinical Trial Comparing COOLIEF* Cooled Radiofrequency to Conventional Radiofrequency Ablation of the Genicular Nerves in the Management of Knee Pain in an Osteoarthritic Patient Population	148	Jun 2022
<i>Unpublished</i>			

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NCT02294864	A Controlled Comparison of Pulsed Radiofrequency Vs Physical Therapy on Treating Chronic Knee Osteoarthritis	50	Apr 2017 (unknown)
NCT02260869	Efficacy of Cooled and Monopolar Radiofrequency Ablation of the Geniculate Nerves for the Treatment of Chronic Osteoarthritic Knee Pain	78	Jun 2019 (completed)
NCT03628482 ^a	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	188	Aug 2019
NCT02925442 ^a	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	150	Feb 2020

NCT: national clinical trial.

^a Industry sponsored or partially sponsored.

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- 05/05/2016 Medical Policy Committee review
- 05/18/2016 Medical Policy Implementation Committee approval. New policy.
- 11/01/2016 Coding update
- 01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
- 05/04/2017 Medical Policy Committee review
- 05/17/2017 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 05/03/2018 Medical Policy Committee review
- 05/16/2018 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 11/08/2018 Medical Policy Committee review
- 11/21/2018 Medical Policy Implementation Committee approval. Title changed from “Radiofrequency Ablation of Peripheral Nerves to Treat Pain” to “Ablation of Peripheral Nerves to Treat Pain”. Added four investigational statements as follows: cryoneurolysis of peripheral nerves to treat pain associated with knee osteoarthritis (OA) or total knee arthroplasty is considered to be investigational; radiofrequency ablation (RFA) of peripheral nerves to treat pain associated with occipital neuralgia or cervicogenic headache is considered to be investigational; diagnostic block performed before radiofrequency ablation (RFA) is considered to be

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investigational; and ablation of peripheral nerves to treat pain in all other conditions, with the exception of facet joint pain is considered to be investigational.

11/07/2019 Medical Policy Committee review

11/13/2019 Medical Policy Implementation Committee approval. Replaced “radiofrequency ablation” with “planned ablation”, so that diagnostic block before any ablation is investigational.

04/02/2020 Medical Policy Committee review

04/08/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

04/01/2021 Medical Policy Committee review

04/14/2021 Medical Policy Implementation Committee approval. Cryoneurolysis was added to the investigational statement on occipital neuralgia or cervicogenic headache.

05/24/2021 Coding update

10/01/2021 Coding update

Next Scheduled Review Date: 04/2022

Coding

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Louisiana

Ablation of Peripheral Nerves to Treat Pain

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contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	64405, 64450, 64454, 64624, 64640
HCPCS	C9752, C9753
ICD-10 Diagnosis	M17.0-M17.9, M72.2, M54.81 Adding codes eff 10/1/2021: M54.50-M54.59

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

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