Ablation of Peripheral Nerves to Treat Pain

Policy # 00503
Original Effective Date: 05/18/2016
Current Effective Date: 05/11/2020

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) 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, 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 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 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.

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 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.

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. 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 – 90â° C	Longer lasting 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	42â° C	Limits tissue damage but results in incomplete and transient pain relief
Cooled RFA	Water circulates through RF electrode to cool the tip	60â° C	Larger lesion with limited thermal injury to tissue. Less complete and shorter durability than standard RFA

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

Cryoneurolysis
Cryoneurolysis is being investigated to alleviate pain in knee OA and to manage pain following total knee arthroplasty. Temperatures of -20° to -100°C applied to a nerve cause Wallerian (anterograde axonal) degeneration, with disruption of nerve structure and conduction but the 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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
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), a water-cooled single-use probe, was cleared by the FDA, listing the Baylis Pain Management Probe as a predicate device. The intended use is with 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

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Rationale/Source

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.

For individuals who have knee osteoarthritis (OA) who receive RFA of peripheral nerves, the evidence includes 2 randomized controlled trials (RCTs) with a total of 211 patients with 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 6-month follow-up and prospective observational studies with 12 months of follow-up. The larger of the 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-pointnumeric rating scale 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. The 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 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 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.

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For individuals who have knee OA or total knee arthroplasty who receive cryoneurolysis 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 Western Ontario McMaster Universities Osteoarthritis Index pain score, Western Ontario McMaster Universities Osteoarthritis Indextotal score, and visual analog scale score at 30 days compared with sham-treated controls. However, subsequent measurements showed no significant benefit of cryoneurolysis on Western Ontario McMaster Universities Osteoarthritis Index score at 60 days or visual analog scale 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 total knee arthroplasty. 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. The 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 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 occipital neuralgia or cervicogenic headache who receive RFA of peripheral nerves, the evidence includes systematic reviews. The 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. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information

Practice Guidelines and Position Statements

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 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
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	188	Aug 2019

	Advanced Osteoarthritis of the Knee		
NCT03381248	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	168	Oct 2019
NCT02925442	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
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

Unpublished			
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)

NCT: national clinical trial.
[a] Industry sponsored or partially sponsored.

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Policy History

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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 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.
05/15/2020	Coding update

Next Scheduled Review Date: 04/2021

Coding

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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	64450, 64454, 64640 Added code eff 1/1/2020: 64624
HCPCS	No codes
ICD-10 Diagnosis	M17.0-M17.9, M72.2, M54.81

*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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