BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Ablative Procedures of Peripheral Nerves for Treatment of Musculoskeletal Conditions

Policy #:	626	Latest Review Date:	February 2021
Category:	Medical	Policy Grade:	C

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*

    - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
    - *Furnished in a setting appropriate to the patient's medical needs and condition;*
    - *Ordered and furnished by qualified personnel;*
    - *One that meets, but does not exceed, the patient's medical need; and*
    - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Effective for dates of service on and after November 1, 2018:

Blue Advantage will treat **peripheral nerve destruction using cryoablation or thermal, electrical, chemical or radiofrequency ablation** to treat pain associated with musculoskeletal conditions as a **non-covered benefit** and as **investigational** for the following conditions, including but not limited to:

- Neuralgia/Neuritis
- Osteoarthritis
- Plantar fasciitis
- Plantar fibromatosis
- Sacroiliitis
- Sprains/Strains
- Trigger point pain

Blue Advantage will treat cryoneurolysis, cyroablation, cryoanalgesia of peripheral nerves to treat pain associated with musculoskeletal conditions as a **non-covered benefit** and **investigational** for the following conditions, including but not limited to:

- Knee osteoarthritis
- Total knee arthroplasty

Effective for dates of service on and after May 10, 2016 through October 31, 2018:

Blue Advantage will treat **radiofrequency ablation of peripheral nerves** to treat pain associated with musculoskeletal conditions as a **non-covered benefit** and as **investigational** for the following conditions, including but not limited to:

- Neuralgia/Neuritis
- Osteoarthritis
- Plantar fasciitis
- Plantar fibromatosis
- Sacroiliitis
- Sprains/Strains
- Trigger point pain

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

Radiofrequency ablation of nerves has been proposed as a treatment for several different types of pain. Radiofrequency ablation can be done in different ways. It can be done using, heat, cold, or pulsed. It has been used to treat a number of clinical pain syndromes by preventing the transmission of pain signals (such as *cervical and lumbar pain or headache syndromes.) This evidence review evaluates the evidence for radiofrequency ablation in peripheral sites distant from the cranium or spine.

**For additional information on headache syndromes, see medical policy # 314 Treatment of Cervicogenic Headache and Occipital Neuralgia.*

**For additional information on cervical and lumbar pain, see medical policy # 141 Facet Joint Denervation.*

**For additional information on sacroiliac joint pain, see medical policy # 558 Diagnosis and Treatment of Sacroiliac Joint Pain.*

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. 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.

Knee Osteoarthritis

Knee 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 for osteoarthritis of the knee aims to alleviate pain and improve function. However, most treatments do not modify the natural history or progression of osteoarthritis and are not considered curative. Nonsurgical modalities 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 policy.

Radiofrequency ablation (RFA) of nerves is a minimally invasive method that involves 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.

Nerve RFA is distinguished from pulsed RF treatment, which has been investigated as a treatment for different types of pain. Pulsed RF involves giving short pulses of radiofrequency waves twice a minute. It differs from standard RF procedures in that the needle is not heated above 42 degrees. 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, 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 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 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	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 is being investigated to alleviate pain in knee osteoarthritis 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 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.

KEY POINTS:

This evidence review was created based on a search of the literature through July 21, 2020.

Summary of Evidence

For individuals who have knee 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. The relevant outcomes include symptoms, functional outcomes, and QOL. Knee OA is a common disorder in older adults. RFA of the genicular nerves has the potential to alleviate pain and improve function in this population, and might also delay or eliminate the need for TKA. To date, the evidence on RFA for knee pain includes 2 RCTs with a total of 211 patients with a 6-month follow-up and prospective observational studies with 12 months of follow-up. The larger of the RCTs compared C-RFA to active control of steroid injection and utilized genicular nerve blocks to select patients for the study. At 1 month after treatment, pain scores on an 11-point NRS differed by less than 1 point, a finding that was statistically significant but of marginal clinical significance. By three months after treatment pain scores had increased in the steroid group, consistent with the known durability of the treatment. Pain scores in the RFA group remained low in patients who remained in the study. Durability of this treatment approach to 1 year has been evaluated in a follow-up to the RCT, a retrospective study, and a small (n=25) independent prospective study. In both of the industry-sponsored publications, 65% of the patients treated with C-RFA reported a greater than 50% reduction in pain scores at 12 months. In an independent and prospective observational study, about one-third continued to show a response at one year after RFA of the genicular nerves. The second RCT used stimulation to identify the genicular nerves, rather than genicular nerve blocks with an anesthetic. None of the studies were blinded, which may have biased the subjective outcome measures. It should be noted that the anatomy of the genicular nerves is variable, and the best method for their identification has not been determined. Study in a larger number of patients, preferably in blinded studies with active control and follow-up longer than 12 months, is needed to determine the benefits and potential harms of this treatment. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have knee osteoarthritis or total knee arthroplasty 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 quality of life. Cryoneurolysis in patients with knee osteoarthritis resulted in a greater decrease in WOMAC pain score, WOMAC total score, and visual analog scale 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 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 (e.g., 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 2 RCTs. Relevant outcomes include symptoms, functional outcomes, and quality of life. 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.

The evidence for radiofrequency ablation for myofascial trigger points includes a small number of case-studies, and one case-series. Limitations across published literature on RF and PRF in trigger-point therapy include small sample sizes, lack of a control group and the mechanism of therapeutic effect remains unknown. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

U.S. Preventive Services Task Force Recommendations
Not applicable.

KEY WORDS:
Radiofrequency ablation, genicular neurotomy, Coblation, osteoarthritis, plantar fasciitis, SInergy®, NeuroTherm® NT 2000, cooled radiofrequency, pulsed radiofrequency, microtenotomy RF, Topaz procedure, trigger point, myofascial pain syndrome, iovera° cryoablation system, Cryo-Touch, RFA, COOLIEF

APPROVED BY GOVERNING BODIES:
A number of radiofrequency (RF) generators and probes have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. 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). "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."

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

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes:

64624	Destruction by neurolytic agent; genicular nerve branches including imaging guidance, when performed (Effective 01/01/20)
64630	Destruction by neurolytic agent; pudendal nerve

64632	Destruction by neurolytic agent; plantar common digital nerve
64640	Destruction by neurolytic agent; other peripheral nerve or branch
64999	Unlisted procedure, nervous system

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POLICY HISTORY:

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