BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Ablative Procedures of Peripheral Nerves for Treatment of Musculoskeletal Conditions

Policy #: 626
Latest Review Date: June 2022
Category: Medical

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:

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

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:

Ablative procedures including radiofrequency ablation (RFA), cooled radiofrequency, pulsed radiofrequency, cryoneurolysis (cryoablation, cryotherapy, cryoanalgesia) and chemical neurolysis (chemodenervation) have been proposed as a treatment of the peripheral nerves to treat pain related to conditions including but not limited to the following: osteoarthritis, neuralgias/neuritis (intercostal neuralgia, inguinal neuralgia), peripheral neuromas and plantar fasciitis. 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. COOLIEF Cooled RF treatment is a minimally invasive outpatient procedure used in the treatment of hip and knee pain associated with osteoarthritis that uses cooled radiofrequency energy to target the sensory nerves causing pain. COOLIEF circulates water through the device while heating nervous tissue to create a treatment area that is larger than conventional RF treatments. This combination targets the pain causing nerves without excessive heating, leading to pain relief.

Pulsed radiofrequency, which uses short bursts of radiofrequency current, has been proposed as a possibly safer alternative to non-pulsed or continuous RFA in the treatment of variety pain syndromes. It also differs from standard RF procedures in that the temperature will not exceed. While the mechanism of action of pulsed RF treatment is uncertain, it is thought that since the temperatures do not exceed 42°C, the heat is not enough to cause tissue coagulation or permanent damage to the nerve. Pulsed RF may cause less damage than standard RFA.

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))

Chemical Neurolysis or chemodenervation is the use of a chemical using phenol, alcohol, glycerol or a hypertonic saline to cause destruction of nerves by causing a temporary degeneration of the nerves fibers to interrupt the transmission of nerves signals for pain relief.

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.

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.

Morton neuroma is a common and painful compression neuropathy of the common digital nerve of the foot that may also be referred to as interdigital neuroma, interdigital neuritis, or Morton metatarsalgia. It is histologically characterized by perineural fibrosis, endoneurial edema, axonal degeneration, and local vascular proliferation. Thus, some investigators do not consider Morton neuroma to be a true neuroma; instead, they consider it to be an entrapment neuropathy occurring secondary to compression of the common digital nerve under the overlying transverse metatarsal ligament. The incidence and prevalence of Morton neuroma are not clear, but it appears 10-fold more often in women than in men, with an average age at presentation of around 50 years. Morton neuroma is usually treated with conservative measures, surgery, or minimally invasive procedures. Alcohol injection is a minimally invasive alternative to open surgery to treat Morton neuroma. Alcohol causes chemical neurolysis through dehydration, necrosis, and precipitation of the treated area, ultimately destroying the lesion after multiple injections.

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.

**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.*

KEY POINTS:

This evidence review was created based on a search of the literature through April 26, 2022.

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. At this time, there is high heterogeneity in methods and comparators. The 2 multi-center trials conducted in the U.S. used anesthetic nerve block under fluoroscopic guidance and compared efficacy of cooled RFA to either steroid injection orhyaluronic acid injection. Both studies reported a responder rate approximately 70% at 6 months, which was significantly greater thanthe control conditions. Given that OA of the knee is a common condition; study in a larger number of patients, preferably blinded with active and sham controls and follow-up of at least 12 months, is needed to determine the benefits and potential harms of thistreatment. 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.

For individuals who have Morton neuroma who receive RFA or intralesional alcohol injection(s), the evidence includes retrospective cases series. Relevant outcomes are symptoms, resource utilization, and treatment-related morbidity. The body of evidence is limited, consisting of case series reporting on the treatment response of patients with refractory Morton neuroma. The available series have generally reported that some patients experience pain relief and express satisfaction with the procedure. Some evidence has suggested that surgery after failed cases of alcohol injections is more complex and challenging than in untreated patients due to the presence of fibrosis. There is a lack of controlled trials comparing alcohol injections with alternative therapies, and there are no controlled studies comparing outcomes for alcohol injections with those for surgery in surgical candidates. Four case series identified reported outcomes for RFA to treat Morton neuroma. The body of evidence is highly heterogeneous regarding RFA protocols, descriptions of prior conservative management, patient characteristics, follow-up durations, outcome measures, and reporting of outcomes. Variable proportions of patients require surgery after RFA, making the benefit of RFA for avoiding more invasive treatment uncertain. Only 2 retrospective case series on the use of cryoablation to treat peripheral nerve pain were identified in a literature review. The case series were heterogeneous regarding cryoablation protocols and length of follow-up. Outcome measures did not provide information on functional end points. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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

In 2018, the American College of Foot and Ankle Surgeons issued a clinical consensus statement on the diagnosis and treatment of adult acquired infracalcaneal heel pain. The panel determined that the following statement were uncertain – neither appropriate nor inappropriate:

- Other surgical techniques (e.g. ultrasonic debridement using microtip device, cryosurgery, and bipolar radiofrequency ablation) are safe and effective options for chronic, refractory plantar fasciitis.

American College Of Rheumatology and Arthritis Foundation

In 2019, the American College of Rheumatology and Arthritis Foundation issued a guideline on the management of osteoarthritis of the hand, hip and knee that included the following recommendation:

"A number of studies have demonstrated potential analgesic benefits with various ablation techniques but, because of the heterogeneity of techniques and controls used and lack of long term safety data, this recommendation is conditional."

Association of Extremity Nerve Surgeons
The Association of Extremity Nerve Surgeons issued practice guidelines (2020) which drew the following conclusions:

- We do not recommend ablation in the primary treatment of Intermetatarsal Nerve Entrapment ("Morton's Neuroma").
    - Alcohol injections: The literature regarding alcohol injections is equivocal. There may be some short-term positive effect, but long-term effect is poor for this therapy. Some of the literature recommends using 30% alcohol solution to get effective results. However, new research has shown the use of 30% ethanol alcohol does not create any measurable change in the histology of nerve tissue. There is also moderate risk of necrosis of surrounding tissues. As a general rule, we do not advocate the use of alcohol injections.
    - Radiofrequency ablation: Radiofrequency ablation has use in the lower extremity, but must be done with caution as this procedure has the potential for thermal necrosis of the adjacent tissues. Judicious use of fluoroscopy and other visualization techniques is advised while utilizing radiofrequency ablation...further research in this technique is needed.
    - Cryoablation: Cryoablation (cryotherapy) should be used with extreme caution, as the amount of literature in the lower extremity is limited.If cryotherapy is used, it should ideally be performed with opentechnique rather than percutaneously for optimal results.

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, cryoneurolysis, chemodenervation, peripheral nerve, genicular nerve, Morton's neuroma, RFA, chemical neurolysis

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."

In 2013, the iovera system (Myoscience, Inc) received 510K clearance from the U.S. Food and Drug Administration (FDA). It is cleared to be used to destroy tissue during surgical procedures by applying freezing cold. It can also be used to produce lesions in peripheral nervous tissue by application of cold to selected site for blocking of pain. The iovera device is not indicated for the treatment of central nervous system tissue.

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:

Adopted for Blue Advantage, January 2016
Medical Policy Group, March 2016
Available for comment March 18 through May 9, 2016
Medical Policy Group, October 2017
Available for comment November 7, 2018 through December 22, 2018
Medical Policy Group, October 2019
Medical Policy Group, December 2019: Annual Coding Update
Medical Policy Group, February 2021
Medical Policy Group, July 2021
Medical Policy Group, September 2021
Medical Policy Group, June 2022
