# Ablation of Peripheral Nerves to Treat Pain

**Medicare Advantage Medical Policy** #MA-175
Original Effective Date: 03/01/2026
Current Effective Date: 03/01/2026

*Applies to all products administered or underwritten by the Health Plan, unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

*Blue Advantage does not cover investigational or experimental services, including any drug, device, procedure, or service provided under the investigational arm of a clinical trial or study unless mandated by the Centers for Medicare and Medicaid Services. Coverage is limited to routine services for Category A IDE studies and to devices and related services for Category B IDE studies when not supplied by the trial sponsor. Approved IDE studies are posted on www.cms.gov/medicare/coverage/evidence.*

# 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 Health Plan considers radiofrequency ablation of peripheral nerves to treat pain associated with knee osteoarthritis or plantar fasciitis to be **investigational.***

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

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

Based on review of available data, the Health Plan considers ablation of peripheral nerves to treat non-cancer pain in all other conditions, with the exception of facet joint pain (per Novitas LCD L34892) to be **investigational.***

# Background/Overview

**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 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 radiofrequency (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. 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 medical policy, nerve RFA should be distinguished from RF energy applied to areas other than the nerve to cause tissue damage. Some individuals 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.

# 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 (≥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 | Pacira (formerly Myoscience) | K133453 | 2014 | GXH |
| COOLIEF®‡ Cooled Radiofrequency Kit | Avanos (formerly Halyard Health) | K163236 | 2016 | GXI |
| COOLIEF®‡ Cooled RF Probe | Avanos (formerly Halyard Health) | K163461 | 2017 | GXI |
| Rulo™‡ Radiofrequency Lesion Probe | Epimed International | K190256 | 2019 | GXI |
| Intracept Intraosseous Nerve Ablation System | Relievant Medsystems, Inc | K222281 | 2022 | GXI |
| Apex 6 Radiofrequency Lesion Generator | RF Innovations, Inc | K220122 | 2023 | GXD |

# Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

**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 radiofrequency ablation (RFA) of peripheral nerves, the evidence includes systematic reviews of randomized controlled trials (RCTs), RCTs with 24 to 200 individuals, and non-randomized comparative studies with up to 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 total knee arthroplasty (TKA). At this time, there is high heterogeneity in methods and comparators. The systematic reviews generally found that RFA had a benefit on pain, function, and composite scores compared to the control treatments at 3 and 6-month follow-up; however, most estimates were determined to have moderate to high heterogeneity. The network meta-analysis compared multiple RFA modalities and found that cooled RFA had significantly improved efficacy for pain and function through 6 months follow-up compared with traditional or pulsed RFA. The 2 multicenter trials conducted in the U.S. used anesthetic nerve block under fluoroscopic guidance and compared efficacy of cooled RFA to either steroid injection or hyaluronic acid injection. Both studies reported a responder rate of approximately 70% at 6 months, which was significantly greater than the control conditions. A small, double-blind RCT of bipolar RFA with genicular nerve block compared to genicular nerve block and sham RFA found no differences between groups for visual analog score (VAS) pain or the Western Ontario and McMaster Universities Arthritis Index (WOMAC) scores through 12 months follow-up. Given that OA of the knee is a common condition; adequately powered studies, 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 this treatment. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have knee OA or TKA who receive cryoneurolysis of peripheral nerves, the evidence includes 2 RCTs with a total of 304 participants, a comparative, retrospective cohort study of 57 participants, and a registry study of 140 individuals. Relevant outcomes include symptoms, functional outcomes, and QOL. In one RCT, cryoneurolysis in individuals 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. Another RCT investigated cryoneurolysis compared to standard of care for patients with knee OA who were planning to undergo TKA. Cryoneurolysis resulted in a lower rate of opioid consumption, a reduction in numeric rating scale (NRS) pain scores, and Knee injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS JR) functional performance at 12 weeks post discharge. The

retrospective cohort study reported superiority of cryoneruolysis on the KOOS JR and Short Form-12 item (SF-12) mental score at 1 year follow-up; no significant differences were observed on the SF-12 physical score at 1 year follow-up or for any outcome at earlier 3 month assessment. A registry study found improved pain and lowered opioid use with cryoneurolysis prior to TKA; however, functional outcomes through 6 months were similar. 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 needs to be established. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have plantar fasciitis who receive RFA of peripheral nerves, the evidence includes 2 RCTs and a meta-analysis. Relevant outcomes include symptoms, functional outcomes, and QOL. The meta-analysis pooled evidence from 2 RCTs and did not demonstrate a significant improvement in pain outcomes compared to the control group. The analysis revealed significant heterogeneity, and the overall quality of evidence was graded as low. One of the randomized trials only evaluated 17 individuals, and assessment of randomized outcomes was limited to 4 weeks post-treatment. A second RCT evaluated 36 individuals out to 12 weeks. Both trials found RFA associated with pain reduction, but 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 that the technology results in an improvement in the net health outcome.

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 of corticosteroid and local anesthetic. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

# Supplemental Information

**Practice Guidelines and Position Statements**

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

**American Academy of Orthopaedic Surgeons et al**
In 2021, the American Academy of Orthopaedic Surgeons published a clinical practice guideline, endorsed by the American Association of Hip and Knee Surgeons and the American Physical Therapy Association, on management of osteoarthritis (OA) of the knee. The guideline did not specifically address RFA or cryoneurolysis, but did include a guideline statement on denervation therapy that included various ablation techniques (e.g., RFA, cryoneurolysis, thermal ablation and chemical ablation). The guideline stated, "denervation therapy may reduce pain and improve function in patients with symptomatic osteoarthritis of the knee" (strength of recommendation: limited).

**American College of Rheumatology and Arthritis Foundation**
The 2019 Guidelines from the American College of Rheumatology and the Arthritis Foundation gave a conditional recommendation for radiofrequency ablation for the treatment of knee OA. 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).

**American Society of Pain and Neuroscience**
The American Society of Pain and Neuroscience (2021) issued consensus guidelines using U.S. Preventive Services Task Force (USPSTF) grading criteria on the use of RFA to treat various pain conditions. The guidelines stated that genicular RFA may be used for the treatment of osteoarthritis-related and post-surgical knee joint pain (Grade B), and may be selectively offered for the treatment of occipital neuralgia pain when greater or lesser nerves have been identified as the etiology of pain via diagnostic blocks (Grade C).

**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 |
|---|---|---|---|
| ***Ongoing*** | | | |
| NCT05286996 | Cryoneurolysis for TKA - a Pilot Study | 20 | Oct 2023 |
| NCT05591768 | Monopolar Versus Biopolar Radiofrequency in OA Knee Pain | 70 | Mar 2024 |
| NCT05700253 | Comparing Pain Outcomes of Treatment Strategies for Osteoarthritis Knee Patients | 76 | Sep 2024 |
| NCT05920382 | Radiofrequency Ablation for the Treatment of Post-knee Arthroplasty Chronic Pain | 86 | Dec 2027 |
| 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 | Jul 2024 |
| NCT06173830 | Comparison of the Effectiveness of Physical Therapy With Ultrasound-Guided Radiofrequency Ablation of the Genicular Nerve in Patients With Chronic Knee Osteoarthritis | 68 | Apr 2024 |
| NCT06094660 | Patients With Knee Pain Caused by Osteoarthritis: Comparison of Conservative Medical Management With RadioFrequency Ablation or Chemical Neurolysis of the Genicular Nerves With Phenol | 192 | Nov 2026 |
| ***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 (terminated due to finances) |
| NCT03818022 | Effectiveness of Preoperative Cryoneurolysis (Iovera) for Postoperative Pain Control in Total Knee Arthroplasty | 100 | Dec 2020 (study withdrawn ) |

| | | | |
|---|---|---|---|
| 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 | 153 | Oct 2022 |

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

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# Policy History

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# Coding

*The five character codes included in the Health Plan Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2025 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.*

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*Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.*



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

| Code Type | Code |
|---|---|
| CPT | 0440T, 0441T, 0442T, 64405, 64450, 64454, 64624, 64632, 64640 |
| HCPCS | C9809 |
| ICD-10 Diagnosis | C00-D49.9, M17.0-M17.9, M72.2 |

*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 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.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services

at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

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

**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Health Plan recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

**NOTICE:** Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

**NOTICE:** All codes listed on the Medical Policy require prior authorization. This ensures appropriate utilization and alignment with current clinical guidelines.

**Medicare Advantage Members**
Established coverage criteria for Medicare Advantage members can be found in Medicare coverage guidelines in statutes, regulations, National Coverage Determinations (NCD)s, and Local Coverage Determinations (LCD)s. To determine if a National or Local Coverage Determination addresses coverage for a specific service, refer to the Medicare Coverage Database at the following link: https://www.cms.gov/medicare-coverage-database/search.aspx. You may wish to review the Guide to the MCD Search here: https://www.cms.gov/medicare-coverage-database/help/mcd-benehelp.aspx.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, internal coverage criteria may be developed. This policy is to serve as the summary of evidence, a list of resources and an explanation of the rationale that supports the adoption of this internal coverage criteria.

**InterQual®**
Interqual® is utilized as a source of medical evidence to support medical necessity and level of care decisions. InterQual® criteria are intended to be used in connection with the independent

professional medical judgment of a qualified health care provider. InterQual® criteria are clinically based on best practice, clinical data, and medical literature. The criteria are updated continually and released annually. InterQual® criteria are a first-level screening tool to assist in determining if the proposed services are clinically indicated and provided in the appropriate level or whether further evaluation is required. The utilization review staff does the first-level screening. If the criteria are met, the case is approved; if the criteria are not met, the case is referred to the medical director.