

Health Plan of Washington

#### MEDICAL POLICY – 7.01.565

# Ablation of Peripheral Nerves to Treat Pain

BCBSA Ref. Policy: 7.01.154

Effective Date: Dec. 1, 2024 RELATED MEDICAL POLICIES:

Last Revised: Jan. 1, 2025 7.01.147 Ablation Procedures for Peripheral Neuromas

Replaces: 7.01.154 7.01.563 Ablative Treatments for Occipital Neuralgia, Chronic Headaches, and

Atypical Facial Pain

7.01.564 Pulsed Radiofrequency

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#### Introduction

Peripheral nerves are the nerves that connect the brain and spinal cord to the body. Nerves transmit sensation, including pain. Newer techniques to try to treat pain arising from the peripheral nerves involve trying to destroy a small part of the nerve. The goal is to try to interrupt pain signals. All techniques to destroy parts of the peripheral nerve, including using devices that create heat or extreme cold and devices that combine heat and cooled water are investigational. That means they need more study to see if they are effective.

**Note:** The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

## **Policy Coverage Criteria**

Service	Investigational
Radiofrequency ablation of	Radiofrequency ablation of peripheral nerves to treat pain
peripheral nerves	associated with knee osteoarthritis or plantar fasciitis is
	considered investigational.
	Radiofrequency ablation of peripheral nerves to treat pain associated with occipital neuralgia or cervicogenic headache is considered investigational.
Cryoneurolysis of	Cryoneurolysis of peripheral nerves to treat pain associated
peripheral nerves	with knee osteoarthritis or total knee arthroplasty is considered investigational.
	Cryoneurolysis of peripheral nerves to treat pain associated with occipital neuralgia or cervicogenic headache is considered investigational.
Chemical neurolysis (aka	Chemical neurolysis (e.g., alcohol, phenol, glycerol) of the
chemical denervation,	peripheral nerves to treat pain associated with knee
chemical ablation,	osteoarthritis or plantar fasciitis is considered investigational.
chemodenervation)	
Ablation of peripheral	Ablation of peripheral nerves to treat pain is considered
nerves	investigational in all other conditions, including but not
	limited to the following: (with the exception of facet joint pain
	(see Related Policies)
	Intercostal neuralgia

# Coding

Code	Description
СРТ	
0441T	Ablation, percutaneous, cryoablation, includes imaging guidance; lower extremity distal/peripheral nerve
64620	Destruction by neurolytic agent, intercostal nerve
64624	Destruction by neurolytic agent, genicular nerve branches including imaging guidance, when performed



Code	Description
64632	Destruction by neurolytic agent; plantar common digital nerve
64640	Destruction by neurolytic agent; other peripheral nerve or branch

**Note**: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Code	Description
HCPCS	
C9808	Nerve cryoablation probe (e.g., cryoice, cryosphere, cryosphere max, cryoice cryosphere, cryoice cryo2), including probe and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with section 4135 of the caa, 2023)
C9809	Cryoablation needle (e.g., iovera system), including needle/tip and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with section 4135 of the caa, 2023)

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# **Related Information**

N/A

#### **Evidence Review**

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



#### **Background**

#### Intercostal Neuralgia

Intercostal neuralgia is a neuropathic pain involving the intercostal nerves and manifests as sharp, shooting, tingling, or burning pain in the thorax affecting the chest wall and upper trunk. Intercostal nerves are peripheral nerves that are below the ribs and so pain may worsen with deep inspiration. Intercostal neuralgia is usually caused by some type of irritation, inflammation, or entrapment of the intercostal nerves which may be due to trauma, thoracotomy surgery, or a viral infection, such as shingles.

#### **Treatment**

Topical medications such as capsaicin cream or lidocaine gels may provide temporary relief. Systemic medications such as gabapentin may be tried as well as an intercostal nerve block if relief is not obtained by the oral or topical medications. RFA (pulsed or non-pulsed) has been proposed as a treatment option.

#### **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 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 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.<sup>1</sup> It does produce some degree of nerve destruction, but 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 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

Туре	Procedure	Tissue	Key Differences
		Temperature	
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)<sup>2</sup>

## 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 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.

## **Chemical Neurolysis**

Chemical neurolysis, also known as chemical ablation, chemodenervation, or chemical denervation, is the application of a chemical destructive agent (e.g., phenol, ethyl alcohol, glycerol, or hypertonic saline) to a nerve to create a long-lasting or permanent interruption of neural transmission. It is usually used to relieve pain. This treatment is proposed for peripheral

nerve pain relief for plantar fasciitis or knee osteoarthritis. However, there is no published peerreviewed evidence for the use of chemical neurolysis for the treatment of plantar fasciitis.

Chemical neurolysis using alcohol or phenol in the treatment of chronic knee osteoarthritis has been shown to provide pain relief (a decrease in the Western Ontario and McMaster Universities Arthritis Index (WOMAC) or increase in the KOOS scores) compared to baseline in a prospective open-label cohort, observational retrospective cohort study, case reports, and a comparison study to RFA, all with small numbers of participants and limited follow-up of three to six months. Although these results are promising, they need to be replicated in well-designed randomized control trials with larger sample sizes and longer term follow-up to determine the efficacy of chemical neurolysis in the treatment of chronic knee osteoarthritis.

#### **Summary of Evidence**

For individuals who have knee osteoarthritis (OA) who receive 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. 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 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 two multi-center trials conducted in the United States (US). 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 two RCTs with a total of 304 participants, a comparative, retrospective cohort study of 57 participants, and a registry study of 140 individuals. The 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 cryoneurolysis on the KOOS JR and Short Form-12 item (SF-12) mental score at one year follow-up; no significant differences were observed on the SF-12 physical score at one year follow-up or for any outcome at earlier three-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. YeSeveral 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 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 two RCTs and a meta-analysis. The 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 four weeks posttreatment. 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. 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, individual-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.

For individuals who have intercostal neuralgia who receive RFA or cryoneurolysis of intercostal nerves, the evidence includes prospective case series/case reports. Most cases are limited by small sample size and short-term follow-up. While some studies demonstrated reduced pain with cryoneurolysis, the studies were limited as well by small sample size and short-term follow-up. Randomized controlled trials with larger sample sizes and longer term follow-up are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

#### **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			
NCT05286996	Cryoneurolysis for TKA - a Pilot Study	20	Oct 2023
NCT05591768	Monopolar Versus Bipolar Radiofrequency in OA Knee Pain	70	Mar 2024
NCT05700253	Comparing Pain Outcomes of Treatment Strategies for Osteoarthritis Knee Patients	76	Sep 2024



NCT No.	Trial Name	Planned	Completion
		Enrollment	Date
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	RFA or Chemical Neurolysis of the Genicular Nerves Compared to Conservative Treatment for Knee Pain Caused by OA (RADIOPHENOL)	192	Nov 2026
NCT04472702	Fluoroscopic Versus Ultrasound Guidance for Cooled Radiofrequency Ablation of Geniculate Nerves in Knee Osteoarthritis: A Randomized Control Trial	90	Oct 2025
NCT06N000709	Comparison Between Ultrasound-Guided Genicular Nerve Phenol Neurolysis and Intra-articular Steroid Injections	40	July 2024
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 (lovera) for Postoperative Pain Control in Total Knee Arthroplasty	100	Dec 2020 (unknown)
NCT04145011 <sup>a</sup>	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	Aug 2022

NCT: national clinical trial. <sup>a</sup> Industry sponsored or partially sponsored.

#### **Practice Guidelines and Position Statements**

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.



Guidelines or position statements will be considered for inclusion 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. 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 OA of the knee.<sup>19</sup> 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.<sup>40</sup> 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.

#### 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.<sup>41</sup> 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 US Preventive Services Task Force (USPSTF) grading criteria on the use of RFA to treat various pain

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conditions.<sup>42</sup> 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).

#### **Medicare National Coverage**

There is no national coverage determination.

#### **Regulatory Status**

A number of RF generators and probes for the peripheral nervous system have been cleared for marketing by the US Food and Drug Administration (FDA) through the 510(k) process. Some examples are listed in **Table 3**.

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 3. 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 (Halyard Health)	K163236	2016	GXI

Device	Manufacturer	Clearance	Date	FDA Product Code
COOLIEF Cooled RF Probe	Avanos (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

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# History

Date	Comments
08/01/18	New policy, approved July 10, 2018. This policy is replacing policy 7.01.154. Policy created with literature review through June 2018. Ablative procedures of peripheral nerves to treat pain for all indications, including but not limited to pain associated with plantar fasciitis or knee osteoarthritis, is considered investigational for the following treatments: cooled radiofrequency ablation (such as, but not limited to COOLIEF), cryoneuroloysis (cryoablation, cryotherapy, cryoanalgesia), or radiofrequency ablation (RFA).
12/01/19	Annual Review, approved November 6, 2019. Policy updated with literature review through July 2019; references added. Title changed to "Ablation of Peripheral Nerves to Treat Pain" from "Ablative Procedures of Peripheral Nerves to Treat Pain". Policy statements unchanged except for minor edits only.
01/01/20	Coding update, added CPT code 64624 (new code effective 1/1/20).
08/01/20	Policy renumbered from 7.01.565 and replaced with 7.01.154, approved July 14, 2020., effective August 1, 2020. Policy statements remain unchanged; CPT codes 0441T, 64624, & 64999 removed.
12/01/20	Interim Review, approved November 3, 2020. Policy updated with literature review through July 2020; references added. Cryoneurolysis was added to the investigational statement on occipital neuralgia or cervicogenic headache, other statements unchanged. Added CPT codes 64624 and 0441T.
12/01/21	Annual Review, approved November 9, 2021. Policy updated with literature review through July 21, 2021; references added. Policy statements unchanged. Listed other conditions considered investigational (intercostal neuralgia) for clarity. Added CPT code 64620.
12/01/22	Annual Review, approved November 7, 2022. Policy updated with literature review through July 14, 2022; references added. Minor editorial refinements to policy statements; intent unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
12/01/23	Annual Review, approved November 6, 2023. Policy updated with literature review through July 27, 2023; references added. Policy statements unchanged.
03/01/24	Policy renumbered from 7.01.154 and replaced with 7.01.565 Ablation of Peripheral Nerves to Treat Pain, approved February 13. 2024. Added policy statement that chemical neurolysis of the peripheral nerves to treat pain associated with knee



Date	Comments
	osteoarthritis or plantar fasciitis is considered investigational. References added. Added CPT code 64632.
12/01/24	Annual Review, approved November 25, 2024. Policy updated with literature review through July 23, 2024; references added. Policy statements unchanged.
01/01/25	Coding update. Added new HCPCS codes C9808 and C9809.

**Disclaimer**: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2025 Premera All Rights Reserved.

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