

Blue Cross Blue Shield of Massachusetts is an Independent Licenses of the Blue Cross and Blue Shield Association

## Medical Policy Ablation of Peripheral Nerves to Treat Pain

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## Policy Number: 794

BCBSA Reference Number: 7.01.154 (For Plan internal use only) NCD/LCD: N/A

## **Related Policies**

None

## **Policy**

# Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue<sup>SM</sup> and Medicare PPO Blue<sup>SM</sup> Members

Radiofrequency ablation of peripheral nerves to treat pain associated with knee osteoarthritis or plantar fasciitis is considered **INVESTIGATIONAL**.

Cryoneurolysis of peripheral nerves to treat pain associated with knee osteoarthritis or total knee arthroplasty is considered **INVESTIGATIONAL**.

Radiofrequency ablation or cryoneurolysis of peripheral nerves to treat pain associated with occipital neuralgia or cervicogenic headache is considered **INVESTIGATIONAL**.

Ablation of peripheral nerves to treat pain is considered **<u>INVESTIGATIONAL</u>** in all other conditions, with the exception of facet joint pain.

## **Prior Authorization Information**

Inpatient

 For services described in this policy, precertification/preauthorization <u>IS REQUIRED</u> for all products if the procedure is performed <u>inpatient</u>.

Outpatient

 For services described in this policy, see below for products where prior authorization <u>might be</u> <u>required</u> if the procedure is performed <u>outpatient</u>.

	Outpatient
Commercial Managed Care (HMO and POS)	This is <b>not</b> a covered service.
Commercial PPO and Indemnity	This is <b>not</b> a covered service.

Medicare HMO Blue <sup>sM</sup>	This is <b>not</b> a covered service.
Medicare PPO Blue <sup>sm</sup>	This is <b>not</b> a covered service.

## CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

According to the policy statement above, the following CPT codes are considered investigational for the conditions listed for <u>Commercial Members: Managed Care (HMO and POS), PPO,</u> Indemnity, Medicare HMO Blue and Medicare PPO Blue:

#### **CPT Codes**

CPT codes:	Code Description
64640	Destruction by neurolytic agent; other peripheral nerve or branch

## **Description**

#### **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.<sup>1,</sup> 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 individuals have been treated for plantar fasciitis with a fasciotomy procedure using an RF device. This procedure does not ablate a specific nerve.

Туре	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.

#### Table 1. Types of Radiofrequency Ablation

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.
			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 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.

#### Summary

#### 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 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 than 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; study in a larger number of individuals, 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 total knee arthroplasty (TKA) who receive cryoneurolysis of peripheral nerves, the evidence includes 2 RCTs with a total of 304 participants and a comparative, retrospective cohort study of 57 participants. Relevant outcomes include symptoms, functional outcomes, and QOL. 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 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. 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 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.

Date	Action
11/2023	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
10/2022	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
10/2021	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
2/2021	Annual policy review. Cryoneurolysis was added to the investigational statement on occipital neuralgia or cervicogenic headache; other statements unchanged. Effective 2/1/2021.
10/2019	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
2/2019	<ul> <li>Annual policy review. New investigational indications described:</li> <li>Cryoneurolysis for knee osteoarthritis or total knee arthroplasty</li> <li>Radiofrequency ablation for occipital neuralgia and cervicogenic headache. Title changed. Effective 2/1/2019.</li> </ul>
7/2016	New medical policy describing investigational indications. Effective 7/1/2016.

#### **Policy History**

## Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information: <u>Medical Policy Terms of Use</u> <u>Managed Care Guidelines</u> <u>Indemnity/PPO Guidelines</u> <u>Clinical Exception Process</u> <u>Medical Technology Assessment Guidelines</u>

## References

- Chua NH, Vissers KC, Sluijter ME. Pulsed radiofrequency treatment in interventional pain management: mechanisms and potential indications-a review. Acta Neurochir (Wien). Apr 2011; 153(4): 763-71. PMID 21116663
- Oladeji LO, Cook JL. Cooled Radio Frequency Ablation for the Treatment of Osteoarthritis-Related Knee Pain: Evidence, Indications, and Outcomes. J Knee Surg. Jan 2019; 32(1): 65-71. PMID 30396206
- Jamison DE, Cohen SP. Radiofrequency techniques to treat chronic knee pain: a comprehensive review of anatomy, effectiveness, treatment parameters, and patient selection. J Pain Res. 2018; 11: 1879-1888. PMID 30271194
- 4. Michael JW, Schluter-Brust KU, Eysel P. The epidemiology, etiology, diagnosis, and treatment of osteoarthritis of the knee. Dtsch Arztebl Int. Mar 2010; 107(9): 152-62. PMID 20305774
- Chen AF, Mullen K, Casambre F, et al. Thermal Nerve Radiofrequency Ablation for the Nonsurgical Treatment of Knee Osteoarthritis: A Systematic Literature Review. J Am Acad Orthop Surg. May 01 2021; 29(9): 387-396. PMID 32701684
- 6. Choi WJ, Hwang SJ, Song JG, et al. Radiofrequency treatment relieves chronic knee osteoarthritis pain: a double-blind randomized controlled trial. Pain. Mar 2011; 152(3): 481-487. PMID 21055873
- Sari S, Aydin ON, Turan Y, et al. Which one is more effective for the clinical treatment of chronic pain in knee osteoarthritis: radiofrequency neurotomy of the genicular nerves or intra-articular injection?. Int J Rheum Dis. Oct 2018; 21(10): 1772-1778. PMID 27515095
- Ray D, Goswami S, Dasgupta SR, Ray S, Basu S. Intra-articular hyaluronic acid injection versus RF ablation of genicular nerve for knee osteoarthritis pain: A randomized open-label, clinical study. Indian J Pain. 2018; 32:36-9.
- Davis T, Loudermilk E, DePalma M, et al. Prospective, Multicenter, Randomized, Crossover Clinical Trial Comparing the Safety and Effectiveness of Cooled Radiofrequency Ablation With Corticosteroid Injection in the Management of Knee Pain From Osteoarthritis. Reg Anesth Pain Med. Jan 2018; 43(1): 84-91. PMID 29095245
- El-Hakeim EH, Elawamy A, Kamel EZ, et al. Fluoroscopic Guided Radiofrequency of Genicular Nerves for Pain Alleviation in Chronic Knee Osteoarthritis: A Single-Blind Randomized Controlled Trial. Pain Physician. Mar 2018; 21(2): 169-177. PMID 29565947
- 11. Shen WS, Xu XQ, Zhai NN, et al. Radiofrequency Thermocoagulation in Relieving Refractory Pain of Knee Osteoarthritis. Am J Ther. Nov/Dec 2017; 24(6): e693-e700. PMID 26938761
- 12. Xiao L, Shu F, Xu C, et al. Highly selective peripheral nerve radio frequency ablation for the treatment of severe knee osteoarthritis. Exp Ther Med. Nov 2018; 16(5): 3973-3977. PMID 30344675
- Liu J, Wang T, Zhu ZH. Efficacy and safety of radiofrequency treatment for improving knee pain and function in knee osteoarthritis: a meta-analysis of randomized controlled trials. J Orthop Surg Res. Jan 15 2022; 17(1): 21. PMID 35033150
- Wu L, Li Y, Si H, et al. Radiofrequency Ablation in Cooled Monopolar or Conventional Bipolar Modality Yields More Beneficial Short-Term Clinical Outcomes Versus Other Treatments for Knee Osteoarthritis: A Systematic Review and Network Meta-Analysis of Randomized Controlled Trials. Arthroscopy. Jul 2022; 38(7): 2287-2302. PMID 35157969
- McCormick ZL, Reddy R, Korn M, et al. A Prospective Randomized Trial of Prognostic Genicular Nerve Blocks to Determine the Predictive Value for the Outcome of Cooled Radiofrequency Ablation for Chronic Knee Pain Due to Osteoarthritis. Pain Med. Aug 01 2018; 19(8): 1628-1638. PMID 29300971
- Davis T, Loudermilk E, DePalma M, et al. Twelve-month analgesia and rescue, by cooled radiofrequency ablation treatment of osteoarthritic knee pain: results from a prospective, multicenter, randomized, cross-over trial. Reg Anesth Pain Med. Feb 16 2019. PMID 30772821
- Hunter C, Davis T, Loudermilk E, et al. Cooled Radiofrequency Ablation Treatment of the Genicular Nerves in the Treatment of Osteoarthritic Knee Pain: 18- and 24-Month Results. Pain Pract. Mar 2020; 20(3): 238-246. PMID 31605667
- Chen AF, Khalouf F, Zora K, et al. Cooled radiofrequency ablation provides extended clinical utility in the management of knee osteoarthritis: 12-month results from a prospective, multi-center, randomized, cross-over trial comparing cooled radiofrequency ablation to a single hyaluronic acid injection. BMC Musculoskelet Disord. Jun 09 2020; 21(1): 363. PMID 32517739

- American Academy of Orthopaedic Surgeons. Management of Osteoarthritis of the Knee (Non-Arthroplasty) Evidence-Based Clinical Practice Guideline. August 31, 2021. Accessed August 30, 2023.
- Lyman J, Khalouf F, Zora K, et al. Cooled radiofrequency ablation of genicular nerves provides 24-Month durability in the management of osteoarthritic knee pain: Outcomes from a prospective, multicenter, randomized trial. Pain Pract. Jul 2022; 22(6): 571-581. PMID 35716058
- 21. Elawamy A, Kamel EZ, Mahran SA, et al. Efficacy of Genicular Nerve Radiofrequency Ablation Versus Intra-Articular Platelet Rich Plasma in Chronic Knee Osteoarthritis: A Single-Blind Randomized Clinical Trial. Pain Physician. Mar 2021; 24(2): 127-134. PMID 33740345
- 22. Malaithong W, Tontisirin N, Seangrung R, et al. Bipolar radiofrequency ablation of the superomedial (SM), superolateral (SL) and inferomedial (IM) genicular nerves for chronic osteoarthritis knee pain: a randomized double-blind placebo-controlled trial with 12-month follow-up. Reg Anesth Pain Med. Dec 21 2022; 48(4): 151-60. PMID 36543391
- Kapural L, Minerali A, Sanders M, et al. Cooled Radiofrequency Ablation Provides Prolonged Pain Relief Compared to Traditional Radiofrequency Ablation: A Real-World, Large Retrospective Clinical Comparison from a Single Practice. J Pain Res. 2022; 15: 2577-2586. PMID 36068792
- Wu BP, Grits D, Foorsov V, et al. Cooled and traditional thermal radiofrequency ablation of genicular nerves in patients with chronic knee pain: a comparative outcomes analysis. Reg Anesth Pain Med. Aug 03 2022. PMID 35922077
- 25. McCormick ZL, Patel J, Conger A, et al. The Safety of Genicular Nerve Radiofrequency Ablation. Pain Med. Feb 23 2021; 22(2): 518-519. PMID 33517427
- Radnovich R, Scott D, Patel AT, et al. Cryoneurolysis to treat the pain and symptoms of knee osteoarthritis: a multicenter, randomized, double-blind, sham-controlled trial. Osteoarthritis Cartilage. Aug 2017; 25(8): 1247-1256. PMID 28336454
- 27. Mihalko WM, Kerkhof AL, Ford MC, et al. Cryoneurolysis before Total Knee Arthroplasty in Patients With Severe Osteoarthritis for Reduction of Postoperative Pain and Opioid Use in a Single-Center Randomized Controlled Trial. J Arthroplasty. May 2021; 36(5): 1590-1598. PMID 33279353
- 28. Lung BE, Karasavvidis T, Sharma AK, et al. Cryoneurolysis Is a Safe, Effective Modality to Improve Rehabilitation after Total Knee Arthroplasty. Life (Basel). Aug 29 2022; 12(9). PMID 36143381
- 29. Gabriel RA, Ilfeld BM. Novel Methodologies in Regional Anesthesia for Knee Arthroplasty. Anesthesiol Clin. Sep 2018; 36(3): 387-401. PMID 30092936
- Guimarães JS, Arcanjo FL, Leporace G, et al. Effects of therapeutic interventions on pain due to plantar fasciitis: A systematic review and meta-analysis. Clin Rehabil. Jun 2023; 37(6): 727-746. PMID 36571559
- Wu YT, Chang CY, Chou YC, et al. Ultrasound-Guided Pulsed Radiofrequency Stimulation of Posterior Tibial Nerve: A Potential Novel Intervention for Recalcitrant Plantar Fasciitis. Arch Phys Med Rehabil. May 2017; 98(5): 964-970. PMID 28209507
- 32. Landsman AS, Catanese DJ, Wiener SN, et al. A prospective, randomized, double-blinded study with crossover to determine the efficacy of radio-frequency nerve ablation for the treatment of heel pain. J Am Podiatr Med Assoc. Jan-Feb 2013; 103(1): 8-15. PMID 23328847
- 33. Kurtoglu A, Kochai A, Inanmaz ME, et al. Effectiveness of radiofrequency ablation for treatment of plantar fasciitis. Medicine (Baltimore). Mar 25 2022; 101(12): e29142. PMID 35357356
- Cozzarelli J, Sollitto RJ, Thapar J, et al. A 12-year long-term retrospective analysis of the use of radiofrequency nerve ablation for the treatment of neurogenic heel pain. Foot Ankle Spec. Dec 2010; 3(6): 338-46. PMID 20817845
- Grandhi RK, Kaye AD, Abd-Elsayed A. Systematic Review of Radiofrequency Ablation and Pulsed Radiofrequency for Management of Cervicogenic Headaches. Curr Pain Headache Rep. Feb 23 2018; 22(3): 18. PMID 29476360
- 36. Ducic I, Felder JM, Fantus SA. A systematic review of peripheral nerve interventional treatments for chronic headaches. Ann Plast Surg. Apr 2014; 72(4): 439-45. PMID 24374395
- 37. Kvarstein G, Hogstrom H, Allen SM, et al. Cryoneurolysis for cervicogenic headache a double blinded randomized controlled study. Scand J Pain. Dec 18 2019; 20(1): 39-50. PMID 31675351
- Kolasinski SL, Neogi T, Hochberg MC, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Management of Osteoarthritis of the Hand, Hip, and Knee. Arthritis Rheumatol. Feb 2020; 72(2): 220-233. PMID 31908163

- Schneider HP, Baca JM, Carpenter BB, et al. American College of Foot and Ankle Surgeons Clinical Consensus Statement: Diagnosis and Treatment of Adult Acquired Infracalcaneal Heel Pain. J Foot Ankle Surg. Mar 2018; 57(2): 370-381. PMID 29284574
- Lee DW, Pritzlaff S, Jung MJ, et al. Latest Evidence-Based Application for Radiofrequency Neurotomy (LEARN): Best Practice Guidelines from the American Society of Pain and Neuroscience (ASPN). J Pain Res. 2021; 14: 2807-2831. PMID 34526815