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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Genicular Nerve Block for Knee Pain

- Coolief Cooled Radiofrequency Ablation for Knee Pain
- Genicular Nerve Ablation
- Genicular Nerve Ablation for Knee Osteoarthritis
- Genicular Nerve Neurolysis
- Thermal Genicular Nerve Radiofrequency Ablation (GNRFA)

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Nerve Blockade for Treatment of Chronic Pain and Neuropathy (L35457)
Local Coverage Article	Billing and Coding: Nerve Blockade for Treatment of Chronic Pain and Neuropathy (A52725)
KPWA Medical Policy	Due to the absence of a NCD, LCD, or other coverage guidance, KPWA has chosen to use their own Clinical Review Criteria, “Genicular Nerve Ablation for Knee Osteoarthritis” for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

Service	Criteria
Neurolysis, Genicular Nerve • Coolief Cooled Radiofrequency Ablation for Knee Pain • Genicular Nerve Ablation for Knee Osteoarthritis	MCG* A-1047 For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access
Thermal Genicular Nerve Radiofrequency Ablation (GNRFA)	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies. This procedure requires review if the ablation is being done as an alternative to surgery. ***Note:** Genicular nerve ablation can also be done during surgical procedures for anesthesia, such as total knee replacement or ligament and tendon repair and does not require review for those circumstances.

Back to Top

If requesting review for these services, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Hayes Technology Assessment

A nerve block is a form of regional anesthesia. The genicular nerve is a sensory nerve that innervates the knee. Genicular nerve blocks are performed to relieve pain in patients who may not be candidates for knee surgery or in advance of total knee replacement surgery. In a genicular nerve block procedure, an anesthetic agent, (e.g., lidocaine, bupivacaine, etc.), is injected on the genicular nerve. Genicular nerve blocks may be performed as a diagnostic step to ensure that blocking the nerve provides pain relief. In these cases, after a genicular nerve block demonstrates pain relief, genicular neurotomy or genicular nerve ablation may be performed as a more permanent solution.

Hayes Rating: D^{2-} Insufficient Evidence: For use genicular nerve blocks combined with a corticosteroid or alone for treatment of pain and loss of function associated with osteoarthritis of the knee or persistent chronic pain following total knee arthroplasty.

This Rating reflects a very-low-quality body of evidence that does not consistently provide proof of benefit. Substantial uncertainty remains due to conflicting evidence and limited follow-up.

Hayes. Hayes Technology Assessment. *Genicular Nerve Block for the Management of Knee Pain*. Dallas, TX: Hayes; June 24, 2020. Retrieved July 13, 2020, from https://evidence.hayesinc.com/report/htb.genicular3323

Background

Osteoarthritis (OA) of the knee is a common chronic degenerative joint disorder and one of the leading causes of physical impairment and decline in the quality of life in older adults in the US and worldwide. It is a progressive condition in which the cartilage between bones in the joint wears away leaving the bones to rub more closely against one another resulting in pain, swelling, stiffness, and loss of function.

Conservative treatment for symptomatic knee OA includes physical therapy, aquatic therapy, weight loss, oral or topical non-steroidal anti-inflammatory drugs, bracing, and orthosis. Intraarticular injection of corticosteroids, hyaluronic acid, and other treatment modalities have also been used to alleviate the pain however, the analgesic effect is short-term with the steroid injection and unproven with some other therapies. Overall, conservative measures may relieve symptoms and improve function in some patients, but they do not restore the normal knee function, reverse the damage, or slow the progression of the disease. Knee joint arthroplasty is the most effective treatment for relieving pain and improving the knee function in patients with severe knee OA, but it is an invasive surgery that may be associated with medical and postsurgical complications. In addition, older individuals with comorbidities might not be good candidates for the surgery and others may be unable or unwilling to undergo the operation (El-Hakiem 2018, Jamison 2018, Erdem 2019).

Over the years, researches have been investigating alternative less invasive therapies for the treatment of patients with refractory knee OA. Several existing and new therapies have thus been or are being evaluated for the alleviation of chronic pain in patients with musculoskeletal disorders including knee OA.

Radiofrequency ablation (RFA) is one of these modalities considered for the treatment of patients with symptomatic knee. RFA is a nonsurgical, minimally invasive procedure that uses radio waves to create an electrical current through the body. The created current delivers heat to the targeted tissue resulting in its destruction, Ablation of the nerve tissues disrupts the ability of the nerve to send pain signals. RFA was first used by a German surgeon in 1931 to treat trigeminal neuralgia and three decades later, the first radiofrequency ablation commercial machine was introduced in the market. The indications of RFA have expanded over the years and is currently being used for the treatment of a variety of medical conditions including chronic low back

Back to Top

pain, cardiac arrhythmias, tumors, varicose veins, obstructive sleep apnea, and several other disorders. More recently RFA gained popularity in alleviating pain due to musculoskeletal disorders. In 2010 Choi and colleagues investigated its use for OA knee pain based on the theory that blocking the sensory innervation for a painful structure will result in pain relief (Choi 2011, Gupta 2017).

The knee joint is innervated by the articular branches of various nerves including the femoral, common peroneal, saphenous, tibial and obturator nerves known as the genicular nerves. Several of these nerves can be approached percutaneously under fluoroscopic or ultrasound guidance to identify the anatomical landmarks around the knee and locate the targeted genicular nerves (Choi 2011, Gupta 2017).

Conventional RFA treatment uses a high temperature probe to impair/destroy the targeted nerve fibers that carry the pain signals to the brain. The high heat originating from the RF probe may potentially damage adjacent tissues as the temperature reaches 70-90^{o}C. In addition, it has been reported that the lesion produced by the heat is limited in size and thus may not reach some target areas. To overcome these limitations, two new techniques the (pulsed RFA (p-RFA) and the cooled RFA (C-RFA) have been investigated for GNRFA (Oladeji 2019).

Coolief™ RFA treatment (the focus of the current review) also known as cooled radiofrequency ablation or neurotomy, follows the same method as the conventional RFA neuronal tissue damage, but uses water-cooled technology to safely impair or destroy the sensory nerves. A radiofrequency generator transmits a small current of RF thermal energy through an insulated electrode placed within the tissue. Sterile water circulates continuously inside the Coolief™ probe to cool it and regulate its temperature while it delivers the RF thermal energy. According the investigators of the technology, the circulating water modulates the thermal heat in the tissue to ≈60^{o}C and alters the size, shape, and projection of the lesions compared to conventional RFA. It is postulated that delivering RF energy through water-cooled electrode enables more RF energy to be safely delivered to the targeted nerves creating larger spherical -shaped lesion that increases the area of denervation and minimizes the risk of excessive heating and damaging the adjacent tissues (Gupta 2017, Oladeji 2019, AVANOS report 2019).

The Cooled RFA (CRFA) procedure is performed in an outpatient setting under local anesthesia, conscious sedation and fluoroscopic or ultrasound guidance. It is performed in 2 stages (McCormick 2017, Davis 2018):

1. A diagnostic genicular nerves block procedure: After positioning the patient in a supine position on a fluoroscopy table, a 25-guage 2.5-3.5-inch Whitacre needle is placed under fluoroscopic guidance at three unique anatomic sites to block the superior lateral, superior medial, and the inferior medical genicular nerves. Accurate placement of the needle is confirmed using fluoroscopy in the AP and lateral planes, then lidocaine is injected in order to numb each genicular nerve. Patients with a positive response (≥50% reduction in pain in the 24hrs following injection) are offered radiofrequency ablation (stage 2) for a more sustained response.
2. Genicular nerve radiofrequency ablation procedure performed under fluoroscopic visualization of the anatomical landmarks for probe placement. The patient is positioned supine on the fluoroscopy table (similar to the diagnostic nerve block procedure), and given conscious sedation, and local anesthesia at each of the 3 anatomic sites for RFA. An introducer needle (50 or 70 mm 17-guage) is then placed to lesion the 3 genicular nerves after which the internally cooled RFA electrode (Coolief, 4-mm, 18-guage active tip) is inserted in the introducer needle and its positioning verified with AP and lateral fluoroscopic views. Lidocaine is then injected through the introducer needle to numb the region before the thermal ablation. Each target undergoes CRFA for 150 seconds at a set temperature of 60^{o}C which produces tissue temperature of 77^{o}C-80^{o}C surrounding the electrode. The needles are then removed, and the patients allowed to recover before they are discharged to home.

Medical Technology Assessment Committee (MTAC)

Coolief Cooled Radiofrequency Ablation for Knee and Hip Pain
10/14/2019: MTAC REVIEW

Evidence Conclusion:

- There is insufficient published evidence to determine the safety and efficacy of cooled RFA treatment for the management of moderate to severe chronic OA knee pain that is refractory to conservative therapy in patients who are not candidates for surgery.
- There is low to moderate quality evidence from one relatively small RCT showing that genicular RFA using Coolief™ system, performed prior to total knee replacement surgery had no significant effect compared to sham ablation, on reducing post-operative pain, use of pain medications, or improving function.

Back to Top

Articles: The literature search for studies on cooled genicular never ablation for symptomatic knee osteoarthritis, published after the March 2018 INCT review yielded less than 10 articles including a report on the 12 months follow-up results of the pivotal RCT (Davis et al 2019). The search also identified a RCT comparing the effect of CRFA versus a sham therapy performed prior to TKA, on postoperative pain. Among the other recently published articles was a randomized trial that evaluated the utility of genicular nerve blocks to predict the outcome of genicular nerve cooled radiofrequency ablation in patients with osteoarthritis (McCormick et al, 2018); a cost-effective analysis of CRFA based on Davis et al's trial (Desai 2019); one observational study with no control or comparison group (House et al, 2019), three technical reports, and a case presentation.
See Evidence Table.

The use of Coolief Cooled Radiofrequency Ablation for Knee and Hip Pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Thermal Genicular Nerve Radiofrequency Ablation (GNRFA) for continued chronic knee pain post total knee replacement
07/13/2020: MTAC REVIEW

Evidence Conclusion:
There is insufficient published evidence to support the use of genicular RFA for reducing postoperative pain after total knee preplacement surgery.

Articles:
There is a paucity of published literature evaluating the use of thermal genicular neve ablation for the management of persistent pain after a total knee replacement surgery. The only published randomized controlled trial identified by the literature search was a small double-blinded trial that compared the efficacy of genicular nerves RFA versus analgesic block with corticosteroids in alleviating pain and improving function and QoL in patients with pain after a TKA (Qudsi-Sinclair S et al, 2017 (Evidence Table 1).

This trial was randomized, controlled, and double-blinded, but had its limitations including the small sample size study (N=30 randomized and 28 included in the analysis), lack of power calculations, randomization method not discussed, and subjective outcomes. There were also some baseline differences between the study groups e.g. their ages, duration of a pain, knee function, QoL, and the use of medication including opioids before the intervention. The differences were not significant, but the numbers may be too small to detect statistically significant differences.

The overall results of the study show the following (details in the evidence table)

- A significant reduction in pain scores in each of the treatment arm compared to baseline values, this was more pronounced in day 1 after each of the two procedures but tended to increase during follow-up.
- At one year the NRS was almost 5 in the RFA group and >5 in the steroid group (a value of 5-10 indicates worst possible pain).,
- Knee functioning also improved vs baseline, in each of the treatment arms, but was still considered poor and unsatisfactory according to the values of the KSS and OKS.
- There were no significant differences between the 2 study groups in any of the outcome measures (pain, function, QoL, or patient satisfaction). Lack of significant difference does not necessarily indicate that the two intervention have similar results as indicated by the authors). The power of the study may have been insufficient to detect statistically significant differences.

The use of Thermal Genicular Nerve Radiofrequency Ablation (GNRFA) for continued chronic knee pain post total knee replacement does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
64450	Injection(s), anesthetic agent(s) and/or steroid; other peripheral nerve or branch

Back to Top

64454	Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed
64624	Destruction by neurolytic agent, genicular nerve branches including imaging guidance, when performed
64640	Destruction by neurolytic agent; other peripheral nerve or branch
ICD-10 Codes	**Description**
M25.561	Pain in right knee
M25.562	Pain in left knee

Non-Medicare - Considered Not Medically Necessary:

CPT® Codes	Description
64450	Injection(s), anesthetic agent(s) and/or steroid; other peripheral nerve or branch
64454	Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed
64624	Destruction by neurolytic agent, genicular nerve branches including imaging guidance, when performed
64640	Destruction by neurolytic agent; other peripheral nerve or branch

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
08/07/2018	08/07/2018[MPC], 08/06/2019[MPC], 08/04/2020[MPC], 08/03/2021[MPC], 08/02/2022[MPC], 08/01/2023[MPC]	09/05/2023

[MPC] Medical Policy Committee

Revision History	Description
08/07/2018	MPC approved to adopt policy of non-coverage for GNA.
12/03/2019	Added MTAC review for Coolief RFA and MPC approved a non-coverage policy for this procedure.
05/18/2020	Added comment about procedure being done for anesthesia during other surgical procedures, which does not require review.
06/23/2020	Added CPT codes 64454 and 64624
08/04/2020	Added Medicare LCD L35457, LCA A52725 and ICD-10 codes M25.561 and M25.562. Removed “hip” from non-coverage policy and added MTAC review from July 2020. MPC approved to retain policy of non-coverage for genicular nerve ablation for non-Medicare patients.
09/05/2023	MPC approved to adopt Neurolysis, Genicular Nerve: MCG A-1047.

Back to Top