MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Ablation/Denervation Techniques for Knee Pain**
Policy Number	**7.01.100**
Category	**Technology Assessment**
Original Effective Date	**05/16/19**
Committee Approval Date	**04/16/20, 11/19/20, 04/15/21, 06/16/22, 06/22/23, 07/18/24**
Current Effective Date	**07/18/24**
Archive Date	**N/A**
Archive Review Date	**N/A**
Product Disclaimer	• *Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare, HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, radiofrequency ablation (RFA)/denervation (including cooled and pulsed) of genicular nerves to treat pain has not been medically proven to be effective and, therefore, is considered **investigational** for all indications, including, but not limited to, knee pain/osteoarthritis (OA).

II. Based upon our criteria and assessment of the peer-reviewed literature, cryoneurolysis/cryoablation to treat pain associated with knee OA or total knee arthroplasty (TKA) has not been medically proven to be effective and, therefore, is considered **investigational**.

III. Based upon our criteria and assessment of the peer-reviewed literature, the addition of an IPACK block to multimodal analgesia regimens to reduce post-operative pain or improve functional performance has not been medically proven to be effective and, therefore, is considered **investigational**.

Refer to Corporate Medical Policy #7.01.42 Radiofrequency Facet and Sacroiliac Joint Ablation/Denervation

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

DESCRIPTION

Radiofrequency Ablation

Nerve RFA is a minimally invasive treatment 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, causing a small sphere of tissue to coagulate 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 damage away from the nerve. The goal of ablating the nerve is the same. COOLIEF (Haylard Health, Inc.) cooled RF treatment is a minimally invasive outpatient procedure 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 and is proposed to relieve hip and knee pain associated with OA.

Nerve RFA is different from pulsed 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, or, if it does produce some degree of nerve destruction, to cause less damage than standard RFA. Some studies refer to pulsed RF treatment as ablation.

Cryoneurolysis

Cryoneurolysis is being investigated to alleviate pain in knee OA and to manage pain following TKA. Temperatures of -20° to -100°C applied to a nerve cause Wallerian (anterograde axonal) degeneration, with disruption of nerve structure and conduction. However, maintenance of the perineural and epineural elements of the nerve bundle purportedly allows near 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.

IPACK

For patients undergoing total knee replacement (TKR), one of the most common surgical procedures in the United States, optimal pain control is paramount to promote rapid recovery, early ambulation and overall patient satisfaction. In addition to general or spinal analgesia, surgeons utilize local infiltration analgesia (LIA) as well as adductor canal block (ACB) as a multi-modal pain protocol. A relatively new technique, known as the IPACK block, describes infiltration between the popliteal artery and capsule of the knee, anesthetizing the distal branches of the genicular nerves and popliteal plexus to innervate the posterior capsule of the knee joint, while retaining the trunk of the tibial and common peroneal nerves.

RATIONALE

Radiofrequency Ablation

A number of RF generators and probes have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the Section 510(k) process. In 2005, the SInergy (Kimberly-Clark/Baylis), a water-cooled single-use probe, was cleared by the FDA, listing the Baylis Pain Management Probe as a predicate device. It is intended for use with an RF generator, to create RF lesions in nervous tissue.

In 2011, the NeuroTherm NT 2000 (NeuroTherm) was cleared for marketing by the FDA through the Section 510(k) process. The FDA determined that this device was substantially equivalent to existing devices for use in lesioning neural tissue. Existing predicate devices included the NeuroTherm NT 1000, Stryker Multi-Gen, and Cosman G4 RF Generator.

In 2013, the Cryo-Touch IV (iovera; Myoscience) was cleared for marketing by the FDA through the Section 510(k) process. Predicate devices were the Cryo-Touch II and Cryo-Touch III.

In December 2016, the COOLIEF Cooled Radiofrequency Kit (Halyard Health Inc., Alpharetta, GA) was cleared by the FDA through the Section 510(k) process for the creation of RF heat lesions in nervous tissue for the relief of pain. The kit includes a fluid delivery system for commonly used fluid agents, limited to contrast medium, saline, and/or anesthetic solution delivery at the target site.

Gupta et al. (2017) completed a systematic review aimed at analyzing published studies on RFA (conventional, pulsed, or cooled radiofrequency) for patients suffering from OA of the knee, as well as patients post-TKA who have developed refractory disabling chronic knee pain. The systematic review was intended to provide an overview of the current knowledge regarding variations in procedures, nerve targets, adverse events and temporal extent of clinical benefit. Seventeen publications were identified in the search, including articles investigating conventional, pulsed, or cooled RFA. These studies primarily targeted either the genicular nerves or used an intra-articular approach. Of the studies, five were small-sized, randomized, controlled trials, although one involved diathermy radiofrequency ablation. There were eight retrospective or prospective case series and four case reports. Utilizing the strength of evidence grading, the study identified a low level of certainty to suggest a superior benefit between targeting the genicular nerve, an intra-articular approach, or targeting the larger nerves such as femoral and tibial nerves. It also identified a low level of certainty supporting the superiority of any specific RFA procedure modality. The majority of the studies reported positive patient outcomes, but the inconsistent procedural methodology, inconsistent patient assessment measures, and small study sizes limit the applicability of any specific study to clinical practice. The authors concluded that, overall, the studies showed promising results for the treatment of severe chronic knee pain by RFA at up to one year, with minimal complications. Numerous studies, however, yielded concerns about procedural protocols, study quality, and patient follow-up. RFA can offer substantial clinical and functional benefit to patients with chronic knee pain due to OA or post-TKA.

In 2018, Davis et al. completed a prospective, multicenter, randomized, crossover clinical trial comparing the safety and effectiveness of cooled RF with corticosteroid injection in the management of knee pain from OA in 151 subjects with chronic knee pain lasting six months or more that was unresponsive to conservative modalities. Knee pain (Numeric Rating Scale [NRS]), Oxford Knee Score, overall treatment effect (Global Perceived Effect), analgesic drug use, and adverse events were compared between cooled RFA and intra-articular steroid (IAS) cohorts at one, three, and six months after intervention. At six months, the cooled RF group had more favorable outcomes in NRS with pain reduction of 50% or greater in 74.1% versus 16.2% of IAS cases. Non-responders consisted of 25.9% in the cooled RFA group and 83.8% in the steroid group. At six months, mean Oxford Knee Score was 35.7 in the cooled RFA group versus 22.4 in the steroid group, and mean improved Global Perceived Effect was 91.4% versus 23.9%, respectively. There was no change in the average daily dose of opioids at six months between the groups. No procedure-related serious adverse events were identified. While the authors concluded that the findings of this study indicated that cooled RFA for genicular nerve ablation is superior to a single corticosteroid injection in osteoarthritic subjects for managing knee pain, the limitations of this study included the following: the comparison group (IAS subjects) underwent a singular injection rather than multiple injections, and the six-month time point at which the primary outcome was assessed is not consistent with the expected duration of effectiveness of a steroid injection; this was an open label trial, and so, not all study site observers were blinded to procedures; medication diaries were not used to record medication usage in this study, which introduced potential for error and/or inability to identify acute changes in medication dosage during the study; and the effect of each treatment on opioid use for OA-related knee pain could not be specifically measured because patients in both study groups used opioids for medical indications other than OA-related knee pain.

In 2019, Davis et al. published a follow-up study investigating the longer-term durability of analgesic effects of cooled RFA for knee pain from OA. A total of 58 patients (82%) from the original IAS cohort who were dissatisfied with their IAS treatment after six months were allowed to crossover to receive cooled RFA treatment. In addition, 58 patients who received cooled RFA were followed for an additional six months, for a total of 12 months' follow-up. At 12 months, 52 patients (78%) in the originally treated cooled RFA group contributed data to the primary endpoint. Diminished pain relative to baseline greater than or equal to 50% was reported as 65% (34/52) after 12 months, and the OKS mean score was 34.3, an increase in baseline by 17.3 points after 12 months. In the crossover group, 49% (18/37) of patients experienced a 50% or more decrease in pain from baseline at six months. No serious adverse events identified were related to cooled RFA. Opioid use stayed consistent with baseline during the trial. The authors are unclear why a difference in analgesic response was seen in the originally treated group (65% at 12 months) and the crossover group (49% at six months); however, the study was not powered or designed to draw conclusions from the crossover group. The authors concluded that statistically significant and clinically relevant pain relief and functional improvements were sustained 12 months following cooled RFA treatment of OA-related knee pain and dysfunction. This study was partially funded by Halyard Health.

In a single, blind, randomized, controlled trial, El-Hakeim et al. (2018) studied the efficacy of fluoroscopic-guided radiofrequency neurotomy of the genicular nerves for alleviation of chronic pain and improvement of function in patients with knee OA. A total of 60 patients with chronic knee OA received either radiofrequency neurotomy of the genicular nerves (n=30), considered Group A, or conventional analgesics only (n=30), identified as Group C. For Group C, the following treatments were prescribed: oral paracetamol (max of 1 gram in six hours), Diclofenac sodium 75mg BID, and physiotherapy, if needed. The outcomes measures included visual analog scale (VAS), Western Ontario and McMaster Universities Index (WOMAC), and Likert scale for patient satisfaction in the second week, third week, and sixth month.

The authors found significant differences in the VAS in the second week, third week, and sixth month between the two groups, and a significant difference in total WOMAC index in the sixth month only. A high percentage ratio of the patients (63.3%) in the conventional Group C received physiotherapy during the follow-up period. No diagnostic block was done prior to radiofrequency, which is a limitation in the study. The authors concluded that RF could ameliorate pain and disability in chronic knee OA in a safe and effective manner.

Qudsi-Sinclair and colleagues (2017) published the results of a double-blinded, randomized, controlled trial comparing traditional RF neurolysis (n=14) to local anesthetic and corticosteroid block (n=14) of the genicular nerves for treatment of persistent pain following TKA. Subjects were followed for one year after treatment and evaluated for pain evolution, knee functionality, quality of life, and degree of patient satisfaction. At three and six months, both groups demonstrated a reduction in pain and significant joint function improvement, with similar results in both groups, including improvement in quality of life and disability and a reduced need for analgesics. The authors could not recommend one treatment option over another and suggested that further clinical trials are needed to establish safety and efficacy. The study is limited by small sample population and short-term outcomes.

While there are a few studies in the published peer-reviewed literature which lend support to improvement in pain after ablative treatment, these studies are limited by variability in RF technique, small sample populations, and differences in patient selection criteria. At present, there is insufficient evidence in the peer-reviewed scientific literature evaluating RF ablative treatment for chronic knee pain. Strong, evidence-based conclusions regarding the effects of this technology on health outcomes cannot be made. Additional well-designed studies involving larger populations and long-term outcomes are needed, to support safety and efficacy and to determine how this treatment compares to other medical and surgical treatments for knee pain.

<u>Cryoneurolysis</u>

A randomized, controlled trial with 180 patients (Radnovich et al., 2017) compared cryoneurolysis with sham treatment in patients who had knee OA. Cryoneurolysis resulted in a greater decrease in WOMAC pain, WOMAC total, and VAS score at 30 days, compared with sham-treated controls. Subsequent measurements showed no significant benefit of cryoneurolysis on WOMAC score at 60 days or in VAS scores at 60 or 90 days. As the trial progressed, patients were able to more accurately guess their treatment group assignment, which may have biased results in favor of active treatment. 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 yet to be resolved. Perioperative cryoneurolysis has shown mixed results in reducing opioid prescriptions/use in patients undergoing TKA (Dasa et al., 2016 and Mihalko et al., 2021). Larger, well-designed trials are needed to determine the effects on health outcomes.

<u>IPACK</u>

A systematic review and meta-analysis (Mou et al., 2021) evaluated level one evidence to determine whether the IPACK block offered analgesic benefits to existing multimodal analgesia regimens. Data on a total of 467 patients who underwent total replacement (TKA) from five randomized controlled studies were included in the analysis. While four studies compared the difference between ACB+IPACK and ACB alone, only one assessed the difference between ACB+LIA+IPACK and ACB+LIA. The primary outcome of pain scores with rest and activity, as well as secondary outcomes of cumulative opioid consumption, cumulative distance ambulated, and length of stay (LOS) were compared between intervention and control groups. While the results indicated significantly improved pain scores with rest or activity at 12 hours post-operatively, no such benefit was observed at subsequent time points throughout the postoperative period. Additionally, IPACK supplementation did not reduced opioid consumption, especially in the first 24 hours after procedure, nor did it improve other secondary outcomes of distance ambulated or LOS. Authors noted heterogeneity among included studies as a limiting factor in conducting meta-analysis of additional secondary outcomes. Researchers concluded that the addition of IPACK block to multimodal analgesic regiments does not improve post-operative opioid consumption nor improve functional performance but may offer immediate analgesic benefit after TKR.

In a 2020 double-blinded randomized controlled trial, Vichainarong et al. evaluated the efficacy of an IPACK block added to local infiltration analgesia and continuous adductor canal block after TKA. A total of 72 patients were randomized to receive either LIA with CACB (control group) or IPACK block with LIA and CACB (intervention group). The primary outcome measure was cumulative intravenous morphine consumption in the first 24 hours post-operatively, as well as secondary outcomes of numerical pain scores, incidence of posterior knee pain, performance test results, patient satisfaction, LOS, and adverse effects. The results indicated no significant intergroup difference in terms of morphine consumption within 24 hours post-operatively ((LIA+CACB; 1.31±1.85 mg vs iPACK+LIA+CACB; 0.61±1.25 mg, p=0.08). There were no clinically significant differences in the overall pain scores between the groups, however, the lower Timed Up and Go test scores on postoperative days one and two, along with a shorter LOS, were found in the iPACK+LIA+CACB group (p<0.05). Researchers concluded the addition of the IPACK to the LIA and CACB does not reduce postoperative opioid consumption nor improve analgesia, but it may improve immediate functional performance and reduce the LOS following TKA.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	**Description**
64450 **(E/I)**	Injection(s), anesthetic agent(s) and/or steroid; other peripheral nerve or branch
64454 (**E/I)**	Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed
64624 **(E/I)**	Destruction by neurolytic agent, genicular nerve branches including imaging guidance, when performed
64640 **(E/I)**	Destruction by neurolytic agent; other peripheral nerve or branch *(when applied to genicular nerve(s))*
64999	Unlisted procedure, nervous system
0441T **(E/I)**	Ablation, percutaneous, cryoablation, includes imaging guidance; lower extremity distal/peripheral nerve *(when applied to genicular nerve(s))*

HCPCS Codes

Code	**Description**
No specific code(s)	

ICD10 Codes

Code	**Description**
M17.0-M17.9 **(E/I)**	Knee osteoarthritis (code range)
M25.561-M25.569 **(E/I)**	Pain in knee (code range)

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*Key Article

KEY WORDS

Cooled radiofrequency ablation, COOLIEF, radiofrequency ablation of peripheral nerve, genicular radiofrequency ablation, iovera, cryoablation, cryoneurolysis, IPACK

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for Induced Lesions of Nerve Tracts (160.1). Please refer to the following NCD website for Medicare members:

[https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=19&ncd] accessed 06/10/24.

There is currently a Local Coverage Determination (LCD) Peripheral Nerve Blocks (L36850) for destruction of genicular nerve branches. Please refer to the following LCD website for Medicare Members:

[https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=36850&ver=24&bc=0] accessed 06/10/24.