MEDICAL POLICY

Medical Policy Title	**Pain Management Techniques for Knee Pain**
Policy Number	**7.01.100**
Current Effective Date	July 17, 2025
Next Review Date	July 2026

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

Ablation or Denervation Techniques

I. Radiofrequency ablation (RFA)/denervation (including cooled and pulsed) of genicular nerves to treat pain is considered **investigational** for all indications, including, but not limited to, knee pain/osteoarthritis (OA).

II. Cryoneurolysis/cryoablation to treat pain associated with knee OA or total knee arthroplasty (TKA) is considered **investigational**.

Injection Treatments for Knee Pain

III. The addition of an IPACK block to multimodal analgesia regimens to reduce post-operative pain or improve functional performance is considered **investigational**.

RELATED POLICIES

Corporate Medical Policy

7.01.42 Radiofrequency Facet and Sacroiliac Joint Ablation/Denervation

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

Not Applicable

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

The IPACK block (infiltration between the popliteal artery and capsule of the posterior knee) is a regional anesthesia technique used to manage posterior knee pain especially after a total knee replacement (TKR) or other knee surgery. It is a relatively recent innovation that provides anesthesia without causing motor weakness particularly of the tibial or common peroneal nerve. The purpose is to provide posterior knee analgesia by targeting the articular branches of nerves in innervating the posterior capsule of the knee. It is used as a supplement to abductor canal blocks (which covers anterior and medial pain) for comprehensive motor sparing analgesia. IPACK is perform under guided ultrasound with the individual in a supine or lateral position. A linear or curved transducer is used to identify the femoral condyles, popliteal artery, and the posterior capsule. A needle is inserted in-plane from medial to lateral, or lateral to medial depending on the preference. Local anesthetic (typically 15-20ml of ropivcacine or bupivacaine) is injected into the interspace between the popliteal artery and posterior capsule of the femur.

SUPPORTIVE LITERATURE

Radiofrequency Ablation

Gupta and colleagues (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.

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.

In 2018, Davis and colleagues 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 a single, blind, randomized, controlled trial, El-Hakeim and colleagues (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.

In 2019, Davis and colleagues 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.

Alemeida et al (2025) conducted a systematic review and meta-analysis of the efficacy and safety of minimally invasive treatments (RFA, genicular nerve blocks (GNB), and cryoneurolysis) targeting the genicular nerves for management of knee OA pain. The primary outcome were pain intensity, physical function, and serious adverse events. Analysis was conducted on 25 randomized control trial (RFA n=16, GNB n=8, and cyroneurolysis n=1)) involving 2049 participants. Secondary outcomes included quality of life, global perceived effect, general adverse events, and withdrawal due to side effects. Key results showed the certainty of evidence was consistently low to very low across all comparisons. RFA may provide some short-term relief at 4 weeks compared to the sham group 4 weeks (Mean difference -1.70, on a 0-10 scale). There was little to no difference in pain at 24-48 weeks, or improvement in function observed at any time and no serious adverse events reported. GNB showed limited and very uncertain evidence. Only one trial suggests small reduction in pain and moderate functional improvements at 4 weeks. For cryoneurolysis very low certainty of evidence was found. Only one trial showed small improvement in pain at 4 weeks and no significant effects at 12 or 24 weeks. This study had a high risk of bias. Lack of blinding, and inadequate outcome measurement protocols were found in 17 out of 25 studies included. Most trial had small sample sizes with short follow up duration. The authors concluded that RFA and other genicular nerve targeting procedures provide at best a modest, short-term benefit in knee OA pain management. There was no reliable evidence that these treatments improve function or quality of lifelong terms.

Cryoneurolysis

A randomized, controlled trial with 180 patients (Radnovich 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 2016; Mihalko 2021). Larger, well-designed trials are needed to determine the effects on health outcomes.

IPACK

In a 2020 double-blinded randomized controlled trial, Vichainarong and colleagues 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 versus 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.

A systematic review and meta-analysis (Mou 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.

Guo et al (2022) conducted a systematic review and met analysis of the effectiveness of combining iPACK block (infiltration between the popliteal artery and capsule of the posterior knee) with adductor canal block (ACB) in managing postoperative pain after total knee arthroplasty (TKA). Included in this analysis were fourteen studies with a total of 758 patients. Primary outcome measures included the visual analog scale (VAS) for pain score, post operative pain measured at 8-hour phase, 12-hour phase, 24-hour phase, 48-hour phase, at discharge, including at rest and with activity. Postoperative morphine consumption, postoperative quadriceps strength, postoperative range of motion, post operative walking distance, time up and go to (TUG) test, hospital stay, and the incidents of postoperative nausea and vomiting (PONV) were measured. VAS at rest and with activity were significantly lower in the ACB+iPACK group compared to ACB alone (at rest SMD=−0.75, 95%CI, with activity, SMD=−0.61). Post operative cumulative morphine consumption was significantly reduced in the ACB+iPACK group (SMD: −0.33, 95%CI:95%. Range of motion improved at all measure time points (SMD: 7.69, 95%CI). Walking distance was better in ACB+iPACK group (SMD: 0.28, 95%CI. Overall TUG score improve performance was noted on post operative day1 and post operative day 2. Hospital stays were shorter in the ACB +iPACK group and there was no significant difference between group on quadricep muscle strength and incidence of postoperative nausea and vomiting. There were significant clinical and methodological heterogeneity in this study. Some

experiments used general anesthesia while others used spinal anesthesia. There was discrepancy in the timing of nerve block administration. Some researchers performed nerve blocks prior to surgery while other performed after the surgery. The Egger test suggested some degree of publication bias in VAS scores at certain time points. Overall researchers concluded that adding iPACK to ACB improves pain control, reduced opioid use, enhances functional recovery, and shortens hospital stays without increasing adverse effects in the management of pain after TKA.

PROFESSIONAL GUIDELINE(S)

American Academy of Orthopaedic Surgeons (AAOS) 2021 recommendation for the management of OA of the knee, states denervation therapy may reduce pain and improve function in patients with symptomatic osteoarthritis of the knee (strength of recommendation limited). AAOS Evidence-Based Clinical Practice Guideline: Management of Osteoarthritis of the Knee (Non-Arthroplasty). Aug 2021. Available from: https://www.aaos.org/globalassets/quality-and-practice-resources/osteoarthritis-of-the-knee/oak3cpg.pdf [accessed 2025 Jun 26]

REGULATORY STATUS

Radiofrequency Ablation

The United States Food and Drug Administration (FDA) regulates radiofrequency ablative devices as medical devices. All radiofrequency ablative devices including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2025 Jun 26]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls on our website by the date that the FDA posts the information on our website. Available from: Medical Device Recalls | FDA [accessed 2025 Jun 26]

There are several RF generators and probes that 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.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

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
Not Applicable	

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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SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Induced Lesions of Nerve Tracts (NCD 160.1) [accessed 2025 Jun 20]

Peripheral Nerve Blocks (L36850) [accessed 2025 Jun 20]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, 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 HISTORY/REVISION

Committee Approval Dates

05/16/19, 04/16/20, 11/19/20, 04/15/21, 06/16/22, 06/22/23, 07/18/24, 07/17/25

Date	Summary of Changes
07/17/25	• Annual review; policy intent unchanged. Revised the policy title to Pain Management Techniques for Knee Pain.
01/01/25	• Summary of changes tracking implemented.
05/16/19	• Original effective date