MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Radiofrequency Knee Ablation/Denervation**
Policy Number	**7.01.100**
Category	**Technology Assessment**
Effective Date	**05/16/19**
Revised Date	**04/16/20**
Product Disclaimer	• *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 product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.* • *If a Medicare 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.*

POLICY STATEMENT

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).

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

Refer to Corporate Medical Policy #11.01.03 Experimental and Investigational Services

POLICY GUIDELINES

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and, thus, these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION

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, 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.

RATIONALE

A number of RF generators and probes have been cleared for marketing by the FDA through the 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 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 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 510(k) process for the creation of RF heat lesions in nervous tissue for the relief of pain and 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-total knee arthroplasty 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 radiofrequency ablation. 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-total knee arthroplasty.

In 2018, Davis *et al*. completed a prospective, multicenter, randomized, crossover clinical trial comparing the safety and effectiveness of cooled radiofrequency ablation (CRFA) 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 CRFA and IAS (intra-articular steroid) cohorts at one, three, and six months after intervention. At six months, the CRFA group had more favorable outcomes in NRS: pain reduction 50% or greater: 74.1% versus 16.2%. Non-responders consisted of 25.9% in the CRFA group and 83.8% in the steroid group. At six months, mean Oxford Knee Score was 35.7 in the CRFA 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 radiofrequency ablation (COOLIEF) 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 CRFA 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 CRFA treatment. In addition, 58 patients who received CRFA 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 CRFA 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 CRFA. 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 CRFA 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 can 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 total knee arthroplasty. 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.

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.*

CPT Codes

Code	Description
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))*

HCPCS Codes

Code	Description
No specific code(s)	

ICD10 Codes

Code	Description
M17.0-M17.9	Knee osteoarthritis (code range)

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*Key Article

KEY WORDS

Cooled radiofrequency ablation, COOLIEF, radiofrequency ablation of peripheral nerve, genicular radiofrequency ablation

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for Induced Lesions of Nerve Tracts. Please refer to the following NCD website for Medicare members: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=19&ncd