Molina Clinical Policy
COOLIEF Cooled Radiofrequency Ablation (CRFA) for the Management of Chronic Pain: Policy No. 386

Last Approval: 12/11/2024
Next Review Due By: December 2025

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Radiofrequency ablation (RFA) uses high-frequency electric current to cause thermal damage to nerves with the intent of stopping the transmission of pain signals without affecting motor or sensory fibers. The COOLIEF cooled radiofrequency ablation (CRFA) technique differs from conventional radiofrequency ablation by the circulation of water through the probe that administers electrical current, which removes heat and keeps the heat produced in the probe to approximately 60°C, which is lower than the 70°C to 80°C typical of conventional radiofrequency ablation. CRFA is intended to create a larger and more spherical neuronal lesion and thereby proposed be more efficacious in reducing pain. Creation of a large spherical lesion is also thought to reduce the chance of excessive heating and tissue damage, while providing more durable pain relief. The lower temperature is thought to prevent charring and insulation where the probe and tissue interface and allows more energy to be applied.

Regulatory Status

The Food and Drug Administration (FDA) (2016; 2017) granted approval for the COOLIEF Cooled Probe through the FDA 510(k) Premarket Notification process under reference numbers K163461 and K163236.

COVERAGE POLICY

COOLIEF cooled radiofrequency ablation is considered **experimental, investigational, and unproven** for the relief of pain associated with the knee; hip; sacroiliac joint; lumbar, thoracic, or cervical spine; or any other indication. There is insufficient evidence in the peer reviewed literature to prove safety, efficacy, patient population, and long-term clinical outcomes.

SUMMARY OF MEDICAL EVIDENCE

The overall quality of the body of evidence for the COOLIEF CRFA system for pain is very low. While studies generally demonstrated a reduction in pain from 6 to 24 months, the clinical significance of this reduction was not consistently demonstrated. The lack of comparison with other minimally invasive techniques and a lack deficiency of long-term follow-up limits conclusions regarding the safety, efficacy, and patient selection criteria for CRFA for any indication. Most published studies are focused on for knee and sacroiliac joint (SIJ) pain.

Randomized Controlled Trials

Cohen et al. (2023) conducted a randomized, multicenter comparative effectiveness study of 210 patients with SIJ pain treated with CRFA versus standard medical management. Patient selection inclusion criteria consisted of age ≥ 21 years; chronic SIJ pain with duration ≥ 3 months; minimum of one or more SIJ provocation test symptoms; ≥ 50% pain relief post local anesthetic injection; NRS low back or buttock score ≥ 4; and no other identifiable source of lower back pain. Patients were randomized in a 1:1 ratio into CRFA or standard medical management groups. The standard medical management group received pharmacotherapy, physical and chiropractic therapy, lifestyle changes,

acupuncture, yoga, and therapeutic injections. CRFA procedure patients received nine lesions for each lateral segment under fluoroscopic guidance in locations S1-S3 sacral foramina and L5 dorsal ramus, with S4 targeted at provider discretion. Patient self-reported outcomes were assessed at 1 and 3 months post-treatment. Responders for this study were patients who reported a ≥30% or 2-point decrease in average daily lower back pain. At the 3 month follow-up appointment 52.3% of the CRFA group were deemed responders (41.9% reported ≥ 50% improvement), compared with 4.3% of the standard medical management group. Of note, several patients in the standard medical management group had previous trials of the interventions provided and reported failure of improvement in lower back pain. Additional limitations included sample size, lack of comparison to standard RFA, placebo effect of SIJ as the primary source of pain, a control group for real-life conditions, and open-label trial bias. Additional clinical trials are needed that include a higher number of patients, longer post-procedure follow-up, comparison to RFA, and a higher percentage of symptom improvement when determining positive response to CRFA treatment is needed to further evaluate this type of intervention.

Desai et al. (2022) conducted a cost-effectiveness analysis from a randomized crossover trial of 177 patients with knee osteoarthritis who received CRFA versus a single hyaluronic acid injection. Inclusion criteria was age ≥ 21 years, chronic knee pain longer than 6 months that interfered with functional activities, at least 3 months of conservative treatment with continued pain, positive response to a single genicular nerve block, pain score on NRS ≥ 6, and radiologic confirmation of arthritis of grade II or higher noted within 6 months. Patient follow-up at 1, 3, 6, and 12 months evaluated knee pain with NRS, WOMAC Index (pain, stiffness, and physical function), and overall quality of life. At the 6-month evaluation patients with an unsatisfactory response to hyaluronic acid injection were allowed to cross-over and receive CRFA. At the 12-month evaluation 65.2% of the CRFA cohort reported ≥50% pain relief after treatment. The cross-over cohort patients at 12 months post CRFA reported a 64.5% pain relief of ≥50%. WOMAC score improvement for the CRFA group saw a 46.2% improvement, and the cross-over group reported a 27.5% improvement. A majority (83%) of the patients initially treated with hyaluronic acid injection elected crossover treatment at the 6-month timepoint. Limitations of this study include sample size, no patient blinding, open-label trial with potential bias, and a more definitive clinical profile of what patients may benefit from CRFA.

Davis et al. (2019) performed a 12-month follow-up to the original 6-month study published in 2018. This study was a prospective, multicenter, randomized clinical trial comparing the safety and efficacy of CRFA with corticosteroid injection (IAS) in the management of knee pain from osteoarthritis. The study included 151 patients with at least a 36-month history of knee pain due to osteoarthritis (via radiographic confirmation). Participants had no other etiology demonstrated as the source of knee pain and all were unresponsive to conservative modalities. Knee pain (NRS), Oxford Knee Score, overall treatment effect (Global Perceived Effect), analgesic drug use, and adverse events were compared between CRFA and IAS cohorts at 1, 3, and 6 months after intervention. At 6 months, the CRFA group had more favorable outcomes in NRS: pain reduction 50% or greater: 74% versus 16%, $P < 0.0001$ (26% and 84% of these study cohorts, respectively, were non - responders). Mean NRS score reduction was 4.9 ± 2.4 versus 1.3 ± 2.2, $P < 0.0001$; mean Oxford Knee Score was 35.7 ± 8.8 vs 22.4 ± 8.5, $P < 0.0001$; mean improved Global Perceived Effect was 91.4% vs 23.9%, $P < 0.0001$; and mean change in nonopioid medication use was CRFA > IAS ($P = 0.02$). There were no procedure-related serious adverse events. At 12 months, 65% of the original CRFA group had pain reduction >50%, and the mean overall drop was 4.3 points on the NRS. Improved effects were reported among 75% of patients. The cross-over group demonstrated improvements in pain and functional capacity. Additional randomized clinical trials with longer reported outcomes are needed to further evaluate CRFA specific for the treatment of knee pain due to osteoarthritis.

McCormick et al. (2019) conducted a randomized, prospective trial of CRFA versus traditional RFA of the medial branch nerves for the treatment of lumbar facet joint pain. According to the study, the primary outcome was the proportion of responders (≥ 50% NRS reduction) at 6 months post procedure. Secondary outcomes included NRS, ODI, and Patient Global Impression of Change. Forty-three participants were randomized to medial branch nerve CRFA (n=21) or traditional RFA (n=22). A ≥ 50% NRS reduction was observed in 52% (95% CI 31% to 74%) and 44% (95% CI 22% to 69%) of participants in the CRFA and traditional RFA groups, respectively (p=0.75). A ≥ 15-point or ≥ 30% reduction in ODI score was observed in 62% (95% CI 38% to 82%) and 44% (95% CI 22% to 69%) of participants in the CRFA and traditional RFA groups, respectively (p=0.21). It was concluded that when using a single diagnostic block paradigm with a threshold of > 75% pain reduction, treatment with both CRFA and traditional RFA resulted in a success rate of approximately 50% when defined by both improvement in pain and physical function at 6-month follow-up. While the success rate was higher in the CRFA group, this difference was not statistically significant. Limitations included small sample size, and lack of statistically significant findings contributed to inconclusive results.

Davis et al. (2018) compared CRFA with steroid injections. The patients receiving CRFA reported statistically significant greater reductions in pain at 1 to 6 months. Four studies reported reductions in pain scores on the numeric rating scale (NRS) or visual analog scale up to 24 months. One systematic review conducted by Gupta et al. (2017) indicated that no radiofrequency ablation procedure modality (e.g., cooled, pulsed, or conventional) could be differentiated as superior. General limitations of this study included inconsistencies in procedure methodology, small sample size, and limited outcome assessment.

Systematic Reviews and Meta-Analyses

Wu et al. (2024) completed a systematic review and network meta-analysis to assess the efficacy of various radiofrequency ablation (RFA) techniques for knee osteoarthritis (OA) to identify the optimal modality, target, electrode number, and imaging guidance for enhancing knee pain relief and function. They evaluated three different radiofrequency modalities (cooled, conventional, and pulsed) and compared them to other osteoarthritis treatments such as corticosteroid injections, hyaluronic acid injections, platelet-rich plasma, NSAIDs, and exercise. A total of 1,818 patients from 21 randomized controlled studies (published between 2011 and 2022) were included. The studies encompassed 10 years of literature, from 10 different countries, including two studies in the United States from 2019 and 2020. The primary outcome was treatment efficacy for analgesia. This was measured using the visual analog scale (VAS) at 3 and 6 months. The secondary outcome was treatment efficacy for knee function, which was measure with the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) at 3 and 6 months. Conventional bipolar genicular nerve RFA (GNRFA) showed the highest net benefit on the Visual Analog Scale (VAS) at 6 months (MD -5.5; 95% CI, -4.3 to -6.7; SUCRA, .98). Meanwhile, cooled monopolar GNRFA had the greatest net benefit on the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) at 6 months (MD, -33; 95% CI, -37 to -29; SUCRA, .99). Bipolar RFA significantly decreased VAS and WOMAC scores more than monopolar RFA in both conventional and pulsed modalities. However, combining pulsed intra-articular RFA with platelet-rich plasma injection did not show additional benefits on VAS or WOMAC at 3 months. The authors noted some limitations with the study. Despite using strict criteria and proper classifications, the treatments involved inconsistencies such as hertz, pulse width, and duration of treatment. Future RCTs should investigate these specific elements of RFA. Additionally, the number of studies, especially involving the cooled modality, was insufficient, and some had small sample sizes. These early results are promising, but more high-quality, multi-arm studies should be conducted. Lastly, the follow-up period ranged from 3 to 24 months, so the long-term efficacy and safety of RFA still need verification. Radiofrequency ablation (RFA) effectively reduces knee pain and improves function in osteoarthritis patients, especially over six months. The cooled version is more effective than conventional and pulsed versions. Bipolar RFA outperforms monopolar in pain relief and function for conventional and pulsed types. No significant differences in pain and function improvement were found between fluoroscopy and ultrasound guidance.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Tinnirello et al. (2017) compared two radiofrequency devices, Simplicity III (conventional radiofrequency) and SInergy (cooled radiofrequency), which are specifically designed to denervate the SIJ. This study of 43 patients with SIJ-derived pain refractory to conservative treatment was divided into 21 and 22 patient cohorts. The separate cohorts received either Simplicity III or SInergy to denervate the SIJ. Mean NRS and Oswestry Disability Index (ODI) scores were determined for each study group up to 12 months post procedure. Secondary outcomes included the average amount of time required to complete each radiofrequency procedure and the adverse effects associated with each technique. Average SInergy group NRS and ODI scores were consistently less than those in the Simplicity III cohort at six- and 12- months post procedure. Study results suggest that SInergy safely afforded patients with greater and more durable analgesia and disability relief than Simplicity III for SIJ-derived pain. The Simplicity III procedure may be more conducive than SInergy for bilateral procedures and for patients who have limited tolerance to be in a radiofrequency procedure-required prone position. Randomized controlled trials are needed to confirm the implication made in this study that SInergy is the preferred radiofrequency denervation option for treating SIJ-derived pain and the disability associated with it.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	Description
22899	Unlisted procedure, spine [when used to report cooled radiofrequency ablation]
27299	Unlisted procedure, pelvis or hip joint [when used to report cooled radiofrequency ablation]
27599	Unlisted procedure, femur or knee [when used to report cooled radiofrequency ablation]
64999	Unlisted procedure, nervous system [when used to report cooled radiofrequency ablation]
64624	Destruction by neurolytic agent, genicular nerve branches including imaging guidance, when performed
64625	Radiofrequency ablation, nerves innervating the sacroiliac joint, with image guidance (i.e., fluoroscopy or computed tomography)
64633	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint
64634	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional facet joint (List separately in addition to code for primary procedure)
64635	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint
64636	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional facet joint (List separately in addition to code for primary procedure)
64640	Destruction by neurolytic agent; other peripheral nerve or branch

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

12/11/2024 Policy reviewed, no changes to criteria. Updated Summary of Medical Evidence and References. IRO Peer Review on November 7, 2024, by a practicing physician board-certified in Physical Medicine and Rehabilitation.
12/13/2023 Policy reviewed, no changes to criteria, updated references.
12/14/2022 Policy reviewed, no changes to criteria, updated references.
12/08/2021 Policy reviewed, no changes to criteria, updated references.
12/09/2020 New policy. IRO Peer Review. Policy reviewed on October 11, 2020, by a practicing, board-certified physician(s) in the areas of Pain Management and Physical Medicine and Rehabilitation.

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