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

Last Approval: 12/14/2022
Next Review Due By: December 2023

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 RFA 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 60oC, which is lower than the 70oC to 80oC typical of conventional RFA. 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

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 number K163236).

COVERAGE POLICY

COOLIEF CRFA **is considered experimental, investigational, and unproven** for the relief of pain associated with the knee, hip, sacroiliac joint (SIJ), lumbar, thoracic and cervical spine and any other indication as there is insufficient evidence in the peer reviewed literature to prove safety, efficacy, patient population and long-term clinical outcomes. It is not identified as widely used and generally accepted for the management of chronic pain reported in nationally recognized peer-reviewed medical literature.

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 6-24 months, the clinical significance of this reduction was not consistently demonstrated. The lack of comparison with other minimally invasive techniques and a lack 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 SIJ pain.

Knee Pain

Studies evaluating the effect of CRFA with the Coolief system on knee pain suggest an improvement in pain. Davis et al. (2018) compared with steroid injections, patients receiving CRFA reported statistically significantly greater reductions in pain at 1-6 months. Four studies reported statistically significant reductions in pain scores on the numeric rating scale (NRS) or visual analog scale (VAS) up to 24 months. One systematic review conducted by Gupta et al. (2017) indicated that no RFA procedure modality (e.g., cooled, pulsed, or conventional) could be differentiated as

superior and found general limitations of the evidence base to include inconsistencies in procedure methodology and methods of outcome assessment and small study sizes.

Davis et al. (2018) performed a prospective, multicenter, randomized clinical trial comparing the safety and effectiveness of Coolief System cooled RFA (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; all patients were unresponsive to conservative modalities. Knee pain (Numeric Rating Scale [NRS]), Oxford Knee Score, overall treatment effect (Global Perceived Effect), analgesic drug use, and AEs 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 AEs. 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 (Davis et al., 2019). Additional randomized clinical trials with longer reported outcomes are needed to further evaluate CRFA specific for the treatment of knee pain due to osteoarthritis.

Sacroiliac Joint (SIJ) Pain
Ho et al. (2013) conducted a meta-analysis was performed to systematically evaluate the efficacy and safety of using cooled radiofrequency (RF) in treating patients with chronic SIJ pain. Seven studies with 240 eligible patients were evaluated. The follow-up time varied from 3 to 24 months. The pooled outcomes positive results as measured by GPE and presented significant decrease of NRS, VAS, and ODI scores, indicating that cooled RF could relieve pain and disability of patients with chronic SIJ pain. However, participant selection in individual studies varied and placebo effects may exist in some the studies. Limitations further include the small number of participants in the retrospective studies reviewed, short term follow-up, heterogeneity of study populations, the use of pain medication, and the utilization of diversiform measures further weakens conclusions. Further research and trials are needed.

Tinnirello et al. (2017) compared two RF devices, Simplicity III (conventional RF), and SInergy (cooled RF), which are specifically designed to denervate the SIJ. According to the study 43 patients with SIJ-derived pain refractory to conservative treatment; 21 and 22 patients, respectively, received Simplicity III or SInergy to denervate the SIJ. Mean numerical rating scale (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 RF procedure and the AEs associated with each technique. Average SInergy group NRS and ODI scores were consistently less than those in the Simplicity III cohort at each post-RF denervation follow-up, and such differences were statistically significant at six and 12 months. 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 an RF procedure-required prone position. Randomized controlled trials are needed to confirm the implication made in this study that SInergy is the preferred RF denervation option for treating SIJ-derived pain and the disability associated with it.

Spine
McCormick et al. (2019) conducted a randomized, prospective trial of CRFA versus traditional RFA (T-RFA) of the medial branch nerves (MBN) for the treatment of lumbar facet joint pain. According to the study. The primary outcome was the proportion of responders (≥50% Numeric Rating Scale (NRS) reduction) at 6 months. Secondary outcomes included NRS, Oswestry Disability Index (ODI), and Patient Global Impression of Change. Forty-three participants were randomized to MBN C-RFA (n=21) or T-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 C-RFA and T-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 C-RFA and T-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 C-RFA and T-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 C-RFA group, this difference was not statistically significant. Limitations included small sample size, and lack of statistically significant findings contributed to inconclusive results.

National and Specialty Organizations

No position statements or clinical practice guidelines addressing CRFA or Coolief are published in the peer reviewed medical literature.

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT Codes

CPT	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

12/14/2022	Policy reviewed, no changes to criteria, updated references.
12/8/2021	Policy reviewed, no changes to criteria, updated references.
12/9/2020	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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Government Agencies

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3. Food and Drug Administration (FDA) Center for Devices and Radiological Health. Coolief cooled RF probe (K163461). Published April 13, 2017. Available from FDA. Accessed November 2022.

Peer Reviewed Publications

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3. Gupta A, Huettner DP, Dukewich M. Comparative effectiveness review of cooled versus pulsed radiofrequency ablation for the treatment of knee osteoarthritis: a systematic review. Pain Physician. 2017 Mar;20(3):155-171. PMID: 28339430.
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Manufacturer websites

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Evidence Based Reviews and Publications

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3. Hayes. Available from Hayes. Registration and login required.
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    b. Evolving evidence review: Coolief cooled RF (Avanos Medical Inc.) for hip pain. Published July 23, 2021. Accessed November 2022.
    c. Evidence Analysis Research Brief. Coolief Cooled RF (Avanos Medical Inc.) for Treatment of Back Pain. Accessed October 14, 2022.
4. Hunter C, Davis T, Loudermilk E, Kapural L, DePalma M. Cooled radiofrequency ablation treatment of the genicular nerves in the treatment of osteoarthritic knee pain: 18- and 24-month results. Pain Pract. 2020 Mar;20(3):238-246. doi: 10.1111/papr.12844.
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