Subject: Coolief Cooled Radiofrequency Ablation (CRFA) for the Management of Chronic Pain		Original Effective Date: 12/9/20
Policy Number: MCP-386	Revision Date(s):	
MCPC Approval Date: 12/9/20	Review Date: 1/19/21	

Contents

DISCLAIMER

This Molina clinical policy is intended to facilitate the Utilization Management process. 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 (i.e., 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 Molina clinical policy document and provide the directive for all Medicare members.[1]

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

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.

FDA: The Coolief Cooled Probe (4/2017), Radiofrequency Kit (12/2016), and Generator (2/2020) (Avanos Medical Inc.) were cleared through the FDA 510(k) Premarket Notification process under reference number (K163236).

RECOMMENDATION

COOLIEF Cooled Radiofrequency Ablation is considered experimental, investigational and unproven for the relief of pain associated with the knee, hip, sacroiliac (SI) joint, 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.

CONTINUATION OF THERAPY

N/A

LIMITATIONS

N/A

SUMMARY OF MEDICAL EVIDENCE

The overall quality of the body of evidence for the Coolief Cooled Radiofrequency Ablation (Avanos Medical Inc.) 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. The majority of studies published are found for knee and sacroiliac joint pain.

Knee Pain: [3-5, 7, 9, 10, 12, 13, 19]

Summary: In the studies evaluating the effect of CRFA with the Coolief system on knee pain, results suggest an improvement in pain. Compared with steroid injections, patients receiving CRFA reported statistically significantly greater reductions in pain at 1-6 months. (Davis et al., 2018). Four studies reported statistically significant reductions in pain scores on the numeric rating scale (NRS) or visual analog scale (VAS) up to 24 months (Chen et al., 2020; Davis et al., 2018; McCormick et al., 2018; Davis et al., 2019; Hunter et al., 2019; Kapural et al., 2019). One systematic review (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 (Halyard Health Inc, Alpharetta, Georgia) cooled RFA (CRFA) with corticosteroid injection (IAS) in the management of knee pain from osteoarthritis. According to the study "One hundred fifty-one patients with at least a 36-month history of knee pain due to osteoarthritis (via radiographic confirmation) was required, with 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: 74.1% versus 16.2%, $P < 0.0001$ (25.9% and 83.8% 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% or greater, and the mean overall drop was 4.3 points on the NRS. Seventy-five per cent reported 'improved' effects. 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 for the treatment of knee pain due to osteoarthritis."

Sacroiliac Joint (SI) Pain: [8, 11, 15-18]

A meta-analysis was performed to systematically evaluate the efficacy and safety of using cooled radiofrequency in treating patients with chronic SIJ pain. (Sun et al., 2018). 7 studies with 240 eligible patients was 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 radiofrequency 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. The authors concluded that "more high-quality and large-scale randomized controlled trials (RCTs) are required to validate our findings."

Tinnirello et al. (2017) compared two radiofrequency (RF) devices, Simplicity III (conventional RF), and SInergy (cooled RF), which are specifically designed to denervate the sacroiliac joint (SIJ). According to the study "Forty-three 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." The authors report that the 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 [6, 14]

McCormick et al. (2019) conducted a randomized, prospective trial of cooled radiofrequency ablation (C-RFA) versus traditional radiofrequency ablation (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). The authors 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 the lack of statistically significant findings contributed to inconclusive results.

Professional Society Guidelines:

No position statements or clinical practice guidelines addressing cooled radiofrequency ablation (CRFA) are published in the peer reviewed medical literature with clinical evidence rated as high.

CODING INFORMATION: THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

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]

HCPCS	Description
	N/A

ICD-10	Description: [For dates of service on or after 10/01/2015]

	Any/All

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Government Agency

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    - COOLIEF Cooled Radiofrequency Kit. K163236. Nov, 2016. Accessed at: https://www.accessdata.fda.gov/cdrh_docs/pdf16/k163236.pdf
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Peer Reviewed Publications

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Professional Society Guidelines: N/A

Other Resources

20. COOLIEF (Avanos Medical, Inc.) [website]: Cooled Radiofrequency Products. Water-cooled technology to deactivate pain-causing sensory nerves. Accessed at: https://avanos.com.au/solutions/chronic-pain/cooled-radiofrequency-products/
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REVISION/REVIEW HISTORY:

12/9/2020: New Policy. Advanced Medical Review (AMR): Policy was reviewed by a practicing MD board certified in Physical Med & Rehab, Pain Management. 10/11/20.