Priority Health

MEDICAL POLICY
No. 91647-R0

NEUROABLATION FOR PAIN MANAGEMENT

Effective Date: March 1, 2025	**Review Dates: 02/25**
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Related policies:

- *Osteoarthritis of the Knee* #91571
- *Spine Procedures* # 91581

I. POLICY/CRITERIA

A. Due to insufficient evidence of impact on long-term health outcomes the following procedures are considered experimental/investigational and/or not medically necessary:

   a. Cooled radiofrequency ablation (e.g., Coolief) for all indications.
   b. Pulsed radiofrequency ablation for all indications.
   c. Cryoneurolysis (e.g., iovera) for all indications.

B. Radiofrequency Ablation (RFA) for Back Pain

   a. RFA, defined as conventional non-pulsed radiofrequency devices generating temperatures ranging from 60 °C to 90 °C, targeting pain originating in the cervical, thoracic, or lumbar spinal regions is medically necessary under the following conditions:
      1. Patient's symptoms are not consistent with identifiable pathology including disc herniation, spondylolisthesis, spinal stenosis.
      2. Absence of any neurologic deficit.
      3. Back or neck pain predominates over leg pain or arm pain, respectively.
      4. Two diagnostic medial branch nerve blocks, provided under a standard protocol that alternates long- and short-acting anesthetic blocks, produce ≥ 50% symptom relief physiologically consistent with medial nerve branch pathology.

   b. RFA is considered experimental/investigational and/or not medically necessary for the following:
      1. RFA of the sacroiliac (SI) joint.
      2. RFA of the sacral nerve.

   c. Intraosseous Basivertebral Radiofrequency Nerve Ablation (e.g., Intracept System) is medically necessary when all the following are met:
      1. Ablation of basivertebral nerves of the L3 through S1 vertebrae; and;
      2. Chronic low back pain of at least six months duration that has not responded to at least six months of conservative care; and
      3. MRI evidence consistent with Type 1 or Type 2 Modic changes; and;

4. None of the contraindications listed below:
5. Severe cardiac or pulmonary compromise.
6. The targeted ablation zone is less 10 mm away from a sensitive structure not intended to be ablated, including the vertebral foramen (spinal canal).
7. Active systemic infection or local infection in the area to be treated.
8. Currently pregnant.
9. Skeletally immature patients (generally < 18 years of age)
10. Has implantable pulse generators (e.g., pacemakers, defibrillators) or other electronic implants.

d. RFA procedure consists of one or more ablations during a single visit.

II. MEDICAL NECESSITY REVIEW

Prior authorization for certain drug, services, and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service, or procedure is medically necessary. For more information, please refer to the Priority Health Provider Manual.

RFA procedures are limited to two per year. RFA procedures beyond two per year require medical review.

III. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- **HMO/EPO:** ***This policy applies to insured HMO/EPO plans.***
- **POS:** ***This policy applies to insured POS plans.***
- **PPO:** ***This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.***
- **ASO:** ***For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.***
- **INDIVIDUAL:** ***For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.***
- **MEDICARE:** ***Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.***
- **MEDICAID/HEALTHY MICHIGAN PLAN:** ***For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between***

this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

IV. BACKGROUND

Neuroablative techniques in pain management consist of surgical and nonsurgical procedures to denervate a nerve such as radiofrequency ablation (conventional, cooled, or pulsed), cryosurgery (cryoablation or cryoneurolysis), or chemical ablation. The goal of denervation is to interrupt the pain signals that are sent to the brain from the joints and nerves.

Radiofrequency Ablation

Radiofrequency Ablation (RFA), also referred to as radiofrequency neurotomy or radiofrequency denervation, delivers high-frequency electric current to cause thermal damage with the intent to modulate the transmission of pain signals. For the purposes of this policy, RFA refers to conventional non-pulsed radiofrequency devices which generate temperature ranging from 60 °C to 90 °C to the target nerve. The RFA electrode generates radiofrequency energy that results in friction from the movement of ions generating heat of approximately 80 °C that causes destruction of target nerves. Charring of surrounding tissue at the electrode interface is a key limitation of standard RFA (Kapural and Deering, 2020). The effects of RFA in general are temporary and generally limited since pain signal transmission will return with peripheral nerve regrowth and regeneration (Choi et al., 2016; Gupta et al., 2017). Prior to RFA, a diagnostic block to confirm the source and level pain is conducted to predict the potential level of pain relief. The block consists of an injection of a local anesthetic near the area of pain. If the diagnostic block provides significant relief, the RFA procedure may move forward.

For the treatment of chronic back pain originating from sacroiliac joint (SIJ), RFA procedures typically target the areas adjacent to the lumbar L5 dorsal ramus and its branches, as well as the lateral branches of the sacral S1 through S3 dorsal rami (Hayes, 2022). For SIJ denervation, there is a lack of consensus regarding the exact innervation of the joint and the contributions of the various nerves. The anatomy of the SIJ is variable between patients and can even differ from one side to the other within the same person (Roberts et al., 2014). Substantial heterogeneity in RFA treatment characteristics exists across studies (Cheng, 2013; Salman, 2016; Vanaclocha, 2018). The reduction in SIJ pain provided by conventional RFA is likely to last up to 6 months, but it is uncertain whether there is a longer durability of effect. Additionally, it is uncertain whether conventional

RFA is associated with change in pain medication use or with improvement in disability/function or QOL.

Newer types of RFA devices were designed to function at lower temperatures and are less destructive to neuronal tissue. These include pulsed radiofrequency (PRF), which operates at 42 °C, and cooled RFA, which operates at 60 °C. PRF involves short, high-voltage bursts at a frequency of 2 Hertz (Hz) (2 pulses per second) that are separated by rest periods (e.g., 480 msec) that allow tissues to cool down, thereby minimizing tissue damage. The mechanism of action of PRF in pain relief is uncertain, but it may be related to effects of PRF on the electrical fields (Choi et al., 2016; Gupta et al., 2017; Cohen and Soriano, 2018; Kucia et al., 2019). Uncertainty remains surrounding the use of PRF due to the lack of standardization in procedural techniques, and there are currently no established treatment guidelines that recommend the use of PRF for chronic shoulder pain (Kucia et al., 2019; Eckmann et al., 2021). The cooled RFA (CRFA) technique circulates water internally through the probe that administers the electrical current, which removes heat and keeps the temperature at approximately 60 °C (Gupta et al., 2017; Oladeji and Cook, 2019). CRFA is intended to deliver more energy to target tissues in a larger ablative area (Kapural and Deering, 2020). The Coolief Cooled RF system (Avanos Medical Inc.) is an RFA system designed for the administration of CRFA. The Coolief system consists of a four-foot connecting cable and tubing, generator, and peristaltic pump unit. A thermocouple in the probe measures the electrode temperature throughout the procedure. A radiopaque marker located at the proximal end can be viewed under fluoroscopy to confirm position. A small current of radiofrequency is transmitted by a radiofrequency generator via an insulated electrode placed within tissue. The friction of charged molecules produces ionic heating that deactivates nerves that send pain signals to the brain. The moving fluid removes heat from where the tip and tissue interface, and large spherical lesions are created (Coolief Cooled RF System).

Coolief is cleared for marketing by the U.S. Food and Drug Administration (FDA) for knee pain and is used off-label at all other sites, including the hip. For the treatment of pain associated with knee osteoarthritis, studies generally demonstrated a reduction in pain from baseline up to 6 months, the clinical significance of this reduction was not consistently demonstrated. In addition, the lack of comparison with other minimally invasive techniques limits conclusions that can be drawn. CRFA generally resulted in a statistically significant reduction in pain with 50% to 77% of patients reporting a clinically significant reduction in pain at 6 months in 2 studies and 37% to 74% of patients achieving at least a 50% improvement in pain at 6 months in 4 studies (Davis et al., 2018; McCormick et al., 2018; Davis et al., 2019; Hunter et al., 2019; Kapural et al., 2019). However, proportions of patients achieving a 50% reduction in pain at longer follow-up were reduced substantially (Davis et al., 2019; Hunter et al., 2019). One study evaluated the effect of CRFA prior to total knee arthroplasty (TKA) on post-

surgical outcomes. No statistically significant differences were noted in pain reduction, functional outcomes, or medication use in the immediate postoperative phase and at 6 months between patients who underwent CRFA compared with patients who underwent sham prior to TKA.

The Intracept® Intraosseous Nerve Ablation System (Relievant Medsystems) uses radiofrequency ablation to interrupt the nerve pathway of the basivertebral nerves (BVN) of the L3 through S1 vertebrae, leading to relief of associated pain. Under fluoroscopic guidance, a cannula is advanced through the pedicle. The cannula is utilized to create a channel to the trunk of the basivertebral nerve. Then a radiofrequency probe is inserted into the curved path and placed at the basivertebral nerve. Finally, a radiofrequency generator is utilized to ablate the basivertebral nerve. The Intracept System is intended for the relief of chronic low back pain of at least six months duration that has not responded to at least six months of conservative nonsurgical care, and is also accompanied by features consistent with Type 1 such as inflammation, edema, vertebral endplate changes, disruption and fissuring of the endplate, vascularized fibrous tissues within the adjacent marrow, hypointensive signals, or Type 2 Modic changes to the vertebral body marrow including replacement of normal bone marrow by fat, and hyperintensive signals on an MRI. Evidence in the peer-reviewed literature include two randomized control trials, and retrospective and prospective case series evaluating the Intracept system for treatment of chronic low back pain. Fischgrund (2018; 2019) compared Intracept treatment to sham treatment and Khalil (2019) compared it to usual care. Fischgrund et al (2018) published a double-blind, a sham-controlled RCT evaluating the safety and efficacy of the Intracept system and RF ablation of the BVN for the treatment of chronic low back pain. A total of 225 participants with chronic (≥ 6 months) isolated lumbar pain who had not responded to at least 6 months of non-operative management were randomized to either a sham (n=78) or treatment (n=147) intervention. In the active treatment group, the RF probe was activated and the temperature at the tip was maintained at 85°C for 15 minutes. The duration of the session in the sham group was the same but the RF treatment was only simulated. Study participants had a minimum ODI of 30 points (on 100 point scale) and a minimum VAS of 4 cm (10 cm scale). The primary efficacy endpoint was the comparative change in ODI from baseline to 3 months. Both intention-to-treat (ITT) and per protocol (PP) analysis were pre-planned. At 3 months, in the ITT analysis, there was no statistically significant difference between groups in the primary outcome, mean ODI. ODI improved a mean of 19.0 points in the treatment group and 15.4 points in the sham group, p=0.107. However, there was a difference between groups in the 3-month PP analysis: the mean ODI in the treatment arm improved 20.5 points and 15.2 points in the sham arm, p=0.019. In the 12-month PP analysis, the difference between the treatment and sham groups in mean ODI was no longer statistically significant (22.6 points versus 25.3 points, p=0.153). PP analyses of pain severity (assessed by VAS) found no significant difference between groups in VAS improvement at 3 months (p=0.083) but significantly greater

improvement in the treatment compared with the control group at 6 and 12 months. Fischgrund et al (2019) reported 24-month results from the above RCT. In this group, the mean improvement in ODI, which was 20.8 points at 3 months, was 23.4 points at 23 months. Data were not available on ODI outcomes at 24 months in the sham-treated group as unblinding occurred after 12 months and most individuals crossed over to treatment with the Intracept system. Fischgrund et al (2020) reported on 5-year treatment arm results. Mean ODI score improved from 42.81 to 16.86 at 5-year follow-up, a reduction of 25.95 points ($p < 0.001$). 66% of patients reported a > 50% reduction in pain, 47% reported a > 75% reduction in pain, and 34% of patients reported complete pain resolution.

Cryoneurolysis

The iovera° system is used to perform cryoneurolysis or cryoanalgesia, in which peripheral nerves are temporarily ablated using extreme cold administered by closed-end microneedles. The iovera° treatment does not include the injection of substances or opioids or other drugs. Cryoneurolysis is distinct and not equivalent to cryoablation, also known as cryoneuroablation, which functions with cooler temperatures (≤ –140°C) and completely destroys surrounding tissues. A randomized, double-blind, sham-controlled, multicenter trial with a 6-month follow-up in patients with mild-to-moderate knee osteoarthritis (OA) found statistically significant reduction in pain and improvement in function with iovera° over sham treatment was observed up to 90 days follow-up, depending on the scale used, with no benefit at 120 and 180 days (Radnovich, 2017). The change from baseline was clinically significant for iovera° treated patients for described measures of pain and function at all follow-up time points. For the sham group, pain and function was not clinically significant up to 150 days follow-up; however, at 180 days, there was a clinically significant reduction for both pain measures, suggesting a potential placebo effect. No studies compared iovera° with active treatment, and none evaluated potential clinical benefits of repeat administration. Currently, no relevant guidance specifically addresses the use of the iovera° system for treatment of osteoarthritis of the knee.

V. CODING INFORMATION

ICD-10 Codes that <u>may</u> apply:

G89.21 – G89.29	Chronic pain, not elsewhere classified
G89.3	Neoplasm related pain (acute) (chronic)
G89.4	Chronic pain syndrome
M54.03 - M54.09	Panniculitis affecting regions of neck and back
M54.5 – M54.9	Other back pain
M62.830	Muscle spasm of back
R52	Pain, unspecified

CPT/HCPCS Codes:

64624 Destruction by neurolytic agent, genicular nerve branches including imaging guidance, when performed
64628 Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; first 2 vertebral bodies, lumbar or sacral
64629 Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; each additional vertebral body, lumbar or sacral (List separately in addition to code for primary procedure.
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
C9808 Nerve cryoablation probe (e.g., cryoice, cryosphere, cryosphere max, cryoice cryosphere, cryoice cryo2), including probe and all disposable system components, non-opioid medical device (must be a qualifying medicare non-opioid medical device for post-surgical pain relief in accordance with section 4135 of the caa, 2023)
C9809 Cryoablation needle (e.g., iovera system), including needle/tip and all disposable system components, non-opioid medical device (must be a qualifying medicare non-opioid medical device for post-surgical pain relief in accordance with section 4135 of the caa, 2023)
0440T Ablation, percutaneous, cryoablation, including image guidance; upper extremity distal/peripheral nerve
0441T Ablation, percutaneous, cryoablation, including image guidance; lower extremity distal/peripheral nerve
0442T Ablation, percutaneous, cryoablation, including image guidance; nerve plexus or truncal nerve (e.g. Brachial plexus, pudendal nerve)

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Radiofrequency ablation

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