NO. 91647

NEUROABLATION FOR PAIN MANAGEMENT

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Policy scope: This policy defines limitations, and medical necessity criteria for neuroablative procedures intended for pain management, including radiofrequency ablation (conventional), intraosseous basivertebral nerve ablation, pulsed and cooled radiofrequency techniques, and cryoneurolysis.

Related policies:

- Osteoarthritis of the Knee No. 91571
- Spine Procedures No. 91581

I. MEDICAL NECESSITY CRITERIA

Inclusions:

The following neuroablative procedures are considered medically necessary when **all** applicable criteria are met:

A. Conventional Radiofrequency Ablation (RFA) for Back and Neck Pain

Conventional radiofrequency ablation (RFA), targeting the medial branch nerves innervating the cervical, thoracic, or lumbar facet joints, is considered medically necessary when **ALL** the following conditions are met:

1. The individual has chronic axial back or neck pain predominating over radicular leg or arm pain, respectively
2. Clinical presentation and diagnostic evaluation do not demonstrate another clear structural cause of the pain, including but not limited to:
    a. Disc herniation
    b. Spondylolisthesis
    c. Spinal stenosis
3. There is no objective neurologic deficit on clinical exam
4. The individual has failed non-surgical conservative management
5. Two diagnostic medial branch nerve blocks have been performed at the levels to be treated, using a standardized protocol alternating long- and short-acting local anesthetic agent; and each block results in greater than 50% improvement in pain relief that is physiologically consistent with the anesthetic used, confirming the facet joint as the pain generator.

B. Repeat Radiofrequency Ablation for Back and Neck Pain:

A repeat radiofrequency joint denervation/ablation is considered medically necessary when **ALL** of the following criteria have been met:

1. Documentation demonstrates:
    a. Pain relief of at least 50% which lasted for a minimum of 12 weeks.
    b. A minimum of 6 months has elapsed since the prior radiofrequency ablation procedure.
    c. Clinical findings and imaging studies suggest no other obvious cause of the cervical, thoracic, or lumbar axial pain (e.g., central spinal stenosis with neurogenic claudication/myelopathy; foraminal stenosis or disc herniation with concordant radicular pain/radiculopathy that has been treated; infection; tumor; fracture; pseudoarthrosis; pain related to spinal instrumentation).

C. Intraosseous Basivertebral Nerve Radiofrequency Ablation

Intraosseous Basivertebral Radiofrequency Nerve Ablation (e.g., Intracept System) is considered medically necessary when **all** the following criteria are met:

1. The ablation procedure targets the basivertebral nerves at vertebral levels L3 through S1; **and**
2. The individual is skeletally mature (≥ 18 years of age); **and**
3. The individual has chronic axial low back pain of at least six months' duration that has not responded to at least six months of conservative treatment (e.g., analgesics, anti-inflammatory drugs, muscle relaxants, exercise, spinal manipulation, physical therapy or home exercise programs); **and**

4. Lumbar MRI demonstrating Type 1 or Type 2 Modic changes at one or more vertebral endplates between L3 and S1 corresponding to the level(s) being treated; **and**
5. None of the following contraindications are present:
    a. Severe cardiac or pulmonary compromise
    b. Targeted ablation zone is less than 10 mm away from a sensitive structure not intended for ablation, including the vertebral foramen (spinal canal)
    c. Active systemic infection or localized infection at treatment site
    d. Pregnancy
    e. Skeletally immature (generally younger than 18 years of age)
    f. Presence of implantable pulse generators (e.g., pacemakers, defibrillators) or other electronic implants

D. Sacroiliac (SI) Joint Radiofrequency Ablation (RFA)

Conventional radiofrequency ablation of the sacroiliac (SI) joint may be considered medically necessary when **ALL** of the following criteria are met:

1. Member is 18 years of age or older
2. Member has diagnosis of chronic sacroiliac joint–mediated pain, supported by **all** of the following:
    a. Localized tenderness to palpation of the posterior SI joint without tenderness of similar severity at other potential pain generators (e.g. greater trochanter, lumbar spine, coccyx)
    b. Positive response to either:
        i. High thrust test OR
        ii. SI Joint compression test; AND
    c. At least two (2) additional positive SI joint provocative tests including:
        i. Gaenslen's test, or
        ii. Distraction test, or
        iii. FABER (Patrick's) test, or
        iv. Posterior provocation (sacral thrust) test
3. The Member has failed a minimum of three months of appropriate conservative management which may include one or more of the following:
    a. Physical therapy
    b. Pharmacologic therapy, and/or
    c. Activity modification
4. The Member has demonstrated an appropriate response to image-guided diagnostic blockade of the L5 primary dorsal ramus and sacral lateral branches (S1-3) defined as:
    a. Greater than or equal to 50% improvement in pain and function
5. Clinical evaluation and/or imaging **do not** suggest another primary cause of pain, including but not limited to:
    a. Tumor
    b. Infection
    c. Inflammatory disease
    d. Osteoarthritis
    e. Neural compression

f. Primary degenerative spinal pathology

6. Contraindications:
    a. The Member must have none of the following:
        i. Sacral fracture
        ii. Malignancy involving the sacrum or adjacent structures
        iii. Active infection at the treatment site or systemic infection
        iv. Uncorrected coagulopathy or bleeding disorder

E. Repeat Radiofrequency Ablation for SI joint:

If the Member has undergone prior SI joint radiofrequency ablation, repeat RFA may be considered medically necessary only when all of the following are met:

1. Documentation demonstrates:
    a. Greater than or equal to 50% reduction in pain, and associated functional improvement
    b. A minimum of 12 weeks following the previous ablation; and
    c. A minimum of 6 months has elapsed since the prior SI joint radiofrequency ablation procedure.

Exclusions:

A. Not Medically Necessary as Considered Experimental/Investigational

The following procedures and applications of radiofrequency ablation are considered experimental/investigational and/or not medically necessary due to insufficient evidence demonstrating improvement in long-term health outcomes:

1. Cooled radiofrequency ablation (e.g., Coolief) for all indications (except Knee OA- See PH medical policy: Osteoarthritis of the knee No. 91571)
2. Pulsed radiofrequency ablation for all indications
3. Cryoneurolysis (e.g., iovera°), including nerve cryoablation (e.g., intercostal nerve cryoablation) and cryodenervation for **all** indications.

Limitations:

A. A radiofrequency ablation procedure may consist of one or more ablations performed during a single treatment visit.

II. CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) COVERAGE DETERMINATION

Any applicable federal or state mandates will take precedence over this medical coverage policy.

Medicare: Refer to the CMS Online Manual System (IOMs) and Transmittals.
For the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA) refer to CMS Medicare Coverage Database.

The information below is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the

most current CMS information may not be contained in this document. MAC jurisdiction for purposes of local coverage determinations is governed by the geographic service area where the Medicare Advantage plan is contracted to provide the service. Please refer to the Medicare Coverage Database website for the most current applicable NCD, LCD, LCA, and CMS Online Manual System/Transmittals.

National Coverage Determinations (NCDs)	
None identified	
Local Coverage Determinations (LCDs)	
CGS Administrators, LLC	LCD - Sacroiliac Joint Injections and Procedures (L39383)
First Coast Service Options, Inc.	LCD - Facet Joint Interventions for Pain Management (L33930) LCD - Peripheral Nerve Blocks (L33933)
Wellpoint Federal (formerly National Government Services, Inc.)	LCD - Sacroiliac Joint Injections and Procedures (L39455) LCD - Facet Joint Interventions for Pain Management (L35936) LCD - Peripheral Nerve Blocks (L36850)
Noridian Healthcare Solutions	LCD - Sacroiliac Joint Injections and Procedures (L39462) LCD - Intraosseous Basivertebral Nerve Ablation (L39642)
Novitas Solutions, Inc.	None identified
Palmetto GBA	LCD - Sacroiliac Joint Injections and Procedures (L39402) LCD - Facet Joint Interventions for Pain Management (L38765) LCD - Thermal Destruction of the Intraosseous Basivertebral Nerve (BVN) for Vertebrogenic Lower Back Pain (L39420)
WPS Insurance Corporation	LCD - Sacroiliac Joint Injections and Procedures (L39475) LCD - Facet Joint Interventions for Pain Management (L38841)

III. BACKGROUND

Neuroablative techniques in pain management consist of surgical and nonsurgical procedures to denervate a nerve such as radiofrequency ablation (conventional, cooled, or pulsed), Cryoanalgesia (e.g., cryoneuroablation, 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 (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). Accordingly, repeat radiofrequency ablation procedures are contingent upon documentation of meaningful, time-limited clinical benefit following prior treatment, consistent with evidence demonstrating temporary denervation and subsequent nerve regeneration. 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.

Cooled Radiofrequency Ablation (e.g., Coolief)
Cooled radiofrequency ablation (CRFA) is a variation of thermal radiofrequency technology that utilizes internally cooled probes to dissipate heat at the electrode–tissue interface, maintaining probe temperatures of approximately 60 °C while allowing surrounding tissues to reach higher temperatures. This design generates larger and more uniform lesion volumes compared with conventional radiofrequency ablation, which has been proposed as a potential advantage in regions with complex or variable innervation (Gupta et al., 2017; Kapural & Deering, 2020; Rodríguez-Merchán et al., 2023).

The Coolief® cooled radiofrequency system (Avanos Medical Inc.) is cleared by the U.S. Food and Drug Administration (FDA) for the treatment of knee pain and is used off-label for all other anatomic sites. While CRFA has been evaluated in several pain conditions, the overall body of evidence is characterized by heterogeneous study designs, variable procedural techniques, inconsistent diagnostic criteria, and limited long-term follow-up, which restricts the ability to draw definitive conclusions regarding durable clinical benefit across indications.

In studies evaluating CRFA for knee osteoarthritis, short-term reductions in pain have been reported, with a proportion of patients achieving clinically meaningful pain relief at approximately six months. However, durability beyond this time frame has been

inconsistent, and the proportion of patients achieving sustained benefit declines substantially at longer follow-up intervals (Davis et al., 2018; Davis et al., 2019; Kapural et al., 2019). In addition, many trials lack comparison with alternative minimally invasive interventions, utilize crossover designs, or rely on short-term endpoints, limiting the strength and generalizability of their findings.

Evidence supporting CRFA for axial spine or sacroiliac joint–related pain is further limited by substantial heterogeneity in patient selection, diagnostic block protocols, target nerve selection, and outcome assessment. Available studies frequently lack blinding and rely on pragmatic or real-world comparators rather than sham-controlled designs, increasing susceptibility to bias. Moreover, no standardized procedural parameters or validated criteria have been established to reliably identify patients most likely to derive durable benefit from treatment (Gupta et al., 2017; Rodríguez-Merchán et al., 2023). Although some studies suggest short-term pain reduction in select populations, the absence of standardized diagnostic pathways, variability in procedural technique, and inconsistent long-term durability limit the applicability of these findings to routine clinical coverage determinations.

Across indications, there remains insufficient high-quality evidence demonstrating consistent, long-term improvements in pain, function, or quality-of-life outcomes attributable to cooled radiofrequency ablation. In the absence of standardized technique, robust sham-controlled trials with durable follow-up, and broad professional society guideline endorsement, cooled radiofrequency ablation remains investigational for pain management outside of limited contexts addressed in separate, indication-specific policies. Accordingly, cooled radiofrequency ablation is not considered medically necessary for routine clinical use.

Cryoanalgesia (e.g., Cryoneuroablation, Cryoneurolysis)
Cryoanalgesia, including cryoneurolysis, is a peripheral nerve intervention that applies extreme cold via closed-end probes or microneedles to temporarily disrupt nerve conduction. Devices such as the iovera® system are designed to produce reversible axonal injury rather than permanent neurodestruction, distinguishing cryoneurolysis from cryoablation procedures that utilize substantially lower temperatures (≤ –140 °C) and result in irreversible tissue destruction. As sensory function is expected to recover with nerve regeneration, the analgesic effect of cryoneurolysis is inherently time-limited, and its role in durable pain management remains uncertain (McMillan et al., 2020).

The evidence base evaluating cryoneurolysis for chronic pain conditions is limited and heterogeneous. A randomized, double-blind, sham-controlled trial assessing cryoneurolysis for knee osteoarthritis demonstrated statistically significant improvements in pain and function compared with sham treatment during early follow-up; however, benefits were transient, with attenuation of effect beyond approximately three months and no sustained improvement demonstrated at later follow-up intervals (Radnovich et al., 2017). The absence of active comparator groups, lack of repeat-treatment data, and signal of placebo response further limit the clinical interpretation of these findings.

Recent systematic reviews and meta-analyses reinforce these limitations. A meta-analysis of minimally invasive genicular nerve–targeted interventions for knee osteoarthritis concluded that evidence supporting cryoneurolysis is of low to very-low certainty, with minimal or inconsistent effects on pain and no reliable demonstration of sustained functional improvement (Almeida et al., 2025). Similarly, a systematic review

comparing nerve ablation techniques with sham procedures reported short-term pain reductions but emphasized substantial heterogeneity in treatment protocols, outcome measures, and follow-up duration, as well as an absence of long-term data sufficient to support routine clinical use (Antunes Júnior et al., 2025).

Cryoneurolysis has also been evaluated in perioperative settings, particularly as an adjunct for short-term analgesia surrounding total knee arthroplasty. While reductions in peri- and early postoperative pain have been reported, these findings reflect temporary perioperative analgesic effects rather than durable treatment of chronic pain. Available studies do not establish long-term benefit, optimal timing, repeat-treatment effectiveness, or sustained functional improvement, limiting their relevance to ongoing pain management indications (Goodwin et al., 2025; Gabriel & Ilfeld, 2018; Gabriel & Ilfeld, 2022).

Across indications, cryoneurolysis has not demonstrated consistent or durable improvements in pain, function, or quality-of-life outcomes, and the body of evidence is characterized by short-term follow-up, low certainty, and substantial methodological variability. In the absence of standardized treatment protocols, validated patient-selection criteria, and high-quality evidence demonstrating sustained clinical benefit, cryoanalgesia remains investigational. Accordingly, cryoneurolysis and related cryoablative techniques are not considered medically necessary for any indication.

Cryoablation of the Intercostal Nerves
Intercostal nerve cryoablation (INC), also known as cryoanalgesia or cryoneurolysis, is a regional analgesic technique in which subzero temperatures are applied to the intercostal nerves to temporarily interrupt sensory nerve conduction and reduce postoperative pain following thoracotomy. Using a cryoprobe, localized freezing disrupts pain signal transmission while preserving nerve structure, with sensory function typically recovering over time as the nerve regenerates. INC has been evaluated as part of multimodal pain management strategies intended to reduce postoperative opioid use.

Despite demonstrated short-term reductions in acute postoperative pain and analgesic requirements, major professional society guidelines raise concerns regarding long-term outcomes. The Society of Cardiovascular Anesthesiologists (SCA) advises against routine use of intercostal cryoanalgesia due to evidence of an increased incidence of persistent post-thoracotomy pain, based on systematic review and expert consensus (Makkad et al., 2023). Similarly, the Enhanced Recovery After Surgery (ERAS) Society and the European Society of Thoracic Surgeons (ESTS) do not recommend cryoanalgesia, citing evidence that it may potentiate chronic postoperative pain and favoring alternative regional analgesic techniques with more favorable safety profiles (Batchelor et al., 2019).

Guidance from the European Society of Regional Anaesthesia and Pain Therapy (ESRA) is more limited, indicating that cryoanalgesia may be considered only in select cases when standard regional analgesia techniques cannot be performed, reflecting conditional and non-routine support rather than endorsement for standard use (Lemoine et al., 2026).Based on the totality of evidence and current society guidelines, intercostal nerve cryoablation is considered experimental, investigational, and/or unproven for routine management of post-thoracotomy pain.

Pulsed RFA

Pulsed radiofrequency ablation (PRF) is a neuromodulatory technique that delivers short bursts of high-voltage radiofrequency energy at lower temperatures (approximately 42 °C), separated by rest intervals (e.g., 480 milliseconds at a frequency of 2 Hz), with the intent of limiting thermal injury to surrounding tissues. Unlike conventional radiofrequency ablation, PRF does not reliably produce neurodestructive lesions, and its proposed analgesic effect—potentially related to transient electrical field modulation rather than nerve ablation—remains incompletely understood (Choi et al., 2016; Gupta et al., 2017; Cohen & Soriano, 2018; Kucia et al., 2019).

The available evidence base for PRF is limited by small sample sizes, short-term follow-up, heterogeneity in procedural techniques, and inconsistent outcome measures across studies. No standardized procedural protocols or validated patient-selection criteria have been established, and results have not been shown to be consistently reproducible. Consequently, PRF has not demonstrated durable or clinically meaningful improvements in pain, function, or quality-of-life outcomes.

Clinical investigations of PRF have largely been condition-specific and exploratory, with most studies evaluating short-term pain outcomes. Randomized and prospective trials conducted in shoulder and upper-extremity pain conditions—including suprascapular nerve PRF and intra-articular PRF—have reported mixed or modest short-term pain reductions when compared with corticosteroid injections, transcutaneous electrical nerve stimulation, or control interventions, without consistent evidence of sustained functional or quality-of-life benefit (Eyigor et al., 2010; Korkmaz et al., 2010; Wu et al., 2014; Ergonenc & Beyaz, 2018; Yan & Zhang, 2019). These studies are further limited by small enrollment sizes, variable comparator arms, lack of blinding in some trials, and short durations of outcome assessment, limiting their generalizability and clinical significance.

According to the 2024 European Association of Urology (EAU) Chronic Pelvic Pain Guidelines, pulsed radiofrequency lesioning is described as an *emerging* intervention, with early evidence suggesting possible benefit in select cases. However, the guideline emphasizes that available studies are characterized by short-term follow-up and insufficient methodological rigor, and that additional high-quality research is required before PRF can be recommended for routine clinical use. Notably, no major professional medical society currently endorses pulsed radiofrequency ablation for the routine treatment of chronic pain conditions.

Taken together, the current body of evidence does not demonstrate consistent, durable improvement in pain, function, or quality-of-life outcomes with pulsed radiofrequency ablation. Due to persistent uncertainty regarding its mechanism of action, lack of standardized technique and patient-selection criteria, and absence of guideline-supported indications, pulsed radiofrequency ablation remains investigational and is not considered medically necessary for any indication.

Sacroiliac (SI joint) Radiofrequency Ablation (RFA)
Chronic low back pain arising from the sacroiliac joint (SIJ) is a recognized clinical entity, accounting for an estimated 15–30% of cases of axial/mechanical low back pain in selected populations (Cohen et al., 2023; Janapala et al., 2024). When SIJ pain is suspected, diagnosis is supported by a combination of clinical findings, including pain reproduction with standardized SIJ provocation tests and confirmation with image-guided diagnostic blocks (Laslett et al., 2005; Cohen et al., 2023). In addition, fluoroscopically guided diagnostic and therapeutic intra-articular SIJ injections have been systematically

reviewed, supporting their role as part of the diagnostic and management pathway for suspected SIJ pain (Kennedy et al., 2015).

Anatomically, SIJ nociceptive input relevant to posterior SIJ complex pain is primarily mediated through the posterior sacral network via the lateral branches of the sacral dorsal rami (most consistently S1–S2, commonly S3) with variable contribution from L5 (and rarely S4), which serve as established targets for SIJ lateral branch RFA techniques (Roberts et al., 2014). Radiofrequency ablation is a commonly used interventional technique across spine and peripheral joint pain conditions and is typically described as thermal lesioning (continuous RFA) with other modalities (e.g., pulsed) discussed as distinct approaches (Wray et al., 2023).

Sacroiliac (SI) joint provocation tests are physical examination maneuvers designed to mechanically stress the SI joint in order to reproduce the patient's characteristic pain. Commonly utilized tests include Gaenslen's test, which applies torsional stress across the pelvis through combined hip flexion and extension; the SI joint distraction (gapping) test, which creates anterior separation of the SI joints via posteriorly directed pressure on the anterior superior iliac spines; the FABER (Patrick's) test, which evaluates pain provocation during combined hip flexion, abduction, and external rotation with posterior pelvic loading; and the posterior provocation test (also referred to as the thigh thrust or sacral thrust test), which generates posterior shear forces across the SI joint through axial loading of the femur. Reproduction of familiar pain during these maneuvers suggests SI joint–mediated pain, particularly when multiple tests are positive, as individual tests demonstrate improved diagnostic validity when used in combination rather than in isolation (Laslett et al., 2005).

Radiofrequency ablation for SIJ-mediated pain is intended to interrupt nociceptive signaling from the L5 dorsal ramus and S1–S3 sacral lateral branches in carefully selected patients who have failed conservative management and demonstrated an appropriate response to diagnostic blockade (Cohen et al., 2024). Evidence supporting RFA for chronic spinal pain includes systematic reviews/meta-analyses of radiofrequency denervation for chronic back pain (Chappell et al., 2020) and meta-analyses comparing radiofrequency approaches for facet and SIJ pain, highlighting variability by technique and study design (Shih et al., 2020). Evidence supporting conventional thermal (continuous) SIJ lateral branch RFA includes randomized and sham-controlled trials demonstrating short-term clinically meaningful improvements in pain and/or function in appropriately selected patients, though outcomes vary (Mehta et al., 2018; Salman et al., 2016; van Tilburg et al., 2016). A sham-controlled randomized trial evaluating a strip-lesioning radiofrequency neurotomy approach reported significant pain improvement versus sham through 3–6 months (Mehta et al., 2018). A randomized blind trial comparing lateral branch RFA to intra-articular steroid injection reported higher responder rates for RFA through 6 months (Salman et al., 2016). Conversely, a multicenter sham-controlled trial of percutaneous RF heat lesioning did not demonstrate a significant difference versus sham at 3 months, underscoring procedural and selection heterogeneity across the SIJ RFA evidence base (van Tilburg et al., 2016). Newer procedural approaches for SIJ RFA have also been described in interventional pain literature (Cheng et al., 2016).

Pooled evidence syntheses generally support RF-based approaches as a selective option for SIJ pain while emphasizing heterogeneity in diagnostic criteria, targets, lesioning parameters, and certainty of evidence (Janapala et al., 2024; Park et al., 2026;

Shih et al., 2020). A 2026 systematic review and network meta-analysis of randomized trials found RF-based interventions generally outperformed sham, steroid injections, and conservative care for short-term pain outcomes but rated certainty as low to very low due to study limitations and imprecision (Park et al., 2026). The broader literature also reflects that SIJ denervation represents one of several management options (including fusion for selected patients), with long-term comparative observational evidence showing variable outcomes across treatment pathways (Vanaclocha et al., 2018).

Cooled SIJ RFA (CRFA) has been studied versus standard medical management in a large randomized comparative-effectiveness trial and demonstrated improvements in a highly selected population (Cohen et al., 2024), with extended outcomes reported at 12 months in the observational/crossover phase (Cohen et al., 2025). However, evidence demonstrating incremental clinical benefit of cooled SIJ RFA over conventional thermal SIJ lateral branch RFA remains limited, and comparative observational evidence has not demonstrated longer duration of relief with cooled versus traditional RFA for SIJ lateral branches (Cheng et al., 2013). Additional mechanistic/imaging work has evaluated ablation zones formed by cooled radiofrequency across multiple axial spine sites, but this does not establish comparative clinical superiority for SIJ outcomes (Desai & Safriel, 2022).

Accordingly, this policy supports criteria-based medical necessity for conventional thermal SIJ lateral branch RFA performed under standardized diagnostic selection (including ≥50% improvement in pain and function following image-guided diagnostic blockade of the L5 dorsal ramus and S1–S3 lateral branches), while maintaining pulsed RF as excluded and cooled SIJ RFA as not medically necessary/investigational due to insufficient evidence demonstrating incremental clinical benefit over conventional thermal RFA (Cohen et al., 2024; Cheng et al., 2013; Janapala et al., 2024; Park et al., 2026; Shih et al., 2020; Wray et al., 2023).

The Intracept® Intraosseous Nerve Ablation System
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 includes two randomized control trials and subsequent prospective follow-up analyses 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.

IV. GUIDELINES / POSITION STATEMENTS

Medical/Professional Society	Guideline
American Academy of Orthopaedic Surgeons (AAOS)	Management of Osteoarthritis of the Knee (Non-Arthroplasty) AAOS-2021
Society of Interventional Radiology Research Consensus Panel	Percutaneous Management of Osteoarthritis in the Knee: Proceedings from the Society of Interventional Radiology Research Consensus Panel (2021)
American Society of Pain and Neuroscience (ASPN)	American Society of Pain and Neuroscience Best Practice (ASPN) Guideline for the Treatment of Sacroiliac Disorders (2024)
North American Spine Society (NASS)	Diagnosis and Treatment of Low Back Pain - Clinical Guideline (2020)
Agency for Healthcare Research and Quality	Comparative Effectiveness Review No. 247_Interventional Treatments for Acute

	and Chronic Pain: Systematic Review (2021)
American Society of Interventional Pain Physicians (ASIPP)	Evidence-Based Guidelines for Facet Joint Interventions in the Management of Chronic Spinal Pain: American Society of Interventional Pain Physicians (ASIPP) Guidelines (2020)
American Academy of Pain Medicine (AAPM) and American Society of Regional Anesthesia & Pain Medicine (ASRA-PM)	Consensus practice guidelines on sacroiliac joint complex pain from a multispecialty, international working group | Pain Medicine | Oxford Academic (2025)
Association of Extremity Nerve Surgeons	The Association of Extremity Nerve Surgeons CPG- 2020
European Association of Urology 2024	EAU-Guidelines-on-Chronic-Pelvic-Pain-2024.pdf
International Society for the Advancement of Spine Surgery	International Society for the Advancement of Spine Surgery Guideline—Intraosseous Ablation of the Basivertebral Nerve (2020)
Society of Cardiovascular Anesthesiologists (SCA)	Practice Advisory for Preoperative and Intraoperative Pain Management of Thoracic Surgical Patients: Part 1 (2023)
Enhanced Recovery After Surgery (ERAS) Society and European Society of Thoracic Surgeons (ESTS)	Guidelines for Enhanced Recovery After Lung Surgery: Recommendations of the Enhanced Recovery After Surgery (ERAS) Society and the European Society of Thoracic Surgeons (ESTS) (2019)
European Society of Regional Anaesthesia and Pain Therapy (ESRA)	Pain Management After Open Thoracotomy 2025: Procedure-Specific Postoperative Pain Management (PROSPECT) Recommendations (2025)

V. REGULATORY (US FOOD AND DRUG ADMINISTRATION)

See U.S. Food & Drug Administration (FDA) Medical Device Databases for the most current information.

Device	Premarket Approval, 513(f)(2)(De Novo), or 510(k) Number	Notice date
iovera° system (Pacira BioSciences)	K133453 K211334 K220656 K243677	03/24/2014 09/10/2021 05/20/2022 12/26/2024

cryoICE® CRYO2 / CRYO3 (AtriCure)	K180138 K200697	02/15/2018 12/23/2020
cryoICE® cryoSPHERE / cryoSPHERE+ (AtiCure)	K182565 K200697 K243157	11/09/2018 12/23/2020 10/28/2024
cryoICE® cryoXT (AtriCure)	K250371	04/10/2025
AtriCure cryoFORM® / cryoICE® CRYO2 Cryoablation Probe	K152337	03/22/2016
AtriCure cryoSPHERE+™, cryoSPHERE MAX™ Cryoablation Probes	K233170	10/26/2023
Coolief* Cooled Radiofrequency Kit (Halyard Health Inc.)	K163236	12/16/2016
Coolief* Cooled RF Probe (Halyard Health Inc.)	K163461	04/13/2017
Coolief* Radiofrequency Generator (CRG) System (Avanos Medical Inc.)	K192491	02/21/2020
Coolief Cooled Radiofrequency Kit Advanced (Avanos Medical Inc.)	K203066	12/22/2020
COOLIEF* Radiofrequency Generator (Avanos Medical Inc.)	K242057	08/14/2024
Electrothermal 20S Spine System (Smith & Nephew Inc.)	K033981	02/25/2004
G4 Radiofrequency Generator, Model RFG-4 (Cosman Medical Inc.)	K082051	10/16/2008
NeuroTherm NT 100 RF Lesioning System (NeuroTherm Inc.)	K052878	01/23/2006
NT 2000 Lesioning Generator (NeuroTherm Inc.)	K111576	09/20/2011
Intracept System (Relievant Medsystems Inc.	K190504	05/03/2019
PainBlocker Cryoneuroablation System (Epimed International Inc.)	K854334	04/30/1986
Intracept Intraosseous Nerve Ablation System	k153272	06/09/2016

VI. CODING

ICD-10 Codes that may support medical necessity

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

Cooled RFA of Spine

22899	Unlisted procedure, spine (when used to report cooled radiofrequency ablation)

Pulsed RFA of Spine

22899	Unlisted procedure, spine (when used to report pulsed RFA for Spinal Pain)
64999	Unlisted procedure, nervous system (when used to report pulsed RFA for Spinal Pain)

Intercostal Nerve Cryoablation (INC)

64999	Unlisted procedure, nervous system [when specified as Intercostal Nerve Cryoablation (INC)]

Sacroiliac (SI) Joint Denervation

64625	Radiofrequency ablation, nerves innervating the sacroiliac joint, with image guidance (i.e., fluoroscopy or computed tomography) (Not covered when billed for **COOLED** Radiofrequency ablation (RFA)

RFA of Intraosseous Basivertebral Nerve for Spine

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)
22899	Unlisted procedure, spine (when used to report the Intracept procedure)

Destruction by Neurolytic Agent

64620	Destruction by neurolytic agent, intercostal nerve
64624	Destruction by neurolytic agent, genicular nerve branches including imaging guidance, when performed
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

Percutaneous Cryoablation

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)
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)

VII. MEDICAL NECESSITY REVIEW

Prior authorization for certain drugs, devices, 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, refer to the Priority Health Provider Manual.

Individual case review may allow coverage for care or treatment that is investigational yet promising for the conditions described. Requests for individual consideration require prior plan approval. All determinations of coverage for experimental, investigational, or unproven treatment will be made by a Priority Health medical director or clinical pharmacist. The exclusion of coverage for experimental, investigational, or unproven treatment may be reviewed for exception if the condition is either a terminal illness, or a chronic, life threatening, severely disabling disease that is causing serious clinical deterioration.

VIII. APPLICATION TO PRODUCTS

Coverage is subject to the 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. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual, 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.

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SUMMARY OF CHANGES

Deletions:

- Removed the prior limit of two RFA procedures per year and requirement for medical review beyond two.
- Removed outdated references.

Changes:

- Conventional sacroiliac joint radiofrequency ablation moved from E/I/U to medically necessary when medical necessity criteria is met. Prior Authorization required.
- Updated E/I/U: Cooled radiofrequency ablation for all indications (except Knee OA)-See PH Medical Policy: Osteoarthritis of the knee No. 91571).

Additions:

- Added medical necessity criteria for repeat radiofrequency ablation for back and neck pain.
- New policy template standardization with Policy Scope, FDA/Regulatory, Medical/Professional Society Guidelines, and CMS sections.

Clarifications:

- Updated background, references, and clarified criteria language.
- Expanded not medically necessary to include nerve cryoablation (such as intercostal nerve cryoablation) and cryodenervation.

Past committee review dates: 02/2025, 02/2026, 05/2026

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