Ablative Treatment for Spinal Pain

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➲ Instructions for Use

Table of Contents **Page**

Related Commercial/Individual Exchange Policies

- Discogenic Pain Treatment
- Epidural Steroid Injections for Spinal Pain
- Facet Joint and Medial Branch Block Injections for Spinal Pain
- Occipital Nerve Injections and Ablation (Including Occipital Neuralgia and Headache)
- Office Based Procedures – Site of Service

Community Plan Policy

- Ablative Treatment for Spinal Pain

Medicare Advantage Policy

- Pain Management

Application

UnitedHealthcare Commercial

This Medical Policy applies to all UnitedHealthcare Commercial benefit plans.

UnitedHealthcare Individual Exchange

This Medical Policy applies to Individual Exchange benefit plans in all states except for Colorado.

Coverage Rationale

Note: Conventional (Thermal) Radiofrequency Ablation requires site of service review. Refer to the Medical Policy titled Office Based Procedures – Site of Service.

The following facet joint nerve ablation techniques are unproven and not medically necessary due to insufficient evidence of efficacy:

- Pulsed Radiofrequency Ablation of the facet nerves of the cervical, thoracic or lumbar region, sacral nerve root, or dorsal root ganglion
- Endoscopic radiofrequency ablation/endoscopic rhizotomy
- Cryoablation (cryodenervation, cryoneurolysis, cryosurgery, or cryoanesthesia)
- Cooled Radiofrequency Ablation
- Chemical ablation (including, but not limited to, alcohol, phenol, or sodium morrhuate)
- Laser ablation (including pulsed, continuous, or low level)

Ablation for treating sacroiliac pain is unproven and not medically necessary due to insufficient evidence of efficacy.

Intraosseous radiofrequency ablation of the basivertebral nerve (e.g., Intracept®) for the treatment of spinal pain is unproven and not medically necessary due to insufficient evidence of efficacy.

Definitions

Conventional (Thermal) Radiofrequency Ablation: The application of continuous high frequency electrical current to ablate nerve tissue

- Temperature ≥ 60° Celsius; and
- Duration of ablation ≥ 40 seconds; and
- Confirmation of needle placement by fluoroscopic guided imaging

Cooled Radiofrequency Ablation: The application of continuous high frequency electrical current to ablate nerve tissue using water-cooled electrodes/probes.

Pulsed Radiofrequency Ablation: Technique that delivers intermittent short bursts of energy, instead of continuous energy, using a probe temperature of 42°-45° Celsius (Hayes, 2023).

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

Coding Clarification: CPT code 64999 is to be used for pulsed radiofrequency ablation (CPT® Assistant, 2016).

CPT Code	Description
22899	Unlisted procedure, spine [when used to report the Intracept procedure or cooled radiofrequency ablation]
27299	Unlisted procedure, pelvis or hip joint
64625	Radiofrequency ablation, nerves innervating the sacroiliac joint, with image guidance (i.e., fluoroscopy or computed tomography)
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)
64999	Unlisted procedure, nervous system

Description of Services

Pulsed RFA delivers short bursts of radiofrequency (RF) energy instead of the conventional technique of continuous energy, allowing the tissue to cool between bursts in a pulsed manner. (Hayes, 2023).

Endoscopic rhizotomy, a posterior endoscopic method, also known as dorsal endoscopic rhizotomy, has been developed as an alternative to percutaneous electrode RFA to target the medial, intermediate and lateral branches of the dorsal ramus using a modification of the Yeung Endoscopic Spinal Surgery (Y.E.S.S.) cannula and a specially designed Ellman radiofrequency bipolar electrode.

Cryoablation involves the use of extreme cold to destroy nerve tissue.

Cooled radiofrequency (e.g., Coolief) transmits thermal radiofrequency energy using water-cooled electrodes/probes. Chemical ablation uses an injection of chemicals, such as phenol or alcohol, to destroy nerve tissue.

Laser ablation destroys nerve tissue using a laser beam.

Clinical Evidence

Pulsed Radiofrequency Ablation

There is insufficient evidence to establish the safety and efficacy of pulsed RFA for treating spinal pain. Well-designed, randomized controlled trials with large sample sizes and long-term follow-up are needed to establish the impact on health outcomes.

An AHRQ comparative effectiveness review evaluated pulsed RFA for treating facet joint pain in the Medicare population. The report concluded that the evidence was insufficient to assess pulsed RFA for presumed facet joint pain versus sham denervation or continuous radiofrequency denervation (Chou et al., 2021).

Kroll et al. (2008) compared the efficacy of continuous radiofrequency (CRF) thermocoagulation with pulsed RFA in a prospective, randomized, double-blinded study of 50 patients with lumbar back pain. Target facet joints were identified with oblique radiographic views. Continuous radiofrequency thermocoagulation was delivered at 80°C for 75 seconds, while PRF was delivered at 42°C with a pulse duration of 20 ms and pulse rate of 2 Hz for 120 seconds. No significant differences in the relative percentage improvement were noted between groups in either VAS or Oswestry Low Back Pain and Disability Questionnaire (OSW) scores. Within the PRF group, comparisons of the relative change over time for both VAS and OSW scores were not significant. However, within the CRF group, VAS and OSW scores showed significant improvement. The investigators concluded that although there was no significant difference between CRF and PRF therapy in long-term outcome in the treatment of lumbar facet syndrome, there was a greater improvement over time noted within the CRF group. Furthermore, the sample size may have been too small to detect clinically significant differences between the interventions.

Chao et al. (2008) retrospectively reviewed a case series of154 patients with lumbar or cervical radicular pain due to a herniated intervertebral disk or previous failed surgery to analyze the efficacy of percutaneous pulsed RFA. Patients had pulsed RFA in 2 to 4 spinal levels unilaterally with follow-up from 1 week to 1 year postoperatively. Fifty three percent of 49 patients with cervical pain and fifty percent patients with lumbar pain had an initial improvement of 50% or more in the first week of follow-up. Fifty-five percent of patients with cervical pain and forty four percent of patients with lumbar pain had pain relief of 50% or more at the 3-month follow-up. The authors concluded that pulsed RFA appears to provide intermediate-term relief of pain; however, further studies with long-term follow-up are necessary. Limitations of this study include lack of a comparison group, retrospective design and inability to generalize results due to wide range of follow-up. Additional well-designed studies are needed to evaluate long-term results of pulsed RFA.

Abejon (2007) completed a retrospective case series of the effectiveness of pulsed RFA applied to the lumbar dorsal root ganglion in 54 patients who underwent 75 PRF procedures. The patients were divided into three groups according to the etiology of the lesion herniated disc, spinal stenosis, and failed back surgery syndrome. The efficacy of the technique was assessed using a 10-point Numeric Rating Scale (at baseline and, along with the Global Perceived Effect (GPE) at 30, 60, 90, and 180 days. The reduction in medications and the number of complications associated with the technique were assessed although not reported. Pain reduction was noted in all groups except for those with failed back surgery syndrome. No complications were noted. The authors concluded that PRF was effective in herniated disc and spinal stenosis, but not failed back surgery syndrome. The flaws of this study include lack of a comparison group undergoing a different treatment, the retrospective design, subjective outcome measures and short-term follow-up.

Van Zundert (2007) studied the effect of pulsed RFA on patients with cervical radicular pain. A randomized sham-controlled trial of 23 patients out of 256 screened, met the inclusion criteria and were randomly assigned in a double-blind fashion to receive either pulsed RFA for 120 seconds or sham intervention. The evaluation was done by an independent observer. At 3 months the pulsed RFA group showed a significantly better outcome with regard to the global perceived effect (> 50% improvement) and VAS (20-point pain reduction). The quality-of-life scales also showed a positive trend in favor of the pulsed RFA group, but significance was only reached in the SF-36 domain vitality at 3 months. The need for pain medication was significantly reduced in the pulsed RFA group after six months. No complications were observed during the study period. The authors concluded that these study results are in agreement with the findings of a previously completed clinical audit that pulsed RFA of the cervical dorsal root ganglion may provide pain relief for a limited number of carefully selected patients with chronic cervical radicular pain as assessed by clinical and neurological examination. Although the study results are promising for certain patients, the small sample size, the use of subjective outcomes and lack of long-term follow-up minimize the generalizations of the conclusions.

Endoscopic Radiofrequency Ablation/Endoscopic Rhizotomy

There is insufficient evidence to establish the safety and efficacy of endoscopic RFA for treating spinal pain. Well-designed, randomized controlled trials with large sample sizes and long-term follow-up are needed to establish the impact on health outcomes.

Meloncelli et al. (2020) conducted a prospective cohort study to assess the effectiveness of endoscopic rhizotomy for denervation of lumbar facet joints in patients with chronic low back pain due to facet joint syndrome. The study included 40 out of 50 screened patients divided into two equal groups: group A patients were previously treated with percutaneous RFA (n = 20) and group B patients were having their first interventional treatment (n = 20). NRS and ODI scores were assessed before and after the procedure. All patients had a reduction in NRS and an improvement in ODI. NRS was reduced significantly after 1 month and remained the same until the end of the study. ODI was significantly improved from 1 month after surgery up to the end of the study. The improvements did not differ whether already treated with percutaneous rhizotomy. Patients less than 60 years or with 1-2 joints treated had better improvement compared with the others. The authors concluded that patients treated with endoscopic rhizotomy achieved pain relief through follow-up at two years. Study limitations include lack of randomization and control and small sample size. Larger randomized studies are needed to confirm these results.

Cryoablation

There is insufficient evidence to establish the safety and efficacy of cryoablation for treating sacroiliac pain. Well-designed, randomized controlled trials with large sample sizes and long-term follow-up are needed to establish the impact on health outcomes.

Birkenmaier et al. (2007) conducted a prospective clinical case series to examine the effects of medial branch cryodenervation (cryoablation) in the treatment of lumbar facet joint pain. Patient selection was based on medical history, physical examination and positive medial branch blocks. Percutaneous medial branch cryodenervation was performed using a Lloyd Neurostat 2000. Target parameters were low back pain (by means of VAS, limitation of activity (McNab) and overall satisfaction. A total of 50 patients were recruited, and 46 completed the study. The follow-up time was 1 year. At 6 weeks, 33 patients (72 %) were pain-free or had major improvement of low back pain; 13 (28 %) had no or little improvement. Including failures, mean low back pain decreased significantly from 7.7 pre-operatively to 3.2 at 6 weeks, 3.3 at 3 months, 3.0 at 6 months and 4.2 at 12 months. However, the authors noted that at the 12-month follow-up period the failure rate rose to 43%. The findings are limited by lack of a comparison group.

A prospective study by Staender et al. (2005) evaluated the therapeutic effect of computerized tomography (CT)–guided cryorhizotomy in the treatment of 76 patients with lumbar facet joint syndrome (LFJS). All of the patients received one treatment after confirmation with a medial branch block using a 1.3cm size needle. Twenty-six patients required 2-4 additional treatments and a 2.0cm needle was used. The VAS was used as an evaluation tool along with reports of return to work and pain med use. Success was determined to be 50% reduction in VAS scores. Pre-treatment the median score was 6.7 and post-treatment was 3.2 for up to 6 months. Patients without prior back surgery had a better result than post-surgical patients. The authors concluded the CT-guided treatment was effective. The intervening variable of the medial branch blocks has to be taken into account as part of the pain relief response which the authors acknowledge. Fifty percent of patients had 50% pain relief for at least up to a year in the reported aggregate data. Six percent of patients failed treatment. Although the results are promising, further study is needed to identify the placebo effect of the medial branch blocks. The findings are limited by lack of a comparison group.

Cooled Radiofrequency Ablation for Facet or Sacroiliac Joints

There is insufficient evidence to establish the safety and efficacy of cooled RFA for treating facet joint or sacroiliac pain. Well-designed, randomized controlled trials with large sample sizes and long-term follow-up are needed to establish the impact on health outcomes.

An AHRQ comparative effectiveness review by Chou et al., (2021) evaluated cooled RFA for treating sacroiliac and facet joint pain. Cooled RFA for sacroiliac pain was associated with a moderate to large reduction in pain and small to large improvement in function versus sham radiofrequency at 1 month. Improvements in pain and function at 3 months were moderate. Evidence beyond 6 months is lacking. Additionally, the trials utilized different techniques, with insufficient evidence to determine the optimal method. Cooled RFA for presumed facet joint pain was associated with a small, no statistically significant reduction in pain versus conventional RFA at 6 months and no difference in function. There were no differences at 1- and 3-month follow-ups. Evidence beyond 6 months is lacking. All studies were limited by small sample size and short-term follow-up. Larger, long-term studies are needed to confirm these findings.

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 for the treatment of lumbar facet joint pain. The primary outcome was the proportion of responders (≥ 50% Numeric Rating Scale [NRS] reduction) at 6 months. Secondary outcomes included NRS, ODI, and Patient Global Impression of Change. Forty-three participants were randomized to medical branch nerve 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. Due to the small sample size, the lack of statistically significant findings could be due to type 2 errors and the study should therefore be considered inconclusive.

Sun et al. (2018) conducted a meta-analysis to assess the efficacy and safety of using cooled radiofrequency ablation (RFA) in treating patients with chronic sacroiliac joint pain in terms of pain and disability relief, patients' satisfaction degree as well as complications. A total of 7 studies with 240 eligible patients were enrolled, but only two of these included a comparison group. The overall pooled results demonstrated that pain intensity decreased significantly after cooled RFA procedures compared with that measured before treatment. The authors suggest that high-quality and large-scale randomized controlled trials are required to validate their findings. The findings are limited by lack of a comparison group in most included studies.

Tinnirello et al. (2017) compared two radiofrequency devices, Simplicity III (conventional RFA), and SInergy (cooled RFA), which are specifically designed to denervate the sacroiliac joint as part of a retrospective cohort study. Forty-three patients with sacroiliac joint-derived pain refractory to conservative treatment; 21 and 22 patients, respectively, received Simplicity III or SInergy to denervate the sacroiliac joint. Mean numerical rating scale (NRS) and 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 RFA 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-RFA 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 sacroiliac joint-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 RFA procedure-required prone position. Randomized controlled trials are needed to confirm the implication made in this study that SInergy is the preferred RFA option for treating sacroiliac joint-derived pain and the disability associated with it. The findings of this study are limited by the observational design of the study, which could have introduced biases.

The use of cooled RFA lateral branch neurotomy to treat chronic sacroiliac joint-mediated low back pain in 126 patients was retrospectively reviewed in a case series by Stelzer et al. (2013, included in the Hayes report cited above). When stratified by time to final follow-up (4-6, 6-12, and > 12 months, respectively): 86%, 71%, and 48% of subjects experienced ≥ 50% reduction in VAS pain scores, 96%, 93%, and 85% reported their QOL as much improved or improved, and 100%, 62%, and 67% of opioid users stopped or decreased use of opioids. The authors concluded that the results show promising, durable improvements in pain, QOL, and medication usage with benefits persisting in some subjects at 20 months after treatment. The findings are however limited by lack of a comparison group.

Chemical Ablation

There is insufficient evidence to establish the safety and efficacy of chemical ablation for treating spinal pain. Well-designed, randomized controlled trials with large sample sizes and long-term follow-up are needed to establish the impact on health outcomes.

Joo et al. (2013), compared alcohol ablation with RFA in a randomized study of 40 patients with recurrent thoracolumbar facet joint pain after thermal RFA treatment. Patients were randomly allocated to two groups, receiving either the same repeated RFA (n = 20) or alcohol ablation (n = 20). At 24-month follow-up, three patients in the alcohol ablation group had recurring pain compared to 19 in the RFA group. The median effective periods were 10.7 months (range 5.4 to 24) for RFA and 24 months (range 16.8 to 24) for alcohol ablation. No significant complications were observed. This study is limited by small sample size and short-term follow-up.

Laser Ablation

There is insufficient evidence to establish the safety and efficacy of laser ablation for treating spinal pain. Well-designed, randomized controlled trials with large sample sizes and long-term follow-up are needed to establish the impact on health outcomes.

Lwatsuki (2007) reported treatment of facet syndrome by laser neurolysis in a case series of 21 participants including 5 who had undergone previous spinal surgery. One year after laser denervation, 17 participants experienced pain reduction of at least 70%. Of the 5 individuals who had previously undergone spinal surgery, 4 did not have a successful outcome from laser denervation at 1-year follow-up. This study is limited by small sample size, short-term follow-up and lack of a control group.

Intraosseous Radiofrequency Ablation of the Basivertebral Nerve

There is insufficient evidence to establish the safety and efficacy of intraosseous RFA of the basivertebral nerve for treating low back pain. Well-designed, randomized controlled trials with large sample sizes and long-term follow-up are needed to establish the impact on health outcomes.

Conger et al. (2021) conducted a systematic review of seven studies (n = 321) evaluating intraosseous basivertebral nerve radiofrequency neurotomy for the treatment of chronic low back pain with type 1 or 2 Modic changes. Studies included comparisons to sham, placebo procedure, active standard care treatment or no treatment. The primary outcome of interest was the proportion of individuals with ≥ 50% pain reduction. Secondary outcomes included ≥ 10-point improvement in function as measured by ODI as well as ≥ 2-point reduction in pain score on the VAS or NRS, and decreased use of pain medication. Reported 3-month success rate for ≥ 50% pain reduction ranged from 45% to 63%. Rates of functional improvement (≥ 10-point ODI improvement threshold) ranged from 75% to 93%. For comparison to sham treatment, the relative risk of treatment success defined by ≥ 50% pain reduction and ≥ 10-point ODI improvement was 1.25 and 1.38, respectively. For comparison to continued standard care treatment the relative risk of treatment success defined by ≥ 50% pain reduction and ≥ 10-point ODI improvement was 4.16 and 2.32, respectively. The authors concluded there is moderate-quality evidence that suggests this procedure is effective in reducing pain and disability in patients with chronic low back pain with type 1 or 2 Modic changes. However, further, high-quality nonindustrial funded studies are needed to confirm these findings. (Fischgrund et al. noted below, and Becker et al. previously cited in this policy are included in this systematic review.)

A Hayes report found minimal support in the clinical evidence for using the Intracept device for chronic low back pain thought to be of vertebrogenic origin. Clinical studies consistently indicated benefits in patient-oriented outcomes after the Intracept system was used to treat chronic low back pain; however, a randomized controlled trial did not convincingly indicate advantages over sham. A second randomized controlled trial did find short-term treatment advantages over continued standard care; however, given the placebo response observed in the sham-controlled trial, Hayes cautioned that the findings of the open-label study should be interpreted carefully. Studies were of generally poor or fair quality (Hayes, 2021; updated 2023).

The manufacturer sponsored INTRACEPT study by Khalil et al., (2019) included in the Hayes report cited above, is a prospective, parallel, randomized, controlled, open label, multicenter clinical trial. The study compared the effectiveness of intraosseous RFA of the basivertebral nerve (BVN) to standard care for the treatment of chronic low back pain thought to be of vertebrogenic origin. A total of 140 patients with chronic low back pain of at least 6 months duration, with Modic Type 1 or 2 vertebral endplate changes between L3 and S1, were randomized 1:1 to undergo either RFA of the BVN (n = 67) or continue standard care (n = 73). The primary outcome was ODI at baseline, 3, 6, 9, and 12-months post procedure. Secondary outcome measures included VAS and quality of life measures. Self-reported patient outcomes were collected using validated questionnaires at each study visit. A prespecified interim analysis for superiority assessment was conducted when 60% of randomized subjects completed their 3-month primary endpoint visit. The interim analysis showed statistical superiority ($p < .001$) for all primary and secondary patient-reported outcome measures in the RFA arm compared with the standard care arm. This resulted in a recommendation to halt enrollment in the study and offer early cross-over to the control arm. At 3 months, results from 104 patients included in the intent-to-treat analysis, included 51 patients in the RFA arm and 53 patients in the standard care arm. The mean changes in ODI at 3 months were -25.3 points versus -4.4 points, respectively, resulting in an adjusted difference of 20.9 points ($p < .001$). Mean changes in VAS were -3.46 versus -1.02, respectively, an adjusted difference of 2.44 cm ($p < .001$). In the RFA arm, 74.5% of patients achieved a ≥ 10-point improvement in ODI, compared with 32.7% in the standard care arm ($p < 0.001$). At 12 months, RFA of the BVN demonstrated a 25.7 ±18.5 point reduction in mean ODI ($p < 0.001$), and a 3.8 ±2.7 cm VAS reduction ($p < 0.001$) from baseline, with 64% demonstrating ≥ 50% reduction and 29% pain free. Similarly, the former standard care patients who elected BVN ablation (92%) demonstrated a 25.9 ±15.5 point mean ODI reduction ($p < 0.001$) from baseline. The proportion of opioid use did not change in either group ($p = 0.56$). Longer-term results from the study are needed to

confirm these findings. The findings are limited by lack of blinding, sham intervention, or comparison with established approaches.

An ECRI report on Intracept focused on how well the procedure worked and how it compared with conservative and other minimally invasive treatments for vertebrogenic low back pain. One randomized controlled trial showed that Intracept and a control sham procedure reduced pain and improved patient functional status at 1-year follow-up; however, the difference in gains between Intracept and sham were too small to be clinically significant. Additional studies suggest that Intracept is more effective than conservative treatment for resolving low back pain; however, the studies report too few events and are at too high a risk of bias to be conclusive. Blinded randomized controlled trials are needed to validate available evidence and compare Intracept with other interventions for treating low back pain (ECRI, 2020b; updated 2022).

In the multi-center, randomized, double-blind, sham-controlled SMART trial, Fischgrund et al. (2018, included in the Hayes report cited above) evaluated the safety and efficacy of RFA of the basivertebral nerve (BVN) for the treatment of chronic low back pain. A total of 225 patients diagnosed with chronic low back pain were randomized to treatment with the Intracept procedure (n = 147) or sham therapy (n = 78). All patients had Type I or Type II Modic changes of the treated vertebral bodies. The primary endpoint was the comparative change in the ODI from baseline to 3 months. At 3 months, the average ODI in the treatment arm decreased 20.5 points, as compared to a 15.2 point decrease in the sham arm in the per-protocol population. A responder analysis based on ODI decrease ≥ 10 points showed that 75.6% of patients in the treatment arm as compared to 55.3% in the sham control arm exhibited a clinically meaningful improvement at 3 months. Two subsequently published open-label extension studies at 2 years follow-up (Fischgrund et al., 2019, included in the Hayes report cited above) and 5 years follow-up (Fischgrund et al., 2020, included in the Hayes report cited above) reported secondary analyses. Participants randomized to the sham control arm were allowed to cross to RFA at 12 months. Due to a high rate of crossover, RFA treated participants acted as their own control in a comparison to baseline. Clinically meaningful improvements in function and pain compared with baseline were sustained through 2-year follow-up; however, 8% at 2 years and 10% at 5 years had inadequate pain relief and underwent surgery.

Clinical Practice Guidelines

American Society of Interventional Pain Physicians (ASIPP)

ASIIP clinical practice guidelines (Manchikanti et al., 2020) reviewed the evidence for facet joint interventions for managing chronic spinal pain. The guidelines make the following recommendations:

- The level of evidence is II with moderate strength of recommendation for cervical and lumbar RFA.
- The level of evidence is III with weak to moderate strength of recommendation with emerging evidence for thoracic RFA.
- For facet joint nerve ablation, the suggested frequency would be 6 months or longer (maximum of 2 times per year) between each procedure, provided that 50% or greater relief is obtained for 5-6 months.
- If the interventional procedures are applied for different regions, they may be performed at intervals of no sooner than one week or preferably 2 weeks for most types of procedures if they are not allowed to be performed in one setting or contraindicated.
- The therapeutic frequency for medial branch neurotomy should remain at intervals of at least 6 months per each region with multiple regions involved. It is further suggested that all regions be treated at the same time, provided all procedures are performed safely.
- In the treatment or therapeutic phase, the interventional procedures should be repeated only as necessary according to the medical necessity criteria.

American Society of Regional Anesthesia (ASRA) Pain Medicine

Consensus practice guidelines on interventions for lumbar facet joint pain from a multispecialty, international working group (Cohen et al., 2020) make the following recommendations:

- Medial branch blocks should be the prognostic screening test of choice before lumbar facet RFA.
- Repeat RFA procedures for recurrence of pain are recommended in patients who experienced a good outcome from the first RFA procedure, typically defined as at least 50% relief of pain at 3 months.
- Given the drop-off in success rates reported in some studies and the mean duration of benefit, the guidelines recommend repeating the procedure no more than two times per year.

National Institute for Health and Care Excellence (NICE)

NICE guidelines (2016; updated 2020) on the management of low back pain and sciatica make the following recommendations:

- Consider referral for assessment for radiofrequency denervation for people with chronic low back pain when:
  - Non-surgical treatment has not worked for them; and

- The main source of pain is thought to come from structures supplied by the medial branch nerve; and
- They have moderate or severe levels of localized back pain (rated as 5 or more on a visual analog scale, or equivalent) at the time of referral.

- Only perform radiofrequency denervation in people with chronic low back pain after a positive response to a diagnostic medial branch block.
- Do not offer imaging for people with low back pain with specific facet joint pain as a prerequisite for radiofrequency denervation.

North American Spine Society (NASS)

NASS clinical guidelines (Kreiner et al., 2020) provide evidence-based recommendations for the diagnosis and treatment of adults with low back pain. The guidelines make the following recommendations regarding RFA:

- Thermal RFA is suggested as a treatment for patients with low back pain from the zygapophyseal joints. The outcomes of this procedure become more reliable when more stringent diagnostic criteria are used. The relief from these ablations is durable for at least six months following the procedure. Grade of recommendation: B - fair evidence (Level II or III studies with consistent findings) for or against recommending intervention.
- Cooled RFA of the sacral lateral branch nerves and dorsal ramus of L5 may be considered in patients with sacroiliac joint pain diagnosed with dual diagnostic blocks. Grade of recommendation: C - poor quality evidence (Level IV or V studies) for or against recommending intervention.
- There is insufficient evidence to make a recommendation for or against the use of cryodenervation for the treatment of zygapophyseal joint pain. Grade of recommendation: I - insufficient or conflicting evidence not allowing a recommendation for or against intervention.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Radiofrequency ablation (RFA) for spinal pain is a procedure and, therefore, not subject to regulation by the FDA. However, the FDA regulates RFA devices, and there are numerous devices listed in the FDA 510(k) database approved for use in performing RFA for neurosurgical procedures. Three product codes are used to represent these devices: radiofrequency lesion generators (GXD), radiofrequency lesion probes (GXI) and electrosurgical cutting and coagulating device and accessories (GEI). Refer to the following website for more information: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed August23, 2023)

Products for other types of spinal ablation therapies can be searched at the following website: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed August 23, 2023)

References

Abejón D, Garcia-del-Valle S, Fuentes ML, et al. Pulsed radiofrequency in lumbar radicular pain: clinical effects in various etiological groups. Pain Pract. 2007 Mar;7(1):21-6.

Aydin SM, Gharibo CG, Mehnert M, et al. The role of radiofrequency ablation for sacroiliac joint pain: a meta-analysis. PM R. 2010 Sep;2(9):842-51.

Becker S, Hadjipavlou A, Heggeness MH. Ablation of the basivertebral nerve for treatment of back pain: a clinical study. Spine J. 2017 Feb;17(2):218-223.

Birkenmaier C, Veihelmann A, Trouillier H, et al. Percutaneous cryodenervation of lumbar facet joints: A prospective clinical trial. Int Orthop. 2007; 31(4):525-530.

Chao SC, Lee HT, Kao TH, et al. Percutaneous pulsed radiofrequency in the treatment of cervical and lumbar radicular pain. Surg Neurol. 2008 Jul;70(1):59-65; discussion 65.

Chen CH, Weng PW, Wu LC, et al. Radiofrequency neurotomy in chronic lumbar and sacroiliac joint pain: A meta-analysis. Medicine (Baltimore). 2019 Jun;98(26):e16230.

Chou R, Fu R, Dana T, et al. Interventional treatments for acute and chronic pain: systematic review. Comparative Effectiveness Review No. 247. (Prepared by the Pacific Northwest Evidence-based Practice Center under Contract No. 75Q80120D00006.) AHRQ Publication No. 21-EHC030. Rockville, MD: Agency for Healthcare Research and Quality; September 2021.

Cohen SP, Bhaskar A, Bhatia A, et al. Consensus practice guidelines on interventions for lumbar facet joint pain from a multispecialty, international working group. Reg Anesth Pain Med. 2020 Jun;45(6):424-467.

Conger A, Schuster NM, Cheng DS, et al. The effectiveness of intraosseous basivertebral nerve radiofrequency neurotomy for the treatment of chronic low back pain in patients with Modic changes: a systematic review. Pain Med. 2021 May 21;22(5):1039-1054.

CPT® Assistant. Frequently Asked Questions. Surgery: Musculoskeletal System. October 2016. p. 11.

ECRI Institute. Clinical Evidence Assessment. Accurian radiofrequency ablation system (Medtronic plc.) for treating nerve pain. October 2020a.

ECRI Institute. Clinical Evidence Assessment. Intracept intraosseous nerve ablation system (Relievant Medsystems, Inc.) for treating low-back pain. October 2020b. Updated August 2022.

Fischgrund JS, Rhyne A, Franke J, et al. Intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 2-year results from a prospective randomized double-blind sham-controlled multicenter study. Int J Spine Surg. 2019 Apr 30;13(2):110-119.

Fischgrund JS, Rhyne A, Franke J, et al. Intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: a prospective randomized double-blind sham-controlled multi-center study. Eur Spine J. 2018 May;27(5):1146-1156.

Fischgrund JS, Rhyne A, Macadaeg K, et al. Long-term outcomes following intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 5-year treatment arm results from a prospective randomized double-blind sham-controlled multi-center study. Eur Spine J. 2020 Aug;29(8):1925-1934.

Geurts JW, van Wijk RM, Stolker RJ, et al. Efficacy of radiofrequency procedures for the treatment of spinal pain: a systematic review of randomized clinical trials. Reg Anesth Pain Med. 2001 Sep-Oct;26(5):394-400.

Gofeld M, Jitendra J, Faclier G. Radiofrequency denervation of the lumbar zygapophysial joints:10-year prospective audit. Pain Physician 2007;10(2):291–300.Hayes, Inc. Evidence Analysis Research Brief. Pulsed radiofrequency in adults for treatment of lumbar facet joint pain. Hayes, Inc.; May 25, 2023.

Hayes Inc. Evolving Evidence Review. Intracept Intraosseous Nerve Ablation System (Relievant Medsystems) for treatment of adults with low back pain. Lansdale, PA: Hayes, Inc.; July 2021. Updated June 2023.

Hayes Inc. Health Technology Assessment. Pulsed radiofrequency application to the dorsal root ganglion for treatment of lumbosacral radicular pain. Lansdale, PA: Hayes, Inc.; May 2019. Updated July 2021. Archived June 2022.

Hayes Inc. Health Technology Assessment. Pulsed radiofrequency application to the dorsal root ganglion for treatment of cervical radicular pain. Lansdale, PA: Hayes, Inc.; May 2019. Updated June 2021. Archived June 2022.

Hayes Inc. Medical Technology Directory. Percutaneous radiofrequency ablation for cervical and thoracic spinal indications. Lansdale, PA: Hayes, Inc.; November 2016a. Updated March 2021. Archived December 2021.

Hayes Inc. Medical Technology Directory. Radiofrequency ablation for facet joint denervation for chronic low back pain. Lansdale, PA: Hayes, Inc.; December 2016b. Updated April 2021. Archived January 2022.

Hayes Inc. Medical Technology Directory. Radiofrequency ablation for sacroiliac joint denervation for chronic low back pain. Lansdale, PA: Hayes, Inc. February 2017. Updated August 2021. Archived December 2022.

Iwatsuki K, Yoshimine T, Awazu K. Alternative denervation using laser irradiation in lumbar facet syndrome. Lasers Surg Med. 2007; 39(3):225-229.

Joo YC, Park JY, Kim KH. Comparison of alcohol ablation with repeated thermal radiofrequency ablation in medial branch neurotomy for the treatment of recurrent thoracolumbar facet joint pain. J Anesth 2013; 27(3):390-5.

Khalil JG, Smuck M, Koreckij T, et al.; INTRACEPT Trial Investigators. A prospective, randomized, multicenter study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain. Spine J. 2019 Oct;19(10):1620-1632.

Kreiner DS, Matz P, Bono CM, et al. Guideline summary review: an evidence-based clinical guideline for the diagnosis and treatment of low back pain. Spine J. 2020 Jul;20(7):998-1024. Erratum in: Spine J. 2021 Feb 24.

Kroll HR, Kim D, Danic MJ, et al. A randomized, double-blind, prospective study comparing the efficacy of continuous versus pulsed radiofrequency in the treatment of lumbar facet syndrome. J Clin Anesth 2008 Nov;20(7):534-7.

Lord SM, Barnsley L, Wallis BJ, et al. Percutaneous radio-frequency neurotomy for chronic cervical zygapophyseal-joint pain. N Engl J Med. 1996 Dec 5;335(23):1721-6.

Manchikanti L, Kaye AD, Soin A, et al. Comprehensive evidence-based guidelines for facet joint interventions in the management of chronic spinal pain: American Society of Interventional Pain Physicians (ASIPP) Guidelines Facet Joint Interventions 2020 Guidelines. Pain Physician. 2020 May;23(3S):S1-S127.

Manchikanti L, Hirsch JA, Falco FJ, Boswell MV. Management of lumbar zygapophysial (facet) joint pain. World J Orthop. 2016 May 18;7(5):315-37.

McCormick Z, Choi H, Reddy R, et al. Randomized prospective trial of cooled versus traditional radiofrequency ablation of the medial branch nerves for the treatment of lumbar facet joint pain. Reg Anesth Pain Med 2019; 44:389–397.

Meloncelli S, Germani G, Urti I, et al. Endoscopic radiofrequency facet joint treatment in patients with low back pain: technique and long-term results. A prospective cohort study. Ther Adv Musculoskelet Dis. 2020 Dec 1;12:1759720X20958979.

National Institute for Health and Care Excellence (NICE). Low back pain and sciatica in over 16s: assessment and management. NG59. November 2016. Updated September 2020.

National Institute of Neurological Disorders and Stroke (NINDS). Complex regional pain syndrome fact sheet. October 2020. Available at: https://www.ninds.nih.gov/sites/default/files/migrate-documents/CRPS_FactSheet-E_508C.pdf . Accessed August 23, 2023.

Qaseem A, Wilt TJ, McLean RM, Forciea MA; Clinical Guidelines Committee of the American College of Physicians. Noninvasive treatments for acute, subacute, and chronic low back pain: a clinical practice guideline from the American College of Physicians. Ann Intern Med. 2017 Apr 4;166(7):514-530.

Smuck M, Khalil J, Barrette K, et al.; INTRACEPT Trial Investigators. Prospective, randomized, multicenter study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 12-month results. Reg Anesth Pain Med. 2021 Aug;46(8):683-693.

Staender M, Maer U, Tonn JS, et al. Computerized tomography-guided kryorhizotomy in 76 patients with lumbar facet joint syndrome. J Neurosurg Spine. 2005 Dec;3(6):444-9.

Stelzer W, Aiglesberger M, Stelzer D, et al. Use of cooled radiofrequency lateral branch neurotomy for the treatment of sacroiliac joint-mediated low back pain: a large case series. Pain Med. 2013;14(1):29-35.

Sun HH, Zhuang SY, Hong X, et al. The efficacy and safety of using cooled radiofrequency in treating chronic sacroiliac joint pain: A PRISMA-compliant meta-analysis. Medicine (Baltimore). 2018 Feb;97(6): e9809.

Tinnirello A, Barbieri S, Todeschini M, et al. Conventional (Simplicity III) and cooled (SInergy) radiofrequency for sacroiliac joint denervation: one-year retrospective study comparing two devices. Pain Med. 2017 Sep 1;18(9):1731-1744.

Van Zundert J. Pulsed radiofrequency adjacent to the cervical dorsal root ganglion in chronic cervical radicular pain: a double blind sham controlled randomized clinical trial. Pain. 2007 Jan;127(1-2):173-82.

Policy History/Revision Information

Date	Summary of Changes
09/01/2024	**Related Policies** • Updated reference link to the Medicare Advantage Medical Policy titled *Pain Management*
02/01/2024	**Related Policies** ***Medicare Advantage Coverage Summary*** • Updated reference link to reflect current policy title for *Pain Management*
01/01/2024	**Definitions** • Updated definition of “Pulsed Radiofrequency Ablation” **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information • Archived previous policy version 2023T0107CC

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance,

CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.