

# Ablative Treatment for Spinal Pain (for North Carolina Only)

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Related Policies
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## Application

This Medical Policy only applies to the state of North Carolina.

## Coverage Rationale

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
- 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 current, instead of continuous current, using a probe temperature of 42° - 45° Celsius (Hayes, 2016a; updated 2021).

## 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 federal, state, or contractual requirements 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

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## Description of Services

Pulsed RFA delivers intermittent bursts of current instead of continuous current, allowing the tissue to cool between bursts (Hayes, 2016a; updated 2021).

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,

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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).

A Hayes report concluded that a very-low-quality, limited body of evidence suggests that pulsed RFA application to the dorsal root ganglion may reduce pain in patients with cervical radicular pain that has failed to respond to conservative treatment; however, the body of evidence is insufficient to draw definitive conclusions (Hayes, 2019; updated 2021).

A Hayes report concluded that the overall quality of the evidence regarding the use of pulsed RFA for treating chronic low back pain is low. There is a paucity of studies evaluating this technology as the primary intervention. There is insufficient evidence to establish definitive patient selection criteria for pulsed RFA as a treatment for chronic low back pain related to the lumbar or lumbosacral facet joints. Additional studies are needed before any definitive conclusions can be reached (Hayes, 2016b; updated 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.

Simopoulos et al. (2008) conducted a prospective study of 76 patients to evaluate the safety and efficacy of pulsed and continuous radiofrequency therapy of the dorsal root ganglion/segmental nerves in patients with chronic lumbosacral radicular pain. To participate in the study, all patients were first treated with a diagnostic/therapeutic selective nerve root block with temporary but complete pain relief of radicular symptoms. Patients were then randomly assigned to receive either pulsed RFA (n = 37), at 42° C for 120 seconds, of the dorsal root ganglion/segmental nerve or pulsed RFA (n = 39) followed immediately by continuous radiofrequency with averaged temperatures at 54° C + (5) for 60 seconds. Follow-up occurred at 8 weeks with monthly follow-ups until 8 months post treatment. Outcomes were measured by VAS. The study failed to identify a statistically significant difference in the percentage of successful response rate or in the average decline in VAS between the 2 groups, but the data suggest better results for the continuous than the pulsed radiofrequency therapy. For both treatment groups there was a steep loss of analgesic effect between 2 to 4 months. By the eighth month, the vast majority of patients returned to their baseline pain intensity. The authors did not find a statistically significant beneficial effect of adding continuous radiofrequency to pulsed RFA. They concluded that pulsed RFA may be beneficial for patients with dorsal root ganglion pain but that the analgesic effect is time limited and determination of the actual efficacy of pulsed RFA in the treatment of chronic lumbosacral radicular pain needs additional further prospective controlled trials to further evaluate its use to treat dorsal root ganglion pain. The sample size may however have been too small to detect clinically significant differences between the interventions.

Chao et al. (2008) retrospectively reviewed a case series of 154 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, included in the Hayes report cited above) 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.

A prospective case series by Vallejo et al. (2006) evaluated the effect of pulsed RFA in 126 patients with chronic low back pain due to sacroiliac joint syndrome. The main outcome measures were visual analog scale (VAS) and quality of life (QOL) questionnaire performed prior to and after the treatment. Of the 126 patients who underwent arthrographically confirmed steroid/local anesthetic sacroiliac joint injection, 52 patients (41.3%) had > 75% pain relief after conservative treatment, while 22 patients failed to respond to the treatment. The 22 patients who failed conservative treatment underwent pulsed RFA of the medial branch of L4, posterior primary rami of L5, and lateral branches S1 and S2. Results showed that 16 patients (72.7%) experienced good (> 50% reduction in VAS), or excellent (> 80% reduction in VAS) pain relief following pulsed RFA. Duration of pain relief range was 6-9 weeks in four patients, 10-16 weeks in five patients, and 17-32 weeks in seven patients. In addition, QOL scores improved significantly in all measured categories. Six patients (26.1%) did not respond to PRFD and had less than 50% reduction in VAS and were considered failures. The authors concluded that pulsed RFA may be an effective treatment for some patients with sacroiliac joint pain that has been unresponsive to other forms of treatment. This study is limited by small sample size and the uncontrolled study design.

Cahana (2006) completed a literature review of current clinical and laboratory data regarding the use of pulsed RFA. The final analysis yielded 58 reports on the clinical use of pulsed RFA in different applications: 33 full publications and 25 abstracts. Also, six basic science reports, five full publications, and one abstract were reviewed. The author concluded that the accumulation of these data shows that the use of pulsed RFA generates an increasing interest of pain physicians for the management of a variety of pain syndromes. Although the mechanism of action has not been completely elucidated, laboratory reports suggest a genuine neurobiological phenomenon-altering the pain signaling, which some have described as neuromodulatory. No side effects related to the pulsed RFA technique were reported to date. The author concluded that further research in the clinical and biological effects is needed.

## 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.

Li et al. (2014) evaluated the effectiveness of surgical dorsal endoscopic rhizotomy in 58 patients with lumbar facetogenic chronic low back pain in a randomized controlled trial. Forty-five patients who experienced > 80% relief of pain with two comparative lumbar medial branch blocks received dorsal endoscopic rhizotomy. The remaining 13 patients received conservative treatment. The authors reported that percentage of pain relief in the operation group at any time point postoperatively were significantly higher than that in the conservative group. Further studies with a comparison group allowing masking to the intervention, larger sample sizes and longer follow-up are needed to further validate the efficacy of this technique.

## **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 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, non-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 (Chou et al., 2021).



A Hayes report on RFA of the sacroiliac joint for low back pain concluded that there is some positive, but inconsistent, moderate-quality evidence suggesting that cooled RFA of the sacroiliac joint is safe and may improve symptoms of low back pain over the short- to intermediate- term compared with sham therapy or alternative therapies. However, questions remain regarding patient selection criteria, long-term outcomes, and the comparative efficacy versus alternative therapies (Hayes, 2017; updated 2021).

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 ( $\geq 50\%$  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  $\geq 50\%$  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  $\geq 15$ -point or  $\geq 30\%$  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  $\geq 50\%$  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.

In a retrospective case series, Ho et al. (2013, included in the Hayes report cited above) evaluated the efficacy of cooled radiofrequency denervation using the SInergy™ cooled radiofrequency system for sacroiliac joint pain. After 2 years, 15 of 20 patients showed a significant reduction in pain (a decrease of at least three points on the NRS). Mean NRS for pain decreased from  $7.4 \pm 1.4$  to  $3.1 \pm 2.5$ , mean Patient Global Impression of Change was "improved" ( $1.4 \pm 1.5$ ), and Global Perceived Effect was reported to be positive in 16 patients at two years following the procedure. The authors concluded that cooled radiofrequency denervation showed long-term efficacy for up to two years in the treatment of sacroiliac joint pain. The findings are however limited by lack of a comparison group.

Hansen et al. (2012) performed a systematic review of therapeutic interventions for sacroiliac joint pain. The primary outcome measure was pain relief (short-term relief = up to 6 months and long-term > 6 months). Secondary outcome measures were improvement in functional status, psychological status, return to work and reduction in opioid intake. Fifty-six studies were considered for inclusion. Of these, 6 randomized trials and 5 non-randomized studies met inclusion criteria for methodological quality assessment, including two randomized trials of cooled radiofrequency ablation, one non-randomized study of conventional radiofrequency ablation, and one non-randomized study of pulsed radiofrequency ablation. The authors concluded that, for sacroiliac pain, the evidence was fair in favor of cooled radiofrequency neurotomy. The limitations of this review include a paucity of literature on therapeutic interventions, variations in technique and variable diagnostic standards for sacroiliac joint pain.

In an observational study, Karaman et al. (2011, included in the Hayes report and excluded from the Hansen systematic review cited above) investigated the efficacy and safety of cooled RFA for sacral lateral-branch denervation (n = 15). At the final control, while 80% of the patients reported at least a 50% decline in pain scores, 86.7% of those reported at least a ten-point reduction in ODI scores. The findings are however limited by lack of a comparison group.

## 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  $\geq 50\%$  pain reduction. Secondary outcomes included  $\geq 10$ -point improvement in function as measured by ODI as well as  $\geq 2$ -point reduction in pain score on the VAS or NRS, and decreased use of pain medication. Reported 3-month success rate for  $\geq 50\%$  pain reduction ranged from 45% to 63%. Rates of functional improvement ( $\geq 10$ -point ODI improvement threshold) ranged from 75% to 93%. For comparison to sham treatment, the relative risk of treatment success defined by  $\geq 50\%$  pain reduction and  $\geq 10$ -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  $\geq 50\%$  pain reduction and  $\geq 10$ -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).

The manufacturer sponsored INTRACEPT study, a prospective, parallel, randomized, controlled, open label, multicenter clinical trial, 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  $\geq 10$ -point improvement in ODI, compared with 32.7% in the standard care arm ( $p < 0.001$ ) (Khalil et al., 2019, included in the Hayes report cited above). At 12 months, RFA of the BVN demonstrated a  $25.7 \pm 18.5$ -point reduction in mean ODI ( $p < 0.001$ ), and a  $3.8 \pm 2.7$  cm VAS reduction ( $p < 0.001$ ) from baseline, with 64% demonstrating  $\geq 50\%$  reduction and 29% pain free. Similarly, the former standard care patients who elected BVN ablation (92%) demonstrated a  $25.9 \pm 15.5$ -point mean ODI reduction ( $p < 0.001$ ) from baseline. The proportion of opioid use did not change in either group ( $p = 0.56$ ) (Smuck et al., 2021). 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).

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  $\geq 10$  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)*

ASIPP clinical practice guidelines 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.

(Manchikanti et al., 2020)

### ***American Society of Regional Anesthesia and 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 November 10, 2021)

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 November 10, 2021)

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## Policy History/Revision Information

Date	Summary of Changes
11/01/2023	<p><b>Related Policies</b></p> <ul style="list-style-type: none"> <li>Updated reference link to reflect current policy title for <i>Facet Joint and Medial Branch Block Injections for Spinal Pain (for North Carolina Only)</i></li> </ul>
07/01/2023	<p><b>Template Update</b></p> <ul style="list-style-type: none"> <li>Created state-specific policy version</li> </ul> <p><b>Coverage Rationale</b></p> <ul style="list-style-type: none"> <li>Removed coverage guidelines for Conventional (Thermal) Radiofrequency Ablation</li> <li>Replaced language indicating: <ul style="list-style-type: none"> <li>“All forms of radiofrequency ablation are unproven and not medically necessary for treating sacroiliac pain” with “ablation for treating sacroiliac pain is unproven and not medically necessary <i>due to insufficient evidence of efficacy</i>”</li> <li>“Intraosseous radiofrequency ablation of the basivertebral nerve (e.g., Intracept®) is unproven and not medically necessary” with “intraosseous radiofrequency ablation of the basivertebral nerve (e.g., Intracept®) <i>for the treatment of spinal pain</i> is unproven and not medically necessary”</li> </ul> </li> <li>Removed language indicating chemical ablation (including, but not limited to, alcohol, phenol, or sodium morrhuate) is unproven and not medically necessary</li> </ul> <p><b>Definitions</b></p> <ul style="list-style-type: none"> <li>Removed definition of: <ul style="list-style-type: none"> <li>Chronic Pain (Nonmalignant)</li> <li>Complex Regional Pain Syndrome (CRPS)</li> <li>Facet Joint Injection</li> <li>Facet Nerve Block</li> <li>Functional Impairment</li> <li>Medial Branch Block</li> </ul> </li> </ul> <p><b>Applicable Codes</b></p> <ul style="list-style-type: none"> <li>Removed CPT codes 64633, 64634, 64635, and 64636 and corresponding notation</li> </ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>Updated <i>Description of Services</i>, <i>Clinical Evidence</i>, and <i>References</i> sections to reflect the most current information</li> </ul>

Date	Summary of Changes
	<ul style="list-style-type: none"> <li>Archived previous policy version CS001.O</li> </ul>

## Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state, or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state, or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state, or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state, or contractual requirements for benefit plan coverage. 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.

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