

## UnitedHealthcare<sup>®</sup> Community Plan Medical Policy

# Ablative Treatment for Spinal Pain (for Indiana Only)

Policy Number: CS001IN.08 Effective Date: January 1, 2024

Instructions for Use

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#### Related Policies

- Discogenic Pain Treatment (for Indiana Only)
- Occipital Nerve Injections and Ablation (Including Occipital Neuralgia and Headache) (for Indiana Only)

## Application

This Medical Policy only applies to the state of Indiana.

## **Coverage Rationale**

**Ablative treatment is medically necessary in certain circumstances**. For medical necessity clinical coverage criteria, refer to the InterQual<sup>®</sup> CP: Procedures, Neuroablation, Percutaneous. If medical necessity cannot be determined using these criteria, refer to the InterQual<sup>®</sup> Medicare: Procedures, Facet Joint Injection or Neuroablation.

Click here to view the InterQual® criteria.

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<sup>®</sup>) for the treatment of spinal pain is unproven and not medically necessary due to insufficient evidence of efficacy.

## **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 Clarifications:**

• CPT code 64999 is to be used for pulsed radiofrequency ablation (CPT<sup>®</sup> 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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**Note**: Codes labeled with an asterisk (\*) are not managed for medical necessity review for the state of Indiana at the time this policy became effective. Refer to the most up to date prior authorization list for Indiana at <u>Prior Authorization and Notification</u>: <u>UnitedHealthcare Community Plan of Indiana</u>.

#### **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 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) 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

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 painfree 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 1.3 cm size needle. Twenty-six patients required 2-4 additional treatments and a 2.0 cm 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 Joints**

There is insufficient evidence to establish the safety and efficacy of cooled RFA for treating facet joint 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 facet joint pain. 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.

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.

#### **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 five who had undergone previous spinal surgery. One year after laser denervation, 17 participants experienced pain reduction of at least 70%. Of the five individuals who had previously undergone spinal surgery, four 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.

#### **Clinical Practice Guidelines**

#### American Society of Interventional Pain Physicians (ASIPP)

ASIIP 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 two 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 (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

#### 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
- 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

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# 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: <u>http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm</u>. (Accessed August 23, 2023)

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

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# **Policy History/Revision Information**

Date	Summary of Changes
01/01/2024	Supporting Information
	<ul> <li>Updated <i>Description of Services</i>, <i>Clinical Evidence</i>, and <i>References</i> sections to reflect the most current information</li> <li>Archived previous policy version CS001IN.07</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.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual<sup>®</sup> criteria, to assist us in administering health benefits. The 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.