Ablative Treatment for Spinal Pain

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➲ Instructions for Use

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Application

UnitedHealthcare Commercial

This Medical Policy applies to UnitedHealthcare Commercial benefit plans.

UnitedHealthcare Individual Exchange

This Medical Policy applies to Individual Exchange benefit plans.

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 radiofrequency ablation (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.

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).

In 2021 Hayes updated a 2019 Health Technology Assessment for the use of pulsed radiofrequency application (PRF) to dorsal root ganglion (DRG) for the treatment of cervical radicular pain that has failed to respond to conservative treatment. The report concluded very-low-quality, limited body of evidence suggests that PRF application to the DRG 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. Considerable limitations to the body of evidence include a small evidence base consisting of 1 fair- and 3 poor-quality RCTs, inconsistency of PRF treatment methods among studies, and lack of long-term follow-up. Additional, robust comparative evidence is needed to determine whether PRF application to DRG is an effective and safe alternative treatment for cervical radicular pain that has failed conservative treatment.

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 DRG 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 DRG 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.

Du et al. (2024) conducted a systematic review and meta-analysis of 11 randomized controlled trials that compared the efficiency of percutaneous RFA and conservative treatment (sham procedures, facet joint injection, physiotherapy, exercise, or oral medication) or compared the efficiency of percutaneous RFA and endoscopic neurotomy for lumbar facet joint syndrome (LFJ) syndrome. Of these 11 articles, 9 reported on the effects of percutaneous RFA, and two studies evaluated the efficiency of endoscopic neurotomy. Of the two reporting on endoscopic neurotomy, the results showed at one month, there was no difference between that and percutaneous RFA or placebo. Twelve-month results showed that when compared to RFA, endoscopic neurotomy can significantly reduce pain. The authors concluded that endoscopic neurotomy can be used success fully as a compliment to the percutaneous technique in patients with therapy-refractory LBP. Compared with percutaneous RFA, endoscopic neurotomy seems to reduce LBP for a longer period of time. Further research with longer follow-up period is needed to confirm these findings.

Hayes published an Evidence Analysis Research Brief in 2024 to summarize and evaluate the evidence related to endoscopic rhizotomy for treatment of low back pain (LBP). A review of abstracts suggests that there is adequate published peer-reviewed literature however conclusions about safety and effectiveness cannot be made within this report. Further investigation is needed before clinical usefulness of this technology is proven.

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 (CLBP) 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 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.

In a 2023 multicenter randomized comparative effectiveness study, Cohen et al. compared cooled radiofrequency ablation (CRFA) to standard medical management for treating chronic sacroiliac joint pain (SIJ). Two hundred and ten patients with clinically suspected sacroiliac joint pain that obtained short-term benefit from diagnostic sacroiliac joint injections and prognostic lateral branch blocks were randomly assigned to receive CRFA of the L5 dorsal ramus and S1–S3 lateral branches or standard medical management that included pharmacotherapy, injections into the sacroiliac ligaments or joint cavity, physical therapy, chiropractic care, lifestyle changes, acupuncture, and yoga. The primary outcome measure was mean reduction in LBP score via numeric pain rating scale at 3 months. Secondary outcomes included quality of life and function as assessed by the ODI, 36-Item Short Form Survey (SF-36) physical function domain, and EuroQoL-5 (EQ-5D-5L). Patient satisfaction was assessed using the Patient Global Impression of Change (PGIC) scale. The results showed that CRFA resulted in superior improvements across all domains when compared to medical management. There was a total of 105 adverse events (CRFA: 65 events in 47 of 96 subjects, 49.0%; SMM: 40 events in 28 of 104 subjects, 26.9%). In the CRFA cohort, 16 of these events were related to the procedure, while in the SMM patients, five events were related to procedures. The majority of CRFA-related adverse events involved worsening pain in the lower back or around the SIJ and reported postprocedural pain. There were no reports of serious related adverse events, including nerve injury, in either group. The authors concluded that CRFA is superior to medical management for treating chronic SIJ pain. This

study is limited by a short follow up period as well as the lack of specific requirements for the control group which could undermine generalizability. Furthermore, the CRFA group may have tried and failed multiple medical management strategies, leading to a “placebo” effect of the treatment. Additional high-quality research with longer follow up is needed to validate these findings.

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 LBP (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 LBP; 13 (28 %) had no or little improvement. Including failures, mean LBP 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.

In 2022 (updated 2023) Hayes Health Technology Assessment safety and effectiveness was evaluated of cooled RFA for the treatment of CLBP that originates from the sacroiliac joint (SIJ). The report concluded an overall low-quality body of evidence which suggests that CRFA of the SIJ is safe and may be effective for reducing the intensity of CLBP and improving physical function for 6 to 12 months. Additional well-designed and well-executed research studies with adequate sample sizes are necessary to evaluate treatment efficacy of cooled RFA.

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 CRFA versus traditional 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 CRFA (n = 21) or traditional 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 CRFA and traditional 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 CRFA and traditional 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 CRFA and traditional 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 CRFA 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 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 LBP 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.

Iwatsuki (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 LBP. Well-designed, randomized controlled trials with large sample sizes and long-term follow-up are needed to establish the impact on health outcomes.

McCormick et al. (2024) conducted a pooled analysis from three prospective clinical trials on the effectiveness and safety of intraosseous BVNA for treating vertebrogenic pain. All participants in the original studies had refractory CLBP for a minimum of six months, with Modic changes (Type 1 and/or Type 2 from L3 to S1). The results demonstrated 247 participants received BVNA and had a one-year follow-up; 205 had a long-term follow -up (mean of 5.3 ±1.33 years). Twenty-seven percent fewer participants initiated conservative care in the year post-BVNA compared to the year preceding BVNA ($p < .001$; 95% CI 19.8–34.5). Of 77/247 participants taking opioids at baseline, 40.3% and 61.7% fewer were taking them at one-year and 5.3 ±1.33 years post-BVNA, respectively ($p < .001$). Of participants receiving lumbosacral spinal injections (LSIs) in the year preceding BVNA, 81.2% fewer received LSI(s) in the year post-BVNA ($p < .001$; 95% CI 70.7–90.7); a 76.4% reduction in LSIs was maintained through a mean of 5.3 ±1.33 years post-BVNA. Lumbosacral RFA rates were 1.6% at 1-year post-BVNA and 8.3% at 5.3 ±1.33 years post-BVNA. Lumbar fusion surgery was 0.8% at 1-year post-BVNA and 6.5% at 5.3 ±1.33 years post-BVNA. The authors concluded in this aggregate analysis of 247 patients with vertebrogenic pain, utilization of conservative care, opioids, and need for functional strengthening activities were substantially reduced through 5 years post-BVNA compared to baseline. Lumbar fusion rates were less than half the published value at 5 years in similar populations. Study limitations include conflict of interest, and all data were derived from an open-label, industry-sponsored data collection series. In addition, there was no long-term comparator group for utilization in the non-surgical care arm due to a cross-over to intervention design.

Mekhail et al. (2023) performed a systematic review and meta-analysis to determine the relative effectiveness and safety profiles of percutaneous and minimally invasive inventions for CLBP. A search for RCTs was conducted over a twenty-year period, twenty-seven studies met the inclusion criteria. BVNA was the subject of comparison to all other therapies with evaluation on pain improvement, level of disability, adverse events, and quality of life utilizing the Visual Analog Scale (VAS) and Oswestry Disability Index (ODI) scores. The comparison of other therapies included in the study were radiofrequency ablation of the basivertebral, disk annulus and facet nerve structures, steroid injection of the disk, facet joint, and medial branch, biological therapies, and multifidus muscle stimulation. The results demonstrated at 6-, 12-, and 24- month follow-up BVNA displayed considerable improvement in VAS and ODI scores but did not show a difference from two of the interventions biological therapy and multifidus muscle stimulation. The authors concluded BVNA, biological therapy, and multifidus stimulation provide improvement in both pain and disability compared with other interventions. The limited number of studies available have resulted in confidence intervals too broad to declare a statistical difference and an inability to estimate accurate effects for each tested treatment. The available evidence is limited with industry-sponsored, overall poor-quality methodology, design, and diversity in reporting outcome measures. (Authors Fischgrund et al. (2018) and Fischgrund et al. (2019), included in this systematic review and meta-analysis are cited in this policy below).

Nwosu et al. (2023) conducted a systematic review to determine the efficacy of intraosseous BVNA in treating non-radiating axial CLBP compared to standard therapy, sham, or without contrast. The population of interest was individuals greater than or equal to 18 years old with chronic non-radiating vertebrogenic pain. The key outcome was the percentage of patients with greater than or equal to 50% pain reduction, greater than or equal to 10-point improvement in function and disability measured by the ODI, greater than or equal to two-point pain reduction in the VAS or numerical pain rating scale, and a decrease in opioid utilization by 10 morphine milligram equivalents. Three databases, PubMed, MEDLINE, and Google Scholar were used to retrieve the studies for the review. There were 286 articles in total, however, only 11 publications with extensive data on 413 participants matched the inclusion criteria and were used for this review. At three months, many of the participants reported greater than or equal to 10-point improvement in the ODI, a measure of functional and disability improvement on a 10-point scale, and greater than or equal to two-point improvement in the VAS. A good number of individuals in the BVNA arm reported complete pain resolution demonstrating therapy success and the superiority of BVNA over sham and standard treatment. The authors concluded that BVNA, among other criteria, is a safe and minimally invasive therapy that significantly lowers pain and impairment in individuals with vertebrogenic pain with distinct Modic type 1 and 2 changes at lumbar vertebra three-sacral vertebra one (L3-S1) vertebral levels. The absence of grey literature is a limitation of the present review. Meta-analysis was not performed because of the novelty of the intervention and the scarcity of RCTs. Proper patient selection and exact procedural methods are essential to the success of basivertebral nerve neurotomy. The findings of the existing investigations require confirmation by non-industry-funded, large-scale, high-quality trials using generalizable study participants. Further investigation is needed before clinical usefulness of this procedure is proven. (Authors Fischgrund et al. (2018), Fischgrund et al. (2019), Fischgrund et al. (2020) and Khalil et al. (2019), included in this systematic review are cited in this policy below).

Schnapp et al. (2023) conducted a follow-up study describing the six-month results of an independent case series for the efficacy and safety of BVNA as a treatment modality for CLBP in a community practice setting. This data represents the clinical outcomes for 16 consecutively treated patients in a community practice setting. BVNAs were performed on 16 consecutive patients by a single surgeon (WS) utilizing the INTRACEPT® device (Relievant Medsystems, Inc.). Evaluations were performed at baseline, one month, three months, and six months. The ODI and VAS, and SF-36 were recorded in Medrio electronic data capture software. All individuals (n = 16) completed the baseline, one month, three

months, and six months follow-up. The ODI, VAS, and SF-36 Pain Component Summary showed improvements above minimal clinically important differences at one month, three months, and six months (all p values < 0.05). Change in ODI pain impact declined 13.1 points [95% CI: 0.01,27.2] at one month from baseline, 16.5 points [95% CI: 2.5,30.6] at three months from baseline, and 21.1 points [95% CI: 7.0,35.2] six-months from baseline. SF-36 Mental Component Summary also showed some improvements, but with significance only at three months (p = 0.0091). The authors concluded that BVNA appears to be a durable, minimally invasive treatment for the relief of CLBP that can be successfully implemented in a community practice setting. However, further research with randomized controlled trials is needed to validate these findings. This study has several limitations in that it is a small-scale study following only 16 patients, with no controls as has been done in the past in much larger studies and therapeutic procedures were not specifically withheld post-BVNA.

Conger et al. (2021) conducted a systematic review of seven studies (n = 321) evaluating intraosseous basivertebral nerve radiofrequency neurotomy for the treatment of CLBP 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 CLBP 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 2021 Hayes report found minimal support in the clinical evidence for using the Intracept device for CLBP thought to be of vertebrogenic origin. Clinical studies consistently indicated benefits in patient-oriented outcomes after the Intracept system was used to treat CLBP; 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. In a 2024 update a review of clinical studies including systematic reviews suggest minimal support for using Intracept for improvement in back pain and function in adults with CLBP. Based on a review of clinical practice guidelines and position statements, guidance appears to confer weak support for the Intracept Intraosseous Nerve Ablation System for CLBP. The review concluded Intracept has the potential to reduce healthcare utilization but more robust data with statistical analyses are needed.

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 CLBP thought to be of vertebrogenic origin. A total of 140 patients with CLBP 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 (2020b; updated 2022) on Intracept focused on how well the procedure worked and how it compared with conservative and other minimally invasive treatments for vertebrogenic LBP. 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 LBP; 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 LBP.

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 CLBP. A total of 225 patients diagnosed with CLBP 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. (Fischgrund et al. (2018) and Fischgrund et al. (2019), are included in the Mekhail et al. (2024) study summary listed above).

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 LBP and sciatica make the following recommendations:

- Consider referral for assessment for radiofrequency denervation for people with CLBP 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 CLBP after a positive response to a diagnostic medial branch block.
- Do not offer imaging for people with LBP 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 which are endorsed by the American Academy of Physical Medicine and Rehabilitation (AAPM&R) and American Association of Neurological Surgeons and Congress of Neurological Surgeons (AANS/CNS), for the diagnosis and treatment of adults with LBP. The guidelines make the following recommendations regarding RFA:

- Thermal RFA is suggested as a treatment for patients with LBP 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.

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 September 20, 2024)

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 September 20, 2024)

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Policy History/Revision Information

Date	Summary of Changes
05/01/2025	**Template Update** • Created shared policy version to support application to Rocky Mountain Health Plans membership **Application** ***Individual Exchange*** • Removed language indicating this Medical Policy does not apply to the state of Colorado **Supporting Information** • Archived previous policy version 2025T0107FF

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.