Ablative Treatment for Spinal Pain (for Kentucky Only)

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Instructions for Use

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Related Policies

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

Application

This Medical Policy only applies to the state of Kentucky.

Coverage Rationale

Ablative treatment is medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Neuroablation, Percutaneous.

Click here to view the InterQual® criteria.

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

- Endoscopic radiofrequency ablation/endoscopic rhizotomy
- Pulsed Radiofrequency Ablation of the facet nerves of the cervical, thoracic, or lumbar region, sacral nerve root, or dorsal root ganglion
- Cooled Radiofrequency Ablation
- Laser ablation (including pulsed, continuous, or low level)

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

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° to 45° C (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 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

Description of Services

Pulsed Radiofrequency Ablation delivers short bursts of radiofrequency 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 radiofrequency ablation to target the medial, intermediate, and lateral branches of the dorsal ramus using a modification of the Yeung Endoscopic Spinal Surgery 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 radiofrequency ablation (RFA) for treating spinal pain. Well-designed, randomized controlled trials (RCTs), with large sample sizes and long-term follow-up, are needed to establish the impact on health outcomes.

An Agency for Healthcare Research and Quality comparative effectiveness review evaluated pulsed RFA for treating facet joint pain in the Medicare population. The report concluded that the evidence is insufficient to assess pulsed RFA for presumed facet joint pain vs sham denervation or continuous radiofrequency (CRF) denervation (Chou et al., 2021).

In 2021, Hayes updated a 2019 Health Technology Assessment for the use of pulsed radiofrequency (PRF) application to the dorsal root ganglion (DRG) for the treatment of cervical radicular pain that has failed to respond to conservative treatment. The report concluded that a very low-quality, limited body of evidence suggests that PRF application to the DRG may reduce pain in individuals 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 one fair- and three 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 the 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 CRF thermocoagulation with pulsed RFA in a prospective, randomized, double-blinded study in 50 participants with lumbar back pain. Target facet joints were identified with oblique radiographic views. CRF thermocoagulation was delivered at 80°C for 75 seconds, while PRF was delivered at 42°C, with a pulse duration of 20 milliseconds and pulse rate of 2 Hz for 120 seconds. No significant differences in the relative percentage improvement were noted between groups in either visual analog scale (VAS) or Oswestry Low Back Pain and Disability Questionnaire (OSW) scores. In the PRF group, comparisons of the relative change over time in both VAS and OSW scores were not significant. However, in the CRF group, VAS and OSW scores showed significant improvement. The investigators concluded that although no significant difference between CRF and PRF therapy in long-term outcome in the treatment of lumbar facet syndrome was observed, a greater improvement over time was noted in 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 two to four spinal levels unilaterally, with follow-up from 1 week to 1 year post operation. Overall, 53% of 49 patients with cervical pain and 50% of patients with lumbar pain had an initial improvement of 50% or more in the first week of follow-up. In total , 55% of patients with cervical pain and 44% 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 the lack of a comparison group, retrospective design and inability to generalize results due to a wide range of follow-up. Additional well-designed studies are needed to evaluate the long-term results of pulsed RFA.

Abejón et al. (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 disk, spinal stenosis, and failed back surgery syndrome. The efficacy of the technique was assessed using a 10-point numeric rating scale (NRS) at baseline and the global perceived effect at 30, 60, 90, and 180 days. The reduction in medications and number of complications associated with the technique were assessed, although these were 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 disk and spinal stenosis, but not failed back surgery syndrome. The flaws of this study include the lack of a comparison group undergoing a different treatment, retrospective design, subjective outcome measures, and short-term follow-up.

Van Zundert (2007) studied the effect of pulsed RFA in participants with cervical radicular pain. Overall, 23 of 256 screened participants in a randomized sham-controlled trial met the inclusion criteria and were randomly assigned in a double-blinded 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 regarding 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 36-Item Short Form Survey (SF-36) domain vitality at 3 months. The need for pain medication was significantly reduced in the pulsed RFA group after 6 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 suggested that pulsed RFA of the cervical DRG may provide pain relief for a limited number of carefully selected individuals with chronic cervical radicular pain, as assessed by clinical and neurological examination. Although the study results are promising for certain individuals, the small sample size, 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 RCTs, 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 RCTs 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. Of these 11 articles, nine 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 that at 1 month, no difference

between that and percutaneous RFA or placebo was observed. Twelve-month results showed that when compared with RFA, endoscopic neurotomy can significantly reduce pain. The authors concluded that endoscopic neurotomy can be used successfully as a complement to the percutaneous technique in individuals with therapy-refractory low back pain (LBP). Compared with percutaneous RFA, endoscopic neurotomy seems to reduce LBP for a longer period of time. Further research, with a 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 the treatment of LBP. A review of abstracts suggested that there is adequate published, peer-reviewed literature; however, conclusions about safety and effectiveness cannot be made in this report. Further investigation is needed before the 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 participants with chronic low back pain (CLBP) due to facet joint syndrome. The study included 40 of 50 screened participants divided into two equal groups: group A participants were previously treated with percutaneous RFA (n = 20), and group B participants were having their first interventional treatment (n = 20). NRS and Oswestry Disability Index (ODI) scores were assessed before and after the procedure. All participants had a reduction in NRS and an improvement in the ODI. NRS was reduced significantly after 1 month and remained the same until the end of the study. The ODI was significantly improved from 1 month after surgery up to the end of the study. The improvements did not differ, despite whether participants were already treated with percutaneous rhizotomy. Participants aged less than 60 years or who had one to two joints treated had better improvement than the others. The authors concluded that participants treated with endoscopic rhizotomy achieved pain relief through follow-up at 2 years. Study limitations include the lack of randomization and a control and the small sample size. Larger, randomized studies are needed to confirm these results.

Cooled Radiofrequency Ablation for Facet Joints

There is insufficient evidence to establish the safety and efficacy of CRFA for treating facet joint pain. Well-designed, RCTs with large sample sizes and long-term follow-up are needed to establish the impact on health outcomes.

An Agency for Healthcare Research and Quality comparative effectiveness review by Chou et al. (2021) evaluated CRFA for treating sacroiliac and facet joint pain. CRFA for sacroiliac pain was associated with a moderate to large reduction in pain and small to large improvement in function vs sham radiofrequency at 1 month. Improvements in pain and function at 3 months were moderate. Evidence beyond 6 months is lacking. Additionally, the trials used different techniques, with insufficient evidence to determine the optimal method. CRFA for presumed facet joint pain was associated with a small, non–statistically significant reduction in pain vs conventional RFA at 6 months and no difference in function. No differences at the 1- and 3-month follow-ups were observed. Evidence beyond 6 months is lacking. All studies were limited by a 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 vs traditional RFA of the medial branch nerves for the treatment of lumbar facet joint pain. The primary outcome was the proportion of responders (≥ 50% NRS reduction) at 6 months. The secondary outcomes included the NRS, ODI, and Patient Global Impression of Change. Overall, 43 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%-74%) and 44% (95% CI, 22%-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%-82%) and 44% (95% CI, 22%-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 the 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.

Laser Ablation

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

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

Intraosseous Radiofrequency Ablation of the Basivertebral Nerve

There is insufficient evidence of low quality to establish the safety and efficacy of intraosseous RFA of the basivertebral nerve (BVN) for treating LBP. Well-designed, non–industry funded RCTs, with large sample sizes and long-term follow-up, are needed to establish the impact on health outcomes.

Sakellariou et al. (2025) performed a retrospective comparative analysis of intradiscal steroid injections (IDSIs) vs intraosseous basivertebral nerve radiofrequency ablation (BVNA) treatments for vertebrogenic CLBP. The study compared two intervention strategies for this condition: IDSIs in one group with 12 patients vs BVNA in another group of 10 patients. The study included patients aged 18 to 70 years, irrespective of sex, while specific inclusion and exclusion criteria were applied. IDSIs involved corticosteroid injections into the intervertebral disc, reducing inflammation and pain, whereas BVNA targeted the BVN to disrupt pain signals. A retrospective analysis of ODI scores in the patients, before and after treatment, revealed that both treatments effectively reduced disability. The IDSIs revealed a higher percentage of complete symptom resolution (at 75%), whereas BVNA appeared to provide more consistent and notable improvements across patients, with complete symptom resolution at 70%. The authors concluded that despite potential side effects, such as transient pain, increased blood sugar levels, nerve damage, or infection, both treatments provided pain relief and reduced disability, presumably underscoring the importance of personalized treatment plans. This study has many limitations, including the retrospective design of the study, small sample size, exclusion of outliers, absence of a placebo or sham control group, methodological flaws, reliance on subjective data (ODI scores), limited follow-up duration, and low statistical power. Taking into consideration the notable limitations of this study, it is essential to emphasize the requirement for further larger-scale research.

Khalil et al. (2024) conducted a pooled analysis from three prospective clinical trials (two randomized and one single-arm study) to assess the clinical impact and safety of intraosseous RFA of the BVN for the treatment of vertebrogenic CLBP and the aggregate long-term outcomes at 5 years from the three studies. The pooled results at 5 years post BVNA are reported for three clinical trials, which had similar inclusion/exclusion criteria and outcomes measurements: (1) a prospective, open-label, single-arm follow-up of the treatment arm of an RCT comparing BVNA with sham ablation (SMART); (2) a prospective, open-label, single-arm follow-up of the treatment arm of an RCT comparing BVNA with standard care (INTRACEPT); and (3) a prospective, open-label, single-arm long-term follow-up study of BVNA-treated participants (CLBP Single-Arm). Paired datasets (baseline and 5 years) for mean changes in ODI and numeric pain scores (NPSs) were analyzed using a two-sided paired t test, with a 0.05 level of significance. The secondary outcomes included responder rates, participant satisfaction, adverse events, and health care utilization. Overall, 249 of 320 BVNA-treated participants (78% participation rate) completed a 5-year visit (mean of 5.6 years of follow-up). At baseline, 71.9% of these participants reported back pain for ≥ 5 years, 27.7% were taking opioids, and 61.8% had prior therapeutic lumbar spinal injections. Pain and functional improvements were noted at 5 years, with a mean improvement in NPS of 4.32 ±2.45 points (95% CI, 4.01-4.63; $p < 0.0001$) from 6.79 ±1.32 at baseline and a mean improvement in the ODI of 28.0 ±17.5 (95% CI, 25.8-30.2; $p < 0.0001$) from 44.5 ±11.0 at baseline. Nearly one-third (32.1%) of participants reported being pain free (NPS = 0) at 5 years, 72.7% of participants indicated that their condition improved, and 68.7% had resumed activity levels that they had prior to the onset of CLBP. In the 69 participants taking opioids at baseline, 65.2% were no longer taking them at 5 years, and spinal injections decreased by 58.1%. The rate of lumbosacral treatment (therapeutic spinal injection, RFA, or surgery) for the same index pain source and vertebral level was 33 of 249 (13.2%) at 5 years post BVNA, including a 6.0% rate of lumbar fusion. There were no serious device- or device procedure–related adverse events reported during the long-term follow-up. The authors concluded that in this 5-year aggregate analysis, BVNA improved pain and function scores compared with baseline. Similarly, there were reductions in opioid consumption and spinal injections post BVNA. The data demonstrate a strong safety profile, with no serious device or device-related events and a low health care utilization rate for the same index pain source through a mean of 5.6 years. The results demonstrate that intraosseous BVNA treatment for individuals with vertebrogenic pain is safe, effective, and durable through 5 years. There are numerous limitations of this pooled analysis, including the open-label design, industry sponsorship (as it is standard for new therapies), and lack of a long-term comparator with the high crossover rate of the standard care/sham arms in the two RCTs. Nonresponders to the therapy continue to exhibit little to no response to other modalities as well. This continues to be an area of potential further study.

McCormick et al. (2024) conducted a pooled analysis from three prospective clinical trials on the effectiveness and safety of BVNA for treating vertebrogenic pain. All participants in the original studies had refractory CLBP for a minimum of 6 months, with Modic changes (type 1 and/or type 2 from L3 to S1). The results demonstrated that 247 participants received BVNA and had a 1-year follow-up; 205 had long-term follow-up (mean, 5.3 ±1.33 years). Overall, 27% fewer participants initiated conservative care in the year post BVNA compared with the year preceding BVNA ($p < 0.001$; 95% CI, 19.8%-34.5%). Of 77 of 247 participants taking opioids at baseline, 40.3% and 61.7% fewer were taking them at 1 year and 5.3 ±1.33 years post BVNA, respectively ($p < 0.001$). Of the participants receiving lumbosacral spinal injections (LSIs) in the year preceding BVNA, 81.2% fewer received an LSI(s) in the year post BVNA ($p < 0.001$; 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 participants with vertebrogenic pain, that use of conservative care and opioids and the need for functional strengthening activities were substantially reduced through 5 years post BVNA compared with baseline. Lumbar fusion rates were less than half the published value at 5 years in similar populations. Study limitations include the 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 use in the non–surgical care arm due to a crossover 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 interventions for CLBP. A search for RCTs was conducted over a 20-year period, and 27 studies met the inclusion criteria. BVNA was the subject of comparison to all other therapies, with evaluation of pain improvement, level of disability, adverse events, and quality of life conducted using VAS and ODI scores. The comparisons of other therapies included in the study were RFA 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 that at the 6-, 12-, and 24-month follow-ups, 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 that BVNA, biological therapy, and multifidus stimulation provide improvement in both pain and disability compared with other interventions. The limited number of studies available has resulted in CIs that are too broad to declare a statistical difference and an inability to estimate accurate effects for each tested treatment. The available evidence is limited, with possible bias related to manufacturer-sponsored study, overall poor-quality methodology and 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 nonradiating axial CLBP compared with standard therapy, sham, or without contrast. The population of interest was individuals who were at least 18 years old with chronic, nonradiating vertebrogenic pain. The key outcome was the percentage of individuals with at least a 50% pain reduction; at least a 10-point improvement in function and disability, measured by the ODI; at least a two-point pain reduction in the VAS or numeric pain rating scale; and a decrease in opioid use by 10 morphine milligram equivalents. Three databases, including PubMed, MEDLINE, and Google Scholar, were used to retrieve the studies for the review. Overall, 286 articles were retrieved; however, only 11 publications with extensive data on 413 individuals matched the inclusion criteria and were used for this review. At 3 months, many of the individuals reported at least a 10-point improvement in the ODI, which is a measure of functional and disability improvement on a 10-point scale, and at least a 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 L3-S1 vertebral levels. The absence of grey literature is a limitation of the present review. A meta-analysis was not performed because of the novelty of the intervention and the scarcity of RCTs. Proper selection of individuals and exact procedural methods are essential to the success of BVN 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 the 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 6-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. These data represent the clinical outcomes in 16 consecutively treated individuals in a community practice setting. BVNAs were performed on 16 consecutive individuals by a single surgeon using the Intracept device (Relievant Medsystems, Inc.). Evaluations were performed at baseline, 1 month, 3 months, and 6 months. The ODI, VAS, and SF-36 were recorded in Medrio electronic data capture software. All individuals (n = 16) completed the baseline, 1-month, 3-month, and 6-month follow-ups. The ODI, VAS, and SF-36 Pain Component Summary showed improvements above minimal clinically important differences at 1 month, 3 months, and 6 months (all p values < 0.05). Change in ODI pain impact declined by 13.1 points [95% CI; 0.01,27.2] at 1 month from baseline, 16.5 points [95% CI; 2.5,30.6] at 3 months from baseline, and 21.1 points [95% CI; 7.0,35.2] 6-months from baseline. The SF-36 Mental Component Summary also showed some improvements, but with significance only at 3 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 RCTs is needed to validate these findings. This study has several limitations; it is a small-scale study that followed up only 16 individuals, with no controls, as has been done in the past in much larger studies, and therapeutic procedures were not specifically withheld post BVNA.

Smuck et al. (2023) conducted a pooled analysis from two prospective clinical trials to assess the aggregate long-term outcomes of intraosseous RFA of the BVN for the treatment of vertebrogenic CLBP. Pooled results at 3 years post BVNA are reported for two studies that had similar inclusion/exclusion criteria and outcomes measurements: (1) a prospective, open-label, single-arm follow-up of the treatment arm of an RCT comparing BVNA with standard care (INTRACEPT trial) and (2) a prospective, open-label, single-cohort, long-term follow-up study of BVNA-treated participants. Paired datasets (baseline and 3 years) for mean changes in the ODI and NPSs were analyzed using a two-sided t test, with a 0.05 level of significance. Overall, 95 of 113 (84%) BVNA participants completed a 3-year visit across 22 study sites. At baseline, 71% of participants reported back pain for ≥ 5 years, 28% were taking opioids, 34% had spinal injections in the prior 12 months, and 14% had prior low back surgery. Pain and functional improvements were significant at 3 years, with a mean reduction in NPS of 4.3 points from 6.7 at baseline (95% CI, 3.8-4.8; $p < 0.0001$) and a mean reduction in the ODI of 31.2 points from 46.1 at baseline (95% CI, 28.4-34.0; $p < 0.0001$). Responder rates, using minimal clinically important differences of ≥ 15 points for the ODI and ≥ 50% reduction in NPS from baseline to 3 years, were 85.3% and 72.6%, respectively (combined response 69.5%), with 26.3% of participants reporting 100% pain relief at 3 years. There was a 74% reduction in the use of opioids and 84% reduction in the use of therapeutic spinal interventions from baseline to 3 years. There were no serious device- or device procedure–related adverse events reported through 3 years. The authors concluded that intraosseous BVNA demonstrated clinically meaningful and durable improvements in pain and function through 3 years in participants with primary vertebrogenic LBP. BVNA-treated participants reduced opioid use and interventions for LBP. The study includes several limitations, including an open-label design, industry sponsorship, small sample size, and lack of a long-term comparator group in the two studies, although the average improvement without BVNA would be expected to follow outcomes reported from nonsurgical care, in which ODI improvement was only 7.4. Well-designed, comparative studies, with larger populations of individuals, are needed to further describe safety and clinical outcomes.

Conger et al. (2021) conducted a systematic review of seven studies (n = 321) evaluating intraosseous BVN radiofrequency neurotomy for the treatment of CLBP with type 1 or 2 Modic changes. Studies included comparisons with sham, placebo procedure, active standard care treatment, or no treatment. The primary outcome of interest was the proportion of individuals with ≥ 50% pain reduction. The secondary outcomes included a ≥ 10-point improvement in function, as measured by the ODI, as well as a ≥ two-point reduction in pain score on the VAS or NRS and decreased use of pain medication. The 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 with the sham treatment, the relative risks of treatment success, defined by ≥ 50% pain reduction and a ≥ 10-point ODI improvement, were 1.25 and 1.38, respectively. For comparison with continued standard care treatment, the relative risks of treatment success, defined by ≥ 50% pain reduction and a ≥ 10-point ODI improvement, were 4.16 and 2.32, respectively. The authors concluded that there is moderate-quality evidence suggesting that this procedure is effective in reducing pain and disability in individuals with CLBP with type 1 or 2 Modic changes. However, further high-quality, non–industry-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 (2021, updated 2025) found minimal support in the clinical evidence for using the Intracept device for CLBP that is thought to be of vertebrogenic origin. Clinical studies consistently indicated benefits in individual-oriented outcomes after the Intracept system was used to treat CLBP; however, an RCT did not convincingly indicate advantages over the sham. A second RCT 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 the most recent update, there were two newly published studies, with no systematic reviews, and no clinical guidelines. A review of these clinical studies indicates no new evidence, which suggests 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 that Intracept has the potential to reduce health care 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 BVN with that of standard care for the treatment of CLBP that is thought to be of vertebrogenic origin. A total of 140 participants 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 the ODI at baseline and 3, 6, 9, and 12 months post procedure. The secondary outcome measures included the VAS and quality-of-life measures. Self-reported participant outcomes were collected using validated questionnaires at each study visit. A prespecified interim analysis for superiority assessment was conducted when 60% of randomized participants completed their 3-month primary end point visit. The interim analysis showed statistical superiority ($p < 0.001$) for all primary and secondary participant-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 crossover to the control arm. At 3 months, results from 104 participants in the intent-to-treat analysis included 51 participants in the RFA arm and 53 participants in the standard care arm. The mean changes in the ODI at 3 months were -25.3 points vs -4.4 points, respectively, resulting in an adjusted difference of 20.9 points ($p < 0.001$). Mean changes in the VAS were -3.46 vs -1.02, respectively, with an adjusted difference of 2.44 cm ($p < 0.001$). In the RFA arm, 74.5% of participants achieved a ≥ 10-point improvement in the 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% of participants demonstrating a ≥ 50% reduction and 29% being pain free. Similarly, the former standard care participants who elected BVNA (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 the lack of blinding, sham intervention, or comparison with established approaches.

An ECRI report (2020b; updated 2024) on Intracept focused on how well the procedure worked and how it compared with conservative and other minimally invasive treatments for vertebrogenic LBP. One RCT showed that Intracept and a control sham procedure reduced pain and improved individuals' functional status at the 1-year follow-up; however, the difference in gains between Intracept and the sham were too small to be clinically significant. One other RCT that compared Intracept with standard care is at a high risk of bias because it reports on subjective outcomes in unblinded individuals and pools outcomes from individuals who received nonsurgical treatments. Additional studies suggest that Intracept is more effective than conservative treatment for resolving LBP; however, the studies reported too few events and are at too high of a risk of bias to be conclusive. Ongoing trials do not address evidence gaps. The assessment of findings suggests that the Intracept system has potential benefits, but too few data exist. Multicenter, blinded RCTs are needed to validate the available evidence and compare Intracept with other interventions for treating LBP.

In the multicenter, randomized, double-blinded, sham-controlled SMART trial, Fischgrund et al. (2018, included in the Hayes report cited above) evaluated the safety and efficacy of RFA of the BVN for the treatment of CLBP. A total of 225 participants diagnosed with CLBP were randomized to treatment with the Intracept procedure (n = 147) or sham therapy (n = 78). All participants had type 1 or type 2 Modic changes of the treated vertebral bodies. The primary end point was the comparative change in the ODI from baseline to 3 months. At 3 months, the average ODI in the treatment arm decreased by 20.5 points, as compared with a 15.2-point decrease in the sham arm in the per-protocol population. A responder analysis based on an ODI decrease of ≥ 10 points showed that 75.6% of participants in the treatment arm, as compared with 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 of follow-up (Fischgrund et al., 2019, included in the Hayes report cited above) and 5 years of follow-up (Fischgrund et al., 2020, included in the Hayes report cited above) reported secondary analyses. Participants who were randomized to the sham control arm were allowed to cross over to RFA at 12 months. Due to a high rate of crossover, RFA-treated participants acted as their own control in a comparison with baseline. Clinically meaningful improvements in function and pain compared with baseline were sustained through the 2-year follow-up; however, 8% of participants at 2 years and 10% at 5 years had inadequate pain relief and underwent surgery. The limitations of the study include the potential bias due to manufacturer-sponsored, poor-quality design related to the sham group crossover to the active treatment group; collection of safety data only up to 3 months; and postoperative follow-up that was limited to 12 months. [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)

ASIPP 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 two times per year) between each procedure, provided that 50% or greater relief is obtained for 5 to 6 months.
- If the interventional procedures are applied for different regions, they may be performed at intervals of no sooner than 1 week or preferably 2 weeks for most types of procedures if they are not allowed to be performed in one setting or are 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:
  - Nonsurgical 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 the VAS, 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 and American Association of Neurological Surgeons and Congress of Neurological Surgeons, 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 6 months following the procedure. Grade of recommendation: B - fair evidence (level II or III studies with consistent findings) for or against recommending intervention.
- CRFA of the sacral lateral branch nerves and dorsal ramus of L5 may be considered in patients with SIJ 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, is 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 October 28, 2025)

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 October 28, 2025)

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Policy History/Revision Information

Date	Summary of Changes
03/01/2026	**Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version CS001KY.09

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, 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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