Molina Clinical Policy
Radiofrequency Nerve Ablation for Neck and Back Pain
Policy No. 469

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DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Chronic Low Back Pain (CLBP), a leading cause of disability in the United States, is defined as persistent pain of the lower back lasting more than 12 consecutive weeks. Historically CLBP is diagnosed as “nonspecific” and managed with broad treatments that are often costly and ineffective in the long term. Diagnosis and treatment has moved towards identifying the specific cause of the pain and treating the identified nerves, or area causing the disruption, with targeted procedures.

Sacroiliac Joint (SIJ) Pain is a condition in which pain is caused by the joint connecting the sacrum and the pelvis (Sun et al. 2018). The SIJ, the largest axial joint in humans, connects the spine at the sacrum to the pelvis at the ilium and functions more as a stabilizing point than a moving joint. Pain, caused by an injury, disease, or surgery, may occur in this highly innervated joint or in the numerous muscles and ligaments that surround and support the joint. The SIJ has been identified as a primary source of CLBP (Wieczorek et al. 2021).

Facet Joint Pain may occur when the synovial membrane that surrounds the facet joint is stretched, strained, or trapped, causing facet joint pain (Manchikanti et al. 2016). The facet joints (zygapophyseal joints or z-joints) are paired synovial joints located in the posterior compartment of the spine and innervated by the dorsal medial rami of the spinal nerves. The role of the facet joints is to limit hyperflexion, extension, lateral flexion, and axial rotation. Facet denervation is intended to provide long-term pain alleviation; however, nerves regenerate, thus repeat treatments may be necessary (Cohen et al. 2020).

Radiofrequency Ablation (RFA), also known as non-pulsed or thermal RFA, is a treatment for chronic pain that utilizes radiofrequency (RF) current to generate heat and destroy sensory nerves. In patients with refractory pain, the goal of this therapy is to disrupt pain signal transmission from the nerves to the brain. RFA is also referred to as RF neurolysis, RF neurotomy, RF coagulation, RF lesioning, and RF denervation (Lee et al. 2021). There are several variations to the standard consistent and thermal radiofrequency ablation, including pulsed radiofrequency ablation, water-cooled radiofrequency ablation, and cryoneurolysis (Wray et al. 2023). These alternative procedures lack of evidence supporting their efficacy compared to traditional RFA for treating CLBP.

Intraosseous Basivertebral Nerve Ablation (BVNA) is a minimally invasive procedure that targets the nociceptors in the vertebral endplates between L3 and S1 that send pain signals through the basivertebral nerve to the central nervous system, contributing to severe CLBP. An increasing body of evidence has arisen highlighting the vertebral endplates as a significant source of CLBP. Pain fibers in the vertebral endplates trace back to the basivertebral nerve located within the vertebral body and proliferate with endplate damage, resulting in vertebrogenic CLBP. Vertebrogenic CLBP can be diagnosed via MRI showing Type 1 or Type 2 Modic changes. BVNA is repeated at each vertebral body identified as a source of pain (Tieppo Francio and Sayed 2023).

Regulatory Status

RFA for spinal pain is a procedure, thus it is not regulated by the FDA. The devices used in the procedure are FDA regulated and can be found in the FDA 510(k) database. These devices are classified according to two product codes: radiofrequency lesion generators (GXD) and radiofrequency lesion probes (GXI).

Intraosseous BVNA is a procedure, and thus not FDA regulated, however any instruments utilized in the procedure are regulated and must be approved. The Intracept Intraosseous Nerve Ablation System by Relievant Medsystems Inc. (Redwood City, CA) received FDA approval on July 9, 2016, through the 510(k) Premarket approval process under product code GXI and 510(k) number K153272. It is classified as a radiofrequency lesion probe.

RELATED POLICIES

MCP-468: Injections and Nerve Blocks for Neck and Back Pain
MCP-386: Cooled Radiofrequency Ablation (CRFA) for the Management of Chronic Pain

COVERAGE POLICY

Intraosseous Basivertebral Nerve Ablation for Chronic Back Pain

Intraosseous Basivertebral Nerve radiofrequency ablation is considered **experimental, investigational, and unproven** for the treatment of chronic lower back pain due to insufficient evidence in the peer-reviewed medical literature to establish long-term safety, efficacy, and effect on net health outcomes.

Sacroiliac Joint Sensory Nerve Ablation for Chronic Back Pain

Radiofrequency ablation (conventional or cooled) is considered **experimental, investigational, and unproven** for the treatment of acute, subacute, or chronic pain associated with the sacroiliac joint due to insufficient evidence in the peer-reviewed medical literature to establish long-term safety, efficacy, and effect on net health outcomes.

Thoracic Facet Joint Nerve Ablation for Chronic Back Pain

Radiofrequency ablation (conventional or cooled) is considered **experimental, investigational, and unproven** for the treatment of facet joint associate acute, subacute, or chronic pain in the thoracic region due to insufficient evidence in the peer-reviewed medical literature to establish long-term safety, efficacy, and effect on net health outcomes.

Cervical or Lumbar Facet Joint Nerve Ablation for Chronic Back Pain

Non-pulsed, conventional (i.e., non-cooled) radiofrequency ablation (RFA) may be **considered medically necessary** for chronic cervical or lumbar pain associated with the facet joint as part of a comprehensive pain management treatment program when ALL the following criteria are met:

1. Member is ≥ 18 years old

2. Diagnosis of chronic severe somatic, non-radicular back pain (cervical or lumbar) defined as persisting beyond three (3) months and affecting activity of daily living functional ability (≥6 on NRS Pain Rating Scale)

3. Inadequate response to a minimum of three (3) months of conservative therapy that includes ALL the following:
   a. Physical therapy for a minimum of eight (8) sessions, unless a documented contraindication or intolerance to physical therapy is provided
   b. Activity or exercise modification
   c. Pharmacologic therapy (e.g., NSAIDS, muscle relaxants, corticosteroids, antidepressants, anticonvulsants, or opioids)

4. Positive response to diagnostic facet injection or medial branch block (MBB) trial* as evidenced by ALL the following:
   a. Dual injections performed in the same anatomic location(s) at two (2) separate points in time, at least one week apart
   b. Significant functional pain relief of 70% measured by a decrease in pain medications and increase in physical function for the duration of the anesthetic administered
   c. Initial diagnostic facet joint injection produced a successful response
   **Note: MCP-468: Injections and Nerve Blocks for Neck and Back Pain addresses qualifications for MBB trial.

5. Absence of ALL the following absolute contraindications:
    a. Previous history of spinal fusion in the area to be treated
    b. Proven specific non-facetogenic causes of back pain, including disc herniation, spondylolisthesis, spondylosis ankylopoietica, spinal stenosis, discogenic or stenotic compression, malignancy, infection, or trauma
    c. Current systemic or local infection over the injection site

6. RFA will not be performed at more than four (4) joints (e.g., two [2] bilateral levels or four [4] unilateral levels) per session for each covered spinal region

Continuation of RFA for Facet Joint Pain Therapy
Repeat RFA therapy for facet joint pain is **considered medically necessary** when ALL the following are met:

1. At least six (6) months have elapsed since the previous RFA treatment

2. Maximum of two (2) procedures over a twelve (12) month period per side and level

3. RFA will not be performed at more than four (4) joints (e.g., two [2] bilateral levels or four [4] unilateral levels) per session for each covered spinal region

4. RFA may be performed at the same level no more than twice (2) annually and only if the initial RFA results in significant pain relief (at least 50%) and improvement in patient specific ADLs for at least six (6) months

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Intraosseous Basivertebral Nerve Ablation for Chronic Back Pain

Randomized Controlled Trials

Koreckij et al. (2021) published a prospective open label single-arm randomized multicenter clinical study evaluating intraosseous BVNA with two-year follow up results. One hundred and forty participants were randomized, 66 to BVNA and 74 to standard care. The primary endpoint was improvement in patient Oswestry Disability Index (ODI) score, Visual Analog Scale (VAS) score for evaluating pain, and Short Form Health Survey (SF-36) scores, these were taken at baseline and in follow up. The secondary endpoint was to review target success of the procedure via an MRI at 6 weeks post BVNA procedure. At a retention rate of 88%, 58 BVNA participants completed the 24-month follow up. At baseline, 67% had back pain for >5 years, 36% were actively taking opioids, 50% had prior epidural steroid injections, and 12% had prior low back surgery. Improvements in ODI, VAS, and SF-36 were statistically significant at all timepoints through 2 years. Participants reported a mean improvement in ODI of 28.5 ± 16.2 points (from a paired baseline of 44.5 to 16.0; $p < 0.001$) and mean improvement in VAS of 4.1 ± 2.7 cm (from 6.6 to 2.5; $p < 0.001$) at 2 years post ablation. A 50% or greater reduction in pain was reported in 72.4% of patients, 31.0% were pain-free, and 62% fewer patients were actively taking opioids. Patient satisfaction results revealed 79% of BVNA patients reported improvement of their condition, 21% reported no change in their condition, 71% reported they had returned to the level of activity that they enjoyed prior to having low back pain, and 84% indicated they would have the procedure again. There were no serious device or device-procedure related adverse events reported at any point during the study period.

The SMART Trial

Fischgrund et al. (2018) conducted a prospective randomized double-blind sham controlled multi-center clinical trial to study intraosseous BVNA for the treatment of CLBP. The primary objective was to evaluate the safety and efficacy of using RF energy to ablate the BVN for the treatment of chronic axial low back pain. All participants were skeletally mature with CLBP for 6 or more months, isolated lumbar pain refractory to 6 months standard treatment, Type 1 or

Type 2 Modic changes on MRI, and report a minimum ODI of 30 points (100-point scale) and a minimum VAS of 4 cm (10 cm scale). Two hundred and twenty-five patients were randomized in a 2:1 block, 78 to sham and 147 to treatment. To maintain blinding, the treating and follow-up physicians differed. At 1 year, patients in the sham arm were permitted to cross-over to the active treatment. Targeting, defined as overlap between the RF created ablation zone and the terminus of the BVN at each level treated observed on 6-week post-procedure MRI, was successful in 129 of 145 patients (89.0%) or in 300 of 317 treated vertebral bodies (94.6%). At the 3-month follow up the treatment group exhibited a 20.5-point improvement in ODI compared to a 15.2-point improvement in the sham group ($p = 0.019$), and a 2.97 cm improvement in VAS scores compared to 2.36 in the sham group. The improvement in VAS in the treatment arm was 3.04, and 2.84 cm at 6, and 12 months, respectively; compared to 2.08, and 2.08 cm at 6, and 12 months, respectively in the sham group ($p = 0.083$, 0.008, and 0.038). The safety profile revealed no device- or procedure-related patient deaths, unanticipated adverse device effects, nor device-related serious adverse events. Eight procedure-related events were reported in six patients, two of which were in the sham group, for a complication rate of 2.7%. The authors concluded that using a 10-point ODI improvement as a threshold, 75.6% of treatment arm patients as opposed to 55.3% of sham arm patients were characterized as responders. The publication highlighted placebo affect research and emphasized that comparison of the difference in outcome score between the sham and treatment groups does not represent the clinical utility of BVNA because a sham treatment is not a clinically acceptable treatment for CLBP, nor is a sham response likely to occur in an open-label setting. The authors urged that the overall therapeutic value of the procedure should be viewed through its safety profile and observed improvements from patient baseline, to which the results of the study supported BVNA as a minimally invasive treatment for CLBP.

The 2-year follow up results of the SMART trial were published by Fischgrund et al. (2019) to include follow up on the 57 (73% of the original 78) sham group participants that elected to cross over into the treatment arm after one year, for a total of 117 participants successfully treated with BVNA. The primary outcomes evaluated were ODI and VAS scores. The mean percent improvements in ODI and VAS compared to baseline at 2 years were 53.7 and 52.9%, respectively. Responder rates for ODI and VAS were also maintained through 2 years with patients showing clinically meaningful improvements in both: ODI ≥ 10-point improvement in 76.4% of patients and ODI ≥ 20-point improvement in 57.5%; VAS ≥ 1.5 cm improvement in 70.2% of patients.

The 5-year follow up results of the SMART trial were published by Fischgrund et al. (2020) to reveal that 100 of the 117 treated participants (85%) were available for review with a mean follow-up of 6.4 years (5.4–7.8 years). Mean ODI score improved from 42.81 to 16.86 at 5-year follow-up, a reduction of 25.95 points ($p < 0.001$). Mean reduction in VAS pain score was 4.38 points (baseline of 6.74, $p < 0.001$). In total, 66% of patients reported a > 50% reduction in pain, 47% reported a > 75% reduction in pain, and 34% of patients reported complete pain resolution. Overall responder rate at 5 years was 75% using thresholds of ≥ 15-point ODI and ≥ 2-point VAS for function and pain.

Systematic Reviews and Meta-Analyses

Nwosu et al. (2023) conducted a systematic review evaluating the effectiveness of intraosseous BVNA in the treatment of non-radiating vertebrogenic CLBP. The authors analyzed 11 publications for a total of 413 patients, these publications were comprised of one systematic review, one meta-analysis, three prospective randomized double-blinded studies, three prospective randomized open-label studies, one prospective single-arm, one randomized single-blinded, and one narrative review. The key outcome analyzed 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. Among the quantifiable data, most of the participants reported greater than or equal to 10-point improvement in the ODI, and greater than or equal to two-point improvement in the VAS at the three-month follow up. In all studies adverse events were rare, however the authors noted that more adverse events may be observed when BVNA becomes a standard procedure. The review noted that all studies except for one systematic review were industry sponsored, thus increasing the risk for reporting and publication bias. The review also comments on the lack of meta-analyses due to the scarcity of quality RCTs. The authors conclude that based on current evidence, the novel procedure of BVNA is a safe and effective treatment for vertebrogenic CLBP.

Conger et al. (2022) published an updated systematic review with single-arm meta-analysis evaluating the effectiveness of intraosseous BVNA for the treatment of vertebrogenic low back pain. The key outcome analyzed was a 50% or more improvement in VAS, with a secondary outcome analysis of a 15 point or greater improvement in ODI score. Twelve publications, for a total of 414 participants, were analyzed. Single-arm meta-analysis showed a success rate of 65% (95% confidence interval [CI] 51–78%) and 64% (95% CI 43–82%) for ≥50% pain relief at 6 and 12 months,

respectively. Rates of ≥15-point ODI score improvement were 75% (95% CI 63–86%) and 75% (95% CI 63–85%) at 6 and 12 months, respectively. The authors concluded there is moderate evidence supporting the efficacy of BVNA in treating vertebrogenic CLBP; however, it is emphasized there is a small pool of data and that larger high quality RCTs are needed to further assess the safety and efficacy of this procedure.

Non-Randomized Studies, Retrospective Reviews and Other Evidence

Khalil et al. (2024) conducted a 5-year pooled analysis of intraosseous BVNA from three prospective clinical trials (two randomized and one single-arm study). The study aimed to evaluate the long-term efficacy and safety of BVNA for chronic low back pain. The analysis included data from multiple centers, with a focus on patient-reported outcomes and imaging results. 249 out of 320 BVNA-treated participants (78% participation rate) completed a five-year visit, with a mean follow-up of 5.6 years. At the start of the study, 71.9% of participants experienced back pain for five or more years, 27.7% were using opioids, and 61.8% had previously received lumbar spinal injections. Significant improvements were noted at five years, with a mean numeric pain scale improvement of 4.32 points and ODI improvement of 28.0 points. Nearly one-third (32.1%) of patients reported being pain-free, 72.7% indicated their condition improved, and 68.7% resumed prior activity levels. Among participants on opioids at baseline, 65.2% were no longer taking them at five years. Spinal injections decreased by 58.1%. The rate of lumbosacral treatment was 13.2%, including a 6.0% rate of lumbar fusion. No serious device-related adverse events were reported. The study found significant improvements in pain and disability scores, with a high percentage of patients reporting reduced pain and improved quality of life. However, the study's reliance on industry-sponsored trials raises concerns about potential bias. The lack of a control group and the open-label design may also contribute to bias, as patients and investigators were aware of the treatment being administered. Overall, while the results are promising, the potential for bias should be considered when interpreting the findings. Further independent studies are needed to confirm the long-term benefits and safety of BVNA.

Sacroiliac Joint Sensory Nerve Ablation for Chronic Back Pain

The therapeutic efficacy and duration of impact of radiofrequency ablation (RFA) in the sacroiliac joint (SIJ) have not been reliably demonstrated in well-designed studies. Randomized controlled trial (RCT) evidence is limited, comprises small sample sizes, and assesses primarily short-term results following RFA treatment. Studies assessed in published systematic reviews, Cochrane reviews, and technology assessments overlap. There is inadequate data in the peer-reviewed scientific literature to establish the safety and efficacy of various ablative modalities (e.g., laser, chemical, or electrical) when used to treat SIJ and other related types of pain.

Randomized Controlled Trials

Salman et al. (2016) completed a prospective, randomized, blinded, steroid-controlled study to compare the effectiveness of RFA and intra-articular steroid injections in managing SIJ pain. Patients and clinicians that performed the follow-up visits were blinded. The physician performing the procedure could not be blinded to the intervention but was blind to the rest of the study protocol. Thirty patients with sacroiliac joint pain were enrolled and randomized into two groups (RF group: 15, Steroid group: 15). The primary outcome was achieving at least 50% pain reduction on the Visual Analog Scale (VAS) at 1-, 3-, and 6-months post-intervention. Secondary outcomes was ≥ 25% reduction in analgesic usage. The radiofrequency group received RFA denervation of L4–L5 primary dorsal rami and S1–S3 lateral sacral branch under fluoroscopy. The steroid group received a fluoroscopy-guided intra-articular injection of methylprednisolone. Non-responders in this group could cross over to RFA treatment at their one month follow up. At 1-, 3-, and 6-months post-intervention, 73%, 60%, and 55% of patients in the RFA group reported ≥50% reduction in pain intensity, respectively. In contrast, only 20% of the steroid group achieved similar pain relief at 1 month, with no improvement at 3 or 6 months. Non-responders in the steroid group who crossed over to RF treatment achieved improved outcomes. Additionally, patients in the RF group exhibited significant reductions in analgesic use (73.3% (n = 11), 60% (n = 9) and 33.3% (n = 5) at 1, 3 and 6 months, respectively) usage compared to the steroid cohort counterparts (16.2% at one month follow-up, with no follow-up data for 3 or 6 months). These findings suggest RFA as a more effective modality for long-term management of SIJ pain. The study attributed these favorable outcomes to the meticulous patient selection process, particularly requiring a ≥75% pain reduction from diagnostic sacroiliac joint blocks, and the RFA technique employed. However, limitations such as the small sample size, the potential for tissue damage from extensive RFA lesions, and the low specificity of diagnostic SIJ blocks were noted. RFA at L4-L5 dorsal rami and S1-S3 lateral sacral branches is a promising intervention for providing effective, long-lasting pain relief in carefully screened patients with chronic sacroiliac joint pain. While these results underscore its therapeutic potential, additional research is warranted to optimize procedural techniques and expand its applicability in clinical practice.

van Tilburg et al. (2016) completed a randomized, double-blind, sham-controlled multicenter trial to investigate the efficacy of percutaneous RFA heat lesioning compared to a sham procedure in patients with SIJ pain lasting more than three months. The study included 60 participants (30 "treatment group" and 30 "sham group"), aged 18 years or older, who exhibited a reduction of at least two points on the Numerical Rating Scale (NRS, 0–10) following a diagnostic SIJ block. Patients in the treatment group received RFA to the lateral branches of S1-S4 nerve roots and the L5 dorsal primary ramus, while those in the sham group underwent identical procedures without actual RFA application. Pain reduction, measured via the NRS, served as the primary outcome, and Global Perceived Effect (GPE) (the patient rates on a numeric scale how much their condition has improved or deteriorated) was the secondary outcome. A crossover was provided for the sham-operated group after 3 months if no significant pain relief was obtained. The results revealed no statistically significant differences in pain reduction or satisfaction between the treatment and sham groups over time. However, pooling data across all participants showed a significant decrease in mean pain levels from baseline to follow-up, regardless of group assignment. In the crossover group (sham patients who later received RFA treatment), 42.1% experienced a pain reduction of two or more points on the NRS, comparable to the 43.3% improvement observed in the primary radiofrequency group. Satisfaction and recovery outcomes also did not differ significantly between groups, and the hypothesis of no difference between treatments could not be rejected. Notably, adverse events were minimal, with only one serious incident reported during follow-up. The study identified several limitations, including the use of a single diagnostic test block instead of the recommended double block, challenges in achieving uniform physiotherapy across centers, and technical difficulties in consistently targeting the S4 branch. Additionally, the diagnostic test block's false-positive rate could have influenced patient selection. This RCT did not demonstrate a significant difference in pain reduction or GPE between RFA and a sham procedure for SIJ pain. These findings suggest that while RFA may offer some pain relief, its efficacy relative to sham interventions remains inconclusive, underscoring the need for further research and refinement of treatment protocols.

Non-Randomized Studies, Retrospective Reviews and Other Evidence

A health technology assessment *Conventional Radiofrequency Ablation for Sacroiliac Joint Denervation for Chronic Low Back Pain* (Hayes 2022) evaluated the effectiveness and safety of conventional RFA for SIJ denervation in addressing lower back pain among adult populations. The assessment encompassed ten studies, comprising 4 randomized controlled trials, four retrospective comparative studies, one prospective pretest-posttest study, and one prospective cohort study, with follow-up periods spanning from 3 months to 6 years. Studies compared conventional RFA with conservative management, sham RFA, SIJ block with corticosteroid injection, cooled RFA, pulsed RFA, and SIJ fusion. Based on a low-quality body of evidence, the assessment suggests that conventional RFA may be effective in mitigating CLBP in adults. However, there is uncertainty regarding its long-term effectiveness in pain alleviation, as well as its influence on long-term pain medication utilization, disability/functionality, and quality of life. The low-quality evidence is attributed to several factors, including the inherent limitations within individual studies, significant procedural heterogeneity across investigations, modest sample sizes in most studies, inconsistent findings concerning functional outcomes, and a paucity of studies examining outcomes beyond pain and functionality. The overall body of evidence suggests that conventional RFA for SIJ denervation is presumably safe and may confer short-term benefits in diminishing CLBP.

Facet Joint Nerve Ablation for Chronic Back Pain

Systematic Reviews and Meta-Analyses

Li et al. (2022) performed a systematic review and network meta-analysis to analyze and compare the efficacy and radiofrequency ablation (RFA) denervation treatments for facet joint derived chronic lower back pain (CLBP). The authors performed searches for eligible RCTs between January 1966 – December 2021. Interventions analyzed included conventional RFA, pulsed radiofrequency denervation (PRF), pulsed radiofrequency treatment of the dorsal root ganglia (PRF-DRG), radiofrequency facet capsule denervation (RF-FC), and radiofrequency ablation under endoscopic guidance (ERFA). Ten RCTs (n = 715 patients) were included in the review. There was moderate evidence demonstrating greater effect with RF denervation on pain relief than sham control in the short term and the long term. Evidence was fair for PRF denervation – it was more effective than sham control for pain over the long term. Fair evidence demonstrated that ERFA denervation was more effective for pain relief when compared to the sham control (short and long term). Fair evidence demonstrated that RF-FC denervation was more effective for pain relief than sham control in the long term. Fair evidence indicated that PRF-DRG denervation was more effective for pain relief than sham control in the short term. The authors concluded that RFA is an effective treatment for patients with CLBP that is derived from the facet joint.

Janapala et al. (2021) performed a systematic review and meta-analysis of randomized trials to determine the efficacy of RFA neurotomy in the treatment of CLBP originating in the facet joints. Six of the 12 studies included in this analysis exhibited both short- and long-term effectiveness, 4 trials demonstrated just short-term effectiveness, and 2 trials demonstrated lack of effectiveness. The authors observed that additional systematic studies (not included in the analysis) provided contradictory results. Maas et al. (2015) found a lack of efficacy in RFA denervation, which reduced pain in the short-term compared to placebo but did not improve long-term pain or function, in a meta-analysis of 23 randomized studies of patients with facet joint discomfort. Schneider et al. (2020) demonstrated efficacy in patients with complete pain alleviation and in roughly 57% of patients with parallel needle implantation. In a meta-analysis, Lee et al. (2017) concluded that conventional radiofrequency denervation led in a significant reduction in CLBP with favorable outcomes when compared to sham operations over a 1-year period. The analysis included 231 participants enrolled in several studies who underwent denervation treatments. In comparison, Poetscher et al. (2014) analyzed 9 RCTs comparing radiofrequency denervation to various forms of treatment and placebo, concluding that radiofrequency denervation was more efficacious than placebo and steroid injection; nonetheless, this evidence should be interpreted cautiously.

Non-Randomized Studies, Retrospective Reviews and Other Evidence

Akgul et al. (2022) conducted a retrospective comparative review of RFA involving the cervical, thoracic, and lumbar spinal regions to understand the long-term efficacy of RFA. The review included 1275 patients aged 18 years and older with a clinical follow-up for at least 1 year and had more than 6 months of back pain prior to intervention. The total included patients with pain in these regions, without radicular pain and without primary and/or metastatic disease in the spinal region. A total of 774 patients underwent RFA (156 cervical, 184 thoracic, 434 lumbar and lumbosacral) were compared with a control group of patients who did not receive RFA. Baseline VAS scores were as follows: cervical 7.1 ± 1.72, thoracic 7.2 ± 2.14, lumbar 7.8 ± 2.86, and control 7.5 ± 2.17. Across all the RFA groups there was a significant improvement in the three month post RFA VAS scores: cervical 2.0 ± 0.52, thoracic 2.1 ± 0.61, lumbar 2.2 ± 0.41, and control 5.7 ± 0.51. There was a noticeable increase in VAS scores at the 24 month time point across all RFA groups only, which implies RFA provides short term relief. However, it is noted that the 24 month VAS are still significantly lower than baseline scores.

Non-pulsed, conventional RFA has a larger body of RCTs for the treatment of CLBP associated with facet joint syndrome in the lumbar and lumbosacral regions, but these studies have produced inconsistent results, whereas pulsed RFA has a significantly smaller body of evidence with a range of comparison groups. The body of evidence supporting non-pulsed RFA in the treatment of CLBP is rated as moderate due to limitations in the quality of some individual studies and inconsistency in findings, whereas the body of evidence supporting pulsed RFA in the treatment of CLBP is rated as low due to a lack of evidence (Hayes 2021). There is insufficient published evidence to assess the safety and/or impact on health outcomes or patient management for pulsed RFA currently.

- In a Health Technology Assessment *Radiofrequency Ablation for Facet Joint Denervation for Chronic Low Back Pain* (Hayes 2021), most of the studies evaluated were for non-pulsed RFA as the primary intervention (10 studies), in comparison to a limited number (3 studies) that specifically assessed pulsed RFA. Non-pulsed RFA appears to be similar or superior to sham and active therapies for CLBP associated with facet joint pain, according to a moderately large body of moderate-quality evidence. Two RCTs examining overall treatment success for non-pulsed RFA against sham therapy, including 1 good-quality research and 1 fair-quality trial (Moussa et al. 2016), preferred RFA versus sham therapy (Nath et al. 2008). There were no significant differences noted in non-pulsed RFA versus sham therapy in 2 high-quality studies (van Wijk et al. 2005; Geurts et al. 2003) and superior to steroid injections in 1 high-quality trial (Zhou et al. 2016).
- A modest body of low-quality evidence suggests that percutaneous pulsed RFA is comparable, but not superior to, sham therapy (1 study), steroid injections (1 study), and non-pulsed and pulsed RFA combined (1 study) in terms of CLBP resolution.
- Treatment efficacy following non-pulsed RFA was evaluated as a primary outcome in 3 studies (Moussa, 2016; Nath et al. 2008; Geurts et al. 2003) and as a secondary outcome in 2 studies. (Zhou et al. 2016; van Wijk et al. 2005). While overall treatment success was not evaluated in the pulsed RFA studies (Hayes 2021) but CLBP relief was reported in 3 studies: 1 good-quality study found no significant benefits from pulsed RFA compared to sham therapy (Tekin et al. 2007); 1 poor-quality study found that pulsed RFA significantly reduced pain compared to steroid injections (Hashemi et al. 2014); and 1 poor-quality study found no difference between pulsed RFA and combined pulsed and non-pulsed RFA (Hashemi et al. 2014; Simopoulos et al. 2008).

National and Specialty Organizations

The **International Society for the Advancement of Spine Surgery** (ISASS) issued *Policy Statement 2022: Literature Review of Intraosseous Basivertebral Nerve Ablation* (Lorio et al. 2022) that highlighted the growing evidence for vertebrogenic origins of CLBP, and the addition of medical codes for BVNA, as well as designated vertebrogenic codes in the International Classification of Diseases, 10th revision, Clinical Modification. The guideline went on to summarize the current evidence supporting BVNA, and stated "Collectively, the studies reviewed demonstrate that BVNA provides clinically meaningful improvements in pain and function at 5+ years with an excellent safety profile. This evidence supports BVNA as a treatment option for a well-defined subpopulation of CLBP patients." The policy statement ended with indications and contraindications for the BVNA procedure.

The **American Society of Pain and Neuroscience** (ASPN) published *Evidence-Based Clinical Guideline of Interventional Treatments for Low Back Pain* (Sayed et al. 2022) that summarized the various current treatment modalities for CLBP, their indications, and safety profiles. The clinical guideline supported the use of intraosseous BVNA at the L3 through S1 vertebrae for the treatment of vertebrogenic CLBP in patients with pain refractory to conservative treatment for at least 6 months, and with evidence of vertebral endplate change on MRI. The guideline reported the adverse event rate is quite low for BVNA, with the most reported adverse event being minor and self-limiting issues, such as incisional pain and transient worsening of back pain. The guideline assigned a Grade A recommendation (The ASPN Back Group recommends the service. There is high certainty that the net benefit is substantial.) with Level 1a Certainty (At least 1 controlled and randomized clinical trial, properly designed).

The **American Society of Pain and Neuroscience** (ASPN) published *Latest Evidence-Based Application for Radiofrequency Neurotomy (LEARN): Best Practice Guidelines from the American Society of Pain and Neuroscience* (Lee et al. 2021) with the following consensus statements:

- Cervical medial branch RFA neurotomy may be used for the treatment of axial neck pain when facet joints have been identified as the etiology of pain via diagnostic blocks. GRADE I A.
- Thoracic medial branch RFA neurotomy may be used for the treatment of thoracic/midback pain when facet joints have been identified as the etiology of pain via diagnostic blocks. GRADE II-3 C.
- Lumbar medial branch RFA neurotomy may be used for the treatment of axial low back pain when facet joints have been identified as the etiology of pain via diagnostic blocks, GRADE I A.
- Lateral sacral branch RFA neurotomy may be used for the treatment of posterior sacral ligament and joint pain following positive response to appropriately placed diagnostic blocks. GRADE II-1 B.

The **American Society of Interventional Pain Physicians** (ASIPP) published *Comprehensive Evidence-Based Guidelines for Facet Joint Interventions in the Management of Chronic Spinal Pain: American Society of Interventional Pain Physicians (ASIPP) Guidelines Facet Joint Interventions 2020 Guidelines* (Manchikanti et al. 2020) that made the following recommendations:

- Cervical and lumbar RFA: The level of evidence is II with moderate strength of recommendation (for lumbar RFA with inclusion of 11 relevant RCTs with 2 negative studies and 4 studies with long-term improvement; for cervical RFA with inclusion of one RCT with positive results and 2 observational studies with long-term improvement.
- Thoracic RFA: The level of evidence is III with weak to moderate strength of recommendation with emerging evidence for with inclusion of one relevant RCT and 3 observational studies.
- For facet joint nerve ablation, the suggested interval between procedures is 6 months or longer (a maximum of two times per year), given that 50% or better pain reduction is attained for 5-6 months. If interventional procedures are applied to multiple locations, they should be performed at intervals of no less than one week and ideally two weeks for most treatments unless they are permitted or contraindicated in one setting.
- The therapy frequency for medial branch neurotomy should be maintained at least 6-month intervals for each region when multiple regions are involved. It is also proposed that all regions be treated at the same time, providing that all treatments are carried out safely.
- Interventional operations should only be repeated as needed during the treatment or therapeutic phase, based on medical necessity criteria.

The **American Society of Regional Anesthesia and Pain Medicine** published *consensus practice guidelines on interventions for lumbar facet joint pain from a multispecialty, international working group* (Cohen et al. 2020) that issued the following recommendations for lumbar facet joint pain from a multispecialty, international working group:

- Prior to lumbar facet RFA, MBB should be used as a prognostic screening test.

- In patients who had a positive success from their initial RFA surgery, which is commonly characterized as at least 50% pain reduction after three months, repeat RFA procedures are indicated for recurrence of pain.
- Due to the low success rates and short duration of benefit observed in some studies, it is recommended to repeat the procedure no more than two times per year.

The **American Society of Regional Anesthesia and Pain Medicine** and the **American Academy of Pain Medicine** published the joint findings *Consensus practice guidelines on interventions for cervical spine (facet) joint pain from a multispecialty international working group* (Hurley et al. 2022). The Cervical Joint Working Group selected twenty questions for developing neck pain guidelines, achieving 100% consensus on 17 topics. Key issues addressed were the importance of history, physical exams, and imaging in patient selection for procedures, the necessity of conservative treatment prior to injections, the requirement for imaging in blocks, and the diagnostic and prognostic value of medial branch blocks and intra-articular joint injections. Additional topics included the effects of sedation and injectate volume, the therapeutic value of facet blocks, the ideal cut-off value for positive blocks, the number of blocks needed before radiofrequency ablation, electrode orientation, the impact of larger lesions on success rates, the use of stimulation prior to radiofrequency ablation, risk mitigation strategies, and the criteria for repeating radiofrequency ablation. The committee concluded that cervical medial branch RFA may benefit well-selected individuals, with medial branch blocks being more predictive than intra-articular injections. Implementing more stringent selection criteria could improve denervation outcomes but may lead to higher false-negative rates, reducing overall success. Clinical trials should be tailored to specific objectives, with some requiring more rigorous selection criteria than those used in standard clinical practice.

The **National Institute for Health and Care Excellence** (NICE) issued the following NICE guideline [NG59] Low *back pain and sciatica in over 16s: assessment and management* (2020) with the following recommendations:

- Consider referral for assessment for radiofrequency denervation for people with CLBP when:
  - Non-surgical treatment has not worked for them
  - The main source of pain is thought to come from structures supplied by the medial branch nerve
  - 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
- Denervation with radiofrequency should be performed only in patients with CLBP have a favorable response to a diagnostic MBB.
- Do not offer imaging for people with CLBP with specific facet joint pain as a prerequisite for RFA. Imaging should not be used as a prerequisite for RFA denervation in patients with CLBP with specific facet joint pain.

The **North American Spine Society** (NASS) published the following guidelines and coverage policy recommendations:

- *Sacroiliac Joint Injections and Radiofrequency Ablation* (NASS 2020) endorses the coverage of SIJ RFA; however, the rational emphasizes a lack of literature to guide clinical decisions. The recommendation states:
  > "Radiofrequency neurotomy of the L5 primary dorsal ramus and sacral dorsal rami lateral branches: Evidence regarding radiofrequency neurotomy for SIJ posterior ligament complex pain remains limited. Based on the available limited data, it is reasonable to estimate a response rate of 35-70% to achieve = 50% improvement in VAS pain scores for at least 3 months, when selected by a positive response (= 50%) to diagnostic injection with anesthetic. Positive response is probably both dependent on patient selection and technique. While an optimal diagnostic/selection protocol has not been confirmed, a multi-specialty collaborative panel of experts published appropriate use criteria for SIJ interventions in 2017 recommending more stringent selection criteria of = 75% temporary improvement in pain or function from anesthetic blocks for selection to thermal radiofrequency neurotomy. Similarly, the optimal procedural technique has not been established, but appears to involve multiple lesions per nerve or bipolar lesioning due to variable anatomy of the lateral sacral branches with single-site, single-depth lesions less likely to be effective."
- *Guideline summary review: an evidence-based clinical guideline for the diagnosis and treatment of low back pain* (Kreiner et al. 2020) with the following RFA recommendations:
  - Thermal RFA is recommended as a therapy option for patients suffering from zygapophyseal joint pain in the low back. When more rigorous diagnostic criteria are utilized, the outcome of this process becomes more dependable. These ablations provide relief for at least six months after the treatment. Grade of recommendation: B (Fair evidence, Level II or III studies with consistent findings, for or against recommending intervention).

- In patients with sacroiliac joint discomfort detected by dual diagnostic blocks, cooled RFA of the **sacral** lateral branch nerves and dorsal ramus of L5 may be considered. Grade of recommendation: C (Poor quality evidence (Level IV or V studies) for or against recommending intervention).
- Cryodenervation for the treatment of zygapophyseal joint pain has inadequate evidence to make a recommendation for or against it. Grade of recommendation: I (Insufficient or conflicting evidence not allowing a recommendation for or against intervention).

SUPPLEMENTAL INFORMATION

The Numeric Rating Scale (NRS-11): Rating Pain Level

0: No Pain
1-3: Mild Pain (nagging, annoying, interfering little with ADLs)
4-6: Moderate Pain (interferes significantly with ADLs)
7-10: Severe Pain (disabling; unable to perform ADLs)

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	Description
64625	Radiofrequency ablation, nerves innervating the sacroiliac joint, with image guidance (e.g., 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)
64633	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint
64634	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional facet joint (List separately in addition to code for primary procedure)
64635	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint
64636	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional facet joint (List separately in addition to code for primary procedure)
64999	Unlisted procedure, nervous system

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

12/10/2025	Policy updated to include clarification that standard RFA is "non-cooled" and added E/I/U statement about thoracic RFA. Reduced minimum PT requirements. Annual review remains April 2026
04/09/2025	New policy due to combination of MCP 033 Sacroiliac Injections and Radiofrequency Ablation (RFA) for Sacroiliac Joint Pain, MCP 085 Radiofrequency Ablation (RFA) for Chronic Back Pain Associated with the Facet Joint, and MCP 452 Intraosseous Basivertebral Nerve Ablation. IRO Peer Review on March 12, 2025, by a practicing physician board-certified in Neurological Surgery.

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APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

Washington

For Medicaid reviews, consider and apply the following state-specific criteria:
Health Technology Assessment (HTA) “Facet Neurotomy” Washington State Healthcare Authority, May 16, 2014
Health Technology Assessment (HTA) “Spinal Injections” Washington State Healthcare Authority, May 20, 2016