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Facet Joint and Sacroiliac Joint Denervation

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

Nonpulsed radiofrequency (RF) denervation of cervical facet joints (C3-4 and below) and lumbar facet joints **may be considered medically necessary** when ALL of the following criteria are met:

- No prior spinal fusion surgery in the vertebral level being treated; AND
- Disabling, non-radicular, low back (lumbosacral) or neck (cervical) pain, suggestive of facet joint origin as evidenced by absence of nerve root compression as documented in the medical record on history, physical, and radiographic evaluations; AND
- Pain has failed to respond to 6 weeks of conservative management, which may consist of therapies such as nonsteroidal anti-inflammatory medications, acetaminophen, manipulation, physical therapy, and a home exercise program; AND
- There has been a successful trial of controlled diagnostic medial branch blocks*****; AND
- If there has been a prior successful radiofrequency (RF) denervation, a minimum time of six months has elapsed since prior RF treatment (per side, per anatomical level of the spine).

***NOTE**: A successful trial of controlled diagnostic medial branch blocks consists of 2 separate positive blocks on different days with local anesthetic (no steroids or other drugs), or a placebo-

controlled series of blocks, under fluoroscopic guidance, that has resulted in at least an 80% reduction in pain for the duration of the local anesthetic used (e.g., 3 hours longer with bupivacaine than lidocaine). No therapeutic intra-articular injections (i.e., steroids, saline, or other substances) should be administered for a period of at least 4 weeks prior to the diagnostic medial branch block. The diagnostic blocks should involve the levels being considered for radiofrequency treatment and should not be conducted under intravenous sedation unless specifically indicated (e.g., the individual is unable to cooperate with the procedure). These diagnostic blocks should be targeted to the likely pain generator. Single-level blocks lead to more precise diagnostic information, but multiple single-level blocks require several visits and additional exposure to radiation.

Radiofrequency (RF) denervation **is considered experimental, investigational and/or unproven** for all uses that do not meet the criteria listed above, including but not limited to treatment of sacroiliac joint (SIJ) pain, chronic spinal or back pain, and thoracic facet joint pain.

All other methods of denervation **are considered experimental, investigational and/or unproven** for the treatment of chronic spinal/back pain, including, but not limited to:

- Pulsed radiofrequency denervation,
- Laser denervation,
- Chemodenervation (e.g., alcohol, phenol, or high-concentration local anesthetics), and
- Cryodenervation.

Therapeutic medial branch blocks **are considered experimental, investigational and/or unproven**.

If there has been a prior successful radiofrequency denervation, additional diagnostic medial branch blocks for the same level of the spine **are considered not medically necessary**.

Policy Guidelines

None.

Description

Percutaneous radiofrequency (RF) facet denervation is used to treat neck or back pain originating in facet joints with degenerative changes. Diagnosis of facet joint pain is confirmed by response to nerve blocks. The goal of facet denervation is long-term pain relief. However, the nerves regenerate and, therefore, repeat procedures may be required.

Facet joint denervation is performed under local anesthetic and with fluoroscopic guidance. A needle or probe is directed to the median branch of the dorsal ganglion innervating the facet joint, where multiple thermal lesions are produced, typically by a radiofrequency generator. A variety of terms may be used to describe radiofrequency denervation (e.g., rhizotomy,

rhizolysis). In addition, the structures to which the RF energy is directed may be referred to as facet joint, facet nerves, medial nerve or branch, median nerve or branch, or dorsal root ganglion.

Alternative methods of denervation include pulsed RF, laser, chemodenervation, and cryoablation. Pulsed RF consists of short bursts of electric current of high voltage in the RF range but without heating the tissue enough to cause coagulation. RF is suggested as a possibly safer alternative to thermal RF facet denervation. Temperatures do not exceed 42°C at the probe tip vs temperatures in the 60°C range reached in thermal RF denervation, and tissues may cool between pulses. It is postulated that transmission across small unmyelinated nerve fibers is disrupted but not permanently damaged, while large, myelinated fibers are not affected. With chemical denervation, injections with a diluted phenol solution, a chemical ablating agent, are injected into the facet joint nerve.

Sacroiliac Joint

Similar to other structures in the spine, it is assumed that the sacroiliac joint (SIJ) may be a source of low back pain. In fact, before 1928, the SIJ was thought to be the most common cause of sciatica. In 1928, the role of the intervertebral disc was elucidated, and from that point forward, the SIJ received less research attention.

Research into SIJ pain has been plagued by lack of a criterion standard to measure its prevalence and against which various clinical examinations can be validated. For example, SIJ pain is typically without any consistent, demonstrable radiographic or laboratory features and most commonly exists in the setting of morphologically normal joints. Clinical tests for SIJ pain may include various movement tests, palpation to detect tenderness, and pain descriptions by the patient. Further confounding study of the SIJ is that multiple structures, (e.g., posterior facet joints, lumbar discs) may refer pain to the area surrounding the SIJ.

Because of inconsistent information obtained from history and physical examination, some have proposed the use of image-guided anesthetic injection into the SIJ for the diagnosis of SIJ pain. Treatments being investigated for SIJ pain include prolotherapy, corticosteroid injection, radiofrequency ablation, stabilization, and arthrodesis.

Regulatory Status

A number of radiofrequency generators and probes have been cleared for marketing through the U.S. Food and Drug Administration's (FDA) 510(k) process. In 2005, the SInergy® (Kimberly-Clark/Baylis), a water-cooled single-use probe, was cleared by the FDA, listing the Baylis Pain Management Probe as a predicate device. The intended use is in conjunction with a radiofrequency generator to create radiofrequency lesions in nervous tissue. FDA product codes: GXD, GXI

Rationale

This medical policy was created August 2014 and updated using the PubMed database. The most recent literature review was performed through September 30, 2022.

Medical policies assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Medical policies assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these policies and credible information on technical reliability is available from other sources.

SUSPECTED FACET JOINT PAIN

Clinical Context and Test Purpose

The purpose of diagnostic medial branch blocks in individuals with suspected facet joint pain is to confirm a diagnosis and proceed to appropriate treatment.

The question addressed in this medical policy is: Does the use of diagnostic medial branch blocks improve the net health outcomes in those with suspected facet joint pain?

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with suspected facet joint pain.

Interventions

The test being considered is diagnostic medial branch blocks.

Comparators

The following practice is currently being used to diagnose facet joint pain: clinical diagnosis.

Outcomes

The general outcomes of interest are an accurate diagnosis of pain etiology, a reduction in symptoms and medication use, and improvements in functional outcomes.

Follow-up after a diagnostic medial branch block is short-term to assess response to the procedure.

Study Selection Criteria

For the evaluation of clinical validity of the test, studies that meet the following eligibility criteria were considered:

- Reported on the accuracy of the marketed version of the technology;

- Included a suitable reference standard;
- Patient/sample clinical characteristics were described;
- Patient/sample selection criteria were described.

Clinically Valid

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Systematic Reviews

Boswell et al. (2015) reported on a systematic review evaluating the accuracy and utility of facet joint injections for the diagnosis of facet joint pain. (1) Coauthors included Manchikanti, who is the primary author on most of the studies included in the systematic review. Of the 13 studies on the diagnosis of lumbar facet joint pain that used a criterion standard of at least 75% pain relief, 11 were conducted by the same group of authors, and all 3 studies on the diagnosis of thoracic facet joint pain were conducted by the same group. Study quality was rated by reviewers who were not coauthors of the primary studies. Using the Quality Appraisal of Diagnostic Reliability checklist, evidence was rated as level I for controlled lumbar facet joint blocks, level II for cervical facet joint blocks, and level II for thoracic facet joint blocks. However, in none of the studies were raters blinded to clinical information or to the reference standard. In addition, there is no criterion standard test for the diagnosis of facet joint pain, which creates difficulties in determining test accuracy.

The Boswell et al. (2015) review included 17 studies on lumbar facet joint pain that used controlled blocks with a diagnostic criterion of at least 75% pain relief. Prevalence was reported as 16% to 41%, with false-positive rates of 25% to 44%. For cervical facet joint pain, 11 controlled diagnostic studies were included, reporting a variable prevalence ranging from 36% to 67% and false-positive rates ranging from 27% to 63%. For thoracic facet joint pain, 3 studies used a criterion standard of 80% or higher pain relief, reporting prevalence rates ranging from 34% to 48% and false-positive rates ranging from 42% to 48%. The systematic review did not specify the reference standard used to determine the prevalence of false-positive rates. Four studies evaluated the influence of diagnostic blocks on therapeutic outcomes; three of them are described below.

Falco et al. (2012) updated several systematic reviews on the diagnosis and treatment of facet joint pain. (2-5) The authors found good evidence for diagnostic nerve blocks with at least 75% pain relief as the criterion standard but only limited to fair evidence for diagnostic nerve blocks with 50% to 74% pain relief.

Randomized Controlled Trials

Cohen et al. (2010) reported a multicenter randomized cost-effectiveness trial comparing 0, 1, or 2 diagnostic blocks before lumbar facet radiofrequency (RF) denervation. (6) Included in the trial were 151 patients with predominantly axial low back pain of 3 months or more in duration, failure to respond to conservative therapy, paraspinal tenderness, and absence of focal neurologic signs or symptoms. Of the 51 patients who received RF denervation without

undergoing diagnostic blocks, 17 (33%) obtained a successful outcome. Of the 16 (40%) patients who had a single diagnostic block followed by RF denervation, 8 (50%) of 16 were considered successful. Of the 14 (28%) patients who had RF denervation after 2 medial branch blocks, 11 (79%) of 14 were considered successful. Three patients were successfully treated after medial branch blocks alone.

Observational Studies
Cohen et al. (2008) compared lumbar zygapophyseal joint RF denervation success rates between the conventional threshold (≥50% pain relief) and the more stringently proposed cutoff (≥80%) in a retrospective multicenter study with 262 patients. (7) A total of 145 patients had between 50% and 80% relief after medial branch block, and 117 obtained 80% or more relief. In the 50% or more group, success rates were 52% and 67% on pain relief and global perceived effect (GPE), respectively, after RF. Among those who had 80% or more relief from diagnostic blocks, 56% achieved at least 50% relief from RF, and 66% had a positive GPE. The study concluded that the more stringent pain relief criteria would be unlikely to improve success rates.

Pampati et al. (2009) conducted an observational study of 152 patients diagnosed with lumbar facet pain using controlled diagnostic blocks. (8) Of 1149 patients identified for interventional therapy, 491 patients were suspected of lumbar facet joint pain and received 1% lidocaine block. Of the 491 patients who received lidocaine, 261 were positive (≥80% reduction of pain and ability to perform previously painful movements lasting at least 2 hours) and underwent bupivacaine blocks. The 152 who responded positively to bupivacaine block were treated with RF neurotomy or medial branch blocks and were followed for 2 years. At 2-year follow-up, 136 (89%) of the 152 patients with a positive response to bupivacaine were considered to have lumbar facet joint pain based on pain relief and functional status improvement after facet joint intervention.

Manchikanti et al. (2010) compared outcomes of 110 patients who underwent facet nerve blocks after meeting positive criteria of 50% pain relief and 2 years of follow-up. (9) At the end of 1 year, the diagnosis of lumbar facet joint pain was confirmed (by sustained relief of pain and improved function) in 75% of patients in the group with 50% relief from diagnostic blocks vs 93% in the group with 80% relief. At 2 years, the diagnosis was sustained in 51% of patients in the group with 50% relief; the diagnosis was sustained in 89.5% of patients who reported 80% relief from diagnostic blocks.

<u>Clinically Useful</u>
A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if individuals receive correct therapy, more effective therapy, or avoid unnecessary therapy or testing.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials (RCTs).

No RCTs were identified assessing the clinical utility of medial branch blocks to diagnose suspected facet joint pain.

Chain of Evidence
Indirect evidence on clinical utility rests on clinical validity.

There is level I evidence supporting the use of medial branch blocks for diagnosing chronic lumbar facet joint pain and level II evidence for diagnosing cervical and thoracic facet joint pain. The evidence available supports a threshold of at least 75% to 80% pain relief to reduce the false-positive rate.

Section Summary: Detection of Facet Joint Pain With Medial Branch Blocks
For individuals who have suspected facet joint pain who receive diagnostic medial branch blocks, the evidence includes systematic reviews, a small, randomized trial, and observational studies. There is considerable controversy about the role of these blocks, the number of positive blocks required, and the extent of pain relief obtained. Studies have reported the use of single or double blocks and at least 50% or 80% improvement in pain and function. This evidence has suggested that there are relatively few patients who exhibit pain relief following 2 nerve blocks, but that these select patients may have pain relief for several months following RF denervation. Other large series have reported the prevalence and false-positive rates following controlled diagnostic blocks, although there are issues with the reference standards used in these studies because there is no criterion standard for the diagnosis of facet joint pain. There is level I evidence for the use of medial branch blocks for diagnosing chronic lumbar facet joint pain and level II evidence for diagnosing cervical and thoracic facet joint pain. The evidence available supports a threshold of at least 75% to 80% pain relief to reduce the false-positive rate.

DIAGNOSED FACET JOINT PAIN
Medical policies assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life (QOL), and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, two domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable

intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The RCT is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Facet Joint Denervation with Radiofrequency Ablation

Clinical Context and Therapy Purpose

The purpose of radiofrequency ablation (RFA) in individuals who have facet joint pain is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this medical policy is: Does the use of RFA improve the net health outcome in those diagnosed with facet joint pain?

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with facet joint pain.

Interventions

The therapy being considered is RFA.

Comparators

The following therapies and practices are currently being used to treat confirmed facet joint pain: intra-articular injection and standard medical therapy.

Outcomes

The general outcomes of interest are reductions in symptoms and medication use, quality of life (QOL), and improvements in functional outcomes.

Follow-up after RFA or medial branch block may be required from 6 to 12 months to monitor for symptom recurrence and the need for additional treatments.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess long-term outcomes, single-arm studies that capture longer periods of follow-up and/or larger populations were sought;

- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews

In a systematic review and meta-analysis by Janapala et al. (2021), 12 RCTs were identified evaluating the efficacy of lumbar RF neurotomy. (10) Studies were excluded from the analysis that included patients with acute causes of low back pain due to trauma, fracture, and malignancy. Four of the 12 studies in the meta-analysis are discussed below: Nath et al. (2008) (11), Tekin et al. (2007) (12), van Wijk et al. (2005) (13), and Lakemeier et al. (2013). (14) Patients across the 12 studies received 1 of the following interventions: RF ablation with a 22-gauge electrode, pulsed RF, medial branch conventional RF, medial branch cooled RF ablation, medial branch RF plus pentoxifylline or methylprednisolone injection, distal approach RF neurotomy, tunnel-vision approach RF neurotomy, RF frequency coagulation of joint capsule, endoscopic neurotomy, intra-articular lumbar steroid injection, or sham treatment. Each RCT included at least 6 months of follow-up, with 7 trials including active controls and 5 trials either sham or placebo control. Sample sizes included a range from 31 to 251 patients. Meta-analysis of pain relief of RF neurotomy versus sham control at 6 months and 12 months included 3 studies in the 6-month assessment (N=160) and 2 studies in the 12-month (N=291). At both timepoints, RF neurotomy was favored for improving visual analog scale (VAS) pain scores; however, differences were not statistically significant and were imprecise with wide confidence intervals (standard mean difference [SMD] at 6 months, 1.98, 95% confidence interval [CI]; -0.50 to 4.47), and (SMD at 12 months, -0.22, 95% CI; -0.83 to 0.39) The interpretation of these findings is limited by high heterogeneity across studies (I^2=95% for 6-month data and I^2=71% for 12-month data), imprecision, risk of bias of individual included studies due to lack of blinding, and the lack of subgroup analyses of patients with predictors of success such as prior response to controlled medial branch blocks and the presence of tenderness over the facet joint.

A systematic review by Manchikanti et al. (2015) identified 9 RCTs and comparative studies assessing RF denervation of lumbar facet joints. (15) Sample sizes ranged from 31 to 100 patients. All studies but one showed a short- or long-term benefit of facet joint denervation. For short-term effectiveness (<6 months), the evidence was level I; for long-term effectiveness (≥6 months), the evidence was level II.

Randomized Controlled Trials (RCT)

The largest study included in the review by Manchikanti et al. (2015) compared facet joint injection with facet joint denervation in 100 patients (Civelik et al. [2012] [16]). There were no sham controls, which limited interpretation of the results. In a double-blind RCT by Lakemeier et al. (2013), RF facet joint denervation was compared with intra-articular steroid injections in 56 patients. (14) Patients were selected first on magnetic resonance imaging findings of hypertrophy of the facet joints followed by a positive response to an intra-articular infiltration of the facet joints with anesthetics. A diagnostic double-block of the facet joint was not performed. At six months, there was no significant difference between the two groups, although it is not clear if the mean visual analog scale (VAS) scores were significantly improved in either group.

In an RCT, Nath et al. (2008) evaluated 40 patients for the short- and intermediate-term effects of RF for lumbar facet pain. (11) To be enrolled in the trial, patients had to obtain at least 80% pain relief following controlled (3 positive separate) medial branch blocks. Screening medial branch blocks were performed in 376 patients; 115 were negative, 261 patients had greater than 80% relief of at least 1 component of their pain and proceeded to controlled blocks. Of the 261, 45 had a negative response to controlled blocks, 105 had prolonged responses, and 71 lived too far away to participate or declined. The 40 patients remaining were randomly assigned, half to RF and half to sham treatment; all participated throughout the 6-month study. Pretreatment, the RF group had significantly more generalized pain, low back pain, and referred pain to the leg. Generalized pain on a VAS was reduced by 1.9 points (from 6.3 to 4.1) in the RF group and by 0.4 points (from 4.4 to 4.8) for placebo (p=0.02). Back pain was reduced in the RF group by 2.1 points (from 5.98 to 3.88) and by 0.7 points (from 4.38 to 3.68) in the placebo group; between-group differences were significant. RF patients experienced significantly more improvement in secondary measures of back and hip movement, QOL variables, the sacroiliac joint test, paravertebral tenderness, and tactile sensory deficit. The interpretation of this trial was limited by baseline differences between groups.

van Wijk et al. (2005) published a multicenter RCT that found no benefit of facet joint denervation. (13) Inclusion criteria consisted of the following: continuous low back pain with or without radiating pain into the upper leg for more than 6 months; focal tenderness over the facet joints without sensory or motor deficits or without the ability to perform the positive straight leg raising test; no indication for low back surgery; and 50% or greater pain reduction 30 minutes after lidocaine block. Of 226 patients screened, 81 were randomized to RF (n=40) or sham (n=41) lesion treatment. Success was defined as a 50% or more reduction of median VAS back pain score without a reduction in daily activities and/or a rise in the analgesic intake or reduction of 25% or more. At 3 months, there was no difference between groups (27.5% of RF patients were successes vs 29.3% of sham patients). This trial used a single (uncontrolled) block, which is known to increase the false-positive rate.

Two RCTs published by Lord et al. (1996) and van Eerd et al. (2021) have evaluated RF for chronic cervical pain at the facet joints. (17, 18). In Lord et al. (1996), patients with C2 to 3 zygapophyseal joint pain were excluded because treatment at this level is technically difficult. Twenty-four patients (of 54 screened) were randomized to RF or sham treatment. (17) Six patients in the control group and 3 in the RF group had an immediate return of pain after the procedure. By 27 weeks, 1 patient in the control group and 7 in the RF group remained free of pain. The median time to return of pretreatment pain of greater than 50% was 263 days in the RF group and 8 days in the placebo group. Two patients in the active group-who had no relief of pain-were found to have pain from adjacent spinal segments. In van Eerd et al. (2021), 76 patients with pain for ≥3 months and conservative management of their cervical pain were randomized to receive RF plus 3 bupivacaine injections or 3 bupivacaine injections alone. Patients with whiplash-associated pain were excluded from the study. (18) For each patient, 3 cervical medial branches were denervated by the cervical facet joint level judged as painful on palpation. Follow-up at 6 months showed no clinically meaningful outcomes in numeric rating scale pain scores between treatment groups. Quality of life improvement, as measured by the

bodily pain domain within the Rand 36-Item Health Survey, showed significant improvement at 6 months, with scores of 61.6 for RF versus 48.6 for no RF (p=.01). Patients with treatment success at 6 months, defined by a pain reduction of at least 30%, received follow-up at 48 months to assess long term effects. The median time to end of treatment success was 42 months in the RF group compared to 12 months with no RF (p=.014). At one year, the proportion of patients still reporting treatment effect was 0.9 (95% CI; 0.75 to 9.97) in the RF group compared to 0.41 (95% CI; 0.19 to 0.62) with no RF.

No controlled trials evaluating RF denervation in thoracic facet joints were identified.

Repeat Procedures

The literature primarily consists of small retrospective studies of repeat procedures after successful RF. (19, 20) A systematic review by Smuck et al. (2012) evaluated 16 studies of repeated medial branch neurotomy for facet joint pain found that repeated RF denervation was successful 33% to 85% of the time when the first procedure was successful. (21) The estimated average duration of pain relief was 7 to 9 months after the first treatment and 11.6 months after a repeated lumbar procedure.

In 2 series, more than 80% of patients had greater than 50% relief from repeat RF treatment, and the mean duration of relief from subsequent RF treatments was comparable to initial treatments. In a report by Rambaransingh et al. (2010), similar improvements in outcomes were observed following the first, second, or third RF treatments in a series of 73 patients who underwent repeat RF denervation for chronic neck or back pain. (22) The average duration of pain relief was 9.9 months after the first treatment and 10.5 months after the second treatment.

Section Summary: Facet Joint Denervation With RFA

For individuals who have facet joint pain who receive RF ablation, the evidence includes systematic reviews and RCTs. While the evidence is limited to RCTs with small sample sizes (N≤ 251 patients), RF facet denervation appears to provide at least 50% pain relief in carefully selected patients. Diagnosis of facet joint pain is difficult. However, response to controlled medial branch blocks and the presence of tenderness over the facet joint appear to be reliable predictors of success. When RF facet denervation is successful, repeat treatments appear to have similar success rates and duration of pain relief. Thus, the data indicate that, in carefully selected individuals with lumbar or cervical facet joint pain, RF treatments can improve outcomes.

Therapeutic Medial Branch Blocks and Alternative Methods of Denervation

Clinical Context and Therapy Purpose

The purpose of therapeutic medial branch blocks or alternative methods of denervation in individuals who have facet joint pain is to provide a treatment option that is an alternative to or an improvement on existing therapies for individuals with facet joint pain.

The question addressed in this medical policy is: Does the use of therapeutic medial branch blocks or alternative methods of denervation improve the net health outcome in those diagnosed with facet joint pain?

The following PICO was used to select literature to inform this policy.

Populations
The relevant population of interest is individuals with facet joint pain.

Interventions
The therapies being considered are therapeutic medial branch blocks and alternative methods of denervation.

Comparators
The following practices are currently being used to treat confirmed facet joint pain: intra-articular injection and standard medical therapy.

Outcomes
The general outcomes of interest are reductions in symptoms and medication use, QOL, and improvements in functional outcomes. Follow-up at 6-12 months is of interest to monitor outcomes.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess long-term outcomes, single-arm studies that capture longer periods of follow-up and/or larger populations were sought;
- Studies with duplicative or overlapping populations were excluded.

Branch Blocks
Medial branch nerve blocks have been evaluated as a therapeutic intervention. However, no RCTs were identified that compared anesthetic nerve blocks with placebo injections. Placebo-controlled studies are important for treatments for which the primary outcome is a measurement of pain to account for the potential placebo effect of an intervention.

Systematic Reviews
The reviews by Falco et al. (2012), discussed above, assessed the diagnosis and treatment of facet joint pain. (2-5) Evidence for the use of therapeutic cervical medial branch blocks was fair, and evidence for therapeutic lumbar facet joint nerve blocks was rated as fair-to-good.

Randomized Controlled Trials

Three, 2010 double-blind RCTs were identified in the systematic review by Manchikanti et al. (2015) that compared the therapeutic effect of medial branch blocks plus bupivacaine alone with bupivacaine and steroid (betamethasone). (23-25) Patients had a diagnosis of facet joint pain (cervical, thoracic, lumbar) with an 80% reduction in pain following 2 diagnostic anesthetic blocks of the medial branches. Patient outcomes were measured at 3, 6, 12, 18, and 24 months with a numeric rating scale for pain and the Oswestry Disability Index (ODI). Significant pain relief was considered to be a decrease of 50% or more on a numeric rating scale. Opioid intake and work status were also evaluated. The trials are described below.

Cervical

One of the randomized trials (Manchikanti et al. [2010]) included 120 patients meeting the diagnostic criteria for cervical facet joint pain. (23) The two groups were further subdivided, with half in each group receiving sarracenia purpurea (Sarapin). Patients were followed at 3-month intervals, and the cervical medial branch blocks were repeated only when reported pain levels decreased to below 50%, with significant pain relief after the previous block. Injections were repeated an average of 5.7 times over a period of two years. Sarapin did not affect the outcome, and the data were reported only for the two main conditions. At 2-year follow-up, 85% of patients in the bupivacaine group and 93% of patients in the steroid group were reported to have significant pain relief, based on intention-to-treat analysis. The average duration of pain relief with each procedure was 17 to 19 weeks. At least 50% improvement on the Neck Disability Index score was seen in 70% of patients in the bupivacaine group and 75% of patients in the bupivacaine plus steroid group. There was no significant change in opioid intake. There was a loss of 38% of the data for the 24-month evaluation. Sensitivity analysis using the last follow-up score, best-case scenario, and the worst-case scenario did not differ significantly.

Lumbar

A second double-blind, randomized trial by Manchikanti et al. (2010) evaluated the efficacy of facet joint nerve blocks in 120 patients with chronic low back pain. (24) In addition to the two main conditions, half the patients in each group received Sarapin. Sarapin did not affect the outcome and the data were reported only for the two main conditions. Patients received five to six treatments during the study. At a 2-year follow-up, significant pain relief (≥50%) was observed in 85% of the patients treated with bupivacaine alone and 90% of the patients treated with bupivacaine plus steroid. The proportion of patients with significant functional status improvement (≥40% on the ODI) was 87% for bupivacaine and 88% for the control group. The average duration of pain relief with each procedure was 19 weeks. There was no significant change in opioid intake. Twenty-four-month results were missing for 20% of the subjects. Sensitivity analysis of numeric rating scale pain scores using the last follow-up score, best-case scenario, and the worst-case scenario did not differ significantly.

Thoracic

One-year results were reported in 2010 and 2-year results reported by Manchikanti et al. (2012) from the randomized, double-blind trial evaluating the efficacy of thoracic medial branch blocks performed under fluoroscopy. (25-26) The 100 patients in this trial received an average of 3.5 treatments per year. An intention-to-treat analysis at 12 months showed a decrease in

average pain scores from 7.9 at baseline to 3.2 in the bupivacaine group, and from 7.8 to 3.1 in the bupivacaine plus steroid group. At least 50% improvement in the ODI score was observed in 80% and 84% of participants, respectively. In both groups, 90% of participants showed significant pain relief (≥50%) at 12 months. The average relief per procedure was 16 weeks for bupivacaine and 14 weeks for bupivacaine plus betamethasone. There was no significant change in the intake of opioids. Efficacy remained the same at a 2-year follow-up, with 80% of patients in the bupivacaine group and 84% of patients in the bupivacaine plus steroid group continuing to show improvements of 50% or more in ODI scores. The average number of procedures over the two years was 5.6 for bupivacaine and 6.2 for bupivacaine plus steroids.

Alternative Methods

Pulsed Radiofrequency (RF) Denervation

Moussa et al. (2020) evaluated pulsed RF in patients diagnosed with chronic lower back pain of facet origin (27) Patients were randomized into 3 groups: percutaneous pulsed RF treatment of the dorsal root ganglia (n=50), percutaneous RF denervation of the medial dorsal branch (n=50), and a control group that didn't receive any RF treatment (n=50). By 3 months post procedure, the pulsed RF group had better incidence of VAS improvement when compared to the other 2 groups (p=.014). At 2-year follow-up, the pulsed RF group maintained significant VAS improvement (p=.041), and this continued to the end of the study duration at 3 years (p=.044). An important limitation of this study is the lack of a sham control group.

Pulsed RF denervation was compared with steroid injection in a randomized trial of 80 patients reported by Hashemi et al. (2014). (28) The patients were selected based on a single medial branch block; outcomes included a numeric rating scale for pain, ODI, and analgesic intake assessment. RF and steroid injection to the medial branch reduced pain to a similar extent at six weeks; however, pain relief with pulsed RF remained low at six months (from 7.4 at baseline to 2.4 at 6 months) but had returned to near baseline levels in the steroid group pain by six months.

Kroll et al. (2008) compared the efficacy of continuous RF with pulsed RF in the treatment of lumbar facet syndrome in an RCT with 50 patients. (29) No significant differences in the relative percentage improvement were noted between groups in VAS (p=0.46) or ODI (p=0.35) scores. Within the pulsed RF group, comparisons of the relative change over time for both VAS (p=0.21) and ODI (p=0.61) scores were not significant. However, within the continuous RF group, VAS (p=0.02) and ODI (p=0.03) score changes were significant. The trial concluded that, although there was no significant difference between continuous RF and pulsed RF in the long-term outcomes, there was greater improvement over time in the continuous RF group.

Van Zundert et al. (2007) randomized 23 patients (of 256 screened) with chronic cervical radicular pain to pulsed RF or sham treatment. (30) Success was defined as a 50% or more improvement in GPE score, 20% or more reduction in VAS score for pain, and reduced pain medication use measured 3 months after treatment. Eighty-two percent of patients in the treatment arm and 33% in the sham arm showed at least 50% improvement in GPE score

(p=0.03) and 82% in the treatment group and 27% in the sham group achieved at least 20% reduction in VAS pain score (p=0.02).

In a study by Tekin et al. (2007), patients were randomized 20 each to conventional RF, pulsed RF, or a control group (local anesthetic only). Outcome measures were pain measured on a VAS and the ODI. (12) Mean VAS and ODI scores were lower in both treatment groups than in controls posttreatment; however, reductions in pain were maintained at 6- and 12-month follow-ups only in the conventional RF group. The number of patients not using analgesics and patient satisfaction were highest in the conventional RF group.

Laser Denervation
Iwatsuki et al. (2007) reported on laser denervation to the dorsal surface of the facet capsule in 21 patients who had a positive response to a diagnostic medial branch block. (31) One year after laser denervation, 17 (81%) patients experienced greater than 70% pain reduction. In 4 (19%) patients who had previously undergone spinal surgery, the response to laser denervation was unsuccessful.

Alcohol Ablation
Joo et al. (2013) compared alcohol ablation with RFA in a randomized study of 40 patients with recurrent thoracolumbar facet joint pain following an initial successful RF neurotomy. (32) At a 24-month follow-up, 3 patients in the alcohol ablation group had recurring pain compared with 19 in the RF group. Median effective periods were 10.7 months (range, 5.4-24 months) for RF and 24 months (range, 16.8-24 months) for alcohol ablation. No significant complications were identified.

Facet Débridement
Haufe and Mork (2010) reported on endoscopic facet debridement in a series of 174 patients with cervical (n=45), thoracic (n=15), or lumbar (n=114) pain who had a successful response to a diagnostic medial branch nerve block. (33) Capsular tissue was removed under direct observation via laparoscopy, followed by electrocautery or holmium lasers to completely remove the capsular region. Treatment was given on a single occasion, with most patients requiring treatment of four joints. At a minimum of a 3-year follow-up, 77%, 73%, and 68% of patients with cervical, thoracic, or lumbar disease, respectively, showed 50% or more reduction in pain, measured by VAS.

Section Summary: Therapeutic Medical Branch Blocks and Alternative Methods of Denervation
For individuals who have facet joint pain who receive therapeutic medial nerve branch blocks or alternative methods of facet joint denervation, the evidence includes a systematic review, randomized trials without a sham control, and uncontrolled case series. Pulsed RF does not appear to be as effective as conventional RF denervation. There is insufficient evidence to evaluate the efficacy of other methods of denervation (e.g., alcohol, laser, cryodenervation) for facet joint pain or the effect of therapeutic medial branch blocks on facet joint pain.

RADIOFREQUENCY DENERVATION OF THE SACROILIAC JOINT (SIJ)

Clinical Context and Therapy Purpose

The purpose of RFA is to provide a treatment option that is an alternative to or an improvement on existing therapies in individuals with SIJ pain.

The question addressed in this medical policy is: Does the use of RFA improve the net health outcome in individuals with SIJ pain?

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with SIJ pain.

Interventions

The therapy being considered is RFA, also known as RF neurotomy. RFA involves heating a portion of a pain-transmitting nerve to create a heat lesion. The goal of the heat lesion is to functionally denervate the SIJ and prevent transmission of pain signals to the brain. Several variations of RFA are available, including water-cooled, pulsed, and conventional continuous RFA. Water-cooled RFA produces larger lesions than the other two modalities, however, lesion size is also dependent on temperature, needles size, and procedure duration. Lateral branch RFA targets the SIJ nerves.

Comparators

The following therapy is currently being used to treat SIJ pain: conservative therapy.

Outcomes

The general outcomes of interest are symptoms (e.g., reductions in pain), functional outcomes, QOL, reductions in medication use, and treatment-related morbidity. Follow-up at 3 and 15 months is of interest to monitor outcomes.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought;
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews

Tables 1 and 2 summarize the characteristics and results of select systematic reviews.

Chou et al. (2021) conducted a systematic review and meta-analysis on interventional treatments for acute and chronic pain for the Agency for Healthcare Research and Quality for

use by the Centers for Medicare and Medicaid Services. (34) The systematic review identified 2 trials (N=79) on cooled RFA versus sham for SIJ pain with results at 3 months, and 1 trial (N=28) on cooled RFA versus sham with results at 1 month. Meta-analysis indicated that cooled RFA is probably more effective for pain and function compared to sham at 1 and 3 months with moderate to large benefits. The strength of evidence was rated moderate for pain and function at 3 months and low for function at 1 month. When comparing cooled RFA to conventional RFA, 1 trial (N=43) showed no differences at 1 or 3-month follow-up and a small, nonstatistically significant reduction in pain at 6 months. The strength of evidence was rated as low.

Chappell et al. (2020) performed a meta-analysis of RFA for chronic back pain. (35) The review included 5 RCTs comparing RFA to sham or medical treatment in patients with chronic SIJ pain with follow-up from 1 to 3 months, and 1 study that had a follow-up to 12 months. This meta-analysis did not include pulsed RFA. Low-quality evidence indicated that RFA led to a modest reduction in pain at 1 to 3-month follow-up, but there was no significant reduction in pain in the single RCT (n=228) that had 6- and 12-month follow-up. (36) The RCT by Juch et al. (2017) with 12-month follow-up is described in greater detail below.

Chen et al. (2019) performed a meta-analysis of 5 RCTs comparing RFA to sham or medical treatment in patients with chronic SIJ pain. (37) Various RFA procedures were represented, including percutaneous, cooled, and palisade SIJ RF neurotomy. Pain outcomes from all RCTs were pooled for the meta-analysis. Disability outcomes were only available for two studies utilizing cooled RFA. While studies showed no significant heterogeneity for disability outcomes, heterogeneity was high for pain outcomes.

Table 1. Characteristics of Systematic Reviews

Study	Dates	Trials	Participants	N (Range)	Design	Duration, month(s)
Chou et al. (2021) (34)	2021	3	Patients with chronic SIJ pain treated by various RFA procedures compared to sham.	122 (28 to 51)	RCTs	1-3
Chappell et al. (2020) (35)	2008-2019	5	Patients with chronic SIJ pain treated by various RFA procedures compared to sham or medical treatment. One trial with 12 months follow-up had 228 participants.	384	RCTs	3-12

Chen et al. (2019) (37)	2012-2018	5	Patients with chronic SIJ pain treated by various RFA procedures compared to sham or medical treatment	311 (28-155)	RCTs	3-6

SIJ: sacroiliac joint; RCT: randomized controlled trial; RFA: radiofrequency ablation.

Table 2. Results of Systematic Reviews

Study	Pain Score	Pain Score	ODI Score	GPE Score
Chou et al. (2021) (34)	**3 months vs sham RFA**	**6 months vs conventional RFA**		
Total N	79			
Cooled RFA	-2.4	-3.8		
Sham or conventional RFA	-0.8	-3.0		
p	.04	.041		
Chappell et al. (2020) (35)	**1-3 months**	**6 months**		
Total N	5 studies[1]; n=384	1 study[1]; n=228		
MD (95% CI)	-1.53 (-2.62 to 0.45)	-0.28 (-1.00 to 0.44)		
p	.02			
I^2 (p)	83%	NA		
Chen et al. (2019) (37) Various RFA				
Total N	5 studies[1]; n=311	See NRS Score[1]	2 studies; n=79	1 study; n=60
MD (95% CI)	-2.13 (-3.4 to -0.87)		-8.91 (-16.44 to -1.38)	0.60 (-0.09 to 1.29)
p	.001		.020	.090
I^2 (p)	82.3% (NR)		44.8% (NR)	NR

CI: confidence interval; GPE: Global Perceived Effect; MD: mean difference; NA: not applicable; NR: not reported; NRS: numerical rating scale; ODI: Oswestry Disability Index; OR: odds ratio; RFA: radiofrequency ablation.

[1] All pain scores (NRS, VAS) utilizing an 11-point scoring system were pooled together for the meta-analysis.

Randomized Controlled Trials

Tables 3 and 4 summarize the characteristics of select RCTs.

Table 3. Characteristics of Key RCTs Assessing Radiofrequency Ablation

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	**Comparator**
Mehta et al. (2018) (38)	United Kingdom	1	2012-2015	Patients with SIJ pain confirmed by diagnostic intra-articular injection; only 17 of 30 enrolled patients were randomized due to results of interim analysis	Multi-probe strip lesion RFA (n=11)	Sham (n=6) 4 patients crossed over to active group after 3-month endpoint
Juch et al. (2017) (36)	Netherlands	16	2013-2014	Patients with chronic low back pain related to the SIJ	RFA + exercise program (n=116) 110 received RFA 81 received Palisade RF treatment 23 received cooled RFA 6 received multi-probe strip lesion RFA	Exercise program (n=112) 69 completed program 18 did not complete program 25 with unknown completion
Van Tilburg et al. (2016) (39)	Netherlands	NR	2012-2014	Patients with SIJ pain	Percutaneous RFA to lateral branch and dorsal root primary ramus (n=30)	Sham (n=30)

Zheng et al. (2014) (40)	China	1	2010-2012	Patients with ankylosing spondylitis and SIJ pain	PSRN with computed tomography guidance (n=82)	Celecoxib treatment (n=73)
Patel et al. (2012; 2016) (41, 42)	United States	NR	2008-2010	Patients with SIJ pain	Lateral branch cooled RFA (n=34)	Sham (n=17)

NR: not reported; PSRN: palisade sacroiliac joint radiofrequency neurotomy; RF: radiofrequency; RFA: radiofrequency ablation; RCT: randomized controlled trial; SIJ: sacroiliac joint.

Table 4. Results of Key RCTs Assessing Radiofrequency Ablation

Study	**Pain Outcomes**		**Functional Outcomes**		**Treatment Success**	
Mehta et al. (2018) (38)	**NRS at Baseline (SD)**	**NRS at Month 3 (SD)**	**PCS[1] at Baseline (SD)**	**PCS at Month 3 (SD)**	**Treatment Success**	
Strip lesion RFA	8.1 (0.8)	3.4 (2.0)	28.4 (7.1)	34.7 (10.8)	NR	
Sham	6.5 (2.0)	7.3 (0.8)	28.6 (5.0)	29.6 (5.6)	NR	
P-Value	NR	<0.001	NR	0.0645	NR	
Juch et al. (2017) (36)	**NRS at Month 3 (95% CI)**	**NRS at Month 12 (95% CI)**	**ODI at Month 3 (95% CI)**	**ODI at Month 12 (95% CI)**	**At Month 3, n/N (%)**	**At Month 12, n/N (%)**
RFA + exercise program	4.77 (4.31 to 5.24)	4.65 (4.16 to 5.13)	27.72 (24.50 to 30.95)	27.29 (23.89 to 30.69)	43/110 (39.10)	49/102 (48.03)
Exercise program	5.45 (4.94 to 5.95)	4.84 (4.30 to 5.38)	29.09 (25.47 to 2.71)	24.49 (20.74 to 28.23)	19/88 (21.59)	24/76 (31.78)
MD/RR (95% CI)	-0.71 (-1.35 to -0.06)	-0.07 (-0.74 to 0.60)	-4.20 (-8.39 to -0.00)	2.11 (-2.25 to 6.47)	1.87 (1.13 to 2.71)	1.46 (0.92 to 2.02)
P-Value	0.03	0.83	0.05	0.34	0.02	0.10
Van Tilburg et al. (2016) (39)	**Mean NRS at Baseline (SD)**	**Mean NRS at Month 1 (SD)**	**Mean GPE at Month 1 (SD)**	**Mean GPE at Month 3 (SD)**	**Treatment Success**	
Percutaneous RFA	7.2 (1.4)	5.4 (1.7)	3.2 (1.1)	3.4 (1.6)	NR	
Sham	7.5 (1.2)	5.4 (1.9)	3.3 (1.0)	3.4 (1.5)	NR	
P Value	NR	NR	NR	NR	NR	

Zheng et al. (2014) (40)	**VAS at Week 12 (95% CI)**	**VAS at Week 24 (95% CI)**	**Mean BASFI[2] at Baseline (95% CI)**	**BASFI at Week 24 (95% CI)**	**Treatment Success**	
PSRN	2.5 (2.2 to 3.0)	2.8 (2.5 to 3.2)	5.4 (5.0 to 5.8)	3.1 (2.7 to 3.6)	NR	
Celecoxib	4.4 (4.0 to 4.9)	5.0 (4.6 to 5.3)	5.3 (4.8 to 5.8)	5.0 (4.5 to 5.5)	NR	
MD (95% CI)	-1.9 (-2.4 to -1.4)	-2.2 (-2.6 to -1.6)	NR	-1.9 (-2.5 to -1.2)	NR	
P Value	<0.0001	<0.0001	NR	<0.0001	NR	
Patel et al. (2012; 2016) (41, 42)	**NRS at Baseline (SD)**	**NRS at Month 3 (SD)**	**ODI at Baseline (SD)**	**ODI at Month 9 (SD)**	**At Month 3, n/N (%)**	**At Month 6, n/N (%)**
Cooled RFA	6.1 (1.3)	-2.4 (2.7)	37 (14)	-11 (17)	16/34 (47)	13/34 (38)
Sham	5.8 (1.3)	-0.8 (2.4)	35 (10)	2 (6)	2/17 (12)	7/16 (44)[3]
P Value	.370	.035	.639	.011	.015	NR

BASFI: Bath Ankylosing Spondylitis Functional Index; CI: confidence interval; GPE: Global Perceived Effect; MD: mean difference; NR: not reported; NRS: Numeric Rating Scale; ODI: Oswestry Disability Index; PCS: Physical Component Score; RCT: randomized control trial; RFA: radiofrequency ablation; RR: relative risk; SD: standard deviation; VAS: Visual Analog Scale;

[1] Higher scores on the SF-12 Physical Component Score (PCS) indicate improved outcomes.

[2] The Bath Ankylosing Spondylitis Functional Index (BASFI) measures overall functional outcomes on a scale from 0-10 with 0 indicating best possible functioning.

[3] Patients assigned to the sham group were allowed to crossover to active treatment after the 3-month study endpoint.

Mehta et al. (2018) published results from a double-blind, randomized, sham-controlled trial assessing the efficacy of radiofrequency neurotomy with a strip-lesioning device in patients with chronic SIJ pain. (38) Seventeen of 30 enrolled patients were randomized to active (n=11) or sham (n=6) treatment. Recruitment was terminated after an interim analysis indicated a statistically significant difference in the pain outcome between groups. After the three-month study endpoint, patients receiving sham treatment were allowed to crossover. While a statistically significant reduction in pain scores was reported at three months, there was no significant difference in functional outcome as measured by the Physical Component Score at three months. Due to the crossover design, it is difficult to gauge long term outcomes and durability of the treatment.

Juch et al. (2017) reported a nonblinded multicenter RCT of RF denervation in 228 of 2498 patients with suspected sacroiliac pain who were asked to participate in the trial. (36) Patient selection criteria included body mass index (<35 kg/m2), age (<70 years old), and pain reduction of at least 50% within 30 to 90 minutes of receiving a diagnostic sacroiliac block (n=228). An additional 202 patients had a negative diagnostic sacroiliac block; 1666 patients declined to participate in the trial. Patients meeting criteria were randomized to exercise plus

radiofrequency denervation (n=116) or an exercise program alone (n=112) and were followed for a year. The RFA group had a modest improvement for the primary outcome at 3 months (-0.71; 95% CI, -1.35 to -0.06), but the control group improved over time and there were no statistically significant differences between the groups for pain intensity score (p=0.09) or in the number of patients who had more than a 30% reduction in pain intensity (p=0.48) at 12 months. Limitations included the use of several techniques to achieve radiofrequency denervation, self-selection, lack of blinding, and a high dropout rate (31%) in the control group.

Van Tilburg et al. (2016) reported a sham-controlled randomized trial of percutaneous RFA in 60 patients with SIJ pain. (39) Patients selected had clinically suspected SIJ pain and a decrease of two or more points on a 10-point pain scale with a diagnostic sacroiliac block. At 3-month follow-up, there was no statistically significant difference in pain level over time between groups (group by period interaction, p=0.56). Both groups improved over time (≥2 points out of 10; p-value for time, p<0.001). In their discussion, trialists mentioned the criteria and method used for diagnosing SIJ pain might have resulted in the selection of some patients without SIJ pain.

Zheng et al. (2014) reported on an RCT of palisade sacroiliac RFA in 155 patients with ankylosing spondylitis. (40) Palisade RFA uses a row of radiofrequency cannula perpendicular to the dorsal sacrum. Inclusion criteria were ages 18 to 75 years; diagnosis of ankylosing spondylitis; chronic low back pain for at least 3 months; axial pain below L5; no peripheral involvement; pain aggravation on manual pressing of the SIJ area; and at least 50% pain relief following fluoroscopically guided anesthetic injection into the joint. Patients who met the inclusion criteria were randomized to palisade RFA or celecoxib. Blinded evaluation to 24 weeks found that RFA (2.8) resulted in lower global VAS scores than celecoxib (5.0; p<0.001) as well as improved scores for secondary outcome measures. This study lacked a sham control.

Patel et al. (2012) reported a randomized, double-blind, placebo-controlled trial of lateral branch neurotomy with a cooled radiofrequency probe. (41) Twelve-month follow-up was reported in 2016. (42) Fifty-one patients who had a positive response to two lateral branch blocks were randomized 2:1 to lateral branch radiofrequency or to sham. At a 3-month follow-up, significant improvements were observed in pain levels (-2.4 vs -0.8), physical function (14 vs 3), disability (-11 vs 2), and quality of life (QOL) (0.09 vs 0.02) for RF treatment compared with controls (all respectively). With treatment success defined as a 50% or greater reduction in numeric rating scale score, 47% of radiofrequency-treated patients and 12% of sham-treated patients achieved treatment success. The treatment response was durable to 12 months in the 25 of 34 patients who completed all follow-up visits. (42) Of the 9 patients who terminated study participation, 4 (12%) of 34 were considered treatment failures.

Tables 5 and 6 display notable relevance, design, and conduct limitations identified in each study.

Table 5. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]

Mehta et al. (2018) (38)				1. Disability outcomes were not reported.	
Juch et al. (2017) (36)	4. Patients older than 70 years were excluded.		2. Not a sham control.		
Van Tilburg et al. (2016) (39)					
Zheng et al. (2014) (40)	1. Patients were required to have a diagnosis of ankylosing spondylitis in addition to chronic low back pain related to the sacroiliac joint.		2. Not a sham control.		
Patel et al. (2012) (2016) (41, 42)					

The study limitations stated in this table are those notable in the current literature review; this is not a comprehensive gaps assessment.

[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.

[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not established and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.

[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 6. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]

Mehta et al. (2018) (38)				3. 66.6% of sham group patients crossed over to treatment group at 3 months	Other: Small study size due to interim analysis	
Juch et al. (2017) (36)		1-2. Study was not blinded.				
Van Tilburg et al. (2016) (39)				3. 63.3% of sham group patients crossed over to treatment group		
Zheng et al. (2014) (40)						
Patel et al. (2012) (2016) (41, 42)				3. Patients in sham group could cross over at 3 months		

The study limitations stated in this table are those notable in the current literature review; this is not a comprehensive gaps assessment.

[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.

[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).

[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

[f] Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Section Summary: Radiofrequency Denervation of the Sacroiliac Joint

Meta-analysis of available sham controlled RCTs suggests that there may be a small effect of RFA on SIJ pain at short-term (1-3 months) follow-up. However, the randomized trials of RFA have methodologic limitations, and there is limited data on the duration of the treatment

effect. The single RCT with 6 and 12-month follow-up showed no significant benefit of RFA compared to an exercise control group at these time points. In addition, heterogeneity of RFA treatment techniques precludes generalizing results across different studies.

Summary of Evidence

For individuals with suspected facet joint pain who receive diagnostic medial branch blocks, the evidence includes systematic reviews, a small, randomized trial, and observational studies. Relevant outcomes are other test performance measures, symptoms, and functional outcomes. There is considerable controversy about the role of these blocks, the number of positive blocks required, and the extent of pain relief obtained. Studies have reported the use of single or double blocks and at least 50% or 80% improvement in pain and function. This evidence has suggested that there are relatively few patients who exhibit pain relief following 2 nerve blocks, but that these select patients may have pain relief for several months following radiofrequency (RF) denervation. Other large series have reported the prevalence and false-positive rates following controlled diagnostic blocks, although there are issues with the reference standards used in these studies because there is no criterion standard for the diagnosis of facet joint pain. There is level I evidence for the use of medial branch blocks for diagnosing chronic lumbar facet joint pain and level II evidence for diagnosing cervical and thoracic facet joint pain. The evidence available supports a threshold of at least 75% to 80% pain relief to reduce the false-positive rate. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with facet joint pain who receive radiofrequency ablation (RFA), the evidence includes systematic reviews and RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and medication use. While the evidence is limited to randomized controlled trials with small sample sizes, RF facet denervation appears to provide at least 50% pain relief in carefully selected patients. Diagnosis of facet joint pain is difficult. However, response to controlled medial branch blocks and the presence of tenderness over the facet joint appear to be reliable predictors of success. When RF facet denervation is successful, repeat treatments appear to have similar success rates and duration of pain relief. Thus, the data indicate that, in carefully selected individuals with lumbar or cervical facet joint pain, RF treatments can improve outcomes. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with facet joint pain who receive therapeutic medial nerve branch blocks or alternative methods of facet joint denervation, the evidence includes a systematic review, randomized trials without a sham control, and uncontrolled case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and medication use. Pulsed RF does not appear to be as effective as conventional RF denervation, and there is insufficient evidence to evaluate the efficacy of other methods of denervation (e.g., alcohol, laser, cryodenervation) for facet joint pain or the effect of therapeutic medial branch blocks on facet joint pain. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have sacroiliac joint (SIJ) pain who receive RFA, the evidence includes 5 RCTs using different radiofrequency applications and case series. Relevant outcomes are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. Meta-analysis of available sham controlled RCTs suggests that there may be a small effect of RFA on SIJ pain at short-term (1-3 months) follow-up. However, the RCTs of RFA have methodologic limitations, and there is limited data on the duration of the treatment effect. The single RCT with 6 and 12-month follow-up showed no significant benefit of RFA compared to an exercise control group at these time points. In addition, heterogeneity of RFA treatment techniques precludes generalizing results across different studies. For RFA with a cooled probe, 2 small RCTs reported short-term benefits, but these are insufficient to determine the overall effect on health outcomes. An RCT on palisade RFA of the SIJ did not include a sham control. Another sham controlled RCT showed no benefit from RFA. Further high-quality controlled trials are needed to compare this procedure in defined populations with sham control and alternative treatments. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

American Association of Neurological Surgeons and Congress of Neurological Surgeons

The American Association of Neurological Surgeons and the Congress of Neurological Surgeons (2014) updated their joint guidelines on the treatment of degenerative disease of the lumbar spine. (43) The two groups provided grade B recommendations: 1) intra-articular injections of lumbar facet joints were not suggested for the treatment of facet-mediated chronic low back pain; 2) medial nerve blocks were suggested for the short-term relief of facet-mediated chronic low back pain; and 3) lumbar medial nerve ablation was suggested for the short-term (3- to 6-month) relief of facet-mediated pain in patients who have chronic lower back pain without radiculopathy from degenerative disease of the lumbar spine.

American Society of Anesthesiologists & American Society of Regional Anesthesia and Pain Medicine

The American Society of Anesthesiologists and the American Society of Regional Anesthesia and Pain Medicine have a 2010 guideline for chronic pain management. (50) The guideline recommends that “Diagnostic sacroiliac joint injections or lateral branch blocks may be considered for the evaluation of patients with suspected sacroiliac joint pain.” Based on the opinions of consultants and society members, the guideline recommends that “Water-cooled radiofrequency ablation may be used for chronic sacroiliac joint pain.”

American Society of Interventional Pain Physicians

In 2020, the American Society of Interventional Pain Physicians published guidelines on use of facet joint interventions for management of chronic spinal pain. (44) Use of facet joint nerve blocks for diagnosis of facet joint pain is recommended with a moderate to strong strength of recommendation for the lumbar spine (evidence level I to II), moderate strength for the cervical spine (evidence level II), and moderate strength for the thoracic spine (evidence level II); a criterion standard of ≥80% pain relief was included for these recommendations. Radiofrequency ablation is recommended for treatment of pain in the lumbar spine (moderate

strength recommendation; evidence level II), cervical spine (moderate strength recommendation; evidence level II), and thoracic spine (weak to moderate strength recommendation; evidence level III). Facet joint nerve blocks are recommended for treatment of pain in the lumbar spine (moderate strength recommendation; evidence level II), cervical spine (moderate strength recommendation; evidence level II), and thoracic spine (weak to moderate strength recommendation; evidence level III). Treatment of facet joint pain with intraarticular injections is a weak strength recommendation with lower levels of evidence (level III, IV, and V evidence for the thoracic, lumbar, and cervical spine respectively).

In 2013, the American Society of Interventional Pain Physicians guideline recommended the use of controlled SIJ blocks with placebo or controlled comparative local anesthetic block when indications are satisfied with suspicion of SIJ pain. (45) A positive response to a joint block is considered to be at least a 75% improvement in pain or in the ability to perform previously painful movements. For therapeutic interventions, the only effective modality with fair evidence was cooled radiofrequency neurotomy, when used after the appropriate diagnosis was confirmed by diagnostic SIJ injections.

American Society of Pain and Neuroscience

In 2021, the American Society of Pain and Neuroscience published practice a guideline on radiofrequency neurotomy. (47) All of the workgroup members utilized radiofrequency neurotomy in clinical practice. A consensus statement, based on Grade II-1 evidence (well-designed, controlled, nonrandomized clinical trial), was that "lateral branch radiofrequency neurotomy may be used for the treatment of posterior sacral ligament and joint pain following positive response to appropriately placed diagnostic blocks."

International Working Group Consensus Guidelines

International consensus guidelines from 13 different pain societies (2020) provide recommendations regarding interventions for lumbar facet joint pain specifically. (46) When used for diagnosis, the guidelines suggest that intra-articular injections are more diagnostic than medial branch blocks but note that intra-articular injections have a high technical failure rate and provide less predictive value when administered prior to radiofrequency ablation (grade B evidence, low level of certainty). For therapeutic treatment of lumbar facet pain the guideline recommends against use of medial branch blocks or intra-articular injections (grade D evidence, moderate level of certainty), although acknowledges certain clinical scenarios which may warrant these techniques, such as a contraindication to radiofrequency ablation.

National Institute for Health and Care Excellence

In 2016, the United Kingdom (U.K.) National Institute for Health and Care Excellence (NICE) published guidance on the assessment and management of low back pain and sciatica in those over 16 years of age. (48) NICE recommended that radiofrequency (RF) denervation can be considered for patients with chronic low back pain when "non-surgical treatment has not worked for them and the main source of pain is thought to come from structures supplied by the medial branch nerve, and they have moderate or severe levels of localized back pain.” RF denervation should only be performed "after a positive response to a diagnostic medial branch

block." The NICE cautioned that the length of pain relief after RF denervation is uncertain, and that results from repeat RF denervation procedures are also uncertain.

North American Spine Society Guideline

In 2020, the North American Spine Society (NASS) published guidance on the diagnosis and management of nonspecific low back pain in those 18 years of age and older. (49) NASS recommends that in facet joint procedures, for patients responsive to a single diagnostic intra-articular injection with 50% relief, it is suggested that intra-articular steroids will provide no clinically meaningful improvement at 6 months (grade B level of evidence; fair evidence). Additionally, in these patients there is insufficient evidence to recommend for or against using radiofrequency neurotomy or periarticular phenol injections (grade I, insufficient or conflicting evidence). There is insufficient evidence for or against the use of single-photon emission computerized tomography (SPECT) imaging or the use of uncontrolled medial branch blocks versus pericapsular blocks for the diagnosis of zygapophyseal joint pain (both grade 1, insufficient or conflicting evidence). There is insufficient evidence to recommend for or against using a 50% pain reduction following medial branch blockade to diagnose zygapophyseal joint pain (grade 1, insufficient or conflicting evidence). The use of cryodenervation has insufficient evidence for the treatment of zygapophyseal joint pain (grade I, insufficient or conflicting evidence); however, thermal radiofrequency ablation is suggested for patients with zygapophyseal joint low back pain, with relief durable for at least 6 months following the procedure (grade B, fair evidence). Cooled radiofrequency ablation of sacral lateral branch nerves and the dorsal ramus of L5 can be considered for sacroiliac joint pain diagnosed by dual blocks (grade C, poor quality evidence).

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in Table 7.

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03601949[a]	A Prospective, Multi-Center, Randomized, Assessor Blind, Controlled Study Comparing Lateral Branch Cooled Radiofrequency Denervation to Conservative Therapy as Treatment for Sacroiliac Joint Pain in a Military and Civilian Population	210	Jul 2022
NCT02073292[a]	A Randomized Controlled Trial Comparing Thermal and Cooled Radiofrequency Ablation Techniques of Thoracic Facets' Medial Branches to Manage Thoracic Pain	61	Dec 2022
NCT03066960	Long Term Efficacy of Radiofrequency Neurotomy for Chronic Zygapophysial (Facet) Joint Related Neck Pain	44	Dec 2022

NCT02148003	Effect of the Temperature Used in Thermal Radiofrequency Ablation on Outcomes of Lumbar Facets Medial Branches Denervation Procedures: A Randomized Double-Blinded Trial	237	Dec 2024
NCT03614793	A Prospective Trial of Cooled Radiofrequency Ablation of Medial Branch Nerves Versus Facet Joint Injection of Corticosteroid for the Treatment of Lumbar Facet Syndrome	120	Mar 2024

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	64625, 64633, 64634, 64635, 64636, 64999
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2022 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <http://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
02/01/2024	Document updated with literature review. Coverage unchanged. Reference 27 added; other(s) removed.
09/01/2022	Document updated with literature review. The following changes were made to Coverage: 1) Failed response to conservative management was changed to six (6) weeks; 2) The pain reduction mentioned in the NOTE regarding a successful trial of controlled diagnostic medial branch blocks consists of 2 separate positive blocks on different days with local anesthetic (no steroids or other drugs), or a placebo-controlled series of blocks, under fluoroscopic guidance, was changed to 80%; 3) Added sacroiliac joint (SIJ) pain to the following statement: Radiofrequency (RF) denervation is considered experimental, investigational and/or unproven for all uses that do not meet the criteria listed above, including but not limited to treatment of sacroiliac joint (SIJ) pain, chronic spinal or back pain, and thoracic facet joint pain. The following references were added: 10, 18, 34-35, 37-39, 49-50.
04/01/2021	Reviewed. No changes.
08/15/2020	Document updated with literature review. Coverage unchanged. The following references were added: 33-34 and 36-37.
03/15/2020	Reviewed. No changes.

06/15/2018	Document updated with literature review. Coverage unchanged. References 43-45 added.
10/15/2017	Reviewed. No changes.
06/15/2016	Document updated with literature review. Sacroiliac joint pain was added as an experimental, investigational and/or unproven indication for radiofrequency denervation; otherwise coverage unchanged. Title changed from Facet Joint Denervation.
03/15/2015	Reviewed. No changes.
08/15/2014	New medical document. Nonpulsed radiofrequency denervation of cervical facet joints (C3-4 and below) and lumbar facet joints may be considered medically necessary when ALL of the 5 listed criteria are met. Radiofrequency denervation for the treatment of chronic spinal/back pain for all uses that do not meet the criteria listed above is considered experimental, investigational and/or unproven, including but not limited to treatment of thoracic facet joint pain. All other methods of denervation are considered experimental, investigational and/or unproven for the treatment of chronic spinal/back pain, including, but not limited to pulsed radiofrequency denervation, laser denervation, chemodenervation (e.g., alcohol, phenol, or high-concentration local anesthetics), and cryodenervation. Therapeutic medial branch blocks are considered experimental, investigational and/or unproven. If there has been a prior successful radiofrequency (RF) denervation, additional diagnostic medial branch blocks for the same level of the spine are considered not medically necessary.