# Medical Policy

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# Title: Facet Joint Denervation

## Description/Background

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. Patients generally are sedated for the RF procedure. The goal of facet denervation is long-term pain relief. However, the nerves regenerate, and 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 the radiofrequency (RF) 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 electrical current of high voltage in the RF range but without heating the tissue enough to cause coagulation. It is suggested as a possibly safer alternative to thermal RF facet denervation. Temperatures do not exceed 42°C at the probe tip versus temperatures in the 60°C 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.

## Regulatory Status

A number of radiofrequency (RF) 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 FDA, listing the Baylis Pain Management Probe as a predicate device. The intended use is with a RF generator to create RF lesions in nervous tissue. FDA product code: GXD

## Medical Policy Statement

- The safety and efficacy of radiofrequency denervation of cervical facet joints (C3-4 and below) and lumbar facet joints have been established. It is considered a useful therapeutic option when the patient selection criteria are met.
- All other methods of denervation are considered experimental/investigational for the treatment of chronic spinal/back pain, including, but not limited to, pulsed radiofrequency denervation, laser denervation, chemodenervation, water-cooled denervation and cryodenervation. They have not been scientifically demonstrated to improve patient clinical outcomes better than conventional treatment.

## Inclusionary and Exclusionary Guidelines

**Inclusions:**
Candidates for radiofrequency facet (RF) denervation must meet **all** of the following criteria:

- No prior spinal fusion surgery in the vertebral level being treated AND
- Disabling 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 the pain is not radicular AND
- Pain has failed to respond to three months 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 medial branch blocks.**
- If there has been a prior successful radiofrequency (RF) denervation, there should be a minimum time of six months since the prior RF treatment (per side, per anatomical level of the spine).

**A successful trial of controlled diagnostic medial branch blocks consists of 2 separate positive blocks on different days with local anesthetic only (no steroids or other drugs), or a placebo controlled series of blocks, under fluoroscopic guidance, which has resulted in at least a 50% 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 RF treatment and should not be conducted under intravenous sedation unless specifically indicated (e.g., the patient 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.

**Exclusions:**

- Radiofrequency denervation is considered experimental/investigational for the treatment of chronic spinal/back pain for all uses that do not meet the criteria listed above, including but not limited to treatment of thoracic or sacroiliac (SI) facet joint pain.
- All other methods of denervation are considered investigational for the treatment of chronic spinal/back pain, including, but not limited to pulsed radiofrequency denervation, laser denervation, chemodenervation, water-cooled radiofrequency denervation, and cryodenervation.
- Therapeutic medial branch blocks.
- If there has been a prior successful radiofrequency (RF) denervation, additional diagnostic medial branch blocks for the same level of the spine are not medically necessary.

Note: In June 2005, the American Medical Association's CPT Editorial Panel determined that the unlisted CPT code 64999 should be used for *pulsed* RF treatment as opposed to other specific codes.

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## CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

### *Established codes:*

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|---|---|---|---|---|---|
| 64633 | 64634 | 64635 | 64636 | 64490 | 64491 |
| 64492 | 64493 | 64494 | 64495 | | |

### *Other codes (investigational, not medically necessary, etc.):*

| | | |
|---|---|---|
| 64999 | C9752 | C9753 |

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## Rationale

**SUSPECTED FACET JOINT PAIN**

Evidence reviews 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. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

**Clinical Context and Therapy Purpose**

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

The following **PICOs** were used to select literature to inform this review.

**Populations**
The relevant population of interest are individuals with suspected facet joint pain.

**Interventions**
The test being considered is diagnostic medial branch blocks.

Medial branch blocks are administered under fluoroscopic guidance in an outpatient setting.

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

**Outcomes**
The general outcomes of interest are reduction in symptoms and medication use and improvements in functional outcomes.

**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).

**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

**Systematic Review**
In 2015, Boswell et al reported a systematic review of the accuracy and utility of facet joint injections for the diagnosis of facet joint pain.[1] Coauthors included Manchikanti, who is primary author on most of the studies included in the systematic review. Of the 13 studies on 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 diagnosis of thoracic facet joint pain were conducted by the same group. Study quality was rated by reviewers who were not authors of the primary studies. Using the Quality Appraisal of Diagnostic Reliability (QAREL) 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 gold standard test for diagnosis of facet joint pain, which creates difficulties in determining test accuracy.

The Boswell et al (2015)[1] 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 included studies used a criterion standard of 80% or higher pain relief, reporting a prevalence 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 or false positive

rates. Four studies were identified that evaluated the influence of diagnostic blocks on therapeutic outcomes. Three of them are described next.

Falco et al (2012) updated several systematic reviews on the diagnosis and treatment of facet joint pain.[2-5] They 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 Trial**

In 2010, Cohen et al reported a multicenter randomized cost-effectiveness trial comparing 0, 1 or 2 diagnostic blocks before lumbar facet RF denervation.[6] Included in the study were 151 patients with predominantly axial low back pain equal to or greater than 3 months 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 patients (40%) who had a single diagnostic block followed by RF denervation, 8 (50% of 16, 16% of 50) were considered successful. Of the 14 patients (28%) who went on to have RF denervation after 2 medical branch blocks, 11 (79% of 14) were considered successful. Three patients were successfully treated after medial branch blocks alone.

**Observational Studies**

In 2008, Cohen et al compared lumbar zygapophyseal joint RF denervation success rates between the conventional threshold (≥50% pain relief) and the more stringently proposed at least 80% cutoff in a retrospective multicenter study with 262 patients.[7] A total of 145 patients had greater than 50% but less than 80% relief after medial branch block, and 117 obtained at least 80% relief. In the greater than 50% group, success rates were 52% and 67% on pain relief and global perceived effect (GPE), respectively, after RF. Among those who had at least 80% 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 are unlikely to improve success rates.

Pampati et al (2009) provide an observational report of experience with 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 (at least 80% reduction of pain and ability to perform previously painful movements lasting at least 2 hours) and underwent bupivacaine blocks; 152 responded positively to bupivacaine block, were treated with RF neurotomy or medial branch blocks and were followed for 2 years. After 2 years of follow-up 136 (89%) of the 152 patients with 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% 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) by 75% of patients in the group with 50% relief from diagnostic blocks versus 93% in the group with 80% relief. At 2 years, the diagnosis was sustained in 51% of patients in the group with 50% relief and sustained in 89.5% of patients who reported 80% relief from diagnostic blocks.

**Clinically Useful**
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 patients receive correct therapy, or 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**
Literature on the effect on health outcomes following use of nerve blocks for patient selection includes a systematic review and a small randomized trial and several large case series. This evidence suggests that there are relatively few patients who exhibit pain relief following 2 nerve blocks, but that these select patients may have relief of pain for several months following RF denervation. A 2015 systematic review identified a number of other large series that reported prevalence and false-positive rates following controlled diagnostic blocks, although there are concerns about the reference standard used in these studies as there is no gold standard for 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 available evidence 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 a meaningful improvement in the net health outcome.

**DIAGNOSED FACET JOINT PAIN**
Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to 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 a technology, 2 domains are examined: the relevance and the 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 randomized controlled trial (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), 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.

The following **PICOs** were used to select literature to inform this review.

### Populations

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

### Interventions

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

RFA, medial branch blocks, and other denervation methods are administered under fluoroscopic guidance in an outpatient setting.

### Comparators

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

### Outcomes

The general outcomes of interest are reduction in symptoms and medication use and improvements in functional outcomes.

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

### Systematic Reviews

Li et al (2022) published a systematic review and meta-analysis of 10 RCTs (N=715) comparing various RF denervation interventions including conventional RF.[10.] Short-term (≤6 months) and long-term (12 months) visual analog scale (VAS) pain scores were evaluated in a network meta-analysis. Conventional RF improved pain compared with placebo in both the short (standardized mean difference [SMD], -1.58; 95% CI, -2.98 to -0.18) and long term (SMD, -4.90; 95% CI, -5.86 to -3.94).

In a systematic review and meta-analysis by Janapala et al (2021), 12 RCTs were identified evaluating the efficacy of lumbar RF neurotomy.[11] 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)[12], Tekin et al (2007)[13], van Wijk et al (2005)[14], and Lakemeier et al (2013).[15] 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 I2=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 2015 systematic review by Manchikanti et al identified 9 RCTs or comparative studies on RF denervation of lumbar facet joints.[16] The sample size ranged from 31 to 100 patients. All studies but one showed short- or long-term benefit of facet joint denervation. For short-term effectiveness (<6 months), the evidence is level I; for long-term effectiveness (≥6 months), the evidence is level II.

**Randomized Controlled Trials**

The largest study included in Manchikanti's systematic review compared facet joint injection and facet joint denervation in 100 patients (Civelik, 2012).[17] There were no sham controls, limiting interpretation of the results. In a 2013 double-blind RCT by Lakemeier et al, RF facet joint denervation was compared with intra-articular steroid injections in 56 patients.[15] 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 6 months, there was no significant difference between the 2 groups, although it is not clear if the mean visual analog scale (VAS) scores were significantly improved in either group.

Nath et al (2008) performed an RCT with 40 patients to evaluate short- and intermediate-term effects of RF for lumbar facet pain.[12] To be included in the study, patients had to obtain at least 80% relief of pain 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 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 versus 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 on secondary measures of back and hip movement, quality-of-life variables, the sacroiliac joint test, paravertebral tenderness, and tactile sensory deficit. Interpretation of this study is limited by the differences in groups at baseline.

In 2005, Van Wijk et al published a multicenter RCT that found no benefit of facet joint denervation.[14] Inclusion criteria were continuous low back pain with or without radiating pain into the upper leg for more than 6 months and with focal tenderness over the facet joints, without sensory or motor deficits or 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 randomly assigned to RF (n=40) or sham (n=41) lesion treatment. Success was defined as at least 50% reduction of median VAS-back score without reduction in daily activities and/or rise in analgesic intake, or a reduction of at least 25% reduction of median VAS-back score and drop in analgesic use of at least 25%. At 3 months, there was no difference between groups (27.5% of RF patients were successes vs 29.3% of the sham group). This study used a single (uncontrolled) block, which is known to increase the false-positive rate.

Two RCTs that evaluated RF for chronic cervical pain at the facet joints [18,19] was published in 1996 by Lord et al and van Eerd et al (2021) Patients with C2-C3 zygapophysial joint pain were excluded because treatment at this level is technically difficult. Twenty–four patients (of 54 screened) were randomly assigned to RF or sham treatment.[18] Six patients in the control group and 3 in the RF group had return of pain immediately after the procedure. By 27 weeks, 1 patient in the control group and 7 in the RF group remained free of pain. Median time to return of greater than 50% of pretreatment pain was 263 days in the RF group versus 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. By 27 weeks, 1 patient in the control group and 7 in the RF group remained free of pain. Median time to return of greater than 50% of pretreatment pain was 263 days in the RF group versus 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.[19] 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.[20,21] A systematic review by Smuck et al (2012) evaluated 16 studies of repeated medial branch neurotomy for facet joint pain and found that repeated RF denervation was successful 33% to 85% of the time when the first procedure was successful.[22,] 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.[23] 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 Radiofrequency Ablation**
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 ≤100 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 appears 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 a meaningful improvement in the net health outcome.

**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 following PICO was used to select literature to inform this review.

***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 to 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.

## Review of Evidence

### 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 Falco review (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).[24-26]

### Cervical

One of the randomized trials (Manchikanti et al [2010]) included 120 patients meeting the diagnostic criteria for cervical facet joint pain.[24] The 2 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 2 years. Sarapin did not affect the outcome, and the data were reported only for the 2 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 in 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 data for the 24-month evaluation. Sensitivity analysis using the last follow-up score, best-case scenario, and 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.[25] In addition to the 2 main conditions, half the patients in each group received Sarapin. Sarapin did not affect the outcome and the data were reported only for the 2 main conditions. Patients received 5 to 6 treatments during the study. At 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 worst case scenario did not differ significantly.

### Thoracic

One-year results were reported in 2010 and 2-year results reported in 2012 from the randomized, double-blind trial of the efficacy of thoracic medial branch blocks performed under fluoroscopy.[26,27] The 100 patients in this study 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 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 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 improvement in ODI scores of 50% or more. The average number of procedures over the 2 years was 5.6 for bupivacaine and 6.2 for bupivacaine plus steroids.

## ALTERNATIVE METHODS OF DENERVATION

### Pulsed RF Facet Denervation

Moussa et al (2020) evaluated pulsed RF in patients diagnosed with chronic lower back pain of facet origin[28]. 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 did not 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 (Hashemi, 2014).[29] The patients were selected based on a single medial branch block; outcomes included a pain numeric rating scale, the Oswestry Disability Index (ODI), and analgesic intake assessment. RF and steroid injection to the medial branch reduced pain to a similar extent at 6 weeks; however, pain relief with pulsed RF remained low at 6 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 6 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.[30] 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) randomly assigned 23 patients (of 256 screened) with chronic cervical radicular pain to pulsed RF or sham treatment.[31] Success was defined as at least 50% improvement on GPE, at least 20% reduction in VAS 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 on GPE (p=0.03) and 82% in the treatment group and 27% in the sham group achieved at least 20% reduction in VAS pain (p=0.02).

In a 2007 study (Tekin et al), patients were randomly assigned, 20 each to conventional RF, pulsed RF and a control group (local anesthetic only). Outcome measures were pain on VAS and Oswestry Disability Index (ODI) scores.[13] Mean VAS and ODI scores were lower in both treatment groups than in controls post-treatment; however, the reduction in pain was maintained at 6- and 12-month follow-up 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**

In 2007, Iwatsuki et al reported laser denervation to the dorsal surface of the facet capsule in 21 patients who had a positive response to a diagnostic medial branch block.[30] One year after laser denervation, 17 patients (81%) experienced greater than 70% pain reduction. In 4 patients (19%) who had previously undergone spinal surgery, the response to laser denervation was not successful. Controlled trials are needed to evaluate this technique.

**Alcohol Ablation**

Joo et al (2013) compared alcohol ablation with RF ablation 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. The median effective periods were 10.7 months (range, 5.4-24) for RF and 24 months (range, 16.8-24) for alcohol ablation. No significant complications were identified. Given the possibility of harm as described in professional society recommendations on chemical denervation (see next), additional study is needed.

**Facet Debridement**
Haufe and Mork (2010) reported 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.[34] 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 4 joints. At a minimum of 3 years' follow-up, 77%, 73%, and 68% of patients with cervical, thoracic, or lumbar disease, respectively, showed at least 50% improvement in pain, measured by a VAS). As noted by the authors, large-scale RCTs are needed to evaluate the efficacy of this treatment approach.

**Section Summary: Therapeutic Medial 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, 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 the effects of the technology on health outcomes.

**SUMMARY OF EVIDENCE**
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. Relevant outcomes are other test performance measures, symptoms, and functional outcomes. There is considerable controversy about the role of the blocks, the number of positive blocks required, and the extent of pain relief obtained. Studies have reported use of single or double blocks and at least 50% or at least 80% improvement in pain and function. This evidence suggests 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 reported 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 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 qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have facet joint pain who receive radiofrequency ablation (RFA), the evidence includes systematic reviews and randomized controlled trials (RCTs). Relevant outcomes are symptoms, functional outcomes, quality of life, and medication use. While evidence is limited to a few studies with small sample sizes ($N \leq 100$ 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 result in improved outcomes. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have facet joint pain who receive therapeutic medial nerve branch or alternative methods of facet joint denervation or therapeutic medial branch blocks, the evidence includes a systematic review, randomized trials without a sham control, and uncontrolled 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. There is insufficient evidence to evaluate the effect of therapeutic medial branch blocks on facet joint pain. The evidence is insufficient to determine the effects of the technology on health outcomes.

### Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

**Table 1. Summary of Key Trials**

| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|---|---|---|---|
| **Ongoing** | | | |
| NCT02073292[a] | A randomized controlled trial comparing thermal and cooled radiofrequency ablation techniques of thoracic facets' medial branches to manage thoracic pain | 16 | Dec 2022 |
| | | | |
| NCT03066960 | Long term efficacy of radiofrequency neurotomy for chronic zygapophysial (facet) joint related neck pain | 44 | Dec 2022 |
| 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 |
| NCT05952518 | Evaluation of Peripheral Nerve Stimulation as an Alternative to Radiofrequency Ablation for Facet Joint Pain | 70 | Oct 2027 |

NCT: national clinical trial
[a] Denotes industry-sponsored or cosponsored trial

## SUPPLEMENTAL INFORMATION

### Clinical Input Received through Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests by Blue Cross Blue Shield Association (BCBSA), input was received from 4 physician specialty societies and 5 academic medical centers (6 responses) while this policy was under review in 2010. The input supported the policy statements. Those providing input supported use of 2 diagnostic blocks achieving a 50% reduction in pain.

## PRACTICE GUIDELINES AND POSITION STATEMENTS

### American Association of Neurological Surgeons (AANS)

In 2014, the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS) published updated guidelines on the treatment of degenerative disease of the lumbar spine.[35] AANS/CNS recommended to use a double-injection technique with an improvement threshold of 80% or greater to establish a diagnosis of lumbar facet-mediated pain (grade B), that this is an option for predicting a favorable response to facet medial nerve ablation by thermocoagulation (grade C), and that there is no evidence to support the use of diagnostic facet blocks as a predictor of lumbar fusion outcome in patients with chronic low-back pain from degenerative lumbar disease (grade I: Inconclusive). AANS/CNS gave grade B recommendations that (1) intra-articular injections of lumbar facet joints are not suggested for the treatment of facet-mediated chronic low back pain; (2) medial nerve blocks are suggested for the short-term relief of facet-mediated chronic low back pain; and (3) lumbar medial nerve ablation is 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 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.[36] 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).

### International Working Group Consensus Guidelines

International consensus guidelines from 13 different pain societies (2020) provide recommendations regarding interventions for lumbar facet joint pain specifically.[37] 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 RFA (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 RFA.

Similarly, 18 pain societies created consensus guidelines on interventions for cervical spine joint pain (2022).[38,] The group states, “Medial branch RFA is considered to be a definitive

durable analgesic treatment for patients with neck pain arising from the cervical facet joints." They also state, "…MBB meet most criteria as a diagnostic intervention for cervical joint-mediated pain…."

**The World Federation of Neurosurgical Societies Spine Committee**

The World Federation of Neurosurgical Societies Spine Committee (2020) released recommendations on the treatment of and pain relief techniques in patients with lumbar spinal stenosis.[39.] Statements that reached a positive committee consensus regarding facet joint pain are listed below.

- "Statement 10: Facet joint injections provide a useful diagnostic tool for LBP [lower back pain]."

**National Institute for Health and Clinical Excellence**

The National Institute for Health and Clinical Excellence (NICE) published guidance in 2016 entitled "Low back pain and sciatica in over 16s: assessment and management."[40] NICE recommended that RF denervation can be considered for patients with chronic low back pain "when other 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. 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.[41] 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).

**U.S. Preventive Services Task Force Recommendations**

Not applicable.

## Government Regulations

### National:

There is no national coverage determination (NCD) on this topic. In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

### Local:

Wisconsin Physician's Services, local coverage determination, "Facet Joint Interventions for Pain Management (L38841)", for services performed on or after 4/25/2021 Revision effective date 03/30/2023.

**Covered Indications FACET JOINT Interventions**
**FACET JOINT** Interventions generally consist of four types of procedures: Intraarticular (IA) **FACET JOINT** Injections, Medial Branch Blocks (MBB), and Radiofrequency Ablations (RFA) and Facet cyst rupture/aspiration:

**FACET JOINT** Interventions are considered medically reasonable and necessary for the diagnosis and treatment of chronic pain in patients who meet **ALL** the following criteria:

1. Moderate to severe chronic neck or low back pain, predominantly axial, that causes functional deficit measured on pain or disability scale*
2. Pain present for minimum of 3 months with documented failure to respond to noninvasive conservative management (as tolerated)
3. Absence of untreated radiculopathy or neurogenic claudication (except for radiculopathy caused by **FACET JOINT** synovial cyst)
4. There is no non-facet pathology per clinical assessment or radiology studies that could explain the source of the patient's pain, including but not limited to fracture, tumor, infection, or significant deformity.

*Pain assessment must be performed and documented at baseline, after each diagnostic procedure and at each follow-up using the same pain scale for each assessment. A disability scale must also be obtained at baseline to be used for functional assessment (if patient qualifies for treatment).

A. **Diagnostic FACET JOINT Procedures (IA or MBB):**
The primary indication of a diagnostic **FACET JOINT** procedure is to diagnose whether the patient has facet syndrome. Intraarticular (IA) facet block(s) are considered reasonable and necessary as a diagnostic test only if medial branch blocks (MMB) cannot be performed due to specific documented anatomic restrictions or there is an indication to proceed with therapeutic intraarticular injections. These restrictions must be clearly documented in the medical record and made available upon request.

Diagnostic procedures should be performed with the intent that if successful, radiofrequency ablation (RFA) procedure would be considered the primary treatment goal at the diagnosed level(s).

A second diagnostic facet procedure is considered medically necessary to confirm validity of the initial diagnostic facet procedure when administered at the same level. The second diagnostic procedure may only be performed a minimum of 2 weeks after the initial diagnostic procedure. Clinical circumstances that necessitate an exception to the two-week duration may

be considered on an individual basis and must be clearly documented in the medical record. For the first diagnostic **FACET JOINT** procedure:

a. For the first diagnostic **FACET JOINT** procedure to be considered medically reasonable and necessary, the patient must meet the criteria outlined under indications for **FACET JOINT** interventions.
b. A second confirmatory diagnostic **FACET JOINT** procedure is considered medically reasonable and necessary in patients who meet **ALL** the following criteria:
    i. The patient meets the criteria for the first diagnostic procedure; **AND**
    ii. After the first diagnostic **FACET JOINT** procedure, there must be a consistent positive response of at least 80% relief of primary (index) pain (with the duration of relief being consistent with the agent used).

Frequency limitation: For each covered spinal region, no more than four (4) diagnostic joint sessions will be reimbursed per rolling 12 months, in recognition that the pain generator cannot always be identified with the initial and confirmatory diagnostic procedure.

B. **Therapeutic FACET JOINT Procedures (IA or MBB):**
Therapeutic **FACET JOINT** procedures is considered medically reasonable and necessary for patients who meet **ALL** the following criteria:
    a. The patient has had two (2) medically reasonable and necessary diagnostic **FACET JOINT** procedures with each one providing a consistent minimum of 80% relief of primary (index) pain (with the duration of relief being consistent with the agent used); **AND**
    b. Subsequent therapeutic **FACET JOINT** procedures at the same anatomic site results in at least consistent 50% pain relief for at least three (3) months from the prior therapeutic procedure or at least 50% consistent improvement in the ability to perform previously painful movements and ADLs as compared to baseline measurement using the same scale; **AND**
    c. Documentation of why the patient is not a candidate for radiofrequency ablation (such as established spinal pseudarthrosis, implanted electrical device)

Frequency Limitations: For each covered spinal region no more than four (4) therapeutic **FACET JOINT** (IA) sessions will be reimbursed per rolling 12 months.

C. **FACET JOINT Denervation:**
The thermal radiofrequency destruction of cervical, thoracic, or lumbar paravertebral **FACET JOINT** (medial branch) nerves are considered medically reasonable and necessary for patients who meet **ALL** the following criteria:
    a. Initial thermal RFA:
        i. After the patient has had at least two (2) medically reasonable and necessary diagnostic MBBs, with each one providing a consistent minimum of 80% sustained relief of primary (index) pain (with the duration of relief being consistent with the agent used) **AND**
        ii. Repeat thermal **FACET JOINT** RFA at the same anatomic site is considered medically reasonable and necessary provided the patient had a minimum of consistent 50% improvement in pain for at least six (6) months or at least 50% consistent improvement in the ability to perform previously painful movements and ADLs as compared to baseline measurement using the same scale;

Frequency Limitation: For each covered spinal region no more than two (2) radiofrequency sessions will be reimbursed per rolling 12 months.

D. **Facet Cyst Aspiration/Rupture**
Intra-articular **FACET JOINT** injection performed with synovial cyst aspiration is considered medically necessary when both of the following criteria are met:

a. Advanced diagnostic imaging study (e.g. MRI/CT/myelogram) confirm compression or displacement of the corresponding nerve root by a **FACET JOINT** synovial cyst; **AND**

b. Clinical and physical symptoms related to synovial facet cyst are documented

Frequency Limitation: Cyst aspiration/rupture may be repeated **once** and only if there is 50% or more consistent improvement in pain for at least three (3) months.

**Limitations**

1. **FACET JOINT** interventions done without CT or fluoroscopic guidance are considered not reasonable and necessary. This includes **FACET JOINT** interventions done without any guidance, performed under ultrasound guidance, or with magnetic resonance imaging (MRI).
2. General anesthesia is considered not reasonable and necessary for **FACET JOINT** interventions. Neither conscious sedation nor monitored anesthesia care (MAC) is routinely necessary for intraarticular **FACET JOINT** injections or medial branch blocks and are not routinely reimbursable. Individual consideration may be given on redetermination (appeal) for payment in rare, unique circumstances if the medical necessity of sedation is unequivocal and clearly documented in the medical record. Frequent reporting of these services together may trigger focused medical review.
3. It is not expected that patients will routinely present with pain in both cervical/thoracic and lumbar spinal regions. Therefore, the routine performance of **FACET JOINT** interventions (both diagnostic and therapeutic) are limited to one spinal region per session.
4. It is not routinely necessary for multiple blocks (e.g., epidural injections, sympathetic blocks, trigger point injections, etc.) to be provided to a patient on the same day as **FACET JOINT** procedures. Multiple blocks on the same day could lead to improper or lack of diagnosis. If performed, the medical necessity of each injection (at the same or a different level[s]) must be clearly documented in the medical record. For example, the performance of both paravertebral **FACET JOINT** procedures(s) and a transforaminal epidural injection (TFESI) at the same or close spinal level at the same encounter would not be expected unless a synovial cyst is compressing the nerve root. In this situation, TFESI may provide relief for the radicular pain, while the facet cyst rupture allows nerve root decompression. Frequent reporting of multiple blocks on the same day may trigger a focused medical review.
5. **FACET JOINT** intraarticular injections and medial branch blocks involve the use of anesthetic, corticosteroids, anti-inflammatories and/or contrast agents, and does not include injections of biologicals or other substances not FDA designated for this use.
6. One to two levels, either unilateral or bilateral, are allowed per session per spine region. The need for a three or four-level procedure bilaterally may be considered under unique circumstances and with sufficient documentation of medical necessity on appeal. A session is a time period, which includes all procedures (i.e., medical branch blocks (MBB), intraarticular injections (IA), facet cyst ruptures, and RFA ablations) that are performed during the same day.
7. If there is an extended time, two years or more, since the last RFA and/or there is a question as to the source of the recurrent pain then diagnostic procedures must be repeated.
8. Therapeutic intraarticular facet injections are not covered unless there is justification in the medical documentation on why RFA cannot be performed. **FACET JOINT**

procedures in patients for the indication of generalized pain conditions (such as fibromyalgia) or chronic centralized pain syndromes are considered not reasonable and necessary. Individual consideration may be considered under unique circumstances and with sufficient documentation of medical necessity on appeal.
9. In patients with implanted electrical devices, providers must follow manufacturer instructions and extra planning as indicated to ensure safety of procedure.

The following are considered not reasonable and necessary and therefore will be denied:
1. Intraarticular and extraarticular **FACET JOINT** prolotherapy
2. Non-thermal modalities for **FACET JOINT** denervation including chemical, low-grade thermal energy (less than 80 degrees Celsius), laser neurolysis, and cryoablation.
3. Intra-facet implants
4. **FACET JOINT** procedure performed after anterior lumbar interbody fusion or ALIF.
5. Definitive clinical and/or imaging findings pointing to a specific diagnosis other than **FACET JOINT** syndrome
6. Diagnostic injections or MMB at the same level as the previously successful RFA procedure

Note: The scales used for measurement of pain and/or disability must be documented in the medical record. Acceptable scales include but are not limited to: verbal rating scales, Numerical Rating Scale (NRS) and Visual Analog Scale (VAS) for pain assessment, and Pain Disability Assessment Scale (PDAS), Oswestry Disability Index (ODI), Oswestry Low Back Pain Disability Questionnaire (OSW), Quebec Back Pain Disability Scale (QUE), Roland Morris Pain Scale, Back Pain Functional Scale (BPFS), and the PROMIS profile domains to assess function.

*(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)*

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## Related Policies

- Facet Arthroplasty
- Interspinous/Intralaminar Stabilization/Distraction Devices (Spacers)

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*The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through January 2024, the date the research was completed.*

## Joint BCBSM/BCN Medical Policy History

| Policy Effective Date | BCBSM Signature Date | BCN Signature Date | Comments |
|---|---|---|---|
| 12/9/05 | 12/9/05 | 12/1/05 | Joint policy established |
| 7/1/07 | 6/14/07 | 5/1/07 | Routine maintenance |
| 3/1/08 | 12/11/07 | 1/6/08 | Changed title to include regular radiofrequency in addition to pulsed radiofrequency treatment. |
| 1/1/10 | 10/13/09 | 10/13/09 | Change in position statement from experimental and investigational to established following specific guidelines. Pulsed RFA is experimental and investigational. Codes for regular RFA added; title of policy changed. |
| 1/1/12 | 10/11/11 | 11/9/11 | Routine maintenance. Reformatted rationale and references to mirror BCBSA policy. No change in status or criteria. |
| 7/1/12 | 4/10/12 | 5/18/12 | New CPT codes added effective 1/1/12. Policy updated with literature review through March 2012. References added, statement on radiofrequency denervation clarified. Laser denervation, cryodenervation, and therapeutic blocks added as experimental and investigational. Policy title changed from "*Radiofrequency Facet Joint Denervation (including Pulsed Radiofrequency"* to *"Facet Joint Denervation"* |
| 11/1/13 | 8/20/13 | 9/3/13 | Updated references; added description, references and policy statement regarding water-cooled radiofrequency procedures. |
| 5/1/15 | 2/17/15 | 2/27/15 | Routine maintenance; updated references and rationale. |
| 5/1/16 | 2/16/16 | 2/16/16 | Routine maintenance; updated references and rationale. Updated codes. |
| 5/1/17 | 2/21/17 | 2/21/17 | Routine policy maintenance. No change in policy status. |
| 5/1/18 | 2/20/18 | 2/20/18 | Routine policy maintenance. Added reference #38. No change in policy status. |

| | | | |
|---|---|---|---|
| 5/1/19 | 2/19/19 | | Added codes C9752 and C9753, effective 1/1/19. No change in policy status. |
| 5/1/20 | 2/18/20 | | Routine policy maintenance. No change in policy status. |
| 5/1/21 | 2/16/21 | | Routine policy maintenance. No change in policy status. |
| 5/1/22 | 2/15/22 | | Routine policy maintenance, added references 10, 18 and 37. Updated government section. No changes in policy status. |
| 5/1/23 | 2/21/23 | | Updated rationale, added reference 38, no change in policy status. (ds) |
| 5/1/24 | 2/20/24 | | Routine maintenance (jf)<br>Vendor Managed: Turning Point, aligned.<br>Ref Added: 10,38,39 |

Next Review Date: 1st Qtr. 2025

# BLUE CARE NETWORK BENEFIT COVERAGE
# POLICY: FACET JOINT DENERVATION

## I. Coverage Determination:

| | |
|---|---|
| **Commercial HMO (includes Self-Funded groups unless otherwise specified)** | Covered; criteria apply. See inclusions/exclusions |
| **BCNA (Medicare Advantage)** | See government section |
| **BCN65 (Medicare Complementary)** | Coinsurance covered if primary Medicare covers the service. |

## II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.