

<b>7.01.116</b>	<b>Facet Joint Denervation</b>		
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<b>Section:</b>	7.0 Surgery	<b>Page:</b>	Page 1 of 21

### Policy Statement

- I. Nonpulsed radiofrequency denervation of cervical facet joints (C3 to 4 and below) and lumbar facet joints may be considered **medically necessary** when **all** of the following criteria are met:
  - A. No prior spinal fusion surgery in the vertebral level being treated
  - B. 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
  - C. Pain has failed to respond to 3 months of conservative management, which may consist of therapies such as nonsteroidal anti-inflammatory medications, acetaminophen, manipulation, physical therapy, and a home exercise program
  - D. There has been a successful trial of controlled medial branch blocks (see Policy Guidelines section)
  - E. If there has been a prior successful radiofrequency (RF) denervation, a minimum time of 6 months has elapsed since prior radiofrequency treatment (per side, per anatomic level of the spine)
  
- II. Radiofrequency denervation is considered **investigational** for the treatment of chronic spinal or back pain for all uses that do not meet the criteria listed above, including but not limited to the treatment of thoracic facet joint pain.
  
- III. All other methods of denervation are considered **investigational** for the treatment of chronic spinal or back pain, including, but not limited to:
  - A. Pulsed radiofrequency denervation
  - B. Laser denervation
  - C. Chemodenervation (e.g., alcohol, phenol, or high concentration local anesthetics)
  - D. Cryodenervation
  
- IV. Therapeutic medial branch blocks are considered **investigational**.
  
- V. If there has been a prior successful radiofrequency denervation, additional diagnostic medial branch blocks for the same level of the spine are considered **investigational**.

**NOTE:** Refer to [Appendix A](#) to see the policy statement changes (if any) from the previous version.

### Policy Guidelines

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, that 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 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.

## Coding

The following CPT codes for facet joint denervation include computed tomography (CT) or fluoroscopic imaging guidance:

- **64633:** Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint
- **64634:** Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional facet joint (List separately in addition to code for primary procedure)
- **64635:** Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint
- **64636:** Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional facet joint (List separately in addition to code for primary procedure)

## Description

Percutaneous radiofrequency (RF) facet denervation is used to treat neck and 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.

## Related Policies

- Facet Arthroplasty

## Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

## Regulatory Status

A number of RF generators and probes have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 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 with an RF generator to create RF lesions in nervous tissue. FDA product code: GXD.

## Rationale

### Background

#### Facet Joint Denervation

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, 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 an RF generator. A variety of terms may be used to describe 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 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 versus 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.

### **Literature Review**

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.

### **Suspected Facet Joint Pain**

#### **Clinical Context and Test Purpose**

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

The question addressed in this evidence review 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 review.

#### ***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).

### **Review of Evidence**

#### **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.<sup>1</sup> 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; 3 of them are described below.

Falco et al (2012) updated several systematic reviews on the diagnosis and treatment of facet joint pain.<sup>2,3,4,5</sup> 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.<sup>6</sup> 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 ( $\geq 50\%$  pain relief) and the more stringently proposed cutoff ( $\geq 80\%$ ) in a retrospective multicenter study with 262 patients.<sup>7</sup> 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.<sup>8</sup> 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 ( $\geq 80\%$  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.<sup>9</sup> 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 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; the diagnosis was 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, 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**

Evidence reviews 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, 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, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 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. Randomized controlled trials 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 patients 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 evidence review 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 review.

***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.

### **Review of Evidence**

#### **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.<sup>10</sup> 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)<sup>11</sup>, Tekin et al (2007)<sup>12</sup>, van Wijk et al (2005)<sup>13</sup>, and Lakemeier et al (2013).<sup>14</sup> Patients across the 12 studies received 1 of the following interventions: RFA with a 22-gauge electrode, pulsed RF, medial branch conventional RF, medial branch cooled RFA, 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.<sup>15</sup> Sample sizes ranged from 31 to 100 patients. All studies but 1 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 ( $\geq 6$  months), the evidence was level II.

#### **Randomized Controlled Trials**

The largest study included in the review by Manchikanti et al (2015) compared facet joint injection with facet joint denervation in 100 patients (Civeliket al [2012]<sup>16</sup>). 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.<sup>14</sup> 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 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.<sup>11</sup> 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 patients, 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 ( $p=.02$ ). 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. Patients receiving RF 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.<sup>13</sup> 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.<sup>17,18</sup> 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.<sup>17</sup> 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  $\geq 3$  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.<sup>18</sup> 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 0.97) 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.<sup>19,20</sup> 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.<sup>21</sup> 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.<sup>22</sup> 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 RFA, the evidence includes systematic reviews and RCTs. While the evidence is limited to RCTs with small sample sizes ( $N \leq 251$  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 patients who have facet joint pain is to provide a treatment option that is an alternative to or an improvement on existing therapies for patients with facet joint pain.

The question addressed in this evidence review 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 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 reviews by Falco et al (2012), discussed above, assessed the diagnosis and treatment of facet joint pain.<sup>2,3,4,5</sup> 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 a steroid (betamethasone).<sup>23,24,25</sup> 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.<sup>23</sup> 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 an 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.<sup>24</sup> 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 a 2-year follow-up, significant pain relief ( $\geq 50\%$ ) 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 ( $\geq 40\%$  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 in 2012 by Manchikanti et al from the randomized, double-blind trial evaluating the efficacy of thoracic medial branch blocks performed under fluoroscopy.<sup>25,26</sup> 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 ( $\geq 50\%$ ) 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 2 years was 5.6 for bupivacaine and 6.2 for bupivacaine plus steroids.

### Alternative Methods

#### Pulsed Radiofrequency Facet Denervation

Moussa et al (2020) evaluated pulsed RF in patients diagnosed with chronic lower back pain of facet origin<sup>27</sup>. 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).<sup>28</sup> The patients were selected based on a single medial branch block; outcomes included a numeric rating scale for pain, ODI, and analgesic intake assessment. Radiofrequency 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.<sup>29</sup> No significant differences in the relative percentage improvement were noted between groups in VAS ( $p=.46$ ) or ODI ( $p=.35$ ) scores. Within the pulsed RF group, comparisons of the relative change over time for both VAS ( $p=.21$ ) and ODI ( $p=.61$ ) scores were not significant. However, within the continuous RF group, VAS ( $p=.02$ ) and ODI ( $p=.03$ ) 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.<sup>30</sup> 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 ( $p=.03$ ) and 82% in the treatment group and 27% in the sham group achieved at least 20% reduction in VAS pain score ( $p=.02$ ).

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.<sup>12</sup> 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.<sup>31</sup> 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.<sup>32</sup> 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 to 24 months) for RF and 24 months (range, 16.8 to 24 months) for alcohol ablation. No significant complications were identified.

### **Facet Debridement**

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.<sup>33</sup> 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 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 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.

### **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 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 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 RCTs 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 .

### **Supplemental Information**

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

### **Clinical Input From 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.

### **2010 Input**

In response to requests, input was received from 4 physician specialty societies and 5 academic medical centers (6 responses) while this policy was under review in 2010. Input supported the use of radiofrequency denervation for facet joint pain. Those providing input supported the use of 2 diagnostic blocks achieving a 50% reduction in pain.

### **Practice Guidelines and Position Statements**

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

### **American Association of Neurological Surgeons and Congress of Neurological Surgeons**

In 2014, the American Association of Neurological Surgeons and the Congress of Neurological Surgeons updated their joint guidelines on the treatment of degenerative disease of the lumbar spine.<sup>34</sup> The 2 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 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.<sup>35</sup> 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  $\geq 80\%$  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.<sup>36</sup> 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.

### **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.<sup>37</sup> 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 Care Excellence**

In 2016, the U.K. NICE published guidance on the assessment and management of low back pain and sciatica in those over 16 years of age.<sup>38</sup> 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."

Radiofrequency 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.<sup>39</sup> 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 I, 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 I, 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.

### Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

### Ongoing and Unpublished Clinical Trials

Currently, ongoing 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
<i>Ongoing</i>			
NCT02073292 <sup>a</sup>	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.

<sup>a</sup> Denotes industry-sponsored or cosponsored trial.

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## Documentation for Clinical Review

### Please provide the following documentation:

- History and physical and/or consultation notes including:
  - Diagnostic facet joint block (medial branch block) results
  - Prior conservative treatment(s) including duration and patient response(s)
  - Treatment plan
- Prior procedure(s) and dates
- Diagnostic radiological reports

**Post Service (in addition to the above, please include the following):**

- Procedure report

**Coding**

*This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.*

*The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.*

Type	Code	Description
CPT®	64625	Radiofrequency ablation, nerves innervating the sacroiliac joint, with image guidance (i.e., fluoroscopy or computed tomography)
	64633	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint
	64634	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional facet joint (List separately in addition to code for primary procedure)
	64635	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint
	64636	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional facet joint (List separately in addition to code for primary procedure)
	64999	Unlisted procedure, nervous system
HCPCS	None	

**Policy History**

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
02/14/2001	Policy approved with exception
02/21/2001	Policy adopted
04/02/2010	Policy Revision with title change from Percutaneous Radiofrequency Neurotomy of Cervical and Lumbar Zygapophyseal (Facet) Joints for Chronic Neck and Low Back Pain
03/13/2012	Coding Update
07/06/2012	Policy title change from Radiofrequency Neurotomy of Facet Joints with position change
09/27/2013	Policy title change from Facet Joint Denervation with position change
12/15/2014	Policy title change from Facet Joint and Sacroiliac Joint Denervation Policy revision with position change 2/15/2015
02/15/2015	Policy revision with position change
06/01/2016	Policy revision without position change

Effective Date	Action
03/01/2023	Policy reactivated. Previously archived from 1/1/2017 to 2/28/2023

## Definitions of Decision Determinations

**Medically Necessary:** Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

## Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at [www.blueshieldca.com/provider](http://www.blueshieldca.com/provider).

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: [MedPolicy@blueshieldca.com](mailto:MedPolicy@blueshieldca.com)

*Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.*

**Appendix A**

POLICY STATEMENT	
BEFORE	AFTER
<p><b>Reactivated policy</b></p> <p><b>Policy Statement:</b> N/A</p>	<p><b>Facet Joint Denervation 7.01.116</b></p> <p><b>Policy Statement:</b></p> <ol style="list-style-type: none"> <li>I. Nonpulsed radiofrequency denervation of cervical facet joints (C3 to 4 and below) and lumbar facet joints may be considered <b>medically necessary</b> when <b>all</b> of the following criteria are met:               <ol style="list-style-type: none"> <li>A. No prior spinal fusion surgery in the vertebral level being treated</li> <li>B. 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</li> <li>C. Pain has failed to respond to 3 months of conservative management, which may consist of therapies such as nonsteroidal anti-inflammatory medications, acetaminophen, manipulation, physical therapy, and a home exercise program</li> <li>D. There has been a successful trial of controlled medial branch blocks (see Policy Guidelines section)</li> <li>E. If there has been a prior successful radiofrequency (RF) denervation, a minimum time of 6 months has elapsed since prior radiofrequency treatment (per side, per anatomic level of the spine)</li> </ol> </li> <li>II. Radiofrequency denervation is considered <b>investigational</b> for the treatment of chronic spinal or back pain for all uses that do not meet the criteria listed above, including but not limited to the treatment of thoracic facet joint pain.</li> <li>III. All other methods of denervation are considered <b>investigational</b> for the treatment of chronic spinal or back pain, including, but not limited to:               <ol style="list-style-type: none"> <li>A. Pulsed radiofrequency denervation</li> <li>B. Laser denervation</li> </ol> </li> </ol>

## POLICY STATEMENT

## BEFORE

## AFTER

C. Chemodenervation (e.g., alcohol, phenol, or high concentration local anesthetics)

D. Cryodenervation

IV. Therapeutic medial branch blocks are considered **investigational**.

V. If there has been a prior successful radiofrequency denervation, additional diagnostic medial branch blocks for the same level of the spine are considered **investigational**.