Title: Facet Joint Denervation

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### 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.

### OBJECTIVE

The objectives of this policy are to determine whether the use of: (1) medial branch blocks to identify individuals with facet joint pain; (2) radiofrequency ablation to treat individuals with facet joint pain; and (3) therapeutic medial branch blocks or alternative methods of denervation to treat individuals with facet joint pain improves the net health outcome.

### 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, therefore, repeat procedures may be required.

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

**REGULATORY STATUS**

A number of radiofrequency (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 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.

**POLICY**

A. Thermal radiofrequency denervation of cervical facet joints (C2-3 and below) and lumbar facet joints is considered **medically necessary** when ALL of the following criteria are met:
   1. No prior posterior spinal fusion surgery in the vertebral level being treated; **AND**
   2. Disabling low back (lumbosacral) or neck (cervical) pain, suggestive of intrinsic facet joint origin as supported by history and physical; **AND**
   3. Pain has failed to respond to three (3) months of conservative management; **AND**
   4. There has been a successful trial of confirming medial branch blocks (see Policy Guidelines); **AND**
   5. If there has been a prior successful radiofrequency (RF) denervation, a minimum time of six (6) months has elapsed since prior RF nerve treatment.

B. 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 facet joint pain.

C. 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 (eg, alcohol, phenol, or high-concentration local anesthetics), and cryodenervation.

D. Therapeutic medial branch blocks are considered **experimental / investigational**.

E. If there has been a prior successful radiofrequency (RF) denervation, additional prognostic blocks at the same level may be considered **medically necessary** to confirm the source of pain is from the same segmental level.
**Policy Guidelines**

1. A successful trial of controlled diagnostic medial branch blocks consists of 2 positive blocks performed on separate days, under fluoroscopic guidance, that have resulted in at least an 80% reduction in pain for the duration of the local anesthetic (no steroids or other drugs) used (eg, 3 hours longer with bupivacaine than lidocaine).

2. No therapeutic intra-articular injections (ie, 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 (eg, 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.

3. **Parallel Needle Placement.** In order to incorporate target nerves reliably, electrodes must be placed close and parallel to the nerve. Electrodes that touch the nerve will reliably incorporate the nerve into the lesion they produce, even if the lesion is of minimal size, as proximity to the nerve is crucial. One method to ensure the target nerve is denervated is to place multiple lesions, in such a fashion as to ensure that a volume of tissue is coagulated that encompasses the entire volume in which the target nerve might lie.

**RATIONALE**

The most recent literature update was performed through September 6, 2018.

**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 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 PICOTS were used to select literature to inform this review.
Patients
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.

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

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

Technically Reliable
Assessment of technical reliability focuses on specific tests and operators and requires review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review and alternative sources exist. This evidence review focuses on the clinical validity and clinical utility.

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

Systematic Reviews
Boswell et al (2015) reported on a systematic review evaluating the accuracy and utility of facet joint injections for the diagnosis of facet joint pain. 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 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, three 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 or false-positive rates. Four studies evaluated the influence of diagnostic blocks on therapeutic outcomes; three of them are described below.

Falco et al (2012) updated several systematic reviews on the diagnosis and treatment of facet joint pain. 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 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. Included in the trial were 151 patients with predominantly axial low back pain of 3 months or more in duration, failure to respond to conservative therapy, paraspinal tenderness, and absence of focal neurologic signs or symptoms. Of the 51 patients who received RF denervation without undergoing diagnostic blocks, 17 (33%) obtained a successful outcome. Of the 16 (40%) patients who had a single diagnostic block followed by RF denervation, 8 (50%) of 16 were considered successful. Of the 14 (28%) patients who had RF denervation after 2 medial branch blocks, 11 (79%) of 14 were considered successful. Three patients were successfully treated after medial branch blocks alone.

**Observational Studies**

Cohen et al (2008) compared lumbar zygapophyseal joint RF denervation success rates between the conventional threshold (≥50% pain relief) and the more stringently proposed cutoff (≥80%) in a retrospective multicenter study with 262 patients. 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. Of 1149 patients identified for interventional therapy, 491 patients were suspected of lumbar facet joint pain and received 1% lidocaine block. Of the 491 patients who received lidocaine, 261 were positive (≥80% reduction of pain and ability to perform previously painful movements lasting at least 2 hours) and underwent bupivacaine blocks. The 152 who responded positively to bupivacaine block were treated with RF neurotomy or medial branch blocks and were followed for 2 years. At 2-year follow-up, 136 (89%) of the 152 patients with a positive response to bupivacaine were considered to have lumbar facet joint pain based on pain relief and functional status improvement after facet joint intervention.

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

**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 avoid unnecessary 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. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

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**
The literature on the effect on health outcomes following the use of nerve blocks for patient selection includes a systematic review, a small randomized trial, and several large case series. This evidence suggests that relatively few patients exhibit pain relief following 2 nerve blocks, but that these select patients might experience pain relief for several months following RF denervation. A 2015 systematic review identified a number of 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 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 there is 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.

**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 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.

Clinical Context and Therapy Purpose
The purpose of radiofrequency ablation (RFA), 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.

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

The following PICOTS were used to select literature to inform this review.

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

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

**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 and improvements in functional outcomes.

**Timing**
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.

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

**Facet Joint Denervation With RFA**

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

The reviews by Falco et al (2012), discussed above, assessed the diagnosis and treatment of facet joint pain.2-5 There was good evidence for conventional RF neurotomy for the treatment of lumbar facet joint pain, fair evidence for cervical RF neurotomy, and limited evidence for intra-articular facet joint injections and pulsed RF thermoneurolysis.

Chou et al (2009) published an evidence review used to inform American Pain Society guidelines on nonsurgical interventions for low back pain.11 Reviewers noted that trials of RF denervation were difficult to interpret, citing lack of controlled trial blocks in some studies, inadequate randomization, and heterogeneity of outcomes; further, reviewers included facet denervation in a list of procedures for which there is insufficient evidence from randomized trials.

**Randomized Controlled Trials**

The largest study included in the review by Manchikanti et al (2015) review compared facet joint injection with facet joint denervation in 100 patients (Civelik et al [2012]12). 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.13 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.

In an RCT, Nath et al (2008) evaluated 40 patients for the short- and intermediate-term effects of RF for lumbar facet pain.14 To be enrolled in the trial, patients had to obtain at least 80% pain relief following controlled (3 positive separate) medial branch blocks. Screening medial branch blocks were performed in 376 patients; 115 were negative, 261 patients had greater than 80% relief of at least 1 component of their pain and proceeded to controlled blocks. Of the 261, 45 had a negative response to controlled blocks, 105 had prolonged responses, and 71 lived too far away to participate or declined. The 40 remaining were randomly assigned, half to RF and half to sham treatment; all participated throughout the 6-month study. Pretreatment, the RF group had significantly more generalized pain, low back pain, and referred pain to the leg. Generalized pain on a VAS was reduced by 1.9 points (from 6.3 to 4.1) in the RF group and by 0.4 points (from 4.4 to 4.8) for placebo (p=0.02). Back pain was reduced in the RF group by 2.1 points (from 5.98 to 3.88) and by 0.7 points (from 4.38 to 3.68) in the placebo group; between-group differences were significant. RF patients experienced significantly more improvement 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 trial was limited by baseline differences between groups.

An RCT that evaluated RF for the treatment of cervicogenic headache was reported by Haspeslagh et al (2006).15 In a pilot study, 15 patients received RF treatments (cervical facet joint denervation, followed by cervical dorsal root ganglion lesions when necessary), and 15 received local injections with steroid and anesthetic at the greater occipital nerve followed by transcutaneous electrical stimulation. VAS, GPE, and quality of life scores were assessed at 8, 16, 24, and 48 weeks. There were no statistically significant differences between groups at any time point in the trial.
Van Wijk et al (2005) published a multicenter RCT that found no benefit of facet joint denervation. 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 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.

The only RCT that evaluated RF for chronic cervical pain at the facet joints was published by Lord et al (1996). Patients with C2-3 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. Six patients in the control group and three in the RF group had an immediate return of pain after the procedure. By 27 weeks, 1 patient in the control group and seven 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.

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

Section Summary: Facet Joint Denervation with RFA
Evidence for RFA for the treatment of facet joint pain consists of a systematic review of 9 RCTs. Some trials reported did not have a sham control and thus provided limited support for RF denervation. The sham-controlled trials of RF denervation reported mixed results, although the trial with negative results had limitations. Overall, there is moderate evidence in favor of RF denervation of the facet joints from controlled trials, for both short-term and long-term effectiveness.

Repeat Procedures
The literature primarily consists of small retrospective studies of repeat procedures after successful RF. A systematic review by Smuck et al (2012) evaluated 16 studies of repeated medial branch neurotomy for facet joint pain found that repeated RF denervation was successful 33% to 85% of the time when the first procedure was successful. 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 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. The average duration of pain relief was 9.9 months after the first treatment and 10.5 months after the second treatment.
Therapeutic Medial Branch Blocks and Alternative Methods of Denervation

**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. 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). 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. 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 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 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; an intention-to-treat analysis was used with the last follow-up visit.

**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. 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 the worst-case scenario did not differ significantly.

Thoracic: One-year results were reported in 2010 and 2-year results reported in 2012 by Manchikanti et al from the randomized, double-blind trial evaluating the efficacy of thoracic medial branch blocks performed under fluoroscopy. 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 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 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 RF Facet Denervation: A single RCT was identified that compared pulsed RF with steroid injection, a small RCT that compared pulsed RF with sham treatment, and 2 studies that compared continuous RF with pulsed RF.

Pulsed RF denervation was compared with steroid injection in a randomized trial of 80 patients reported by Hashemi et al (2014). The patients were selected based on a single medial branch block; outcomes included a numeric rating scale for pain, ODI, and analgesic intake assessment. RF and steroid injection to the medial branch reduced pain to a similar extent at 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. No significant differences in the relative percentage improvement were noted between groups in VAS (p=0.46) or ODI (p=0.35) scores. Within the pulsed RF group, comparisons of the relative change over time for both VAS (p=0.21) and ODI (p=0.61) scores were not significant. However, within the continuous RF group, VAS (p=0.02) and ODI (p=0.03) score changes were significant. The trial concluded that, although there was no significant difference between continuous RF and pulsed RF in the long-term outcomes, there was greater improvement over time in the continuous RF group.

Van Zundert et al (2007) randomized 23 patients (of 256 screened) with chronic cervical radicular pain to pulsed RF or sham treatment. Success was defined as a 50% or more improvement in GPE score, 20% or more reduction in VAS score for pain, and reduced pain medication use measured 3 months after treatment. Eighty-two percent of patients in the treatment arm and 33% in the sham arm showed at least 50% improvement in GPE score (p=0.03) and 82% in the treatment group and 27% in the sham group achieved at least 20% reduction in VAS pain score (p=0.02).

In a study by Tekin et al (2007), patients were randomized 20 each to conventional RF, pulsed RF, or a control group (local anesthetic only). Outcome measures were pain measured on a VAS and the ODI. 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.³⁰ 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.³¹ At 24-month follow-up, 3 patients in the alcohol ablation group had recurring pain compared with 19 in the RF group. Median effective periods were 10.7 months (range, 5.4-24 months) for RF and 24 months (range, 16.8-24 months) for alcohol ablation. No significant complications were identified.

**Facet Débridement:** Haufe and Mork (2010) reported on endoscopic facet débridement 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.³² 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-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**

The longer term outcomes from 3 double-blind RCTs of therapeutic medial branch blocks are intriguing, given the apparent long duration of efficacy of this short-acting anesthetic and the lack of a known mechanism. However, placebo-controlled studies are important for treatments in which the primary outcome is the measurement of pain. No trials were identified that compared medial branch nerve blocks with placebo. RCTs that compare therapeutic nerve blocks with placebo injections and with the current standard of care (RF denervation) are needed to fully evaluate this treatment approach.

RCT results have shown that pulsed RF denervation is a more effective treatment than standard steroid injection for facet joint pain; however, pulsed RF was not shown to be more effective than conventional RF.

There are no comparative studies on the use of laser denervation or facet débridement to treat facet joint pain. A small RCT compared alcohol ablation with RFA for the treatment of facet joint pain. Additional research is needed to assess the effectiveness of these alternative methods.

**SUMMARY OF EVIDENCE**

For individuals who have suspected facet joint pain who receive diagnostic medial branch blocks, the evidence includes a systematic review of 17 diagnostic accuracy studies, a small randomized trial, and several large case series. 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 a meaningful improvement in the net health outcome.

For individuals who have facet joint pain who receive RFA, the evidence includes a systematic review of RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and medication use. While evidence is limited to a few randomized controlled trials with small sample sizes, RF facet denervation appears to provide at least 50% pain relief in carefully selected patients. Diagnosis of facet joint pain is difficult. However, response to controlled medial branch blocks and the presence of tenderness over the facet joint 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.

For individuals who have facet joint pain who receive therapeutic medial nerve branch blocks or alternative methods of facet joint denervation, the evidence includes uncontrolled case series and randomized trials without a sham control. 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 (eg, 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.

**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, 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**

Association of Neurological Surgeons and Congress of Neurological Surgeons
The American Association of Neurological Surgeons and the Congress of Neurological Surgeons (2014) updated their joint guidelines on the treatment of degenerative disease of the lumbar
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
Updated guidelines on interventional techniques for the management of chronic spinal pain from the American Society of Interventional Pain Physicians were published in 2013.34 Diagnostic lumbar facet joint nerve blocks were recommended in patients with suspected facet joint pain, based on good evidence for diagnostic lumbar facet joint nerve blocks with 75% to 100% pain relief as the criterion standard. For the treatment of facet joint pain, evidence was considered good for conventional radiofrequency (RF), limited for pulsed RF, fair-to-good for lumbar facet joint nerve blocks, and limited for intra-articular injections. Based on the evidence review, the Society recommended treatment with conventional RF neurotomy or therapeutic facet joint nerve blocks.

American Society of Anesthesiologists et al
Practice guidelines on chronic pain management from the American Society of Anesthesiologists and the American Society of Regional Anesthesia and Pain Medicine were published in 2010.35 The guidelines included the following recommendations:

"Radiofrequency ablation: Conventional (e.g., 80°C) or thermal (e.g., 67°C) radiofrequency ablation of the medial branch nerves to the facet joint should be performed for low back (medial branch) pain when previous diagnostic or therapeutic injections of the joint or medial branch nerve have provided temporary relief."

“Chemical denervation (e.g., alcohol, phenol, or high concentration local anesthetics) should not be used in the routine care of patients with chronic noncancer pain.”

American Pain Society
The American Pain Society (2009) practice guidelines on nonsurgical interventions for low back pain stated that “there is insufficient (poor) evidence from randomized trials (conflicting trials, sparse and lower quality data, or no randomized trials) to reliably evaluate” a number of interventions including facet denervation.11

National Institute for Health and Care Excellence
The National Institute for Health and Care Excellence (NICE; 2016) published guidance on the assessment and management of low back pain and sciatica in those over 16 years of age.36 NICE recommended that RF denervation can be considered for patients with chronic low back pain when “non-surgical treatment has not worked for them and the main source of pain is thought to come from structures supplied by the medial branch nerve and they have moderate or severe levels of localized back pain.” RF denervation should only be performed “after a positive response to a diagnostic medial branch block.” NICE cautioned that the length of pain relief after RF denervation is uncertain, and that results from repeat RF denervation procedures are also uncertain.

California Technology Assessment Forum
The California Technology Assessment Forum (2001) published a review of the evidence for percutaneous RF neurotomy of cervical and lumbar zygapophyseal joints for chronic neck and low
back pain; it concluded that the technology met its criteria for efficacy and safety for treatment of lower cervical (C3 and below) and for lumbar pain but not for treatment of upper (C2-3) levels. The Forum (2007) reviewed the evidence for treatment of C2-3 joints and did not reverse its position.37

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS

Not applicable.

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

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tr>
<td>NCT02073292</td>
<td>A Randomized Controlled Trial Comparing Thermal and Cooled Radiofrequency Abatement Techniques of Thoracic Facets' Medial Branches to Manage Thoracic Pain</td>
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<tr>
<td>NCT03066960</td>
<td>Long Term Efficacy of Radiofrequency Neurotomy for Chronic Zygapophysial (Facet) Joint Related Neck Pain</td>
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<td>NCT02148003</td>
<td>Effect of the Temperature Used in Thermal Radiofrequency Ablation on Outcomes of Lumbar Facets Medial Branches Denervation Procedures: A Randomized Double-Blinded Trial</td>
<td>237</td>
<td>Feb 2020</td>
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<tr>
<td>NCT02179476</td>
<td>A Multi-Site Study of the Zyga Glyder Facet Restoration Device in Subjects with Lumbar FacET Pain Syndrome (DUET)</td>
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<td>May 2018 (suspended)</td>
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Unpublished

| NCT02478437 | A Prospective Trial of Cooled Radiofrequency Ablation of Medial Branch Nerves for the Treatment of Lumbar Facet Syndrome | 48                 | Aug 2018 (completed) |
| NCT02002429 | Medial Branch Blocks vs. Intra-articular Injections: Randomized, Controlled Study | 225               | Aug 2017 (completed) |

NCT: national clinical trial.

a Denotes industry-sponsored or cosponsored trial.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. 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.

CPT/HCPCS

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
ICD-10 Diagnoses

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<td>M43.06</td>
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REVISIONS

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<td>02-08-2010</td>
<td>The Facet Joint Denervation medical policy is a new freestanding policy developed from the Minimally Invasive Procedures for Spine Pain medical policy which was effective October 18, 2004. The Minimally Invasive Procedures for Spine Pain is no longer an active medical policy.</td>
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<td>Description section updated</td>
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<td>12-02-2013</td>
<td>Revised Title from &quot;Facet Joint Denervation&quot; to &quot;Facet Joint Denervation (Cervical and Lumbar)&quot;</td>
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### Description section updated

#### In Policy section:
- Revised A from "Facet joint denervation (percutaneous radiofrequency facet denervation, percutaneous radiofrequency facet ablation, facet rhizotomy, facet thermocoagulation) of cervical facet joints (C3-4 and below) and lumbar facet joints is considered medically necessary when ALL of the following criteria are met:" to "Non-pulsed radiofrequency denervation of cervical facet joints (C3-4 and below) and lumbar facet joints is considered medically necessary when ALL of the following criteria are met:"
- Added to Item A 2 "disabling" to read "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"
- Revised Item A 4 from "A trial of controlled diagnostic medial branch blocks (See Policy Guidelines) under fluoroscopic guidance has resulted in at least a 50% reduction in pain;" to "There has been a successful trial of controlled medial branch blocks (See Policy Guidelines)"
- Revised Item B from, "Facet joint denervation (percutaneous Radiofrequency facet denervation, percutaneous radiofrequency facet ablation, facet rhizotomy, facet thermocoagulation) 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 facet or sacroiliac (SI) joint pain." to "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 facet joint pain."
- Revised Item C from, "Pulsed radiofrequency denervation is considered experimental / investigational for the treatment of chronic spinal / back pain."
- Added Item D, "Therapeutic medial branch blocks are considered experimental / investigational."
- Added Item E, "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."

#### In Policy Guidelines:
Revised from, "The diagnostic blocks should involve the levels being considered for RF treatment. 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." to, "A successful trial of controlled diagnostic medial branch blocks consists of:
1. 2 separate positive blocks on different days with local anesthetic only (no steroids or other drugs), or
2. 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 (eg, 3 hours longer with bupivacaine than lidocaine)."
No therapeutic intra-articular injections (ie, 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 (eg, 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."

Rationale section updated

In Coding section:
- Nomenclature updated on CPT codes: 64636, 77003
- Nomenclature updated on ICD-9 codes: 722.82, 722.83
- Removed ICD-9 codes: 721.2, 721.41, 722.82, 724.1
- ICD-10 Codes added

Referenced updated

In Policy section:
- In Item A revised "Non-pulsed-radiofrequency" to read "Thermal radiofrequency denervation...".
- In Item A revised “C3-4 and below” to “C2-3 and below” to read "...cervical facet joints (C 2-3 and below) and lumbar facet joint..."
- In Item A 1 revised "No prior spinal fusion surgery” to read "No prior posterior spinal fusion...".
- In Item A 2 revised "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” to read "Disabling low back (lumbosacral) or neck (cervical) pain, suggestive of intrinsic facet joint origin as supported by history and physical”.
- In Item A 3 revised “Pain has failed to respond to three (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” to read “Pain has failed to respond to three (3) months of conservative management”.
- In Item A 4 revised “There has been a successful trial of controlled medial branch blocks (See Policy Guidelines)” to read “There has been a successful trial of confirming medial branch blocks (See Policy Guidelines)”.
- In Item A 5 revised "If there has been a prior successful radiofrequency (RF) denervation, a minimum time of six (6) months has elapsed since prior RF treatment (per side, per anatomical level of the spine).” to read “If there has been a prior successful radiofrequency (RF) denervation, a minimum time of six (6) months has elapsed since prior RF nerve treatment”.
- In Policy Guideline 2 revised "series of blocks," to "series of dual confirming blocks" and "50% reduction in pain" to "80% reduction in pain" to read, “a placebo controlled series of dual confirming blocks, under fluoroscopic guidance, that has resulted in at least an 80% reduction in pain..."

Updated Description section.

In Policy section:
- Added Item 3 to Policy Guidelines.

Updated Rationale section.

In Coding section:
- Removed CPT code 77003.

Updated References section.

In Policy section:
- In Item E, removed "diagnostic medial branch blocks for the same level of the spine are not medically necessary" and added "prognostic blocks at the same level may be considered medically necessary to confirm the source of pain is from the same segmental level" to read, "If there has been a prior successful radiofrequency (RF) denervation, additional prognostic blocks at the same level may be considered medically necessary to confirm the source of pain is from the same segmental level."
In Policy Guidelines, removed "a) 2 separate positive blocks on different days with local anesthetic only (no steroids or other drugs), or b) a placebo controlled series of dual confirming" and added "two positive", "performed on separate days", and "(no steroids or other drugs)" to read, "A successful trial of controlled diagnostic medial branch blocks consists of 2 positive blocks performed on separate days, under fluoroscopic guidance, that have resulted in at least an 80% reduction in pain for the duration of the local anesthetic (no steroids or other drugs) used (eg, 3 hours longer with bupivacaine than lidocaine)."

Updated References section.

01-30-2018
Revised Policy title from "Facet Joint Denervation (Cervical and Lumbar)."
Updated Description section.
Updated Rationale section.
In Coding section:
- Removed ICD-9 codes.
Updated References section.

06-11-2018
Policy published to the bcbsks.com website on 05-09-2018 with an effective date of 06-11-2018.
In Coding section:
- Added ICD-10 codes: M43.04, M43.14, M46.84, M46.94, M47.14, M47.24, M47.814, M47.894, M48.04, M54.14, M54.6.

01-04-2019
Updated Description section.
Updated Rationale section.
In Coding section:
- Removed coding bullets.
Updated References section.

REFERENCES


**Other References**