Title: Facet Joint Denervation (Cervical and Lumbar)

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<tr>
<td>Individuals: • Who are suspected of having facet joint pain</td>
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Populations
Individuals:
• With facet joint pain

Interventions
Interventions of interest are:
• Alternative methods of denervation
• Therapeutic medial branch blocks

Comparators
Comparators of interest are:
• Intra-articular Injection
• Standard medical therapy

Outcomes
Relevant outcomes include:
• Symptoms
• Functional outcomes
• Quality of life
• Medication use

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

Background
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 8, 2015.

Assessment of efficacy for therapeutic interventions involves a determination of whether the intervention improves health outcomes. The optimal study design for a therapeutic intervention is a randomized controlled trial (RCT) that includes clinically relevant measures of health outcomes. It is recognized that RCTs are extremely important to assess treatments of painful conditions and low back pain in particular, due both to the expected placebo effect and the subjective nature of pain assessment in general, and also the variable natural history of low back pain that often responds to conservative care. Although radiofrequency (RF) facet denervation has been in use for more than 20 years, evidence of its efficacy is limited to small RCTs and to larger case series.

In 2009, Chou et al published a review of the evidence used for an American Pain Society guideline on nonsurgical interventions for low back pain. The authors noted that trials of RF denervation are difficult to interpret, citing lack of controlled trial blocks in some studies, inadequate randomization, and heterogeneity of outcomes, and included facet denervation in a list of procedures for which there is insufficient evidence from randomized trials. In 2012, Falco et al updated their 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. 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. 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.

Following is a summary of key studies to date.

**Patient Selection**

Patient selection for facet joint interventions, and particularly the utility of diagnostic blocks, is discussed in a number of articles. Evidence is presented for use of dual blocks at thresholds of 50%, 75%, or 80% pain relief.

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

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

In 2010, Cohen et al reported a multicenter randomized cost-effectiveness trial comparing 0, 1, or 2 diagnostic blocks before lumbar facet RF denervation.7 Included in the study 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 patients (40%) who had a single diagnostic block followed by RF denervation, 8 (50% of 16) were considered successful. Of the 14 patients (28%) who went on to have RF denervation after 2 medial branch blocks, 11 (79% of 14) were considered successful. Three patients were successfully treated after medial branch blocks alone. The cost-effectiveness of proceeding to RF denervation without diagnostic blocks was discussed. The same group of investigators compared lumbar zygapophyseal joint RF denervation success rates between the conventional at least 50% pain relief threshold and the more stringently proposed at least 80% cutoff in a retrospective multicenter study with 262 patients.8 A total of 145 patients had greater than 50% but less than 80% relief after medial branch block, and 117 obtained at least 80% relief. In the greater than 50% group, success rates were 52% and 67% on pain relief and global perceived effect (GPE), respectively, after RF. Among those who had at least 80% relief from diagnostic blocks, 56% achieved at least 50% relief from RF and 66% had a positive GPE. The study concluded that the more stringent pain relief criteria are unlikely to improve success rates.

Pampati et al provide an observational report of experience with 152 patients diagnosed with lumbar facet pain using controlled diagnostic blocks.9 Of 1149 patients identified for interventional therapy, 491 patients were suspected of lumbar facet joint pain and received 1% lidocaine block. Of the 491 patients who received lidocaine, 261 were positive (at least 80% reduction of pain and ability to perform previously painful movements lasting at least 2 hours) and underwent bupivacaine blocks; 152 responded positively to bupivacaine block, were treated with RF neurotomy or medial branch blocks and were followed for 2 years. 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 compared outcomes of 110 patients who underwent facet nerve blocks after meeting positive criteria of 50% 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) by 75% of patients in the group with 50% relief from diagnostic blocks versus 93% in the group with 80% relief. At 2 years, the diagnosis was sustained in 51% of patients in the group with 50% relief, and sustained in 89.5% of patients who reported 80% relief from diagnostic blocks.

**Section Summary**

Literature on the effect on health outcomes following use of nerve blocks for patient selection includes 1 small randomized trial and several large case series. This evidence suggests that there are relatively few patients who exhibit pain relief following 2 nerve blocks, but that these select patients may have relief of pain for several months following RF denervation. A 2015 systematic review identified a number of other large series that reported prevalence and false-positive rates following controlled diagnostic blocks, although there are concerns about the reference standard used in these studies. The available evidence supports a threshold of at least 75% to 80% pain relief to reduce the false-positive rate.

**Facet Joint Denervation**

A 2015 systematic review by Manchikanti et al identified 9 RCTs or comparative studies on RF denervation of lumbar facet joints. The sample size ranged from 31 to 100 patients. All studies but one showed short- or long-term benefit of facet joint denervation, and the overall body of evidence was rated as level II. Several of these studies are described next.

The largest study included in Manchikanti’s systematic review compared facet joint injection and facet joint denervation in 100 patients. There were no sham controls, limiting interpretation of the results. In a 2013 double-blind RCT by Lakemeier et al, RF facet joint denervation was compared with intra-articular steroid injections in 56 patients. Patients were selected first on magnetic resonance imaging findings of hypertrophy of the facet joints followed by a positive response to an intra-articular infiltration of the facet joints with anesthetics. A diagnostic double-block of the facet joint was not performed. At 6 months, there was no significant difference between the 2 groups, although it is not clear if the mean visual analog scale (VAS) scores were significantly improved in either group.

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

In 2005, van Wijk et al. published a multicenter RCT that found no benefit of facet joint denervation.\textsuperscript{15} Inclusion criteria were continuous low back pain with or without radiating pain into the upper leg for more than 6 months and with focal tenderness over the facet joints, without sensory or motor deficits or positive straight leg raising test, no indication for low back surgery, and 50% or greater pain reduction 30 minutes after lidocaine block. Of 226 patients screened, 81 were randomly assigned to RF (n=40) or sham (n=41) lesion treatment. Success was defined as at least 50% reduction of median VAS back score without reduction in daily activities and/or rise in analgesic intake or reduction of at least 25% and drop in analgesic use of at least 25%. At 3 months, there was no difference between groups (27.5% of RF patients were successes vs 29.3% of the sham group). This study used a single (uncontrolled) block, which is known to increase the false-positive rate.

The only RCT that evaluated RF for chronic cervical pain at the facet joints was published in 1996 by Lord et al.\textsuperscript{16} Patients with C2-3 zygapophyseal joint pain were excluded because treatment at this level is technically difficult. Twenty-four patients (of 54 screened) were randomly assigned to RF or sham treatment. Six patients in the control group and 3 in the RF group had 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. Median time to return of greater than 50% of pretreatment pain was 263 days in the RF group versus 8 days in the placebo group. Two patients in the active group who had no relief of pain were found to have pain from adjacent spinal segments.

One RCT that evaluated RF for treatment of cervicogenic headache was identified.\textsuperscript{17} In a pilot study, 15 patients received a sequence of 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.

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

Section Summary

There are several small RCTs of RF denervation. Some trials reported did not have a sham control and thus provide limited support for RF denervation. The sham-controlled trials of RF denervation had mixed results, although the trial with negative results has limitations. Overall, there is moderate evidence in favor of RF denervation of the facet joints from controlled trials.

Repeat Procedures

The literature primarily consists of small retrospective studies of repeat procedures after successful RF.\textsuperscript{18,19} 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 the initial treatment. In a 2010 report, 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.\textsuperscript{20} The average duration of pain relief was 9.9 months after the first treatment and 10.5 months after the second treatment. A 2012 systematic review of 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.\textsuperscript{21} The average duration of pain relief was estimated to be 7 to 9 months after the first treatment and 11.6 months after a repeated lumbar procedure.

**Pulsed Radiofrequency Facet Denervation**

We identified 1 RCT that compared pulsed RF with steroid injection, 1 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.\textsuperscript{22} The patients were selected based on a single medial branch block; the percent reduction in pain was not described. RF and steroid injection to the medial branch reduced pain to a similar extent at 6 weeks. 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.

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

In a 2007 study, patients were randomly assigned, 20 each to conventional RF, pulsed RF, and a control group (local anesthetic only). Outcome measures were pain on VAS and Oswestry Disability Index (ODI) scores.\textsuperscript{24} Mean VAS and ODI scores were lower in both treatment groups than in controls posttreatment; however, the reduction in pain was maintained at 6- and 12-month follow-up only in the conventional RF group. The number of patients not using analgesics and patient satisfaction were highest in the conventional RF group. Kroll et al compared the efficacy of continuous versus pulsed RF in the treatment of lumbar facet syndrome in an RCT with 50 patients.\textsuperscript{25} 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) scores changes were significant. The study concluded that, although there was no significant difference between continuous and pulsed RF in the long-term outcomes, there was greater improvement over time in the continuous RF group.

**Laser Denervation**

In 2007, Iwatsuki et al reported laser denervation to the dorsal surface of the facet capsule in 21 patients who had a positive response to a diagnostic medial branch block.\textsuperscript{26} One year after laser denervation, 17 patients (81%) experienced greater than 70% pain reduction. In 4 patients (19%) who had previously undergone spinal surgery, the response to laser denervation was not successful. Controlled trials are needed to evaluate this technique.

**Alcohol Ablation**

Joo et al compared alcohol ablation with RF ablation in a randomized study of 40 patients with recurrent thoracolumbar facet joint pain following an initial successful RF neurotomy.\textsuperscript{27} 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.
Given the possibility of harm as described in professional society recommendations on chemical denervation (see next), additional study is needed.

**Facet Debridement**

Haufe and Mork reported 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. 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 at least 50% improvement in pain, measured by VAS. As noted by the authors, large-scale RCTs are needed to evaluate the efficacy of this treatment approach.

**Therapeutic Facet Joint Nerve Blocks**

Medial branch nerve blocks have also 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 in order to account for the potential placebo effect of an intervention.

Three 2010 double-blind RCTs were identified from Manchikanti et al that compared the therapeutic effect of medial branch blocks with bupivacaine alone to 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 ODI. Significant pain relief was considered to be a decrease of 50% or more on the numeric rating scale. Opioid intake and work status were also evaluated.

**Cervical**

One of the randomized trials 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 in the Neck Disability Index was seen in 70% of patients in the bupivacaine group and 75% of patients in the bupivacaine plus steroid group. There was no significant change in opioid intake. There was a loss of 38% of data for the 24-month evaluation. Sensitivity analysis using the last follow-up score, best-case scenario, and worst-case scenario were not significantly different, and intention-to-treat analysis with the last follow-up visit was used.

**Lumbar**

A second randomized double-blind trial by Manchikanti and colleagues evaluated the efficacy of facet joint nerve blocks in 120 patients with chronic low back pain. In addition to the 2 main conditions, half of 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 about 5-6 treatments over the course of 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 and 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 Pain Rating scores using the last follow-up score, best case scenario, and worst case scenario were not significantly different.

Thoracic

One-year results were reported in 2010 and 2-year results reported in 2012 from the randomized double-blind trial of the efficacy of thoracic medial branch blocks performed under fluoroscopy. The 100 patients in this study received an average of 3.5 treatments per year. Intent-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 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-years' follow-up, with 80% of patients in the bupivacaine group and 84% of patients in the bupivacaine plus steroid group continuing to show improvement in the ODI by 50% or more. The average number of procedures over the 2 years was 5.6 for bupivacaine and 6.2 for bupivacaine plus steroids.

Section Summary

The longer-term outcomes from these 3 randomized double-blind trials 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 a measurement of pain. No trials were identified that compare 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.

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

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<td>Medial Branch Blocks vs. Intra-articular Injections: Randomized, Controlled Study</td>
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<td>A Randomized Controlled Trial Comparing Thermal and Cooled Radiofrequency Ablation Techniques of Thoracic Facets' Medial Branches to Manage Thoracic Pain</td>
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<td>Percutaneous Radiofrequency Denervation of the Cervical Facet Joints Compared With Cervical Medial Branch Block of the Facet Joints for Patients With Chronic Degenerative Neck Pain: A Prospective Randomized Clinical Study</td>
<td>84</td>
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NCT: national clinical trial.
a Denotes industry-sponsored or cosponsored trial.

### Summary of Evidence

The evidence for diagnostic medial branch blocks in individuals who are suspected of having facet joint pain includes 1 small randomized trial and several large case series. Relevant outcomes are test accuracy, other test performance measures, symptoms, and functional outcomes. There is considerable controversy about the role of the blocks, the number of positive blocks required, and the extent of pain relief obtained. Studies have reported use of single or double blocks and at least 50% or at least 80% improvement in pain and function. This evidence suggests that there are relatively few patients who exhibit pain relief following 2 nerve blocks, but that these select patients may have pain relief for several months following radiofrequency (RF) denervation. Other large series reported prevalence and false-positive rates following controlled diagnostic blocks, although there are issues with the reference standards used in these studies. The evidence available supports a threshold of at least 75% to 80% pain relief to reduce the false-positive rate. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence for radiofrequency ablation to treat individuals with facet joint pain includes several randomized controlled trials. Relevant outcomes are symptoms, functional outcomes, quality of life, and medication use. While evidence is limited to a few studies 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 result in improved outcomes. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence for therapeutic medial branch blocks and alternative methods of facet joint denervation in patients who have facet joint pain 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 nonpulsed RF denervation, and there is insufficient evidence to evaluate the efficacy of other methods of denervation (eg, alcohol, laser, cryodenervation) for facet joint pain. There is insufficient evidence to evaluate the effect of therapeutic medial branch blocks on facet joint pain. The evidence is insufficient to determine the effects of the technology on health outcomes.

### 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**

In 2014, the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS) published updated guidelines on the treatment of degenerative disease of the lumbar spine.\(^{33}\) AANS/CNS recommended to use a double-injection technique with an improvement threshold of 80% or greater to establish a diagnosis of lumbar facet–mediated pain (grade B), that this is an option for predicting a favorable response to facet medial nerve ablation by thermocoagulation (grade C), and that there is no evidence to support the use of diagnostic facet blocks as a predictor of lumbar fusion outcome in patients with chronic low back pain from degenerative lumbar disease (grade I: Inconclusive). AANS/CNS gave grade B recommendations that (1) intra-articular injections of lumbar facet joints are not suggested for the treatment of facet-mediated chronic low back pain; (2) medial nerve blocks are suggested for the short-term relief of facet-mediated chronic low back pain; and (3) lumbar medial nerve ablation is suggested for the short-term (3- to 6-month) relief of facet-mediated pain in patients who have chronic lower back pain without radiculopathy from degenerative disease of the lumbar spine.

**American Society of Interventional Pain Physicians**

Updated guidelines on interventional techniques in the management of chronic spinal pain from the American Society of Interventional Pain Physicians (ASIPP) 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 criterion standard. For the treatment of facet joint pain, evidence was considered to be good for conventional radiofrequency, limited for pulsed radiofrequency, fair to good for lumbar facet joint nerve blocks and limited for intraarticular injections. Based on the evidence review, ASIPP recommends treatment with conventional radiofrequency neurotomy or therapeutic facet joint nerve blocks.

**American Society of Anesthesiologists et al**

Practice guidelines for chronic pain management by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine were published in 2010.\(^{35}\) The guidelines include the following recommendations:

- **Radiofrequency ablation**: Conventional (eg, 80°C) or thermal (eg, 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**: Chemical denervation (eg, alcohol, phenol, or high-concentration local anesthetics) should not be used in the routine care of patients with chronic noncancer pain.
American Pain Society
A 2009 American Pain Society Clinical Practice Guideline on nonsurgical interventions for low back pain states 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.1

National Institute for Health and Clinical Excellence
The United Kingdom’s National Institute for Health and Clinical Excellence (NICE) 2009 guidelines on the early management of non-specific low back pain states that people should not be referred for radiofrequency facet joint denervation.36

In 2001, the California Technology Assessment Forum published a review of the evidence for percutaneous RF neurotomy of cervical and lumbar zygapophysial joints for chronic neck and low back pain and concluded that the technology met their criteria for efficacy and safety for treatment of lower cervical (C3 and below) and for lumbar pain but not for treatment of upper (C2-C3) levels. In 2007, the California Technology Assessment Forum 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.

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

- Effective for 2012, there are new codes for facet joint denervation that include the CT or fluoroscopic imaging guidance: 64633, 64634, 64635, 64636.
- The American Medical Association’s CPT Editorial Panel decided in June 2005 that the unlisted CPT code 64999 should be used for pulsed RF treatment as opposed to other specific codes.
ICD-9 Diagnoses
721.0  Cervical spondylosis without myelopathy
721.1  Cervical spondylosis with myelopathy
721.3  Lumbosacral spondylosis without myelopathy
721.42 Spondylosis with myelopathy; lumbar region
722.81 Postlaminectomy syndrome; cervical region
722.83 Postlaminectomy syndrome; lumbar region
723.1  Cervicalgia
724.2  Lumbago

ICD-10 Diagnoses (Effective October 1, 2015)
M47.12 Other spondylosis with myelopathy, cervical region
M47.13 Other spondylosis with myelopathy, cervicothoracic region
M47.16 Other spondylosis with myelopathy, lumbar region
M47.17 Other spondylosis with myelopathy, lumbosacral region
M47.22 Other spondylosis with radiculopathy, cervical region
M47.23 Other spondylosis with radiculopathy, cervicothoracic region
M47.812 Spondylosis without myelopathy or radiculopathy, cervical region
M47.816 Spondylosis without myelopathy or radiculopathy, lumbar region
M47.817 Spondylosis without myelopathy or radiculopathy, lumbosacral region
M47.892 Other spondylosis, cervical region
M47.893 Other spondylosis, cervicothoracic region
M47.896 Other spondylosis, lumbar region
M47.897 Other spondylosis, lumbosacral region
M54.2  Cervicalgia
M54.5  Low back pain
M96.1  Postlaminectomy syndrome, not elsewhere classified

REVISIONS
02-08-2010  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.

04-04-2011  Description section updated
Policy Guidelines section added
Rationale section updated
In Coding section:
  Updated wording for 77003
References section updated

01-01-2012  In Coding section:
  Removed CPT Codes: 64622, 64623, 64626, 64627
  Added CPT Codes: 64633, 64634, 64635, 64636

12-02-2013  Revised Title from “Facet Joint Denervation” to “Facet Joint Denervation (Cervical and Lumbar)"
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." to "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."
- 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
<table>
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<th>Date</th>
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<tr>
<td>04-30-2015</td>
<td>- <strong>ICD-10 Codes added</strong>&lt;br&gt;- Referenced updated</td>
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|            | - In Policy section:<br>  - 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..." |
| 01-07-2016 | - 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.                                                               |
| 10-01-2016 | - 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)." |
REFERENCES


Other References
1. Blue Cross and Blue Shield of Kansas Anesthesiology Liaison Committee, May 2014; May 2015; July 2016.