**Facet Joint Denervation**

**Introduction**

Back pain is a common symptom and leads to pain and disability in some people. Despite extensive knowledge of the bones, nerves, muscles, tendons, and structures of the spine, it is still very difficult to identify a specific source of pain for many people. A part of the spine felt to cause pain for some people are the facet joints. Facet joints connect the bones of the spine (vertebrae) to both stabilize your back and help your spine move. Arthritis or boney changes can develop in these small joints. It is felt that nerves can be compressed by the arthritic changes and lead to pain. Studies have shown that for a small number of people, back pain can be improved by destruction of these nerves (denervation). The nerves are destroyed using a form of electrical waves known as non-pulsed radiofrequency waves. Often the denervation must be repeated every 6 to 12 months because the nerves grow back. Because only a small number of people respond to this treatment, it is important to undergo temporary nerve blocks to identify who will get relief from the radiofrequency treatment. This service must be pre-approved by the plan before it is covered. Records that show at least two successful temporary nerve blocks are needed. Studies have shown that other methods of destroying these nerves (such as pulsed radiofrequency, heat, laser, chemical or freezing) do not work.

**Note:** The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a
Policy Coverage Criteria

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Coverage Criteria</th>
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<tbody>
<tr>
<td>Radiofrequency denervation</td>
<td>Radiofrequency (RF) denervation is considered investigational for the treatment of chronic spinal/back pain for all uses that do not meet the criteria listed below, including but not limited to treatment of thoracic facet joint pain.</td>
</tr>
<tr>
<td></td>
<td>Non-pulsed radiofrequency (RF) 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:</td>
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<tr>
<td></td>
<td>• No prior spinal fusion surgery in the vertebral level is being treated</td>
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<td>• Patient has experienced disabling low back (lumbosacral) or neck (cervical) pain for greater than three (3) months, 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 radicular pain has been ruled out.</td>
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<td>• 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.</td>
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<td>• There has been a successful trial of two controlled medial branch blocks (MBBs) with an indication of at least 80% relief for the duration of the anesthetic prior to performing the second MBB (see Related Information).</td>
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<td>• 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).</td>
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</tbody>
</table>
### Procedure Coverage Criteria

- **There should be a progress note supporting response to prior RF treatment.**

### Investigational denervation procedures

- **Pulsed radiofrequency (RF) denervation**
- **Laser denervation**
- **Chemodenervation**
- **Cryodenervation**

All other methods of denervation are considered investigational for the treatment of chronic spinal/back pain, including, but not limited to pulsed radiofrequency (RF) denervation, laser denervation, chemodenervation (e.g., alcohol, phenol, or high-concentration local anesthetics), and cryodenervation.

### Therapeutic medial branch blocks

Therapeutic medial branch blocks are considered investigational.

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.

### Coding

#### CPT

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>64633</td>
<td>Destruction by neurolytic agent, paravertebral facet joint nerve(s) with imaging guidance (CT or fluoroscopy); cervical or thoracic, single facet joint</td>
</tr>
<tr>
<td>64634</td>
<td>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)</td>
</tr>
<tr>
<td>64635</td>
<td>Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint</td>
</tr>
<tr>
<td>64636</td>
<td>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)</td>
</tr>
<tr>
<td>64999</td>
<td>Unlisted procedure, nervous system</td>
</tr>
</tbody>
</table>
Diagnostic Medial Branch Block Criteria

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

- A placebo-controlled series of blocks, under fluoroscopic guidance, that has resulted in at least an 80% reduction in pain for the duration of the local anesthetic used (e.g., 3 hours longer with bupivacaine than lidocaine).

- No therapeutic intra-articular injections (i.e., steroids, saline, or other substances) should be administered for a period of at least 4 weeks prior to the diagnostic medial branch block.

- The diagnostic blocks should involve the levels being considered for RF treatment and should not be conducted under intravenous sedation unless specifically indicated (e.g., the patient is unable to cooperate with the procedure).

- These diagnostic blocks should be targeted to the likely pain generator. Single-level blocks lead to more precise diagnostic information, but multiple single-level blocks require several visits and additional exposure to radiation.

Definition of Terms

**Diagnosis of facet-mediated pain** requires the establishment of pain relief following dual medial branch blocks (MBBs) performed at different sessions. Neither physical exam nor imaging has adequate diagnostic power to confidently distinguish the facet joint as the pain source.

**Facet joints (also referred to as zygapophyseal or Z-joints)** enable the spine to bend and twist. Each vertebra has a set of facet joints at the top and bottom. Two medial branch (MB) nerves innervate the zygapophyseal joints.

A **region** is all injections performed in cervical/thoracic or all injections performed in lumbar (not sacral) spinal areas.
A **session** is defined as all injections/blocks/RF procedures performed on one day and includes medial branch blocks (MBB), intraarticular injections (IA), facet cyst ruptures, and RF ablations.

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**Evidence Review**

This policy was created in 2009 and updated periodically using the MEDLINE database. The most recent literature review was performed through September 2016.

**Description**

Facet joint denervation is performed under local anesthesia with fluoroscopic guidance. A needle or probe is directed to the median branch of the dorsal ganglion innervating the facet joint, where multiple thermal lesions are produced, typically by a radiofrequency generator. A variety of terms may be used to describe radiofrequency (RF) denervation (e.g., rhizotomy, rhizolysis). In addition, the structures to which the RF energy is directed may be referred to as facet joint, facet nerves, medial nerve or branch, median nerve or branch, or dorsal root ganglion.

**Background**

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

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

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. Intermediate outcome measures, also known as surrogate outcome measures, may also be adequate if there is an established link between the intermediate outcome and true health outcomes. Nonrandomized comparative studies and uncontrolled studies can sometimes provide useful information on health outcomes, but are prone to biases such as noncomparability of treatment groups, the placebo effect, and variable natural history of the condition.

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 randomized-controlled trials (RCTs) and to larger case series. Comparative studies are important for treatments in which the primary outcome is a measurement of pain in order to account for the potential placebo effect of an intervention.

In 2009, Chou et al published a review of the evidence for nonsurgical interventions for low back pain for an American Pain Society guideline.¹ 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 include facet denervation in a list of procedures for which there is insufficient evidence from randomized trials.

A 2009 systematic review of diagnostic utility and therapeutic effectiveness of cervical facet joint interventions by Falco et al found level II-1 or II-2 evidence (controlled trials without randomization, and cohort or case control studies from more than one center) for RF neurotomy in the cervical spine using U.S. Preventive Services Task Force (USPSTF) quality ratings.² Using the same rating system, Datta and colleagues found level II-2 and level II-3 (cohort or case control studies from more than one center, and multiple time series with or without the intervention) evidence for lumbar RF neurotomy.³

In 2012, Falco and colleagues updated their systematic reviews on the diagnosis and treatment of facet joint pain.⁴⁻⁷ They found good evidence for diagnostic nerve blocks with at least 75% pain relief as the criterion standard but were limited to fair evidence for diagnostic nerve blocks with 50% to 74% pain relief. There was good evidence for conventional radiofrequency neurotomy for the treatment of lumbar facet joint pain, fair evidence for cervical radiofrequency
neurotomy, and limited evidence for intra-articular facet joint injections and pulsed radiofrequency thermoneuromodulation. 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. Key studies to date are described below.

**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 with a threshold of 50% or a threshold of 80% pain relief.

In 2010, Cohen et al reported a multicenter randomized cost-effective trial comparing 0, 1, or 2 diagnostic blocks before lumbar facet joint RF denervation. 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 zygapophysial 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. 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 and others provide an observational report of experience with 152 patients diagnosed with lumbar facet pain using controlled diagnostic blocks. Of 1149 patients were 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 and underwent bivucaine blocks; 152 responded positively to bivucaine block, were treated with RF neurotomy or medial branch blocks and were followed for 2 years. After 2 years of follow-up 136 (89%) of the 152 patients with positive response to bivucaine were considered to have lumbar facet joint pain based on pain relief and functional status improvement after facet joint intervention.
In a 2010 report, Manchikanti et al compared outcomes of 110 patients who underwent facet nerve blocks and had 2 years of follow-up after meeting positive criteria of 50% relief. 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 use of nerve blocks for patient selection consists of 1 small randomized trial and several large case series. This limited evidence suggests that there are a 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. The limited evidence available is mixed regarding the optimum threshold of pain relief needed with diagnostic nerve blocks to proceed to RF denervation, but tends to support a threshold of 80% or greater pain relief.

**Facet Joint Denervation**

RCTs that evaluated RF for low back pain reached different conclusions.

In 2005, van Wijk et al published a multicenter RCT. 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).

A 2013 RCT by Lakemeier et al compared RF facet joint denervation versus intra-articular steroid injections in 56 patients in a randomized double-blind trial. Patients were selected first on magnetic resonance imaging (MRI) findings of hypertrophy of the facet joints followed by a positive response to an intra-articular infiltration of the facet joints with anesthetics. A diagnostic double-block of the facet joint was not performed. At 6 months, there was no significant difference between the 2 groups, although it is not clear if the mean VAS scores were
significantly improved in either group. The proportion of patients who achieved a 50% decrease in VAS was not reported.

Nath and colleagues performed an RCT with 40 patients to evaluate short- and intermediate-term effects of RF for lumbar facet pain.\textsuperscript{14} To be included in the study, patients had to be able to identify at least 1 component of their pain that was attributable to 1 or more lumbar zygapophyssial joints, have paravertebral tenderness, and 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; 45 had a negative response to controlled blocks, 105 had prolonged responses, and 71 of the remaining 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. Multiple lesions were performed in each RF patient. Pretreatment, the RF group had significantly more generalized pain, low back pain, and referred pain to the leg. On patient's own global assessment, the RF group improved by 1.1 U and the placebo group by 0.3 U (p=0.004). Generalized pain on VAS was reduced by 1.9 U (from 6.3 to 4.1) in the RF group versus 0.4 U (from 4.4 to 4.8) for placebo (p=0.02). Back pain was reduced in the RF group by 2.1 U (from 5.98 to 3.88) and referred pain by 1.6 U (from 4.33 to 2.73), while back pain was reduced in the placebo group by 0.7 U (from 4.38 to 3.68) and referred pain by 0.13 (from 2.68 to 2.55); between group differences were significant on both measures. 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.

The only RCT that evaluated RF for chronic cervical pain at the facet joints was published in 1995 by Lord et al\textsuperscript{15} (Patients with C2-C3 zygapophysial joint pain were excluded because treatment at this level is technically difficult. Twenty–four patients (of 54 screened) were randomly assigned to RF or sham treatment. Six patients in the control group and 3 in the RF group had return of pain immediately after the procedure. By 27 weeks, 1 patient in the control group and 7 in the RF group remained free of pain. Median time to return of greater than 50% of pretreatment pain was 263 days in the RF group versus 8 days in the placebo group. Two patients in the active group who had no relief of pain were found to have pain from adjacent spinal segments.

One RCT that evaluated RF for treatment of cervicogenic headache was identified.\textsuperscript{16} 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 (TENS). 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 that evaluated RF denervation in thoracic facet joints were identified.

**Section Summary**

There are several small RCTs of RF denervation. These sham-controlled trials of RF denervation have mixed results and provide limited evidence for RF denervation. This is in contrast to the large case series previously described, which find as many as 93% of patients with pain relief following RF denervation when selected by double blocks.

**Repeat Procedures**

The literature primarily consists of small retrospective studies of repeat procedures after successful RF. In two 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. 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. The average duration of pain relief was estimated to be 7-9 months after the first treatment and 11.6 months after a repeated lumbar procedure.

**Pulsed Radiofrequency Facet Denervation**

One RCT that compared pulsed RF to steroid injection, 1 small RCT that compared pulsed RF to sham treatment and 2 studies that compared continuous RF and pulsed RF were identified.

Pulsed RF denervation was compared with steroid injection in a randomized trial of 80 patients. The patients were selected by 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 and colleagues randomly assigned 23 patients (of 256 screened) with chronic cervical radicular pain to pulsed RF or sham treatment.\textsuperscript{22} Success was defined as at least 50% improvement on GPE, at least 20% reduction in pain on VAS, and reduced pain medication use measured three months after treatment. Nine of 11 patients in the treatment arm and four of 12 in the sham arm showed at least 50% improvement on GPE (P=0.03), and nine of 11 in the treatment group and three of 12 in the sham group achieved at least 20% reduction in pain on VAS (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{23} Mean VAS and ODI scores were lower in both treatment groups than in controls post-treatment; however, the reduction in pain was maintained at 6- and 12-month follow-up only in the conventional RF group. The number of patients not using analgesics and patient satisfaction were highest in the conventional RF group.

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{24} No significant differences in the relative percentage improvement were noted between groups in either VAS (p=0.46) or ODI scores (p=0.35). Within the pulsed RF group, comparisons of the relative change over time for both VAS (p=0.21) and ODI scores (p=0.61) were not significant. However, within the continuous RF group, VAS (p=0.02) and ODI scores (p=0.03) 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{25} 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{26} At 24-month follow-up, 3 patients in the alcohol ablation group had recurring pain compared to 19 in the RF group. The median effective periods were 10.7 months (range 5.4 to 24) for RF and 24
months (range 16.8 to 24) for alcohol ablation. No significant complications were identified. Given the possibility of harm as described in professional society recommendations on chemical denervation (see below), additional study is needed.

Facet Debridement

Haufe and Mork reported endoscopic facet debridement in a series of 174 patients with cervical (n=45), thoracic (n=15) or lumbar (n=114) pain who had a successful response to a diagnostic medial branch nerve block.27 The capsular tissue was removed under direct observation via laparoscopy, followed by electrocautery or holmium lasers to completely remove the capsular region. Treatment was given on a single occasion, with most patients requiring treatment of 4 joints. At a minimum of 3 years' follow-up, 77%, 73%, and 68% of patients with cervical, thoracic, or lumbar disease, respectively, showed at least 50% improvement in pain, measured by a VAS). As noted by the authors, large-scale RCTs are needed to evaluate the efficacy of this treatment approach.

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 randomized double-blind controlled trials were identified from Manchikanti et al in 2010 that compared the therapeutic effect of medial branch blocks with bupivacaine alone to bupivacaine and steroid (betamethasone).28-30 Patients included had a diagnosis of facet joint pain (cervical, thoracic, and 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 with the ODI. Significant pain relief was considered to be a decrease of 50% or greater 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.28 The 2 groups were further subdivided, with half of the patients in each group
receiving 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 intent-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 the intake of opioids. 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 intent-to-treat analysis with the last follow-up visit was utilized.

**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**

A search of the online site [Clinical Trials.gov](https://clinicaltrials.gov) identified several randomized trials on facet joint denervation.

<table>
<thead>
<tr>
<th>Trial</th>
<th>Summary</th>
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<tbody>
<tr>
<td>NCT01743326</td>
<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 has an estimated enrollment of 84 patients and a target completion date of June 2014. (Still recruiting September 2016.)</td>
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<tr>
<td>NCT02002429</td>
<td>A randomized double-blind comparison of medial branch blocks versus intra-articular injections, has target enrollment of 225 patients with completion expected January 2017.</td>
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<tr>
<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 has an estimated enrollment of 237 patients and a target completion date of February 2016. (Still recruiting September 2016.)</td>
</tr>
<tr>
<td>NCT02073292</td>
<td>A randomized controlled trial comparing thermal and cooled radiofrequency ablation techniques of thoracic facets’ medial branches to manage thoracic pain, has an estimated enrollment of 61 patients with completion expected February 2017.</td>
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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.

Summary of Evidence

The evidence for diagnostic testing consists mainly of studies using single or double blocks and experiencing at least 50% or at least 80% improvement in pain and function. There is considerable controversy about the role of the blocks, the number of positive blocks required, and the extent of pain relief obtained. Based on review of the evidence and clinical input, the statement in the Policy Guidelines section states that at least 80% improvement on 2 positive blocks (or a placebo-controlled series of blocks) is required.

There is limited evidence for RF denervation of the facet joint from sham controlled trials. Evidence from large uncontrolled series suggests that RF facet denervation appears to provide at least 50% pain relief in 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.

Pulsed radiofrequency does not appear to be as effective as non-pulsed radiofrequency denervation, and there is insufficient evidence to evaluate the efficacy of other methods of denervation (e.g., alcohol, laser or cryodenervation) for facet joint pain. Therefore, these techniques are considered investigational.

There is insufficient evidence to evaluate the effect of therapeutic medial branch blocks on facet joint pain. This treatment is considered investigational.
Practice Guidelines and Position Statements

American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS)

In 2014, the AANS and CNS published updated guidelines on the treatment of degenerative disease of the lumbar spine.\textsuperscript{32} 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) intraarticular 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 (ASIPP)

Updated guidelines on interventional techniques in the management of chronic spinal pain from the ASIPP were published in 2013.\textsuperscript{33} 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 intra-articular injections. Based on the evidence review, ASIPP recommends treatment with conventional radiofrequency neurotomy or therapeutic facet joint nerve blocks.
**American Society of Anesthesiologists (ASA)**

Practice guidelines for chronic pain management by the ASA Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine were published in 2010. The guidelines include 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:** Chemical denervation (e.g., alcohol, phenol, or high-concentration local anesthetics) should not be used in the routine care of patients with chronic noncancerous pain.

**American Pain Society (APS)**

A 2009 APS 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.

**National Institute for Health and Clinical Excellence (NICE)**

The 2009 NICE guidelines on the early management of non-specific low back pain state that people should not be referred for radiofrequency facet joint denervation.

**California Technology Assessment Forum (CTAF)**

In 2001, the CTAF 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.
Medicare National Coverage

There is no national coverage determination. Noridian Healthcare Solutions issued a local coverage determination (LCD) on March 5, 2014 with an update effective May 01, 2015.

Regulatory Status

A number of radiofrequency generators and probes have been cleared for marketing through the U.S. Food and Drug Administration’s (FDA) 510(k) process.

One device, the Sinergy® by Kimberly Clark/Baylis, is a water-cooled single-use probe that received FDA clearance in 2005, listing the Baylis Pain Management Probe as a predicate device. The intended use is in conjunction with a radiofrequency generator to create radiofrequency lesions in nervous tissue.

FDA product code: GXD

References

8. Cohen SP, Strassels SA, Kurihara C et al. Randomized study assessing the accuracy of cervical facet joint nerve (medial branch) blocks using different injectate volumes. Anesthesiology 2010; 112(1):144-152. PMID 19996954


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**History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
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<tbody>
<tr>
<td>05/12/14</td>
<td>New PR policy replacing 7.01.116, same title. Policy coverage on non-pulsed RF now considered medically necessary for level C2-3 (is investigational at C2 in policy 7.01.116) when criteria are met including two controlled medial branch blocks (MBBs) with an indication of at least 80% relief for the duration of the anesthetic prior to performing the second MBB. Unlisted CPT code 64999 removed; there are CPT codes specific to this policy referenced within. ICD-9 and ICD-10 diagnosis and procedure</td>
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<td>05/27/15</td>
<td>codes removed; these to not facilitate adjudication, this is outpatient.</td>
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<tr>
<td>02/16/16</td>
<td>Coding update. Added 64999.</td>
</tr>
<tr>
<td>10/11/16</td>
<td>Annual review. Literature search. No changes to policy statement. Policy moved into new format. Removed unlisted CPT code 64999 from coding section.</td>
</tr>
</tbody>
</table>

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2016 Premera All Rights Reserved.

**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
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  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
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  - Qualified interpreters
  - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

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Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592. TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at:
https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-722-1471 (TTY: 800-842-5357).

Arabic (Arabic):
ويحوي هذا الإشعار معلومات هامة. قد يحتوي هذا الإشعار معلومات مهمة بخصوص تلك أو أشياء أخرى قد تكون هناك تأثير مهمة. Premera Blue Cross
لا توجد المعلومات المذكورة. في هذه الإشارات، قد تتأثر إجراءات تأثيرية على التأثيرات الصحية والاجتماعية في ذلك التأثير. يُحتج كخطوة أولية على هذه المعلومات والمساعدة بذلك دون تأكد أي كتلة في المصل 800-722-1471 (TTY: 800-842-5357).

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Română (Romanian):

Русский (Russian):
Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении о страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть указаны ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

Español (Spanish):
Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas clave en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

TAGALOG (Tagalog):

ไทย (Thai):
ข้อร้องขอที่สำคัญที่สุดคือ การแจ้งข้อมูลที่เกี่ยวข้องกับการขอหรือขอรับการประกันสุขภาพของคุณ Premera Blue Cross และคุณจะมีสิทธิในการรับข้อมูลที่คุณจะต้องการ เพื่อให้คุณสามารถดำเนินการในกำหนดระยะเวลาที่มีผลหรือจะเรียกข้อร้องขอของคุณจากสัญญาที่มี การส่งข้อมูลที่ไม่มีความสอดคล้องกับข้อมูลที่คุณขอ โปรดติดต่อ Premera Blue Cross TTY 800-722-1471 (TTY: 800-842-5357).

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