Name of Policy:  
Facet Joint Denervation

Policy #:  141       Latest Review Date: September 2014
Category:  Surgery       Policy Grade:  A

Background/Definitions:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
**Description of Procedure or Service:**
Radiofrequency (RF) facet denervation is performed under local anesthetic and with fluoroscopic guidance. A needle is directed to the median branch of the dorsal ganglion in the facet joint, where multiple thermal lesions are produced, typically by a radiofrequency generator. The procedure is usually performed with conscious sedation. 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.

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.

**Policy:**
*Effective for dates of service on or after December 29, 2012:*
Non-pulsed radiofrequency denervation of cervical facet joints (C3-4 and below) and lumbar facet joints meets Blue Cross and Blue shield of Alabama’s medical criteria for coverage when all of the following criteria are met:
- No prior spinal fusion surgery in the vertebral level being treated; **AND**
- Disabling **non-radicular** 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**
- Pain has failed to respond to three months of conservative therapy*; **AND**
- There has been a successful trial** of controlled medial branch blocks; **AND**
- If there has been a prior successful radiofrequency (RF) denervation, a minimum time of six months has elapsed since prior RF treatment (per side, per anatomical level of the spine).

*Conservative therapy is the use of structured physician-directed modalities which may include: prescription strength analgesics/anti-inflammatory medications if not contraindicated; participation in physical therapy modality(ies) when rendered by an eligible provider (including active exercise)
A successful trial of controlled diagnostic medial branch blocks consists of:

- **Two separate positive** blocks on **different days** with **local anesthetic only** (no steroids or other drugs), or a placebo controlled series of blocks, under fluoroscopic guidance, that has resulted in at least a 50% reduction in pain for the duration of the local anesthetic used (e.g., three hours longer with bupivacaine than lidocaine).
- **No therapeutic intraarticular injections** (i.e., steroids, saline, or other substances) should be administered for a period of at **least four 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).
- The 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.

**Radiofrequency denervation does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered **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.

**All other methods of denervation do not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and are considered **investigational** for the treatment of chronic spinal/back pain, including, but not limited to pulsed radiofrequency denervation, laser denervation, chemodenervation (e.g., alcohol, phenol, or high-concentration local anesthetics), and cryodenervation.

**Therapeutic medial branch blocks do not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and 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 do **not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage.

**Effective for dates of service February 27, 2012 through December 28, 2012:**
Radiofrequency denervation of **cervical facet joints (C3-4 and below) and lumbar facet joints meets** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when all of the following criteria are met.
- No prior spinal fusion surgery in the vertebral level being treated; **AND**
- Disabling low back (lumbosacral) or neck (cervical) pain, suggestive of facet joint origin as evidenced by absence of nerve root compression as documented in the medical record on history, physical, and radiographic evaluations; and the pain is not radicular; **AND**
• Pain has failed to respond to three months of conservative management, which may consist of therapies such as nonsteroidal anti-inflammatory medications, acetaminophen, manipulation, physical therapy, and a home exercise program; AND
• A trial of controlled diagnostic medial branch blocks with two separate positive blocks conducted on different days with local anesthetic only (no steroids or other drugs), or a placebo controlled series of blocks, under fluoroscopic guidance, has resulted in at least a 50% reduction in pain for the duration of the local anesthetic used (e.g., three hours longer with bupivacaine than lidocaine); AND
• The diagnostic blocks involve the levels being considered for RF treatment and are not conducted under intravenous sedation unless specifically indicated (e.g., the patient is unable to cooperate with the procedure); AND
• The diagnostic blocks are targeted to the likely pain generator.; AND
• No therapeutic intra-articular injections (i.e., steroids, saline or other substances) have been administered for a period of at least four weeks prior to the diagnostic medical branch block: AND
• If there has been a prior successful radiofrequency (RF) denervation, a minimum time of six months has elapsed since prior RF treatment (per side, per anatomical level of the spine).

Radiofrequency denervation does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered 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.

All other methods of denervation do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and are considered investigational for the treatment of chronic spinal/back pain, including, but not limited to pulsed radiofrequency denervation, laser denervation, and cryodenervation.

Therapeutic medial branch blocks do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and 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 do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage.

Effective for dates of service November 3, 2009 through February 26, 2012:
Radiofrequency denervation of cervical facet joints (C3-4 and below) and lumbar facet meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when the following criteria are met:

• No prior spinal fusion surgery in the vertebral level being treated;
• 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;
• 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;
• A trial of controlled diagnostic medial branch blocks (3 separate positive blocks or placebo controlled series of blocks) under fluoroscopic guidance has resulted in at least a 50% reduction in pain; and
• 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).

**Radiofrequency denervation does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered **investigational** for the treatment of chronic spinal/back pain for all other uses not listed above, including but not limited to treatment of thoracic facet or sacroiliac (SI) joint pain.

**Pulsed radiofrequency denervation does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered **investigational** for the treatment of chronic spinal/back pain.

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*Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member’s contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.*

**Key Points:**
This policy was created in 2009 and updated periodically using the MEDLINE database. The most recent literature update was performed through September 16, 2014.

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.

In 2009, Chou et al published a review of the evidence for nonsurgical interventions for low back pain for an American Pain Society guideline. 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. 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.

In 2012, Falco and colleagues 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 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 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.

Key studies to date are described in the following pages.

**Patient Selection**

Patient selection for facet joint interventions, and particularly the utility of diagnostic blocks, is discussed in a number of papers. 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-effectiveness trial comparing 0, 1, or 2 diagnostic blocks before lumbar facet RF denervation. Included in the study were 151 patients with predominantly axial low back pain of three 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, eight (50% of 16) were considered successful. Of the 14 patients (28%) who went on to have RF denervation after two 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 et al provide an observational report of experience with 152 patients diagnosed with lumbar facet pain using controlled diagnostic blocks. Of 1149 patients identified for interventional therapy, 491 patients were suspected of lumbar facet joint pain and received 1% lidocaine block. Of the 491 patients who received lidocaine, 261 were positive (at least 80% reduction of pain and ability to perform previously painful movements lasting at least two hours) and underwent bivucaine blocks; 152 responded positively to bivucaine block, were treated with RF neurotomy or medial branch block and were followed for two years. After two 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. Manchikanti et al compared outcomes of 110 patients who underwent facet nerve blocks after meeting positive criteria of 50% relief and had two years of follow-up. At the end of one 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 two 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.

Literature on the use of nerve blocks for patient selection consists of one small randomized trial and several large case series. Case series can sometimes provide useful information on health outcomes, but are prone to biases such as non-comparability of treatment groups, the placebo effect, and variable natural history of the condition. This limited evidence suggests that there are relatively few patients who exhibit pain relief following two 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 six 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 three 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 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 six months, there was no significant difference between the two 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. To be included in the study, patients had to be able to identify at least one component of their pain that was attributable to one or more lumbar zygapophyseal joints, have paravertebral tenderness, and obtain at least 80% relief of pain following controlled (three 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 one 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 six-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. Patients with C2-C3 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 three in the RF group had return of pain immediately after the procedure. By 27 weeks, one patient in the control group and seven 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 eight 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. 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.

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 seven to nine 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, one small RCT that compared pulsed RF to sham treatment and two 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 six weeks. Pain relief with pulsed RF remained low at six months (from 7.4 at baseline to 2.4 at six months), but had returned to near baseline levels in the steroid group pain by six months.

Van Zundert and colleagues randomly assigned 23 patients (of 256 screened) with chronic cervical radicular pain to pulsed RF or sham treatment. 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 eleven 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, twenty 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. Mean VAS and ODI scores were lower in both treatment groups than in controls posttreatment; however, the reduction in pain was maintained at six- 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 and others compared the efficacy of continuous versus pulsed RF in the treatment of lumbar facet syndrome in an RCT with 50 patients. No significant differences in the relative percentage improvement were noted between groups in either VAS (p=0.46) or OSW scores (p=0.35). Within the pulsed RF group, comparisons of the relative change over time for both VAS (p=0.21) and OSW scores (p=0.61) were not significant. However, within the continuous RF group, VAS (p=0.02) and OSW scores (p=0.03) changes were significant. The authors conclude 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. One year after laser denervation, 17 patients (81%) experienced greater than 70% pain reduction. In four 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. At 24-month follow-up, three 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 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. 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 four joints. At a minimum of three 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). Patients included had a diagnosis of facet joint pain (cervical, thoracic, and lumbar) with an 80% reduction in pain following two 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. The two groups were further subdivided, with half of the patients in each group receiving Sarapin. Patients were followed at three-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 two years. Sarapin did not affect the outcome, and the data were reported only for the two main conditions. At two-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 two 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 two main conditions. Patients received about five to six treatments over the course of the study. At two-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 two-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 two 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 two years was 5.6 for bupivacaine and 6.2 for bupivacaine plus steroids.

The longer-term outcomes from these three 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.

**Summary**

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 50% improvement on two positive blocks (or a placebo-controlled series of blocks) is required.

There is limited evidence for radiofrequency (RF) denervation of the facet joint from sham controlled trials. Evidence from large uncontrolled series suggests that RF facet denervation may 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.

Pulsed radiofrequency does not appear to be as effective as nonpulsed 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**

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. 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 (three- to six-month) relief of facet-mediated pain in patients who have chronic lower back pain without radiculopathy from degenerative disease of the lumbar spine.

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. 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.

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. 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 noncancer pain.

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.

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

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.
**U.S. Preventive Services Task Force Recommendations**
The U.S. Preventative Services Task Force (USPSTF) has not addressed facet joint denervation.

**Key Words:**
Percutaneous radiofrequency facet denervation, radiofrequency facet denervation, zygapophyseal joint, radiofrequency ablation, neurotomy, therapeutic medial nerve branch block, radiofrequency denervation, pulsed radiofrequency denervation, laser denervation, cryodenervation, chemodenervation, Singery®, medial branch block, Dorsal root ganglion, Non pulsed radiofrequency ablation

**Approved by Governing Bodies:**
A number of radiofrequency generators and probes have been cleared for marketing through the 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.

**Benefit Application:**
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply
FEP contracts: FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

**Current Coding:**
CPT codes:
- 64633 Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint (Effective January 1, 2012)
- 64634 ; each additional facet joint (List separately in addition to code for primary procedure) (Effective January 1, 2012)
- 64635 ; lumbar or sacral, single facet joint (Effective January 1, 2012)
- 64636 ; lumbar or sacral, each additional facet joint (List separately in addition to code for primary procedure) (Effective January 1, 2012)
- 64999 Unlisted procedure, nervous system. (should be used for pulsed radiofrequency ablation as opposed to specific codes. (Effective January 1, 2012)
Previous Coding:

64622  Destruction by neurolytic agent, paravertebral facet joint nerve, lumbar or sacral, single level (Deleted effective January 1, 2012)

64623  Destruction by neurolytic agent, paravertebral facet joint nerve, lumbar or sacral, each additional level (Deleted effective January 1, 2012)

64626  Destruction by neurolytic agent, paravertebral facet joint nerve, cervical or thoracic, single level (Deleted effective January 1, 2012)

64627  Destruction by neurolytic agent, paravertebral facet joint nerve, cervical or thoracic, each additional level (Deleted effective January 1, 2012)

76005  Fluoroscopic guidance (Code deleted effective January 1, 2007)

77003  Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinal diagnostic or therapeutic injection procedures (epidural, transforaminal epidural, subarachnoid, paravertebral facet joint, paravertebral facet joint nerve, or sacroiliac joint), including neurolytic agent destruction (Deleted effective January 1, 2012)

References:


Policy History:
Medical Policy Group, October 2003
Medical Policy Administration Committee, October 2003
Medical Policy Group, September 2005 (1)
Medical Policy Group, September 2008 (1)
Medical Policy Group, September 2009 (3)
Medical Policy Administration Committee, September 2009
Available for comment September 18-November 2, 2009
Medical Policy Group, October 2010 (1): Key Points update, references added, no change in policy statement
Medical Policy Group, November 2010 Codes updated for 1/1/2011
Medical Policy Group, November 2011(1): Added/Deleted CPT Codes for 2012 effective 1/1/12
Medical Policy Panel, October 2011
Medical Policy Group, December 2011 (2): Policy, Key Words, Key Points, References updated
Medical Policy Administration (3): January 2012
Available for comment January 11 – February 27, 2012
Medical Policy Panel, October 2012
Medical Policy Group, October 2012 (2): Chemodenervation added to investigational policy statement. Sacroiliac joint removed for the investigational policy statement. Description, Key Points, Key Words, Approved by Governing Bodies, & References updated.
Medical Policy Administration, November 2012
Available for comment November 14 through December 28, 2012
Medical Policy Group February 2013 (4): added (e.g., alcohol, phenol, or high-concentration local anesthetics) to policy statement. Added 64999 as unlisted codes to be used for pulsed radiofrequency ablation and updated Key Points, Key Words & References.
Medical Policy Panel, October 2013
Medical Policy Group, September 2014 (3): 2013 Updates to references; no change in policy statement; removed old policy statements (prior to 2009)
Medical Policy Group, September 2014 (3): added word “modality(ies)” to description of physical therapy in conservative therapy definition per Medical Director
Medical Policy Panel, October 2014
Medical Policy Group, October 2014 (3): 2014 Updates to Key Points & References; no change in policy statement

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.