BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Radiofrequency Denervation

Policy # 00199
Original Effective Date: 12/20/2006
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Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider radiofrequency (RF) denervation of cervical facet joints and lumbar facet joints when ALL of the following criteria are met to be **eligible for coverage.**

Patient Selection Criteria
Coverage eligibility will be considered when all of the following criteria are met:

- 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
- 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 radiofrequency (RF) treatment (per side, per anatomical level of the spine).

When Services Are Considered Not Medically Necessary
Based on review on available data, the Company considers if there has been a prior successful radiofrequency (RF) denervation, additional diagnostic medial branch blocks for the same level of the spine to be **not medically necessary.****

When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers radiofrequency (RF) denervation for the treatment of chronic spinal/back pain for all uses that do not meet the criteria listed above, including but not limited to treatment of thoracic facet or sacroiliac (SI) joint pain to be **investigational.***

Based on review of available data, the Company considers all other methods of denervation for the treatment of chronic spinal/back pain, including, but not limited to pulsed radiofrequency (RF) denervation, laser denervation, chemodenervation, and cryodenervation to be **investigational.***

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Based on review of available data, the Company considers therapeutic medial branch blocks to be **investigational.***

Based on review of available data, the Company considers the use of radiofrequency (RF) denervation of cervical facet joints and lumbar facet joints when patient selection criteria are not met to be **investigational.***

Background/Overview

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

Percutaneous 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, 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.

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 intra-articular 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). 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.

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FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
A number of RF generators and probes have been cleared for marketing through the U.S. FDA's 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 RF generator to create RF lesions in nervous tissue.

Centers for Medicare and Medicaid Services (CMS)
There is no national coverage determination.

Rationale/Source

Although 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.

A 2003 systematic review of the literature by Niemistö and colleagues cited methodologic weaknesses of small sample sizes, short follow-up, deficiencies in patient selection, outcome assessment, and statistical analyses and concluded that "there is limited evidence that RF denervation offers short-term relief for chronic neck pain of zygapophysial joint origin and for chronic cervicobrachial pain, and conflicting evidence for its effectiveness for lumbar zygapophysial joint pain." Carragee et al., in a 2008 report of the Bone and Joint Decade 2000-2010 Task Force on Neck Pain and its Associated Disorders, concluded that "Radiofrequency neurotomy, cervical facet injections, cervical fusion and cervical arthroplasty for neck pain without radiculopathy are not supported by current evidence." A 2008 review of diagnostic utility and therapeutic effectiveness of thoracic facet joint interventions found two studies of low quality (retrospective evaluation without a comparative group, lack of diagnosis by controlled blocks, small number of patients, without adequate outcome measures). Karnezis found limited evidence of the value of facet neurotomy. Van Boxem and colleagues in a review of evidence for continuous and pulsed RF, note that RF at the cervical and lumbar level has produced the most solid evidence, and differences in outcome among RCTs can be attributed to differences in patient selection and/or inappropriate technique. Studies of cervical radicular pain suggest a comparable efficacy of continuous and pulsed RF. The authors suggest that future research should be conducted in carefully selected populations and that tests used to select patients for such trials could help physicians select patients for treatment. A 2008 review that considered only RCTs in which at least one diagnostic block was used for patient selection concluded that "when done with proper technique, percutaneous RF lumbar and cervical medial branch neurotomy are both effective."

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.

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 papers. Falco and Datta (both et al.), in the reviews mentioned above cite level I (evidence from RCTs) or II-1 for diagnosis of cervical facet joint pain with controlled comparative local anesthetic blocks. A systematic review of the diagnostic accuracy of thoracic facet joint nerve blocks rated the level of evidence as good, although 1 study was retrospective and all 3 included manuscripts originated from a single group of investigators. Combined results showed a prevalence of 40% with dual blocks and a false-positive rate of 42% with a single block.

To identify demographic, clinical, and treatment factors associated with outcomes of RF denervation, Cohen et al. gathered data from three academic medical centers on 92 patients with chronic neck pain who received RF treatment. They determined that the only clinical variable associated with success was paraspinal tenderness. Factors associated with treatment failure included radiation to the head, opioid use, and pain exacerbated by neck extension or rotation.

In a retrospective multicenter study with 262 patients, Cohen and colleagues 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. 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 authors concluded that the more stringent pain relief criteria are unlikely to improve success rates, may lead to misdiagnosis and withholding of potentially helpful treatment.

Pampati and others provide an observational report of experience with 152 patients diagnosed with lumbar facet pain using controlled diagnostic blocks. Diagnostic blocks were described as follows. A block of 1% lidocaine was administered. Patients with lidocaine-positive results (at least 80% reduction of pain and ability to perform previously painful movements lasting at least two hours) were followed up with a 0.25% bivucaine block 3-4 weeks after the first injection. After bivucaine block, pain relief had to last at least three hours or longer than the duration of relief after lidocaine to be considered positive. A single physician saw 1,499 patients from January 2004-June 2007, 1,149 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 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. Information on outcomes by treatment intervention were not included in this paper, and the efficacy of facet joint blocks as a therapeutic measure has not been described by other authors.

O'Neill and Owens state, in an 2009 editorial commenting on opinions expressed by investigators on the use of local anesthetic blocks in the diagnosis of lumbar facet pain, that "anesthetic blocks were a valiant attempt to provide objective criteria to diagnose a vague syndrome. However, it is time to recognize that one) anesthetic blocks are not a valid test to diagnose facet joint pain and two) the treatment effect and cost-effectiveness of anesthetic medial branch blocks are unknown." They note variation in diagnostic block protocols described in the literature and some questions about their validity; the 2-block paradigm (2 blocks with anesthetics having different duration issues of action), triple block (two different local anesthetics regardless of duration of action coupled with a placebo control), false-positives caused by aberrant spread of the local anesthetic, and potential false-positive responses related to changes in the relationship between signals from the periphery and perception of pain in patients with chronic pain that make it possible to relieve pain by anesthetizing a noninjured structure. The authors suggest that diagnostic RCTs that encompass cost-effective measures are needed to define the role of anesthetic medial branch blocks, as well as other available diagnostic tools in the selection of patients for facet rhizotomy. Binder and Nampiaparampil also acknowledge the pitfalls associated with facet joint blocks and the lack of consensus about the definition of a successful diagnostic block but conclude that they are a valid, safe, and reliable diagnostic tool and urge development of a universal algorithm for evaluating facet joint pain.

In 2010, Cohen and colleagues 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 equal to or greater than three months 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, 16% of 50) were considered successful. Of the 14 patients (28%) who went on to have RF denervation after two medical branch blocks, 11 (79% of 14, 22% of 50) were considered successful. Three patients were successfully treated after medial branch blocks alone. The investigators concluded that proceeding to RF denervation without a diagnostic block is the most cost-effective paradigm.

Cohen and colleagues also reported a randomized study assessing the accuracy of cervical facet joint nerve (medial branch) blocks using different injectate volumes to explore the hypothesis that inaccurate diagnostic block may be caused by inadvertent extravasation of injectate into adjacent pain-generating structures. Twelve patients received 0.5 mL and 12 received 0.25 mL of bupivacaine mixed with contrast. Half of the patients in each group received the blocks in the prone position and the other half through a lateral approach. On computed tomography (CT) scan, 16 instances of aberrant spread were observed in 9 patients receiving bocks using 0.5 mL versus 7 occurrences in six patients in the 0.25 mL group. ($p = 0.07$). Aberrant spread was most commonly observed (57%) when an injection at C3 engulfed the third occipital nerve. Among the 86 blocks, foraminal spread occurred in five instances using 0.5 mL and in two cases with 0.25 mL. Three nerves in each group were "missed." The authors conclude that reducing the volume of anesthetic may improve precision and accuracy.

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In a 2010 report, Manchikanti et al. compared outcomes of 110 patients who underwent facet nerve blocks and had two years of follow-up after meeting positive criteria of 50% relief. 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. The prevalence of patients with 50% improvement was 73% after a single block and 61% after double blocks. The prevalence of patients with 80% improvement was 53% after a single block and 31% after double blocks. The authors conclude that controlled diagnostic lumbar facet joint nerve blocks are valid utilizing the criteria of 80% relief and the ability to perform previously painful movements, with a sustained diagnosis of lumbar facet joint pain in at least 89.5% of the patients at the end of a 2-year follow-up.

Facet Joint Denervation
Two 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 or sham lesion treatment. The primary outcome was determined using a predefined multidimensional combined outcome measure comprising changes in visual analog scale (VAS)-back score, daily physical activities, and use of analgesics. 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%. Information was collected in weekly diaries mailed in by patients. Failures at three months were unblinded and, if the patient had received sham treatment, RF was offered. Follow-up after successful treatment was at 6, 9, and 12 months. At three months, there was no difference between groups (27.5% of RF patients were successes vs. 29.3% of the sham group). VAS-back score was significantly reduced in both groups (RF pretreatment mean 5.8 and mean change 2.1, sham pretreatment mean 6.5 and mean change 1.6). There were no between-group differences on VAS-back score, VAS-leg, physical activities, or intake of analgesics. These results persisted until 12 months, however, because blinding was ended at the 3-month follow-up in more than 70% of patients, a mix of additional treatments was performed between the 3- and 12-month follow-ups, and some patients in both groups were lost to follow-up, outcome data collected after three months was difficult to interpret. Significantly more RF patients (62%) than sham patients (39%) achieved greater than 50% pain relief on the GPE measured on a 4-point Likert scale ($p = 0.044$). Subgroup analysis showed RF to be superior to sham in female patients, older patients, patients with longer pain history, patients with employment, and patients without history of low back surgery.

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 zygapophysial 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 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 SI joint test, paravertebral tenderness, and tactile sensory deficit. Analgesic use was reported to be reduced more in the RF group; however, details about this measure were not provided.

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 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. Patient perception of pain was confirmed by placebo-controlled blocks (three blocks, the first with 2% or 5% lidocaine, the second with saline, and the third with lidocaine). In the RF group, 2 or 3 lesions were made at each location. In telephone interviews at 3–5 days and 2–3 weeks and at formal interviews at three months, patients completed VAS and the McGill Pain questionnaire, indicated whether activities of daily living had been restored and were asked if their usual pain was present and if they required further treatment for pain. After three months and after outcome measures were recorded, patients who did not have any relief of pain or who had early return of pain were offered RF. Those who obtained relief at three months were asked to report when pain returned to 50% or more of pretreatment level. They were interviewed again at one year. 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.

Aydin et al. published a meta-analysis of RF ablation (RFA) for SI pain in 2010. Nine studies were included that reported the primary outcome measure of a reduction of pain of 50% or greater, including 1 randomized placebo controlled study, 3 prospective observational studies, and 5 retrospective studies. All of the studies

used injection of local anesthetic to determine if RFA was indicated for the patient. Seven studies reported follow-up to 3 months, and 6 studies reported follow-up to 6 months. Meta-analysis indicated that half or greater of the patients who received RFA to the SI joint showed a reduction in their pain of 50% or more at 3 and 6 months. Analysis found no evidence of publication bias, but heterogeneity in studies was observed for the 6-month follow-up. This systematic review is limited by the low quality of included studies and lack of RCTs. In addition, as noted by the authors, no standards have been established for the specific nerves to ablate or type of technique.

Two small RCTs were identified for this literature review. The first was published in 2008 and was the single RCT included in the systematic review. This study examined the effect of lateral branch RF denervation with a cooled probe in 28 patients with injection-diagnosed SI joint pain. Two of 14 patients (14%) in the placebo-control group reported pain relief at 1-month follow-up. None reported benefit at 3-month follow-up. Of the 14 patients treated with RF denervation, 11 (79%) reported pain relief at 1 month, 9 (64%) at 3 months, and 8 (57%) at 6 months.

In 2012, Patel et al. reported a randomized double-blind placebo-controlled trial of lateral branch neurotomy with a cooled RF probe. Fifty-one patients who had a positive response to 2 lateral branch blocks were randomized in a 2:1 ratio to lateral branch RF or sham. At 3- month follow-up, significant improvements in pain (-2.4 vs. -0.8), physical function (14 vs. 3), disability (- 11 vs. 2), and quality of life (0.09 vs. 0.02) were observed for RF treatment compared to controls (all respectively). With treatment success defined as a 50% or greater reduction in the numerical rating scale (NRS), 47% of RF-treated patients and 12% of sham patients achieved treatment success. The treatment response was durable out to 9 months.

Repeat Procedures
Two reports of small (20 and 24 patients) retrospective studies of repeat procedures after successful RF were identified from 2004 and 2008. In both 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.

Pulsed Radiofrequency Facet Denervation
One small RCT that compared pulsed RF to sham treatment and two studies that compared continuous RF and pulsed RF were identified.

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 11 patients in the treatment arm and 4 of 12 in the sham arm showed at least 50% improvement on GPE ($p = 0.03$), and 9 of 11 in the treatment group and 3 of 12 in the sham group achieved at least 20% reduction in pain on VAS ($p = 0.02$). At 6-month follow-up, more patients in the treatment group reduced their use of pain medication, but the difference was not significant. There was a trend toward

more positive outcomes in the pulsed RF group on quality-of-life scores. The authors concluded that pulsed RF may provide pain relief for a limited number of carefully selected patients.

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. 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 and others compared the efficacy of continuous versus pulsed RF in the treatment of lumbar facet syndrome in an RCT with 50 patients. Outcome measures, pain on VAS and Oswestry Low Back Pain and Disability Questionnaire (OSW), were administered at baseline and three months after treatment and relative percentage improvement compared between groups. 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.

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. 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 concluded 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.

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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 equal to or greater than 50% 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 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 two years. Sarapin did not affect the outcome, and the data were reported only for the two 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 1719 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 5-6 treatments over the course of the study. At 2-year follow-up, significant pain relief ($\geq$ 50%) was observed in 85% of the patients treated with bupivacaine alone and 90% of the patients treated with bupivacaine and steroid. The proportion of patients with significant functional status improvement ($\geq$ 40% on the ODI) was 87% for bupivacaine and 88% for the control group. The average duration of pain relief with each procedure was 19 weeks. There was no significant change in opioid intake. Twenty-four month results were missing for 20% of the subjects. Sensitivity analysis of Numeric 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 from the randomized double-blind trial of the efficacy of thoracic medial branch blocks. 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 ($\geq$ 50%) at 12 months. The average relief per procedure was 16 weeks for

bupivacaine and 14 weeks for bupivacaine plus betamethasone. There was no significant change in the intake of opioids.

Conclusions
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.

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers
In response to requests, input was received from four physician specialty societies and five academic medical centers (six responses) while this policy was under review in 2010. 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. The input supported the policy statements. Those providing input supported use of two diagnostic blocks achieving a 50% reduction in pain.

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

While evidence is limited to a few comparative studies with small sample sizes, RF facet denervation appears to provide at least 50% pain relief in carefully selected patients. Diagnosis of facet joint pain is difficult, however, response to controlled medial branch blocks and the presence of tenderness over the facet joint appear to be reliable predictors of success.

When RF facet denervation is successful, repeat treatments appear to have similar success rates and duration of pain relief. Thus, the data indicate that in carefully selected individuals with lumbar or cervical facet joint pain, RF treatments can result in improved outcomes.

For RF ablation, there are two small RCTs that report short-term benefit, but these are insufficient to determine the overall effect on health outcomes. Further high-quality controlled trials are needed that compare specific procedures in defined populations to placebo and to alternative treatments. Case series are inadequate evidence due to the variable natural history of back pain, the presence of confounders of outcome, and the potential for a placebo effect.

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Pulsed RF does not appear to be as effective as non-pulsed RF denervation, and there is insufficient evidence to evaluate the efficacy of laser denervation 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.

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Code Type	Code
CPT	64633, 64634, 64635, 64636, 64999
HCPCS	No code
ICD-9 Diagnosis	All diagnoses
ICD-9 Procedure	03.96

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12/06/2006	Medical Director review
12/20/2006	Medical Policy Committee approval
12/03/2008	Medical Director review
12/17/2008	Medical Policy Committee approval. No change to coverage.
12/01/2010	Medical Policy Committee review
12/15/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/12/2012	Medical Policy Committee review
04/25/2012	Medical Policy Implementation Committee approval. Policy name changed to "Facet Joint Denervation." Policy extensively rewritten. Coverage for radiofrequency denervation of cervical facet joints (C3-4 and below) and lumbar facet joints was added with criteria. When there has been a prior successful radiofrequency (RF) denervation, additional diagnostic medial branch blocks for the same level of the spine is considered not medically necessary. Radiofrequency denervation 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 is considered investigational. All other methods of denervation for the treatment of chronic spinal/back pain, including, but not limited to pulsed radiofrequency denervation, laser denervation, and cryodenervation is considered investigational. Therapeutic medial branch blocks is considered investigational. The use of radiofrequency denervation of cervical facet joints (C3-4 and below) and lumbar facet joints when patient selection criteria are not met is investigational.
03/07/2013	Medical Policy Committee review
03/20/2013	Medical Policy Implementation Committee approval. Policy title changed from "Facet Joint Denervation" to "Radiofrequency Denervation". Removed "(C3-4 and below)" from the eligible for coverage statement. Chemodenervation added to the investigational policy statement.
12/12/2013	Medical Policy Committee review
12/18/2013	Medical Policy Implementation Committee approval. Removed criteria bullet, "no spinal fusion surgery in the vertebral level being treated".

Next Scheduled Review Date: 12/2014

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*****Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. in accordance with nationally accepted standards of medical practice;
B. clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and 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.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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