

Medical Policy



Title: Facet Joint Denervation (Cervical and Lumbar)

Professional

Original Effective Date: October 18, 2004
Last Review: January 2010
Revision Date(s): September 7, 2005;
February 21, 2006; May 6, 2006;
July 27, 2006; September 14, 2006;
October 31, 2006; January 1, 2007;
November 18, 2009, February 8, 2010;
April 4, 2011; January 1, 2012;
December 2, 2013
Current Effective Date: December 2, 2013

Institutional

Original Effective Date: July 1, 2005
Last Review: January 2010
Revision Date(s): September 7, 2005;
February 21, 2006; May 6, 2006;
July 27, 2006; September 14, 2006;
October 31, 2006; January 1, 2007;
November 18, 2009; February 8, 2010;
April 4, 2011; January 1, 2012;
December 2, 2013
Current Effective Date: December 2, 2013

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DESCRIPTION

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

energy is directed may be referred to as facet joint, facet nerves, medial nerve or branch, median nerve or branch, or dorsal root ganglion.

Background

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

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

Regulatory Status

A number of radiofrequency generators and probes have been cleared for marketing through the U.S. Food and Drug Administration's (FDA) 510(k) process. One device, the SInergy® by Kimberly Clark/Baylis, is a water-cooled single-use probe that received FDA clearance in 2005, listing the Baylis Pain Management Probe as a predicate device. The intended use is in conjunction with a radiofrequency generator to create radiofrequency lesions in nervous tissue.

POLICY

- A. Non-pulsed-radiofrequency denervation of cervical facet joints (C3-4 and below) and lumbar facet joints is considered **medically necessary** when ALL of the following criteria are met:
1. No prior spinal fusion surgery in the vertebral level being treated
and
 2. 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
 3. 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
and

4. There has been a successful trial of controlled medial branch blocks (See Policy Guidelines)
and
 5. If there has been a prior successful radiofrequency (RF) denervation, a minimum time of six (6) months has elapsed since prior RF treatment (per side, per anatomical level of the spine).
- B. Radiofrequency denervation is considered **experimental / investigational** for the treatment of chronic spinal / back pain for all uses that do not meet the criteria listed above, including but not limited to treatment of thoracic facet joint pain.
- C. All other methods of denervation are considered **experimental / investigational** for the treatment of chronic spinal / back pain, including, but not limited to pulsed radiofrequency denervation, laser denervation, chemodenervation (e.g., alcohol, phenol, or high-concentration local anesthetics), and cryodenervation.
- D. Therapeutic medial branch blocks are considered **experimental / investigational**.
- E. If there has been a prior successful radiofrequency (RF) denervation, additional diagnostic medial branch blocks for the same level of the spine are **not medically necessary**.

Policy Guidelines

A successful trial of controlled diagnostic medial branch blocks consists of:

1. 2 separate positive blocks on different days with local anesthetic only (no steroids or other drugs), or
2. a placebo controlled series of blocks, under fluoroscopic guidance, that has resulted in at least a 50% reduction in pain for the duration of the local anesthetic used (e.g., 3 hours longer with bupivacaine than lidocaine).

No therapeutic intra-articular injections (i.e., steroids, saline, or other substances) should be administered for a period of at least 4 weeks prior to the diagnostic medial branch block. The diagnostic blocks should involve the levels being considered for RF treatment and should not be conducted under intravenous sedation unless specifically indicated (e.g., the patient is unable to cooperate with the procedure). These diagnostic blocks should be targeted to the likely pain generator. Single level blocks lead to more precise diagnostic information, but multiple single level blocks require several visits and additional exposure to radiation.

RATIONALE

The most recent literature update was performed through September 5, 2013.

Although radiofrequency (RF) facet denervation has been in use for more than 20 years, evidence of its efficacy is limited to small randomized controlled trials (RCTs) and to larger case

series. Comparative studies are important for treatments in which the primary outcome is a measurement of pain in order to account for the potential placebo effect of an intervention.

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 radiofrequency 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.” (1) 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.” (2) A 2008 review of diagnostic utility and therapeutic effectiveness of thoracic facet joint interventions found 2 studies of low quality (retrospective evaluation without a comparative group, lack of diagnosis by controlled blocks, small number of patients, without adequate outcome measures). (3) Karnezis found limited evidence of the value of facet neurotomy. (4) 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 randomized controlled trials (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. (5) A 2008 review that considered only RCTs in which at least 1 diagnostic block was used for patient selection concluded that “when done with proper technique, percutaneous radiofrequency lumbar and cervical medial branch neurotomy are both effective.” (6)

In 2009, Chou et al. published a review of the evidence for nonsurgical interventions for low back pain for an American Pain Society guideline. (7) 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. (8) 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. (9)

In 2012, Falco and colleagues updated their systematic reviews on the diagnosis and treatment of facet joint pain. (10-13) They found good evidence for diagnostic nerve blocks with at least 75% pain relief as the criterion standard but 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 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 (8, 9) 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. (14) 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 3 academic medical centers on 92 patients with chronic neck pain who received RF treatment. (15) 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. (16) 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. (17) 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 2 hours) were followed up with a 0.25% bupivacaine block 3-4 weeks after the first injection. After bupivacaine block, pain relief had to last at least 3 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 bupivacaine blocks; 152 responded positively to bupivacaine block, were treated with RF neurotomy or medial branch blocks and were followed for 2 years. After 2 years of follow-up 136 (89%) of the 152 patients with positive response to bupivacaine 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 1) anesthetic blocks are not a valid test to diagnose facet joint pain and 2) the treatment effect and cost-effectiveness of anesthetic medial branch blocks are unknown.” (18) 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 (2 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. (19)

In 2010, Cohen and colleagues reported a multicenter randomized cost-effectiveness trial comparing 0, 1, or 2 diagnostic blocks before lumbar facet RF denervation. (20) Included in the study were 151 patients with predominantly axial low back pain equal to or greater than 3 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 2 medial 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. (20) 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 blocks using 0.5 mL versus 7 occurrences in 6 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 5 instances using 0.5 mL and in 2 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.

In a 2010 report, Manchikanti et al. compared outcomes of 110 patients who underwent facet nerve blocks and had 2 years of follow-up after meeting positive criteria of 50% relief. (21) At the end of 1 year, the diagnosis of lumbar facet joint pain was confirmed (by sustained relief of pain and improved function) by 75% of patients in the group with 50% relief from diagnostic blocks versus 93% in the group with 80% relief. At 2 years, the diagnosis was sustained in 51% of patients in the group with 50% relief, and sustained in 89.5% of patients who reported 80% relief from diagnostic blocks. 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

RCTs that evaluated RF for low back pain reached different conclusions. In 2005, van Wijk et al. published a multicenter RCT. (22) Inclusion criteria were continuous low back pain with or without radiating pain into the upper leg for more than 6 months and with focal tenderness over the facet joints, without sensory or motor deficits or positive straight leg raising test, no indication for low back surgery, and 50% or greater pain reduction 30 minutes after lidocaine block. Of 226 patients screened, 81 were randomly assigned to RF (n=40) or sham (n=41) lesion treatment. 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 3 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 3 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 3 months was difficult to interpret.

Nath and colleagues performed an RCT with 40 patients to evaluate short- and intermediate-term effects of RF for lumbar facet pain. (23) To be included in the study, patients had to be able to identify at least 1 component of their pain that was attributable to 1 or more lumbar zygapophysial joints, have paravertebral tenderness, and obtain at least 80% relief of pain following controlled (3 positive separate) medial branch blocks. Screening medial branch blocks were performed in 376 patients; 115 were negative, 261 patients had greater than 80% relief of at least 1 component of their pain and proceeded to controlled blocks; 45 had a negative response to controlled blocks, 105 had prolonged responses, and 71 of the remaining lived too far away to participate or declined. The 40 remaining were randomly assigned, half to RF and half to sham treatment; all participated throughout the 6-month study. Multiple lesions were performed in each RF patient. Pretreatment, the RF group had significantly more generalized pain, low back pain, and referred pain to the leg. On patient's own global assessment, the RF group improved by 1.1 U and the placebo group by 0.3 U ($p=0.004$). Generalized pain on VAS was reduced by 1.9 U (from 6.3 to 4.1) in the RF group versus 0.4 U (from 4.4 to 4.8) for placebo ($p=0.02$). Back pain was reduced in the RF group by 2.1 U (from 5.98 to 3.88) and referred pain by 1.6 U (from 4.33 to 2.73), while back pain was reduced in the placebo group by 0.7 U (from 4.38 to 3.68) and referred pain by 0.13 (from 2.68 to 2.55); between group differences were significant on both measures. RF patients were significantly more improved on secondary measures of back and hip movement, quality-of-life variables, the sacroiliac joint test,

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

A 2013 RCT by Lakemeir et al. compared RF facet joint denervation versus intra-articular steroid injections in 56 patients in a randomized double-blind trial. (24) 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 6 months, there was no significant difference between the 2 groups, although it is not clear if the mean VAS scores were significantly improved in either group. The proportion of patients who achieved a 50% decrease in VAS was not reported.

The only RCT that evaluated RF for chronic cervical pain at the facet joints was published in 1995 by Lord et al. (25) 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 (3 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 3 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 3 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 3 months were asked to report when pain returned to 50% or more of pretreatment level. They were interviewed again at 1 year. Six patients in the control group and 3 in the RF group had return of pain immediately after the procedure. By 27 weeks, 1 patient in the control group and 7 in the RF group remained free of pain. Median time to return of greater than 50% of pretreatment pain was 263 days in the RF group versus 8 days in the placebo group. Two patients in the active group who had no relief of pain were found to have pain from adjacent spinal segments.

One RCT that evaluated RF for treatment of cervicogenic headache was identified. (26) 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.

Repeat Procedures

The literature consists primarily of small retrospective studies of repeat procedures after successful RF. (27, 28) In 2 series, more than 80% of patients had greater than 50% relief from repeat RF treatment, and mean duration of relief from subsequent RF treatments was comparable to the initial treatment. In a 2010 report, similar improvements in outcomes were observed following the first, second, or third RF treatments in a series of 73 patients who underwent repeat RF denervation for chronic neck or back pain. (29) 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. (30) The average duration of pain relief was estimated to be 7-9 months after the first treatment and 11.6 months after a repeated lumbar procedure.

Pulsed Radiofrequency Facet Denervation

One small RCT that compared pulsed RF to sham treatment and 2 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. (31) Success was defined as at least 50% improvement on GPE, at least 20% reduction in pain on VAS, and reduced pain medication use measured 3 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. (32) 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. (33) Outcome measures, pain on VAS and Oswestry Low Back Pain and Disability Questionnaire (OSW), were administered at baseline and 3 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. (34) One year after laser denervation, 17 patients (81%) experienced greater than 70% pain reduction. In 4 patients (19%) who had previously undergone spinal surgery, the response to laser denervation was not successful. Controlled trials are needed to evaluate this technique.

Alcohol Ablation

Joo et al. compared alcohol ablation with RF ablation in a randomized study of 40 patients with recurrent thoracolumbar facet joint pain following an initial successful RF neurotomy. (35) At 24-month follow-up, 3 patients in the alcohol ablation group had recurring pain compared to 19 in

the RF group. The median effective periods were 10.7 months (range 5.4 to 24) for RF and 24 months (range 16.8 to 24) for alcohol ablation. No significant complications were identified. Given the possibility of harm as described in professional society recommendations on chemical denervation (see below), additional study is needed.

Facet Debridement

Haufe and Mork reported endoscopic facet debridement in a series of 174 patients with cervical (n=45), thoracic (n=15) or lumbar (n=114) pain who had a successful response to a diagnostic medial branch nerve block. (36) The capsular tissue was removed under direct observation via laparoscopy, followed by electrocautery or holmium lasers to completely remove the capsular region. Treatment was given on a single occasion, with most patients requiring treatment of 4 joints. At a minimum of 3 years' follow-up, 77%, 73%, and 68% of patients with cervical, thoracic, or lumbar disease, respectively, showed at least 50% improvement in pain, measured by a VAS). As noted by the authors, large-scale RCTs are needed to evaluate the efficacy of this treatment approach.

Therapeutic Facet Joint Nerve Blocks

Medial branch nerve blocks have also been evaluated as a therapeutic intervention. However, no RCTs were identified that compared anesthetic nerve blocks with placebo injections. Placebo-controlled studies are important for treatments for which the primary outcome is a measurement of pain in order to account for the potential placebo effect of an intervention.

Three randomized double-blind controlled trials were identified from Manchikanti et al. in 2010 that compared the therapeutic effect of medial branch blocks with bupivacaine alone to bupivacaine and steroid (betamethasone). (37-39) Patients included had a diagnosis of facet joint pain (cervical, thoracic, and lumbar) with an 80% reduction in pain following 2 diagnostic anesthetic blocks of the medial branches. Patient outcomes were measured at 3, 6, 12, 18, and 24 months with a Numeric Rating Scale for pain and with the ODI. Significant pain relief was considered to be a decrease of 50% or greater on the Numeric Rating Scale. Opioid intake and work status were also evaluated.

Cervical. One of the randomized trials included 120 patients meeting the diagnostic criteria for cervical facet joint pain. (37) The 2 groups were further subdivided, with half of the patients in each group receiving Sarapin. Patients were followed at 3-month intervals, and the cervical medial branch blocks were repeated only when reported pain levels decreased to below 50%, with significant pain relief after the previous block. Injections were repeated an average of 5.7 times over a period of 2 years. Sarapin did not affect the outcome, and the data were reported only for the 2 main conditions. At 2-year follow-up, 85% of patients in the bupivacaine group and 93% of patients in the steroid group were reported to have significant pain relief, based on intent-to-treat analysis. The average duration of pain relief with each procedure was 17 to 19 weeks. At least 50% improvement in the Neck Disability Index was seen in 70% of patients in the bupivacaine group and 75% of patients in the bupivacaine plus steroid group. There was no significant change in the intake of opioids. There was a loss of 38% of data for the 24-month evaluation. Sensitivity analysis using the last follow-up score, best case scenario, and worst case scenario were not significantly different, and intent-to-treat analysis with the last follow-up visit was utilized.

Lumbar. A second randomized double-blind trial by Manchikanti and colleagues evaluated the efficacy of facet joint nerve blocks in 120 patients with chronic low back pain. (38) In addition to

the 2 main conditions, half of the patients in each group received Sarapin. Sarapin did not affect the outcome and the data were reported only for the 2 main conditions. Patients received about 5-6 treatments over the course of the study. At 2-year follow-up, significant pain relief (>50%) was observed in 85% of the patients treated with bupivacaine alone and 90% of the patients treated with bupivacaine and steroid. The proportion of patients with significant functional status improvement (>40% on the ODI) was 87% for bupivacaine and 88% for the control group. The average duration of pain relief with each procedure was 19 weeks. There was no significant change in opioid intake. Twenty-four month results were missing for 20% of the subjects. Sensitivity analysis of Numeric Pain Rating scores using the last follow-up score, best case scenario, and worst case scenario were not significantly different.

Thoracic. One-year results were reported in 2010 and 2-year results reported in 2012 from the randomized double-blind trial of the efficacy of thoracic medial branch blocks performed under fluoroscopy. (39, 40) The 100 patients in this study received an average of 3.5 treatments per year. Intent-to-treat analysis at 12 months showed a decrease in average pain scores from 7.9 at baseline to 3.2 in the bupivacaine group and from 7.8 to 3.1 in the bupivacaine plus steroid group. At least 50% improvement in the ODI was observed in 80% and 84% of participants, respectively. In both groups, 90% of participants showed significant pain relief (>50%) at 12 months. The average relief per procedure was 16 weeks for bupivacaine and 14 weeks for bupivacaine plus betamethasone. There was no significant change in the intake of opioids. Efficacy remained the same at 2-years' follow-up, with 80% of patients in the bupivacaine group and 84% of patients in the bupivacaine plus steroid group continuing to show improvement in the ODI by 50% or more. The average number of procedures over the 2 years was 5.6 for bupivacaine and 6.2 for bupivacaine plus steroids.

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

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 4 physician specialty societies and 5 academic medical centers (6 responses) while this policy was under review in 2010. The input supported the policy statements. Those providing input supported use of 2 diagnostic blocks achieving a 50% reduction in pain.

Summary

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 2 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.

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

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

Practice Guidelines and Position Statements

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. (41) Diagnostic lumbar facet joint nerve blocks were recommended in patients with suspected facet joint pain, based on good evidence for diagnostic lumbar facet joint nerve blocks with 75% to 100% pain relief as criterion standard. For the treatment of facet joint pain, evidence was considered to be good for conventional radiofrequency, limited for pulsed radiofrequency, fair to good for lumbar facet joint nerve blocks and limited for intraarticular injections. Based on the evidence review, ASIPP recommends treatment with conventional radiofrequency neurotomy or therapeutic facet joint nerve blocks.

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. (42) 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. (7)

The United Kingdom's National Institute for Health and Clinical Excellence (NICE) 2009 guidelines on the early management of non-specific low back pain states that people should not be referred for radiofrequency facet joint denervation. (43)

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. (44)

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT/HCPCS

64633	Destruction by neurolytic agent, paravertebral facet joint nerve(s) with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint
64634	Destruction by neurolytic agent, paravertebral facet joint nerve(s) with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional facet joint (List separately in addition to code for primary procedure)
64635	Destruction by neurolytic agent, paravertebral facet joint nerve(s) with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint
64636	Destruction by neurolytic agent, paravertebral facet joint nerve(s) with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional facet joint (List separately in addition to code for primary procedure)
64999	Unlisted procedure, nervous system
77003	Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinous diagnostic or therapeutic injection procedures (epidural, subarachnoid)

- Effective for 2012, there are new codes for facet joint denervation that include the CT or fluoroscopic imaging guidance: 64633, 64634, 64635, 64636.
- The American Medical Association's CPT Editorial Panel decided in June 2005 that the unlisted CPT code 64999 should be used for pulsed RF treatment as opposed to other specific codes.

ICD-9 Diagnoses

721.0	Cervical spondylosis without myelopathy
721.1	Cervical spondylosis with myelopathy
721.3	Lumbosacral spondylosis without myelopathy
721.42	Spondylosis with myelopathy; lumbar region
722.81	Postlaminectomy syndrome; cervical region
722.83	Postlaminectomy syndrome; lumbar region
723.1	Cervicalgia
724.2	Lumbago

ICD-10 Diagnoses (Effective October 1, 2014)

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

REVISIONS

02-08-2010	The Facet Joint Denervation medical policy is a new freestanding policy developed from the Minimally Invasive Procedures for Spine Pain medical policy which was effective October 18, 2004. The Minimally Invasive Procedures for Spine Pain is no longer an active medical policy.
04-04-2011	Description section updated
	Policy Guidelines section added
	Rationale section updated
	In Coding section: <ul style="list-style-type: none"> ▪ Updated wording for 77003
	References section updated
01-01-2012	In Coding section: <ul style="list-style-type: none"> ▪ Removed CPT Codes: 64622, 64623, 64626, 64627 ▪ Added CPT Codes: 64633, 64634, 64635, 64636
12-02-2013	Revised Title from "Facet Joint Denervation" to "Facet Joint Denervation (Cervical and Lumbar)
	Description section updated
	In Policy section: <ul style="list-style-type: none"> ▪ Revised A from "Facet joint denervation (percutaneous radiofrequency facet denervation, percutaneous radiofrequency facet ablation, facet rhizotomy, facet thermocoagulation) of cervical facet joints (C3-4 and below) and lumbar facet joints is considered medically necessary when ALL of the following criteria are met:" to "Non-pulsed radiofrequency denervation of cervical facet joints (C3-4 and below) and lumbar facet joints is considered medically necessary when ALL of the following criteria are met:" ▪ Added to Item A 2 "disabling" to read "Disabling low back (lumbosacral) or neck (cervical) pain, suggestive of facet joint origin as evidenced by absence of nerve root compression as documented in the medical record on history, physical and radiographic evaluations; and the pain is not radicular"

	<ul style="list-style-type: none"> ▪ Revised Item A 4 from "A trial of controlled diagnostic medial branch blocks (See Policy Guidelines) under fluoroscopic guidance has resulted in at least a 50% reduction in pain;"to "There has been a successful trial of controlled medial branch blocks (See Policy Guidelines)" ▪ Revised Item B from, "Facet joint denervation (percutaneous Radiofrequency facet denervation, percutaneous radiofrequency facet ablation, facet rhizotomy, facet thermocoagulation) is considered experimental / investigational for the treatment of chronic spinal / back pain for all uses that do not meet the criteria listed above, including but not limited to treatment of thoracic facet or sacroiliac (SI) joint pain." to "Radiofrequency denervation is considered experimental / investigational for the treatment of chronic spinal / back pain for all uses that do not meet the criteria listed above, including but not limited to treatment of thoracic facet joint pain." ▪ Revised Item C from, "Pulsed radiofrequency denervation is considered experimental / investigational for the treatment of chronic spinal / back pain." to "All other methods of denervation are considered experimental / investigational for the treatment of chronic spinal / back pain, including, but not limited to pulsed radiofrequency denervation, laser denervation, chemodenervation (e.g., alcohol, phenol, or high-concentration local anesthetics), and cryodenervation." ▪ Added Item D, "Therapeutic medial branch blocks are considered experimental / investigational." ▪ Added Item E, "If there has been a prior successful radiofrequency (RF) denervation, additional diagnostic medial branch blocks for the same level of the spine are not medically necessary."
	<p>In Policy Guidelines: Revised from, "The diagnostic blocks should involve the levels being considered for RF treatment. These diagnostic blocks should be targeted to the likely pain generator. Single level blocks lead to more precise diagnostic information, but multiple single level blocks require several visits and additional exposure to radiation." to, "A successful trial of controlled diagnostic medial branch blocks consists of:</p> <ol style="list-style-type: none"> 1. 2 separate positive blocks on different days with local anesthetic only (no steroids or other drugs), or 2. a placebo controlled series of blocks, under fluoroscopic guidance, that has resulted in at least a 50% reduction in pain for the duration of the local anesthetic used (e.g., 3 hours longer with bupivacaine than lidocaine). <p>No therapeutic intra-articular injections (i.e., steroids, saline, or other substances) should be administered for a period of at least 4 weeks prior to the diagnostic medial branch block. The diagnostic blocks should involve the levels being considered for RF treatment and should not be conducted under intravenous sedation unless specifically indicated (e.g., the patient is unable to cooperate with the procedure). These diagnostic blocks should be targeted to the likely pain generator. Single level blocks lead to more precise diagnostic information, but multiple single level blocks require several visits and additional exposure to radiation."</p>
	<p>Rationale section updated</p>

	<p>In Coding section:</p> <ul style="list-style-type: none"> ▪ Nomenclature updated on CPT codes: 64636, 77003 ▪ Nomenclature updated on ICD-9 codes: 722.82, 722.83 ▪ Removed ICD-9 codes: 721.2, 721.41, 722.82, 724.1 ▪ ICD-10 Codes added
	Referenced updated

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