

ABLATIVE TREATMENT FOR SPINAL PAIN

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Related Policies:

- [Epidural Steroid and Facet Injections for Spinal Pain](#)
- [Discogenic Pain Treatment](#)
- [Occipital Neuralgia and Headache Treatment](#)

INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD) and Medicaid State Contracts) may differ greatly from the standard benefit plans upon which this Medical Policy is based. In the event of a conflict, the enrollee's specific benefit document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the enrollee specific plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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BENEFIT CONSIDERATIONS

Essential Health Benefits for Individual and Small Group:

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this guideline, it is important to refer to the enrollee's specific plan document to determine benefit coverage.

COVERAGE RATIONALE

Thermal radiofrequency ablation of facet joint nerves is proven and medically necessary for chronic cervical, thoracic and lumbar pain when confirmed by:

- Temperature 60 degrees Celsius or more
- Duration of ablation 40 - 90 seconds
- Positive response to medial branch block injection at the side and level of the proposed ablation **and**
- Confirmation of needle placement by fluoroscopic guided imaging

Thermal radiofrequency ablation is proven and medically necessary:

- When performed at a frequency of six months or longer (maximum of 2 times over a 12 month period) **and**
- Provided there has been a 50% or greater documented reduction in pain for 10 to 12 weeks

Thermal radiofrequency ablation is unproven and not medically necessary:

- When performed more frequently than every six months; or
- When there has been no significant improvement after medial branch block injection

Ablation procedures performed more frequently than every 6 months increase the risk of adverse events without improving the clinical outcome.

Documentation requirements for the aforementioned procedures must include:

- Temperature of administration of procedure
- Duration of ablation
- Specific identification of side and level of medial branch blocks
- Specific cervical, thoracic and/or lumbar ablated by side and level
- Percentage of pain relief with prior ablation if applicable
- Duration of improvement from previous ablation if applicable.

For additional information regarding frequency guidelines click [here](#).

Thermal radiofrequency ablation is unproven and not medically necessary for the treatment of all other causes of spinal pain including but not limited to the following:

- Diabetic neuropathy
- Sacroiliac pain
- Complex regional pain syndrome or regional pain disorders and syndromes in the absence of spinal pain
- Definitive clinical and/or imaging findings identifying a condition requiring surgical treatment
- Identified specific causes of spinal pain (e.g., disc herniation) requiring definitive treatment

Studies of radiofrequency ablation for other conditions were limited, uncontrolled, and insufficient to support conclusions regarding efficacy or duration of effect. Additional well-designed, longer-term randomized controlled trials are required to evaluate the safety and efficacy of radiofrequency ablation and to compare this technique with other medical or surgical therapies for pain.

The following ablation procedures are unproven and not medically necessary for the treatment of spinal pain:

- Pulsed radiofrequency therapy of the facet nerves of the cervical, thoracic, or lumbar region, sacral nerve root or dorsal root ganglion.
- Radiofrequency ablation with temperature less than 60 degrees Celsius

- Endoscopic radiofrequency ablation (rhizotomy)
- Cryoablation (cryodenervation, cryoneurolysis, cryosurgery, or cryoanesthesia)
- Chemical ablation (including but not limited to alcohol, phenol or sodium morrhuate)
- Laser ablation (including pulsed, continuous, or low level)

There is insufficient evidence to establish the efficacy of the ablation therapies bulleted immediately above to reduce or relieve spinal pain. Studies are limited by small sample size and lack of long term follow-up. Additional well designed studies are needed to establish the efficacy of these procedures.

APPLICABLE CODES

The Current Procedural Terminology (CPT[®]) codes and Healthcare Common Procedure Coding System (HCPCS) codes listed in this policy are for reference purposes only. Listing of a service code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the enrollee specific benefit document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other policies and coverage determination guidelines may apply. This list of codes may not be all inclusive.

CPT [®] Code	Description
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 paraspinal diagnostic or therapeutic injection procedures (epidural or subarachnoid)

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Coding Clarification

CPT codes 64633, 64634, 64635, and 64636 only apply to thermal radiofrequency ablation. CPT code 64999 is to be used for pulsed radiofrequency ablation.

Question: What is the appropriate code to report for pulsed radiofrequency (PRF)?

AMA Comment: Currently, there is not a specific CPT code that accurately describes PRF.

Therefore, the unlisted code 64999, Unlisted procedure, nervous system, should be reported. It should also be noted that it is not appropriate to report Destruction by Neurolytic Agent codes 64600-64681 for PRF. When reporting an unlisted code to describe a procedure or service, it will be necessary to submit supporting documentation (eg, procedure report) along with the claim to provide an adequate description of the nature; extent; need for the procedure; and the time, effort, and equipment necessary to provide the service.

DESCRIPTION OF SERVICES

There are two types of radiofrequency ablation, thermal or non-pulsed and pulsed. Thermal ablation involves the percutaneous placement of a needle or electrode that destroys the bone lesion or nerves around the facet joint. Once the probe is placed, lesions or nerves are then targeted unilaterally or bilaterally for 40 to 90 seconds at temperatures of 60 to 90°C. The other type of radiofrequency ablation is pulsed RFA (PRFA) which has been introduced as a nonablative alternative to RFA. Pulsed radiofrequency ablation delivers short bursts of radiofrequency current rather than the continuous flow utilized in standard RFA. Pulsed radiofrequency ablation allows the tissue to cool between bursts. This technique is reported to reduce the risk of destruction of neighboring tissue. It does not destroy targeted nerves and therefore requires less precise electrode placement.

Recently, a posterior endoscopic method also known as dorsal endoscopic rhizotomy has been developed as alternative to percutaneous electrode radiofrequency ablation to target the medial, intermediate and lateral branches of the dorsal ramus using a modification of the Yeung Endoscopic Spinal Surgery (Y.E.S.S.) cannula and a specially designed Ellman radiofrequency bipolar electrode.

Cryoablation is a minimally invasive procedure that involves the use of extreme cold to destroy abnormal tissue.

Percutaneous alcohol ablation (PAA) is a neurolytic procedure that involves directing an injection needle through the skin to the specific nerve or nerve plexus that transmits signals for the problematic pain and injecting a solution of 50% to 100% ethyl alcohol, or ethanol, into the target nerve tissue in order to destroy that tissue. The damage to nerve tissue reduces its ability to transmit pain signals, thereby reducing pain sensation.

Laser ablation involves the removal of material from a solid (or occasionally liquid) surface by irradiating it with a laser beam. Usually, laser ablation refers to removing material with a pulsed laser, but it is possible to ablate material with a continuous wave laser beam if the laser intensity is high enough.

CLINICAL EVIDENCE

Thermal Radiofrequency Ablation for Sacroiliac Pain

In a systematic review, Hansen and colleagues (2012) evaluated the effectiveness of thermal radiofrequency ablation of the sacro-iliac joint (SIJ). The quality assessment and clinical relevance criteria utilized were the Cochrane Musculoskeletal Review Group criteria for randomized trials of interventional techniques and the criteria developed by the Newcastle-Ottawa Scale for observational studies. The level of evidence was classified as good, fair, or poor based on the definitions developed by the U.S. Preventive Services Task Force (USPSTF). Data sources included relevant literature published from 1966 through December 2011 that was identified through searches of PubMed and EMBASE, and manual searches of the bibliographies of known primary and review articles. The primary outcome measure was pain relief (short-term relief = up to 6 months and long-term relief = greater than 6 months). The authors concluded that the evidence was fair in favor of cooled RF neurotomy and poor for short-term and long-term PRF, and conventional RF neurotomy.

A 2012 Hayes Directory Report on Radiofrequency Ablation for Sacroiliac Joint Pain states that although the data is insufficient to draw any definitive conclusions about the efficacy and safety of radiofrequency ablation (RFA) in patients with sacroiliac (SI) joint pain, there is some limited evidence that conventional RFA can provide short-term (3 to 6 months) pain relief in patients who have SI joint pain that is responsive to injection of local anesthetic. Several studies suggest that cooled RFA may have a pain-relieving effect that is comparable to that of conventional RFA, although the evidence is too sparse to support conclusions about the relative

efficacy of the two techniques. Data from a single study of pulsed RFA are insufficient to evaluate the efficacy of this technique. No serious safety issues were reported in the studies, although patients often reported increased pain for a period of days after the RFA procedure.

A review of clinical evidence by Boswell et al. (2007) found that the evidence for radiofrequency neurotomy for sacroiliac joint pain is limited. There has not been sufficient evidence to effectively evaluate the efficacy of radiofrequency ablation of the sacroiliac joint.

Aydin et al. (2010) conducted a meta-analysis to assess the effectiveness of radiofrequency ablation of the sacroiliac joint for pain relief. While it appears that patients had > 50% pain relief at both 3 and 6 months post-treatment, the study was limited by variability between each study and lack of randomized controlled trials to evaluate the use of radiofrequency ablation of the sacroiliac joint. The authors concluded that further studies are needed, preferably randomized controlled studies, to evaluate whether radiofrequency ablation improves health outcomes in patients with sacroiliac joint pain.

Cohen et al. (2008) conducted a randomized placebo-controlled study in 28 patients with injection-diagnosed sacroiliac joint pain. Patients were randomized equally to receive both a L4-L5 primary dorsal rami and S1-S3 lateral branch radiofrequency denervation using cooling-probe technology after a local anesthetic block, or local anesthetic block followed by placebo denervation. Patients who did not respond to placebo injections crossed over and were treated with radiofrequency denervation using conventional technology. At 1, 3, and 6 months after the procedure, 11 (79%), 9 (64%), and 8 (57%) radiofrequency-treated patients experienced pain relief of 50% or greater and significant functional improvement. In contrast, only 2 patients (14%) in the placebo group experienced significant improvement at their 1-month follow-up, and none experienced benefit 3 months after the procedure. In the crossover group (n = 11), 7 (64%), 6 (55%), and 4 (36%) experienced improvement 1, 3, and 6 months after the procedure. One year after treatment, only 2 patients (14%) in the treatment group continued to demonstrate persistent pain relief. The authors concluded radiofrequency denervation may provide intermediate-term pain relief and functional benefit in selected patients with suspected sacroiliac joint pain; however, larger studies are needed to confirm these results and to determine the optimal candidates and treatment parameters for this disorder.

Thermal Radiofrequency Ablation for Facet Joint Pain

A systematic review concluded that there was limited evidence that radiofrequency denervation offers short-term relief for chronic neck pain and chronic cervicobrachial pain (Niemisto 2003). There was conflicting evidence on the short-term effect of RFA on pain and disability in chronic low back pain. The meta-analysis included 7 randomized controlled trials of 275 patients, 141 of whom received active treatment.

A systematic literature review of randomized controlled trials on radiofrequency ablation procedures for spinal pain performed by Geurts et al. (2001) reported moderate evidence that radiofrequency lumbar facet denervation is more effective for chronic low back pain than placebo.

In another systematic review evaluating medial branch neurotomy, Manchikanti et al. (2003) concluded that there was strong evidence for short-term pain relief and moderate evidence for long-term pain relief of chronic low back, thoracic, and neck facet joint pain.

There is conflicting evidence from randomized controlled studies regarding the efficacy of RFA for chronic low back pain. In one randomized trial, RFA of 70°C for 90 seconds did not improve facet joint pain compared with placebo treatment (Brandense 2001), whereas two randomized controlled trials documented short-term improvement of symptoms compared with the placebo procedure (Leclaire 2001, Gallagher 1994). In only 1 of these studies, symptom relief was maintained for up to 6 months (Gallagher 1994). In another study, only 1 of the 5 outcome measures was significantly improved in the active treatment group compared with the placebo group at 4 weeks, but the beneficial effect was not maintained. By 12 weeks following the

procedure, there was no statistical difference between the sham and active RFA groups for any outcome measure (Leclaire 2001).

Nath et al. (2008) conducted a randomized controlled study of percutaneous radiofrequency neurotomy in 40 patients with chronic low back pain (20 active and 20 controls). All patients were examined by an orthopaedic surgeon before and 6 months after the treatment (sham or active). Inclusion criteria were 3 separate positive facet blocks. The active treatment group showed statistically significant improvement not only in back and leg pain but also back and hip movement as well as the sacro-iliac joint test. There was significant improvement in quality of life variables, global perception of improvement, and generalized pain. The improvement seen in the active group was significantly greater than that seen in the placebo group. The investigators concluded that radiofrequency facet denervation could be used in the treatment of carefully selected patients with chronic low back pain.

Van Wijk et al. (2005) conducted a randomized double-blind, sham lesion controlled trial of 81 patients with chronic low back pain who were randomized to undergo RFA (n=40) or sham treatment (n=41). Three months after treatment, combined outcome measure indicated no difference between RFA and sham treatment. The global perceived effect was in favor of RFA.

In a randomized controlled trial conducted by Geurts et al. (2003), 83 patients were assigned to receive radiofrequency lesion treatment or sham treatment. After 3 months, 16% of RF patients and 25% of the sham group patients reported pain reduction.

A prospective study by Burnham et al. (2009) of 44 patients (101 facet joints) assessed the effect of radiofrequency denervation (RFD) for chronic low back pain (LBP) of facet joint origin. Radiofrequency ablation was delivered at 80°C for 90 seconds. Outcomes were measured at 1, 3, 6, 9, and 12 months post-RFD by self-reported pain intensity, frequency, bothersomeness, analgesic intake, satisfaction, disability, back pain–related costs, and employment with significant improvements peaking at 3 to 6 months and gradually diminished thereafter. The authors concluded that RFD provides short-term improvement in pain, analgesic requirements, and function in patients with chronic LBP of facet origin. This study is limited by short-term follow-up as well as subjective outcome measurements.

Gofeld et al. (2007) conducted a prospective audit of 174 patients with complaints of low back pain for more than 6 months. Patients were asked to estimate total perceived pain reduction (on a scale from 0% to 100%) at 6 weeks and at 6, 12, and 24 months after the procedure. Fifty-five reported no benefit from the procedure and 119 reported good (>50%) to excellent (> 80%) pain relief lasting from 6 to 24 months. The authors concluded that radiofrequency denervation of the lumbar zygapophysial joints provides long-term pain relief. This study is limited by use of subjective outcome measurements.

Barnsley (2005) investigated 35 patients with chronic neck pain who underwent radiofrequency neurotomy. Twelve patients had 2 procedures. Thirty-six of 45 assessable procedures (80%) achieved significant relief of pain. Pain relief continued after a median follow-up of 35 weeks.

The usefulness of radiofrequency ablation (RFA) was investigated in a study of 28 patients with chronic cervicobrachialgia (Shin 2006). Six months following RFA, 19 (68%) patients reported successful outcome and 8 (42%) of these patients reported complete pain relief. Four patients had recurrence of pain between 6 and 12 months.

Evidence from several small, uncontrolled studies indicated that RFA reduced thoracic spinal pain in 40% to 75% of patients (Pevsner 2003, Van Kleef 1995, Stolker 1994, Tzaan 2000). Duration of efficacy varied considerably among the trials; pain relief was maintained for over 2 years in 12% to 49% of patients (Van Kleef 1995, Stolker 1994).

Definitive patient selection criteria for RFA as a treatment for chronic spinal pain have not been established. Relative or absolute contraindications to RFA mentioned in the reviewed literature include:

- Neurologic abnormalities
- Definitive clinical and/or imaging findings
- Proven specific causes of low back pain, including disc herniation, spondylolisthesis, spondylosis ankylopoietica, spinal stenosis, discogenic or stenotic compression, malignancy, infection, and trauma
- Patients with more than one pain syndrome
- Lack of response to diagnostic nerve blocks
- Patients with unstable medical conditions or psychiatric illness (Hayes, 2007b)

American Society of Interventional Pain Physicians (ASIPP): A 2009 practice guideline states that the suggested therapeutic frequency for medial branch neurotomy should remain at intervals of at least 6 months or longer per each region (maximum of 2 times per year) between each procedure, provided that 50% or greater relief is obtained for 10 to 12 weeks. It is further suggested that all regions be treated at the same time, provided all procedures are performed safely. (Manchikanti et al. 2009)

American Society of Anesthesiologists (ASA): A 2010 guideline states that 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. Conventional radiofrequency ablation may be performed for neck pain, and water-cooled radiofrequency ablation may be used for chronic sacroiliac joint pain. Conventional or thermal radiofrequency ablation of the dorsal root ganglion should not be routinely used for the treatment of lumbar radicular pain.

Quality of Evidence and Additional Research: According to Hayes, the clinical studies of RFA for chronic spinal pain have significant methodological limitations that can affect interpretation of the data. Few randomized controlled or comparative trials of RFA with adequate sample size and follow-up duration have been published; the preponderance of the evidence is derived from small randomized controlled trials, and prospective uncontrolled studies, case series, and retrospective chart analyses. Uncertainties regarding several aspects of RFA for spinal pain necessitate additional research. Questions remain about the etiology of facet joint syndrome, the prognostic validity of diagnostic nerve blocks, standard outcome measures, the role of the placebo effect in treatment success, and the radiofrequency denervation technique. The validation of radiofrequency for chronic spinal pain management relies upon the resolution of these technical issues, as well as issues regarding patient selection and long-term efficacy. (Hayes, 2007b)

Pulsed Radiofrequency Ablation (PRFA)

Pulsed radiofrequency (PRF), a technology related to continuous radiofrequency, is unique in that it provides pain relief without causing significant damage to nervous tissue. The mechanism by which PRF controls pain is unclear, but it may involve a temperature-independent pathway mediated by a rapidly changing electrical field. Although much anecdotal evidence exists in favor of PRF, there are few well-designed, statistically robust studies substantiating its utility.

Lee et al (2011) noted that recently, clinical reports using PRFA have shown favorable effects in the treatment of a variety of focal pain areas, including non-nervous system tissues; however, the mechanism of effect underlying this treatment to non-nervous system tissue remains unclear.

A prospective study by Vallejo et al. (2006) evaluated the effect of PRFA in 126 patients with chronic low back pain due to sacroiliac joint syndrome (SIJ). The main outcome measures were visual analog scale (VAS) and quality of life (QOL) questionnaire performed prior to and after the treatment. Of the 126 patients who underwent arthrographically confirmed steroid/local anesthetic SIJ injection, 52 patients (41.3%) had > 75% pain relief after conservative treatment, while 22

patients failed to respond to the treatment. The 22 patients who failed conservative treatment underwent PRFA of the medial branch of L4, posterior primary rami of L5, and lateral branches S1 and S2. Results showed that 16 patients (72.7%) experienced good (> 50% reduction in VAS), or excellent (> 80% reduction in VAS) pain relief following PRFA. Duration of pain relief range was 6-9 weeks in four patients, 10-16 weeks in five patients, and 17-32 weeks in seven patients. In addition, QOL scores improved significantly in all measured categories. Six patients (26.1%) did not respond to PRFD and had less than 50% reduction in VAS and were considered failures. The authors concluded that PRFA may be an effective treatment for some patients with SIJ pain that has been unresponsive to other forms of treatment. This study is limited by small sample size and the uncontrolled study design.

Kroll et al. (2008) compared the efficacy of continuous radiofrequency (CRF) thermocoagulation with pulsed radiofrequency (PRF) in a prospective, randomized, double-blinded study of 50 patients with lumbar back pain. Target facet joints were identified with oblique radiographic views. Continuous radiofrequency thermocoagulation was delivered at 80°C for 75 seconds, while PRF was delivered at 42°C with a pulse duration of 20 ms and pulse rate of 2 Hz for 120 seconds. No significant differences in the relative percentage improvement were noted between groups in either visual analog scale (VAS) or Oswestry Low Back Pain and Disability Questionnaire (OSW) scores. Within the PRF group, comparisons of the relative change over time for both VAS and OSW scores were not significant. However, within the CRF group, VAS and OSW scores showed significant improvement. The investigators concluded that although there was no significant difference between CRF and PRF therapy in long-term outcome in the treatment of lumbar facet syndrome, there was a greater improvement over time noted within the CRF group.

Simopoulos et al. (2008) conducted a prospective study of 76 patients to evaluate the safety and efficacy of pulsed and continuous radiofrequency therapy of the dorsal root ganglion/segmental nerves in patients with chronic lumbosacral radicular pain. To participate in the study, all patients were first treated with a diagnostic/therapeutic selective nerve root block with temporary but complete pain relief of radicular symptoms. Patients were then randomly assigned to receive either pulsed radiofrequency therapy (n=37), at 42°C for 120 seconds, of the dorsal root ganglion/segmental nerve or pulsed radiofrequency (n=39) followed immediately by continuous radiofrequency with averaged temperatures at 54°C + (5) for 60 seconds. Follow-up occurred at 8 weeks with monthly follow-ups until 8 months post treatment. Outcomes were measured by visual analog scale (VAS). There was no significant difference in the percentage of successful response rate or in the average decline in VAS between the 2 groups. For both treatment groups there was a steep loss of analgesic effect between 2 to 4 months. By the eighth month, the vast majority of patients returned to their baseline pain intensity. The authors did not find a significant beneficial effect of adding continuous radiofrequency to pulsed radiofrequency treatment. Pulsed radiofrequency ablation may be beneficial for patients with dorsal root ganglion pain however the analgesic effect is time limited and determination of the actual efficacy of pulsed radiofrequency therapy in the treatment of chronic lumbosacral radicular pain needs additional further prospective controlled trials to further evaluate its use to treat dorsal root ganglion pain.

Abejon (2007) completed a retrospective analysis of the effectiveness of pulsed radiofrequency (PRF) applied to the lumbar dorsal root ganglion in 54 patients who underwent 75 PRF procedures. The patients were divided into three groups according to the etiology of the lesion herniated disc, spinal stenosis, and failed back surgery syndrome. The efficacy of the technique was assessed using a 10-point Numeric Rating Scale (at baseline and, along with the Global Perceived Effect (GPE) at 30, 60, 90, and 180 days. The reduction in medications and the number of complications associated with the technique were assessed although not reported. Pain reduction was noted in all groups except for those with failed back surgery syndrome. No complications were noted. The authors concluded that PRF was effective in herniated disc and spinal stenosis, but not failed back surgery syndrome. The flaws of this study include the retrospective design, subjective outcome measures and short term follow-up.

Van Zundert (2007) studied the effect of pulsed radiofrequency treatment on patients with cervical radicular pain in a prospective audit that showed satisfactory pain relief for a mean period of 9.2 months. Then a randomized sham controlled trial of 23 patients out of 256 screened, met the inclusion criteria and were randomly assigned in a double blind fashion to receive either pulsed radiofrequency for 120 seconds or sham intervention. The evaluation was done by an independent observer. At 3 months the pulsed radiofrequency group showed a significantly better outcome with regard to the global perceived effect (>50% improvement) and visual analogue scale (20 point pain reduction). The quality of life scales also showed a positive trend in favor of the pulsed radiofrequency group, but significance was only reached in the SF-36 domain vitality at 3 months. The need for pain medication was significantly reduced in the pulsed radiofrequency group after six months. No complications were observed during the study period. These study results are in agreement with the findings of a previously completed clinical audit that pulsed radiofrequency treatment of the cervical dorsal root ganglion may provide pain relief for a limited number of carefully selected patients with chronic cervical radicular pain as assessed by clinical and neurological examination. Although the study results are promising for certain patients, the small sample size, the use of subjective outcomes and lack of long term follow-up minimize the generalizations of the conclusions.

An editorial that accompanied the study by Van Zundert et al, Jensen (2007) noted that early studies show good short-term results of PRF. However, there is currently insufficient evidence to use PRF routinely for chronic cervical radicular pain. Jensen stated that more research is needed to ascertain the best way to use PRF and its analgesic mechanism. This is in agreement with the observation of Tella and Stojanovic (2007) who stated that more studies are needed to support the routine use of PRF for treating patients with chronic cervical radicular pain.

Chao et al. (2008) retrospectively reviewed 154 cases of patients with lumbar or cervical radicular pain due to a herniated intervertebral disk or previous failed surgery to analyze the efficacy of percutaneous pulsed radiofrequency. Patients had pulsed radiofrequency therapy in 2 to 4 spinal levels unilaterally with follow-up from 1 week to 1 year postoperatively. Fifty three percent of 49 patients with cervical pain and fifty percent patients with lumbar pain had an initial improvement of 50% or more in the first week of follow-up. Fifty-five percent of patients with cervical pain and forty four percent of patients with lumbar pain had pain relief of 50% or more at the 3 month follow-up. The authors concluded that pulsed radiofrequency appears to provide intermediate-term relief of pain; however, further studies with long-term follow-up are necessary. Limitations of this study include retrospective design and inability to generalize results due to wide range of follow-up. Additional well-designed studies are needed to evaluate long-term results of pulsed radiofrequency therapy.

A retrospective study by Mikeladze et al. (2003) of 114 patients cervical or lumbar facet joint pain responsive to diagnostic medial branch blocks and subsequently treated with PRF at 42°C for 120 seconds found that 68 patients had significant pain relief (> 50% pain reduction) that lasted an average of nearly 4 months. Eighteen patients had the procedure repeated with the same duration of pain relief that was achieved initially. The authors concluded that due to the short duration of pain relief with pulse radiofrequency therapy, this therapy is less effective than standard thermal radiofrequency ablation and improvement following pulsed radiofrequency therapy lasting more than 4 months is possibly the result of the natural course of the disease rather than the procedure itself.

Similarly, Lindner et al. (2006) performed a retrospective analysis of 48 patients with low back pain treated with PRF at 42°C for 120 seconds after reporting pain relief with one series of diagnostic medial branch blocks. The authors found a successful outcome (> 60% improvement) at 4 months in 21 of 29 patients without a history of back surgery and 5 of 19 patients who had undergone surgery, demonstrating not only a significant PRF effect in each group, but also a significant difference in PRF efficacy between the groups. The study is limited by small sample size and short term follow-up.

Cahana (2006) completed a literature review of current clinical and laboratory data regarding the use of PRFA. The final analysis yielded 58 reports on the clinical use of pulsed radiofrequency in different applications: 33 full publications and 25 abstracts. Also six basic science reports, five full publications, and one abstract were reviewed. The accumulation of these data shows that the use of pulsed radiofrequency generates an increasing interest of pain physicians for the management of a variety of pain syndromes. Although the mechanism of action has not been completely elucidated, laboratory reports suggest a genuine neurobiological phenomenon altering the pain signaling, which some have described as neuromodulatory. No side effects related to the pulsed radiofrequency technique were reported to date. The author concluded that further research in the clinical and biological effects is needed.

Tekin et al. (2007) compared the effects of conventional radiofrequency (CRF) and pulsed RF (PRF) denervation to medial branches of dorsal rami in the treatment of facet joint pain. Local anesthetic was applied in the control group (n=20), whereas 80°C CRF for 90 seconds were applied in the CRF (n=20) and 2 Hz PRF at 42° C for 120 seconds were applied in the PRF group (n=20). Pain relief was evaluated by visual analog scale (VAS) and Oswestry Disability Index (ODI) at pre-procedure, at procedure, at 6 months and 1 year after the procedure. Mean preprocedural VAS and ODI scores were higher than postprocedural scores in all groups. Both VAS and ODI scores of PRF and CRF groups were lower than the score of the control group at the postprocedural evaluation. Although a decrease of the pain score was maintained in the CRF group at 6 months and at 1-year, this decrease discontinued in the PRF group at the follow-up periods. The number of patients not using analgesics and patient satisfaction were highest in CRF group. The investigators concluded that PRF and CRF are effective and safe alternatives in the treatment of facet joint pain but PRF is not as long lasting as CRF.

Studies of PRFA for chronic LBP were limited, uncontrolled, and insufficient to support conclusions regarding efficacy or duration of effect. Additional well-designed, longer-term RCTs are required to evaluate the safety and efficacy of RFA and PRFA and to compare these techniques with other medical or surgical therapies for chronic cervical and thoracic pain. (Hayes, 2007b)

Endoscopic radiofrequency ablation (rhizotomy)

A search of the medical peer-reviewed literature did not identify any clinical studies that evaluated endoscopic rhizotomy for the treatment of spinal pain. The clinical outcomes from a pilot study evaluating this technology were presented as a professional society conference abstract. (Yeung et al., 2011)

Cryoablation

Birkenmaier et al. (2007) conducted a prospective clinical case series to examine the effects of medial branch cryodenervation (cryoablation) in the treatment of lumbar facet joint pain. Patient selection was based on medical history, physical examination and positive medial branch blocks. Percutaneous medial branch cryodenervation was performed using a Lloyd Neurostat 2000. Target parameters were LBP (by means of visual analog scale [VAS], limitation of activity (McNab) and overall satisfaction. A total of 50 patients were recruited, and 46 completed the study. The follow-up time was 1 year. At 6 weeks, 33 patients (72 %) were pain-free or had major improvement of LBP; 13 (28 %) had no or little improvement. Including failures mean LBP decreased significantly from 7.7 pre-operatively to 3.2 at 6 weeks, 3.3 at 3 months, 3.0 at 6 months and 4.2 at 12 months. However, the authors noted that at the 12 month follow-up period the failure rate rose to 43%

A prospective study by Staender et al. (2005) evaluated the therapeutic effect of computerized tomography (CT)-guided kryorhizotomy in the treatment of 76 patients with lumbar facet joint syndrome (LFJS). All of the patients received one treatment after confirmation with a medial branch block using a 1.3cm size needle. Twenty-six patients required 2-4 additional treatments and a 2.0cm needle was used. The visual analog scale (VAS) was used as an evaluation tool along with reports of return to work and pain med use. Success was determined to be 50%

reduction in VAS scores. Pre-treatment the median score was 6.7 and post treatment was 3.2 for up to 6 months. Individual scores pre and post treatment were not reported. Patients without prior back surgery had a better result than post-surgical patients. The authors concluded the CT guided treatment was effective. The intervening variable of the medial branch blocks has to be taken into account as part of the pain relief response which the authors acknowledge. Fifty percent of patients had 50% pain relief for at least up to a year in the reported aggregate data. Six percent of patients failed treatment. Although the results are promising, further study is needed to identify the placebo effect of the medial branch blocks.

Jones and Murrin (1987) conducted a retrospective study of 70 patients treated with cryoablation for thoracic nerve pain. Each patient completed cryoablation under anesthesia and then was asked to complete a questionnaire. A total of 58 patients completed the questionnaire for a response rate of 82.8%. There was a difference in patients who suffered from scar pain versus those with post herpetic lesions. 61% of patients with scar had pain relief for up to 12 weeks. 78% of post herpetic lesion patients had pain relief for 0-1 week. 60% of scar pain patients had some to no pain relief. 87% of post herpetic lesion patients had some to no pain relief. It is noted that 48% of patients stated they would not have the procedure again. The authors concluded that therapy was effective for pain of short duration and thoracic scar pain but not effective for post herpetic lesion pain. The retrospective study design, lack of control group and subjective evaluation of pain relief limits the usability of the findings. Nearly 1/5 of patients were lost during follow up. The characteristics of these patients were not reported so it can't be determined if these patients were different than the reported group. Also the intervening variable of the anesthesia has to be taken into account as part of the pain relief response.

Lloyd et al. (1976) conducted a manufacturer sponsored study of 64 patients with intractable pain. The treatment was completed under anesthesia. The method used to evaluate the effectiveness was not discussed. The median interval of pain relief was 11 days for patients with intercostal, low back, cancer and general pain (N=15). Twenty-one days of pain relief was reported by patients with facial pain. The overall range was 0-224 days but a patient by patient distribution was not included. Duration of pain relief was reported as the last contact carried forward. Nineteen percent of patients had no pain relief. The authors concluded that this procedure was effective for acute pain but further study was needed to determine the effectiveness in chronic pain. The study results are limited by the bias from a manufacturer sponsored trial, the last contact carried forward reporting which assumes that the patient had the same pain relief and the lack of distribution of pain relief per patient making it impossible to determine the exact pain relief point. Given that the median response was 11, one could assume that the duration of pain relief had a narrow band of time with some outliers up to 224 days. Also the intervening variable of the anesthesia has to be taken into account as part of the pain relief response.

Professional Societies

A 2010 guideline by the **American Society of Anesthesiologists (ASA)** states that cryoablation may be used in the care of selected patients for low back pain (medial branch).

Chemical Ablation (AA)

The use of chemical facet injections such as phenol, alcohol and hypertonic saline has been proposed as an option for pain relief. However, there is a lack of published data to support the safety and efficacy of this technique.

Only two studies involved percutaneous alcohol ablation (PAA) of the cervical, thoracic, lumbar, or sacral nerves. An early study entailed CT-guided PAA for pain due to advanced malignancy in 20 patients. PAA was a clinical success, defined as significant pain relief based on one 100-point pain scale, for ≥ 4 weeks or for the remainder of life in 90% of 10 thoracic nerve procedures, 50% of 4 cervical nerve procedures, and 43% of 14 lumbar/sacral nerve procedures. Lumbar and sacral nerve PAA was performed on patients with pelvic tumors, which characteristically have complex innervation and invade adjacent neural networks, hampering the success of these procedures. While no complications occurred, some patients in the study had motor deficits prior

to PAA, and it is known that motor deficits can occur with cervical, lumbar, or sacral nerve PAA and urinary and pelvic incontinence can occur with sacral nerve PAA. The later study involved fluoroscopic guidance for transdiscal lumbar nerve procedures in 13 patients with chronic lower extremity pain due to arteriosclerosis obliterans, thromboangitis obliterans, Raynaud's syndrome, reflex sympathetic dystrophy, or postherpetic neuralgia, who had previous unsuccessful lumbar nerve PAA using a conventional paravertebral approach. Based on patient interview, complete or partial pain relief up to 1 month after PAA occurred in 38% and 62%, respectively (total, 100%), although criteria for defining pain relief were not provided. (Hayes, 2004)

A 2004 Hayes Directory Report on Percutaneous Alcohol Ablation for Palliative Treatment of Pain states that the evidence regarding the use of PAA for pain transmitted by the spinal nerve branch is very limited and, therefore, no conclusions regarding safety, efficacy, or appropriate patient selection criteria can be drawn.

A detailed search of the medical peer-reviewed literature did not identify any clinical studies that evaluated the use of iced saline solution for the treatment of spinal pain.

American Society of Anesthesiologists (ASA): A 2010 guideline states that chemical denervation (e.g., alcohol, phenol, or high-concentration local anesthetics) should not be used in the routine care of patients with chronic non-cancer pain.

Laser Ablation

A detailed search of the medical peer-reviewed literature did not identify any clinical studies that evaluated laser ablation for the treatment of spinal pain.

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Radiofrequency ablation (RFA) for spinal pain is a procedure and, therefore, is not subject to regulation by the FDA. However, the FDA regulates RFA devices, and there are numerous devices listed in the FDA 510(k) database approved for use in performing RFA for neurosurgical procedures. Two product codes are dedicated for these devices, one for radiofrequency lesion generators (GXD) and the other for radiofrequency lesion probes (GXI). See the following Web site for more information: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmnm.cfm>. Accessed March 4, 2014.

The Radionics RFG-3C radiofrequency lesion generator (Radionics, Inc., Burlington, MA), which is used in most clinical studies, was approved in 1991 for the creation of lesions in neurosurgical procedures. See the following Web site for more information: (Use 501K number K901540) <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmnm.cfm>. Accessed March 4, 2014.

Percutaneous alcohol ablation (PAA) is a procedure and is not regulated by the FDA. However, PAA involves the use of injectable anesthetics, needles, and radiographic devices, which do require FDA approval. Several preparations of injectable lidocaine hydrochloride (HCl), bupivacaine HCl, and mepivacaine HCl, agents typically used for prognostic nerve block prior to PAA are FDA approved. No information could be found regarding injectable alcohol.

Additional Products

Devices used for thermal radiofrequency ablation include but are not limited to the following: Leksell Neurogenerator, Radionics Radiofrequency Lesion Generator, and RadioTherapeutics RF Ablation System.

Devices used for either thermal or pulsed radiofrequency ablation include Baylis Pain Management Generator, OWL Radiofrequency System, Radiofrequency Lesion Generator, RFG-3CF Radionics.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not have a National Coverage Determination (NCD) for Ablative Treatments for Spinal Pain. Local Coverage Determinations (LCDs) do exist. Refer to the LCDs for Pain Management, Paravertebral Facet Joint Nerves, Paravertebral Facet Joint Block and Facet Joint Denervation, Paravertebral Facet Joint Block, Paravertebral facet joint nerve blockade, Paravertebral Facet Joint/Nerve Denervation and Surgery lumbar facet blockade.

(Accessed March 6, 2014)

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
09/01/2014	<ul style="list-style-type: none"> • Updated related policies reference link; <ul style="list-style-type: none"> ○ Replaced <i>Occipital Neuralgia and Cervicogenic, Cluster and Migraine Headaches</i> (title changed 09/01/14) with <i>Occipital Neuralgia and Headache Treatment</i>
06/01/2014	<ul style="list-style-type: none"> • Reorganized policy content • Added benefit considerations language for <i>Essential Health Benefits for Individual and Small Group</i> plans to indicate: <ul style="list-style-type: none"> ○ For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs") ○ Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs; however, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-

	<p>Grandfathered plans</p> <ul style="list-style-type: none">○ The determination of which benefits constitute EHBs is made on a state by state basis; as such, when using this guideline, it is important to refer to the enrollee's specific plan document to determine benefit coverage● Updated coverage rationale; added language to indicate if service is "medically necessary" or "not medically necessary" to applicable proven/unproven statement● Updated supporting information to reflect the most current clinical evidence, CMS information and references● Archived previous policy version 2013T0107M
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