

<b>Subject: Radiofrequency Ablation (RFA) for chronic back pain associated with the facet joint</b> <b>NOTE:</b> RFA is also called percutaneous radiofrequency facet denervation, percutaneous facet coagulation, percutaneous radiofrequency neurotomy, radiofrequency facet rhizotomy, and radiofrequency articular rhizolysis.		<b>Original Effective Date:</b> 7/5/07
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### PREFACE

*This Medical Guidance is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the following website: <http://www.cms.hhs.gov/center/coverage.asp>.*

### FDA INDICATIONS

Percutaneous radiofrequency facet denervation uses a device to generate the radiofrequency energy used to coagulate nerve fibers.<sup>1</sup> Radionics manufactures several models of such a radiofrequency-generating (RFG) device. The Physician Industries radiofrequency ablation needle and Radionics Pole needle are approved by the FDA for radiofrequency lesioning and percutaneous nerve blocks with anesthetic agent. The RFG is intended for use in creating lesions in nervous tissue. The RFG is indicated for use in neurosurgical lesioning procedures. Examples of these procedures include lesioning of nerve fibers for the treatment of pain and lesioning of the brain or spinal cord as in thalamotomies, pallidotomies, cordotomies, and hypophysectomies. This description does not specify all possible procedures for which the device might be used and, in particular, does not specify percutaneous radiofrequency facet denervation, but rather gives some example of procedures.

### CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

*The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina medical coverage guidance (MCG) document and provide the directive for all Medicare members. The directives from this MCG document may be followed if there are no available NCD or LCD documents available and outlined below.*

There is a long standing National Coverage Determination (NCD) for Inducted Lesions of Nerve Tracts(160.1) that applies to this technology.<sup>2</sup> This NCD outlines that program payment may be made for these denervation procedures when used in selected cases (concurrent in by contractor's medical staff) to treat chronic pain.<sup>2</sup>

There are various LCD's on Facet Joint Denervation. These LCD's outline that when a facet joint block has been effective in managing the back pain under consideration, then a permanent denervation may be considered, but should be restricted only to the level or levels that, from the results of the blocks, can be reasonably considered the source of the pain. Repeat denervation procedures at the same joint/nerve level will only be considered medically necessary when the patient has had significant improvement of pain after the initial facet joint nerve destruction that lasted an appropriate period of time (greater than or equal to six months.)<sup>2</sup>

**INITIAL COVERAGE CRITERIA**

Radiofrequency ablation may be considered medically necessary and **may** be authorized for chronic cervical, thoracic, or lumbar facet joint pain when all of the following criteria are met: **[ALL]**

- ❑ Prescriber and physician administering procedure is a Board certified Pain Management Specialist
  - Documented comprehensive pain evaluation with a comprehensive treatment plan has been submitted (e.g., medications, rehabilitation, and, psychological assessment and intervention as appropriate).
  
- ❑ Diagnosis of chronic severe somatic, **nonradicular** back pain<sup>3 4</sup> (cervical, thoracic, or lumbar): **[ALL]**
  - Chronic back pain is defined as persisting beyond 3 months: **[ALL]**<sup>48</sup>
    - ◇ Affecting activity of daily living functional ability: > 6 on the NRS Pain Rating Scale\*
    - ◇ Unresponsive to the following methods of pain control:
  - A trial of conservative treatment modalities<sup>15 23 34 38 48</sup> have been tried and failed for a minimum of 3 months: **[ALL]**
    - ◇ Medications: NSAIDS, muscle relaxants, corticosteroids, antidepressants, anticonvulsants, or opiates;
    - ◇ activity modification; and
    - ◇ physical therapy

**\*The Numeric Rating Scale (NRS-11): Rating Pain Level**<sup>47</sup>

- 0: No Pain
- 1 – 3: Mild Pain (nagging, annoying, interfering little with ADLs)
- 4 – 6: Moderate Pain (interferes significantly with ADLs)
- 7 – 10: Severe Pain (disabling; unable to perform ADLs)

- ❑ Neuro-imaging studies are negative of pathology;<sup>3,4</sup> requires treatment of pathology before consideration of facet injections (not an all-inclusive listing) **[ALL]**
  - Disc herniation
  - Spinal stenosis
  - Spondylolisthesis
  - Fracture
  - Remedial spinal lesions

- Ankylopoietica
  - Discogenic or stenotic compression
  - Malignancy
  - Infection
  - Trauma
- Age 18 or older <sup>6,8</sup>
- None of the following absolute contraindications: **[NONE]**
- previous history of spinal fusion in the area treated<sup>34</sup>
  - significant narrowing of the vertebral canal or spinal instability
  - unstable medical conditions or psychiatric illness<sup>3,4</sup>
- Documentation of a successful diagnostic facet injection trial as evidenced by 80% <sup>34</sup> symptom or pain relief (using visual analog scale or verbal descriptor scale) for the duration of the anesthetic administered.  
<sup>34,44</sup>
- No more than two joint levels are to be performed at one time** <sup>61</sup>

#### CONTINUATION OF THERAPY

Repeat radiofrequency ablation therapy may be authorized for members who meet the following criteria:<sup>34</sup>  
**[ALL]**

- At least six months have elapsed since the previous radiofrequency ablation treatment (maximum of 2 procedures per region annually;<sup>34</sup> **and**
  - Cervical/thoracic are considered one region and lumbar/sacral are considered one region; and <sup>34</sup>
  - No more than two joint levels are to be performed at one time; and** <sup>61</sup>
- 80% pain relief is obtained, with associated functional improvement, for at least ten weeks following the previous treatment; and <sup>34</sup>
  - Documented evidence of functional improvement; and <sup>61</sup>
  - Documented of decreased use of pain medications <sup>61</sup>

#### COVERAGE EXCLUSIONS

- All other requests that do not meet the 'Coverage Criteria' section above are considered **experimental/investigational or unproven** and will not be authorized.
- Lateral branch nerve radiofrequency ablation of the sacroiliac joint is considered an **experimental/investigational procedure** as there is insufficient evidence from clinical trials to support its safety and effectiveness.<sup>45,46</sup>

- ❑ Pulsed radiofrequency ablation is considered an experimental/investigational procedure as there is insufficient evidence from clinical trials to support its safety and effectiveness.<sup>3 4 39-41 55</sup>

## DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

### Radiofrequency ablation (RFA)<sup>3 4</sup>

Radiofrequency ablation (RFA) is a percutaneous treatment for chronic spinal pain using radiowave-induced heat to create a lesion in a spinal sensory nerve. RFA is also called percutaneous radiofrequency facet denervation, percutaneous facet coagulation, percutaneous radiofrequency neurotomy, radiofrequency facet rhizotomy, and radiofrequency articular rhizolysis. The RF probe is inserted, and the target nerves are generally targeted unilaterally or bilaterally for 40 to 90 seconds using an electrode temperature of 60°C to 90°C. The goal of RFA is to relieve pain by interrupting the transmission of pain signals from the sensory nerve to the brain.

### Pulsed Radiofrequency Denervation (PRFD)<sup>3 4</sup>

Pulsed RFA (PRFA) has been introduced as a nonablative alternative to RFA. PRFA delivers short bursts of radiofrequency (RF) current, instead of the continuous flow of RF current produced by continuous RF generators. This allows the tissue to cool between bursts, resulting in considerably lower maximum temperatures as compared with the continuous mode, and reduces the risk of neighboring tissue destruction. It does not destroy targeted nerves and surrounding tissue and therefore requires less precise electrodes placement. During PRFA, intermittent low temperature electric currents of 2 Hz at temperatures not exceeding 42°C are transmitted to the nerve.

Both RFA and PFRA are performed in the outpatient setting.

## GENERAL INFORMATION

### Summary of Medical Evidence

Radiofrequency denervation procedures for back pain are controversial.<sup>3,4,14</sup> According to the Institute for Clinical Systems Improvement (ICSI), controversy in the literature regarding the efficacy of lumbar RF neurotomy has arisen from fundamentally flawed clinical trials that have used inappropriate patient selection criteria, and improper procedural technique.<sup>43</sup>

There is some limited evidence from randomized-control trials that these interventions are consistently effective.<sup>3,4,5,7,12,29,30</sup> Studies have shown that up to 50% pain relief can be achieved following radiofrequency ablation procedures.<sup>13,23,26</sup> Although, there is conflicting evidence from randomized-control trials, RFA is a pain-reduction technique that may be considered for patients with back pain that is unresponsive to conservative therapy and for which there is no clear indication for surgery.<sup>3,4</sup> The Institute for Clinical Systems Improvement (ICSI) pain relief can be provided for carefully selected patients in the context of a comprehensive pain management plan.<sup>43</sup>

### Radiofrequency Denervation for Cervical and Thoracic Back Pain

Two studies in patients with presumed facet joint pain, based on results of uncontrolled diagnostic blocks, reported conflicting results for radiofrequency denervation. In one randomized, placebo controlled trial using RFA in 20 patients with chronic cervicobrachial pain.<sup>20</sup> At least 3 diagnostic blockades of different cervical spinal roots were performed in all patients prior to treatment. Half of the patients received RFA limited to one spinal root, while the other half received sham treatment with an unheated electrode. Patients who received radiofrequency denervation experienced moderately greater improvement than patients randomized to sham treatment on scores of mean pain (-2.4 versus -0.4 on a 0 to 10 scale) and function through two months. In addition, radiofrequency denervation was associated with a higher likelihood of a 2 point or greater reduction in 10 point visual analogue pain scores (67 versus 37.5 percent). The second trial evaluated low back pain. The radiofrequency denervation group, compared to sham treatment, experienced greater improvement in one measure of functional status scores at four weeks (8.4 versus 2.2 percent improvement), but not at 12 weeks. There were no significant differences in the Oswestry measure of functional status or in pain scores.<sup>16</sup>

A second double-blind randomized-control trial evaluated 24 patients with cervical facet pain following whiplash.<sup>21</sup> The RFA treatment group (n=12) and the placebo group (n=12) had pain in 1 or greater zygapophyseal joints after an automobile accident with failed medical treatment. At the 27 week follow-up, 7 patients in the RFA group were pain free versus 1 in the sham group. The study limitation is small sample size no placebo group, lack of statistical analysis.

A randomized comparative trial investigated RFA for treatment of cervicobrachial pain, evaluating two different temperatures (67°C versus 40°C).<sup>22</sup> Both treatments resulted in statistically significant and similar reductions in VAS scores, with similar side effects (e.g., neuritis). Follow-up was at 3 months, and no longer-term outcomes were reported. Results of this study raised some questions regarding whether the application of a low temperature is equally as effective as a higher temperature or whether there was a large placebo effect at work.

A small prospective uncontrolled study evaluated CT-guided RFA in 43 patients with chronic cervical zygapophyseal joint pain.<sup>26</sup> Over 50% of the patients obtained some reduction in pain, although only a small number of patients reported complete pain relief, and only 13% of patients were satisfied with the results of treatment.

One study evaluated 40 patients with chronic whiplash injury-associated disorders.<sup>42</sup> The purpose of the study was to assess the procedure's efficacy by adding outcome measures other than pain and psychological distress factors as previously done. Patients were evaluated prior to and at two separate sessions following radiofrequency treatment. The evaluations included the Neck Disability Index, cervical range of motion, isometric cervical muscle strength, cervical pressure pain threshold, Symptom Check List-90 Revised, and subjective Self Report of Improvement (SRI). The authors reported that cervical radiofrequency neurotomy had a significantly positive effect on all measured parameters. Using strict cutoff values taking improvement

followed by regression into account, between 30% and 60% of patients experienced measurable improvement. Evaluation of SRI results indicated that 80% of patients were satisfied with the procedure.

Rambaransingh et al (2010) assessed the effectiveness of repeated radiofrequency neurotomy (RFN) on pain, disability, and treatment effect duration. One hundred-four patients who underwent repeat RFN for chronic neck or back pain were prospectively followed using a Pain Disability Questionnaire-Spine (PDQ-S). Complete data sets were available for 73, 73, and 36 patients for the 1st, 2nd, and 3rd RFN, respectively. Pain intensity, pain frequency, and patient-specific disability measures were significantly improved post-initial, second, and third RFN. Moreover, there was no statistically significant difference among the PDQ-S scores post-RFN 1, 2, and 3. There was no statistical significance between the duration of pain relief post-RFN 1 and pain relief post-RFD 2. The authors concluded that repeated cervical and lumbar RFN reduces pain and disability with equal effectiveness for approximately 10 months in patients with facetogenic chronic neck and back pain.<sup>56</sup>

#### Radiofrequency Denervation for Low back pain

Trials for radiofrequency denervation reported inconsistent results among small numbers of higher quality trials and technical and methodological shortcomings in the trials make it difficult to reach conclusions regarding any benefits to the procedure.<sup>7</sup>

A randomized-control trial of 28 patients with sacroiliac joint pain was conducted to evaluate lateral branch radiofrequency denervation.<sup>13</sup> Fourteen patients received L4-5 primary dorsal rami and S1-3 lateral branch radiofrequency denervation using cooling-probe technology following a local anesthetic block, and 14 patients received the local anesthetic block followed by placebo denervation. One, 3 and 6-months post-procedure, 11 (79%), 9 (64%) and 8 (57%) of radiofrequency treated patients experienced  $\geq 50\%$  pain relief and significant functional improvement. In contrast, only 2 (14%) patients in the placebo group experienced significant improvement at their 1-month follow-up, and none experienced benefit 3-months post-procedure. In the crossover group (n=11), 7 (64%), 6 (55%) and 4 (36%) patients experienced improvement 1, 3 and 6-months post-procedure. One year after treatment, only 2 (14%) patients in the treatment group continued to demonstrate persistent pain relief. The authors concluded that larger studies are needed to confirm results.

A randomized-control double-blind trial of 83 patients with lumbosacral radicular pain for > 6 months had dorsal root ganglia identified on 3 separate diagnostic blocks.<sup>15</sup> They were randomized to radiofrequency lesioning of dorsal root ganglia versus control group (same procedure but no active current), 16% treatment group versus 25% control group had successful results at 3 months (p=0.43).

A prospective double-blind randomized controlled trial was performed on 70 patients with low back pain > 3 months and following a good response after intra-articular facet injections under fluoroscopy.<sup>16</sup> The participants were randomized to percutaneous radiofrequency articular facet denervation under fluoroscopic guidance (neurotomy) vs. sham procedure without effective denervation (placebo), mean improvement in Roland-Morris scale of functional disability at 4 weeks was 8.4% vs. 2.2% (p = 0.05 but not clinically

significant) but no significant differences in Oswestry scale of functional disability or visual analog scale of pain; no significant differences in any of these measures at 12 weeks.

A small prospective double-blind randomized trial was conducted with 31 patients with chronic low back pain originating from the lumbar zygapophysial joints for at least 1 year, and positive response to diagnostic nerve block to evaluate the clinical efficacy of percutaneous radiofrequency denervation of the lumbar zygapophysial joints in reducing pain, functional disability, and physical impairment.<sup>17</sup> They were randomized to radiofrequency lesioning of dorsal root ganglia (15 patients) versus control group, same procedure but no active current (16 patients). Eight weeks after treatment, there were 10 success patients in the radiofrequency group (n = 15) and 6 in the sham group (n = 16). The unadjusted odds ratio was 3.3 (P = 0.05, not significant), and the adjusted odds ratio was 4.8 (P < 0.05, significant). The differences in effect on the visual analog scale scores, global perceived effect, and the Oswestry disability scale were statistically significant. Three, 6, and 12 months after treatment, there were significantly more success patients in the radiofrequency group compared with the sham group. The study was statistically underpowered.

One well conducted trial with a low risk of bias found no effect on pain at 4 or 12 weeks and short term improvement in function at 4 weeks but not at 12 weeks.<sup>6</sup> Seventy participants were included in the RCT, other inclusion criteria were: aged from 18 to 65 years, with lower back pain for more than 3 months duration with previous significant relief for at least 24 hours during the week after facet joint injection. Participants were excluded if they had sciatic pain with neurologic deficit, lower back pain not relating to a mechanical disorder, had undergone low back surgery. A total of 36 patients were randomized to percutaneous radiofrequency articular facet denervation, and 34 were randomized to the same procedure without denervation. Treatment effect results at four weeks were 6.2 (-1.3 to 13.8, P = 0.05), 0.6 (-4.5 to 5.7) and 4.2 (-6.9 to 15.4) for the RMDQ, ODI and pain scores respectively. At twelve weeks the treatment effect results were 2.6 (-6.2 to 11.4), (-3.2 to 7) and -7.6 (-20.3 to 5.1) for the Roland Morris Disability Questionnaire, Oswestry scale and pain scores respectively. The authors concluded that radiofrequency facet joint denervation is not shown to be of benefit as determined by functional disability at 12 weeks and no effect on pain at 4 or 12 weeks.

A small randomized-control trial evaluated the effect of percutaneous radiofrequency zygapophysial joint neurotomy in reducing pain and physical impairment in patients with pain from lumbar zygapophysial joints.<sup>7</sup> The only trial that enrolled patients based on controlled facet joint blocks. Adult patients were included if they had continuous low back pain for at least 2 years, had not responded to previous treatment and were able to identify at least one component of their pain which could be attributed to one or more lumbar zygapophysial joints, had paravertebral tenderness and obtained at least 80% relief of pain following controlled, medial branch blocks. Patients who underwent radiofrequency denervation experienced moderately greater reduction (-1.4 to -1.9 points on a 10 point scale) in generalized back and leg pain, and analgesic use after six months, compared to patients who underwent a sham procedure. However, the sample size was small (n = 40), there were significant differences in baseline pain scores (about 1.6 points), final pain scores were similar in the two groups, and results did not reach statistical significance. It is also unclear why radiofrequency denervation of the facet joint should improve leg (but not back) pain. The author concluded that RFA can be used successfully as a complement to other interventions to reduce pain in carefully selected patients. It should be noted that the groups were significantly different (intervention group had higher pain) at the start of the trial which could have confounded results. This was a trial with a high risk of bias.

A randomized-control trial with 81 participants assessed the efficacy of radiofrequency facet joint denervation compared to sham procedure for treatment of chronic low back pain.<sup>8</sup> The inclusion criteria was aged over 17 years, lower back pain with or without radiating pain into the upper leg for more than 6 months with focal tenderness over facet joints, no radicular symptoms, at least 50% pain relief on a visual analog scale 30 minutes after a diagnostic block. Forty patients were randomized to the RFA group and forty one to the sham procedure. Outcome measures taken at 3 months included visual analog scale, physical activities scale, use of analgesics scale, global perceived effect back pain. Success in the combined outcome measure showed no significant differences between the groups 27.5% in intervention and 29.3% in control ( $P = 0.86$ ). No differences in VAS back or leg or medication use between two groups. More people in the intervention group reported greater than 50% reduction in pain at 3 months 61.5% vs. 39%  $P = 0.044$ . The global perceived effect, however, improved in the radiofrequency group. The researchers observed that the lack of improvement in physical function despite reduction pain scores underlines the need to combine these procedures with subsequent structured rehabilitation programs. The authors concluded that in selected patients, radiofrequency facet denervation appears to be more effective than sham treatment. It has been questioned whether the technique in this trial resulted in inadequate coagulation of the nerve target due to incorrect electrode placement.<sup>27,28</sup>

Falco et al (2012) evaluated the effect of therapeutic lumbar facet joint interventions in managing chronic low back pain in a systematic review. The available literature on lumbar facet joint interventions in managing chronic low back pain was reviewed. The quality assessment and clinical relevance criteria utilized were the Cochrane Musculoskeletal Review Group criteria as utilized for interventional techniques for randomized trials and the criteria developed by the Newcastle-Ottawa Scale criteria for observational studies. The level of evidence was classified as good, fair, and limited or poor based on the quality of evidence developed by the U.S. Preventative Services Task Force. Data sources included relevant literature identified through searches of PubMed and EMBASE from 1966 through June 2012, and manual searches of the bibliographies of known primary and review articles. The primary outcome measure was pain relief with short-term relief defined as up to 6 months and long-term relief as 12 months. Secondary outcome measures were improvement in functional status, psychological status, return to work, and reduction in opioid intake. For this systematic review, 122 studies were identified. Of these, 11 randomized trials and 14 observational studies met inclusion criteria for methodological quality assessment. The evidence for radiofrequency neurotomy is good and fair to good for lumbar facet joint nerve blocks for short- and long-term improvement; whereas the evidence for intraarticular injections and pulsed radiofrequency neurotomy is limited. The authors concluded that there is good evidence for the use of conventional radiofrequency neurotomy, and fair to good evidence for lumbar facet joint nerve blocks for the treatment of chronic lumbar facet joint pain resulting in short-term and long-term pain relief and functional improvement. There is limited evidence for intraarticular facet joint injections and pulsed radiofrequency thermoneurolysis.<sup>50</sup>



Civelek and associates (2012) compared the clinical effectiveness of facet joint injections (FJI) and facet joint radiofrequency (FJRF) denervation in patients with chronic low back pain. This study included 100 patients; 50 in FJI 50 in FJRF group. VNS, NASS and EQ-5D were used to evaluate the outcomes. All outcome assessments were performed at baseline, 3 months, 6 months and 12 months. FJI in early post-op but FJRF in 1st, 6th and 12th month VNS showed better results ( $p < 0.001$ ). There was no significant difference in the 1st ( $p=1$ ) and 6th month ( $p=0.13$ ) but in 12th month ( $p=0.04$ ) in NASS. Increase in level number showed positive effect in NASS in FJRF group ( $p=0.018$ ) but no effect in FJI group ( $p=0.823$ ) in the 12th month follow-up. There was no significant difference with respect to 1st month ( $p=0.17$ ), 6th month ( $p=0.22$ ) and 12th month ( $p=0.11$ ) post-procedure follow-ups in EQ-5D. At the short term FJI was more effective than FJRF however in midterm follow-up FJRF had more satisfying results than FJRF. Investigators concluded the first choice should be the FJI and if pain reoccurs after a period of time or injection is not effective, RF procedure should be used for the treatment of chronic lumbar pain.<sup>49</sup>

A randomized, multicenter study (2010) was performed in 151 subjects with suspected lumbar facetogenic pain comparing three treatment paradigms. Group 0 received radiofrequency denervation based solely on clinical findings; group 1 underwent denervation contingent on a positive response to a single diagnostic block; and group 2 proceeded to denervation only if they obtained a positive response to comparative blocks done with lidocaine and bupivacaine. A positive outcome was predesignated as  $\geq 50\%$  pain relief coupled with a positive global perceived effect persisting for 3 months. In group 0, 17 patients (33%) obtained a successful outcome at 3 months versus eight patients (16%) in group 1 and 11 (22%) patients in group 2. Denervation success rates in groups 0, 1, and 2 were 33, 39, and 64%, respectively. Pain scores and functional capacity were significantly lower at 3 months but not at 1 month in group 2 subjects who proceeded to denervation compared with patients in groups 0 and 1. The costs per successful treatment in groups 0, 1, and 2 were \$6,286, \$17,142, and \$15,241, respectively. The authors concluded that using current reimbursement scales, these findings suggest that proceeding to radiofrequency denervation without a diagnostic block is the most cost-effective treatment paradigm.<sup>51</sup>

Speldewinde (2011) sought to evaluate the analgesic, physical, and psychological outcomes of percutaneous radiofrequency neurotomy for persistent zygapophysial and sacroiliac joint pain in a community setting. A prospective evaluation of 379 consecutive neurotomies was conducted in a single specialist practice over an extended period 2001-2010. All patients who had positive responses to diagnostic blocks, performed according to the guidelines of the International Spine Intervention Society by three trained specialists, underwent percutaneous radiofrequency thermal neurotomies. Numerical Rating Scale for Pain, Functional Rating Index, 4-Activities of Daily Living Scale, General Health Questionnaire, Depression Anxiety Stress Scale, duration of pain relief, "whether they would do it again," and overall amount of pain relief were the outcomes measured. The results showed that of 379 procedures, 272 (72%) were regarded as successful by the patients, irrespective of region treated. Adverse events were infrequent and relatively minor. Repetitions of the procedure were highly successful. The author concluded that neurotomy of the cervical, thoracic, lumbar, and sacroiliac joints

were uniformly successful with 72% recipients obtaining an average of 86% reduction in pain for a period of 12 months.<sup>54</sup>

Cohen et al. (2011) prospectively recorded data in 61 consecutive patients undergoing lumbar facet radiofrequency denervation in those who experienced significant pain relief after medial branch blocks. For each nerve lesioned, multiple attempts were made to maximize sensory stimulation threshold (SST). Mean SST was calculated on the basis of the lowest stimulation perceived at 0.1-V increments for each medial branch. A positive outcome was defined as a  $\geq 50\%$  reduction in back pain coupled with a positive satisfaction score lasting  $\geq 3$  months. The relationship between mean SST and denervation outcomes was evaluated via a receiver's operating characteristic (ROC) curve, and stratifying outcomes on the basis of various cutoff values. No correlation was noted between mean SST and pain relief at rest (Pearson's  $r = -0.01$ , 95% confidence interval [CI]: -0.24 to 0.23,  $P = 0.97$ ), with activity ( $r = -0.17$ , 95% CI: -0.40 to 0.07,  $P = 0.20$ ), or a successful outcome. No optimal SST could be identified. The authors concluded that there is no significant relationship between mean SST during lumbar facet radiofrequency denervation and treatment outcome, which may be due to differences in general sensory perception. Because stimulation threshold was optimized for each patient, these data cannot be interpreted to suggest that sensory testing should not be performed, or that high sensory stimulation thresholds obtained on the first attempt should be deemed acceptable.<sup>58</sup>

### Pulsed Radiofrequency Ablation (PRFA)

Studies of pulsed radiofrequency consist primarily of small trials with limited follow-up. Most studies are case series in which the safety and efficacy of pulsed radiofrequency cannot be evaluated against alternative treatment methods.<sup>39-41</sup>

A small randomized, placebo-controlled with 23 patients reported that PRFA appears to provide pain relief in some patients with chronic cervical radicular pain.<sup>23</sup> Patients were eligible with neck pain radiating over the posterior shoulder to the arm persisting for  $>$  six months, had symptoms of cervical spinal nerve involvement, and were unresponsive to conventional therapy. The primary outcomes were measured three months after the intervention: defined as minimally, 50% pain improvement of the global perceived effect (GPE); a reduction of at least 20% in the VAS pain score; and reduced pain medication intake. An improvement of the GPE of at least 50% was achieved in 9/11 (82%) patients in the PRFA group and 4/12 (33%) in the sham group ( $p = 0.03$ ). A reduction of 20% in the VAS pain score was seen in 82% of the patients in the radiofrequency group compared to 25% in the sham group ( $p = 0.02$ ). A reduction in pain medication intake was noted in the radiofrequency group, but no significance was reached at three months. The need for pain medication was significantly reduced in the pulsed radiofrequency group after six months. The authors concluded that pulsed radiofrequency treatment of the cervical dorsal root ganglion may provide pain relief for a limited number of carefully selected patients. The authors indicated since percutaneous pulsed radiofrequency is presumed to be less neurodestructive, this approach may have a better risk/benefit ratio than continuous radiofrequency lesioning, but this hypothesis needs to be confirmed in larger studies. The study limitations included small volume of participants contributing to the trial being statistically underpowered and short follow-up duration.

A small randomized, controlled double-blind trial study of 40 patients compared radiofrequency denervation with pulsed radiofrequency denervation.<sup>38</sup> Patients 17-years or older, with continuous low back pain for 6 months or more, with or without radiating pain with focal tenderness over the facet joints, pain on hyperextension, absence of neurologic defect, unresponsiveness to conservative treatment, no radicular syndrome, and no indication for low back surgery were included in the study. The patients were randomized to treatment with continuous radiofrequency (n=20), treatment with pulsed radiofrequency (n=20), or to a control group (n=20). Radiofrequency treatment was subsequently made available to patients in the control group who experienced no pain relief. Pain relief was evaluated using a VAS and Oswestry Disability Scale (ODI) prior to the procedure, at the time of the procedure, and six and twelve months post-procedure. Pre-procedure VAS and ODI scores were similar in all groups. Mean pre-procedure VAS and ODI scores were higher than all post-procedure scores in all groups. Mean VAS and ODI scores were lower in both radiofrequency groups than in the control group at the post-procedure evaluation. The decrease in pain was maintained in the continuous radiofrequency group at six months and one year but was not maintained in the pulsed radiofrequency group. Analgesic usage was lower and patient satisfaction was higher in the continuous radiofrequency

Chau and associates (2011) evaluated the efficacy of Pulsed Radiofrequency (PRF) treatment in chronic pain management in randomized clinical trials (RCTs) and well-designed observational studies. The information was classified in two tables, one focusing only on RCTs, and another, containing prospective studies. Date of last electronic search was 30 May 2010. Six RCTs were found that evaluated the efficacy of PRF, one against corticosteroid injection, one against sham intervention, and the rest against conventional RF thermocoagulation. Two trials were conducted in patients with lower back pain due to lumbar zygapophyseal joint pain, one in cervical radicular pain, one in lumbosacral radicular pain, one in trigeminal neuralgia, and another in chronic shoulder pain. The authors concluded that from the available evidence, the use of PRF to the dorsal root ganglion in cervical radicular pain is compelling. With regards to its lumbosacral counterpart, the use of PRF cannot be similarly advocated in view of the methodological quality of the included study. PRF application to the supracapular nerve was found to be as efficacious as intra-articular corticosteroid in patients with chronic shoulder pain. The use of PRF in lumbar facet arthropathy and trigeminal neuralgia was found to be less effective than conventional RF thermocoagulation techniques.<sup>55</sup>

Hayes, Cochrane, UpToDate, MD Consult etc.

A Hayes directory report is available for radiofrequency ablation for chronic low back pain.<sup>3</sup> There is limited evidence from studies with poor methodologies to support the effectiveness of RFA in patients with lower back pain and no previous surgical intervention that have failed conservative treatment following a positive diagnostic block. All other patient types have no proven effectiveness. Pulsed radiofrequency ablation has not proven effectiveness in chronic lumbar facet pain patients. The last Hayes update review performed at the time of this document revision was July 11, 2011. This review identified additional studies regarding efficacy but the Hayes suggested ratings were not impacted.

Definitive patient selection criteria for RFA as a treatment for chronic spinal pain have not been established. Relative or absolute contraindications to RFA include:<sup>3,4</sup>

- 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

A Hayes directory report is available for radiofrequency ablation for cervical and thoracic back pain.<sup>4</sup> There is limited evidence to support effectiveness of radiofrequency ablation in patients with cervicobrachialgia or chronic cervical pain that have had a positive diagnostic nerve block and have failed conservative treatments. All other patient types have no proven effectiveness. Annual Hayes literature reviews have been conducted with no change to the Hayes ratings. The last Hayes update review performed at the time of this document revision was September 26, 2011.

A Cochrane systematic review evaluated seven randomized-control trials of radiofrequency denervation for musculoskeletal pain neck and back pain disorders.<sup>14</sup> Six of the seven were considered to be high-quality. The trials included a total of 275 randomized patients, 141 of whom received active treatment. One study examined cervical zygapophyseal joint pain, two cervicobrachial pain, three lumbar zygapophyseal joint pain, and one discogenic low-back pain. The study sample sizes were small, follow-up times short, and there were some deficiencies in patient selection, outcome assessments, and statistical analyses. There was limited evidence regarding the short-term effectiveness of radiofrequency denervation for cervical zygapophyseal joint and cervicobrachial pain, and conflicting evidence for lumbar zygapophyseal joint pain. There is limited evidence that radiofrequency denervation offers short-term relief for chronic neck pain of zygapophyseal joint origin and for chronic cervicobrachial pain; conflicting evidence on the short-term effect of radiofrequency lesioning on pain and disability in chronic low-back pain of zygapophyseal joint origin. The authors suggested that further high quality randomized-control trials are necessary with larger sample sizes and data evaluating long-term effects as the current evidence is inconclusive.

A systematic review of the literature was performed including 146 articles to evaluate nonmalignant pain treated by destructive procedures.<sup>12</sup> The majority of studies (131) were low quality Class III evidence. There were eleven Class I and 4 Class II studies of which 13 of 15 evaluated radiofrequency rhizotomies for different pain origins, including lumbar facet syndrome and cervical facet pain. The authors concluded the evidence supporting destructive procedures for benign pain conditions remains limited.

### UpToDate:

In a report called Subacute and Chronic Low Back Pain: nonsurgical interventional treatment, the following is summarized:<sup>52</sup>

- Radiofrequency denervation has been used for treatment of presumed facet joint pain (target nerve = medial branch of the primary dorsal ramus), presumed discogenic back pain (ramus communicans), and radicular back pain (dorsal root ganglia). Evidence supporting the use of radiofrequency denervation for chronic low back pain is limited.

In a report called Treatment of Neck Pain the following is summarized:<sup>53</sup>

- Percutaneous radiofrequency neurotomy has shown modest short-term relief for chronic neck pain related to the zygapophyseal joint, based on six randomized controlled studies evaluated in a systematic review.
- Longer-term relief was demonstrated in one randomized double-blinded trial in 24 patients with whiplash injury; the median time before pain returned to at least 50 percent of the level prior to the procedure was prolonged in the treatment compared to control group (263 versus 8 days).
- The evidence for percutaneous radiofrequency neurotomy has been better demonstrated in post whiplash-related cervicogenic headaches and neck pain.

### Professional Organizations

The American Society of Interventional Pain Physicians (ASIPP) practice guideline (2009) entitled Interventional Techniques in the Management of Chronic Spinal Pain<sup>34</sup> provides an IC/strong evidence for cervical radiofrequency neurotomy and lumbar radiofrequency neurotomy recommendation. The guidelines suggest a frequency for medial branch neurotomy of six months or longer, with a maximum of two times per year, provided that > 50% relief is obtained for 10–12 weeks. It is suggested that all regions be treated at the same time, provided all procedures can be performed safely. The guidelines indicate that the evidence for pulsed radiofrequency of medial branches in the cervical and lumbar region is indeterminate, and the evidence for pulsed radiofrequency of the SI joint is limited. There is insufficient evidence in the published medical literature to demonstrate the safety and efficacy of pulsed radiofrequency in the treatment of spinal pain. Studies published to date do not allow conclusions regarding the safety, efficacy, and duration of effect of this technique. Additional well-designed trials are needed to determine how this treatment compares to other medical and surgical treatments for chronic spinal pain. There have been no further updates to this guideline since 2009.

The American Pain Society practice guidelines for low back pain (2009) recommends against facet joint steroid injections, therapeutic medial branch block, and radiofrequency denervation for persistent nonradicular low back pain.<sup>5,29</sup> There is insufficient evidence from randomized trials that these interventions are effective. Trials for radiofrequency denervation reported inconsistent results among small numbers of higher quality

trials and technical and methodological shortcomings in the trials make it difficult to reach conclusions regarding any benefits to the procedure.<sup>5,7,29</sup> There have been no further updates to this guideline since 2009.

The National Institute for Health and Clinical Excellence (NICE) has developed a guideline for the management of persistent or recurrent low back pain (2009) defined as non-specific low back pain that has lasted for more than 6 weeks, but for less than 12 months.<sup>10</sup> It does not address the management of severe disabling low back pain that has lasted longer than 12 months. Evidence review from this group indicates that there is evidence that pain arising from the facet joints can be a cause of low back pain, but the role of specific therapeutic interventions remains unclear. Case studies provide some evidence for the effectiveness of facet joint injections and medial branch blocks, but randomized controlled trials give conflicting evidence. NICE does not recommend referral for facet injections or radiofrequency denervation procedures. There have been no further updates to this guideline since 2009.

The Institute for Clinical Systems Improvement (ICSI) entitled “Assessment and Management of Chronic Pain” (Updated November 2011) indicates that Percutaneous radiofrequency (RF) neurotomy is a treatment for neck or back pain generated by facet joints. Properly selected candidates for this procedure should experience complete or nearly complete relief of their pain following fluoroscopically guided, low-volume local anesthetic blocks of the medial branch nerves that innervate the pain-generating joint(s). To minimize false-positive results, an equivalent degree of relief of appropriate pharmacologic duration should be carefully documented on two separate occasions, using two different types of local anesthetic. Radiofrequency neurotomy can provide pain relief for carefully selected patients, but this procedure should be performed only by an experienced pain medicine physician in the context of a longitudinal and comprehensive care plan. Proper patient selection and appropriate technique in positioning the radiofrequency electrodes are absolutely essential to the success of the procedure. Controversy in the literature regarding the efficacy of lumbar radiofrequency neurotomy has arisen from fundamentally flawed clinical trials that have used inappropriate patient selection criteria, and improper procedural technique.<sup>11</sup>

The American College of Occupational and Environmental Medicine have developed clinical practice guidelines (updated in 2011) for low back disorders.<sup>17</sup> The guidelines indicate that many invasive therapies are intended to cure or manage low back pain, however no strong evidence exists to support that they accomplish this as successfully as therapies that focus on restoring functional ability without focusing on pain. The guidelines on low back disorders indicate one diagnostic facet joint injection may be recommended for patients with chronic low back pain that is significantly exacerbated by extension and rotation or associated with lumbar rigidity, and is not alleviated with other conservative treatments e.g., NSAID, progressive aerobic exercises, other exercises, and manipulation). This diagnostic injection may determine whether specific interventions targeting the facet joint are recommended. Repeated diagnostic injections in the same location are not recommended.

The Official Disability Guidelines for low back pain (2013) indicate specific criteria for use of facet joint radiofrequency neurotomy<sup>57</sup> that include the following:

- Treatment requires a diagnosis of facet joint pain using a medial branch block.
- While repeat neurotomies may be required, they should not occur at an interval of less than 6 months from the first procedure. A neurotomy should not be repeated unless duration of relief from the first procedure is documented for at least 12 weeks at  $\geq 50\%$  relief. The current literature does not support that the procedure is successful without sustained pain relief (generally of at least 6 months duration). No more than 3 procedures should be performed in a year's period.
- Approval of repeat neurotomies depends on variables such as evidence of adequate diagnostic blocks, documented improvement in VAS score, decreased medications and documented improvement in function.
- No more than two joint levels are to be performed at one time.
- If different regions require neural blockade, these should be performed at intervals of no sooner than one week, and preferably 2 weeks for most blocks.
- There should be evidence of a formal plan of additional evidence-based conservative care in addition to facet joint therapy.

**CODING INFORMATION:** THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS A COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	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 [when specified as pulsed radiofrequency]

HCPCS	Description
	NONE ASSOCIATED

ICD-9	Description
03.96	Percutaneous denervation of facet (ICD9 Hospital Procedure Code)
722.81	Postlaminectomy syndrome, cervical
722.83	Postlaminectomy syndrome, lumbar
723.1	Cervicalgia
724.1	Pain in thoracic spine
724.2	Pain in lumbar spine
724.8	Other symptoms referable to back Ossification of posterior longitudinal ligament, NOS Panniculitis, sacral or affecting back
338.29	Other chronic pain (use in conjunction with above codes)

ICD-10 CM	Description
M96.1	Postlaminectomy syndrome NEC
M54.2	Cervicalgia
M54.6	Pain in thoracic spine
M54.5	Low Back Pain
G89.4	Other Chronic Postprocedural Pain

ICD-10 PCS	Description
01513ZZ	Destruction cervical nerve percutan apprch
01583ZZ	Destruction thoracic nerve percutan apprch
015B3ZZ	Destruction lumbar nerve percutan apprch
015R3ZZ	Destruction sacral nerve percutan apprch

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