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Medical Policy Manual Surgery, Policy No. 156

Pulsed Radiofrequency for Chronic Spinal Pain

Effective: March 1, 2022

Next Review: December 2022
Last Review: January 2022

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Pulsed bursts of radiofrequency current are applied to disrupt nerve tissue in an effort to relieve pain at a lower temperature than conventional radiofrequency treatments.

MEDICAL POLICY CRITERIA

Notes:

- This policy does not address conventional percutaneous radiofrequency facet denervation which may be considered medically necessary for the treatment of facet joint pain that is not responding to conservative treatments.
- This policy addresses only pulsed radiofrequency procedures that are performed to achieve facet joint denervation; clinical records should clearly document that the pain being treated originates from the facet joint(s), verified by nerve block, and that the goal of the treatment is facet joint denervation.

Pulsed radiofrequency lesioning of spinal structures (e.g., dorsal root ganglion; medial branch nerve) is considered **investigational** for the treatment of pain from any cause in any level of the spine, including but not limited to the following:

A. Cervicobrachialgia
B. Cervicogenic headache
C. Degenerative conditions such as spondylosis, spondylolisthesis, or degenerative disc disease
D. Facet joint or zygapophyseal joint arthropathy
E. Failed back surgery syndrome (FBSS)
F. Herniated intervertebral disc
G. Nerve root compression
H. Neuropathic spinal pain
I. Radiculopathy, radiculitis, or radicular pain
J. Scoliosis
K. Spinal stenosis
L. Trauma or injury

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, and Biacuplasty, Surgery, Policy No. 118
2. Decompression of Intervertebral Discs Using Laser Energy (Laser Discectomy) or Radiofrequency Energy (Nucleoplasty), Surgery, Policy No. 131
3. Intraosseous Radiofrequency Ablation of the Basivertebral Nerve, Surgery, Policy No. 225

BACKGROUND

Percutaneous radiofrequency (RF) denervation is a procedure used to treat certain types of neck or back pain originating in facet joints. The goal is long-term pain relief. However, the nerves regenerate, and repeat procedures may be required. RF therapy may be performed using either conventional continuous RF current, which is considered the current standard of care for RF denervation, or pulsed RF current. In conventional continuous RF therapy, probe tip temperatures reach at least 60°C and are intended to produce long-term pain relief through coagulation of tissue. Pulsed radiofrequency (PRF), which consists of short bursts of current, is suggested as a possibly safer alternative to thermal radiofrequency. Temperatures for PRF do not exceed 43°C at the probe tip and do not heat the tissue enough to cause coagulation. In addition, with PRF, tissues may cool between pulses. It is postulated that with PRF denervation transmission across small unmyelinated nerve fibers is disrupted but not permanently damaged, while large myelinated fibers are not affected.

A variety of terms may be used to describe RF denervation (e.g., rhizotomy, rhizolysis, neurolysis, neurotomy, lesioning). In addition, the structures to which the RF energy is directed may be referred to as facet joint, facet nerves, medial nerve or branch, median nerve or branch, segmental nerves, dorsal ramus, or dorsal root ganglion.

EVIDENCE SUMMARY

The principal outcome for treatment of pain is symptom relief and improved functional level. Relief of pain can be subjective depending on the validity of the measurement tool used. Randomized controlled trials (RCTs) are desirable to control for the placebo effect and determine whether any treatment effect provides a significant advantage over the placebo. In addition, well-designed studies comparing pulsed radiofrequency (PRF) therapy with conventional continuous radiofrequency (RF) therapy are important to determine the overall effectiveness of this therapy for the treatment of chronic spinal pain.

SYSTEMATIC REVIEWS

In a systematic review with meta-analysis by Janapala (2021), 12 RCTs were identified evaluating the efficacy of lumbar RF neurotomy.[1] Studies were excluded from the analysis that included patients with acute causes of low back pain due to trauma, fracture, and malignancy. Patients across the 12 studies received one of the following interventions: RF ablation with a 22-gauge electrode, pulsed RF, medial branch conventional RF, medial branch cooled RF ablation, medial branch RF plus pentoxifylline or methylprednisolone injection, distal approach RF neurotomy, tunnel-vision approach RF neurotomy, RF frequency coagulation of joint capsule, endoscopic neurotomy, intra-articular lumbar steroid injection, or sham treatment. Each RCT included at least six months of follow-up, with seven trials including active controls and five trials either sham or placebo control. Sample sizes ranged from 31 to 251 patients. Cochrane quality assessment found 10 trials were of high-quality and two trials were of moderate quality. Meta-analysis of pain relief following RF neurotomy versus sham control was evaluated at six months (three studies, N=160) and 12 months (two studies, N=291). At both timepoints, RF neurotomy was favored for improving visual analog scale (VAS) pain scores, however, differences were not statistically significant and were imprecise with wide confidence intervals (standard mean difference [SMD] at six months, 1.98, 95% confidence interval [CI]; -0.50 to 4.47), and (SMD at 12 months, -0.22, 95% CI; -0.83 to 0.39) The interpretation of these findings is limited by high heterogeneity across studies (I2=95% for six-month data and I2=71% for 12-month data), imprecision, risk of bias of individual included studies due to lack of blinding, and the lack of subgroup analyses of patients with predictors of success such as prior response to controlled medial branch blocks and the presence of tenderness over the facet joint.

Chua (2011) evaluated four RCTs that compared PRF of spinal structures with sham intervention or with conventional continuous RF thermocoagulation.[2] The authors considered the evidence for PRF of the dorsal root ganglion “compelling” for treatment of cervical radicular pain, but found the evidence for PRF for lumbosacral pain to be of low methodological quality. The following is a summary of these key RCTs:

- One small RCT comparing pulsed RF to sham treatment was identified in the literature review. Van Zundert randomized 23 patients (of 256 screened) with chronic cervical radicular pain.[3] Success was defined as at least 50% improvement on global perceived effect (GPE), at least 20% reduction in pain on visual analog scale (VAS), and reduced pain medication use measured three months after treatment. Nine out of 11 patients in the treatment arm and 4 out of 12 in the 3 out of 12 in the sham group achieved at least 20% reduction in pain on VAS (P=0.02). At six-month follow-up, more patients in the treatment group reduced their use of pain medication, but the difference was not significant. There was a trend toward more positive outcomes in the pulsed RF group on quality of life scores. The authors conclude that pulsed RF may provide pain relief for a limited number of carefully selected patients. These findings must be

confirmed in larger studies before drawing conclusions regarding the efficacy of pulsed RF.

- Tekin (2007) randomized sixty patients with lumbar facet joint pain, 20 each to conventional RF, pulsed RF and a control group (local anesthetic only).[4] Outcome measures were pain on VAS and Oswestry Disability Index (ODI) scores. Mean VAS and ODI scores were lower in both treatment groups than in controls post-treatment; however the reduction in pain was maintained at six- and twelve-month follow-up only in the conventional RF group. The number of patients not using analgesics and patient satisfaction were highest in the conventional RF group.
- A randomized, double blind, prospective trial by Kroll compared the efficacy of continuous versus pulsed in the treatment of lumbar facet syndrome in an RCT with 50 patients.[5] Outcome measures, pain on visual analog scale (VAS) and Oswestry Low Back Pain and Disability Questionnaire (OSW), were administered at baseline and three months after treatment and relative percentage improvement compared between groups. No significant differences in the relative percentage improvement were noted between groups in either VAS ($p = 0.46$) or OSW scores ($p = 0.35$). Within the percutaneous RF group, comparisons of the relative change over time for both VAS ($p = 0.21$) and OSW scores ($p = 0.61$) were not significant. However, within the continuous RF group, VAS ($p = 0.02$) and OSW scores ($p = 0.03$) changes were significant. The authors conclude that though there was no significant difference between continuous and pulsed RF in the long-term outcomes, there was greater improvement over time in the continuous RF group.
- Simopoulos randomized 76 patients with chronic refractory lumbosacral radicular pain to one of two groups who received either PRF alone or PRF followed immediately by continuous RF.[6] Two months after the procedure 70% and 82%, respectively, reported successful reduction of pain. These effects were lost by eight months in most patients. The between-group difference was not significant. The authors concluded that additional RCTs are required to determine the effectiveness of PRF.

The authors concluded that the lumbosacral RCTs were either of poor quality or that participants returned to their initial pain intensity eight months after the study. The authors noted the results of the cervical RCT were compelling, but the RCT itself concluded larger studies are needed.

RANDOMIZED CONTROLLED TRIALS

In addition to the randomized controlled trials (RCTs) summarized above, several recent RCTs have been published.

In a RCT by van Eerd (2021), 76 patients with cervical pain for at least three months with conservative management were randomized to receive RF plus three bupivacaine injections or three bupivacaine injections alone.[7] Patients with whiplash-associated pain were excluded from the study. For each patient, three cervical medial branches were denervated by the cervical facet joint level judged as painful on palpation. Follow-up at six months showed no clinically meaningful outcomes in numeric rating scale pain scores between treatment groups. Quality of life, as measured by the bodily pain domain within the Rand 36-Item Health Survey, showed significant improvement at six months, with scores of 61.6 for RF versus 48.6 for no RF ($p=0.01$). Patients with treatment success at six months, defined by a pain reduction of at least 30%, received follow-up at 48 months to assess long term effects. The median time to end of treatment success was 42 months in the RF group compared to 12 months with no RF

(p=0.014). At one year, the proportion of patients still reporting treatment effect was 0.9 (95% CI; 0.75 to 9.97) in the RF group compared to 0.41 (95% CI; 0.19 to 0.62) with no RF.

A 2017 RCT was published by Do comparing intra-articular lumbar facet joint PRF and intra-articular lumbar facet joint CI in 60 patients with lumbar facet joint (LFJ) pain.[8] Changes in NRS scores for pain were assessed at baseline and three additional time points. Both groups had significantly reduced NRS scores for pain at each time point compared to baseline scores. At six months of follow-up, there was no significant difference in pain scores between the groups.

Chang (2017) compared the effectiveness of bipolar PRF and monopolar PRF in patients with chronic lumbosacral radicular pain.[9] A total of 50 patients were randomly assigned to one of two treatment groups and pain intensity was evaluated using NRS at baseline as well as one, two, and three months post-treatment. Patients in both groups showed significant improvement in NRS scores at each follow-up compared to baseline scores. The bipolar PRF treatment group showed greater reductions in NRS scores.

Halim (2016) evaluated the efficacy of percutaneous nucleoplasty (PCN) compared to pulsed radio frequency (PRF) in patients with contained cervical disk herniation.[10] The trial evaluated 34 patients with radicular pain from a single contained cervical disk herniation. A health survey, visual analog scale (VAS), and the Neck Disability Index (NDI) were completed one, two, and three months after treatment. Data was collected for treatment satisfaction and complications. The PCN group (n = 17, mean age 52 years, 10 female/7 male) was treated at C5 to C6 (8 cases) or C6 to C7 (9 cases). The PRF group (n = 17, mean age 50 years, 8 female/9 male) was treated at C3 to C4 (1 case), C5 to C6 (10 cases), or C6 to C7 (6 cases). At three months, the PRF group was not superior to the PCN group in pain improvement.

Wang (2016) evaluated 62 patients in a randomized comparative trial to determine the efficacy between cervical nerve root block (CNRB), pulsed radiofrequency (PRF), and CNRB plus PRF for cervical radicular pain.[11] The patients were randomized into three groups and received either CNRB, PRF, or CNRB with PRF. A numeric rating scale (NRS) was used to measure pain intensity, and global perceived effect (GPE) was scored by the patient on a 7-point scale. A score of (-3) equaled much worse, (0) equaled no change, and (+3) equaled total improvement. The outcomes were evaluated at one week, one month, three months, and six months. Side effects and complications were noted. The combination therapy yielded statistically significant lower NRS and higher GPE,than either CNRB or PRF alone. There were no statistically significant differences in NRS or GPE between the CNRB and PRF groups

Jena (2016) evaluated a comparative randomized, double-blind trial, for management of low back pain.[12] Forty patients with chronic discogenic low back pain received continuous radiofrequency (CRF) plus intradiscal triamcinolone or pulsed radiofrequency (PRF) plus intradiscal triamcinolone. Outcome data included immediate as well as long-term pain relief, over six months using visual analog scale (VAS), the Oswestry Disability Index (OSI) and straight leg raising test. The results indicated that the CRF group had statistically significant improved pain and straight leg raise.

Lee (2016) evaluated the comparative effectiveness of pulsed radiofrequency (PRF) administered to a targeted dorsal root ganglion (DRG) and transforaminal epidural steroid injections (TFESI) for the treatment of radicular pain due to disc herniation.[13] The RCT included 193 patients who received TFESI (2ml of 0.125% bupivacaine and 5mg dexamethasone) for spinal radicular pain. Patients who presented with a visual analogue scale

(VAS; 0-10mm) of > 4 and an Oswestry Disability Index (ODI) or Neck Disability Index (NDI) > 30%, after the first TFESI were administered either PRF or an additional TFESI. The additional procedures were randomly allocated to 38 patients (PRF group n=19; TFESI group n=19) and given within two to six weeks after the first TFESI. These 38 patients were re-evaluated at two, four, eight, and twelve weeks. No statistically significant differences in effectiveness were noted at any follow-up time period, between the two groups.

Arsanious (2016) evaluated a double-blinded, RCT, that determined if post-procedural pain scores and post-procedural oral analgesic use would be reduced in patients receiving pulsed dose radiofrequency (PDRF), immediately followed by continuous thermal radiofrequency ablation (RFA) versus continuous RFA alone, for zygopophaseal joint disease.[14] Fifty-five patients were included in this study. The results noted patients receiving PDRF prior to continuous thermal RFA had less post-procedural pain and reduced analgesic requirements, during the first 24 hours. Arsanious noted a study size of 55 patients provided statistically significant data, but that long-term follow-up and studies with a larger population would be beneficial.

Koh (2015) evaluated a comparative RCT in which patients with lumbar spinal stenosis were given both pulsed radiofrequency (PRF) and transforaminal epidural injection (TFEI) or TFEI alone, for chronic refractory lumbar radicular pain.[15] Sixty-two patients were randomized to either group. The primary outcome was defined as: 1) ≥50% or 4-point pain reduction in the numerical rating scale (NRS) without an increase in the Oswestry disability index (ODI) or medication quantification scale (MQS), or mean score <4 in the global perceived effect (GPE) scale; or 2) ≥30% or 2-point pain reduction in NRS with a simultaneous decrease in ODI, MQS, or ≥6 points in the GPE scale. The authors concluded that TFEI provided short-term pain relief, but that the group who had PRF administered in addition to TFEI showed statistically significantly improved treatment results versus the group that received TFEI alone. Although this RCT showed statistically significant improvement for patients that received PRF and TFEI, larger comparative studies are needed with longer follow-up timeframes.

NONRANDOMIZED STUDIES

The remaining evidence is limited to a small number of nonrandomized case series[16-19] and retrospective reviews[20, 21] that are difficult to compare due to heterogeneity of participants, definitions of success, and procedure techniques. Evidence from nonrandomized studies are considered unreliable due to no randomization, lack of a comparator group, small sample size, and heterogenous study populations.

PRACTICE GUIDELINE SUMMARY

THE VETRANS AFFAIRS / DEPARTMENT OF DEFENSE

The 2017 VA/DoD Clinical Practice Guidelines on the Diagnosis and Treatment of Low Back Pain states “there is inconclusive evidence to recommend for or against radiofrequency ablative denervation for patients with low back pain.”[22]

AMERICAN PAIN SOCIETY

In 2009, the American Pain Society (APS) published an evidence-based clinical practice guideline on nonsurgical interventions for low back pain addressed RF therapy but did not differentiate between continuous and pulsed RF denervation techniques.[23] The guideline

states that “there is insufficient (poor) evidence from randomized trials (conflicting trials, sparse and lower quality data, or no randomized trials) to reliably evaluate” a number of interventions including RF facet denervation.

AMERICAN SOCIETY OF INTERVENTIONAL PAIN PHYSICIANS

In 2020, the American Society of Interventional Pain Physicians (ASIPP) published guidelines on use of facet joint interventions for management of chronic spinal pain.[24] Radiofrequency ablation is recommended for treatment of pain in the lumbar spine (moderate strength recommendation; evidence level II), cervical spine (moderate strength recommendation; evidence level II), and thoracic spine (weak to moderate strength recommendation; evidence level III).

The 2013 ASIPP evidence-based guidelines for interventional treatment for chronic back pain rated the evidence on pulsed RF therapy as “limited” based on only one RCT currently published.[25] The guidelines include recommendations for conventional RF, but do not include pulsed RF for any indication.

NORTH AMERICAN SPINE SOCIETY

In 2020, the North American Spine Society (NASS) published guidance on the diagnosis and management of nonspecific low back pain in patients 18 years of age and older. NASS recommends that in facet joint procedures, for patients responsive to a single diagnostic intra-articular injection with 50% relief, there is insufficient evidence to recommend for or against using radiofrequency neurotomy or periarticular phenol injections (grade I, insufficient or conflicting evidence). Thermal radiofrequency ablation is suggested for patients with zygapophyseal joint low back pain, with relief durable for at least six months following the procedure (grade B, fair evidence). Cooled radiofrequency ablation of sacral lateral branch nerves and the dorsal ramus of L5 can be considered for sacroiliac joint pain diagnosed by dual blocks (grade C, poor quality evidence).

SUMMARY

There is not enough research to know if or how well pulsed radiofrequency works to treat people with chronic spinal pain. This does not mean that it does not work, but more research is needed to know. Therefore, pulsed radiofrequency lesioning of spinal structures at any spinal level is considered investigational for the treatment of pain from any cause.

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CODES

NOTE: The nerve destruction codes within the 64600-64681 code range are not appropriate for reporting therapies that are not destructive of the target nerve, including but not limited to pulsed radiofrequency.

Codes	Number	Description
CPT	64999	Unlisted procedure, nervous system
HCPCS	None	

Date of Origin: *April 2008*