

Pulsed Radiofrequency for Chronic Spinal Pain

Effective: February 1, 2019

Next Review: December 2019

Last Review: January 2019

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

None

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

Chua (2011) evaluated four RCTs that compared PRF of spinal structures with sham intervention or with conventional continuous RF thermocoagulation.^[1] 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.^[2] 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 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).^[3] 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.^[4] 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.^[5] 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 RCTs summarized above, several recent RCTs have been published.

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.^[6] 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.^[7] 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.^[8] 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.^[9] 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.^[10] 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.^[11] 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 zygapophyseal joint disease.^[12] 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.^[13] Sixty-two patients were randomized to either group. The primary outcome was defined as: 1) $\geq 50\%$ 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) $\geq 30\%$ 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^[14-17] and retrospective reviews^[18,19] 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

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.^[20] 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

The 2013 updated American Society of Interventional Pain Physicians (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.^[21] The guidelines include recommendations for conventional RF, but do not include pulsed RF for any indication.

THE AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS

The American Academy of Orthopaedic Surgeons endorses the 2009 APS guidelines.^[22]

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.

REFERENCES

1. Chua, NH, Vissers, KC, Sluijter, ME. Pulsed radiofrequency treatment in interventional pain management: mechanisms and potential indications-a review. *Acta Neurochir (Wien)*. 2011 Apr;153(4):763-71. PMID: 21116663
2. Van Zundert, J, Patijn, J, Kessels, A, Lame, I, van Suijlekom, H, van Kleef, M. Pulsed radiofrequency adjacent to the cervical dorsal root ganglion in chronic cervical radicular pain: a double blind sham controlled randomized clinical trial. *Pain*. 2007 Jan;127(1-2):173-82. PMID: 17055165
3. Tekin, I, Mirzai, H, Ok, G, Erbuyun, K, Vatansever, D. A comparison of conventional and pulsed radiofrequency denervation in the treatment of chronic facet joint pain. *Clin J Pain*. 2007 Jul-Aug;23(6):524-9. PMID: 17575493
4. Kroll, HR, Kim, D, Danic, MJ, Sankey, SS, Gariwala, M, Brown, M. A randomized, double-blind, prospective study comparing the efficacy of continuous versus pulsed radiofrequency in the treatment of lumbar facet syndrome. *J Clin Anesth*. 2008 Nov;20(7):534-7. PMID: 19041042
5. Simopoulos, TT, Kraemer, J, Nagda, JV, Aner, M, Bajwa, ZH. Response to pulsed and continuous radiofrequency lesioning of the dorsal root ganglion and segmental nerves in patients with chronic lumbar radicular pain. *Pain Physician*. 2008 Mar-Apr;11(2):137-44. PMID: 18354708
6. Do, KH, Ahn, SH, Cho, YW, Chang, MC. Comparison of intra-articular lumbar facet joint pulsed radiofrequency and intra-articular lumbar facet joint corticosteroid injection for management of lumbar facet joint pain: A randomized controlled trial. *Medicine*. 2017 Mar;96(13):e6524. PMID: 28353611

7. Chang, MC, Cho, YW, Ahn, SH. Comparison between bipolar pulsed radiofrequency and monopolar pulsed radiofrequency in chronic lumbosacral radicular pain: A randomized controlled trial. *Medicine*. 2017 Mar;96(9):e6236. PMID: 28248888
8. Halim, W, van der Weegen, W, Lim, T, Wullems, JA, Vissers, KC. Percutaneous Cervical Nucleoplasty vs. Pulsed Radio Frequency of the Dorsal Root Ganglion in Patients with Contained Cervical Disk Herniation; A Prospective, Randomized Controlled Trial. *Pain Pract*. 2016 Sep 09. PMID: 27611826
9. Wang, F, Zhou, Q, Xiao, L, et al. A Randomized Comparative Study of Pulsed Radiofrequency Treatment With or Without Selective Nerve Root Block for Chronic Cervical Radicular Pain. *Pain Pract*. 2016 Oct 14. PMID: 27739217
10. Jena, BR, Paswan, A, Singh, Y, Loha, S, Singh, AP, Rastogi, V. A comparative study of continuous versus pulsed radiofrequency discectomy for management of low backache: Prospective randomized, double-blind study. *Anesth Essays Res*. 2016;10:602-6. PMID: 27746559
11. Lee, DG, Ahn, SH, Lee, J. Comparative Effectiveness of Pulsed Radiofrequency and Transforaminal Steroid Injection for Radicular Pain due to Disc Herniation: a Prospective Randomized Trial. *Journal of Korean medical science*. 2016 Aug;31(8):1324-30. PMID: 27478346
12. Arsanious, D, Gage, E, Koning, J, et al. Pulsed Dose Radiofrequency Before Ablation of Medial Branch of the Lumbar Dorsal Ramus for Zygapophyseal Joint Pain Reduces Post-procedural Pain. *Pain Physician*. 2016 Sep-Oct;19(7):477-84. PMID: 27676664
13. Koh, W, Choi, SS, Karm, MH, et al. Treatment of chronic lumbosacral radicular pain using adjuvant pulsed radiofrequency: a randomized controlled study. *Pain Med*. 2015 Mar;16(3):432-41. PMID: 25530347
14. Masala, S, Nano, G, Mammucari, M, Marcia, S, Simonetti, G. Medial branch neurotomy in low back pain. *Neuroradiology*. 2012 Jul;54(7):737-44. PMID: 22006423
15. Shabat, S, Pevsner, Y, Folman, Y, Gepstein, R. Pulsed radiofrequency in the treatment of patients with chronic neuropathic spinal pain. *Minim Invasive Neurosurg*. 2006 Jun;49(3):147-9. PMID: 16921454
16. Van Zundert, J, Lame, IE, de Louw, A, et al. Percutaneous pulsed radiofrequency treatment of the cervical dorsal root ganglion in the treatment of chronic cervical pain syndromes: a clinical audit. *Neuromodulation*. 2003 Jan;6(1):6-14. PMID: 22150908
17. Vallejo, R, Benyamin, RM, Kramer, J, Stanton, G, Joseph, NJ. Pulsed radiofrequency denervation for the treatment of sacroiliac joint syndrome. *Pain Med*. 2006;7:429-34. PMID: 17014602
18. Mikeladze, G, Espinal, R, Finnegan, R, Routon, J, Martin, D. Pulsed radiofrequency application in treatment of chronic zygapophyseal joint pain. *Spine J*. 2003 Sep-Oct;3(5):360-2. PMID: 14588947
19. Lindner, R, Sluijter, ME, Schleinzer, W. Pulsed radiofrequency treatment of the lumbar medial branch for facet pain: a retrospective analysis. *Pain Med*. 2006 Sep-Oct;7(5):435-9. PMID: 17014603
20. Chou, R, Loeser, JD, Owens, DK, et al. Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the American Pain Society. *Spine (Phila Pa 1976)*. 2009 May 1;34(10):1066-77. PMID: 19363457
21. Manchikanti, L, Abdi, S, Atluri, S, et al. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: guidance and recommendations. *Pain Physician*. 2013 Apr;16(2 Suppl):S49-283. PMID: 23615883

22. Heggeness MH. AAOS endorses back pain guidelines. American Academy of Orthopaedic Surgeons. [cited 1/3/2019]; Available from: <http://www.aaos.org/news/aaosnow/sep10/cover1.asp>
23. BlueCross BlueShield Association Medical Policy Reference Manual "Facet Joint Denervation." Policy No. 7.01.116

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