Clinical Policy Bulletin:  
Pulsed Radiofrequency

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Policy

Aetna considers pulsed radiofrequency experimental and investigational for all indications, including those in the following list, because its effectiveness has not been established.

- Chronic pain following inguinal herniotomy
- Discogenic pain
- Facet and sacroiliac joint arthropathy
- Headache
- Low back pain
- Lower extremity neuralgia
- Lumbo-sacral radicular syndrome
- Metatarso-phalangeal joint pain
- Myofascial or neuromatous pain
- Neck pain
- Occipital neuralgia
- Orchalgia
- Osteoarthritis of the knee
- Pain associated with tumors involving peripheral nerves
- Pelvic pain
- Plantar fasciitis
- Post-herpetic neuralgia
- Premature ejaculation
- Pudendal neuralgia
- Reflex sympathetic dystrophy/complex regional pain syndrome
- Sacro-iliac joint pain
- Shoulder pain
- Tarsal tunnel syndrome
- Testicular pain (orchialgia)
- Trapeziometacarpal joint pain
- Trigeminal neuralgia
- Urinary urgency and hesitancy
Vulvodynia
Zygapophyseal joint pain.

See CPB 0016 Back Pain - Invasive Procedures for conventional radiofrequency facet denervation.

Background

Radiofrequency (RF) treatment is a minimally invasive procedure that has been used for over three decades in treating various chronic pain syndromes such as trigeminal neuralgia, post-herpetic neuralgia, low back pain (LBP), and complex regional pain syndrome/reflex sympathetic dystrophy. It is a palliative treatment not without complications. Radiofrequency procedures have been reported to be associated with high number of complications compared with other ablative neurosurgical techniques. Furthermore, conventional (continuous) RF treatment occasionally results in worsening and even new onset of pain. The use of pulsed radiofrequency (PRF, also known as cold RF), a non- or minimally-neurodestructive and thus less painful technique, serves as an alternative to conventional RF therapy. Pulsed radiofrequency treatment, performed under fluoroscopic guidance, entails the use of pulsed time cycle that delivers short bursts of RF energy to nervous tissue.

The available evidence on the effectiveness of PRF in the treatment of patients with various chronic pain syndromes is largely based on retrospective, case series studies. Its clinical value needs to be examined in well-designed, randomized controlled trials with large sample size and long-term follow-up.

In a case series study, Mikeladze and colleagues (2003) reported that application of PRF to medial branches of the dorsal rami in patients with chronic facet joint arthropathy provided temporary pain relief in 57.6 % (68 of 118) of patients. The procedure was successful and lasted on average 3.93 +/- 1.86 months.

Pevzner and co-workers (2005) reported the findings in 28 patients (LBP = 20, cervical pain = 8; average age of 56.7 years) who were treated by PRF and followed for 3, 6 and 12 months. The 3-month follow-up revealed the following results: excellent results in 2 cases (7.1 %), good results in 12 cases (42.9 %), fair in 9 (32.1 %), and 5 (17.9 %) reported that their condition have not changed. Results after 6 and 12 months were excellent in 2 (both groups), good in 7 and 6 respectively, 11 fair (both groups), and unresponsive to treatment was noticed in 8 patients after 6 and 9 patients after 12 months. Significant reduction was found in the visual analog scale (VAS) for pain from an average of 8.8 to 4.2 after 3 months, 4.8 after 6 months and 4.9 after 1 year. The authors concluded that PRF is a safe and simple procedure to control radicular pain in the lumbar and cervical regions. Moreover, they emphasized the need for further prospective, double-blind studies to better ascertain the clinical value of this technique.

Bayer and associates (2005) evaluated the effectiveness of sphenopalatine ganglion PRF (SPG-PRF) treatment in patients suffering from chronic head and face pain. A total of 30 patients were observed from 4 to 52 months after PRF treatment. The primary outcome measures were reduction in oral medication use...
(including opioids), time to next treatment modality for presenting symptoms, duration of pain relief, and the presence of residual symptoms. Secondary outcome measures included the evaluation of adverse effects and complications. All data were derived from patient charts, phone conversations, and clinical follow-up visits. A total of 14 % of respondents reported no pain relief, 21 % had complete pain relief, and 65 % of the patients reported mild-to-moderate pain relief from SPG-PRF treatment. A total of 65 % of the respondents reported mild-to-moderate reduction in oral opioids. None of the patients developed significant infection, bleeding, hematoma formation, dysesthesia, or numbness of palate, maxilla, or posterior pharynx. The authors concluded that these findings suggested that a prospective, randomized, controlled study to confirm the safety and effectiveness of PRF treatment for chronic head and face pain is justified.

Vallejo and co-workers (2006) presented a prospective case series on the treatment of intractable sacroiliac joint (SIJ) dysfunction with PRF denervation (PRFD) of lateral branches from L4 to S3. A total of 126 patients with presumptive SIJ dysfunction based on history and physical examination underwent arthrographically confirmed steroid/local anesthetic SIJ injection. Fifty-two patients (41.3 %) had greater than 75 % pain relief after 2 consecutive injections, physical therapy, repeated SIJ injections, and/or analgesics. A total of 22 patients failed to respond; these individuals underwent PRFD of the medial branch of L4, posterior primary rami of L5, and lateral branches S1 and S2. Visual analog score and quality of life (QOL) assessments were performed before and after treatment. Sixteen patients (72.7 %) experienced "good" (greater than 50 % reduction in VAS), or "excellent" (greater than 80 % reduction in VAS) pain relief following PRFD. Duration of pain relief ranged from 6 to 9 weeks in 4 patients, 10 to 16 weeks in 5 patients, and 17 to 32 weeks in 7 patients. In addition, QOL scores improved significantly in all measured categories. Six patients (26.1 %) did not respond to PRFD and had less than 50 % reduction in VAS and were considered failures. The authors concluded that PRFD of the lateral branch of the medial branch of L4, posterior primary rami of L5, and lateral branches S1 and S2 is an effective treatment for some patients with SIJ pain unresponsive to other forms of therapy.

Teixeira and Sluijter (2006) stated that intra-discal RF, with the electrode placed in the center of the nucleus pulposus, has been a controversial procedure in patients with discogenic pain. These researchers examined the effect of high-voltage, long-duration intra-discal PRF in patients with 1-level discogenic LBP (n = 8), as confirmed by discography. The pain intensity score on a 0 to 10 NRS was used as outcome measure. The mean duration of pain was 6.3 years (range of 0.5 to 16 years, median of 4 years). The mean NRS score was 7.75 (range of 5 to 9). Disc height was reduced 60 % in 1 patient and up to 30 % in the remaining subjects. A 15-cm, 20-G needle with a 15-mm active tip was placed centrally in the disc. Pulsed radiofrequency was applied for 20 mins at a setting of 2 x 20 ms/s and 60 V. There was a very significant drop in the NRS scores over the first 3 months (p < 0.0001). On an individual basis, all patients had a fall of the NRS score of at least 4 points at the 3-month follow-up. A follow-up of 12.8 months (range of 6 to 25 months, median of 9 months) was available for 5 patients. All these patients are now pain-free, except for 1 patient with an NRS score of 2. The authors concluded that this method merits a controlled, prospective study.
Lindner et al (2006) noted that the use of PRF for the treatment of lumbar medial branch for facet pain is controversial. These investigators reported the findings of a retrospective study of PRF treatment of the medial branch in 48 patients with chronic LBP. Patients who did not respond were offered treatment with conventional RF heat lesions. Patients with LBP and greater than 50% pain relief following a diagnostic medial branch block were included in the study. The mean age was 53.1 +/- 13.5 years; the mean duration of pain was 11.4 +/- 10.9 years. Nineteen patients had undergone surgery. Pain scores on a NRS of 1 to 10 were noted before and after the diagnostic nerve block, before the procedure, and at 1-month and 4-month follow-up. PRF was applied for 2 mins at a setting of 2 x 20 ms/s and 45 V at a minimum of 2 levels using a 22-G electrode with a 5-mm active tip. Heat lesions were made at 80 degrees Centigrade (C) for 1 min. A successful outcome was defined as a greater than 60% improvement on the NRS at 4-month follow-up. In 21/29 non-operated patients and 5/19 operated patients, the outcome was successful. In the unsuccessful patients who were subsequently treated with heat lesions, the success rate was 1/6. The authors concluded that the setup of the study did not allow a comparison with the results of conventional/continuous RF (CRF) for the same procedure, other than the detection of an obvious trend. When comparing these findings with various studies on CRF of the medial branch such a trend could not be found. Based on these retrospective data, prospective and randomized studies (e.g., PRF versus CRF) are justified.

In the only prospective, randomized, double-blinded, controlled trial of PRF for trigeminal neuralgia published to date, Erdine and colleagues (2007) compared PRF to CRF in the treatment of idiopathic trigeminal neuralgia. A total of 40 patients were randomly assigned to PRF or CRF. Visual analog scale scores decreased significantly ($p < 0.001$) and patient satisfaction scale (PSS) scores improved significantly ($p < 0.001$) after the procedure in subjects assigned to CRF. The VAS score decreased in only 2 of 20 patients from the PRF group and pain recurred 3 months following the procedure. At the end of 3 months, CRF was performed in patients assigned to PRF because all patients in this group still exhibited intractable pain. The authors concluded that PRF is ineffective in treating trigeminal neuralgia.

In a Cochrane review, Zakrzewska and Akram (2011) evaluated the efficacy of neurosurgical interventions for classical trigeminal neuralgia in terms of pain relief, quality of life and any harms, and determined if there are defined subgroups of patients more likely to benefit. These investigators searched the Cochrane Neuromuscular Disease Group Specialized Register, (May 13, 2010), CENTRAL (issue 2, 2010 part of the Cochrane Library), Health Technology Assessment (HTA) Database, NHS Economic Evaluation Database (NHSEED) and Database of Abstracts of Reviews of Effects (DARE) (issue 4, 2010 (HTA, NHSEED and DARE are part of the Cochrane Library)), MEDLINE (January 1966 to May 2010) and EMBASE (January 1980 to May 2010) with no language exclusion. Randomized controlled trials (RCTs) and quasi-RCTs of neurosurgical interventions used in the treatment of classical trigeminal neuralgia were selected for analysis. Two authors independently assessed trial quality and extracted data. They contacted authors for clarification and missing information whenever possible. A total of 11 studies involving 496 participants met some of the inclusion
criteria stated in the protocol. One hundred and eighty patients in 5 studies had peripheral interventions, 229 patients in 5 studies had percutaneous interventions applied to the Gasserian ganglion, and 87 patients in 1 study underwent 2 modalities of stereotactic radiosurgery (Gamma Knife) treatment. No studies addressing microvascular decompression (which is the only non-ablative procedure) met the inclusion criteria. All but 2 of the identified studies had a high-to-medium risk of bias because of either missing data or methodological inconsistency. It was not possible to undertake meta-analysis because of differences in the intervention modalities and variable outcome measures. Three studies had sufficient outcome data for analysis. One trial, which involved 40 participants, compared 2 techniques of RF thermocoagulation (RFT) of the Gasserian ganglion at 6 months. Pulsed RFT resulted in return of pain in all participants by 3 months. When this group were converted to conventional (continuous) treatment these participants achieved pain control comparable to the group that had received conventional treatment from the outset. Sensory changes were common in the continuous treatment group. In another trial, of 87 participants, investigators compared radiation treatment to the trigeminal nerve at 1 or 2 isocenters in the posterior fossa. There were insufficient data to determine if one technique was superior to another. Two isocenters increased the incidence of sensory loss. Increased age and prior surgery were predictors for poorer pain relief. Relapses were non-significantly reduced with 2 isocenters (risk ratio (RR) 0.72, 95% confidence interval (CI): 0.30 to 1.71). A 3rd study compared 2 techniques for RFT in 54 participants for 10 to 54 months. Both techniques produced pain relief (not significantly in favor of neuronavigation (RR 0.70, 95% CI: 0.46 to 1.04) but relief was more sustained and side effects fewer if a neuronavigation system was used. The remaining 8 studies did not report outcomes as pre-determined in the protocol. The authors concluded that there is very low quality evidence for the efficacy of most neurosurgical procedures for trigeminal neuralgia because of the poor quality of the trials. All procedures produced variable pain relief, but many resulted in sensory side effects. There were no studies of microvascular decompression which observational data suggested gives the longest pain relief. There is little evidence to help comparative decision making about the best surgical procedure. They stated that well-designed studies are urgently needed.

In a case series study, Martin and colleagues (2007) reported the effectiveness of PRF in the treatment of patients with lumbosacral spondylosis. This case series reviewed 22 patients who had been previously treated with PRF with good results. Patients who had been prescribed opioids were excluded from this study. During the PRF application, tissue temperature was limited to 43 degrees C. A minimum of 200 mA of current was delivered in each case. The minimum current (at 50 Hz) necessary to stimulate the involved nerve was recorded. The time from PRF treatment until the patient requested a subsequent application was documented. The effective duration of PRF in patients treated for lumbosacral spondylosis ranged from 5 to 18 months (mean +/- SD: 9 +/- 3.7 months; n = 16). Administrations of PRF to dorsal root ganglion (DRG) were effective from 2 to 12 months (7 +/- 3.8 months; n = 8). Similar results were observed when PRF was applied to cervical medial branch nerves, one suprascapular nerve, and one stellate ganglion. The mean sensory stimulation thresholds obtained before treatment ranged from 0.08 V to 0.14 V. The authors concluded that in this select
population of patients who did not receive opioids, and had a favorable response to a previous PRF application, the duration of pain relief supported the use of PRF as an effective pain treatment.

In a retrospective study, Abejon and associates (2007) assessed the effectiveness of PRF applied to the lumbar DRG for the treatment of LBP. This study analyzed the findings of 54 patients who underwent 75 PRF procedures. Patients were divided into 3 groups according to the etiology of the lesion: (i) herniated disc (HD), (ii) spinal stenosis (SS), and (iii) failed back surgery syndrome (FBSS). The analgesic effectiveness of the technique was assessed using a 10-point Numeric Rating Scale (NRS) at baseline and, along with the Global Perceived Effect (GPE), at 30, 60, 90, and 180 days. The reduction in pain medications and the number of complications associated with the technique were assessed. A decrease in the NRS score was observed in patients with HD (p < 0.05) and SS (p < 0.001), but not in those with FBSS. The GPE scores confirmed this finding. No complications were noted. The authors concluded that PRF of the DRG was significantly more effective in HD and SS than in FBSS patients. The application of PRF was ineffective in FBSS.

Van Zundert and associates (2007) examined the effect of PRF for the treatment of patients with chronic cervical radicular pain. A total of 23 patients, out of 256 screened, met the inclusion criteria and were randomly assigned in a double-blind fashion to receive either PRF or sham intervention. The evaluation was carried out by an independent observer. At 3-month follow-up, the PRF group showed a significantly better outcome with regard to the global perceived effect (i.e., greater than 50% improvement) and VAS (i.e., 20 point pain reduction). The quality of life scales also showed a positive trend in favor of the PRF group, but significance was only reached in the SF-36 domain vitality at 3 months. The need for pain medication was significantly reduced in the PRF group after 6 months. No complications were observed during the study period. These findings are in agreement with the results of the authors’ previous clinical audit that PRF treatment of the cervical DRG may provide pain relief for a limited number of carefully selected patients with chronic cervical radicular pain as assessed by clinical and neurological examination.

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

Cahana and associates (2006) stated that the clinical advantages and mechanisms of PRF remain unclear. These investigators reviewed clinical and laboratory data on PRF. The final analysis yielded 58 reports on the clinical use of PRF in different applications: 33 full publications and 25 abstracts. They also retrieved 6 basic science reports, 5 full publications, and 1 abstract. The authors stated that the accumulation of these data showed that the use of PRF generates an increasing interest of pain physicians for the management of a variety of pain
syndromes. Although the mechanism of action has not been fully elucidated, laboratory reports suggested a neurobiological phenomenon altering the pain signaling, which some researchers have described as neuromodulatory. No side effects related to PRF were reported to date. The authors concluded that further research in the clinical and biological effects of this technique is justified.

In a review on PRF treatment, Gallagher (2006) stated that "we should cautiously prescribe this promising intervention following clinical algorithms that are based upon the best clinical evidence available. However, it is critically important to avoid the mistake of creating a "carte blanche" environment for those practitioners who would abuse the privilege and opportunity presented by this new technology, besmirching our credibility and ultimately impeding the opportunity to use this treatment to the benefit of the public. Ultimately, evidence, not reimbursement, should determine whether pulsed radiofrequency finds a place in our clinical toolbox".

It should be noted that the Reflex Sympathetic Dystrophy Syndrome Association (2006) did not recommend PRF for the treatment of patients with complex regional pain syndrome. It stated that future studies may expand on the role of PRF techniques or such unstudied techniques as cryosurgery as alternative therapies to treat patients with sympathetically maintained pain. The Transport Accident Commission, a government-owned organization of the State of Victoria in Melbourne, Australia (2007) does not consider PRF neurotomy/denervation as part of spinal injection therapy.

Malik and Benzon (2007) reviewed the available literature on PRF and determined its clinical efficacy. Their search of the literature yielded 341 citations; and 51 relevant articles were found. There were 4 review articles: 44 articles pertained to the application of PRF by an electrode placed in the vicinity of a neural structure. Of these, only 2 were randomized controlled trials (RCTs). Of the remaining 42 articles, 1 was a non-RCT, 3 were prospective uncontrolled trials: there were 6 retrospective studies, 11 case reports, 8 laboratory studies, 2 position papers, 5 editorials and 7 items of correspondence, while 1 publication reported 2 studies. Three articles pertained to transcutaneous application of PRF. Of the 2 RCTs, 1 reported efficacy of the PRF while the other reported it to be ineffective. The majority of the uncontrolled and observational studies reported clinical efficacy of PRF, however many of these studies had limitations. The authors concluded that further RCTs are needed for pain physicians to clearly understand the role of PRF in the treatment of various chronic pain syndromes. Furthermore, these investigators (Malik and Benzon, 2008) stated that larger RCTs are needed to (i) assess the long-term effects of RF applications (pulsed and continuous mode) to dorsal root ganglia and (ii) determine the precise mode of action of this technique.

Simopoulos and colleagues (2008) prospectively evaluated the response and safety of pulsed and continuous RF lesioning of the dorsal root ganglion/segmental nerves in patients with chronic lumbosacral radicular pain. A total of 76 patients with chronic lumbosacral radicular pain refractory to conventional therapy met the inclusion criteria and were randomly assigned to 1 of 2 types of treatment, PRF lesioning of the dorsal root ganglion/segmental nerve or PRF followed immediately by continuous RF. Patients were carefully evaluated for neurological deficits and side effects. The response was evaluated at 2 months
and was then tracked monthly. A Kaplan-Meier analysis was used to illustrate the probability of success over time and a Box-Whisker analysis was applied to determine the mean duration of a successful analgesic effect. Two months after undergoing RF treatment, 70% of the patients treated with PRF and 82% treated with pulsed and continuous RF had a successful reduction in pain intensity. The average duration of successful analgesic response was 3.18 months (+/- 2.81) in the group treated with PRF and 4.39 months (+/- 3.50) in those patients treated with pulsed and continuous RF lesioning. A Kaplan-Meier analysis illustrated that in both treatment groups the chance of success approached 50% in each group at 3 months. The vast majority of patients had lost any beneficial effects by 8 months. There was no statistical difference between the 2 treatment groups. No side effects or neurological deficits were found in either group. The authors concluded that pulsed mode RF of the dorsal root ganglion of segmental nerves appears to be a safe treatment for chronic lumbosacral radicular pain. A significant number of patients can derive at least a short-term benefit. The addition of heat via continuous radiofrequency does not offer a significant advantage. A RCT trial is now required to ascertain the effectiveness of PRF.

Byrd and Mackey (2008) stated that the mechanism by which PRF controls pain is unclear, but it may involve a temperature-independent pathway mediated by a rapidly changing electrical field. Although much anecdotal evidence exists in favor of PRF, there are few quality studies substantiating its utility.

In a pilot study, Misra et al (2009) evaluated the effectiveness of PRF of spermatic cord in the treatment of chronic testicular pain. A total of 10 patients with chronic testicular pain were treated with PRF stimulation of the spermatic cord. A RF probe placed percutaneously into the spermatic cord was used to deliver four 120-second cycles of 20-millisecond pulses at 2 Hz. Test stimulation was first used to confirm the precise placement of the probe. The short-form McGill Pain Questionnaire was used to assess pain before treatment and at 3 months. Patients who had experienced improvement were followed-up by telephone, to determine if pain relief was sustained. Ten patients were entered into the study but 1 was lost to follow-up. Of the 9 patients evaluated, 4 had complete resolution of pain, while 1 had partial pain relief. Three patients experienced no change and 1 reported that his pain was worse. All patients who experienced complete and partial pain relief continued to do so at a mean long-term follow-up of 9.6 months (range of 3 to 14 months). There were no complications observed immediately or during the follow-up period. The authors reported that pain scores improved in 5 out of 9 patients. They concluded that PRF of spermatic cord appears to be a safe minimally invasive outpatient procedure that should be investigated further with placebo-controlled trials.

In a case series study, Tamimi and colleagues (2009) examined the use of PRF in the treatment of myofascial trigger points and scar neuromas. A total of 9 patients were treated over an 18-month period. All patients had longstanding myofascial or neuromatous pain that was refractory to previous medical management, physical therapy, and trigger point injections. Eight out of 9 patients experienced 75% to 100% reduction in their pain following PRF treatment at initial evaluation 4 weeks following treatment. Six out of 9 (67%) patients experienced 6 months to greater than 1 year of pain relief. One patient experienced no better relief in terms of degree of pain reduction or duration of benefit when compared with previous
trigger point injections. No complications were noted. The authors stated that these findings suggested that PRF could be a minimally invasive, less neurodestructive treatment modality for these painful conditions and that further systematic evaluation of this treatment approach is needed.

Basal et al (2010) noted that premature ejaculation (PE) is the most common sexual problem experienced by men, and affecting 20 to 30 % of them. Pulsed radiofrequency neuromodulation has been studied as a treatment for various pain conditions. These researchers used PRF to treat PE by desensitizing dorsal penile nerves in patients resistant to conventional treatments. A total of 15 patients with a lifelong history of PE, defined as an intra-vaginal ejaculatory latency time (IELT) of less than 1 min that occurred in more than 90 % of intercourses and resistant to conventional treatments, were enrolled in this study. Patients with erectile dysfunction were excluded. The mean age of the patients was 39 +/- 9 years. Before and 3 weeks after the treatment, IELT and sexual satisfaction scores (SSS) (for patients and their partners) were obtained. The mean IELT before and 3 weeks after procedure were 18.5 +/- 17.9 and 139.9 +/- 55.1 seconds, respectively. There were no side effects. Mean SSS of patients before and after treatment were 1.3 +/- 0.3 and 4.6 +/- 0.5 and mean SSS of partners before and after treatment were 1.3 +/- 0.4 and 4.4 +/- 0.5, respectively. In all cases, IELT and SSS were significantly increased (p < 0.05). None of the patients and their wives defined any treatment failure during the follow-up period. The mean follow-up time was 8.3 +/- 1.9 months. The authors stated that it is early to conclude that this new treatment modality might be used widely for the treatment of PE, however being an innovative modality, placebo controlled studies (e.g., sham procedure), with larger number of patients, including assessment of penile sensitivity (e.g., biothesiometry) are needed.

Pudendal neuralgia (PN) involves severe, sharp pain along the course of the pudendal nerve, often aggravated with sitting. The ideal management for PN has not been determined. Rhame and colleagues (2009) presented a case of a female with 1.5 years of sharp, burning pain of the left gluteal and perineal regions. She could not sit for longer than 10 to 15 mins. Sacroiliac joint, epidural, and piriformis injections did not improve her pain. She had tried acupuncture, massage, occupational therapy, and physical therapy but the pain persisted. Medication treatment with amitriptyline, gabapentin, extended release morphine sulfate, and oxycodone-acetaminophen provided only minor relief and she had failed other multi-analgesic therapy. She had been unable to work at her desk job for over 1 year. She had a positive response to 2 diagnostic pudendal nerve blocks with lidocaine that provided pain relief for several hours. This patient elected to undergo PRF of the left pudendal nerve in hopes of achieving a longer duration and improved pain relief. Pulsed RF was performed at a frequency of 2 Hz and a pulse width of 20 milliseconds for a duration of 120 seconds at 42 degrees Celsius. After the procedure, she reported tolerating sitting for 4 to 5 hrs. Her multi-analgesic therapy was successfully weaned. At 5 months follow-up, she felt motivated to return to work. One and a half years after the procedure the patient is only taking oxycodone-acetaminophen for pain relief and still has good sitting tolerance. There were no procedure-related complications. To the authors' knowledge PRF for the treatment of PN has not been reported elsewhere in the literature. It is a relatively new procedure and is felt to be safer than continuous RF. Current literature suggests that PRF delivers an electromagnetic field, which
modifies neuro-cellular function with minimal cellular destruction. The authors concluded that PRF of the pudendal nerve offers promise as a potential treatment of PN that is refractory to conservative therapy.

Vanelderen et al (2010) reported on the results of a prospective trial with 6 months of follow-up in which PRF treatment of the greater and/or lesser occipital nerve was used to treat occipital neuralgia. Patients presenting with clinical findings suggestive of occipital neuralgia and a positive test block of the occipital nerves with 2 ml of local anesthetic underwent a PRF procedure of the culprit nerves. Mean scores for pain, quality of life, and medication intake were measured 1, 2, and 6 months following the procedure. Pain was measured by the visual analog and Likert scales, quality of life was measured by a modified brief pain questionnaire, and medication intake was measured by a Medication Quantification Scale. During a 29-month period, 19 patients were included in the study. Mean VAS and median Medication Quantification Scale scores declined by 3.6 units \((p = 0.002)\) and 8 units \((p = 0.006)\), respectively, during 6 months. Approximately 52.6 % of patients reported a score of 6 (pain improved substantially) or higher on the Likert scale after 6 months. No complications were reported. The authors concluded that PRF treatment of the greater and/or lesser occipital nerve is a promising treatment of occipital neuralgia. They stated that this study warrants further placebo-controlled trials.

Choi et al (2012) reported the results of PRF treatment of the occipital nerve, which was used to treat occipital neuralgia. Patients were diagnosed with occipital neuralgia according to the International Classification of Headache Disorders classification criteria. These investigators performed PRF neuromodulation when patients presented with clinical findings suggestive occipital neuralgia with positive diagnostic block of the occipital nerves with local anesthetics. Patients were analyzed according to age, duration of symptoms, surgical results, complications and recurrence. Pain was measured every month after the procedure using the visual analog and total pain indexes. From 2010, a total of 10 patients were included in the study. The mean age was 52 years (34 to 70 years). The mean follow-up period was 7.5 months (6 to 10 months). Mean VAS and mean total pain index scores declined by 6.1 units and 192.1 units, respectively, during the follow-up period. No complications were reported. The authors concluded that PRF neuromodulation of the occipital nerve is an effective treatment for occipital neuralgia. Moreover, they stated that further controlled prospective studies are needed to evaluate the exact effects and long-term outcomes of this treatment method.

In a randomized, double-blinded, placebo controlled trial, Taverner and colleagues (2010) examined if transcutaneous-PRF treatment (TCPRFT) was able to reduce the pain experienced by patients awaiting total knee joint replacement (TKJR). Patients on the waiting list for assessment for TKJR were invited to participate and were examined in the clinic if they satisfied the inclusion criteria. Patients were randomized to receive active or sham TCPRFT. The alteration in pain and function of the treated knee after a single TCPRFT was assessed at examination at 1 and 4 weeks using VAS at rest and after 20-m and 400-m walks. The results of 50 patients showed a statistically significant reduction in VAS at 1 and 4 weeks compared with baseline in the group who received active treatment. These researchers also demonstrated what is considered a clinically significant
improvement in this group that became more pronounced at week 4 compared with week 1 and also more after a 400-m walk compared with a 20-m walk. Maximum improvement observed in group data was 19/100 VAS. Patients receiving sham treatment showed no statistically significant improvement. The authors believed this to be the first report of a controlled study of TCPRFT. They stated that the findings of this pilot study showed a benefit of the technique that justifies future research.

Basal et al (2012) evaluated the effectiveness of PRF denervation of spermatic cord for the treatment of chronic orchialgia. A total of 5 patients were evaluated with a thorough medical and psychiatric history, physical examination and scrotal doppler ultrasound, urinary system X-ray film and urine analysis. One of the patients had bilateral chronic orchialgia. All the patients had pain for at least a period more than 3 months, and multiple conservative therapies failed to alleviate the pain. Patients, who had temporary pain relief after undergoing outpatient diagnostic cord block, were determined to be candidates for PRF denervation. Pulsed RF denervation of spermatic cord was performed for 6 testicular units. Visual analog scores were noted before and after the procedure. There were no pathologic conditions that indicated chronic orchialgia in any of the patients. No complications including testicular atrophy or hypoesthesia of the scrotal or penile skin occurred after the procedure. Mean VAS before and after the procedure was 9 and 1, respectively. None of the patients needed any analgesics after the procedure and during the follow-up period. Mean follow-up period was 20 +/- 2.5 weeks. No recurrence was noted and none of the patients needed additional therapy. The authors concluded that this is a limited case report on the short-term use of PRF. They stated that randomized, placebo-controlled and long follow-up period studies are needed to better assess the effectiveness of this procedure for chronic orchalgia.

In a review on "radiofrequency and pulsed radiofrequency treatment of chronic pain syndromes" van Boxem et al (2008) stated that there are currently 6 reviews on PRF for the management of spinal pain. Two reviews on interventional pain management techniques in general also discussed RF. The outcomes of those reviews depend on the type of studies included and the opinion of the reviewers, which may result in different evidence levels. Radiofrequency denervation at the cervical and lumbar level has produced the most solid evidence. The differences in treatment outcome registered in the 5 RCTs regarding lumbar facet denervation can be attributed to differences in patient selection and/or inappropriate technique. There is insufficient evidence supporting the use of RF facet denervation for the management of cervicogenic headache. The studies examining the management of cervical radicular pain suggested a comparable efficacy for RF and pulsed RF (PRF). The PRF treatment is supposed to be safer and therefore should be preferred. The superiority of RF treatment adjacent to the lumbar dorsal root ganglion for the management of lumbar radicular pain has not been demonstrated in an RCT. Information regarding RF treatment of sacro-iliac joint pain is accumulating. No randomized sham-controlled trials on the value of RF treatment of the Gasserian ganglion for the management of idiopathic trigeminal neuralgia have been published. One RCT indicated superiority of RF over PRF for the management of idiopathic trigeminal neuralgia. The authors concluded that future research to confirm or deny the efficacy of (P)RF should be conducted in carefully selected patient populations. The tests used for patient
inclusion in such a trial could potentially help the clinician in selecting patients for this type of treatment. They also stated that the value of PRF treatment of the peripheral nerves also needs to be confirmed in well-designed trials.

Chua et al (2011) evaluated the effectiveness of PRF treatment in chronic pain management in RCTs and well-designed observational studies. The physics, mechanisms of action, and biological effects were discussed to provide the scientific basis for this promising modality. These investigators systematically searched for clinical studies on PRF. They searched the MEDLINE (PubMed) and EMBASE database, using the free text terms: pulsed radiofrequency, radio frequency, radiation, isothermal radiofrequency, and combination of these. They classified the information in 2 tables, 1 focusing only on RCTs, and another, containing prospective studies. Date of last electronic search was May 30, 2010. These researchers found 6 RCTs that evaluated the efficacy of PRF, 1 against corticosteroid injection, 1 against sham intervention, and the rest against conventional RF thermocoagulation. Two trials were conducted in patients with LBP due to lumbar zygapophyseal joint pain, 1 in cervical radicular pain, 1 in lumbo-sacral radicular pain, 1 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 lumbo-sacral counterpart, the use of PRF can not be similarly advocated in view of the methodological quality of the included study. Pulsed RF application to the supracapular nerve was found to be as effective 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.

van Boxem et al (2011) noted that lumbosacral radicular syndrome (LRS) is probably the most frequent neuropathic pain syndrome. Three months to 1 year after onset, 30 % of the patients still experience ongoing pain. The management of those patients is complex, and treatment success rates are rather low. The beneficial effect of PRF therapy has been described for the treatment of LRS in case reports and in retrospective and prospective studies. Up until now, no neurological complications have been reported after PRF treatment. These investigators performed a clinical audit to evaluate the amount of pain relief after a single PRF treatment. A total of 60 consecutive patients who received a PRF treatment adjacent to the lumbar-dorsal root ganglion for the management of LRS in the period 2007 to 2009 were included. The main study objective was to measure the reduction of pain after the PRF treatment by using the global perceived effect. The primary end point was defined as at least 50 % pain relief for a period of 2 months or longer. The primary end point was achieved in 29.5 % of all the PRF interventions. After 6 months, 50 % pain relief was still present in 22.9 % of the cases and after 12 months in 13.1 % of the cases. The need for pain medication was significantly lower after PRF treatment in the success group compared with the non-success group. The authors concluded that PRF treatment can be considered for the management of LRS patients. Moreover, they stated that these results need to be confirmed in a RCT.

In a systematic review, Hansen and colleagues (2012) evaluate the effectiveness of therapeutic sacro-iliac joint (SIJ) interventions. The available literature on therapeutic SIJ interventions in managing chronic LBP and lower extremity pain
was reviewed. The quality assessment and clinical relevance criteria utilized were
the Cochrane Musculoskeletal Review Group criteria for randomized trials of
interventional techniques and the criteria developed by the Newcastle-Ottawa
Scale for observational studies. The level of evidence was classified as good, fair,
or poor based on the quality of evidence developed by the U.S. Preventive
Services Task Force (USPSTF). Data sources included relevant literature
published from 1966 through December 2011 that was identified through searches
of PubMed and EMBASE, and manual searches of the bibliographies of known
primary and review articles. The primary outcome measure was pain relief (short-
term relief = up to 6 months and long-term relief = greater than 6 months).
Secondary outcome measures were improvement in functional status,
psychological status, return to work, and reduction in opioid intake. For this
systematic review, a total of 56 studies were considered for inclusion. Of these,
45 studies were excluded and a total of 11 studies met inclusion criteria for
methodological quality assessment with 6 randomized trials and 5 non-randomized
studies. The evidence for cooled radiofrequency neurotomy in managing SIJ pain
is fair. The evidence for effectiveness of intra-articular steroid injections is poor.
The evidence for peri-articular injections of local anesthetic and steroid or
botulinum toxin is poor. The evidence for effectiveness of conventional RF
neurotomy is poor. The evidence for PRF is poor. The authors concluded that the
evidence was fair in favor of cooled RF neurotomy and poor for short-term and
long-term relief from intra-articular steroid injections, peri-articular injections with
steroids or botulin toxin, PRF, and conventional RF neurotomy.

Werner et al (2012) stated that in the United States, it is estimated that between
6,000 and 18,000 individuals each year present with disabling pain after inguinal
hernia repair. Although surgical treatment with mesh removal is one of few
options available, effective alternatives to non-surgical management are needed.
The use of PFR, leading to non-destructive lesions of nerve structures, has been
proposed as a treatment option. To examine the evidence of treatment efficacy, a
systematic literature search was made. From the databases PubMed, Embase,
and CINAHL, 4 case reports were retrieved and 8 patients were included for
analysis. The PFR treatment was peripheral (n = 4) and central (n = 4). Pain
relief varied between 63 % and 100 %, the follow-up period was 3 to 9 months, and
no adverse effects or complications were reported. The authors concluded that the
evidence base of PRF in persistent pain following inguinal herniotomy is fairly
limited. They also presented suggestions for improved research strategies in this
field.

Taverner et al (2013) reported a retrospective audit of transcutaneous PRF
treatment therapy (TCPRFT) for shoulder pain over a 4-year period. Electronic
and manual case review revealed that TCPRFT had been performed on 13
patients, with 15 painful shoulders, using a single treatment session between 2006
and 2010 in an out-patient setting. Of the 15 shoulders treated, 10 had pain relief
for over 3 months with an average pain score reduction of 6.1 of 10 and an
average duration of pain relief of 395 days. Two experienced pain relief of less
than 3 months with an average reduction in pain score of 4.3 of 10 and an average
duration of effect of 11 days. Three cases experienced no pain relief from the
treatment. These results suggested TCPRFT may provide clinically useful pain
relief and be another treatment modality for shoulder pain. The authors concluded
that these findings justifies further research, and they are proceeding with a double
-blind placebo RCT to determine the effectiveness of TCPRFT in chronic shoulder pain.

Fang et al (2014) examined the effectiveness and clinical utility of CT-guided PRF for treatment of trigeminal neuralgia (TN). Patients who were diagnosed with severe TN between September 2010 and October 2010 were included. Pulsed radiofrequency treatment was employed to treat TN. To verify the accurate needle position, a thin-section cranial CT scan was performed by using a multi-detector CT scanner. Three-dimensional reconstruction was performed to visualize the location of the needle and the foramen ovale. A total of 20 patients were included in the study. Seven patients (35 %) had favorable outcome 1 year after the PRFT. The numeric rating scale in the 7 patients with good outcome was significantly lower than the 13 patients with bad outcome at 1 day, 1 week, and 2 weeks after the treatment. The remaining 13 patients had residual pain 2 weeks after the PRFT and had to receive RF thermo-coagulation (RFTC). The authors concluded that these findings demonstrated that CT-guided PRFT is not an effective method of pain treatment for idiopathic TN as compared with conventional RFTC. However, CT-guided PRFT is associated with less complication than RFTC.

Rana and Matchett (2013) stated that pain associated with cancer is often difficult to treat, even more so when tumors involve peripheral nerves. Therapy is complex and often requires a multi-modal approach that can include medications, radiation, and interventional techniques. These components are utilized with variable success, but are also limited by known complications or adverse effects. These investigators presented the case of a 53-year old woman with a metastatic axillary tumor that involved her brachial plexus. Attempts to control her pain with medication were unsuccessful despite escalation and use of adjunct agents. She was not deemed to be a surgical candidate due to the size and location of the tumor. Radiation was discussed but, obviously, would not work immediately. These investigators decided to employ a brachial plexus catheter for continuous nerve block, which provided almost complete relief of pain. Since her pain was deemed to be of peripheral etiology, PRF ablation of her brachial plexus was used for more long-term pain relief. The patient responded very well with minimal pain issues and no apparent complications. On follow-up, the patient had good relief for almost 2 months. Pulsed radiofrequency is a poorly understood technology that has increasing evidence for certain pain conditions; however, for cancer and peripheral nerves the evidence is slim to none. The authors noted that this case presented a successful use for pain management of a brachial plexopathy due to a tumor. They proposed that PRF may present a non-neurodestructive pain management technique for tumors involving peripheral nerves, although more data are definitely needed.

Bui et al (2013) reported on the utility of a pudendal nerve block by PRF ablation for the treatment of male pelvic pain and urinary urgency and hesitancy. The patient was an 86-year old man with a 30-year history of urinary hesitancy and urgency. The patient also had pain in the area of the perineum but considered it a secondary issue. The patient was seen by a number of specialists, tried various medications, and underwent a variety of procedures to no avail. Therefore, the patient underwent a PRF ablation of the pudendal nerve. The patient reported marked improvement in his pelvic pain as well as a drastic reduction in his urinary
urgency and hesitancy. The authors concluded that urinary urgency and hesitancy and male pelvic pain are some of the most common symptoms affecting men. Pudendal nerve block by PRF ablation is an effective treatment of pelvic pain. It may also hold some therapeutic value in the treatment of urinary urgency and hesitancy as this case demonstrated. Moreover, they stated that further studies are needed to help clarify both the anatomy of the pelvis as well as if pudendal blocks are effective in treating more than pelvic pain.

Kestranek et al (2013) described a new treatment of refractory severe vulvodynia. These researchers reported on the successful use of the PRF treatment in a patient with intractable chronic vulvodynia. To the authors' knowledge, this is the first report of a successful use of PRF in the treatment of chronic vulvodynia. They concluded that if the effectiveness of PRF is confirmed by more studies, it would be a welcome addition to the treatment modalities used to treat this sometimes truly intractable condition.

The American Society of Interventional Pain Physicians' updated guidelines on "Interventional techniques in chronic spinal pain" (Manchikanti et al, 2013) noted that the evidence is limited for pulsed radiofrequency neurotomy as a therapeutic lumbar facet joint interventions; and the evidence is limited for both pulsed radiofrequency and conventional radiofrequency neurotomy as a therapeutic sacroiliac joint interventions.

Schianchi et al (2013) evaluated the effectiveness of intra-articular (IA) PRF in a group of 57 consecutive patients with chronic joint pain. Patients with intractable joint pain for more than 6 months were treated with IA PRF 40 to 45 V for 10 to 15 mins in small joints and 60 V for 15 mins in large joints using fluoroscopic confirmation of correct needle position. A total of 28 shoulders, 40 knees, 10 trapezio-metacarpal, and 11 first metatarso-phalangeal joints were treated. Results were evaluated at 1, 2, and 5 months. The procedure was repeated after 1 month in 10 patients with initial suboptimal results. Success was defined as a reduction of pain score by at least 50 %. All groups showed significant reductions in pain scores at all 3 follow-up visits. Success rates were higher in small joints (90 % and 82 %, respectively) than large ones (64 % and 60 %, respectively). Interestingly, IA PRF was successful in 6 out of 10 patients who had undergone previous surgery, including 3 with prosthetic joint replacement and in 6 of the 10 repeated procedures. There were no significant adverse effects or complications. The authors concluded that IA PRF induced significant pain relief of long duration in a majority of the patients with joint pain. The exact mechanism is unclear, but may be related to the exposure of immune cells to low-strength RF fields, inducing an anti-inflammatory effect. The success rate appears to be highest in small joints. The authors recommended additional research including control groups to further investigate and clarify this method; these data suggested that PRF may represent a useful modality in the treatment of arthrogenic pain.

Kim and colleagues (2014) noted that amputation neuroma can cause very serious, intractable pain. Many treatment modalities are suggested for painful neuroma. Pharmacologic treatment shows a limited effect on eliminating the pain, and surgical treatment has a high recurrence rate. These investigators applied PRF treatment at the neuroma stalk under ultrasonography guidance. The long-term outcome was very successful, prompting these researchers to report this
case. These preliminary findings from a single-case study need to be validated by well-designed studies.

Terkawi and Romdhane (2014) stated that chronic orchalgia is a frustrating clinical problem for both the patient and the physician. These researchers presented a 17-year-old boy with a bilateral idiopathic chronic intractable orchalgia with failed conservative treatment. For 2 years, he suffered from severe attacks of scrotal pain that affected his daily activities and caused frequent absence from school. These investigators performed ultrasound-guided PRF ablation of the genital branches of the genito-femoral nerve after local anesthetic nerve block confirmed the diagnosis and yielded 6 weeks of symptom relief. The authors noted that 7-month follow-up revealed complete satisfactory analgesia. The clinical value of this non-invasive approach to treat intractable chronic orchalgia needs to be further researched.

Thapa and Ahuja (2014) stated that plantar fasciitis (PF) is the most common cause of chronic heel pain, which may be bilateral in 20 to 30% of patients. The management includes both pharmacological and operative procedures with no single proven effective treatment modality. In the present case series, these investigators managed 3 patients with PF (1 with bilateral PF). Following a diagnostic medial calcaneal nerve (MCN) block at its origin, these researchers observed reduction in verbal numerical rating scale (VNRS) in all 3 patients; 2 patients had relapse of PF pain that was managed with MCN block followed with PRF. All the patients were pain-free at the time of reporting. The authors concluded that this case series study highlighted the possible role of combination of diagnostic MCN block near its origin followed with PRF as a new modality in management of patients with PF. These preliminary findings need to be validated by well-designed studies.

Park et al (2014) noted that post-herpetic neuralgia (PHN) is one of the most difficult pain syndromes to treat. Invasive treatments may be considered when patients fail to obtain adequate pain relief from noninvasive treatment approaches. These researchers presented 3 cases of PHN in the mandibular branch treated with ultrasound-assisted mental nerve block and PRF treatment. None of the patients had adequate pain relief from the medical therapy, so these investigators performed the mental nerve block on the affected side under ultrasound assistance. Two patients showed satisfactory pain relief continuously over 12 months without any further interventions, whereas 1 patient only had short-term pain relief. For the patient who had short-term pain relief, these researchers performed PRF treatment on the left mental nerve under ultrasound assistance. After PRF treatment, the patient had adequate pain relief for 6 months and there was no need for further management. These preliminary findings from a single patient need to be validated by well-designed studies.

Chon and colleagues (2014) stated that tarsal tunnel syndrome (TTS) is a compression neuropathy that results from entrapment of the posterior tibial nerve or its branches. Tarsal tunnel syndrome may be treated either by conservative measures, including physical therapy, medications, and steroid injections, or by surgical decompression. Despite a variety of treatments, a few cases of TTS will relapse, and many cases of recurrent TTS will require re-operation. These researchers reported a new application of ultrasound-guided PRF in 2 cases of
intractable TTS. Both patients had a long duration of severe foot pain and had been treated with various therapeutic modalities without lasting relief. These investigators applied ultrasound-guided PRF to the affected posterior tibial nerve in each patient, and both had significantly reduced pain intensity scores and analgesic requirements without any complications. The authors concluded that ultrasound-guided PRF for intractable TTS relieved severe foot pain; it may supersede surgery as a reliable treatment for intractable TTS. These preliminary findings need to be validated by well-designed studies.

In summary, there is currently insufficient evidence to support the use of PRF in the treatment of various chronic pain syndromes. Well-designed studies (prospective, randomized, placebo-controlled trials with large sample size and long-term follow-up) are needed to ascertain the clinical value of this approach.

CPT Codes / HCPCS Codes / ICD-9 Codes

There are no specific codes for pulsed radiofrequency:

ICD-9 codes not covered for indications listed in the CPB (not all-inclusive):

- 215.0 - 215.9 Other benign neoplasm of connective tissue and other soft tissue [neuromatous pain]
- 302.75 Premature ejaculation
- 337.20 - 337.29 Reflex sympathetic dystrophy [complex regional pain syndrome]
- 338.21 - 338.29 Chronic pain
- 338.3 Neoplasm related pain (acute) (chronic) [tumors involving peripheral nerves]
- 350.1 Trigeminal neuralgia
- 355.0 - 355.9 Mononeuritis of lower limb [pudendal nerve entrapment or neuropathy] [lower extremity neuralgia]
- 608.9 Unspecified disorder of male genital organs [testicular pain]
- 625.70 - 625.79 Vulvodynia
- 715.16, 715.26, 715.36, 715.96 Osteoarthrosis of knee
- 716.98 Arthropathy unspecified, other specified sites [facet and sacroiliac joint]
719.40 - Pain in joint [zygapophyseal]
719.49

723.1 Cervicalgia
723.8 Other syndromes affecting cervical region [occipital neuralgia]
724.2 Lumbago
724.4 Thoracic or lumbosacral neuritis or radiculitis, unspecified [lumbosacral radicular syndrome]
724.5 Backache, unspecified
724.6 Disorders of sacrum as not covered [sacroiliac joint pain]
729.1 Myalgia and myositis, unspecified [myofascial pain]
729.2 Neuralgia, neuritis, and radiculitis, unspecified [ pudendal]
784.0 Headache
788.63 Urgency of urination
788.64 Urinary hesitancy

The above policy is based on the following references:


