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
- Diabetic peripheral neuropathy
- Discogenic pain
- Face and head pain
- Facet and sacroiliac joint arthropathy
- Headache
- Inguinal neuralgia
- Low back pain
- Lower extremity neuralgia Lumbo-sacral radicular syndrome
- Metatarso-phalangeal joint pain
- Morton's neuroma
- Myofascial or neuromatous pain
- Neck pain
- Occipital neuralgia
- Orchalgia

Number: 0735
*Please see amendment for Pennsylvania Medicaid at the end of this CPB.

Policy History

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Review History

Definitions

Additional Information

Clinical Policy Bulletin Notes
Osteoarthritis of the knee
- Pain associated with tumors involving peripheral nerves
- Pelvic pain
- Plantar fasciitis Post-
- herpetic itch Post-herpetic
- neuralgia Premature
- ejeculation Pudendal
- neuralgia
- Reflex sympathetic dystrophy/complex regional pain syndrome
- Sacro-iliac joint pain
- Shoulder pain
- Striae rubra
- Tarsal tunnel syndrome
- Testicular pain (orchialgia)
- Thoracic pain Trapezio-
- metacarpal joint pain Trigeminal
- neuralgia
- Urinary urgency and hesitancy
- Vaginismus
- Ventricular arrhythmias (fibrillation or tachycardia)
- Vulvodynia
- Zygapophyseal joint pain.

See [CPB 0016 Back Pain - Invasive Procedures (.//1_99/0016.html)] 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.

Pulsed radiofrequency is a proposed alternative to traditional radiofrequency neurotomy. Pulsed radiofrequency delivers short bursts of radiofrequency current instead of a continuous flow, which allows the needle to remain relatively cool so that the tissue cools slightly between each burst, reducing the risk of destroying nearby 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 Numeric Rating Scale (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 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 penil 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'r 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 suprascapular 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 (TCPFRFT) for shoulder pain over a 4-year period. Electronic and manual case review revealed that TCPFRFT 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 TCPFRFT 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 TCPFRFT 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.

and clinical relevance criteria utilized were the Cochrane Musculoskeletal Review Group criteria for RCTs and the Newcastle-Ottawa Scale criteria for observational studies. The level of evidence was classified as good, fair, and poor based on the quality of evidence. The primary outcome measures were reduction in pain scores and improvement in quality of life. The primary outcome measures were headache relief and improved quality of life. A total of 25 studies were identified for full text review; of these, 9 studies met inclusion criteria. There were 5 non-randomized, among them 4/5 were of moderate quality, 3/5 showed RF ablation and 1/5 showed PRF as an effective intervention for CHA. There were 4 randomized trials among them 2/4 were of high quality, 3/4 investigated RF ablation as an intervention for CHA, 1/4 investigated PRF ablation as an intervention for CHA and none of the randomized studies showed strong evidence for RF and PRF ablation as an effective intervention for CHA. The authors concluded that there is limited evidence to support RF ablation for management of CHA as there are no high quality RCTs and/or multiple consistent non-RCTs without methodological flaws. They also noted that there is poor evidence to support the use of PRF for the treatment of CHA as there are no high quality RCTs or non-RCTs.

**Face and Head Pain:**

Akbas et al (2016) retrospectively evaluated the satisfaction of PRF treatment in patients suffering from chronic face and head pain. Infra-zygomatic approach was used for the PRF of the sphenopalatine ganglion under fluoroscopic guidance. After the tip of the needle reached the target point, 0.25 to 0.5 ms pulse width was applied for sensory stimulation at frequencies from 50 Hz to 1 V. Paraesthesias were exposed at the roof of the nose at 0.5 to 0.7V. To rule out trigeminal contact that led to rhythmic mandibular contraction, motor stimulation at a frequency of 2 Hz was applied. Then, 4 cycles of PRF lesioning were performed for 120s at a temperature of 42° C. Pain relief could not be achieved in 23 % of the patients (unacceptable), whereas pain was completely relieved in 35 % of the patients.
(excellent) and mild-to-moderate pain relief could be achieved in 42% of the patients (good) through spheno-palatine ganglion-PRF treatment. The authors concluded that PRF of the spheno-palatine ganglion is effective in treating the patients suffering from intractable chronic facial and head pain. Moreover, they stated that there is a need for prospective RCTs in order to confirm the safety and effectiveness of this new treatment modality in chronic face and head pain.

Inguinal Neuralgia:

In a randomized, double-blind controlled trial, Makharita and Amr (2015) evaluated the effectiveness of PRF in management of chronic inguinal neuralgia. A total of 21 patients were allocated into 2 groups. Group 1 received 2 cycles of PRF for each nerve root. In Group 2, after stimulation, these researchers spent the same time to mimic PRF. Both groups received bupivacaine 0.25% + 4 mg dexamethasone in 2 ml for each nerve root; VAS was assessed. Duration of the first block effective pain relief was reported. Repeated PRF blockade was allowed for any patient who reported a VAS greater than 30 mm in both groups during the 1 year follow-up period. The number and duration of blocks were reported and adverse effects were also reported. Significantly longer duration of pain relief was noticed in Group 1 (p = 0.005) after the first block, while the durations of pain relief of the second block were comparable (p = 0.59). In Group 1 the second PRF produced pain relief from the 24th week until the 10th month while in Group 2, pain relief was reported from the 16th week until the 8th month after the use of PRF. All patients in Group 2 received 3 blocks (the first was a sham PRF) during the 1 year follow-up period. Meanwhile, 2 PRF blocks were sufficient to achieve pain relief for patients in Group 1 except 4 patients who needed a third PRF block. No adverse events were reported. The authors concluded that for intractable chronic inguinal pain, PRF for the dorsal root ganglion represents a promising treatment modality. The main drawback of this study was its small sample size (n = 20)
Morton’s Neuroma:

Deniz and associates (2015) stated that Morton's neuroma is a perineural fibrosis of an inter-metatarsal plantar nerve. Burning, numbness, paresthesia, and tingling down the interspaces of involved toes may also be experienced. Taking into account all of this information, these researchers designed a prospective open-label study to evaluate the effectiveness of PRF on Morton's neuroma. A total of 20 patients with Morton's neuroma were experiencing symptomatic neuroma pain in the foot not relieved by routine conservative treatment. All of the patients had been evaluated by a specialized orthopedist and were offered PRF as a last option before having surgery. Initially, pain level (numerical rating scale), successful pain control (a greater than or equal to 50 % pain decrease was accepted as successful pain control), comfort when walking (yes or no), and satisfaction level (satisfied or not satisfied) were evaluated. These investigators reported a decrease in the pain level in 18 of 20 patients, successful pain control in 12, and wearing shoes and walking without pain in 16. Overall, satisfaction was rated as excellent or good by 12 patients with Morton's neuroma in this series. The authors concluded that these findings indicated that ultrasound-guided PRF is a promising treatment modality in the management of Morton's neuroma pain.

Post-Herpetic Itch:

Ding and colleagues (2014) reported the findings of a patient with intractable post-herpetic itch lasting for 1 year. The itch was mainly from the left vertex, frontal and ophthalmic regions and extended to the left neck area. The patient had negative response to the ophthalmic nerve block. Under the initial positive response to the great occipital nerve block, PRF was performed on the position of the great occipital nerve. After 4 months treatment, the itch was completely vanished. The authors concluded that this case study demonstrated the effectiveness of PRF for intractable post-herpetic itch originating in the head and neck. However, they stated that
more patients are needed to verify this management.

Thoracic Pain:

In a retrospective data analysis involving 49 patients, Cohen et al (2006) compared treatment outcomes between pharmacotherapy, PRF of the intercostal nerves (ICN) and PRF of the dorsal root ganglia (DRG) in chronic postsurgical thoracic pain (CPTP). At 6-week follow-up, 61.5 % of the PRF DRG group reported greater than or equal to 50 % pain relief versus 27.3 % in the medical management (MM) group and 21.4 % in the IC group (p = 0.12). At 3-month follow-up, 53.8 % in the DRG group continued to report greater than or equal to 50 % pain relief versus 19.9 % in the MM and 6.7 % in the ICN groups, respectively (p = 0.02). Among the PRF patients who did report a successful outcome, the mean duration of pain relief was 2.87 months in the ICN group and 4.74 months in the DRG group (p = 0.01). The authors concluded that PRF of the DRG was a superior treatment to pharmacotherapy and PRF of the ICN in patients with CPTP. Moreover, they stated that prospective studies are needed to confirm these results and identify the best candidates for this treatment.

In a prospective, randomized, double-blinded study, Ke and colleagues (2013) examined the safety and effectiveness of PRF for treating thoracic PHN through the puncture of the angulus costae. A total of 96 patients with thoracic (T2-L1) PHN were equally randomized assigned into 2 groups. The electrode needle punctured through the angulus costae of each patient guided by x-ray; PRF at 42° C for 120 seconds was applied after inducing paresthesia involving the affected dermatome area. Pulsed RF was applied in the PRF group (n = 48) twice. It was also applied in the sham group (n = 48) twice without RF energy output. The treatment was done once-weekly for 3 weeks. Tramadol was used for flare pain when the VAS was greater than or equal to 3. The therapeutic effect was evaluated by VAS, SF-36 health survey questionnaire, side effects (type, frequency, and onset time) before treatment, at days 3, 7, and 14, and at months 1, 2, 3 and 6 after PRF. The average of
tramadol (mg/day) administered within the 1st month after treatment was also recorded. The post-procedure VAS scores in the PRF group were significantly lower than those in the sham group and lasted for 6 months after treatment (p < 0.05). The SF-36 score, such as physical functioning, physical role, pain, general perceptions of health, social function, emotional role, and mental health index were significantly improved until 6 months after treatment in the PRF group compared to the sham group (p < 0.01 to 0.05). The average dosage of tramadol administrated (mg/day) within the 1st month after treatment was also significantly reduced in the PRF group compared to the sham group (p < 0.05). There were no obvious signs of pneumothorax, bleeding, infection, or other severe side effects in either group (p > 0.05). The authors concluded that the strategy that the angulus costae be used as the PRF puncture point of an electrode needle and the final localization of the needle tip as determined by sensory testing was an effective and safe therapeutic alternative for thoracic PHN treatment. They stated that the benefits included that the procedure was minimally invasive, provided short-term pain relief, and improved quality of life. The main drawbacks of this study were its single-center study, relatively small number of patients, and mid-term follow-up duration (6 months).

The Work Loss Data Institute’s guideline on “Low back -- lumbar & thoracic (acute & chronic)” (2013) listed PRF treatment as one of the interventions/procedures were considered, but are not recommended.

Gulati et al (2015) noted that tumors invading the chest wall and pleura are often incurable, and treatment is targeted toward palliation of symptoms and control of pain. When patients develop tolerance or side effects to systemic opioid therapy, interventional techniques can better optimize a patient’s pain. These investigators performed a retrospective review of 146 patients from April 2004 to January 2014 who underwent diagnostic and therapeutic procedures for pain relief. Using 4 patients as a paradigm for neurolytic approaches to pain relief, these researchers presented a therapeutic
algorithm for treating patients with intractable thoracic chest wall pain in the oncologic population. For each patient, these researchers described the use of intercostal/paravertebral nerve blocks and neurolysis, PRF ablation (PRFA) of the thoracic nerve roots, or intrathecal pump placement to successfully treat the patient's chest wall pain. Analysis of 146 patient charts was also performed to assess effectiveness of therapy. A total of 79% of patients undergoing an intercostal nerve diagnostic blockade (with local anesthetic and steroid) stated that they had improved pain relief with 22% having prolonged pain relief (average of 21.5 days). Only 32% of successful diagnostic blockade patients elected to proceed to neurolysis, with a 62% success rate; 7 patients elected to proceed to intrathecal drug delivery. The authors concluded that intercostal nerve diagnostic blockade with local anesthetic and steroid may lead to prolonged pain relief in this population. Furthermore, depending on tumor location, the authors have developed a paradigm for the treatment of thoracic chest wall pain in the oncologic population. Pulled RF ablation was not discussed as a successful means of treating thoracic chest wall pain associated with tumors.

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.

*Diabetic Peripheral Neuropathy:*

Naderi and associates (2015) compared the effectiveness of transcutaneous electrical nerve stimulation (TENS) and PRF lumbar sympathectomy in treating painful diabetic peripheral neuropathy (DPN). A total of 65 patients with painful DPN refractory to conventional treatment were randomly and evenly assigned to either the TENS or PRF lumbar sympathectomy groups. Pain evaluations were based on the 10-point NRS. Subjects were followed for 3 months and had a total of 4 study
visits (baseline and 1 week, 1 month, and 3 months after treatment); 60 patients completed all study visits. In both groups, the NRS rating significantly decreased after treatment, with a marked pain reduction observed at the first follow-up evaluation. In the PRF group, the NRS decreased from 6.46 at baseline to 2.76 at the 1 week visit. One and 3 months after treatment, the NRS was 4.30 and 5.13, respectively (p < 0.0001). In the TENS group, the NRS decreased from 6.10 at baseline to 3.96 at the 1 week visit. One and 3 months after treatment, the NRS was 5.23 and 5.90, respectively (p < 0.0001). Unfortunately, the NRS steady increased almost back to baseline levels in the TENS group. The NRS only slightly increased during the follow-up period in the PRF group, but did not reach baseline levels. The authors concluded that both TENS and PRF lumbar sympathectomy are promising pain relief treatments for painful DNP. However, PRF lumbar sympathectomy appeared to have a superior efficacy. They stated that further studies with a larger sample size and a longer follow-up period are needed.

**Striae Rubra:**

Karia and colleagues (2016) noted that striae are linear atrophic depressions that form in areas of dermal damage in the skin. Currently, no consensus or protocol exists for the treatment of stria rubra. Topical retinoids, chemical peels, microdermabrasion, radiofrequency, photothermolysis, intense pulsed light and lasers are some of the modalities used. These researchers compared the effectiveness of various therapeutic modalities in striae rubra. This prospective cohort study comprised of a total of 50 patients from August 2012 to October 2013 in a tertiary care center in Western India, Gujarat having striae rubra. They were randomly divided into 5 groups of 10 patients each. Patients were evaluated on the basis of visual assessment, both by doctor as well as the patient. Group I was given topical tretinoin (0.1 % w/w) gel applied once at night, Group II: microdermabrasion (MDA) combined with trichloroacetic acid (TCA) (30 %) peel, Group III: mesotherapy, Group IV: Q-switched Nd: YAG laser, and Group V-
treatment of microdermabrasion, salicylic acid peel and retinol (yellow) peel. Patients were treated at an interval of 15 days for 2 months and then at monthly intervals. Objective assessment was done at 2nd month, 6th month, and at the end of 1st year. Patients in Group I treated with topical tretinoin showed the least response with 80% (n = 8) of them showing minimal clinical improvement (0 to 25 %) as compared to patients in Group V in which 60 % (n = 6) patients showed moderate clinical improvement (50 to 75 %). While the majority of the patients in Group II, III, and IV showed mild clinical improvement (25 to 50 %). The authors concluded that striae rubra is a common cause of concern for adolescent population. Combination treatment with microdermabrasion, salicylic acid and retinol yellow peel gave superior results as compared to other therapeutic options. Mild-to-moderate improvement was seen with Nd: YAG laser, mesotherapy and MDA + TCA whereas minimal improvement were seen with topical tretinoin.

**Vaginismus:**

Carvalho and co-workers (2015) stated that vaginismus is a poorly understood disorder, characterized by an involuntary muscular spasm of the pelvic floor muscles and outer third of the vagina during intercourse attempt, which results in aversion to penetration. It is reported to affect 1% to 7% of women worldwide. The authors described the case of a young patient with vaginismus in whom techniques usually from the chronic pain domain (e.g., PRF and trigger point infiltration) were used as part of her multi-modal therapeutic regimen. The clinical benefit of PRF for the treatment of vaginismus needs to be further investigated.

**Ventricular Arrhythmias (Fibrillation or Tachycardia):**

Hayase and associates (2016) stated that there is increasing interest in interventional therapies targeting the cardiac sympathetic nervous system to suppress ventricular arrhythmias. In this case report, these researchers described an
80-year old patient with ischemic cardiomyopathy and multiple implantable cardioverter-defibrillator shocks due to refractory ventricular tachycardia and ventricular fibrillation who was unable to continue bi-weekly stellate ganglion block procedures using bupivacaine 0.25 % for suppression of his arrhythmias. He had previously failed anti-arrhythmic drug therapy with amiodarone, catheter ablation, and attempted surgical autonomic denervation. He underwent PR treatment (3 lesions, 2 minutes each, temperature 42°C, 2-Hz frequency, 20-millisecond pulse width) of the left stellate ganglion resulting in persistent arrhythmia suppression for more than 12 months duration. This represented the first report of a PR stellate ganglion lesion providing long-term suppression of ventricular arrhythmias. The authors concluded that further study of this technique in patients with refractory ventricular tachycardia or ventricular fibrillation is needed.

### CPT Codes / HCPCS Codes / ICD-10 Codes

*Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+".*

**ICD-10 codes will become effective as of October 1, 2015:**

There are no specific codes for pulsed radiofrequency:

**ICD-10 codes not covered for indications listed in the CPB (not all-inclusive):**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>B02.21</td>
<td>Zoster with other nervous system involvement [post-herpetic neuralgia]</td>
</tr>
<tr>
<td>B02.29</td>
<td></td>
</tr>
<tr>
<td>D21.0</td>
<td>Other benign neoplasms of connective and other soft tissue [neuromatous pain]</td>
</tr>
<tr>
<td>D21.9</td>
<td></td>
</tr>
<tr>
<td>D36.10</td>
<td>Benign neoplasm of peripheral nerves and automatic nervous system [neuromatous pain]</td>
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<tr>
<td>D36.17</td>
<td></td>
</tr>
<tr>
<td>F52.4</td>
<td>Premature ejaculation</td>
</tr>
<tr>
<td>G44.1</td>
<td>Vascular headache, not elsewhere classified</td>
</tr>
<tr>
<td>G50.0</td>
<td>Trigeminal neuralgia</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>-------------</td>
</tr>
<tr>
<td>G57.0</td>
<td>Mononeuropathies of lower limb [ pudendal nerve entrapment or neuropathy] [ lower extremity neuralgia] [ tarsal tunnel syndrome]</td>
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<tr>
<td>G57.92</td>
<td></td>
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<tr>
<td>G58.8</td>
<td>Other specified and unspecified mononeuropathy [ pudendal nerve entrapment or neuropathy]</td>
</tr>
<tr>
<td>G58.9</td>
<td></td>
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<tr>
<td>G89.21</td>
<td>Chronic pain, not elsewhere classified</td>
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<tr>
<td>G89.28</td>
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<tr>
<td>G89.3</td>
<td>Neoplasm related pain (acute) (chronic) [tumors involving peripheral nerves]</td>
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<tr>
<td>G90.50</td>
<td>Complex regional pain syndrome I (CRPSI)</td>
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<tr>
<td>G90.59</td>
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<tr>
<td>M12.9</td>
<td>Arthropathy, unspecified [ facet and sacroiliac joint]</td>
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<tr>
<td>M17.0</td>
<td>Osteoarthritis of knee</td>
</tr>
<tr>
<td>M17.9</td>
<td></td>
</tr>
<tr>
<td>M25.50</td>
<td>Pain in joint [ zygapophyseal] [ metatarso-phalangeal] [ trapezio-metacarpal]</td>
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<tr>
<td>M25.57</td>
<td></td>
</tr>
<tr>
<td>M51.15</td>
<td>Thoracolumbar and lumbosacral intervertebral disc disorders with radiculopathy</td>
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<tr>
<td>M51.17</td>
<td></td>
</tr>
<tr>
<td>M51.9</td>
<td>Unspecified thoracic, thoracolumbar and lumbosacral intervertebral disc disorder [ discogenic pain]</td>
</tr>
<tr>
<td>M53.3</td>
<td>Sacrococcygeal disorders, not elsewhere classified [ sacroiliac joint pain]</td>
</tr>
<tr>
<td>M54.10</td>
<td>Radiculopathy, site unspecified [ pudendal]</td>
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<tr>
<td>M54.17</td>
<td>Radiculopathy, lumbosacral region</td>
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<tr>
<td>M54.18</td>
<td>Radiculopathy, sacral and sacrococcygeal region [ pudendal]</td>
</tr>
<tr>
<td>M54.2</td>
<td>Cervicalgia</td>
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<tr>
<td>M54.5</td>
<td>Low back pain [ lumbago]</td>
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<tr>
<td>M54.6</td>
<td>Pain in thoracic spine</td>
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<tr>
<td>M54.81</td>
<td>Occipital neuralgia</td>
</tr>
<tr>
<td>M54.89</td>
<td>Other and unspecified dorsalgia</td>
</tr>
<tr>
<td>M54.9</td>
<td></td>
</tr>
</tbody>
</table>
M72.2  Plantar fascial fibromatosis
M79.1  Myalgia [myofascial pain]
M79.2  Neuralgia and neuritis, unspecified [ pudendal]
N50.8  Other specified disorders of male genital organs [testicular pain]
N94.810 - N94.819  Vulvodyia
R39.11  Hesitancy of micturition
R39.15  Urgency of urination
R51  Headache
R52  Pain, unspecified [chronic pain NOS]

The above policy is based on the following references:


39. Choi HJ, Oh IH, Choi SK, Lim YJ. Clinical outcomes of


49. Schianchi PM, Sluijter ME, Balogh SE. The treatment of joint pain with intra-articular pulsed radiofrequency.


59. Ding DF, Li RC, Xiong QJ, et al. Pulsed radiofrequency to


AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: 0735
Pulsed Radiofrequency

There are no amendments for Medicaid.