

Ablative Treatment for Spinal Pain

Policy Number: 2020T0107W
Effective Date: January 1, 2020

[Instructions for Use](#)

Table of Contents	Page
Coverage Rationale	1
Documentation Requirements	2
Definitions	2
Applicable Codes	3
Description of Services	3
Clinical Evidence	4
U.S. Food and Drug Administration	10
Centers for Medicare and Medicaid Services	10
References	10
Policy History/Revision Information	12
Instructions for Use	13

<p>Related Commercial Policies</p> <ul style="list-style-type: none"> Discogenic Pain Treatment Epidural Steroid and Facet Injections for Spinal Pain Occipital Neuralgia and Headache Treatment Office Based Procedures – Site of Service Omnibus Codes
<p>Community Plan Policy</p> <ul style="list-style-type: none"> Ablative Treatment for Spinal Pain
<p>Medicare Advantage Coverage Summary</p> <ul style="list-style-type: none"> Pain Management and Pain Rehabilitation

Coverage Rationale

[Thermal Radiofrequency Ablation](#) of facet joint nerves is proven and medically necessary for the following:

- Initial treatment of [chronic](#) cervical (C3 and below), thoracic and lumbar pain when:
 - Clinical documentation shows a [Functional Impairment](#) due to facet pain; and
 - Clinical documentation of a diagnostic [Facet Joint Injection](#) and/or [Facet Nerve Block](#) (i.e., Medial Branch Block) to localize the source of spinal pain to the facet joint confirms the following:
 - At least a 50% reduction in pain from baseline at the specific side and level of the proposed ablation; and
 - The reduction in pain is sufficient to allow a measurable functional improvement; and
 - The diagnostic procedure is not performed on the same day as the ablation procedure
- Repeat treatment of [chronic](#) cervical (C3 and below), thoracic and lumbar pain when:
 - Performed at a frequency of six months or longer (maximum of 2 times over a 12 month period per side and level); and
 - There has been a 50% or greater documented reduction in pain for at least 10 weeks following the previous ablation

[Thermal Radiofrequency Ablation](#) of facet joint nerves is unproven and not medically necessary in the following circumstances due to insufficient evidence of efficacy:

- The source of back pain at the proposed ablation level is from a cause other than facet joint syndrome that requires a different treatment approach. Examples include disc herniation, spinal stenosis, foraminal narrowing, vertebral fracture and spondylolisthesis; or
- All other pain indications. Examples include, but are not limited to, [occipital neuralgia](#), [headache](#), sacroiliac pain or [Complex Regional Pain Syndrome](#)

The following facet joint nerve ablation techniques are unproven and not medically necessary due to insufficient evidence of efficacy:

- [Pulsed Radiofrequency Ablation](#) of the facet nerves of the cervical, thoracic or lumbar region, sacral nerve root or dorsal root ganglion
- Endoscopic radiofrequency ablation/endoscopic rhizotomy
- Cryoablation (cryodenervation, cryoneurolysis, cryosurgery or cryoanesthesia)

- For information on cooled radiofrequency ablation, refer to the related Medical Policy titled [Omnibus Codes](#)
- Chemical ablation (including, but not limited to, alcohol, phenol or sodium morrhuate)
- Laser ablation (including pulsed, continuous or low level)
- Intraosseous radiofrequency ablation of the basivertebral nerve (e.g., Intracept®)

Documentation Requirements

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The documentation requirements outlined below are used to assess whether the member meets the clinical criteria for coverage but do not guarantee coverage of the service requested.

CPT Codes*	Required Clinical Information
Ablative Treatment for Spinal Pain	
22899 64633 64635	Medical notes documenting all of the following: <ul style="list-style-type: none"> ● Temperature of procedure ● Duration of ablation ● Functional Impairment due to facet pain ● Specific identification of side and level of Medial Branch Blocks and ablation ● Percentage of pain relief with Medial Branch Blocks or prior ablation, if applicable ● Duration of improvement from Medial Branch Blocks or prior ablation, if applicable

*For code descriptions, see the [Applicable Codes](#) section.

Definitions

Chronic Pain (Nonmalignant): Pain lasting longer than 3 months (Qaseem et al., 2017; Chou et al., 2009).

Complex Regional Pain Syndrome (CRPS): A [Chronic Pain](#) condition that affects a limb (arm, hand, leg or foot) usually after an injury to a nerve. CRPS is divided into two types: CRPS-I and CRPS-II. Individuals without a confirmed nerve injury are classified as having CRPS-I (previously known as reflex sympathetic dystrophy syndrome). CRPS-II (previously known as causalgia) is when there is an associated, confirmed nerve injury (National Institute of Neurological Disorders and Stroke, 2018).

Facet Joint Injection: The injection of a local anesthetic and/or corticosteroid into the facet joint. A facet joint injection/block may be diagnostic (to determine whether the facet joint is the source of pain) and/or therapeutic (to relieve pain).

Facet Nerve Block: The injection of a local anesthetic and/or corticosteroid along the nerves supplying the facet joints. A facet nerve block may be diagnostic (to determine whether the facet joint is the source of pain) and/or therapeutic (to relieve pain).

Functional Impairment: A physical or functional or physiological impairment causes deviation from the normal function of a tissue or organ. This results in a significantly limited, impaired or delayed capacity to move, coordinate actions or perform physical activities and is exhibited by difficulties in one or more of the following areas: physical and motor tasks; independent movement; performing basic life functions.

Medial Branch Block: Refer to [Facet Nerve Block](#).

Pulsed Radiofrequency Ablation: Technique that delivers intermittent bursts of current, instead of continuous current, using a probe temperature of 42°-45° Celsius (Hayes, 2016a; updated 2018).

Thermal Radiofrequency Ablation:

- Temperature ≥60° Celsius; and
- Duration of ablation ≥40 seconds; and
- Confirmation of needle placement by fluoroscopic guided imaging

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

Coding Clarifications:

- CPT codes 64633, 64634, 64635, and 64636 only apply to thermal (non-pulsed) radiofrequency ablation
- CPT code 64999 is to be used for pulsed radiofrequency ablation (CPT® Assistant, 2016)

CPT Code	Description
22899	Unlisted procedure, spine [when used to report the Intracept procedure]
64625	Radiofrequency ablation, nerves innervating the sacroiliac joint, with image guidance (i.e., fluoroscopy or computed tomography)
64633	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint
64634	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional facet joint (List separately in addition to code for primary procedure)
64635	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint
64636	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional facet joint (List separately in addition to code for primary procedure)
64999	Unlisted procedure, nervous system

CPT® is a registered trademark of the American Medical Association

Description of Services

Radiofrequency ablation (RFA) is a percutaneous treatment that uses radiowave-induced heat to create a lesion in a spinal sensory nerve. Following a prognostic blockade to target the affected nerve(s), radiofrequency (RF) current is applied in a pulsed or continuous manner for several minutes via a needle electrode to the targeted nerves under image guidance. The goal of RFA is to relieve pain and symptoms by interrupting pain signal transmission from the sensory nerve to the brain (Hayes, 2016a; updated 2018).

Thermal (non-pulsed) and pulsed are two types of RFA. Thermal RFA involves the constant application of energy via an image-guided needle electrode inserted through the skin (percutaneously) to the affected nerve (Hayes, 2016a; updated 2018). Once the probe is placed, lesions or nerves are then targeted unilaterally or bilaterally for 40 to 90 seconds at temperatures of 60 to 90°C.

Pulsed RFA delivers intermittent bursts of current instead of continuous current, allowing the tissue to cool between bursts (Hayes, 2016a; updated 2018).

Endoscopic rhizotomy, a posterior endoscopic method, also known as dorsal endoscopic rhizotomy, has been developed as an alternative to percutaneous electrode RFA to target the medial, intermediate and lateral branches of the dorsal ramus using a modification of the Yeung Endoscopic Spinal Surgery (Y.E.S.S.) cannula and a specially designed Ellman radiofrequency bipolar electrode.

Cryoablation involves the use of extreme cold to destroy nerve tissue.

Chemical ablation uses an injection of chemicals, such as phenol or alcohol, to destroy nerve tissue.

Laser ablation destroys nerve tissue using a laser beam.

Clinical Evidence

Thermal Radiofrequency Ablation for Facet Joint Pain

In a systematic review, Manchikanti et al. (2016) investigated the diagnostic validity and therapeutic value of lumbar facet joint interventions in managing chronic low back pain. The review process applied systematic evidence-based assessment methodology of controlled trials of diagnostic validity and randomized controlled trials of therapeutic efficacy. Inclusion criteria encompassed all facet joint interventions performed in a controlled fashion. Pain relief of greater than 50% was the outcome measure for diagnostic accuracy assessment of the controlled studies with ability to perform previously painful movements. For randomized controlled therapeutic efficacy studies, the primary outcome was significant pain relief, and the secondary outcome was a positive change in functional status. For the inclusion of the diagnostic controlled studies, all studies must have utilized either placebo controlled facet joint blocks or comparative local anesthetic blocks. In assessing therapeutic interventions, short-term and long-term reliefs were defined as either up to 6 months of relief or greater than 6 months of relief. Each manuscript included in the assessment was reviewed for methodologic quality or risk of bias assessment utilizing the Quality Appraisal of Reliability Studies checklist for diagnostic interventions, and Cochrane review criteria and the Interventional Pain Management Techniques - Quality Appraisal of Reliability and Risk of Bias Assessment tool for therapeutic interventions. Evidence based on the review of the systematic assessment of controlled studies was graded utilizing a modified schema of qualitative evidence with best evidence synthesis, variable from level I to level V. Across all databases, 16 high quality diagnostic accuracy studies were identified. In addition, multiple studies assessed the influence of multiple factors on diagnostic validity. In contrast to diagnostic validity studies, therapeutic efficacy trials were limited to a total of 14 randomized controlled trials, assessing the efficacy of intraarticular injections, facet or zygapophysial joint nerve blocks and radiofrequency neurotomy of the innervation of the facet joints. The evidence for the diagnostic validity of lumbar facet joint nerve blocks with at least 75% pain relief with ability to perform previously painful movements was level I, based on a range of level I to V derived from a best evidence synthesis. For therapeutic interventions, the evidence was variable from level II to III, with level II evidence for lumbar facet joint nerve blocks and radiofrequency neurotomy for long-term improvement (>6 months), and level III evidence for lumbosacral zygapophysial joint injections for short-term improvement only. This review provides significant evidence for the diagnostic validity of facet joint nerve blocks, and moderate evidence for therapeutic radiofrequency neurotomy and therapeutic facet joint nerve blocks in managing chronic low back pain.

A systematic literature review of randomized controlled trials on radiofrequency ablation (RFA) procedures for spinal pain performed by Geurts et al. (2001) reported moderate evidence that radiofrequency lumbar facet denervation is more effective for chronic low back pain than placebo.

Nath et al. (2008) conducted a randomized controlled study of percutaneous radiofrequency neurotomy in 40 patients with chronic low back pain (20 active and 20 controls). All patients were examined by an orthopaedic surgeon before and 6 months after the treatment (sham or active). Inclusion criteria were 3 separate positive facet blocks. The active treatment group showed statistically significant improvement not only in back and leg pain but also back and hip movement as well as the sacroiliac joint test. There was significant improvement in quality of life variables, global perception of improvement and generalized pain. The improvement seen in the active group was significantly greater than that seen in the placebo group. The investigators concluded that radiofrequency facet denervation could be used in the treatment of carefully selected patients with chronic low back pain.

Van Wijk et al. (2005) conducted a randomized double-blind, sham lesion controlled trial of 81 patients with chronic low back pain who were randomized to undergo RFA (n=40) or sham treatment (n=41). Three months after treatment, combined outcome measure indicated no difference between RFA and sham treatment. The global perceived effect was in favor of RFA.

Gofeld et al. (2007) conducted a prospective audit of 174 patients with complaints of low back pain for more than 6 months. Patients were asked to estimate total perceived pain reduction (on a scale from 0% to 100%) at 6 weeks and at 6, 12 and 24 months after the procedure. Fifty-five reported no benefit from the procedure and 119 reported good (>50%) to excellent (>80%) pain relief lasting from 6 to 24 months. The authors concluded that radiofrequency denervation of the lumbar zygapophysial joints provides long-term pain relief.

Definitive patient selection criteria for RFA as a treatment for chronic spinal pain have not been established.

Relative or absolute contraindications to RFA mentioned in the reviewed literature include:

- Neurologic abnormalities
- Definitive clinical and/or imaging findings
- Proven specific causes of low back pain, including disc herniation, spondylolisthesis, spondylosis ankylopoietica, spinal stenosis, discogenic or stenotic compression, malignancy, infection and trauma
- Allergy to radiopaque contrast or local anesthetic
- Patients with more than one pain syndrome
- Lack of response to diagnostic nerve blocks
- Patients with unstable medical conditions or psychiatric illness (Hayes, 2016a; updated 2018)

Thermal Radiofrequency Ablation for Sacroiliac Pain

A Hayes report concluded that the overall quality of the evidence regarding the use of thermal RFA for treating chronic SI joint pain is low. There is positive but inconsistent evidence suggesting that thermal RFA of the SI joint is safe and may improve symptoms of pain over the short to intermediate term compared with sham therapy or alternative therapies. The lack of a standard RF denervation technique for RFA prevents definitive conclusions regarding the efficacy and safety of the procedure. An inherent challenge to the efficacy of RFA is the variable anatomy of targeted lateral branch nerves in the SI joint. Questions remain regarding patient selection criteria, long-term outcomes and the comparative efficacy versus alternative therapies (Hayes, 2017; updated 2018).

In a randomized, double-blind multicenter study; van Tilburg et al. (2016) compared percutaneous RFA with a sham procedure in 60 patients with SI joint pain. The treatment group received RFA to the lateral branches of S1, S2, S3 and S4 nerve roots and the posterior dorsal ramus of L5. Primary outcome was pain reduction. The authors found that pain was significantly reduced in both the conventional RFA and sham groups, with no statistically significant difference between the mean pain scores in the RFA treatment group versus the sham treatment group at 1-month follow-up. The pooled mean score for pain in both groups decreased significantly by 1 month. Study limitations include small sample size, short-term follow-up and presence of placebo effect.

Hansen et al. (2012) performed a systematic review of therapeutic interventions for sacroiliac joint pain. The primary outcome measure was pain relief (short-term relief = up to 6 months and long-term > 6 months). Secondary outcome measures were improvement in functional status, psychological status, return to work and reduction in opioid intake. Fifty-six studies were considered for inclusion. Of these, 6 randomized trials and 5 non-randomized studies met inclusion criteria for methodological quality assessment. The authors concluded that the evidence for conventional and pulsed RFA is poor. The limitations of this review include a paucity of literature on therapeutic interventions, variations in technique and variable diagnostic standards for sacroiliac joint pain.

Aydin et al. (2010) conducted a meta-analysis to assess the effectiveness of RFA of the SI joint for pain relief. While it appears that patients had > 50% pain relief at both 3 and 6 months post-treatment, the study was limited by variability between each study and lack of randomized controlled trials to evaluate the use of RFA of the SI joint. The authors concluded that further studies are needed, preferably randomized controlled studies, to evaluate whether RFA improves health outcomes in patients with SI joint pain.

Cohen et al. (2008) conducted a randomized placebo-controlled study in 28 patients with injection-diagnosed SI joint pain. Patients were randomized equally to receive both a L4-L5 primary dorsal rami and S1-S3 lateral branch radiofrequency denervation using cooling-probe technology after a local anesthetic block, or local anesthetic block followed by placebo denervation. Patients who did not respond to placebo injections crossed over and were treated with radiofrequency denervation using conventional technology. At 1, 3 and 6 months after the procedure, 11 (79%), 9 (64%) and 8 (57%) radiofrequency-treated patients experienced pain relief of 50% or greater and significant functional improvement. In contrast, only 2 patients (14%) in the placebo group experienced significant improvement at their 1-month follow-up, and none experienced benefit 3 months after the procedure. In the crossover group (n = 11), 7 (64%), 6 (55%) and 4 (36%) experienced improvement 1, 3 and 6 months after the procedure. One year after treatment, only 2 patients (14%) in the treatment group continued to demonstrate persistent pain relief. The authors concluded radiofrequency denervation may provide intermediate-

term pain relief and functional benefit in selected patients with suspected SI joint pain; however, larger studies are needed to confirm these results and to determine the optimal candidates and treatment parameters for this disorder.

Pulsed Radiofrequency Ablation

A Hayes report concluded that a very-low-quality, limited body of evidence suggests that pulsed RFA application to the dorsal root ganglion may reduce pain in patients with cervical radicular pain that has failed to respond to conservative treatment; however, the body of evidence is insufficient to draw definitive conclusions (Hayes, 2019a).

A Hayes report concluded that the overall quality of the evidence regarding the use of pulsed RFA for treating chronic low back pain is low. There is a paucity of studies evaluating this technology as the primary intervention. There is insufficient evidence to establish definitive patient selection criteria for pulsed RFA as a treatment for chronic low back pain related to the lumbar or lumbosacral facet joints. Additional studies are needed before any definitive conclusions can be reached (Hayes, 2016b; updated 2018).

Lee et al (2011) noted that recently, clinical reports using pulsed RFA have shown favorable effects in the treatment of a variety of focal pain areas, including non-nervous system tissues; however, the mechanism of effect underlying this treatment to non-nervous system tissue remains unclear.

A prospective study by Vallejo et al. (2006) evaluated the effect of pulsed RFA in 126 patients with chronic low back pain due to SI joint syndrome. The main outcome measures were visual analog scale (VAS) and quality of life (QOL) questionnaire performed prior to and after the treatment. Of the 126 patients who underwent arthrographically confirmed steroid/local anesthetic SIJ injection, 52 patients (41.3%) had > 75% pain relief after conservative treatment, while 22 patients failed to respond to the treatment. The 22 patients who failed conservative treatment underwent pulsed RFA of the medial branch of L4, posterior primary rami of L5, and lateral branches S1 and S2. Results showed that 16 patients (72.7%) experienced good (> 50% reduction in VAS), or excellent (> 80% reduction in VAS) pain relief following pulsed RFA. Duration of pain relief range was 6-9 weeks in four patients, 10-16 weeks in five patients, and 17-32 weeks in seven 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 pulsed RFA may be an effective treatment for some patients with SIJ pain that has been unresponsive to other forms of treatment. This study is limited by small sample size and the uncontrolled study design.

Kroll et al. (2008) compared the efficacy of continuous radiofrequency (CRF) thermocoagulation with pulsed RFA in a prospective, randomized, double-blinded study of 50 patients with lumbar back pain. Target facet joints were identified with oblique radiographic views. Continuous radiofrequency thermocoagulation was delivered at 80°C for 75 seconds, while PRF was delivered at 42°C with a pulse duration of 20 ms and pulse rate of 2 Hz for 120 seconds. No significant differences in the relative percentage improvement were noted between groups in either VAS or Oswestry Low Back Pain and Disability Questionnaire (OSW) scores. Within the PRF group, comparisons of the relative change over time for both VAS and OSW scores were not significant. However, within the CRF group, VAS and OSW scores showed significant improvement. The investigators concluded that although there was no significant difference between CRF and PRF therapy in long-term outcome in the treatment of lumbar facet syndrome, there was a greater improvement over time noted within the CRF group.

Simopoulos et al. (2008) conducted a prospective study of 76 patients to evaluate the safety and efficacy of pulsed and continuous radiofrequency therapy of the dorsal root ganglion/segmental nerves in patients with chronic lumbosacral radicular pain. To participate in the study, all patients were first treated with a diagnostic/therapeutic selective nerve root block with temporary but complete pain relief of radicular symptoms. Patients were then randomly assigned to receive either pulsed RFA (n=37), at 42°C for 120 seconds, of the dorsal root ganglion/segmental nerve or pulsed RFA (n=39) followed immediately by continuous radiofrequency with averaged temperatures at 54°C + (5) for 60 seconds. Follow-up occurred at 8 weeks with monthly follow-ups until 8 months post treatment. Outcomes were measured by VAS. There was no significant difference in the percentage of successful response rate or in the average decline in VAS between the 2 groups. For both treatment groups there was a steep loss of analgesic effect between 2 to 4 months. By the eighth month, the vast majority of patients returned to their baseline pain intensity. The authors did not find a significant beneficial effect of adding continuous radiofrequency to pulsed RFA. Pulsed RFA may be beneficial for patients with dorsal root ganglion pain however the analgesic effect is time limited and determination of the actual efficacy of pulsed RFA in the treatment of chronic lumbosacral radicular pain needs additional further prospective controlled trials to further evaluate its use to treat dorsal root ganglion pain.

Abejon (2007) completed a retrospective analysis of the effectiveness of pulsed RFA applied to the lumbar dorsal root ganglion in 54 patients who underwent 75 PRF procedures. The patients were divided into three groups according to the etiology of the lesion herniated disc, spinal stenosis, and failed back surgery syndrome. The efficacy of the technique was assessed using a 10-point Numeric Rating Scale (at baseline and, along with the Global Perceived Effect (GPE) at 30, 60, 90, and 180 days. The reduction in medications and the number of complications associated with the technique were assessed although not reported. Pain reduction was noted in all groups except for those with failed back surgery syndrome. No complications were noted. The authors concluded that PRF was effective in herniated disc and spinal stenosis, but not failed back surgery syndrome. The flaws of this study include the retrospective design, subjective outcome measures and short term follow-up.

Van Zundert (2007) studied the effect of pulsed RFA on patients with cervical radicular pain in a prospective audit that showed satisfactory pain relief for a mean period of 9.2 months. Then a randomized sham controlled trial of 23 patients out of 256 screened, met the inclusion criteria and were randomly assigned in a double blind fashion to receive either pulsed RFA for 120 seconds or sham intervention. The evaluation was done by an independent observer. At 3 months the pulsed RFA group showed a significantly better outcome with regard to the global perceived effect (>50% improvement) and VAS (20 point pain reduction). The quality of life scales also showed a positive trend in favor of the pulsed RFA 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 pulsed RFA group after six months. No complications were observed during the study period. These study results are in agreement with the findings of a previously completed clinical audit that pulsed RFA of the cervical dorsal root ganglion may provide pain relief for a limited number of carefully selected patients with chronic cervical radicular pain as assessed by clinical and neurological examination. Although the study results are promising for certain patients, the small sample size, the use of subjective outcomes and lack of long term follow-up minimize the generalizations of the conclusions.

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. The author 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.

Chao et al. (2008) retrospectively reviewed 154 cases of patients with lumbar or cervical radicular pain due to a herniated intervertebral disk or previous failed surgery to analyze the efficacy of percutaneous pulsed RFA. Patients had pulsed RFA in 2 to 4 spinal levels unilaterally with follow-up from 1 week to 1 year postoperatively. Fifty three percent of 49 patients with cervical pain and fifty percent patients with lumbar pain had an initial improvement of 50% or more in the first week of follow-up. Fifty-five percent of patients with cervical pain and forty four percent of patients with lumbar pain had pain relief of 50% or more at the 3 month follow-up. The authors concluded that pulsed RFA appears to provide intermediate-term relief of pain; however, further studies with long-term follow-up are necessary. Limitations of this study include retrospective design and inability to generalize results due to wide range of follow-up. Additional well-designed studies are needed to evaluate long-term results of pulsed RFA.

Cahana (2006) completed a literature review of current clinical and laboratory data regarding the use of pulsed RFA. The final analysis yielded 58 reports on the clinical use of pulsed RFA in different applications: 33 full publications and 25 abstracts. Also six basic science reports, five full publications, and one abstract were reviewed. The accumulation of these data shows that the use of pulsed RFA generates an increasing interest of pain physicians for the management of a variety of pain syndromes. Although the mechanism of action has not been completely elucidated, laboratory reports suggest a genuine neurobiological phenomenon altering the pain signaling, which some have described as neuromodulatory. No side effects related to the pulsed RFA technique were reported to date. The author concluded that further research in the clinical and biological effects is needed.

Tekin et al. (2007) compared the effects of conventional radiofrequency (CRF) and pulsed RF (PRF) denervation to medial branches of dorsal rami in the treatment of facet joint pain. Local anesthetic was applied in the control group (n=20), whereas 80°C CRF for 90 seconds were applied in the CRF (n=20) and 2 Hz PRF at 42° C for 120 seconds were applied in the PRF group (n=20). Pain relief was evaluated by VAS and Oswestry Disability Index (ODI) at pre-procedure, at procedure, at 6 months and 1 year after the procedure. Mean preprocedural VAS and ODI scores were higher than postprocedural scores in all groups. Both VAS and ODI scores of PRF and CRF groups were lower than the score of the control group at the postprocedural evaluation. Although a decrease of the pain score was maintained in the CRF group at 6 months and at 1-year, this decrease discontinued in the PRF group at the follow-up periods. The number of patients not using analgesics and patient satisfaction

were highest in CRF group. The investigators concluded that PRF and CRF are effective and safe alternatives in the treatment of facet joint pain but PRF is not as long lasting as CRF.

Endoscopic Radiofrequency Ablation/Endoscopic Rhizotomy

Clinical outcomes from a pilot study evaluating endoscopic RFA were presented as a professional society conference abstract (Yeung et al., 2011).

Li et al. (2014) evaluated the effectiveness of surgical dorsal endoscopic rhizotomy in 58 patients with lumbar facetogenic chronic low back pain. Forty-five patients who experienced >80% relief of pain with two comparative lumbar medial branch blocks received dorsal endoscopic rhizotomy. The remaining 13 patients received conservative treatment. The authors reported that percentage of pain relief in the operation group at any time point postoperatively were significantly higher than that in the conservative group. Further studies with larger sample sizes and longer follow-up are needed to further validate the efficacy of this technique.

Cryoablation

Birkenmaier et al. (2007) conducted a prospective clinical case series to examine the effects of medial branch cryodeneration (cryoablation) in the treatment of lumbar facet joint pain. Patient selection was based on medical history, physical examination and positive medial branch blocks. Percutaneous medial branch cryodeneration was performed using a Lloyd Neurostat 2000. Target parameters were low back pain (by means of VAS, limitation of activity (McNab) and overall satisfaction. A total of 50 patients were recruited, and 46 completed the study. The follow-up time was 1 year. At 6 weeks, 33 patients (72 %) were pain-free or had major improvement of low back pain; 13 (28 %) had no or little improvement. Including failures, mean low back pain decreased significantly from 7.7 pre-operatively to 3.2 at 6 weeks, 3.3 at 3 months, 3.0 at 6 months and 4.2 at 12 months. However, the authors noted that at the 12 month follow-up period the failure rate rose to 43%.

A prospective study by Staender et al. (2005) evaluated the therapeutic effect of computerized tomography (CT)-guided cryorhizotomy in the treatment of 76 patients with lumbar facet joint syndrome (LFJS). All of the patients received one treatment after confirmation with a medial branch block using a 1.3cm size needle. Twenty-six patients required 2-4 additional treatments and a 2.0cm needle was used. The VAS was used as an evaluation tool along with reports of return to work and pain med use. Success was determined to be 50% reduction in VAS scores. Pre-treatment the median score was 6.7 and post-treatment was 3.2 for up to 6 months. Individual scores pre- and post-treatment were not reported. Patients without prior back surgery had a better result than post-surgical patients. The authors concluded the CT-guided treatment was effective. The intervening variable of the medial branch blocks has to be taken into account as part of the pain relief response which the authors acknowledge. Fifty percent of patients had 50% pain relief for at least up to a year in the reported aggregate data. Six percent of patients failed treatment. Although the results are promising, further study is needed to identify the placebo effect of the medial branch blocks.

Chemical Ablation

Joo et al. (2013), compared alcohol ablation with RFA in a randomized study of 40 patients with recurrent thoracolumbar facet joint pain after thermal RFA treatment. Patients were randomly allocated to two groups, receiving either the same repeated RFA (n=20) or alcohol ablation (n=20). At 24-month follow-up, three patients in the alcohol ablation group had recurring pain compared to 19 in the RFA group. The median effective periods were 10.7 months (range 5.4 to 24) for RFA and 24 months (range 16.8 to 24) for alcohol ablation. No significant complications were observed. This study is limited by small sample size and short-term follow-up.

Laser Ablation

Iwatsuki (2007) reported treatment of facet syndrome by laser neurolysis in 21 study participants including 5 who had undergone previous spinal surgery. One year after laser denervation, 17 participants experienced pain reduction of at least 70%. Of the 5 individuals who had previously undergone spinal surgery, 4 did not have a successful outcome from laser denervation at 1-year follow-up. This study is limited by small sample size, short-term follow-up and lack of a control group.

Intraosseous Radiofrequency Ablation of the Basivertebral Nerve

A Hayes report concluded that there was insufficient evidence to inform definitive conclusions about the clinical safety and efficacy of the Intracept procedure (Hayes, 2018).

In the multi-center, randomized, double-blind, sham-controlled SMART trial, Fischgrund et al. (2018) evaluated the safety and efficacy of RFA of the basivertebral nerve (BVN) for the treatment of chronic low back pain. A total of 225 patients diagnosed with chronic low back pain were randomized to treatment with the Intrasept procedure (n=147) or sham therapy (n=78). All patients had Type I or Type II Modic changes of the treated vertebral bodies. The primary endpoint was the comparative change in the ODI from baseline to 3 months. At 3 months, the average ODI in the treatment arm decreased 20.5 points, as compared to a 15.2 point decrease in the sham arm. A responder analysis based on ODI decrease ≥ 10 points showed that 75.6% of patients in the treatment arm as compared to 55.3% in the sham control arm exhibited a clinically meaningful improvement at 3 months. The same authors reported 2-year clinical outcomes (Fischgrund et al., 2019). Participants randomized to the sham control arm were allowed to cross to RFA at 12 months. Due to a high rate of crossover, RFA treated participants acted as their own control in a comparison to baseline for the 24-month outcomes. Clinical improvements were statistically significant compared to baseline at all follow-up time points through 2 years. The mean percent improvements in ODI and VAS compared to baseline at 2 years were 53.7 and 52.9%, respectively. Responder rates for ODI and VAS were also maintained through 2 years with patients showing clinically meaningful improvements in both: ODI ≥ 10 -point improvement in 76.4% of patients and ODI ≥ 20 -point improvement in 57.5%; VAS ≥ 1.5 cm improvement in 70.2% of patients. NCT01446419.

An industry-sponsored study by Becker et al. (2017) assessed the efficacy of intraosseous BVN ablation, with the Intrasept system, in 17 patients with chronic low back pain. Sixteen patients were treated successfully. Self-reported outcome measures were collected prospectively at each follow-up interval. There was a significant decrease in the average ODI at 3 months postoperatively, which was maintained at 12 months. Significant improvement in the VAS scores and quality of life were also reported at the 3-month follow-up. This study is limited by small sample size, lack of randomization and control and short-term follow-up.

Professional Societies

American Society of Interventional Pain Physicians (ASIPP)

ASIPP clinical practice guidelines review the evidence for several interventional techniques for managing chronic spinal pain. The guidelines recommend that patient selection for RFA rely on response to controlled diagnostic blocks (Manchikanti et al., 2013).

ASIPP guidelines state that the suggested therapeutic frequency for medial branch neurotomy should remain at intervals of at least 6 months or longer per each region (maximum of 2 times per year) between each procedure, provided that 50% or greater relief is obtained for 10 to 12 weeks. It is further suggested that all regions be treated at the same time, provided all procedures are performed safely (Manchikanti et al., 2013).

American Society of Anesthesiologists (ASA)

ASA clinical practice guidelines (2010) review the evidence for chronic pain management techniques. The guidelines state that neuroablative procedures should be used as part of a comprehensive pain management regimen, performed only as a last resort when pain is refractory to other therapies. Recommendations for ablative therapies include the following:

- RFA:
 - Conventional (e.g., 80°C) or thermal (e.g., 67°C) RFA of the medial branch nerves to the facet joint should be performed for low back pain when previous diagnostic or therapeutic injections of the joint or medial branch nerve have provided temporary relief. Category A1 evidence – based on multiple, randomized controlled trials.
 - RFA may be performed for neck pain. Category A3 evidence – based on a single randomized controlled trial.
 - Conventional or thermal radiofrequency ablation of the dorsal root ganglion should not be routinely used for the treatment of lumbar radicular pain. Category C2 evidence – insufficient or inconsistent findings.
- Cryoablation may be used in the care of selected patients, including those with low back pain (medial branch). Category B2 evidence – based on noncomparative observational studies.
- Chemical ablation (e.g., alcohol, phenol or high-concentration local anesthetics) should not be used in the routine care of patients with chronic non-cancer pain. Category B2 and B3 evidence – based on noncomparative observational studies or case reports.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Radiofrequency ablation (RFA) for spinal pain is a procedure and, therefore, not subject to regulation by the FDA. However, the FDA regulates RFA devices, and there are numerous devices listed in the FDA 510(k) database approved for use in performing RFA for neurosurgical procedures. Three product codes are used to represent these devices: radiofrequency lesion generators (GXD), radiofrequency lesion probes (GXI) and electrosurgical cutting and coagulating device and accessories (GEI). See the following website for more information: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmnm.cfm>. (Accessed April 3, 2019)

Products for other types of spinal ablation therapies can be searched at the following website: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmnm.cfm>. (Accessed April 3, 2019)

Centers for Medicare and Medicaid Services (CMS)

Medicare does not have a National Coverage Determination (NCD) for ablative treatment for spinal pain. Local Coverage Determinations (LCDs) exist; see the LCDs for [Destruction of Paravertebral Facet Joint Nerve\(s\)](#), [Facet Joint Injections](#), [Medial Branch Blocks](#), and [Facet Joint Radiofrequency Neurotomy](#) and [Facet Joint Interventions for Pain Management](#).

Medicare does not have an NCD specifically for the use of the Intracept procedure in the treatment of chronic low back pain. LCDs do not exist at this time. (Accessed June 25, 2019)

References

- Abejón D, Garcia-del-Valle S, Fuentes ML, et al. Pulsed radiofrequency in lumbar radicular pain: clinical effects in various etiological groups. *Pain Pract.* 2007 Mar;7(1):21-6.
- American Society of Anesthesiologists (ASA). Practice guidelines for chronic pain management. An updated report by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine. *Anesthesiology.* 2010 Apr;112(4):810-33.
- Aydin SM, Gharibo CG, Mehnert M, et al. The role of radiofrequency ablation for sacroiliac joint pain: a meta-analysis. *PM R.* 2010 Sep;2(9):842-51.
- Becker S, Hadjipavlou A, Heggeness MH. Ablation of the basivertebral nerve for treatment of back pain: a clinical study. *Spine J.* 2017 Feb;17(2):218-223.
- Birkenmaier C, Veihelmann A, Trouillier H, et al. Percutaneous cryodenervation of lumbar facet joints: A prospective clinical trial. *Int Orthop.* 2007; 31(4):525-530.
- Cahana A, Van Zundert J, Macrea L, et al. Pulsed radiofrequency: current clinical and biological literature available. *Pain Med.* 2006 Sep-Oct;7(5):411-23.
- Chao SC, Lee HT, Kao TH, et al. Percutaneous pulsed radiofrequency in the treatment of cervical and lumbar radicular pain. *Surg Neurol.* 2008 Jul;70(1):59-65; discussion 65.
- Chou R, Loeser JD, Owens DK, et al.; American Pain Society Low Back Pain Guideline Panel. Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the American Pain Society. *Spine (Phila Pa 1976).* 2009 May 1;34(10):1066-77.
- Cohen SP, Huang JH, Brummett C. Facet joint pain - advances in patient selection and treatment. *Nat Rev Rheumatol.* 2013 Feb;9(2):101-16.
- Cohen SP, Hurley RW, Buckenmaier CC 3rd, et al. Randomized placebo-controlled study evaluating lateral branch radiofrequency denervation for sacroiliac joint pain. *Anesthesiology.* 2008 Aug;109(2):279-88.
- CPT® Assistant. Frequently Asked Questions. Surgery: Musculoskeletal System. October 2016. p. 11.

ECRI Institute. Hotline Response. Radiofrequency denervation for treating cervical facet joint pain. April 2018.

Fischgrund JS, Rhyne A, Franke J, et al. Intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 2-year results from a prospective randomized double-blind sham-controlled multicenter study. *Int J Spine Surg*. 2019 Apr 30;13(2):110-119.

Fischgrund JS, Rhyne A, Franke J, et al. Intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: a prospective randomized double-blind sham-controlled multi-center study. *Eur Spine J*. 2018 May;27(5):1146-1156.

Geurts JW, van Wijk RM, Stolker RJ, et al. Efficacy of radiofrequency procedures for the treatment of spinal pain: a systematic review of randomized clinical trials. *Reg Anesth Pain Med*. 2001 Sep-Oct;26(5):394-400.

Gofeld M, Jitendra J, Faclier G. Radiofrequency denervation of the lumbar zygapophysial joints:10-year prospective audit. *Pain Physician* 2007;10(2):291-300.

Hansen H, Manchikanti L, Simopoulos TT, et al. A systematic evaluation of the therapeutic effectiveness of sacroiliac joint interventions. *Pain Physician*. 2012 May-Jun;15(3):E247-78.

Hayes Inc. Health Technology Brief. Pulsed radiofrequency application to the dorsal root ganglion for treatment of cervical radicular pain. Lansdale, PA: Hayes, Inc.; May 2019a.

Hayes Inc. Search and Summary. Radiofrequency ablation of the dorsal root ganglion for treatment of back pain. Lansdale, PA: Hayes, Inc.; January 2019b.

Hayes Inc. Clinical Research Response. Intracept Procedure (Relieva Medsystems, Inc.) for treatment of low back pain. Lansdale, PA: Hayes, Inc.; July 2018.

Hayes Inc. Medical Technology Directory. Percutaneous radiofrequency ablation for cervical and thoracic spinal indications. Lansdale, PA: Hayes, Inc.; November 2016a. Updated October 2018.

Hayes Inc. Medical Technology Directory. Radiofrequency ablation for facet joint denervation for chronic low back pain. Lansdale, PA: Hayes, Inc.; December 2016b. Updated December 2018.

Hayes Inc. Medical Technology Directory. Radiofrequency ablation for sacroiliac joint denervation for chronic low back pain. Lansdale, PA: Hayes, Inc. February 2017. Updated February 2018.

Iwatsuki K, Yoshimine T, Awazu K. Alternative denervation using laser irradiation in lumbar facet syndrome. *Lasers Surg Med*. 2007; 39(3):225-229.

Jensen TS. Pulsed radiofrequency: A novel treatment for chronic cervical radicular pain? *Pain*. 2007;127(1-2):3-4.

Joo YC, Park JY, Kim KH. Comparison of alcohol ablation with repeated thermal radiofrequency ablation in medial branch neurotomy for the treatment of recurrent thoracolumbar facet joint pain. *J Anesth* 2013; 27(3):390-5.

Kroll HR, Kim D, Danic MJ, et al. A randomized, double-blind, prospective study comparing the efficacy of continuous versus pulsed radiofrequency in the treatment of lumbar facet syndrome. *J Clin Anesth* 2008 Nov;20(7):534-7.

Lee JS, Yoon KB, Kim IK, Yoon DM. Pulsed radiofrequency treatment of pain relieving point in a soft tissue. *Korean J Pain*. 2011;24(1):57-60.

Li ZZ, Hou SX, Shang WL, et al. Evaluation of endoscopic dorsal ramus rhizotomy in managing facetogenic chronic low back pain. *Clin Neurol Neurosurg*. 2014 Nov;126:11-7.

Manchikanti L, Hirsch JA, Falco FJ, Boswell MV. Management of lumbar zygapophysial (facet) joint pain. *World J Orthop*. 2016 May 18;7(5):315-37.

Manchikanti L, Abdi S, Atluri S, et al. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: guidance and recommendations. *Pain Physician*. 2013; 16:S49-283.

Manchikanti, K., Atluri, S., Singh, V., et al. An update of evaluation of the therapeutic thoracic facet joint interventions. *Pain Physician*. 2012 Jul-Aug; 15(4):E463-81.

Nath S, Nath CA, Pettersson K. Percutaneous lumbar zygapophysial (facet) joint neurotomy using radiofrequency current, in the management of chronic low back pain: a randomized double-blind trial. *Spine*. 2008 May 20;33(12):1291-7; discussion 1298.

National Institute for Health and Care Excellence (NICE). Low back pain and sciatica in over 16s: assessment and management. NG59. November 2016.

National Institute of Neurological Disorders and Stroke (NINDS). Complex regional pain syndrome fact sheet. July 2018. Available at: <https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Complex-Regional-Pain-Syndrome-Fact-Sheet%20>. Accessed April 3, 2019.

Qaseem A, Wilt TJ, McLean RM, Forcica MA; Clinical Guidelines Committee of the American College of Physicians. Noninvasive treatments for acute, subacute, and chronic low back pain: a clinical practice guideline from the American College of Physicians. *Ann Intern Med*. 2017 Apr 4;166(7):514-530.

Simopoulos TT, Kraemer J, Nagda JV, et al. Response to pulsed and continuous radiofrequency lesioning of the dorsal root ganglion and segmental nerves in patients with chronic lumbar radicular pain. *Pain Physician*. 2008 Mar-Apr;11(2):137-44.

Staender M, Maer U, Tonn JS, et al. Computerized tomography-guided kryorhizotomy in 76 patients with lumbar facet joint syndrome. *J Neurosurg Spine*. 2005 Dec;3(6):444-9.

Tekin I, Mirzai H, Ok G, Erbuyun K, Vatanserver D. A comparison of conventional and pulsed radiofrequency denervation in the treatment of chronic facet joint pain. *Clin J Pain*. 2007 Jul-Aug;23(6):524-9.

Tella P, Stojanovic M. Novel therapies for chronic cervical radicular pain: does pulsed radiofrequency have a role? *Expert Rev Neurother*. 2007;7(5):471-472.

Vallejo R, Benyamin RM, Kramer J, et al. Pulsed radiofrequency denervation for the treatment of sacroiliac joint syndrome. *Pain Med*. 2006;7(5):429-434.

van Tilburg CW, Schuurmans FA, Stronks DL, et al. Randomized sham-controlled double-blind multicenter clinical trial to ascertain the effect of percutaneous radiofrequency treatment for sacroiliac joint pain: three-month results. *Clin J Pain*. 2016 Nov;32(11):921-926.

van Wijk RM, Geurts JW, Wynne HJ, et al. Radiofrequency denervation of lumbar facet joints in the treatment of chronic low back pain: a randomized, double-blind, sham lesion-controlled trial. *Clin J Pain*. 2005;21(4):335-44.

Van Zundert J. Pulsed radiofrequency adjacent to the cervical dorsal root ganglion in chronic cervical radicular pain: a double blind sham controlled randomized clinical trial. *Pain*. 2007 Jan;127(1-2):173-82.

Yeung AT, Zheng Y, Yeung C, Filed J, Meredith C. Endoscopic dorsal rhizotomy, a new anatomically guided MIS procedure is more effective than traditional pulsed radiofrequency lesioning for non-discogenic axial back pain. The International Society for the Advancement of Spine Surgery Annual Meeting 2011.

Policy History/Revision Information

Date	Summary of Changes
11/01/2020	<p>Related Policies</p> <ul style="list-style-type: none"> Added reference link to the Utilization Review Guideline titled <i>Office Based Procedures – Site of Service</i>
08/01/2020	<p>Template Update</p> <ul style="list-style-type: none"> Reformatted policy; transferred content to new template
01/01/2020	<p>Coverage Rationale</p> <ul style="list-style-type: none"> Revised list of unproven and not medically necessary indications; replaced: <ul style="list-style-type: none"> “The source of back pain at the proposed ablation level is from a cause other than facet joint <i>nerves</i> that requires a different treatment approach” with “the source of back pain at the proposed ablation level is from a cause other than facet joint <i>syndrome</i> that requires a different treatment approach” “All other pain indications, <i>including</i>, but not limited to, occipital neuralgia, headache, sacroiliac pain or Complex Regional Pain Syndrome <i>in the absence of spinal pain</i>” with “all other pain indications; <i>examples include</i>, but are not limited to, occipital neuralgia, headache, sacroiliac pain or Complex Regional Pain Syndrome in the absence of spinal pain” <p>Applicable Codes</p> <ul style="list-style-type: none"> Updated list of applicable CPT codes to reflect annual code edits; added 64625 <p>Supporting Information</p> <ul style="list-style-type: none"> Archived previous policy version 2019T0107V

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence ([Medicare IOM Pub. No. 100-16, Ch. 4, §90.5](#)).

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.