

ABLATIVE TREATMENT FOR SPINAL PAIN

Policy Number: PAIN 021.13 T2

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[Instructions for Use](#) ⓘ

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Related Policies

- [Discogenic Pain Treatment](#)
- [Epidural Steroid and Facet Injections for Spinal Pain](#)
- [Occipital Neuralgia and Headache Treatment](#)
- [Office Based Program](#)
- [Omnibus Codes](#)

CONDITIONS OF COVERAGE

Applicable Lines of Business/Products	This policy applies to Oxford Commercial plan membership.
Benefit Type	General benefits package
Referral Required (Does not apply to non-gatekeeper products)	No ^{1,2}
Authorization Required (Precertification always required for inpatient admission)	Yes ^{1,2}
Precertification with Medical Director Review Required	Yes ^{1,2}
Applicable Site(s) of Service (If site of service is not listed, Medical Director review is required)	Office ^{1,2} , Outpatient ^{1,2}
Special Considerations	<p>¹CPT codes 64633, 64635, and 64999 (when used for pulsed radiofrequency ablation) require precertification with Medical Director review in all sites of service.</p> <p>²Participating Providers in the Office Setting: Precertification is required for CPT codes 64633, 64635, and 64999 (when used for pulsed radiofrequency ablation) when performed in the office of a participating provider. Non-Participating/Out-of-Network Providers in the Office Setting: Precertification is not required, but is encouraged for CPT codes 64633, 64635, and 64999 (when used for pulsed radiofrequency ablation) when performed in the office of an out-of-network provider. If precertification is not obtained, Oxford will review for out-of-network benefits and medical necessity after the service is rendered.</p>

COVERAGE RATIONALE

Note: For purposes of this policy, facet nerve blocks are considered the same as medial branch blocks.

Thermal Radiofrequency Ablation of facet joint nerves is proven and medically necessary for treating chronic cervical (C3 and below), thoracic, and lumbar pain when confirmed by documentation of analgesic

response to facet nerve blocks (i.e., medial branch blocks) at the specific side and level of the proposed ablation.

For use as a diagnostic procedure, facet nerve blocks and/or medial branch blocks should not be performed on the same day as the ablation procedure.

For additional information, see the related policies titled [Epidural Steroid and Facet Injections for Spinal Pain](#) and [Occipital Neuralgia and Headache Treatment](#).

Thermal Radiofrequency Ablation of facet joint nerves is unproven and not medically necessary in the the following circumstances:

- There has been no analgesic response to facet nerve blocks (i.e., medial branch blocks); or
- The procedure has been performed more frequently than every six months; or
- The source of back pain at the specific side and level of the proposed ablation is demonstrated to arise from a cause other than facet joint nerves that requires a different treatment approach. Examples include disc herniation, spinal stenosis, foraminal narrowing, vertebral fracture and spondylolisthesis; or
- ALL other pain indications, including, but not limited to:
 - Diabetic neuropathy
 - Sacroiliac pain
 - Complex regional pain syndrome or regional pain disorders and syndromes in the absence of spinal pain.

Studies of Thermal Radiofrequency Ablation for other conditions are limited, uncontrolled and insufficient to support conclusions regarding efficacy or duration of effect. Additional well-designed, longer-term randomized controlled trials are required to evaluate the safety and efficacy of Thermal Radiofrequency Ablation and to compare this technique with other medical or surgical therapies for pain.

For additional information regarding frequency guidelines, click [here](#).

Repeat Treatment

A repeat Thermal Radiofrequency Ablation of the same facet joint nerves is proven and medically necessary 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.

Documentation Requirements for Aforementioned Procedures

- Temperature of procedure
- Duration of ablation
- Specific identification of side and level of medial branch blocks
- Specific identification of side and level of 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.

The following ablation procedures are unproven and not medically necessary for treating spinal pain:

- Pulsed radiofrequency therapy 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, see the related policy titled [Omnibus Codes](#).
- Chemical ablation (including but not limited to alcohol, phenol or sodium morrhuate)
- Laser ablation (including pulsed, continuous, or low level)

There is insufficient evidence to establish the safety and efficacy of the ablation therapies bulleted immediately above to reduce or relieve spinal pain. Studies are limited by small sample size and retrospective design. The clinical value needs to be examined in well-designed, randomized controlled trials with large sample size and long-term follow-up.

DEFINITIONS

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

Thermal Radiofrequency Ablation is defined as follows:

- Temperature $\geq 60^{\circ}$ Celsius; and

- Duration of ablation \geq 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 may apply.

CPT Code	Description
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

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Coding Clarification:

- 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)

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 2017)

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 2017). 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 2017)

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 2017)

Thermal Radiofrequency Ablation for Sacroiliac Pain

The sacroiliac (SI) joint has been identified as a primary source of chronic low back pain. Studies provide limited evidence regarding the efficacy and safety of thermal RFA for individuals with SI joint pain, and contain insufficient

data that allows for definitive conclusions. Further high quality controlled trials are needed that compare this procedure in defined populations with placebo and with alternative treatments.

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)

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

There is insufficient evidence in the published clinical literature to determine the safety and efficacy of pulsed RFA for the treatment of spinal pain.

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)

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

There is insufficient evidence in the published clinical literature to determine the safety and efficacy of endoscopic RFA for the treatment of spinal pain.

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

Cryoablation has been proposed as an option for relief of spinal pain; however, there is a lack of published data to support the safety and efficacy of this technique.

Birkenmaier et al. (2007) conducted a prospective clinical case series to examine the effects of medial branch cryodenervation (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 cryodenervation 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

Chemical facet injections have been proposed as an option for relief of spinal pain; however, there is a lack of published data to support the safety and efficacy of this technique.

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

Laser ablation has been proposed as an option for relief of spinal pain; however, there is a lack of published data to support the safety and efficacy of this technique.

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.

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.,)

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 branchnerve 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

Radiofrequency ablation (RFA) for spinal pain is a procedure and, therefore, is 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 electro-surgical cutting and coagulating device and accessories (GEI). See the following website for more information:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>. (Accessed September 4, 2018)

Products for other types of spinal ablation therapies can be searched at the following website:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>. (Accessed September 4, 2018)

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The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by UnitedHealthcare Medical Technology Assessment Committee. [2018T0107T]

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
01/01/2019	<ul style="list-style-type: none"> • Reorganized policy template: <ul style="list-style-type: none"> ○ Simplified and relocated <i>Instructions for Use</i> ○ Removed <i>Benefit Considerations</i> section • Updated conditions of coverage/special considerations; modified notation to clarify: <ul style="list-style-type: none"> ○ For participating providers in the office setting: Precertification is required for CPT codes 64633, 64635, and 64999 (when used for pulsed radiofrequency ablation) when performed in the office of a participating provider ○ For non-participating/out-of-network providers in the office setting: Precertification is not required, but is encouraged for CPT codes 64633,

Date	Action/Description
	<p>64635, and 64999 (when used for pulsed radiofrequency ablation) when performed in the office of an out-of-network provider; if precertification is not obtained, Oxford will review for out-of-network benefits and medical necessity after the service is rendered</p> <ul style="list-style-type: none"> • Revised coverage rationale: <ul style="list-style-type: none"> ○ Modified language to clarify the listed services are: <ul style="list-style-type: none"> ▪ Proven and medically necessary (as described) ▪ Unproven and not medically necessary (as described) ○ Updated and reorganized coverage criteria for: <p>Thermal Radiofrequency Ablation</p> <p>Proven/Medically Necessary</p> <ul style="list-style-type: none"> ▪ Added language to indicate: <ul style="list-style-type: none"> - For purposes of this policy, facet nerve blocks are considered the same as medial branch blocks - For use as a diagnostic procedure, facet nerve blocks and/or medial branch blocks should not be performed on the same day as the ablation procedure ▪ Replaced language indicating "Thermal Radiofrequency Ablation of facet joint nerves is proven <i>and/or</i> medically necessary for treating chronic cervical (C3 and below), thoracic and lumbar pain when confirmed by <i>positive</i> response to medial branch block at the side and level of the proposed ablation" with "Thermal Radiofrequency Ablation of facet joint nerves is proven <i>and</i> medically necessary for treating chronic cervical (C3 and below), thoracic and lumbar pain when confirmed by <i>documentation of analgesic</i> response to <i>facet nerve blocks (i.e., medial branch blocks)</i> at the <i>specific</i> side and level of the proposed ablation" ▪ Removed language pertaining to needle placement and operative notes for Thermal Radiofrequency Ablation (relocated to <i>Definitions</i> section of the policy) ▪ Added reference link to the policy titled <i>Epidural Steroid and Facet Injections for Spinal Pain</i> for additional information <p>Unproven/Not Medically Necessary</p> <ul style="list-style-type: none"> ▪ Replaced language indicating "Thermal Radiofrequency Ablation of facet joint nerves is unproven <i>and/or</i> not medically necessary when there has been no <i>positive</i> response to medial branch block <i>injection</i>" with "Thermal Radiofrequency Ablation of facet joint nerves is unproven <i>and</i> not medically necessary [when] there has been no <i>analgesic</i> response to <i>facet nerve blocks (i.e., medial branch blocks)</i>" ▪ Added language to indicate Thermal Radiofrequency Ablation of facet joint nerves is unproven and not medically necessary when the source of back pain at the specific side and level of the proposed ablation is demonstrated to arise from a cause other than facet joint nerves that requires a different treatment approach ▪ Removed language indicating Thermal Radiofrequency Ablation of facet joint nerves is unproven and not medically necessary when definitive clinical and/or imaging findings that identify a specific cause for the spinal pain which requires a different treatment approach (e.g., surgery) <p>Repeat Treatment</p> <ul style="list-style-type: none"> ▪ Replaced criteria requiring: <ul style="list-style-type: none"> - "[The procedure is] performed at a frequency of six months or longer (maximum of 2 times over a 12 month period)" with "[the procedure is] performed at a frequency of six months or longer (maximum of 2 times over a 12 month period <i>per side and level</i>)" - "There has been a 50% or greater documented reduction in pain for <i>10 to 12 weeks</i> following the previous ablation" with "there has been a 50% or greater documented reduction in pain for <i>at least 10 weeks</i> following the previous ablation" <p>Documentation Requirements</p> <ul style="list-style-type: none"> ▪ Replaced criteria requiring documentation of: <ul style="list-style-type: none"> - "Percentage of pain relief with prior ablation, if applicable" with "percentage of pain relief with <i>medial branch blocks</i> or prior ablation, if applicable"

Date	Action/Description
	<ul style="list-style-type: none"> - "Duration of improvement from previous ablation, if applicable" with "duration of improvement from <i>medial branch blocks or prior</i> ablation, if applicable" • Added definition of: <ul style="list-style-type: none"> ○ Chronic Pain (Nonmalignant) ○ Thermal Radiofrequency Ablation • Updated supporting information to reflect the most current description of services and references • Archived previous policy version PAIN 021.12 T2

INSTRUCTIONS FOR USE

This Clinical Policy provides assistance in interpreting UnitedHealthcare Oxford 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 Oxford reserves the right to modify its Policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice.

The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. UnitedHealthcare Oxford Clinical 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.