Clinical Policy Title: Radiofrequency ablation treatment for spine pain

Clinical Policy Number: 03.02.02

Effective Date: June 1, 2013
Initial Review Date: March 21, 2013
Most Recent Review Date: February 6, 2018
Next Review Date: February 2019

Related policies:
None.

ABOUT THIS POLICY: Select Health of South Carolina has developed clinical policies to assist with making coverage determinations. Select Health of South Carolina's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Select Health of South Carolina when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Select Health of South Carolina's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Select Health of South Carolina's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Select Health of South Carolina will update its clinical policies as necessary. Select Health of South Carolina's clinical policies are not guarantees of payment.

Coverage policy

Select Health of South Carolina considers non-pulsed radiofrequency ablation for spine pain to be proven and medically necessary for individuals with intractable spine pain when all of the following are met (Aydin, 2010; Engel, 2016; Falco, 2012; Itz, 2016; Leggett, 2014; Nath, 2008; Smith, 2014):

- Facet joint origin of pain is suspected and medial branch block/injection of facet joint with local anesthetic results in the notable decrease or temporary amelioration in the intensity of pain.
- At least two medial branch block/facet joint injections have been administered with achievement of ≥50 percent reduction in pain.
- The spinal pain is exacerbated by extension and rotation, or associated with lumbar rigidity.
- The pain is unresponsive to conservative medical management.
- The pain impairs or impedes activities of occupation or recreation for more than three months.

Limitations:

Policy contains:

- Non-pulsed radiofrequency ablation.
Non-pulsed radiofrequency ablation for the spine is considered unproven and not medically necessary for certain indications. This list of indications includes, but is not limited to, the following:

- The pain is of cervical or thoracic origin.
- Instances of no improvement in pain after a medial branch block injection.
- Less than a six-month interval between treatments at the same anatomical site.
- More than two treatments at the same anatomical site within a 12-month period.

Additionally, non-pulsed radiofrequency ablation is not to be used in the presence of the following:

- Any neurological deficits.
- Diabetic neuropathies.
- Regional pain disorders and syndromes in the absence of spinal pain.
- Clinically diagnosed causes of spinal pain that require other specific treatment, including, but not limited to, disc herniation, infection, malignancy, and trauma.

Non-pulsed radiofrequency ablation for the thoracic spine and sacroiliac joint is considered unproven and not medically necessary, as no evidence for its use has been established in peer-reviewed professional literature.

Long-term, maintenance denervation by non-pulsed radiofrequency ablation is considered unproven and not medically necessary for any indication, as its use has not been established in peer-reviewed professional literature.

Pulsed radiofrequency ablation for all indications is not considered to be evidence-based, as its use is unsupported in peer-reviewed professional literature, and is not a covered service.

All other uses of non-pulsed radiofrequency ablation therapies are not medically necessary.

As pain relief from denervation may not be permanent, repeat non-pulsed radiofrequency ablation to the same levels of the spine may be considered medically necessary as follows:

- When prior treatment has been successful, as evidenced in the achievement of a 50 percent or greater reduction in pain for 10 to 12 weeks and concurrent functional improvement.
- When more than six months have elapsed since the last treatment per level, per side.

**Alternative covered services:**

- Pharmaceutical therapy (e.g., analgesics).
- Physical and occupational therapy.

**Background**
Back pain affects the health of a large segment of the population. Demographic data shows a greater incidence and severity of spine pain in populations with less education. Although most cases of back pain are resolved with conservative treatment such as rest and physical therapy, in certain instances back pain may become a chronic condition. Primary areas of chronic back pain may be located in the upper, mid-, and lower spine, or in the sacroiliac joints. Effective treatment may be difficult without a clear cause of the pain. Nerve block studies may be used for chronic neck and back pain, with findings that point to a disorder of the facet joint. Individuals with a confirmed ability for pain relief following a nerve block study may be considered for non-pulsed radiofrequency ablation treatment.

There are two types of radiofrequency ablation: non-pulsed radiofrequency ablation and pulsed radiofrequency ablation. Typically, non-pulsed radiofrequency ablation systems are made of three components: a generator, needle electrodes, and grounding pads. Non-pulsed radiofrequency ablation uses the placement of an electrode and an undis rupted high-voltage, high-frequency electrical current for a predetermined amount of time to disrupt pain signals that are sent to the brain from a specific body area. The current produces heat and coagulation, causing denervation in the targeted tissue sites. Denervation is thought to be achieved by selectively destroying sensory afferent pain fibers without causing untoward motor dysfunction, sensory loss, or other complications. Treatment should be directed to at least two levels of a single joint for successful denervation. Destruction of nerve fibers may be temporary or permanent. In some cases, the treated nerve repairs itself and becomes less irritable, resulting in continued need for pain abatement.

Pulsed radiofrequency ablation delivers short bursts of radiofrequency current instead of the continuous flow of radiofrequency current produced by continuous radiofrequency generators. The interrupted, short bursts of high-voltage electrical current allows the tissue to cool, resulting in lower maximum temperatures than non-pulsed radiofrequency ablation, and does not cause tissue coagulation. Pulsed radiofrequency ablation has been introduced as a non-ablative alternative to non-pulsed radiofrequency ablation; however, it has not been studied in large prospective clinical trials, and there is a paucity of peer-reviewed professional literature addressing its therapeutic effectiveness.

**Searches**

Select Health of South Carolina searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on January 8, 2018. Search terms were: "radiofrequency ablation" (MeSH), "spine pain" (MeSH), and "treatment back pain."

We included:
• **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.

• **Guidelines based on systematic reviews.**

• **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

Guidelines from medical professional societies and studies from peer-reviewed professional literature indicate that non-pulsed radiofrequency ablation therapy does provide evidence of effectiveness. Professional literature suggests that non-pulsed radiofrequency ablation to a facet joint of the cervical and lumbar regions provides pain relief by interruption or denervation, and that the success rate is dependent on the careful selection of individuals to receive the treatment.

The Dutch Society of Anesthesiologists, in collaboration with the Dutch Orthopedic Association and the Dutch Neurosurgical Society, developed guidelines (Itz, 2016) for spinal low back pain, which describe the evidence regarding diagnostics and invasive treatment of the most common spinal low back pain syndromes, that is, facet joint pain, sacroiliac joint pain, coccygodynia, pain originating from the intervertebral disk, and failed back surgery syndrome. The committee further noted that in facet joint pain, if conservative therapy has failed, radiofrequency ablation of the innervating medial branches of the rami dorsalis of the affected segmental nerves can be performed with the expectation of pain control for three to 12 months and functional improvement for three to six months. The committee also positively affirmed in patients with discogenic low back pain without a positive effect from conservative treatments a radiofrequency lesion of the ramus may be considered. Finally, the committee confirmed that pulsed radiofrequency is ineffective for treatment of lumbar facet pain, and found that patients with discogenic low back pain with insufficient effect of conservative treatment should not be treated with a radiofrequency lesion of the discus.

A systematic review (Leggett, 2014) that assessed the efficacy of non-pulsed radiofrequency ablation included participants who had experienced back pain for at least three months. The review retrieved 1,063 abstracts, of which 11 sham-controlled randomized controlled trials (RCTs) were included: three studies involving discogenic back pain, six studies involving lumbar facet joint pain, and two studies involving sacroiliac joint pain. The authors concluded that the medical evidence supports NPRFA as an efficacious treatment for lumbar facet joint and sacroiliac joint pain, with five of six and both of the RCTs demonstrating statistically significant pain reductions, respectively. The evidence supporting radiofrequency ablation for the treatment of discogenic pain, however, was mixed. While the majority of the studies focusing on lumbar facet joints and sacroiliac joints suggested that non-pulsed radiofrequency ablation significantly reduces pain in short-term follow-up, the evidence base for
discogenic low back pain was equivocal. There was no RCT evidence in support of non-pulsed radiofrequency ablation for the coccyx.

The 2010 American Society of Anesthesiologists (ASA) practice guidelines support the use of non-pulsed radiofrequency ablation of the medial branch nerves to the facet joint for low back (medial branch) pain when previous diagnostic or therapeutic injections of the joint or medial branch nerve have provided temporary relief.

A randomized controlled study of non-pulsed radiofrequency ablation (Nath, 2008) was conducted in patients with chronic low back pain (20 active and 20 controls). Inclusion criteria were three separate positive diagnostic blocks, and subjects were examined before and after the treatment (sham or active). The active treatment group showed statistically significant improvement in back and leg pain, and also back and hip movement. There was significant improvement in quality of life variables, global perception of improvement, and generalized pain. The improvement noted in the active group was significantly greater than that of the placebo group. None of the study participants had complications other than transient post-procedure pain. The study concluded that radiofrequency facet denervation could be used in the treatment of carefully selected patients with chronic low back pain.

The American Society of Interventional Pain Physicians (ASIPP) practice guidelines (Manchikanti, 2009) state that the suggested therapeutic frequency for radiofrequency treatment should remain at intervals of at least six months or longer per each region treated (maximum of two times per year), provided that 50 percent 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.

A systematic review (Manchikanti, 2012) to determine the clinical utility of therapeutic thoracic interventions for the management of chronic pain in the upper and mid-spine area identified a total of four studies that met inclusion criteria for methodological quality assessment. The primary outcome measure was pain relief, and the secondary outcome measures were improvement in functional and psychological status, reduction in analgesic intake, and return to work. The evidence was fair for therapeutic thoracic facet joint nerve blocks and limited for radiofrequency therapy. The review concluded that the evidence for the use of radiofrequency therapy for the thoracic spine was limited due to a lack of peer-reviewed professional literature.

A systematic review of therapeutic cervical facet joint interventions from 1966 to 2012 (Falco, 2012) studied pain relief (short-term relief up to six months and long-term more than six months) from non-pulsed radiofrequency ablation. Secondary outcome measures were improvement in functional status, psychological status, return to work, and reduction in opioid intake. The authors concluded that the medical evidence for cervical radiofrequency neurotomy is fair, and the evidence for cervical medial branch blocks is fair. A paucity of the overall published literature, and specifically lack of literature for intra-articular cervical facet joint injections and cervical medial branch blocks, was cited as a substantial limitation of the study.
Smith (2014) studied 53 individuals with chronic whiplash associated disorder symptoms versus 30 healthy controls pre- and post-radiofrequency neurotomy. Following cervical radiofrequency ablation neurotomy, there were significant early (within one month) and sustained (three months) improvements in pain, disability, local and widespread hyperalgesia to pressure and thermal stimuli, nociceptive flexor reflex threshold, and brachial plexus provocation test responses, as well as increased neck range of motion (all \( P < 0.0001 \)).

Clinical studies for the use of radiofrequency ablation for chronic spinal pain have significant methodological limitations that may impact the interpretation of data. Few randomized controlled or comparative trials of radiofrequency ablation with adequate sample size and follow-up duration have been published, and the majority of evidence is taken from small randomized controlled trials, prospective uncontrolled studies, case series, and retrospective chart analyses.

A systematic review and meta-analysis (Aydin, 2010) to assess the effectiveness of radiofrequency ablation of the SI joint for pain relief at three months and six months identified 10 articles ranging from inception to January 1, 2010. The main outcome measure was a reduction of pain by \( \geq 50 \) percent post-radiofrequency ablation. At three months, a range of 0.538 – 0.693 was found to have a 95 percent CI, with a pooled mean difference of 0.616. At six months, a 95 percent CI of 0.423 – 0.576 was found, with a pooled mean difference of 0.499. The authors concluded that radiofrequency ablation is an effective treatment for sacroiliac joint pain at three months and six months.

ASIPP 2010 practice guidelines for chronic spinal pain state that the evidence for non-pulsed radiofrequency ablation and pulsed radiofrequency ablation of the sacroiliac joint is limited. These guidelines also state that the evidence for pulsed radiofrequency for sacroiliac pain is inconclusive.

**Policy updates:**

In the 2017 update, we identified a systematic review (Engel, 2016) from the International Spine Intervention Society that sought to examine cervical radiofrequency ablation in treatment of chronic neck pain of zygapophysial joint origin, looking for 100 percent relief of pain six and 12 months after treatment as endpoints. The evidence showed a majority of patients were pain free at six months after treatment and over a third were pain free at one year. The number of treatments required for complete pain relief at six months was two. The authors noted few side effects and concluded that fluoroscopically guided cervical radiofrequency ablation is effective for abolishing zygapophysial joint pain and carries only minor risks.

In the 2018 update, we did not identify any relevant newly published literature.

**Summary of clinical evidence:**
<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td><strong>Engel (2016)</strong></td>
<td>The effectiveness and risks of fluoroscopically-guided cervical medial branch thermal radiofrequency neurotomy: a systematic review with comprehensive analysis of the published data</td>
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<tr>
<td><strong>Key points:</strong></td>
<td>• Systematic review of cervical radiofrequency ablation in treatment of chronic neck pain.</td>
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<td>• Evidence showed a majority of patients were pain free at six months after treatment and over a third were pain free at one year.</td>
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<tr>
<td><strong>Itz (2016)</strong></td>
<td>Dutch multidisciplinary guideline for invasive treatment of pain syndromes of the lumbosacral spine</td>
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<tr>
<td><strong>Key points:</strong></td>
<td>• The Dutch Society of Anesthesiologists, Dutch Orthopedic Association, and the Dutch Neurosurgical Society issued guidelines in 2016 on spinal low back pain.</td>
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<td>• Most common syndromes include facet joint pain, sacroiliac joint pain, coccygodynia, pain originating from the intervertebral disc, and failed back surgery syndrome.</td>
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<td>• Outcome measures of pain, function, and quality of life were deemed the most important criteria for assessment.</td>
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<td>• The guideline committee concluded that the categorization of low back pain into merely specific or nonspecific gives insufficient insight into the low back pain problem and does not adequately reflect which therapy is effective for the underlying disorder of a pain syndrome.</td>
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<td>• The committee further noted that in facet joint pain, if conservative therapy has failed, radiofrequency ablation of the innervating medial branches of the rami dorsalis of the affected segmental nerves can be performed with the expectation of pain control for three to 12 months and functional improvement for three to six months.</td>
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<td>• The committee also positively affirmed in patients with discogenic low back pain without a positive effect from conservative treatments that a radiofrequency lesion of the ramus may be considered.</td>
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<td>• Finally, the committee confirmed that pulsed radiofrequency is ineffective for treatment of lumbar facet pain, and found that patients with discogenic low back pain with insufficient effect of conservative treatment should not be treated with a radiofrequency lesion of the discus.</td>
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<td><strong>Smith (2014)</strong></td>
<td>Cervical radiofrequency neurotomy reduces central hyperexcitability and improves neck movement in individuals with chronic whiplash</td>
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<tr>
<td><strong>Key points:</strong></td>
<td>• Prospective observational study of 53 individuals with chronic whiplash-associated disorder symptoms (Grade 2) compared to 30 healthy controls.</td>
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<td>• Measures were made at four time points: two prior to radiofrequency neurotomy, and at one and three months post-radiofrequency neurotomy.</td>
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<td>• Measures included were comprehensive quantitative sensory testing (including brachial plexus provocation test), nociceptive flexion reflex and motor function (cervical range of movement, and superficial neck flexor activity during the craniocervical flexion test).</td>
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<td>• Self-reported pain scores and disability measures were also collected.</td>
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<td>• Following cervical radiofrequency neurotomy, there were significant early (within one month) and sustained (within three months) improvements in pain, disability, local and widespread hyperalgesia to pressure and thermal stimuli, nociceptive flexor reflex</td>
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<td>Content, Methods, Recommendations</td>
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| Leggett (2014) | Threshold, and brachial plexus provocation test responses, as well as increased neck range of motion (all P < 0.0001).  
- A nonsignificant trend for reduced muscle activity with the craniocervical flexion test (P > 0.13) was measured. |
| Falco (2012) | Key points:  
- Systematic review of non-pulsed radiofrequency ablation for chronic low back pain associated with lumbar facet joints, sacroiliac joints, discogenic low back pain, and the coccyx.  
- Eleven sham-controlled RCTs were included: three studies involving discogenic back pain, six studies involving lumbar facet joint pain, and two studies involving sacroiliac joint pain. No studies were identified assessing the coccyx.  
- The evidence supports non-pulsed radiofrequency ablation as an efficacious treatment for lumbar facet joint and SI joint pain, with statistically significant pain reductions, respectively.  
- The evidence supporting radiofrequency ablation for the treatment of discogenic pain is mixed.  
- There is no RCT evidence for radiofrequency ablation for the coccyx.  
- Future studies should examine the clinical significance of the achieved pain reduction and the long-term efficacy of radiofrequency ablation. |
| Manchikanti (2012) | Key points:  
- Systematic review to determine the clinical utility of therapeutic thoracic facet joint interventions for the management of chronic pain in the upper- and mid-spine area.  
- Identified a total of four studies that met inclusion criteria for methodological quality assessment.  
- The primary outcome measure was pain relief; the secondary outcome measures were improvement in functional and psychological status, reduction in analgesic intake, and return to work.  
- The evidence was fair for therapeutic thoracic facet joint nerve blocks and limited for radiofrequency therapy. |
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Hayes (2012)</td>
<td><strong>Key points:</strong></td>
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</table>
| Radiofrequency ablation for sacroiliac joint pain | - Clinical studies for the use of radiofrequency ablation for chronic spinal pain have significant methodological limitations that may impact the interpretation of data.  
- Few randomized controlled or comparative trials of radiofrequency ablation with adequate sample size and follow-up duration have been published; the majority of evidence is taken from small randomized controlled trials, prospective uncontrolled studies, case series, and retrospective chart analyses.  
- Uncertainties regarding several aspects of radiofrequency ablation for spinal pain necessitate additional research.  
- Questions remain about the etiology of facet joint syndrome, the prognostic validity of diagnostic nerve blocks, standard outcome measures, the role of the placebo effect in treatment success, and the radiofrequency denervation technique.  
- The validation of radiofrequency for chronic spinal pain management relies on the resolution of these technical issues, as well as issues regarding patient selection and long-term efficacy. |
| Aydin (2010)          | **Key points:**                   |
| The role of radiofrequency ablation for sacroiliac joint pain: a meta-analysis | - Systematic review of 10 articles to assess the effectiveness of radiofrequency ablation ranging from inception to January 1, 2010.  
- The main outcome measure was a reduction of pain by at least 50 percent post-radiofrequency ablation procedure. At three months, seven groups met the criteria and at six months, six groups met the criteria.  
- A meta-analysis with a forest plot was done at the three- and six-month patient follow-up intervals.  
- At three months, a range of 0.538 – 0.693 was found to have a 95 percent CI, with a pooled mean difference of 0.616.  
- At six months, a 95 percent CI of 0.423 – 0.576 was found, with a pooled mean difference of 0.499.  
- The meta-analysis demonstrated that RFA is an effective treatment for sacroiliac joint pain at three months and six months. |
| ASA (2010)            | **Key points:**                   |
| Practice guidelines for chronic pain management | - ASA practice guidelines support the use of conventional non-pulsed radiofrequency ablation of the medial branch nerves to the facet joint for low back (medial branch) pain when previous diagnostic or therapeutic injections of the joint or medial branch nerve have provided temporary relief.  
- Conventional radiofrequency ablation may also be considered for neck pain. |
| Manchikanti (2009)    | **Key points:**                   |
|                       | - ASIPP 2009 practice guidelines. |
### Citation and Content, Methods, Recommendations

<table>
<thead>
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| Comprehensive evidence-based guidelines | - Committee concluded that the suggested therapeutic frequency for radiofrequency treatment should remain at intervals of at least six months or longer per each region treated (maximum of two times per year, provided that 50 percent or greater relief is obtained for 10 to 12 weeks.  
- Further suggested that all regions be treated at the same time, provided all procedures are performed safely. |
| Nath (2008) | **Key points:**  
- A randomized controlled study of non-pulsed radiofrequency ablation was conducted in patients with chronic low back pain (20 active and 20 controls).  
- Inclusion criteria were three separate positive diagnostic blocks, and subjects were examined before and after the treatment (sham or active).  
- The active treatment group showed statistically significant improvement in back and leg pain and also back and hip movement.  
- There was significant improvement in quality of life variables, global perception of improvement, and generalized pain.  
- The improvement noted in the active group was significantly greater than that of the placebo group.  
- None of the study participants had complications other than transient post-procedure pain.  
- The study concluded that radiofrequency facet denervation could be used in the treatment of carefully selected patients with chronic low back pain. |

### References

**Professional society guidelines/other:**


Hayes Inc., Hayes Medical Technology Report. *Radiofrequency ablation for sacroiliac joint pain*. Lansdale,


**Peer-reviewed references:**


CMS National Coverage Determinations (NCDs):

No NCDs identified as of the writing of this policy.

Local Coverage Determinations (LCDs):

No LCDs identified as of the writing of this policy.

Commonly submitted codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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<th>CPT Code</th>
<th>Description</th>
<th>Comments</th>
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<td>64633</td>
<td>Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint</td>
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<td>64634</td>
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<td>64635</td>
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<tr>
<td>64636</td>
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<tr>
<td>64999</td>
<td>Pulsed radiofrequency ablation</td>
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<tr>
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<th>Description</th>
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<tr>
<td>M54.2</td>
<td>Cervalgia</td>
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<tr>
<td>M54.4</td>
<td>Low back pain</td>
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<tr>
<td>M54.9</td>
<td>Dorsalgia unspecified</td>
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