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: March 15, 2017
Next Review Date: March 2018

Related policies:
None.

ABOUT THIS POLICY: AmeriHealth Caritas Pennsylvania has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Pennsylvania’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 AmeriHealth Caritas Pennsylvania 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. AmeriHealth Caritas Pennsylvania’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. AmeriHealth Caritas Pennsylvania’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Pennsylvania will update its clinical policies as necessary. AmeriHealth Caritas Pennsylvania’s clinical policies are not guarantees of payment.

Coverage policy

AmeriHealth Caritas Pennsylvania considers non-pulsed radiofrequency ablation (NPRFA) for spine pain to be proven and medically necessary for individuals with intractable spine pain when all of the following are met:

- 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 lumber 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:

NPRFA 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 medical 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, NPRFA 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.

NPRFA for the thoracic spine and sacroiliac (SI) 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 NPRFA 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 (PRFA) 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 NPRFA therapies are not medically necessary.

As pain relief from denervation may not be permanent, repeat NPRFA 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 more reduction in pain for 10–12 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 SI 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 NPRFA treatment.

There are two types of radiofrequency ablation (RFA): NPRFA and PRFA. Typically, NPRFA systems are made of three components: a generator, needle electrodes, and grounding pads. NPRFA uses the placement of an electrode and an undisrupted 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.

PRFA delivers short bursts of radiofrequency (RF) current instead of the continuous flow of RF current produced by continuous RF generators. The interrupted, short bursts of high-voltage electrical current allows the tissue to cool, resulting in lower maximum temperatures than NPRFA, and does not cause tissue coagulation. PRFA has been introduced as a non-ablative alternative to NPRFA; 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**

AmeriHealth Caritas Pennsylvania 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 30, 2017. 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 NPRFA therapy does provide evidence of effectiveness. Professional literature suggests that NPRFA 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, SI 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, RFA 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 an RF 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 an RF lesion of the discus.

A systematic review (Leggett, 2014) that assessed the efficacy of NPRFA 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 SI joint pain. The authors concluded that the medical evidence supports NPRFA as an efficacious treatment for lumbar facet joint and SI joint pain, with five of six and both of the RCTs demonstrating statistically significant pain reductions, respectively. The evidence supporting RFA for the treatment of discogenic pain, however, was mixed. While the majority of the studies focusing on lumbar facet joints and SI joints suggested that NPRFA 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 NPRFA for the coccyx.

The 2010 American Society of Anesthesiologists (ASA) practice guidelines support the use of NPRFA 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 NPRFA (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 RF 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 10–12 weeks. It is further suggested that all regions be treated at the same time, provided all procedures are performed safely.

A systemic 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 months) from NPRFA. 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-RF neurotomy. Following cervical RF 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 RFA for chronic spinal pain have significant methodological limitations that may impact the interpretation of data. Few randomized controlled or comparative trials of RFA 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
A systematic review and meta-analysis (Aydin, 2010) to assess the effectiveness of RFA 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 ≥50 percent post-RFA. At three months, a range of 0.538–0.693 was found to have a 95 percent CI, with a pooled mean of 0.616. At six months, a 95 percent CI of 0.423–0.576 was found, with a pooled mean of 0.499. The authors concluded that RFA is an effective treatment for SI joint pain at three months and six months.

The American Society of Interventional Pain Physicians (ASIPP) 2010 practice guidelines for chronic spinal pain state that the evidence for NPRFA and PRFA of the SI joint is limited. These guidelines also state that the evidence for pulsed radiofrequency for SI pain is inconclusive.

Policy updates:

A systematic review (Engel, 2016) from the International Spine Intervention Society sought to examine cervical RFA 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 RFA is effective for abolishing zygapophysial joint pain and carries only minor risks.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td>Engel (2016)</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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<td>Itz (2016)</td>
<td>Dutch Multidisciplinary Guideline for Invasive Treatment of Pain Syndromes of the Lumbosacral Spine</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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<tr>
<td>Smith (2014)</td>
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<td></td>
<td>Cervical radiofrequency neurotomy reduces central hyperexcitability and improves neck movement in individuals with chronic whiplash</td>
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<td>Leggett (2014)</td>
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<td></td>
<td>Radiofrequency ablation for chronic low back pain: a systematic review of randomized controlled trials</td>
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<td>Falco (2012)</td>
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- The primary outcome measure was pain relief (short-term relief equals up to six months and long-term > six months).  
- Secondary outcome measures were improvement in functional status, psychological status, return to work, and reduction in opioid intake.  
- The evidence for cervical radiofrequency neurotomy and for cervical medial branch blocks was judged to be of fair quality.  
- Based on two RCTs, the evidence for cervical intra-articular injections and cervical medial branch blocks was judged as limited in quality. |
| Manchikanti (2012) An update of evaluation of therapeutic thoracic facet joint interventions | **Key points:**  
- Systemic review 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, 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. |
| Hayes (2012) Radiofrequency Ablation for Sacroiliac Joint Pain | **Key points:**  
- Clinical studies for the use of radiofrequency ablation (RFA) for chronic spinal pain have significant methodological limitations that may impact the interpretation of data.  
- Few randomized controlled or comparative trials of RFA 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 RFA 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) The role of radiofrequency ablation for sacroiliac joint pain: a meta-analysis | **Key points:**  
- Systematic review of 10 articles to assess the effectiveness of RFA ranging from inception to January 1, 2010, were found.  
- The main outcome measure was a reduction of pain by ≥50 percent post-RFA 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 |
At three months, a range of 0.538–0.693 was found to have a 95 percent CI, with a pooled mean of 0.616. At six months, a 95 percent CI of 0.423–0.576 was found, with a pooled mean of 0.499. The meta-analysis demonstrated that RFA is an effective treatment for SI joint pain at three months and six months.


Key points:
- ASA practice guidelines support the use of conventional radiofrequency ablation (NPRFA) 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 (NPRFA) may also be considered for neck pain.


Key points:
- ASIPP 2009 practice guidelines.
- Committee concluded that the suggested therapeutic frequency for RF 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 10–12 weeks.
- Further suggested that all regions be treated at the same time, provided all procedures are performed safely.

Nath (2008) Percutaneous lumbar zygapophyseal (facet) joint neurotomy using radiofrequency current

Key points:
- A randomized controlled study of NPRFA 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:


**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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