RADIOFREQUENCY ABLATION FOR CHRONIC SPINAL PAIN

Policy Number: 2016M0019B  Effective Date: February 1, 2016

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INSTRUCTIONS:

“Medical Policy assists in administering UCare benefits when making coverage determinations for members under our health benefit plans. When deciding coverage, all reviewers must first identify enrollee eligibility, federal and state legislation or regulatory guidance regarding benefit mandates, and the member specific Evidence of Coverage (EOC) document must be referenced prior to using the medical policies. In the event of a conflict, the enrollee’s specific benefit document and federal and state legislation and regulatory guidance supersede this Medical Policy. In the absence of benefit mandates or regulatory guidance that govern the service, procedure or treatment, or when the member’s EOC document is silent or not specific, medical policies help to clarify which healthcare services may or may not be covered. This Medical Policy is provided for informational purposes and does not constitute medical advice. In addition to medical policies, UCare also uses tools developed by third parties, such as the InterQual Guidelines®, to assist us in administering health benefits. The InterQual Guidelines 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. Other Policies and Coverage Determination Guidelines may also apply. UCare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary and to provide benefits otherwise excluded by medical policies when necessitated by operational considerations.”
## POLICY DESCRIPTION:

This medical policy provides information on Radiofrequency Ablation (RFA), sometimes referred to as neurotomy or facet rhizotomy, for the treatment of chronic spinal joint pain. The procedure involves the use of radio wave, applied via a percutaneous probe in order to generate heat, and create a lesion in a spinal sensory nerve. The goal of this therapy is to relieve pain by interrupting the transmission of pain signals from sensory nerves to the brain in patients with refractory spinal joint pain. For the procedure to be effective, multiple lesions must be performed at each nerve location using fluoroscopic guidance. The nerves do regenerate over time, so pain relief is not permanent, but the procedure can be repeated. Successful RFA neurotomy usually provides from 6 to 18 months of relief.

## COVERAGE RATIONALE / CLINICAL CONSIDERATIONS:

Denervation of the facet joint via radiofrequency nerve root ablation may be MEDICALLY NECESSARY for chronic cervical or lumbar facet-mediated spinal pain that is refractory to conservative therapy. The procedure must be conducted under fluoroscopic guidance to assure proper needle positioning. All of the following criteria must be met for the authorization request to be approved:

- **INITIAL PROCEDURE:**
  1. Patient has severe neck or back pain that limits daily activities, due to facet joint syndrome (symptoms of facet joint syndrome include absence of radiculopathy, pain that is aggravated by extension, rotation, or lateral bending of the spine, and is not typically associated with any neurological deficits).
  2. The facet-mediated spinal pain has been diagnosed by comparative, controlled medial branch nerve blocks (a single facet joint injection diagnostic block is not sufficient). The diagnostic nerve blocks must:
     - Provide > 50% pain relief using the Visual Analog Scale (VAS) or other validated tool (at least one hour for lidocaine and two hours for bupivacaine) during follow-up assessment.
     - Not be conducted under intravenous sedation unless specifically indicated.
     - Not include steroid injections.

    **REQUIRED DOCUMENTATION:** Written description of diagnostic procedure and patient response, including degree of pain relief and, if applicable, indications for sedation.

  3. Facet-mediated pain has been unresponsive to appropriate conservative therapy (such as structured exercise, physical therapy, activity modification, pharmacological management, therapeutic nerve blocks, and joint injections) for a period of at least six months.

    **REQUIRED DOCUMENTATION:** Written description of prior therapies attempted and patient’s response.

- **REPEAT PROCEDURE (same level):**

  Repeat procedures will be approved at intervals of no less than three months, provided greater than 50% relief using the Visual Analog Scale (VAS), or other validated tool was obtained for at least 10-12 weeks following the previous procedure. No more than three procedures per 12-month period will be approved.
REQUIRED DOCUMENTATION: Date of last radiofrequency nerve root ablation treatment and subsequent patient response (including degree of pain relief).

Denervation of the facet joint, via radiofrequency nerve root ablation or any method, is considered **EXPERIMENTAL AND INVESTIGATIONAL** for treating other conditions. This includes, but is not limited to, the following diagnoses:
- Radiofrequency ablation for treatment of coccygodynia.
- Radiofrequency ablation of dorsal root ganglia.
- Radiofrequency ablation of terminal (peripheral) nerve endings.
- Radiofrequency ablation of the sacroiliac (SI) joint.

Studies of radiofrequency ablation for other conditions were 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 radiofrequency ablation and to compare this technique with other medical or surgical therapies for pain.

**The use of any other ablative procedures/techniques** for treating chronic spinal pain are considered **EXPERIMENTAL/INVESTIGATIONAL**, including but not limited to the following:
- Pulsed radiofrequency
- Chemical neurolysis (also referred to as chemical ablation, chemical denervation or chemodenervation)
- Cooled radiofrequency denervation
- Cryoablation/cryodenervation
- Endoscopic radiofrequency ablation (rhizotomy)
- Laser ablation
- Intradiscal electrothermal procedures

These technologies are considered experimental/investigational as they are not identified as widely used and generally accepted for the proposed uses as reported in published, peer-reviewed medical literature.

**Note:** Radiofrequency (RF) ablation may also be referred to as radiofrequency neurotomy, radiofrequency denervation, radiofrequency neuroablation, radiofrequency lesioning, radiofrequency coagulation, facet rhizotomy, percutaneous radiofrequency neuroablation, radiofrequency neurolysis or articular rhizolysis.

### Clinical Considerations:
- **Required Documentation:**
  - Written description of diagnostic nerve block procedures and that patient response, including degree of pain relief and, if applicable, indications for sedation.
  - Written description of prior therapies attempted and patient’s response (conservative therapy is required for a period of at least six months).
  - Date of last radiofrequency nerve root ablation treatment and subsequent patient response (including degree of pain relief). No more than three procedures per 12-month period will be approved.
- **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 herniation, spondylolisthesis, spondylosis ankylopoetica, spinal stenosis, discogenic or stenotic compression, extensive multi-level spondylosis, clinical radiculopathy, multiple sclerosis, coagulation disorders, pregnancy, 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.
− Language barrier.
− Psychiatric disorders.

Caution is recommended for RFA treatment in patients with diabetes mellitus and in those who have undergone prior back surgery at the pain site.

- Possible Complications: In the reviewed studies, RFA for cervical and thoracic pain included the following complications:
  - RFA for cervical pain: Numbness (97%), ataxia (92%), transient neck pain (17%), hypersensitivity (15%), itch (10%), dyesthesias (55%), hypoesthesia (5% to 11.1%), heavy feeling in arm (5%), transient burning pain (35% to 77%), transient sensory loss in dermatome (35%), increased sensory evoked potential CS dermatomal latency (11.8%), neuritis (18.8%), and decreased pinch force at 3 months (6.3%). No motor complications were reported in any of the studies.
  - RFA for thoracic pain: Transient burning pain in the corresponding dermatome (13.3% to 32.6%), and minor transient sensory loss in the corresponding dermatome (4.4% to 16.3%). No motor complications or pneumothoraces were reported to occur, and no patients reported worsening of their pain.

- The most commonly complications of facet joint interventions, including RFA, are related to needle placement, drug administration, and neurolysis: intravascular injection of anesthetic, subarachnoid spread, spinal anesthesia, chemical meningitis, neural trauma, pneumothorax, radiation trauma, facet capsule rupture, hematoma formation, and steroid side effects. Other potential side effects included dysesthetic pain, radicular pain, increased pain due to neuritis or neurogenic inflammation, anesthesia dolorosa, cutaneous hyperesthesia, and deafferentation pain.

**BACKGROUND:**

In the United States, back pain has an adult lifetime incidence of 75% to 85%, with a yearly prevalence of 15% to 20%. Back pain may occur at any portion of the spine, but is most frequent in the cervical and lumbar portions, with a prevalence of 65% to 80%. Pain in the thoracic region is less frequent, and most studies report a prevalence of thoracic pain between 5% and 15%. One study evaluated the prevalence of facet joint pain by spinal region in patients with chronic spine pain syndrome and found the prevalence of cervical facet (zygapophysial) joint pain in patients with neck pain was 55%, thoracic facet joint pain in patients with mid-back or upper-back pain was 42%, and lumbar facet joint pain in patients with low back pain was 31%. The common classifications based on pain duration, include acute (2 weeks or less), subacute (2 to 12 weeks), and chronic (longer than 12 weeks). Men and women are equally affected by low back pain until age 60, when it becomes more prevalent in women. It has been reported that the total annual healthcare costs for back pain in the United States is more than $100 billion, with direct costs ranging from $25 to $33 billion per year. LBP is considered the second leading cause of physician visits and
hospitalizations and is believed to result in more disability among working-age adults than any other health condition.

Chronic cervical pain may be associated with different innervated structures in the cervical region, including zygapophyseal joints, discs, cervical segmental nerve roots, ligaments, and myofascial structures. Disorders of the cervical spine may produce referred symptoms originating from multiple locations into the shoulder, arm, and facial regions, as well as causing headaches. Cervico brachialgia is pain originating from the cervical spine radiating from the neck beyond the glenohumeral joint into the upper limb with referral to a particular spinal segment. The prevalence of cervical pain is similar to low back pain (LBP).

Acute cervical pain may be caused by a whiplash injury associated with sudden extension and flexion of the neck. This occurs as a result of motor vehicle collisions, falls, sports injuries, and work-related injuries. Cervicogenic headache and occipital neuralgia refer to specific types of unilateral headaches thought to arise from impingement or entrapment of the occipital nerves and/or the upper spinal vertebrae. Compression and injury of the occipital nerves within the muscles of the neck and compression of the second and third cervical nerve roots are generally thought to be responsible for the symptoms, including unilateral and, occasionally, bilateral head, neck, and arm pain.

Low back pain (LBP) is defined as pain affecting the area between the lower rib cage and gluteal folds, often radiating into the thighs. According to this definition, chronic LBP may originate from the vertebrae, intervertebral discs, spinal cords, nerve roots, facet joints, ligaments, muscles, and sacroiliac, atlanto-axial, and atlanto-occipital joints.

Pain in the sacroiliac joint (SI) may be caused by a wide variety of events, including infection; benign or malignant tumors; inflammatory arthritis; injuries caused by sudden impact during motor vehicle accidents; athletic injury; protracted lifting and bending; torsional strain; altered gait mechanics; and spine misalignment.

The exact location and possible structural causes of back pain are diagnosed with x-ray, myelography, magnetic resonance imaging (MRI), computerized tomography (CT), bone scans, and electrodiagnostic studies. However, even with the aid of these imaging techniques, the cause of back pain can only be identified in relatively few patients, and pain centers report that 40% to 67% of patients are referred with an inaccurate or incomplete diagnosis. Diagnosis of SI joint pain is complicated and often involves in-depth knowledge of a patient’s clinical history, physical examination, radiological studies, and prior interventional procedures. SI joint pain is typically diagnosed by exclusion with the use of analgesic injections, lateral branch blockades (“blocks”), or provocative discography for evaluation of discogenic pain.

Most back pain resolves spontaneously or is treated with conservative and noninvasive therapies such as medication (analgesics, anti-inflammatory drugs, muscle relaxants), cold therapy, exercise and physical therapy, chiropractic manipulation, immobilization, stabilization, and muscle balancing. Fully interventional procedures involve trigger point injections with local anesthetics or nerve blockades (“blocks”), transcutaneous nerve stimulation, viscosupplementation, cryoneurolysis or cryoablation. Surgery may be required for the conditions with underlying pathology as determined by radiological findings. Most surgical treatments, including spinal fusion, rhizotomy, discectomy, laminectomy, and myotomy, are used to decompress a nerve root, stabilize an unstable painful joint, or to reduce a deformity. However, in many patients, the cause of cervical, thoracic, and LBP pain is unknown, and there are no clear pathological abnormalities amenable to surgical treatment. These patients may be referred for pain reduction techniques, such as radiofrequency ablation (RFA), that are directed at the nervous
innervation of pain-producing structures.

Radiofrequency ablation is a percutaneous procedure in which sensory afferent nerve fibers are selectively destroyed by heat produced by radio waves delivered through an electrode. RFA has been investigated as a treatment modality for patients with a variety of chronic spinal pain syndromes, including flexion-extension injury (whiplash), neck and shoulder pain, intercostals neuralgia, sacroiliac syndrome, and facet joint pain syndrome. Treatment objectives are to eliminate pain, reduce the likelihood of recurrence, and prolong the time to recurrence by selectively destroying pain fibers without inducing excessive sensory loss, motor dysfunction, or other complications.

Pulsed RFA (PRFA) has been introduced as a nonablative alternative to RFA. PRFA delivers short bursts of radiofrequency (RF) current, instead of the continuous flow of RF current produced by continuous RF generators. This allows the tissue to cool between bursts, resulting in considerably lower maximum temperatures, compared with the continuous mode, and reduces the risk of neighboring tissue destruction. It does not destroy targeted nerves and surrounding tissue and, therefore, requires less precise electrodes placement. The mechanism by which PFRA works is not well understood. The current hypothesis for its mechanism of action is that electrical fields reversibly disrupt the transmission of nerve impulses across small unmyelinated fibers without destroying them, while larger fibers are not affected.

Generally intravenous conscious sedation is used during the initial phase of the procedure so that the patient can assist the physician in identifying the site of pain and the correct placement of the neurolytic agent. Using fluoroscopic guidance, a needle is inserted into the affected nerve root. Once the physician has determined that the electrode is positioned at the site responsible for the pain, a local anesthetic is administered and radiofrequency is applied using a solar or microwave current. This procedure may be an outpatient or office-based procedure.

REGULATORY STATUS:

1. **U.S. FOOD AND DRUG ADMINISTRATION (FDA):**

   RFA for back pain is a procedure and, therefore, is not subject to regulation by the Food and Drug Administration (FDA). However, the FDA regulates RFA devices, and there are numerous devices listed in the FDA 510(k) Premarket Notification database that are cleared for radiofrequency ablation (RFA) therapy (CDRH, 2015a). Two product codes are dedicated for these devices, one for radiofrequency (RF) lesion generators (GXD) and the other for RF lesion probes (GXI) (CDRH, 2015b). The following generators received FDA clearance within the past 5 years:
   
   - Erase Pen and Erase Tip System for Nerve Ablation, Models HC-0001 and CS-0001 (Cheng Medical Corp.; K101592; approved October 6, 2011) (CDRH, 2011a)
   - NT 2000 Lesioning Generator (Neurotherm Inc.; K111576; Approved September 20, 2011) (CDRH, 2011b)
   - Diros OWL™ URF-3AP(ML) (Diros Technology Inc.; K093185; approved January 22, 2010) (CDRH, 2010)
   - Cosman G4 Radiofrequency Generator (Cosman Medical Inc.; K082051; approved October 16, 2008) (CDRH, 2008)
2. CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS):

CMS has not established a National Coverage Determination (NCD) at this time that addresses RFA for spine joint pain (CMS, March 2013).

Local Coverage Determination (LCD): Paravertebral FACET Joint Block and FACET Joint DENERVATION (L30483). Reviewed 11/12/2015, no change in coverage.

Facet Joint Denervation: Facet joint block is one of the methods used to document/confirm suspicions of posterior elemental biomechanical pain of the back. The patient with this condition usually has back pain that does not have a strong radicular component, no associated neurologic deficit and the pain is aggravated by hyperextension of the spine.

Facet joint injections are considered medically necessary for the diagnosis or treatment of chronic pain that has failed conservative therapy.

If the patient gets sufficient relief of pain from a facet joint block for a meaningful period of time but the pain recurs, one of the options is to denervate the facet joint. This procedure requires placement of a needle in the facet joint under fluoroscopic or CT guidance, injection of a local anesthetic agent, and if the pain is relieved (confirming that the needle is in the area desired to be denervated), injection of a neurolytic agent to destroy the facet joint nerve. This denervation can also be achieved by passing an electric current through a similarly placed electrode, by applying heat or by using radiofrequency.

When facet joint block has been effective in managing the back pain under consideration, then a permanent denervation may be considered, but should be restricted only to the level or levels that, from the results of the blocks, can be reasonably considered the source of the pain. This may not include all the levels that were blocked.

Limitations:

The effects of denervation should last from six months to one year or longer. In some instances the effects may be permanent. Repeat denervation procedures at the same joint/nerve level will only be considered medically necessary when the patient has had significant improvement of pain after the initial facet joint nerve destruction that lasted an appropriate period of time (greater than or equal to six months.)

3. MINNESOTA DEPARTMENT OF HUMAN SERVICES (DHS):


MHCP will approve radiofrequency nerve root ablation as medically necessary for chronic cervical or lumbar facet-mediated spinal pain that is refractory to conservative therapy. The procedure must be conducted under fluoroscopic guidance to assure proper needle positioning. All of the following criteria must be met for the authorization request to be approved:

Initial Procedure:

- Patient has facet-mediated spinal pain diagnosed by comparative, controlled medial branch nerve blocks (single diagnostic blocks are not sufficient). The diagnostic nerve blocks must:
  - Provide > 50% pain relief using the Visual Analog Scale (VAS) or other validated tool (at least
one hour for lidocaine and two hours for bupivacaine) during follow-up assessment.

- Not be conducted under intravenous sedation unless specifically indicated.
- Not include steroid injections.

REQUIRED DOCUMENTATION: Written description of diagnostic procedure and patient response, including degree of pain relief and, if applicable, indications for sedation.

- Facet-mediated pain has been unresponsive to appropriate conservative therapy (such as structured exercise, physical therapy, activity modification, pharmacological management, therapeutic nerve blocks, and joint injections) for a period of at least six months.

REQUIRED DOCUMENTATION: Written description of prior therapies attempted and patient’s response.

Repeat Procedure (same level):
Repeat procedures will be approved at intervals of no less than three months, provided greater than 50% relief using the Visual Analog Scale (VAS) or other validated tool was obtained for at least 10-12 weeks following the previous procedure. No more than three procedures per 12-month period will be approved.

REQUIRED DOCUMENTATION: Date of last radiofrequency nerve root ablation treatment and subsequent patient response (including degree of pain relief).

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**CLINICAL EVIDENCE**

**Summary:**

**Radiofrequency Ablation for Cervical, Thoracic, and Chronic Low Back Pain:** While there was some evidence from uncontrolled and a few controlled studies that RFA may provide short-term pain relief in selected patients with chronic LBP, the majority of patients did not experience complete pain relief, and the durability of effect remains unclear. In addition, a number of the controlled studies documented a substantial placebo effect, which suggests that uncontrolled studies may overestimate the magnitude of benefit of RFA procedures. Studies of PRFA for chronic LBP were limited, uncontrolled, and insufficient to support conclusions regarding efficacy or duration of effect. Additional well-designed, longer-term RCTs are required to evaluate the safety and efficacy of RFA and PRFA and to compare these techniques with other medical or surgical therapies for chronic cervical and thoracic pain.

**Radiofrequency Ablation for Sacroiliac Joint Pain:** Although the data are insufficient to draw any definitive conclusions about the efficacy and safety of radiofrequency ablation (RFA) in patients with sacroiliac (SI) joint pain, there is some limited evidence that conventional RFA can provide short-term (3 to 6 months) pain relief in patients who have SI joint pain that is responsive to injection of local anesthetic. Several studies suggest that cooled RFA may have a pain-relieving effect that is comparable to that of conventional RFA, although the evidence is too sparse to support conclusions about the relative efficacy of the two techniques. Data from a single study of pulsed RFA are insufficient to evaluate the efficacy of this technique. No serious safety issues were reported in the studies, although patients often reported increased pain for a period of days after the RFA procedure.
**APPLICABLE CODES:**

The Current Procedural Terminology (CPT®) codes and HCPCS codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other medical policies and coverage determination guidelines may apply.

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<td>Pelvic bones, sacrum, and coccyx</td>
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<td>719.48</td>
<td>Facet (zygapophyseal) joint pain</td>
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<td>722.4</td>
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REFERENCES:


28. CIGNA. Coverage Policies and Criteria / Medical and Pharmacy Index. 2012.


94. Rocco AG. Radiofrequency lumbar sympathectomy. The evolution of a technique for managing sympathetically


POLICY HISTORY:

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QUESTIONS AND ANSWERS:

Q1: A1:

ATTACHMENTS: