IEHP UM Subcommittee Approved Authorization Guidelines

Percutaneous Radiofrequency Neurotomy
(Facet Denervation: Neurotomy, Rhizotomy, or Articular Rhizolysis)

Policy:
Percutaneous Radiofrequency Neurotomy (also referred to as Radiofrequency Ablation) is the treatment of Facet Arthropathy (joint pain) of the spine when medically necessary as outlined by the indications that follow.

Definitions

- A **zygopophyseal (facet) joint “level”** refers to the zygapophyseal joint or the two medial branch (MB) nerves that innervate that zygapophyseal joint.
- A **“session”** is defined as all injections/blocks/RF procedures performed on one region of the spine during one office visit on one day and includes medial branch blocks (MBB), intraarticular injections (IA), facet cyst ruptures, and radiofrequency (RF) ablations pertinent to the targeted region being tested/treated.
- A **“region”** is all injections performed in cervical/thoracic, lumbar or sacral spinal areas.
- **"Diagnosis"** of facet-mediated pain requires the establishment of pain relief following dual (two sessions) medial branch blocks (MBBs) performed at different sessions. Neither physical exam nor imaging has adequate diagnostic power to confidently distinguish the facet joint as the pain source.
- A **“Quantitative Pain Scale”** refers to a member’s overall pain level and will be defined as a numerical score of ZERO (0) to TEN (10) based on the Numeric Pain Rating Scale (NPRS). This score will be used as the primary determinant in a Member’s response to treatment or diagnostic testing. The scale is based on the Numerical Rating Scale (Appendix A).
- **“Relief of Pain”: Pain** will be determined to be controlled when a Member’s pain level is less than or equal to 3 out of 10 (with 10 being the greatest amount of pain).
- **“Partial Relief of Pain”** will be determined when a Member has experienced at least 25 percent to 50 percent of pain relief. For example, if a Member’s pain level decreased from a pre-treatment / pre-test procedure of 8/10 to 6/10 (a decrease of 2 points) it would be considered a 25 percent improvement.
- **“No Relief” / “Failure of Treatment-Testing”** will be defined as a less than 25 percent decrease of pain, and / or failure to obtain SUSTAINED control / relief of pain for the stated expected duration of relief and control that would be obtained from a specific procedure (for each type of specific treatment or testing modality).
Indications

Percutaneous Radiofrequency Neurotomy of the spine is considered medically necessary for treatment of Members with intractable cervical, thoracic, lumbar or sacral back pain with or without sciatica in the outpatient setting when **ALL** of the following are met:

1. The Member has experienced moderate to severe pain limiting activities of daily living for at least THREE (3) months; and  
2. The Member has tried and failed conservative treatments:  
   A. At least 2 different classes of medications for at least 6 weeks each  
   B. Nonpharmacologic modalities (a trial of at least 2 of the following for at least 6 weeks  
      i. Bracing/taping/immobilization  
      ii. Physical Therapy/Occupational Therapy  
      iii. Chiropractic care (for eligible Medicare and Medi-Cal recipients)  
      iv. Acupuncture (for eligible Medi-Cal recipients)  
   OR  
   v. Documentation of inability to complete the above due to contraindications  
3. Pain should be primarily axial (of the spine), and the facet joints, foraminae and central canal should be normal or minimally / mildly affected at worst; and  
4. There should not be an associated radiculopathy or neurogenic claudication; and  
5. The Member should not have had prior spinal fusion surgery; and  
6. MRI, CT, and electromyelogram/nerve conduction studies (EMG/NCS) should be negative or show minimal changes with regard to the facet joints, vertebral disc herniations, neuroforaminal narrowing, central canal stenosis, and instability (as in spondylosis, spondylolisthesis or other malalignments).  
7. Once Percutaneous Radiofrequency Neurotomy has been started, additional testing (with Medial Branch Blocks) will not be considered medically necessary. Testing will be considered complete with the source having been identified for Percutaneous Radiofrequency Neurotomy treatment.  
8. Initial treatment with Percutaneous Radiofrequency Neurotomy (Radiofrequency Ablation) may be considered when both of the following are shown:  
   A. Two sessions (a “diagnostic” and “confirmatory” session) of Medial Branch Nerve Blocks (facet joint injections) have been successful in relieving or reducing the pain by at least eighty percent (80%). Medial Branch Blocks should not be done any closer than one week and no longer than 1 month apart.  
   B. The pain source and location must be declared precisely, indicating the region, specific facet joint levels and whether unilateral or bilateral.
9. At least 6 months has elapsed since a prior denervation treatment (per side, per anatomical spine level). Repeat denervation procedures involving the same joint(s) are considered medically necessary if there is greater than or equal to 50% pain improvement and improvement in pain-specific activities of daily living documented.

10. The numeric quantitative pain score will be used to determine the level of improvement. If a provider submits conflicting data on the Member’s level of overall improvement, the Numeric Pain Score will be taken as the primary measurement to determine the level of treatment efficacy. For example, if a provider submits records that state a Member had an 80% improvement of pain, but also documents a numeric pain score of 8/10, then the numeric pain score will take precedence as the measure of efficacy.

11. If a provider reports only a percentage score and not a numeric pain score after treatment, then a numeric pain score will be calculated based on pre-treatment pain levels from other prior records from any other provider.

   A. For example, if documentation only states a 50% improvement with no comparative pain score level and prior records show pain levels of 9/10, this will translate into a 4.5/10 pain level when compared to pre-treatment levels.

Limitations of Coverage:

1. A maximum of two (2) Percutaneous Radiofrequency Neurotomy (Radiofrequency Ablation) sessions may be performed per 12 month period in any region (cervical, thoracic, lumbar or sacral spine) once treatment has begun.

2. For each covered spinal region (cervical, thoracic, or lumbar spine), a MAXIMUM OF FOUR (4) JOINTS per session, that is, two (2) bilateral levels or four (4) unilateral levels will be allowed.

3. Once a Percutaneous Radiofrequency Neurotomy (Radiofrequency Ablation) session has been completed, treating the same region on the contralateral side of the spine will not be considered medically necessary unless it was tested prior to treatment, with documentation to show a bilateral involvement.

4. Neither conscious sedation nor Monitored Anesthesia Care (MAC) is routinely necessary and is not covered. Individual consideration may be given in rare unique circumstances if the medical necessity for sedation is unequivocal and clearly documented.

5. Non-thermal RF modalities for facet joint denervation including chemical, low grade thermal energy (<80 degrees Celsius), and pulsed RF are not covered. Nonpulsed radiofrequency facet denervation is considered experimental and investigational for all other indications.

6. Intraarticular and/or extraarticular facet joint prolotherapy is not covered.
7. Fluoroscopy is expected to be used as the only imaging modality to complete Percutaneous Radiofrequency Neurotomy (Radiofrequency Ablation) when the treatment is approved.

8. Other imaging modalities such as myelography or epidurography are not medically necessary if submitted on the same pre-service request with medial branch nerve blocks / facet joint injections.

Covered CPT Codes:

64633 - DESTRUCTION BY NEUROLYTIC AGENT, PARAVERTEBRAL FACET JOINT NERVE(S), WITH IMAGING GUIDANCE (FLUOROSCOPY OR CT); CERVICAL OR THORACIC

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)

**All other CPT CODES submitted with RADIOFREQUENCY CODES will be considered not medically necessary.

CMS Local Coverage Determination for Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy (L34993):

Facet joints are paired diarthrodial articulations of the superior and inferior articular processes of adjacent vertebrae. The medial branches (MB) of the dorsal rami of the segmental nerves innervate facet joints and the MB nerves from the two adjacent dorsal rami innervate each joint.

Facet joint injection techniques are used in the diagnosis and/or treatment of chronic neck and back pain. 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) an injection of a neurolytic agent will be administered 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 neck or 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.

The evidence of clinical efficacy and utility has not been well-established with non-comparable and inadequately designed studies in the medical literature. There is also a lack of long-term outcome reports, especially with steroid dosages used. These drugs alone may provide the relief experienced by patients but are associated with serious adverse health events and could as well be administered orally. Hence, ongoing coverage requires outcomes reporting to allow future analysis of clinical efficacy.

**Medi-Cal:**

*Update*

General Medicine | July 2010 | Bulletin 433

**ECRI: Evidence Based Research:**

Searches identified 169 articles, and 154 of these were excluded because they did not meet our 12 pre-specified inclusion criteria. An additional five studies were excluded due to several large baseline differences between groups. The remaining 10 articles described nine unique studies: six compared RF denervation to sham; one compared RF annuloplasty to conservative management; one compared RF annuloplasty to IDET, and one compared coblation nucleoplasty to conservative management.

**Conclusions:**

The evidence is insufficient to determine whether radiofrequency denervation yields different outcomes from sham denervation. The insufficiency of evidence to answer the Key question should not be interpreted as evidence that RFA does not work. Rather, ECRI deemed the evidence insufficient to determine the answer to the question.

Overall, the six RF denervation studies were well-designed and conducted. All six randomized patients to groups, and all 6 blinded patients to group assignment. Five of the six also blinded the managing physician, and the sixth (the Oh study) 64 did not report whether the managing physician was blinded. Three of the six RF denervation studies used concealment of allocation, and the other three did not report this information. Attrition was generally low. The scores for internal validity were High or Moderate for all outcomes in all of these 6 studies, with scores ranging from 7.3 to 9.1 on the 0-10 scale (with 10 indicating high internal validity).
### Table 3. Evidence Base:

<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Centers</th>
<th>Enrollment Dates</th>
<th>N for RFA</th>
<th>N for Other Treatment</th>
<th>Length of Follow up</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>RF Denervation vs. Sham</strong></td>
<td></td>
<td></td>
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<tr>
<td>van Wijk et al. (2005)</td>
<td>The Netherlands</td>
<td>4 medical centers in the Netherlands</td>
<td>May 96 - Jan 99</td>
<td>40</td>
<td>41</td>
<td>At least 3 months in all patients.</td>
</tr>
<tr>
<td>Leclaire et al. (2001)</td>
<td>Canada</td>
<td>Center Hospitalier de l'Universite de Montreal, Hopital Notre-Dame, Montreal</td>
<td>Oct 93- Dec 96</td>
<td>36</td>
<td>34</td>
<td>66/70 (94%) were followed for 3 months; the other 4 (6%) were followed for 1 month.</td>
</tr>
<tr>
<td>van Kleef et al. (1999)</td>
<td>The Netherlands</td>
<td>Pain Management and Research Centre, University Hospital Maastricht</td>
<td>June 94 - April 96</td>
<td>15</td>
<td>16</td>
<td>3 mos in all pts. Failures were excluded then, therefore reported timepoints at 6 &amp; 12 mos were only for 3 mos successes.</td>
</tr>
<tr>
<td>Lord et al. (1996)</td>
<td>Australia</td>
<td>Cervical Spine Research Unit, Mater Misericordiac Hospital, Newcastle</td>
<td>NR</td>
<td>12</td>
<td>12</td>
<td>&lt;100 days: 14/24 (58%) 100-200 days: 2/24 (8%) 200-300 days: 3/24 (12%) &gt;300 days: 5/24 (21%)</td>
</tr>
<tr>
<td>Oh et al. (2004)</td>
<td>South Korea</td>
<td>Clinical Pain Research Center, Samsung Fine Hospital, Seoul</td>
<td>Jan 01 - Sept 01</td>
<td>26</td>
<td>23</td>
<td>Mean 4 months (neither range nor dispersion reported)</td>
</tr>
<tr>
<td>Geurts et al. (2003)</td>
<td>The Netherlands</td>
<td>4 medical centers in the Netherlands</td>
<td>July 96 - Jan 99</td>
<td>45</td>
<td>38</td>
<td>&lt;3 months: 3/83 (4%) 3-6 months: 66/83 (80%) 6-9 months: 9/83 (11%) 9-12 months: 2/83 (2%) &gt;12 months: 3/83 (4%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Systematic Review Study</th>
<th>Conclusions Specific to RFA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kirpalani et al. (2008)</td>
<td>RF denervation: “RF neurotomy through a continuous or pulsed approach has been shown through limited studies to provide lasting pain relief from cervical facet joint dysfunction for several months” (p773)</td>
</tr>
</tbody>
</table>
### Medical Review Criteria:

**Apollo & InterQual Concur this is covered under specific circumstances:**

Facet Denervation: Neurotomy, Rhizotomy, or Articular Rhizolysis

**Coverage** – All of the following must be met:

1. Severe pain limiting activities of daily living for at least 6 months.
2. No prior spinal fusion surgery.
3. Neuroradiologic studies are negative or fail to confirm disc herniation.
4. No significant narrowing of the vertebral spinal canal or spinal instability requiring surgery is present.
5. Patient has tried and failed conservative therapy for a period of 3 months or longer – e.g., physical therapy, home exercise programs, and pharmacologic therapies.
6. The cervical zygapophyseal or lumbar joint pain has been confirmed by local anesthetic blocks with at least a 50% reduction in pain.

### Table

<table>
<thead>
<tr>
<th>Study</th>
<th>Population Details</th>
<th>Procedure Description</th>
<th>Successful Outcome at 3 Months</th>
<th>Costs per Successful Treatment</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cohen et al. 2010</td>
<td>151 total patients</td>
<td>Group 0 received RF denervation based solely on clinical findings; Group 1 underwent denervation contingent on a positive response to a single diagnostic block; and Group 2 proceeded to denervation only if they obtained a positive response to comparative blocks done with lidocaine and bupivacaine</td>
<td>Group 0: 17 patients (33%) Group 1: 8 patients (16%) Group 2: 11 patients (22%)</td>
<td>Group 0 ($6,286) Group 1 ($17,142) Group 2 ($15,241)</td>
<td>Using current reimbursement scales, these findings suggest that proceeding to RF denervation without a diagnostic block is the most cost-effective treatment paradigm.</td>
</tr>
<tr>
<td>Nath et al. 2008</td>
<td>40 patients with chronic low-back pain (LBP)</td>
<td>Percutaneous RF denervation vs. Sham</td>
<td>Greater improvement seen in the treated group; no between-group comparative data provided in the abstract. The treated group had &quot;transient postoperative pain that was easily managed.&quot;</td>
<td>&quot;Our study indicates that [RF] facet denervation is not a placebo and could be used in the treatment of carefully selected patients with chronic [LBP].&quot;</td>
<td></td>
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</tbody>
</table>

Manchikanti et al. (2008)

Low back pain interventions

RF denervation: “Based on the ACOEM [American College of Occupational and Environmental Medicine] quality of evidence criteria, the evidence category is B - moderate, with evidence based on at least one high quality study, in managing cervical and lumbar facet joint pain.” (p425)
7. At least 6 months has elapsed since a prior denervation treatment (per side, per anatomical spine level).

**Note:** only 1 denervation procedure is usually indicated within a 12-month period.

**Major Insurance Carriers (Aetna, Anthem, Cigna):**

Nonpulsed radiofrequency facet denervation (also known as facet neurotomy, facet rhizotomy, or articular rhizolysis) is considered medically necessary for treatment of members with cervical facet pain (C1-C2 thru C7-T1 vertebrae) and lumbosacral facet pain (T12-L1 thru L5-S1 vertebrae) is considered medically necessary when all of the following criteria are met:

1. Member has experienced severe pain (non radicular) limiting activities of daily living for at least 6 months; **and**
2. Member has had no prior spinal fusion surgery in the vertebral level being treated; **and**
3. Neuroradiologic studies are negative or fail to confirm disc herniation; **and**
4. Member has no significant narrowing of the vertebral canal or spinal instability requiring surgery; **and**
5. Member has tried and failed conservative treatments such as bed rest, back supports, physiotherapy, correction of postural abnormality, as well as pharmacotherapies (e.g., anti-inflammatory agents, analgesics and muscle relaxants); **and**
6. A diagnostic, temporary block with local anesthetic of the facet nerve (medial branch block) or injection under fluoroscopic guidance into the facet joint has resulted in at least a 50% reduction in pain for the duration of the specific local anesthetic effect used [e.g. generally 3-4 hours for bupivacaine (Marcaine®, Sensorcaine®) and 30 minutes to 1 hour for lidocaine (Xylocaine®)]; and
7. A minimum time of six (6) months has elapsed since prior RF treatment (per side, per anatomical level of the spine). **Note:** a diagnostic, temporary block (as above) is not required for repeat RF at a previously treated site, if it has been less than one year since the last RF.

Nonpulsed radiofrequency facet denervation is considered experimental and investigational for all other indications.

Only 1 treatment procedure per level per side is considered medically necessary in a 6-month period.

**Background:**

Radiofrequency facet (RF) neurolysis is a procedure in which sensory afferent nerve fibers are selectively destroyed with heat produced by radio waves delivered through an electrode. 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.
Definitions

**Ablation:** the removal or destruction of a body part or tissue or its function. Ablation may be performed by surgery, hormones, drugs, radiofrequency, heat or other methods.

**Facet:** interlocking bones on the vertebrae which allow the spine to flex while maintaining its stability.

**Neurolysis:** the destruction of nerves or nerve tissue by heat, cutting or by chemical injection.

**Radiofrequency:** an invasive procedure that involves heating tissue in order to destroy it.

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August 10, 2016

**Bibliography:**

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