MEDICAL POLICY DETAILS

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<tr>
<th>Medical Policy Title</th>
<th>RADIOFREQUENCY JOINT ABLATION/DENERVATION</th>
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<tr>
<td>Policy Number</td>
<td>7.01.42</td>
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<tr>
<td>Category</td>
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| Product Disclaimer   | • If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.  
                      • If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.  
                      • If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit. |

POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, radiofrequency joint denervation/ablation has been medically proven to be effective and therefore, medically necessary for ANY of the following indications:

A. For facet mediated pain resulting from disease, injury or surgery when the following criteria are met:
   1. Clinical findings and imaging studies suggest no other obvious cause of the pain (e.g., central spinal stenosis with neurogenic claudication/myelopathy, foraminal stenosis or disc herniation with concordant radicular pain/radiculopathy, infection, tumor, fracture, pseudoarthrosis, pain related to spinal instrumentation);
   2. Failure of at least three (3) months of conservative therapy (e.g., exercise, physical methods including physical therapy, chiropractic care, Nonsteroidal anti-inflammatory drugs [NSAID’s] and/or analgesics) unless contraindicated and the reason(s) for the contraindication(s) is/are documented in the medical record.
   3. Two positive diagnostic facet joint injections/medial branch block using a local anesthetic as evidenced by 80% pain relief for the duration of the local anesthetic used.

B. For an individual with a spinal fusion and facet mediated pain resulting from disease, injury, or surgery, when the procedure is performed at an unfused spinal segment located either above or below the fused spinal segment, and BOTH of the following criteria are met:
   1. Clinical findings and imaging studies suggest no other obvious cause of the pain (e.g., central spinal stenosis with neurogenic claudication/myelopathy, foraminal stenosis or disc herniation with concordant radicular pain/radiculopathy, infection, tumor, fracture, pseudoarthrosis, pain related to spinal instrumentation);
   2. Failure of at least three (3) months of conservative therapy (e.g., exercise, physical methods including physical therapy, chiropractic care, NSAID’s and/or analgesies) unless contraindicated and the reason(s) for the contraindication(s) is/are documented in the medical record;
   3. Two positive diagnostic facet joint injections/medial branch block using a local anesthetic as evidenced by 80% pain relief for the duration of the local anesthetic used.

C. A repeat radiofrequency joint denervation/ablation when BOTH of the following criteria are met:
   1. There is documented pain relief of at least 50% which has lasted for a minimum of 12 weeks;
   2. The procedure is performed at a minimum of six months following the prior denervation/ablation procedure.

II. Based upon the literature and/or available information, radiofrequency joint denervation/ablation is not medically necessary in the absence of two sequential positive diagnostic facet joint injections/medial branch blocks.

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III. Based upon the literature and/or available information, radiofrequency joint denervation/ablation is not medically necessary when performed for neck pain or low back pain in the absence of an untreated radiculopathy.

IV. Based upon the literature and/or available information, radiofrequency joint denervations/ablation is not medically necessary for ANY of the following:
   A. When performed without the use of fluoroscopic guidance;
   B. Performing more than two procedures at the same level(s) during a 12 month period of time;
   C. In the absence of two sequential positive diagnostic facet joint injections/medial branch blocks;
   D. When performed for neck pain or low back pain in the presence of an untreated radiculopathy;
   E. When performed at a posteriorly fused spinal motion segment;
   F. When performed on more than three levels during the same session/procedure;
   G. When performed to treat pain arising from above C2-C3 and below L5-S1 spinal levels.

V. Based upon our criteria and the lack of peer-reviewed literature, these methods of ablation have not been medically proven to be effective and are considered investigational for all of the following:
   A. Pulsed radiofrequency ablation for chronic pain syndromes;
   B. Endoscopic radiofrequency denervation/endoscopic dorsal ramus rhizotomy;
   C. Cryoaiblation/cryoneurolysis/cryodenervation;
   D. Chemical ablation (e.g., alcohol, phenol, glycerol);
   E. Laser ablation;
   F. Ablation by any method for sacroiliac (SI) joint pain; and
   G. Cooled radiofrequency ablation.

Refer to Corporate Medical Policy #11.01.03 regarding Experimental and Investigational Services.

Refer to Corporate Medical Policy #7.01.87 regarding Spinal Injections (Epidural and Facet Injections) for Pain Management

DESCRIPTION

The facet joints (zygapophyseal joints) are located at the posterior aspect of the spine and are designed to provide stability and control motion between the vertebrae. These small joints are prone to injury, deterioration, and inflammation. There are a number of proposed causes of facet joint syndrome. The facet joints may be irritated from trauma, repetitive movements, or arthritic changes. It is very common to develop degenerative changes in facet joints after trauma to the spine, as a result of an injury to the intervertebral disc or secondary to degenerative disc disease. If the intervertebral disc is damaged and the cushioning effect of the disc is lost, the facet joints at that level will undergo more stress, which may result in degeneration of the facet joint. Diagnosis of facet joint pain is confirmed by response (pain alleviation) to nerve blocks with a least a 50% improvement on 2 positive blocks being required.

Percutaneous radiofrequency facet denervation is a low-risk means of treating “mechanical” pain syndromes in previously unoperated patients with back and/or leg pain. Under local anesthesia, needle placement is made under fluoroscopy to the facet (zygapophyseal) joint. The cannula is then redirected until contact with the bone is lost. Following the removal of the guide needle stylet, a thermal monitoring electrode with an exposed tip is passed, and the guide needle pulled back on the electrode beyond the skin. Electrostimulation is then performed and a lesion is made using a radiofrequency lesion generator. Control of the temperature over the nerve roots permits selective denervation of the pain conduction fibers. The nerves regenerate, and repeat procedures are effective though it is not known how many times the procedure can be repeated or if the duration of relief will change.

Pulsed radiofrequency consists of short bursts of electrical current of high voltage in the radio frequency range but without heating the tissue enough to cause coagulation. It is suggested as a possibly safer alternative to thermal radio frequency facet denervation. Temperatures do not exceed 42°C at the probe tip vs. temperatures in the 60s C. reached in thermal radiofrequency denervation, and tissues may cool between pulses. It is postulated that transmission across small unmyelinated nerve fibers is disrupted but not permanently damaged, while large myelinated fibers are not affected.
RATIONALE

Radiofrequency facet denervation as a procedure does not require FDA approval. Several RF generators and probes have been cleared for marketing through the FDA’s 510(k) process.

Peer-reviewed literature reporting small randomized, controlled studies of the efficacy and safety of radiofrequency facet denervation as well as evidence from larger case series is sufficient to permit conclusions that the technology provides significant and sustained relief of pain with minimal side effects in appropriately selected patients.

There is very limited literature on pulsed radiofrequency denervation. The mechanism of its action not completely understood, and published data is insufficient to draw conclusions about its efficacy.

CODES

- Eligibility for reimbursement is based upon the benefits set forth in the member’s subscriber contract.
- CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.
- Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

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REFERENCES


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*Levin JH. Prospective, double-blind, randomized placebo-controlled trials in interventional spine: what the highest quality literature tells us. Spine J 2008 Sep 11 [Epub ahead of print].


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RADIOFREQUENCY JOINT ABLATION/DENERVATION

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*Key Article

**KEY WORDS**

Denervation, Facet, Radiofrequency

**CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS**

There is currently a Local Coverage Determination that addresses Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy (L35936). Please refer to the following LCD web site for Medicare Members:

https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35936&ContrId=298&ver=22&ContrVer=1&CntrctrSelected=298*1&Cntrctr=298&name=National+Government+Services%2c+Inc.+(13201%2c+A+and+B+and+HHH+MAC%2c+J+-+K)&s=All&DocType=Active&bc=AggAAAQAAAAA%3d%3d#0