Introduction

Back pain is a common symptom and disability in some people. Despite extensive knowledge of the bones, nerves, muscles, tendons, and structures of the spine, it is still very difficult to identify a specific source of back pain for many people. A part of the spine felt to cause pain for some people are the facet joints. Facet joints connect the bones of the spine (vertebrae) to both stabilize your back and help your spine move. Arthritis or boney changes can develop in these small joints. It is felt that nerves can be compressed by the arthritic changes and lead to pain. Studies have shown that for a small number of people, back pain can be improved by destruction of these nerves (denervation). The nerves are destroyed using a form of electrical waves known as non-pulsed radiofrequency waves. Often the denervation must be repeated every 6 to 12 months because the nerves grow back. Because only a small number of people respond to this treatment, it is important to undergo temporary nerve blocks to identify who will get relief from the radiofrequency treatment. This service must be pre-approved by the plan before it is covered. Records that show at least two successful temporary nerve blocks are needed. Studies have shown that other methods of destroying these nerves (such as pulsed radiofrequency, heat, laser, chemical or freezing) do not work.
be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Medical Necessity</th>
</tr>
</thead>
</table>
| Cervical/Lumbar Radiofrequency denervation | **Non-pulsed radiofrequency denervation of cervical facet joints (C2-3 and below) and lumbar facet joints is considered medically necessary when ALL of the following criteria are met:**  
  - There is no prior spinal fusion surgery in the vertebral level being treated  
  **AND**  
  - Patient has experienced disabling low back (lumbosacral) or neck (cervical) pain for greater than three (3) months, suggestive of facet joint origin and other causes of cervical or lumbar pain such as disc herniation or narrowing of the vertebral canal have been excluded as documented in the medical record and radiographic imaging  
  **AND**  
  - Pain has failed to respond to three (3) months of conservative management, which may consist of therapies such as oral analgesics (nonsteroidal anti-inflammatory medications, acetaminophen), manipulation or physical therapy, and a home exercise program  
  **AND**  
  - There has been a successful trial of two controlled medial branch blocks (MBBs) with at least 80% pain relief for the duration of the anesthetic prior to performing the second MBB (see Related Information)  
  **AND**  
  - If there has been a prior successful radiofrequency denervation, a minimum time of six (6) months has elapsed since prior RF treatment (per side, per anatomical level of the spine)  
    - There should be a progress note supporting response to prior RF treatment |
| Additional diagnostic            | **If there has been a prior successful radiofrequency**                                                                                                                                                           |
### Procedure | Medical Necessity
---|---
medial branch blocks | denervation, additional diagnostic medial branch blocks for the same level of the spine are not medically necessary.

### Procedure | Investigational
---|---
Thoracic Radiofrequency denervation | Radiofrequency denervation is considered investigational for the treatment of chronic spinal/back pain for all uses that do not meet the criteria listed above including but not limited to treatment of thoracic facet joint pain.

All other methods of facet denervation | All other methods of denervation are considered investigational for the treatment of chronic spinal/back pain, including, but not limited to
- Pulsed radiofrequency denervation
- Laser denervation
- Chemodenervation
  - alcohol, phenol, or high-concentration local anesthetics
- Cryodenervation
- Cooled radiofrequency ablation for facet denervation

### Documentation Requirements
For requests for non-pulsed radiofrequency denervation of cervical facet joints (C2-3 and below) and lumbar facet joints, please provide the following current clinical notes:
- The level and side (right or left) you are planning to treat
- Documentation that no prior spinal fusion surgery was done in the vertebral level (the specific area) being treated
- Detailed history and physical with notes detailing how long the patient has experienced disabling low back or neck pain
- Evidence that suggests the pain is is arising from the facet joint and documentation that other causes of the pain have been ruled out (eg, copy of imaging showing absence of disc herniation or narrowing of the vertebral canal)
- Conservative treatment tried/failed for at least 3 months (conservative treatment may consist of therapies such as oral analgesics [nonsteroidal anti-inflammatory medications, acetaminophen], manipulation or physical therapy, and a home exercise program)
- Documentation of successful trial of controlled diagnostic medial branch blocks.
**Documentation Requirements**

Documentation shows at least 80% pain relief for the duration of anesthetic from the first medical branch block before the second medical branch block is performed:

- Medial branch blocks should consist of 2 separate positive blocks on different days with local anesthetic only (no steroids or other drugs)
- Medial branch blocks should involve the vertebral levels being considered for radiofrequency treatment and should not be conducted under intravenous sedation unless specifically indicated (eg, the patient is unable to cooperate with the procedure)

- If there has been a prior successful radiofrequency denervation:
  - There should be documentation that a minimum of six (6) months has passed since prior radiofrequency treatment (per side, per vertebral level of the spine)
  - Clinical note showing response to prior radiofrequency treatment

**Coding**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td></td>
</tr>
<tr>
<td>64633</td>
<td>Destruction by neurolytic agent, paravertebral facet joint nerve(s) with imaging guidance (CT or fluoroscopy); cervical or thoracic, single facet joint</td>
</tr>
<tr>
<td>64634</td>
<td>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)</td>
</tr>
<tr>
<td>64635</td>
<td>Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint</td>
</tr>
<tr>
<td>64636</td>
<td>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)</td>
</tr>
</tbody>
</table>

**Related Information**
**Definition of Terms**

**Diagnosis of facet-mediated pain:** This requires the establishment of pain relief following dual 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.

**Facet joints (also referred to as zygapophyseal or Z-joints):** These enable the spine to bend and twist. Each vertebra has a set of facet joints at the top and bottom. Two medial branch (MB) nerves innervate the zygapophyseal joints.

**Region:** All injections performed in cervical/thoracic or all injections performed in lumbar (not sacral) spinal areas.

**Session:** All injections/blocks/RF procedures performed on one day and includes medial branch blocks (MBB), intraarticular injections (IA), facet cyst ruptures, and RF ablations.

**Diagnostic Medial Branch Block Criteria**

- A successful trial of controlled diagnostic medial branch blocks consists of 2 separate positive blocks on different days with local anesthetic only (no steroids or other drugs), OR

- A placebo-controlled series of blocks, under fluoroscopic guidance, that has resulted in at least an 80% reduction in pain for the duration of the local anesthetic used (eg, 3 hours longer with bupivacaine than lidocaine).

- No therapeutic intra-articular injections (ie, steroids, saline, or other substances) should be administered for a period of at least 4 weeks prior to the diagnostic medial branch block.

- The diagnostic blocks should involve the levels being considered for RF treatment and should not be conducted under intravenous sedation unless specifically indicated (eg, the patient is unable to cooperate with the procedure).

- These diagnostic blocks should be targeted to the likely pain generator. Single-level blocks lead to more precise diagnostic information, but multiple single-level blocks require several visits and additional exposure to radiation.
Description

Facet joint denervation is performed under local anesthesia with fluoroscopic guidance. A needle or probe is directed to the median branch of the dorsal ganglion innervating the facet joint, where multiple thermal lesions are produced, typically by a radiofrequency generator. A variety of terms may be used to describe radiofrequency (RF) denervation (eg, rhizotomy, rhizolysis). In addition, the structures to which the RF energy is directed may be referred to as facet joint, facet nerves, medial nerve or branch, median nerve or branch, or dorsal root ganglion.

Background

Percutaneous radiofrequency (RF) facet denervation is used to treat neck or back pain originating in facet joints with degenerative changes. Diagnosis of facet joint pain is confirmed by response to nerve blocks. Patients generally are sedated for the RF procedure. The goal of facet denervation is long-term pain relief. However, the nerves regenerate, and repeat procedures may be required.

Alternative methods of denervation include pulsed RF, laser, chemodenervation and cryoablation. Pulsed RF consists of short bursts of electrical current of high voltage in the RF range but without heating the tissue enough to cause coagulation. It is suggested to possibly be a safer alternative to thermal RF facet denervation. Temperatures do not exceed 42°C at the probe tip versus temperatures in the 60°s C reached in thermal RF 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. With chemical denervation, injections with a diluted phenol solution, a chemical ablating agent, are injected into the facet joint nerve.

Assessment of efficacy for therapeutic interventions involves a determination of whether the intervention improves health outcomes. The optimal study design for a therapeutic intervention is a randomized controlled trial (RCT) that includes clinically relevant measures of health outcomes. Intermediate outcome measures, also known as surrogate outcome measures, may also be adequate if there is an established link between the intermediate outcome and true health outcomes. Nonrandomized comparative studies and uncontrolled studies can sometimes provide useful information on health outcomes, but are prone to biases such as noncomparability of treatment groups, the placebo effect, and variable natural history of the condition.
It is recognized that RCTs are extremely important to assess treatments of painful conditions and low back pain in particular, due both to the expected placebo effect and the subjective nature of pain assessment in general, and also the variable natural history of low back pain that often responds to conservative care. Although radiofrequency (RF) facet denervation has been in use for more than 20 years, evidence of its efficacy is limited to small randomized-controlled trials (RCTs) and to larger case series. Comparative studies are important for treatments in which the primary outcome is a measurement of pain in order to account for the potential placebo effect of an intervention.

Literature on the use of nerve blocks for patient selection consists of 1 small randomized trial and several large case series. This limited evidence suggests that there are a few patients who exhibit pain relief following 2 nerve blocks, but that these select patients may have relief of pain for several months following RF denervation. The limited evidence available is mixed regarding the optimum threshold of pain relief needed with diagnostic nerve blocks to proceed to RF denervation, but tends to support a threshold of at least 80% pain relief.

There are several small RCTs of RF denervation. These sham-controlled trials of RF denervation have mixed results and provide limited evidence for RF denervation. This is in contrast to larger case series, which find as many as 93% of patients with pain relief following RF denervation when selected by double blocks.

Summary of Evidence

The evidence for diagnostic testing consists mainly of studies using single or double blocks and experiencing at least 50% or at least 80% improvement in pain and function. There is considerable controversy about the role of the blocks, the number of positive blocks required, and the extent of pain relief obtained. Based on review of the evidence and clinical input, the statement in the Policy Guidelines section states that at least 80% improvement on 2 positive blocks (or a placebo-controlled series of blocks) is required.

There is limited evidence for RF denervation of the facet joint from sham controlled trials. Evidence from large uncontrolled series suggests that RF facet denervation appears to provide at least 50% pain relief in selected patients. Diagnosis of facet joint pain is difficult; however, response to controlled medial branch blocks and the presence of tenderness over the facet joint appear to be reliable predictors of success.

When RF facet denervation is successful, repeat treatments appear to have similar success rates and duration of pain relief. Thus, the data indicate that in carefully selected individuals with lumbar or cervical facet joint pain, RF treatments can result in improved outcomes.
Pulsed radiofrequency does not appear to be as effective as non-pulsed radiofrequency denervation, and there is insufficient evidence to evaluate the efficacy of other methods of denervation (eg, alcohol, laser or cryodenervation) for facet joint pain. Therefore, these techniques are considered investigational.

There is insufficient evidence to evaluate the effect of therapeutic medial branch blocks on facet joint pain. This treatment is considered investigational.

McCormick et al (2014) stated that while cooled radiofrequency ablation (C-RFA) appeared to be a promising technology for joint denervation, outcomes of this technique for the treatment of lumbar facet syndrome have not been described. The authors concluded that the findings in this case series study suggested that C-RFA may improve function and to a lesser degree pain at long-term follow-up. However, a randomized, controlled trial is needed.

**Ongoing and Unpublished Clinical Trials**

A search of the online site [Clinical Trials.gov](http://Clinical Trials.gov) identified several randomized trials on facet joint denervation.

<table>
<thead>
<tr>
<th>Trial</th>
<th>Summary</th>
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<tbody>
<tr>
<td>NCT01743326</td>
<td>Percutaneous radiofrequency denervation of the cervical facet joints compared with cervical medial branch block of the facet joints for patients with chronic degenerative neck pain: A prospective randomized clinical study has an estimated enrollment of 84 patients estimated completion date of June 2015. (Status Unknown).</td>
</tr>
<tr>
<td>NCT02002429</td>
<td>A randomized double-blind comparison of medial branch blocks versus intra-articular injections, has target enrollment of 225 patients with completion expected March 2018.</td>
</tr>
<tr>
<td>NCT02148003</td>
<td>Effect of the temperature used in thermal radiofrequency ablation on outcomes of lumbar facets medial branches denervation procedures: A randomized double-blinded trial has an estimated enrollment of 237 patients and a target completion date of February 2018. Still recruiting October 2017.</td>
</tr>
<tr>
<td>NCT02073292</td>
<td>A randomized controlled trial comparing thermal and cooled radiofrequency ablation techniques of thoracic facets' medial branches to manage thoracic pain, has an estimated enrollment of 61 patients with an estimated completion date of December 2017.</td>
</tr>
</tbody>
</table>
Clinical Input Received through Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

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In response to requests, input was received from 4 physician specialty societies and 5 academic medical centers (a total of 6 responses) while this policy was under review in 2010. The input supported the policy statements. Those providing input supported use of 2 diagnostic blocks achieving a 50% reduction in pain.

Practice Guidelines and Position Statements

American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS)

In 2014, the AANS and CNS published updated guidelines on the treatment of degenerative disease of the lumbar spine.\textsuperscript{32} AANS/CNS recommended to use a double-injection technique with an improvement threshold of 80% or greater to establish a diagnosis of lumbar facet-mediated pain (Grade B), that this is an option for predicting a favorable response to facet medial nerve ablation by thermocoagulation (Grade C), and that there is no evidence to support the use of diagnostic facet blocks as a predictor of lumbar fusion outcome in patients with chronic low-back pain from degenerative lumbar disease (Grade I: Inconclusive).

AANS/CNS gave Grade B recommendations that 1) intraarticular injections of lumbar facet joints are not suggested for the treatment of facet-mediated chronic low-back pain; 2) medial nerve blocks are suggested for the short-term relief of facet-mediated chronic low-back pain; and 3) lumbar medial nerve ablation is suggested for the short-term (3- to 6-month) relief of facet-mediated pain in patients who have chronic lower-back pain without radiculopathy from degenerative disease of the lumbar spine.
**American Society of Interventional Pain Physicians (ASIPP)**

Updated guidelines on interventional techniques in the management of chronic spinal pain from the ASIPP were published in 2013.\(^3\) Diagnostic lumbar facet joint nerve blocks were recommended in patients with suspected facet joint pain, based on good evidence for diagnostic lumbar facet joint nerve blocks with 75% to 100% pain relief as criterion standard. For the treatment of facet joint pain, evidence was considered to be good for conventional radiofrequency, limited for pulsed radiofrequency, fair to good for lumbar facet joint nerve blocks and limited for intra-articular injections. Based on the evidence review, ASIPP recommends treatment with conventional radiofrequency neurotomy or therapeutic facet joint nerve blocks.

**American Society of Anesthesiologists (ASA)**

Practice guidelines for chronic pain management by the ASA Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine were published in 2010.\(^4\) The guidelines include the following recommendations:

- **Radiofrequency ablation:** Conventional (eg, 80°C) or thermal (eg, 67°C) radiofrequency ablation of the medial branch nerves to the facet joint should be performed for low back (medial branch) pain when previous diagnostic or therapeutic injections of the joint or medial branch nerve have provided temporary relief.

- **Chemical denervation:** Chemical denervation (eg, alcohol, phenol, or high-concentration local anesthetics) should not be used in the routine care of patients with chronic noncancerous pain.

**American Pain Society (APS)**

A 2009 APS Clinical Practice Guideline on nonsurgical interventions for low back pain states that “there is insufficient (poor) evidence from randomized trials (conflicting trials, sparse and lower quality data, or no randomized trials) to reliably evaluate” a number of interventions including facet denervation.\(^1\)
National Institute for Health and Clinical Excellence (NICE)

The 2009 NICE guidelines on the early management of non-specific low back pain state that people should not be referred for radiofrequency facet joint denervation. \(^\text{35}\)

Medicare National Coverage

There is no national coverage determination. Noridian Healthcare Solutions issued a local coverage determination (LCD) \(^\text{37}\) on March 5, 2014 with an update effective May 01, 2015.

Regulatory Status

A number of radiofrequency generators and probes have been cleared for marketing through the U.S. Food and Drug Administration’s (FDA) 510(k) process. One device, the SInergy® by Kimberly Clark/Baylis, is a water-cooled single-use probe that received FDA clearance in 2005, listing the Baylis Pain Management Probe as a predicate device. The intended use is in conjunction with a radiofrequency generator to create radiofrequency lesions in nervous tissue.

FDA product code: GXD

References

8. Cohen SP, Strassels SA, Kurihara C et al. Randomized study assessing the accuracy of cervical facet joint nerve (medial branch) blocks using different injectate volumes. Anesthesiology 2010; 112(1):144-152. PMID 19996954
22. Smuck M, Crisostomo RA, Trivedi K et al. Success of initial and repeated medial branch neurotomy for zygapophysial joint pain: a systematic review. PM R Sep 2012; 4(9):686-692. PMID 22980421


**History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>05/12/14</td>
<td>New PR policy replacing 7.01.116, same title. Policy coverage on non-pulsed RF now considered medically necessary for level C2-3 (is investigational at C2 in policy 7.01.116) when criteria are met including two controlled medial branch blocks (MBBs) with an indication of at least 80% relief for the duration of the anesthetic prior to performing the second MBB. Unlisted CPT code 64999 removed; there are CPT codes specific to this policy referenced within. ICD-9 and ICD-10 diagnosis and procedure codes removed; these to not facilitate adjudication, this is outpatient.</td>
</tr>
<tr>
<td>02/16/16</td>
<td>Coding update. Added 64999.</td>
</tr>
<tr>
<td>11/01/16</td>
<td>Annual Review, approved October 11, 2016. Literature search. No changes to policy statement. Policy moved into new format. Removed unlisted CPT code 64999 from coding section.</td>
</tr>
<tr>
<td>03/01/18</td>
<td>Minor update; added Documentation Requirements section. Updated Related Policy number; 6.01.23 changed to 6.01.524.</td>
</tr>
<tr>
<td>07/01/18</td>
<td>Interim Review, minor update approved June 22, 2018. Added cooled radiofrequency ablation to list of all other methods of denervation which are considered investigational. Reference 45 added.</td>
</tr>
</tbody>
</table>

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply.
Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
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  - Information written in other languages

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PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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Oromo (Cushite):

Italiano (Italian):