FEP Medical Policy Manual

FEP 7.01.116 Facet Joint Denervation

Effective Policy Date: April 1, 2021

Original Policy Date: June 2012

Related Policies:

7.01.120 - Facet Arthroplasty

Facet Joint Denervation

Description

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

Facet joint denervation is performed under local anesthetic and 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 an RF generator. A variety of terms may be used to describe 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.

Alternative methods of denervation include pulsed RF, laser, chemodenervation, and cryoablation. Pulsed RF consists of short bursts of electric current of high voltage in the RF range but without heating the tissue enough to cause coagulation. RF is suggested as a possibly safer alternative to thermal RF facet denervation. Temperatures do not exceed 42°C at the probe tip versus temperatures in the 60°C range 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.

OBJECTIVE

The objectives of this evidence review are to determine whether the use of (1) medial branch blocks to identify individuals with facet joint pain; (2) radiofrequency ablation to treat individuals with facet joint pain; and (3) therapeutic medial branch blocks or alternative methods of denervation to treat individuals with facet joint pain improves the net health outcome.

POLICY STATEMENT

Nonpulsed radiofrequency denervation of cervical facet joints (C3-4 and below) and lumbar facet joints is considered **medically necessary** when ALL of the following criteria are met.

- No prior spinal fusion surgery in the vertebral level being treated; AND
- Disabling low back (lumbosacral) or neck (cervical) pain, suggestive of facet joint origin as evidenced by absence of nerve root compression as documented in the medical record on history, physical, and radiographic evaluations; and the pain is not radicular; AND
- Pain has failed to respond to 3 months of conservative management, which may consist of therapies such as nonsteroidal anti-inflammatory medications, acetaminophen, manipulation, physical therapy, and a home exercise program; AND
- There has been a successful trial of controlled medial branch blocks (see Policy Guidelines section); AND
- If there has been a prior successful radiofrequency denervation, a minimum time of 6 months has elapsed since prior radiofrequency treatment (per side, per anatomic level of the spine).

Radiofrequency denervation is considered **investigational** for the treatment of chronic spinal or 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 denervation are considered **investigational** for the treatment of chronic spinal or back pain, including, but not limited to pulsed radiofrequency denervation, laser denervation, chemodenervation (eg, alcohol, phenol, or high concentration local anesthetics), and cryodenervation.

Therapeutic medial branch blocks are considered **investigational**.

If there has been a prior successful radiofrequency denervation, additional diagnostic medial branch blocks for the same level of the spine are **not medically necessary**.

POLICY GUIDELINES

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 a 50% 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 radiofrequency 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.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

A number of RF generators and probes have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. In 2005, the SInergy (Kimberly Clark/Baylis), a water-cooled single-use probe, was cleared by the FDA, listing the Baylis Pain Management Probe as a predicate device. The intended use is with an RF generator to create RF lesions in nervous tissue. FDA product code: GXD.

RATIONALE

Summary of Evidence

For individuals who have suspected facet joint pain who receive diagnostic medial branch blocks, the evidence includes systematic reviews, a small randomized trial, and observational studies. Relevant outcomes are other test performance measures, symptoms, and functional outcomes. There is considerable controversy about the role of these blocks, the number of positive blocks required, and the extent of pain relief obtained. Studies have reported the use of single or double blocks and at least 50% or 80% improvement in pain and function. This evidence has suggested that there are relatively few patients who exhibit pain relief following 2 nerve blocks, but that these select patients may have pain relief for several months following RF denervation. Other large series have reported the prevalence and false-positive rates following controlled diagnostic blocks, although there are issues with the reference standards used in these studies because there is no criterion standard for the diagnosis of facet joint pain. There is level I evidence for the use of medial branch blocks for diagnosing chronic lumbar facet joint pain and level II evidence for diagnosing cervical and thoracic facet joint pain. The evidence available supports a threshold of at least 75% to 80% pain relief to reduce the false-positive rate. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have facet joint pain who receive RF ablation, the evidence includes systematic reviews and RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and medication use. While the evidence is limited to randomized controlled trials with small sample sizes (N ≤100 patients), RF facet denervation appears to provide at least 50% pain relief in carefully 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 improve outcomes. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have facet joint pain who receive therapeutic medial nerve branch blocks or alternative methods of facet joint denervation, the evidence includes a systematic review, randomized trials without a sham control, and uncontrolled case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and medication use. Pulsed RF does not appear to be as effective as conventional RF denervation, and there is insufficient evidence to evaluate the efficacy of other methods of denervation (eg, alcohol, laser, cryodenervation) for facet joint pain or the effect of therapeutic medial branch blocks on facet joint pain. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American Association of Neurological Surgeons and Congress of Neurological Surgeons

In 2014, the American Association of Neurological Surgeons and the Congress of Neurological Surgeons updated their joint guidelines on the treatment of degenerative disease of the lumbar spine.[31] The 2 groups provided grade B recommendations: (1) intra-articular injections of lumbar facet joints were not suggested for the treatment of facet-mediated chronic low back pain; (2) medial nerve blocks were suggested for the short-term relief of facet-mediated chronic low back pain; and (3) lumbar medial nerve ablation was 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

In 2020, the American Society of Interventional Pain Physicians published guidelines on use of facet joint interventions for management of chronic spinal pain.[32] Use of facet joint nerve blocks for diagnosis of facet joint pain is recommended with a moderate to strong strength of recommendation for the lumbar spine (evidence level I to II), moderate strength for the cervical spine (evidence level II), and moderate strength for the thoracic spine (evidence level II); a criterion standard of ≥80% pain relief was included for these recommendations. Radiofrequency ablation is recommended for treatment of pain in the lumbar spine (moderate strength recommendation; evidence level II), cervical spine (moderate strength recommendation; evidence level II), and thoracic spine (weak to moderate strength recommendation; evidence level III). Facet joint nerve blocks are recommended for treatment of pain in the lumbar spine (moderate strength recommendation; evidence level II), cervical spine (moderate strength recommendation; evidence level II), and thoracic spine (weak to moderate strength recommendation; evidence level III). Treatment of facet joint pain with intraarticular injections is a weak strength recommendation with lower levels of evidence (level III, IV, and V evidence for the thoracic, lumbar, and cervical spine respectively).

American Society of Anesthesiologists et al

Practice guidelines on chronic pain management from the American Society of Anesthesiologists and the American Society of Regional Anesthesia and Pain Medicine were published in 2010.[33] The guidelines included the following recommendations:

"Radiofrequency ablation: Conventional (e.g., 80C) or thermal (e.g., 67C) 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 (*e.g.*, alcohol, phenol, or high concentration local anesthetics) should *not* be used in the routine care of patients with chronic noncancer pain."

International Working Group Consensus Guidelines

International consensus guidelines from 13 different pain societies (2020) provide recommendations regarding interventions for lumbar facet joint pain specifically.[34] When used for diagnosis, the guidelines suggest that intra-articular injections are more diagnostic than medial branch blocks, but note that intra-articular injections have a high technical failure rate and provide less predictive value when administered prior to radiofrequency ablation (grade B evidence, low level of certainty). For therapeutic treatment of lumbar facet pain the guideline recommends against use of medial branch blocks or intra-articular injections (grade D evidence, moderate level of certainty), although acknowledges certain clinical scenarios which may warrant these techniques, such as a contraindication to radiofrequency ablation.

National Institute for Health and Care Excellence

In 2016, the U.K. National Institute for Health and Care Excellence (NICE) published guidance on the assessment and management of low back pain and sciatica in those over 16 years of age.[35,] NICE recommended that RF denervation can be considered for patients with chronic low back pain when "non-surgical treatment has not worked for them and the main source of pain is thought to come from structures supplied by the medial branch nerve and they have moderate or severe levels of localized back pain." RF denervation should only be performed" after a positive response to a diagnostic medial branch block." The NICE cautioned that the length of pain relief after RF denervation is uncertain, and that results from repeat RF denervation procedures are also uncertain.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
June 2012	New policy	
March 2014	Replace policy	Policy updated with literature review. References 10-13, 24, 30, 35, 37- 38, and 41-42 added and reordered. Policy Guidelines added. Types of chemodenervation added to not medically necessary statement.
March 2015	Replace policy	Policy updated with literature review through September 16, 2014; Rationale section revised; references 20 and 31 added; some references removed; policy statements unchanged.
March 2018	Replace policy	Policy updated with literature review through September 11, 2017; reference 38 added. Policy statements unchanged except "not medically necessary" corrected to "investigational" due to FDA 501(k) status in the following statements: Radiofrequency denervation is considered investigational for the treatment of chronic spinal or 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 denervation are considered investigational for the treatment of chronic spinal or back pain, including, but not limited to pulsed radiofrequency denervation, laser denervation, chemodenervation (eg, alcohol, phenol, or high concentration local anesthetics), and cryodenervation; Therapeutic medial branch blocks are considered investigational.
March 2019	Replace policy	Policy updated with literature review through September 6, 2018; no references added. Policy statements unchanged.
March 2020	Replace policy	Policy updated with literature review through September 9, 2019; no references added. Policy statements unchanged.
March 2021	Replace policy	Policy updated with literature review through September 18, 2020; references added. Policy statements unchanged.