BlueCross BlueShield Federal Employee Program.

FEP 7.01.116 Facet Joint Denervation

Effective Date: April 15, 2018

Related Policies:
6.01.23 Diagnosis and Treatment of Sacroiliac Joint Pain
7.01.120 Facet Arthroplasty

Facet Joint Denervation

Description

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. The goal of facet denervation is long-term pain relief. However, the nerves regenerate and, therefore, repeat procedures may be required.

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 FDA, listing the Baylis Pain Management Probe as a predicate device. The intended use is with a RF generator to create RF lesions in nervous tissue. FDA product code: GXD.

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).

RATIONALE

Summary of Evidence

For individuals who have suspected facet joint pain who receive diagnostic medial branch blocks, the evidence includes a systematic review of 17 diagnostic accuracy studies, a small randomized trial, and several large case series. Relevant outcomes are test accuracy, 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 at least 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 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 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 radiofrequency ablation, the evidence includes a systematic review of randomized controlled trials. Relevant outcomes are symptoms, functional outcomes, quality of life, and medication use. While evidence is limited to a few randomized controlled trials with small sample sizes, 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 appears to be reliable predictors of success. When RF facet denervation is successful, repeat treatments appear to have similar success rates and durations 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. 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 uncontrolled case series and randomized trials without a sham control. 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

Association of Neurological Surgeons and Congress of Neurological Surgeons

In 2014, the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS) updated their joint guidelines on the treatment of degenerative disease of the lumbar spine.[33] AANS and CNS provided grade B recommendations: (1) intra-articular 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

Updated guidelines on interventional techniques for the management of chronic spinal pain from the American Society of Interventional Pain Physicians were published in 2013.[34] Diagnostic lumbar facet joint nerve blocks were recommended in patients with suspected facet joint pain, based on good evidence for diagnostic lumber facet joint nerve blocks with 75% to 100% pain relief as the criterion standard. For the treatment of facet joint pain, evidence was considered good for conventional radiofrequency (RF), limited for pulsed RF, fair-to-good for lumbar facet joint nerve blocks, and limited for intra-articular injections. Based on the evidence review, the Society recommended treatment with conventional RF neurotomy or therapeutic facet joint nerve blocks.

American Society of Anesthesiologists et al

Practice guidelines for chronic pain management by the American Society of Anesthesiologists and the American Society of Regional Anesthesia and Pain Medicine were published in 2010.[35] The guidelines included the following recommendations:

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

American Pain Society

The 2009 American Pain Society clinical practice guidelines on nonsurgical interventions for low back pain stated 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 Care Excellence

The National Institute for Health and Care Excellence (NICE) published guidance in 2016 on assessment and management of low back pain and sciatica in those over 16 years of age.[36] NICE recommended that RF denervation can be considered for patients with chronic low back pain "when other 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. NICE cautioned that the length of pain relief after RF denervation is uncertain, and that results from repeat RF denervation procedures are also uncertain.

California Technology Assessment Forum

In 2001, the California Technology Assessment Forum published a review of the evidence for percutaneous RF neurotomy of cervical and lumbar zygapophyseal joints for chronic neck and low back pain; it concluded that the technology met its criteria for efficacy and safety for treatment of lower cervical (C3 and below) and for lumbar pain but not for treatment of upper (C2-3) levels. In 2007, the Forum reviewed the evidence for treatment of C2-3 joints and did not reverse its position.[37]

Dutch Society of Anesthesiologists et al

In 2016, the Dutch Society of Anesthesiologists, in collaboration with the Dutch Orthopedic Association and the Dutch Neurosurgical Society issued joint guidelines on invasive treatment of lumbosacral spine pain.[38] For facet joint pain, the guidelines concluded that there was evidence that RF has a beneficial effect on functionality for 3 to 6 months. The guidelines also concluded that "pulsed RF has no place in the treatment of lumbar facet pain."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

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

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POLICY HISTORY

Date	Action	Description
June 2012	New Policy	
March 2014	Update 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	Update 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	Update 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 501k 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.