Protocol

Facet Joint Denervation

(701116)

Medical Benefit		**Effective Date**: 01/01/16	**Next Review Date**: 11/19
Preauthorization	Yes	**Review Dates**: 09/09, 09/10, 07/11, 07/12, 05/13, 05/14, 01/15, 11/15, 11/16, 11/17, 11/18	

Preauthorization is required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: • With suspected facet joint pain	Interventions of interest are: • Diagnostic medial branch blocks	Comparators of interest are: • Clinical diagnosis	Relevant outcomes include: • Test accuracy • Other test performance measures • Symptoms • Functional outcomes
Individuals: • With facet joint pain	Interventions of interest are: • Radiofrequency ablation	Comparators of interest are: • Intra-articular Injection • Standard medical therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use
Individuals: • With facet joint pain	Interventions of interest are: • Therapeutic medial branch blocks • Alternative methods of denervation	Comparators of interest are: • Intra-articular Injection • Standard medical therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use

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.

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 two 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 (RCTs). Relevant outcomes are symptoms, functional outcomes, quality of life, and medication use. While evidence is limited to a few RCTs 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 (e.g., 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.

POLICY

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 three 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); AND
- If there has been a prior successful radiofrequency denervation, a minimum time of six 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 (e.g., 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 two 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 (e.g., three hours longer with bupivacaine than lidocaine). No therapeutic intra-articular injections (i.e., steroids, saline, or other substances) should be administered for a period of at least four 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 (e.g., 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.

MEDICARE ADVANTAGE

These policy statements do not address sacral conditions or injections or neurotomies.

Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy may be considered **medically necessary** when all of the following indications are met:

- Patient must have history of at least three months of moderate to severe pain with functional impairment and pain is inadequately responsive to conservative care such as NSAIDs, acetaminophen, physical therapy (as tolerated).
- Pain is predominantly axial and, with the possible exception of facet joint cysts, not associated with radiculopathy or neurogenic claudication.
- There is no non-facet pathology that could explain the source of the patient's pain, such as fracture, tumor, infection, or significant deformity.
- Clinical assessment implicates the facet joint as the putative source of pain.

Thermal Medial Branch Radiofrequency Neurotomy (includes RF and microwave technologies) may be considered **medically necessary**:

- Only when dual MBBs provide greater than or equal to 80% relief of the primary or index pain and duration of relief is consistent with the agent employed may facet joint denervation with RF medial branch neurotomy be considered.
- Repeat denervation procedures involving the same joint will only be considered medically necessary if the patient experienced greater than or equal to 50% improvement of pain and improvement in patient specific ADLs documented for at least six months**.**

Non-thermal RF modalities for facet joint denervation including chemical, low grade thermal energy (less than 80 degrees Celsius), as well as pulsed RF are considered **investigational**.

MEDICARE ADVANTAGE POLICY GUIDELINES

General Procedure Requirements indicate that facet joint interventions (diagnostic and/or therapeutic) must be performed under fluoroscopic or computed tomographic (CT) guidance.

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, 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 a RF generator. A variety of terms may be used to describe RF denervation (e.g., 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 vs. 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.

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.

RELATED PROTOCOLS

Diagnosis and Treatment of Sacroiliac Joint Pain

Facet Arthroplasty

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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