Facet Joint Denervation

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.

RELATED PROTOCOLS

Diagnosis and Treatment of Sacroiliac Joint Pain

Facet Arthroplasty

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DESCRIPTION

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.
SUMMARY OF EVIDENCE

For individuals with 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 an improvement in the net health outcome.

For individuals with facet joint pain who receive RF ablation, the evidence includes systematic reviews and randomized controlled trials (RCTs). Relevant outcomes are symptoms, functional outcomes, quality of life, and medication use. While the evidence is limited to 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 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 an improvement in the net health outcome.

For individuals with 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 (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 that the technology results in an improvement in the net health outcome.

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 investigative 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 investigative 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 investigative.

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 Interventions may be considered medically necessary for the diagnosis and treatment of chronic pain in patients who meet ALL the following criteria:

• Moderate to severe chronic neck or low back pain, predominantly axial, that causes functional deficit measured on pain or disability scale

• Pain present for minimum of three months with documented failure to respond to noninvasive conservative management (as tolerated)

• Absence of untreated radiculopathy or neurogenic claudication (except for radiculopathy caused by facet joint synovial cyst)

• There is no non-facet pathology per clinical assessment or radiology studies that could explain the source of the patient’s pain, including but not limited to fracture, tumor, infection, or significant deformity.

For the first diagnostic facet joint procedure to be considered medically necessary, the patient must meet the above criteria, outlined under indications for facet joint interventions.

A second confirmatory diagnostic facet joint procedure may be considered medically necessary in patients who meet ALL the following criteria:
• The patient meets the criteria for the first diagnostic procedure; AND
• After the first diagnostic facet joint procedure, there must be a consistent positive response of at least 80% relief of primary (index) pain (with the duration of relief being consistent with the agent used).

Frequency limitation: For each medically necessary spinal region procedure, no more than four (4) diagnostic joint sessions will be allowed per rolling 12 months, in recognition that the pain generator cannot always be identified with the initial and confirmatory diagnostic procedure.

Therapeutic facet joint procedures are considered **medically necessary** for patients who meet ALL the following criteria:
• The patient has had two (2) medically reasonable and necessary diagnostic facet joint procedures with each one providing a consistent minimum of 80% relief of primary (index) pain (with the duration of relief being consistent with the agent used); AND
• Subsequent therapeutic facet joint procedures at the same anatomic site results in at least consistent 50% pain relief for at least three (3) months from the prior therapeutic procedure or at least 50% consistent improvement in the ability to perform previously painful movements and ADLs as compared to baseline measurement using the same scale; AND
• Documentation of why the patient is not a candidate for radiofrequency ablation (such as established spinal pseudarthrosis, implanted electrical device).

Frequency Limitations: For each medically necessary spinal region procedure, no more than four (4) therapeutic facet joint (IA) sessions will be allowed per rolling 12 months.

The thermal radiofrequency destruction of cervical, thoracic, or lumbar paravertebral facet joint (medial branch) nerves may be considered **medically necessary** for patients who meet ALL the following criteria:
• Initial thermal RFA:
  o After the patient has had at least two (2) medically reasonable and necessary diagnostic MBBs, with each one providing a consistent minimum of 80% sustained relief of primary (index) pain (with the duration of relief being consistent with the agent used) AND
  o Repeat thermal facet joint RFA at the same anatomic site is considered medically reasonable and necessary provided the patient had a minimum of consistent 50% improvement in pain for at least six (6) months or at least 50% consistent improvement in the ability to perform previously painful movements and ADLs as compared to baseline measurement using the same scale;

Frequency Limitation: For each medically necessary spinal region procedure, no more than two (2) radiofrequency sessions will be allowed per rolling 12 months.

Facet Joint Interventions are considered **not medically necessary** when the above criteria are not met.

In addition, the following are considered **not medically necessary**:
• Intraarticular and extraarticular facet joint prolotherapy
• Non-thermal modalities for facet joint denervation including chemical, low-grade thermal energy (less than 80 degrees Celsius), laser neurolysis, and cryoablation
• Intra-facet implants
• Facet joint procedure performed after anterior lumbar interbody fusion or ALIF
• Definitive clinical and/or imaging findings pointing to a specific diagnosis other than facet joint syndrome
Diagnosis injections or medial branch blocks at the same level as the previously successful RFA procedure.

**MEDICARE ADVANTAGE POLICY GUIDELINES**

The primary indication of a diagnostic facet joint procedure is to diagnose whether the patient has facet syndrome. Intraarticular (IA) facet block(s) are considered medically necessary as a diagnostic test only if medial branch blocks (MMB) cannot be performed due to specific documented anatomic restrictions or there is an indication to proceed with therapeutic intraarticular injections. These restrictions must be clearly documented in the medical record and made available upon request.

Diagnostic procedures should be performed with the intent that if successful, radiofrequency ablation (RFA) procedure would be considered the primary treatment goal at the diagnosed level(s).

A second diagnostic facet procedure may be considered medically necessary to confirm validity of the initial diagnostic facet procedure when administered at the same level. The second diagnostic procedure may only be performed a minimum of two weeks after the initial diagnostic procedure. Clinical circumstances that necessitate an exception to the two-week duration may be considered on an individual basis and must be clearly documented in the medical record.

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 an 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 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.

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


