MEDICAL POLICY

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MEDICAL POLICY DETAILS	
Medical Policy Title	**Radiofrequency Facet and Sacroiliac Joint Ablation/Denervation**
Policy Number	**7.01.42**
Category	**Technology Assessment**
Original Effective Date	**09/21/00**
Committee Approval Date	**09/19/01, 07/18/02, 06/19/03, 03/18/04, 02/15/07, 01/17/08, 01/15/09, 01/21/10, 01/20/11, 01/19/12, 01/17/13, 01/16/14, 12/18/14, 12/17/15, 11/17/16, 11/16/17, 06/21/18, 12/20/18, 06/20/19, 08/20/20, 04/15/21, 05/19/22, 05/18/23, 10/17/24**
Current Effective Date	**02/01/25**
Archived Date	**(ARCHIVED: 01/20/05 - 02/15/07)**
Archive Review Date	**N/A**
Product Disclaimer	• *Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, radiofrequency joint denervation/ablation has been medically proven to be effective and, therefore, is considered **medically appropriate** for facet-mediated axial cervical, thoracic, or lumbar pain resulting from disease, injury, or surgery, when **ALL** the following criteria have been met:
   A. Clinical findings and imaging studies suggest no other obvious cause of the pain (e.g., central spinal stenosis with neurogenic claudication/myelopathy, foraminal stenosis or disc herniation with concordant radicular pain/radiculopathy, infection, tumor, fracture, pseudoarthrosis, pain related to spinal instrumentation);
   B. Pain has persisted for at least three (3) months;
   C. In the past three (3) months, pain has persisted despite at least four (4) weeks of conservative treatment that includes **ALL** of the following:
      1. exercise;
      2. manual therapy;
      3. patient education;
      4. psychosocial support; **and**
      5. medications to include nonsteroidal anti-inflammatory drugs [NSAIDS] or analgesics.
   D. Two (2) positive sequential diagnostic facet joint injections/medial branch blocks at the same level(s), using a local anesthetic, as evidenced by 80% relief of the facet mediated pain for at least the expected minimum duration of effect (relief) of the local anesthetic used;
   E. The spinal motion segment(s) is not posteriorly fused at the requested level(s). An exception is allowed for individuals with clinically suspected pseudoarthrosis at the posteriorly-fused spinal motion segment(s).

II. Based upon our criteria and assessment of the peer-reviewed literature, for an individual patient with a prior spinal fusion, radiofrequency joint denervation/ablation performed at an unfused spinal segment located either above or

below the fused spinal segment has been medically proven to be effective and, therefore, is considered **medically appropriate,** when **ALL** the criteria set forth in Policy Statement I.A., I.B., I.C., and I.D. above criteria have been met.

III. Based upon our criteria and assessment of the peer-reviewed literature, a repeat radiofrequency joint denervation/ablation has been medically proven to be effective and, therefore, is considered **medically appropriate,** when **BOTH** of the following criteria have been met:
   A. There is documented pain relief of at least 50% that has lasted for a minimum of 12 weeks;
   B. The procedure is performed at a minimum of (6) months following the prior denervation/ablation procedure.

IV. Based upon our criteria and assessment of the peer-reviewed literature and/or other available information, radiofrequency joint denervation/ablation is considered **not medically necessary** when performed under **ANY** of the following circumstances:
   A. Without the use of computerize tomography (CT) or fluoroscopic guidance;
   B. More than two (2) radiofrequency joint denervation/ablation procedures at the same level(s) during a rolling 12-month period of time. Note: At least six (6) months is required between radiofrequency joint denervation/ablation procedures;
   C. In the absence of two (2) sequential, positive, diagnostic facet joint injections/medial branch blocks at the same level(s) for an initial radiofrequency treatment; or, for a repeat radiofrequency treatment, in the absence of at least 50% relief of facet-mediated pain for 12 weeks and/or a timeframe of less than a minimum of six (6) months after a previous radiofrequency treatment at the same level(s);
   D. For axial cervical, thoracic, or lumbar pain, in the presence of an untreated radiculopathy;
   E. At a posteriorly fused spinal motion segment;
   F. On more than three (3) contiguous facet joint levels (whether unilateral or bilateral) during the same session/procedure;
   G. To treat pain arising from above C2-C3 and below L5-S1 spinal levels, including ablation of the atlanto-occipital articulation and/or atlanto-axial articulation;
   H. On the same day of service as another invasive modality or procedure for the diagnosis and/or treatment of pain (e.g., facet joint injection, medial branch block, epidural steroid injection, and sacroiliac joint injection);
   I. Clinical findings and imaging studies suggest other obvious cause of the pain (e.g., central spinal stenosis with neurogenic claudication/myelopathy; foraminal stenosis or disc herniation with concordant radicular pain/radiculopathy; infection; tumor; fracture; pseudoarthritis; or pain related to spinal instrumentation).

V. Based upon our criteria and the lack of peer-reviewed literature, denervation/ablation of facet and sacroiliac joints using **ANY** of the following techniques have has not been medically proven to be effective and, therefore, are considered **investigational**:
   A. Pulsed radiofrequency ablation;
   B. Endoscopic radiofrequency denervation/endoscopic dorsal ramus rhizotomy;
   C. Cryoablation/cryoneurolysis/cryodenervation;
   D. Chemical ablation (e.g., alcohol, phenol, glycerol);
   E. Laser ablation;
   F. L5 medial nerve branch and sacral lateral nerve branch blocks and/or ablations/neurotomies for the diagnosis and/or treatment of sacroiliac (SI) joint pain;
   G. Cooled radiofrequency ablation;
   H. Radiofrequency ablation of the intraosseous basivertebral nerve for the treatment of vertebrogenic back pain.

Refer to Corporate Medical Policy #7.01.87 Spinal Injections (Epidural and Facet Injections) for Pain Management

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

POLICY GUIDELINES

I. This policy applies to radiofrequency joint denervation/ablation for facet mediated pain. It does not address other procedures and/or indications/conditions that are not in the scope of management for this policy (e.g., third occipital nerve [TON] ablation for cervicogenic headaches).

II. The radiofrequency joint denervation/ablation applies directly to the facet joint(s) denervated/ablated and not to the number of nerves that innervate the facet joint(s).

III. Only one (1) invasive modality or procedure will be performed on the same date of service (e.g., facet joint block, epidural steroid injection, or lumbar sympathetic chain block).

IV. The following are not facet joints: Atlanto-occipital articulation (located between occiput - atlas [C1]), the atlanto-axial articulation (located between atlas [C1] and the axis [C2], and below L5-S1 (sacrum).

V. Radiofrequency joint denervation/ablation ~~of~~ are permitted on no more than three (3) contiguous facet levels (whether unilateral or bilateral) during the same session. If performed bilaterally during the same session, a total of up to a total of six (6) radiofrequency joint denervations/ablations at contiguous facet levels may be performed during that session.

VI. When performing a repeat radiofrequency joint denervation/ablation at the same spinal level(s) as a prior successful denervation/ablation procedure, further diagnostic facet joint injections/medial branch blocks at that spinal level(s) are not required.

DESCRIPTION

Definitions

Axial: Relating to or situated in the central part of the body, in the head and trunk as distinguished from the limbs, e.g., axial skeleton.

Cervical Facet Pain: Pain located in the cervical spine, which may be characterized by chronic headaches, restricted motion, and axial neck pain, which may radiate sub-occipitally to the shoulders or mid-back.

Facet Joint Pain: A set of concurrent signs or symptoms to describe the facet joint as the pain generator. The typical clinical signs or symptoms may include local paraspinal tenderness; pain that is brought about or increased on hyperextension, rotation, and lateral bending; low back stiffness; absence of neurologic deficit; absence of root tension signs (non- radiating below the knee, absence of paresthesia).

Facet (Zygapophyseal) Joints: paired, diarthrodial synovial joints located between the superior and inferior articular pillars in the posterior spinal column, innervated medial branch nerves, from C2-3 to L5-S1. Note: The following articulations are not facet joints:

- Atlanto-occipital articulation (located between occiput - atlas [C1])
- Atlanto-axial articulation (located between atlas [C1] and the axis [C2])
- Below L5-S1 (sacrum)

Facet Level: the zygapophyseal joint or the two medial branch (MB) nerves that innervate that zygapophyseal joint. Each level has a pair of facet joints: one on the right side and one of the left side of the spine.

Positive Response (to a diagnostic facet joint injection/medial branch block): at least 80% relief of facet mediated pain for at least the expected minimum duration of the effect of the local anesthetic used.

Radiofrequency Joint Denervation/Ablation (RFA) (i.e., facet neurotomy, facet rhizotomy): Traditional or standard RFA involves the insertion of a radiofrequency probe (under fluoroscopic guidance) towards the medial branch of the posterior primary rami, which supplies the innervation to the facet joints. The radiofrequency electrode is then utilized to create a "continuous" heat lesion by coagulating the nerve supplying the joint with the intention of providing pain relief by

denervating the painful facet joint. Note: The radiofrequency joint denervation/ablation applies directly to the facet joint(s) denervated ablated and not to the number of nerves denervated/ablated that innervate the facet joint(s).

Region: describes the segments of the spine as follows:

- Cervical/Thoracic region= C1-C7 / T1-T12
- Lumbar/Sacral region= L1-L5 / S1-S5

Sacral Lateral Nerve Block: an injection of corticosteroid and/or local anesthetic adjacent to the sacral lateral nerve resulting in the temporary interruption of conduction of impulses for analgesia. Sacral lateral nerve blocks attempt to block pain signals and theoretically provide relief from pain. The duration of the block depends on the dose, concentration, and type of pharmacological agent injected.

Sacroiliac Joint (SIJ): the synovial joint formed at the junction ilium.

Sacroiliac Joint (SIJ) Pain: pain originating from the s injury, disease, or surgery. sacroiliac joint as a result of injury, disease, or surgery. Note: The presence of pain over the sacroiliac joint in the absence of radicular findings in and of itself does not substantiate the diagnosis of sacroiliac joint pain.

Session: a time period, which includes all procedures (i.e., medial branch block [MBB], intra-articular [IA] facet joint injection, and radiofrequency ablation [RFA]) performed on a single date of service.

The facet joints (zygapophyseal joints) are located at the posterior aspect of the spine and are designed to provide stability and control motion between the vertebrae. These small joints are prone to injury, deterioration, and inflammation. There are a number of proposed causes of facet joint syndrome. The facet joints may be irritated from trauma, repetitive movements, or arthritic changes. It is very common to develop degenerative changes in facet joints after trauma to the spine, as a result of an injury to the intervertebral disc, or secondary to degenerative disc disease. If the intervertebral disc is damaged, and the cushioning effect of the disc is lost, the facet joint at that level will undergo more stress, which may result in degeneration of the facet joint. Diagnosis of facet joint pain is confirmed by response (pain alleviation) to nerve blocks, with a least a 50% improvement after the required two positive blocks.

Percutaneous radiofrequency facet denervation is a low-risk means of treating “mechanical” pain syndromes in previously unoperated patients with back and/or leg pain. Under local anesthesia, needle placement, under fluoroscopy, is made to the facet (zygapophyseal) joint. The cannula is then redirected until contact with the bone is lost. Following the removal of the guide needle stylet, a thermal monitoring electrode with an exposed tip is passed, and the guide needle is pulled back on the electrode beyond the skin. Electrostimulation is then performed, and a lesion is made using a radiofrequency lesion generator. Control of the temperature over the nerve roots permits selective denervation of the pain conduction fibers. The nerves regenerate, and repeat procedures are effective, though it is not known how many times the procedure can be repeated or if the duration of relief will change.

Pulsed radiofrequency consists of short bursts of electrical current of high voltage in the radio frequency range, but without heating the tissue enough to cause coagulation. It is suggested as a possibly safer alternative to thermal radio frequency facet denervation. Temperatures do not exceed 42°C at the probe tip, as opposed to the temperatures in the 60°s C. reached in thermal radiofrequency 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.

Intraosseous basivertebral nerve (BVN) ablation is a minimally invasive spinal procedure intended for the treatment of chronic low back pain (CLBP). Per the American Society of Pain and Neuroscience (Sayed et al., 2022), recent study findings and treatments have discovered that the vertebral endplates play a large role in CLBP in a term defined as vertebrogenic back pain (VBP). As the vertebral endplates are highly innervated via the basivertebral nerve (BVN), this has resulted in a target for treating patients suffering from vertebrogenic low back pain (VLBP). The application of BVN ablation for patients suffering from VLBP is still in its early stages of adoption and integration into spine care pathways. The North American Spine Society (2023) also supports that there is a growing body of published evidence that damage to the innervated vertebral endplates can result in vertebrogenic back pain (VBP) transmitted through branches of the

BVN, with radiofrequency ablation of the BVN, via a percutaneous interosseous approach, emerging as a possible interventional therapy for this condition.

The Intracept Intraosseous Nerve Ablation System (Relievant MedSystems, Inc, Redwood City, CA) received FDA approval in 2016 for use as a minimally invasive radiofrequency system for treatment of chronic lumbar back pain at one or more levels (i.e., L3 to S1), when back pain is present despite at least six months of conservative care and is accompanied by either Type I or Type 2 Modic changes on MRI. Under fluoroscopic guidance, a trocar is advanced into the vertebral body from a unilateral transpedicular approach. A curved stylet is then guided to the location of the basivertebral nerve (BVN), creating a channel for placement of a bipolar RFA electrode. Ablation of the BVN is achieved by heating the electrode to a temperature of 85 degrees Celsius for 15 minutes, resulting in an approximate one-cm3 spherical lesion within the vertebral body.

RATIONALE

Radiofrequency facet denervation as a procedure does not require approval of the United States Food and Drug Administration (FDA); however, several radiofrequency generators and probes have been cleared for marketing through the FDA's Section 510(k) process.

Peer-reviewed literature reporting small, randomized, controlled studies of the efficacy and safety of radiofrequency facet denervation, as well as evidence from larger case series, is sufficient to permit conclusions that the technology provides significant and sustained relief of pain with minimal side effects in appropriately selected patients.

There is very limited literature on pulsed radiofrequency denervation. The mechanism of its action is not completely understood, and published data are insufficient to draw conclusions about its efficacy.

Radiofrequency ablation of the SI joint randomized trials have methodologic limitations, with limited data on the duration of treatment effect. There is heterogeneity of radiofrequency treatment techniques utilized across studies. The evidence is insufficient to determine the effects of the technology on health outcomes. The North American Spine Society Coverage Recommendations (NASS, 2020) acknowledges the limited available data, and that the optimal procedural technique has not been established for the procedure. However, based on this limited data, NASS indicates it is reasonable to offer coverage for thermal radiofrequency neurotomy at the L5 dorsal ramus and S2-S3 sacral dorsal rami lateral branches for SIJ posterior ligament complex pain.

Percutaneous interosseous radiofrequency ablation of BVN is reportedly grounded in a solid foundation of both pre-clinical and clinical evidence (Sayed et al., 2022) and demonstrates consistent short- to intermediate-term improvements in function and pain for percutaneous interosseous ablation of BVN (NASS, 2023). Becker et al. (2017) conducted the pilot study with 16 patients, followed by the SMART randomized controlled trial (Fischgrund et al., 2018).

Published evidence assessing efficacy of BVN ablation consists of two industry-sponsored randomized controlled trials (Fischgrund et al., 2019; Khalil et al., 2019), three independent meta-analyses (Conger et al., 2022; Loan et al., 2021; Mekhail et al., 2023), and several prospective single arm cohort studies. Schnapp et al. (2023) is the first independently funded US study (n=16) on basivertebral nerve ablation, reporting 1-, 3-, and 6-month follow-up findings. Additional longer-term outcomes evaluating this procedure in standard clinical practice and non-industry funded research studies are needed.

The NASS 2023 Basivertebral Nerve Ablation (BVN) Coverage Recommendations support the use of percutaneous interosseous radiofrequency ablation of the BVN, for the following indications:

- Patients are skeletally mature and have CLBP for at least 6 months, and lower back pain is their main symptom.
- Patients have failed to adequately improve despite attempts at nonsurgical management.
- Patients have Type 1 or Type 2 Modic changes on MRI — endplate hypointensity (Type 1) or hyperintensity (Type 2) on T1 images plus hyperintensity on T2 images (Type 1) involving in the endplates between L3 and S1.

The NASS does not support transforaminal epiduroscopic BVN laser ablation, stating that although the results from a single-arm case series were promising the procedure remains to be further investigated.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
64451 **(E/I)**	Injection(s), anesthetic agent(s) and/or steroid; nerves innervating the sacroiliac joint, with image guidance (i.e., fluoroscopy or computed tomography)
64625 **(E/I)**	Radiofrequency ablation, nerve innervating the sacroiliac joint, with image guidance (i.e., fluoroscopy or computed tomography)
64628 **(E/I)**	Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; first 2 vertebral bodies, lumbar or sacral
64629 **(E/I)**	Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; each additional vertebral body, lumbar or sacral (List separately in addition to code for primary procedure)
64633	Destruction by neurolytic agent, paravertebral facet joint nerves(s) with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint
64634	cervical or thoracic each additional facet joint
64635	lumbar or sacral, single facet joint
64636	lumbar or sacral, each additional facet joint

HCPCS Codes

Code	Description
No codes	

ICD10 Codes

Code	Description
M47.011-M47.9	Spondylosis (code range)
M54.10-M54.9	Dorsalgia (code range)

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*Key Article

KEY WORDS

Denervation, Facet, Radiofrequency, Ablation, Basivertebral nerve

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based on our review, intraosseous basivertebral nerve (BVN) ablation is not addressed in National or Local Medicare coverage determinations or policies.

There is currently a Local Coverage Determination (LCD) (L35936) for Facet Joint Intervention for Pain Management. Please refer to the following LCD web site for Medicare Members: [https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=35936] accessed 08/29/24.

There is currently a Local Coverage Determination (LCD) (L33622), Pain Management - Injection of tendon sheaths, ligaments, ganglion cysts, carpal and tarsal tunnels, for radiofrequency ablation for sacroiliac joint pain. Please refer to the following LCD web site for Medicare Members: [https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=35936] accessed 08/29/24.

There is current a Local Coverage Determination Article (A52863), Billing and Coding: Pain Management - injection of tendon sheaths, ligaments, ganglion cysts, carpal and tarsal tunnels, for radiofrequency ablation for sacroiliac joint pain. Please refer to the following LCD we site for Medicare Members: [https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=52863&ver=51&=] accessed 08/29/24.