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**
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Archive Review Date	**N/A**
Product Disclaimer	• *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 are 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 months.
C. In the past three months, pain has persisted despite at least four weeks of conservative therapy (e.g., exercise, physical therapy, chiropractic care, or nonsteroidal anti-inflammatory drugs [NSAIDs] and/or analgesics). If conservative therapy is contraindicated, the reason(s) for the contraindication(s) is/are required to be documented in the medical record.
D. Two positive sequential diagnostic facet joint injections/medial branch blocks, using a local anesthetic, as evidenced by 80% relief of the facet mediated pain, and the onset and minimum duration of relief is consistent with the local anesthetic used.
E. The spinal motion segment(s) is not posteriorly fused at the requested level(s). An exception is allowed for patients with clinically suspected pseudarthrosis at the posteriorly-fused spinal motion segment(s).

II. Based upon our criteria and assessment of the peer-reviewed literature, for an individual 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 are 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 are 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 least six months after 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. At the same level(s) as two or more prior procedures within the preceding 12-month period;
C. In the absence of two 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 at least six months after a previous radiofrequency treatment at the same level(s);
D. For neck pain or low-back pain, in the presence of an untreated radiculopathy;
E. At a posteriorly fused spinal motion segment;
F. On more than three 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 injections for the diagnosis and/or treatment of pain (e.g., facet joint injection, medial branch block, epidural steroid injection, and sacroiliac joint injection); or
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 joints using **ANY** of the following techniques have 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; or
H. Basivertebral nerve radiofrequency ablation (e.g., Intracept)

Refer to Corporate Medical Policy #11.01.03 Experimental and Investigational Services.

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

POLICY GUIDELINES

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

II. Only one invasive modality or procedure will be performed on the same date of service.

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

IV. 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

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.

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.

Randomized trials of radiofrequency ablation of the SI joint 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.

Despite some preliminarily positive long-term clinical outcomes evaluating basivertebral nerve (BVN) radiofrequency ablation (RFA), outcomes evaluating this procedure in standard clinical practice and non-industry funded research studies are needed. Of note, not all patients in published trials responded positively to BVN RFA, and the current body of literature consists of industry-sponsored studies fraught with limitations. Although the North American Spine Society's (NASS) 2023 coverage recommendations for BVN support use for four indications, additional peer-reviewed trials are needed to determine the effects of the technology on health outcomes.

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
64636	lumbar or sacral, each additional facet joint

HCPCS Codes

Code	Description

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

There is currently a Local Coverage Determination that addresses Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy (L35936). Please refer to the following LCD web site for Medicare Members:

[https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=35936&ver=43&CntrctrSelected=298*1&Cntrctr=298&name=National+Government+Services%2c+Inc.+(13201%2c+A+and+B+and+HHH+MAC%2c+J+-+K)&s=All&DocType=Active&bc=AggAAAQAgAAA&=]

There is currently a Local Coverage Determination (LCD), Pain Management, that addresses radiofrequency ablation for sacroiliac joint pain (L33622). Please refer to the following LCD web site for Medicare Members:

[https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33622&ver=31&bc=0]