



Louisiana

Facet Radiofrequency Denervation

Policy # 00199

Original Effective Date: 12/20/2006

Current Effective Date: 11/01/2018

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider non-pulsed radiofrequency (RF) denervation of cervical facet joints (from C2-C3 through C7-T1 levels) and lumbar facet joints (from T12-L1 through L5-S1 levels) when ALL of the following criteria are met to be **eligible for coverage**.

Patient Selection Criteria

Coverage eligibility will be considered when all of the following criteria are met:

- Procedures are performed with image guidance, either fluoroscopy or computed tomography (CT); AND
- Documentation of moderate to severe pain with functional impairment of at least three (3) months' duration when all are documented:
 - Lack of improvement or resolution following at least six (6) weeks of conservative management; AND
 - Predominant axial pain that is not attributable to radiculopathy (**with the exception of synovial cysts), myelopathy, or neurogenic claudication; AND
 - Physical exam findings which are consistent with the facet joint as the presumed source of pain; AND
 - Absence of non-facet pathology that could explain the source of the patient's pain, such as fracture, tumor, or infection; AND
- Absence of prior surgical fusion at the proposed level (i.e., posterolateral fusion or posterior instrumentation); AND
- Dual diagnostic medial branch block (MBB) injections, performed with an anesthetic alone, each produce $\geq 80\%$ relief of the primary (index) pain and the onset and minimum duration of relief is consistent with the agent employed; AND
- RF denervation may be performed at the same level no more than twice annually and only if the initial RF lesion results in significant pain relief (at least 50%) and improvement in patient specific ADLs for at least six (6) months; AND
- For each covered spinal region (cervical or lumbar), RF denervation should be performed at no more than four (4) joints per session (e.g., two [2] bilateral levels or four [4] unilateral levels); AND

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers if there has been a prior successful RF denervation, additional diagnostic MBBs for the same level of the spine to be **not medically necessary**.**

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Note:

One additional diagnostic block may be indicated prior to a repeat neurotomy when there is diagnostic uncertainty about the source of pain.

Based on review of available data, the Company considers RF denervation for the treatment of chronic pain for all uses that do not meet the criteria listed above, including but not limited to conditions below to be **not medically necessary**.**

- Therapeutic MBB, involving administration of a corticosteroid, with or without an anesthetic; OR
- RF denervation performed at C0-C1, or C1-C2 levels, or at sacroiliac joints; OR
- Use of MBB or RF denervation in the thoracic region with the exception of C7-T1 and T12-L1; OR
- Use of MBB or RF denervation in the setting of moderate to severe spondylolisthesis (grade 2 or higher); OR
- Use of MBB or RF denervation in the setting of an isolated pars defect: OR
- Use of MBB or RF denervation at the level of a posterolateral fusion or posterior instrumentation; OR
- Use of non-thermal RF modalities for medial branch ablation, including chemical neurolysis (e.g., alcohol, phenol, or high concentration local anesthetics), laser neurolysis, cooled RF denervation or low grade thermal energy (<80 degrees Celsius), pulsed RF, and cryodenervation (cryoablation): OR
- Any facet joint interventions performed under ultrasound guidance.

Background/Overview

Paravertebral facet joints, also referred to as zygapophyseal joints or Z-joints, have been implicated as a source of chronic neck and low back pain with a prevalence of up to 70% in the cervical spine, and up to 30% in the lumbar spine. Neither physical exam nor imaging has adequate diagnostic power to confidently identify the facet joint as a pain source. Facet joint injection techniques have evolved primarily as a diagnostic tool for pain originating in these joints.

Injections may be performed at one of two sites, either the joint itself (intraarticular injection) or the nerve that supplies it (medial branch of the dorsal ramus of segmental spinal nerves). Diagnostic injections are performed with an anesthetic agent alone. Following confirmation of facet pathology using a diagnostic MBB, select patients may undergo a RF nerve ablation procedure. Studies have validated the efficacy of this intervention in chronic pain of facet origin.

Definitions

Conservative management should include a combination of strategies to reduce inflammation, alleviate pain, and improve function, including but not limited to the following:

- Prescription strength anti-inflammatory medications and analgesics;
- Adjunctive medications such as nerve membrane stabilizers or muscle relaxants;
- Physician-supervised therapeutic exercise program or physical therapy;

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- Manual therapy or spinal manipulation;
- Alternative therapies such as acupuncture;
- Appropriate management of underlying or associated cognitive, behavioral, or addiction disorders.

Documentation of compliance with a plan of therapy that includes elements from these areas is required.

Reporting of symptom severity – Severity of pain and its impact on activities of daily living (ADLs) is a key factor in determining the need for intervention. For purposes of this guideline, significant pain and functional impairment refers to pain that is at least 3 out of 10 in intensity, and is associated with inability to perform at least two (2) ADLs.

Imaging studies – All imaging must be performed and read by an independent radiologist. If discrepancies should arise in the interpretation of the imaging, the radiologist report will supersede. The results of all imaging studies should correlate with the clinical findings in support of the requested procedure.

DIAGNOSTIC MEDIAL BRANCH BLOCKS

The primary utility of MBBs is to determine the suitability of the patient for a RF neurotomy of painful segmental levels in order to achieve long-term pain management. A positive response is defined as at least 80% relief of the primary (index) pain, with the onset and duration of relief being consistent with the agent employed.

Note: The patient must be experiencing pain at the time of the injection (generally rated at least 3 out of 10 in intensity) in order to determine whether a response has occurred. Provocative maneuvers or positions which normally exacerbate index pain should also be assessed and documented before and after the procedure.

- Dual MBBs, defined as injections performed in the same location(s) on two (2) separate occasions at least one week apart, are necessary to confirm the diagnosis due to the unacceptably high false positive rate of single MBB injections.
- A confirmatory injection is indicated only if the first injection results in a positive response. If the second injection also results in a positive response, the target joint(s) is/are the confirmed pain generator(s).

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

A number of RF generators and probes have been cleared for marketing by the U.S. FDA through the 510(k) process. In 2005, the SInergy^{®±} (Halyard; formerly Kimberly-Clark), 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 in conjunction with a RF generator to create RF lesions in nervous tissue. FDA product code: GXD.

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A number of percutaneous or minimally invasive fixation/fusion devices have been cleared for marketing by the FDA through the 510(k) process. They include the iFuse[®] Implant System (SI Bone), the Rialto[™] SI Joint Fusion System (Medtronic), SIJ-Fuse (Spine Frontier), the SImmetry[®] Sacroiliac Joint Fusion System (Zyga Technologies), Silex[™] Sacroiliac Joint Fusion System (XTANT Medical), SambaScrew[®] (Orthofix), and the SI-LOK[®] Sacroiliac Joint Fixation System (Globus Medical). FDA product code: OUR.

Centers for Medicare and Medicaid Services (CMS)

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

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. FDA approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, Blue Cross and Blue Shield Association technology assessment program (TEC) and other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

References

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9. North American Spine Society, Facet Joint Interventions - NASS Coverage Policy Recommendations, (August 2016) Burr Ridge IL, 16 pgs.
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12/06/2006 Medical Director review

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12/20/2006	Medical Policy Committee approval
12/03/2008	Medical Director review
12/17/2008	Medical Policy Committee approval. No change to coverage.
12/01/2010	Medical Policy Committee review
12/15/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/12/2012	Medical Policy Committee review
04/25/2012	Medical Policy Implementation Committee approval. Policy name changed to "Facet Joint Denervation." Policy extensively rewritten. Coverage for radiofrequency denervation of cervical facet joints (C3-4 and below) and lumbar facet joints was added with criteria. When there has been a prior successful radiofrequency (RF) denervation, additional diagnostic medial branch blocks for the same level of the spine is considered not medically necessary. Radiofrequency denervation for the treatment of chronic spinal/back pain for all uses that do not meet the criteria listed above, including but not limited to treatment of thoracic facet or sacroiliac (SI) joint pain is considered investigational. All other methods of denervation for the treatment of chronic spinal/back pain, including, but not limited to pulsed radiofrequency denervation, laser denervation, and cryodenervation is considered investigational. Therapeutic medial branch blocks is considered investigational. The use of radiofrequency denervation of cervical facet joints (C3-4 and below) and lumbar facet joints when patient selection criteria are not met is investigational.
03/07/2013	Medical Policy Committee review
03/20/2013	Medical Policy Implementation Committee approval. Policy title changed from "Facet Joint Denervation" to "Radiofrequency Denervation". Removed "(C3-4 and below)" from the eligible for coverage statement. Chemodenervation added to the investigational policy statement.
12/12/2013	Medical Policy Committee review
12/18/2013	Medical Policy Implementation Committee approval. Removed criteria bullet, "no spinal fusion surgery in the vertebral level being treated".
11/06/2014	Medical Policy Committee review
11/21/2014	Medical Policy Implementation Committee approval. Added the sacro-iliac joint to be eligible for coverage with criteria. Added sacral nerve blocks to be eligible for coverage with criteria. Deleted sacro-iliac joint pain from the investigational section. Deleted "spinal/back" from the description of chronic pain in the investigational statements.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
10/29/2015	Medical Policy Committee review
11/16/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged. Added "non-pulsed to clarify policy statement.
11/03/2016	Medical Policy Committee review
11/16/2016	Medical Policy Implementation Committee approval. Description of successful trial added to coverage criteria.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes.
08/03/2017	Medical Policy Committee review
08/23/2017	Medical Policy Implementation Committee approval. "Facet" added to the beginning of the policy title. Coverage eligibility changed to adopt AIM policy guidelines.
08/09/2018	Medical Policy Committee review
08/15/2018	Medical Policy Implementation Committee approval. Coverage eligibility follows AIM 2018 Guidelines. Moved "with the exception of synovial cysts" to the end of the criteria bullet regarding predominant axial pain that is not attributable to radiculopathy. Added "(i.e., posterolateral fusion or posterior instrumentation)" to clarify the criteria bullet regarding the absence of prior surgical fusion at the proposed level. Deleted "A maximum of six (6) facet joint procedural sessions per region

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(cervical or lumbar) may be performed in a 12-month period, regardless of type or indication” from the criteria. Added a “Note” in our policy’s Not Medically Necessary section from AIM’s 2018 Guidelines for clarification and consistency as follows: “One additional diagnostic block may be indicated prior to a repeat neurotomy when there is diagnostic uncertainty about the source of pain. Changed the 7th Not Medically Necessary criteria bullet to read, “Use of non-thermal radiofrequency (RF) modalities for medial branch ablation, including chemical neurolysis (e.g., alcohol, phenol, or high concentration local anesthetics), laser neurolysis, cooled radiofrequency denervation or low grade thermal energy (<80 degrees Celsius), pulsed radiofrequency (RF), and cryodenervation (cryoablation).

Next Scheduled Review Date: 08/2019

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)†, copyright 2017 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0441T, 64633, 64634, 64635, 64636, 64999
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

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1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

****Medically Necessary (or "Medical Necessity")** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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