



Louisiana

Facet Radiofrequency Denervation

Policy # 00199

Original Effective Date: 12/20/2006

Current Effective Date: 07/28/2024

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 after completing at least six (6) weeks of conservative management for the current condition or episode of pain (see Policy Guidelines section); **AND**
 - Predominant axial pain that is not attributable to radiculopathy (with the exception of facet joint 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; **AND**

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- Dual diagnostic medial branch block (MBB) injections, performed with local 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**
- Radiofrequency (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 may be performed at a maximum of two (2) levels, either unilateral or bilateral, per session. For each covered spinal region, a maximum of two (2) radiofrequency sessions are considered medically reasonable and necessary per rolling 12 months.

When Services Are Considered Not Medically Necessary

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 radiofrequency (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 or diagnostic medial branch block (MBB), involving administration of a corticosteroid, with or without an anesthetic; **OR**
- Radiofrequency (RF) denervation performed at C0-C1 or C1-C2 levels, and sacral lateral branch RF ablation by any method (denervation of the sacroiliac joint); **OR**
- Use of medial branch block (MBB) or radiofrequency (RF) denervation in the thoracic region with the exception of C7-T1 and T12-L1; **OR**
- Use of medial branch block (MBB) or radiofrequency (RF) denervation in the setting of moderate to severe spondylolisthesis (grade 3 or higher); **OR**
- Use of medial branch block (MBB) or RF denervation in the setting of an isolated pars defect; **OR**
- Use of medial branch block (MBB) or radiofrequency (RF) denervation at the level of a prior fusion; **OR**
- Use of non-thermal modalities for medial branch ablation, including chemical neurolysis (e.g., alcohol, phenol, or high concentration local anesthetics), laser neurolysis, cooled

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radiofrequency (RF) denervation or low-grade thermal energy (<80 degrees Celsius), pulsed RF, and cryodenervation (cryoablation); **OR**

- Facet RF denervation in more than one spinal region in a single session; **OR**
- Use of open surgical neurolysis; **OR**
- Any facet joint interventions performed under ultrasound guidance.

Policy Guidelines

Documentation supporting medical necessity should be submitted at the time of the request and must include the following components:

Conservative management should include a combination of strategies to reduce inflammation, alleviate pain, and correct underlying dysfunction, including physical therapy **AND** at least **ONE** complementary conservative treatment strategy.

Physical therapy requirement includes **ANY** of the following:

- Physical therapy rendered by a qualified provider of physical therapy services;
- Supervised home treatment program that includes **ALL** of the following:
 - Participation in a patient specific or tailored program
 - Initial active instruction by MD/DO/PT with redemonstration of patient ability to perform exercises
 - Compliance (documented or by clinician attestation on follow-up evaluation)
- Exception to the physical therapy requirement in unusual circumstances (for instance, intractable pain so severe that physical therapy is not possible) when clearly documented in the medical record.

Complementary conservative treatment requirement includes **ANY** of the following:

- Anti-inflammatory medications and analgesics (in the absence of contraindications);
- Adjunctive medications such as nerve membrane stabilizers or muscle relaxants (in the absence of contraindications);
- Alternative therapies such as acupuncture, chiropractic manipulation, massage therapy, activity modification, and/or a trial period of rest (e.g., from the aggravating/contributing factors) where applicable.

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Clinical reevaluation. In most cases, reevaluation should include a physical examination. Direct contact by other methods, such as telephone communication or electronic messaging, may substitute for in-person evaluation when circumstances preclude an office visit.

Failure of conservative management requires **ALL** of the following:

- Patient has completed a full course of conservative management (as defined above) for the current episode of care
- Worsening of or no significant improvement in signs and/or symptoms upon clinical reevaluation
- More invasive forms of therapy are being considered

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

Reporting of symptom severity – Severity of pain and its associated impact on activities of daily living (ADLs) and instrumental ADLs (IADLs) are key factors 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 and/or IADLs.

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.

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, but have been widely utilized to treat chronic pain shown to be of facet origin.

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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.

DIAGNOSTIC MEDIAL BRANCH BLOCKS WITH LOCAL ANESTHETIC

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. Diagnostic MBBs are to be performed with local anesthetic agents only. The concurrent use of steroids are not medically necessary as they may compromise the integrity of the diagnostic test.

- 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 (defined as at least 80% or more relief in primary pain index). If the second injection also results in a positive response, the target joint(s) is/are the confirmed pain generator(s).
- For each covered spinal region, a maximum of four (4) diagnostic joint sessions are considered medically reasonable and necessary per rolling 12 months, in recognition that the pain generator cannot always be identified with the initial and confirmatory diagnostic procedure.
- A maximum of only 2 diagnostic sessions per level given on separate occasions are appropriate and medically necessary for the determination of the patient's candidacy for radiofrequency ablation in a given year (cervical or lumbar).

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- For each covered spinal region (cervical or lumbar), diagnostic MBBs may be performed a maximum of two (2) levels, either unilateral or bilateral per session.
- A single or dual diagnostic MBB may be indicated for confirming a pars defect as the primary pain generator for low back pain (except in isolated pars defects in young athletes). Documentation of planned surgery or surgical consultation is required.

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, GXI.

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. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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Policy History

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- 12/06/2006 Medical Director review
- 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

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- 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 (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.

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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).

08/01/2019 Medical Policy Committee review

08/14/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged. Reporting of symptom severity expanded to include IADL’s as functional impairment.

09/05/2019 Medical Policy Committee review

09/11/2019 Medical Policy Implementation Committee approval. Radiofrequency “RF” removed from the not medically necessary conditions for the use of non-thermal modalities for medial branch ablation.

05/07/2020 Medical Policy Committee review

05/13/2020 Medical Policy Implementation Committee approval. Primarily tracks AIM GLs. Added a reference to the Policy Guidelines section in the Patient Selection Criteria. Moved the Conservative management section from the Background/Overview to a newly created Policy Guidelines section.

07/20/2020 Coding update

05/06/2021 Medical Policy Committee review

05/12/2021 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

05/05/2022 Medical Policy Committee review

05/11/2022 Medical Policy Implementation Committee approval. Revised the first and forth criteria bullets in the Eligible for Coverage section to track AIM Guidelines Procedural Requirements section. Changed the grade from 2 or higher to 3 or higher for moderate to severe spondylolisthesis in the fourth Not Medically Necessary bullet. Added “Facet RF denervation in more than one spinal region in a single session” as an eighth Not Medically Necessary bullet.

01/05/2023 Medical Policy Committee review

01/11/2023 Medical Policy Implementation Committee approval. Revisions made to Coverage criteria, Not Medically Necessary conditions and Policy Guidelines to track Carelon Medical Benefits Management.

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05/04/2023 Medical Policy Committee review

05/10/2023 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

05/02/2024 Medical Policy Committee review

05/08/2024 Medical Policy Implementation Committee approval. Added facet joint to specify synovial cysts in the Patient Selection Criteria. Coverage intent is unchanged.

Next Scheduled Review Date: 05/2025

Coding

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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	64625, 64633, 64634, 64635, 64636, 64640, 64999
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

****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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NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

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