



# Louisiana

## Facet Radiofrequency Denervation

Policy # 00199

Original Effective Date: 12/20/2006

Current Effective Date: 08/16/2020

*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 (see Policy Guidelines section); **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; **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**
- 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 two (2) bilateral levels or three (3) unilateral levels).

## 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 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 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 RF denervation or low grade thermal energy (<80 degrees Celsius), pulsed RF, and cryodenervation (cryoablation); **OR**
- Any facet joint interventions performed under ultrasound guidance.

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## **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 improve function, including requirements for physical therapy **AND** at least **ONE** complementary conservative management strategy.

Physical therapy requirement includes ANY of the following:

- Physical therapy;
- Physician or physical therapist-supervised home treatment program which includes flexibility and muscle strengthening exercises;
- 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 management requirement includes ANY of the following:

- Complementary alternative medicine including, but not limited to, chiropractic care, acupuncture, cognitive behavioral or massage therapy;
- Anti-inflammatory medications and analgesics.

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.

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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.

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.

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- 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).
- If the first session of diagnostic MBBs is negative, a maximum of ONE (1) additional session may be performed to determine the primary levels of involvement prior to proceeding with confirmatory blocks.
- For each covered spinal region (cervical or lumbar), diagnostic MBBs should be performed at no more than two (2) bilateral levels or three (3) unilateral levels per session.

## **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<sup>®‡</sup> (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.

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<sup>®‡</sup> Implant System (SI Bone), the Rialto<sup>™‡</sup> SI Joint Fusion System (Medtronic), SIJ-Fuse (Spine Frontier), the SIMmetry<sup>®‡</sup> Sacroiliac Joint Fusion System (Zyga Technologies), Silex<sup>™‡</sup> Sacroiliac Joint Fusion System (XTANT Medical), SambaScrew<sup>®‡</sup> (Orthofix), and the SI-LOK<sup>®‡</sup> 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, Blue Cross and Blue Shield Association technology assessment program

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(TEC) and other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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3. Centers for Medicare and Medicaid Services, Local Coverage Determinations: Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy, (2016) Baltimore MD, 62 pgs.
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10. North American Spine Society, Facet Joint Interventions - NASS Coverage Policy Recommendations, (August 2016) Burr Ridge IL, 16 pgs.
11. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, “Facet Joint Denervation”, 7.01.116, December 2019.

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12. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, Diagnosis and Treatment of Sacroiliac Joint Pain”, 6.01.23, December 2019.

### **Policy History**

Original Effective Date: 12/20/2006

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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

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	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 (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

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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).

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

Next Scheduled Review Date: 05/2021

## **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	64633, 64634, 64635, 64636, 64640, 64999 Add code eff date 1/1/2020: 64625
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.

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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.

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