Facet Radiofrequency Denervation

Policy # 00199
Original Effective Date: 12/20/2006
Current Effective Date: 11/01/2017

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***, 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
- Dual diagnostic medial branch block (MBB) injections, performed with an anesthetic alone, each produce ≥ 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 radiofrequency (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
- 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.

***With the exception of synovial cysts
Facet Radiofrequency Denervation

Policy # 00199
Original Effective Date: 12/20/2006
Current Effective Date: 11/01/2017

When Services Are Considered Not Medically Necessary
Based on review of available data, the Company considers if there has been a prior successful radiofrequency (RF) denervation, additional diagnostic medical branch blocks (MBBs) for the same level of the spine to be not medically necessary.**

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 medial branch block (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 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 2 or higher); OR
- Use of medial branch block (MBB) or radiofrequency (RF) denervation in the setting of an isolated pars defect: OR
- Use of medial branch block (MBB) or RF denervation at the level of a posterolateral fusion or posterior instrumentation; OR
- Use of non-thermal radiofrequency (RF) modalities for facet joint denervation, including chemical, laser, low grade thermal energy (<80 degrees Celsius), pulsed radiofrequency (RF), and cryodenervation: 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;
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 through the U.S. FDA’s 510(k) process. One device, the Synergy® by Kimberly Clark/Baylis, is a water-cooled single-use probe that received FDA clearance in 2005, 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.
Facet Radiofrequency Denervation

Policy # 00199
Original Effective Date: 12/20/2006
Current Effective Date: 11/01/2017

Centers for Medicare and Medicaid Services (CMS)
There is no national coverage determination.

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. FDA product code: GXD.

References

Policy History
Original Effective Date: 12/20/2006
Current Effective Date: 11/01/2017
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
04/12/2012 Medical Policy Committee review

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.
Facet Radiofrequency Denervation

Policy # 00199
Original Effective Date: 12/20/2006
Current Effective Date: 11/01/2017

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

11/03/2016 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

Next Scheduled Review Date: 08/2018

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 2016 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.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.
Facet Radiofrequency Denervation

Policy # 00199
Original Effective Date: 12/20/2006
Current Effective Date: 11/01/2017

Information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

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

<table>
<thead>
<tr>
<th>Code Type</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>0441T, 64633, 64634, 64635, 64636, 64999</td>
</tr>
<tr>
<td>HCPCS</td>
<td>No codes</td>
</tr>
<tr>
<td>ICD-10 Diagnosis</td>
<td>All related diagnoses</td>
</tr>
</tbody>
</table>

**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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

**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.