Local Coverage Determination (LCD) for Lumbar Facet Blockade (L30809)

Contractor Information

Contractor Name	Contractor Number	Contractor Type
Noridian Administrative Services, LLC	00821	Carrier

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LCD Information

Document Information

LCD ID Number
L30809

LCD Title
Lumbar Facet Blockade

Contractor's Determination Number
B2010.01

AMA CPT/ADA CDT Copyright Statement

Primary Geographic Jurisdiction
Alaska
Oregon
Washington

Oversight Region
Region X

Original Determination Effective Date
For services performed on or after 11/16/2010

Original Determination Ending Date

Revision Effective Date

Revision Ending Date

CMS National Coverage Policy
Section 1862(a)(1)(A) of Title XVIII of the Social Security Act excludes expenses incurred for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Section 1833(e) of Title XVIII of the Social Security Act prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

CMS Manual System. Publication 100-2, Medicare Benefit Policy Manual, Chapter 15, §80 describes coverage for physician supervision of diagnostic x-ray, lab and other diagnostic tests.

CMS Manual System. Publication 100-3, Medicare National Coverage Determinations Manual, Chapter 1, Part 1, §30.3 states that acupuncture is not considered a reasonable and necessary service and will not be reimbursed for Medicare beneficiaries.

CMS Manual System. Publication 100-3, Medicare National Coverage Determinations Manual, Chapter 1, Part 2, §150.7 states that prolotherapy is not considered a reasonable and necessary service and will not be reimbursed for Medicare beneficiaries.

Indications and Limitations of Coverage and/or Medical Necessity
ABSTRACT:

For the purposes of this policy, a zygapophyseal (aka facet) joint “level” refers to the zygapophyseal joint or the two medial branch nerves that innervate that zygapophyseal joint.

The spinal facet joints are potential causes of somatic low back pain. The facet or zygapophyseal joint is a paired diarthrodial articulation at the junction of the superior and inferior articular processes of adjacent vertebrae. Facet joints are innervated by the medial branches of the dorsal rami of the segmental nerves. The medial branch nerves from two adjacent dorsal rami innervate each joint. The L5-S1 facet joint is an exception as it is innervated by the L4 medial branch and the L-5 dorsal ramus.

Facet joint injection techniques are used in the diagnosis and/or treatment of chronic low back pain (LBP). Lumbar facet joint injection techniques may alleviate low back pain (LBP) associated with:

• Hypertrophic arthropathy of the facet joints;
• Post-traumatic injury states; and/or
• Suspected motion segment instability/hypermobility or pseudoarthrosis following fusion.

History and physical exam may suggest, but cannot discriminate facet pain from other anatomic sources of pain. There are no imaging modalities (e.g. MRI, SPECT, CT, plain radiographs) or physiological tests (e.g. ROM testing) that have adequate diagnostic power to confidently incriminate the facet joint as the pain generator.

Both intraarticular blocks (IA) and medial branch blocks (MBB) have been used for diagnosis and treatment of LBP due to facet arthropathy. Although IA blocks have traditionally been used in the diagnosis of facet pain, a definitive diagnosis of facet mediated pain requires dual medial branch blocks at separate injection sessions as single medial branch blocks have an unacceptably high rate of false positive responses. Thermal radiofrequency neurotomy has been used to denervate the target joint in hopes of providing longer term duration of relief after a definitive diagnosis is established via dual medial branch blocks.

The efficacy of intraarticular facet joint injection techniques in the treatment of LBP has not been established in the literature. There are emerging evidence and outcomes documented by our providers that intraarticular facet injections in carefully selected patients may provide benefit; albeit, to a limited extent. NAS will cover lumbar intraarticular facet injections in accordance with the following Indications of Coverage for a period no greater than five years. Thereafter, a review of the literature and assessment of outcomes databases will determine whether NAS will continue coverage of these injections.

INDICATIONS OF COVERAGE

Evaluation of the Patient
Care of the patient with chronic LBP should be undertaken within the context of a comprehensive, multidisciplinary treatment program. The decision to diagnose or treat chronic pain by invasive or neuro-destructive procedures must be based on a thorough evaluation of the patient and include a specific pain history, musculoskeletal and neurological physical examination, and review of pertinent imaging.

Documentation in the patient's medical record must indicate how the provider arrived at the presumptive diagnosis of facet mediated pain (or definitive diagnosis if considering RF) and the provider’s intended plan of care for the patient. The medical record must include all the following specific information.

• A detailed clinical pain history including prior treatment and response to treatment.

• Objective measurements of functional impairment.

• History of moderate to severe pain ≥ 3 months; which pain causes functional impairment including limitation of the patient’s activities of daily living.

• Documentation of a poor or inadequate response to or inability to tolerate conservative management. Conservative management includes active exercise centered physical therapy and other treatments such as manual therapy and medications management. A minimum appropriate

conservative treatment trial includes active exercise-centered physical therapy for at least six (6) treatment sessions.

• Evidence that pain is primarily axial with or without minimal somatic referred pain. Pain that is not associated with radiculopathy or neurogenic claudication (with or without association with spinal stenosis, fracture, tumor, infection, inflammatory disease, or degenerative disease associated with significant deformity.)

• Absence of known or obvious non-facet pathology that could explain the source of the patient's LBP.

• A detailed musculoskeletal/neurological physical examination that excludes other more obvious sources of pain and implicates the facet joint as the putative pain source. The examination must include segmental palpation to determine potential symptomatic levels and response to facet loading maneuvers such as hyperextension of the spine.

• Review of all pertinent prior diagnostic tests, including spinal imaging and injections even if performed at other than the current treatment centers.

• At a minimum, the findings of plain films that rule out more significant pathology, which should be addressed before facet injection techniques are considered.

General Requirements

• Appropriate consideration must be given to the adverse effects of the injection, e.g. adrenal suppression due to exogenous corticosteroids.

• Appropriate consideration must also be given to the adverse effects of exposure to radiation.

• Facet joint interventions (diagnostic and/or therapeutic) must be performed under fluoroscopic or computed tomographic (CT) guidance.

• Contrast medium is required to confirm an "intra-articular" injection of the target joint and to document subsequent flow within the joint cavity. With a "medial branch block", contrast medium must be used to demonstrate absence of vascular uptake and adequate flow over the target medial branch.

• In order to maintain target specificity:

-total intraarticular injection volume should not exceed 1.5 ml per joint, including contrast. Larger volumes may be used only when performing a purposeful facet cyst rupture.

-total medial branch block anesthetic volume should be limited to a maximum of 0.5 cc per nerve.

• With the exception of steroids, no drugs other than local anesthetics should be injected for therapeutic facet injections. No more than 100 mg of triamcinolone or methyprednisolone or 15 mg of betamethasone or dexamethasone shall be injected in total at one injection session, regardless of the number of joints injected.

• Before proceeding with any additional facet interventions, the

physician must establish, by reviewing the patient's pain diary/log, patient report, or other mechanism, significant improvement in the patient's function following the initial block. Ideally, after any initial facet intervention, the patient would document her/his own assessment of pain relief and/or the affect of the block on ADLs. Precise data on the actual duration and degree of relief and functional improvements as judged by the patient represent invaluable outcomes information.

• Following any facet joint injection procedure, if ≥ 50% pain reduction for at least 12 weeks with functional improvement is documented in an appropriate fashion, then a second injection may be performed for therapeutic purposes.

• A maximum of four (4) facet joint injection sessions (inclusive of medial branch blocks (MBB), intraarticular injections (IA), or facet cyst rupture) may be performed per year in the lumbar spine. A session is defined as all injections performed on one single date of service. (A maximum of two (2) facet joint thermal RF, and no other denervation treatment sessions are allowed per year in the lumbar spine. See section: "Thermal Lumbar Medial Branch Radiofrequency Neurotomy" in this LCD.)

Diagnostic Facet Joint Block (MBB)

The primary utility of facet injection techniques is diagnostic especially in the context of other potential pain generators. Although intraarticular (IA) injections (with or without corticosteroid) have traditionally been used in the diagnosis of facet pain, IA injections are less anatomically accurate, specific and reliable than medial branch blocks. A definitive contemporaneous diagnosis of facet mediated pain requires dual medial branch blocks one injection at two separate injection sessions. If the patient experiences significant (≥ 80%) relief of their primary or index pain after each set of medial branch blocks, and with duration of relief consistent with the physiological effects of the anesthetic utilized then the diagnosis of facet pain emanating from the blocked joints is considered established.

• Immediately prior to the block, the patient must have adequate pain to discern if the pain improves after the diagnostic block.

• Pre and post-procedural pain scores (numeric or visual analogue) must be documented and compared. A post-procedural re-examination must include an assessment for tenderness and pain and evaluation during performance of activities that would normally elicit or aggravate the patient's pain. This examination should be performed before the patient is discharged at least 20-30 minutes post block.

• If after the first injection, ≥ 80% pain reduction is documented while the patient engages in activities that typically elicit or aggravate the pain and thermal medial branch neurotomy is anticipated, a second confirmatory injection may be performed ≥ one week after the first injection. Ideally, the patient's response would be self- monitored and documented with regard to the degree and duration of pain relief after the patients leaves the medical facility for a minimum of 6 hours. During this pain diary (or electronic equivalent reporting) time period, the patient should participate in activities that would usually elicit pain.

Therapeutic Facet Injections (IA & MBB)

• If a therapeutic injection technique involves the use of anesthetic then immediately prior to the block, the patient must have adequate pain to discern if the pain improves after the injection.

• If a therapeutic injection technique involves the use of anesthetic, pre and post-procedural pain scores (numeric or visual analogue) must

be documented and compared. A post-procedural re-examination for tenderness and functional improvement must be performed at least 20-30 minutes after the procedure and include activities that would normally elicit or aggravate the patient's pain.

• Ideally, if a therapeutic injection technique involves the use of anesthetic, the patient would keep a pain diary for a minimum of 6 hours post-injection (or report via equivalent online form), which the physician will review prior to a second injection to assure the diagnosis of facet pain remains valid.

• Therapeutic injections may be either by intra-articular injection or injection of the medial branch nerves of the dorsal rami.

Intra-articular Facet Blocks Injections
Emerging evidence suggests that benefit from palliative care with IA injections may accrue to some elderly patients who suffer from

• symptomatic *degenerative* facet joint disease, or
• facet pain above or below a posterior spinal fusion, preventing appropriate technical performance of medial branch blocks and RF neurotomy or
• limitations to the performance of thermal RF neurotomy due to an implantable spinal cord stimulator or cardiac pacemaker

Emerging evidence suggests that in those with symptomatic synovial cysts

• iatrogenic synovial cyst rupture via an IA injection may be beneficial.

Thermal Lumbar Medial Branch Radiofrequency Neurotomy
If adequate, but short term relief occurs from prior facet joint injection techniques then RF neurotomy may be a reasonable treatment option in those with a secure diagnosis of facet pain. Thermocoagulation with radiofrequency energy may achieve long-lasting pain relief via axonotmesis of the sensory afferent medial branch.

• Clinical evaluation alone and/or intra-articular blocks cannot establish the utility and/or medical necessity of RF neurotomy. Dual medial branch blocks are the only validated and reimbursable prognostic test for thermal RF neurotomy.

• Only when dual medial branch blocks provide ≥ 80% relief of the primary or index pain consistent with the expected physiological effects of the anesthetics utilized may facet joint denervation with radiofrequency (RF) neural ablation be considered.

• Under multiplanar fluoroscopic imaging the RF needle/cannula is placed adjacent and maximally parallel to "each" of the two medial branch nerves innervating the target joint. This best assures an optimal lesion and subsequent prolonged duration of relief. Additionally, several parallel needle placements should be used to compensate for variation in the location of the target medial branches; especially when using needles with a smaller diameter than an 18 g electrode. Large gauge (e.g. 16 & 18G) electrodes, a longer active tip (e.g. 10 mm), and temperature of ≥ 80 degrees Celsius for ≥ 60 seconds more reliably capture the target nerve than smaller gauge needles, shorter active tips, lower temperatures or shorter lesion time. Pre-lesion and before injection of local anesthetic, electrical stimulation should be performed to assure safety in performing subsequent thermal denervation at the same needle position. Neurolysis is performed such that radiofrequency lesion volumes are sufficient to incorporate the target nerve in its

anatomic location.

• The effects of appropriately performed denervation should last at least six (6) months or more and, in some cases, are permanent. Repeat denervation procedures of the same joint will only be considered medically necessary when the patient had ≥ 50% improvement of pain and functional improvement documented for at least 6 months.

• A maximum of two (2) facet joint denervation treatment sessions are allowed per year in the lumbar spine.

LIMITATIONS OF COVERAGE:

• Facet joint nerve injections for the treatment of acute back pain (<3 months' duration) are considered not medically necessary.

• Radiculopathy precludes coverage of facet blockade except radiculopathy caused by a facet joint synovial cyst.

• A maximum of four (4) facet joint injection sessions (inclusive of medial branch blocks (MBB), intraarticular injections (IA), or facet cyst rupture) may be performed per year in the lumbar spine. A session is defined as all injections performed on one single date of service. (A maximum of two (2) facet joint thermal RF, and no other denervation treatment sessions are allowed per year in the lumbar spine. See section: "Thermal Lumbar Medial Branch Radiofrequency Neurotomy" in this LCD.)

• Performance of more than one type of injection for pain treatment, such as epidural, sacroiliac joint injections or lumbar sympathetic injections, on the same day as facet joint interventions is not considered medically necessary. Performance of more than one type of block on the same day (with the exceptions listed below) makes it impossible to determine which injection resulted in pain relief.

Only one of these procedures is allowed on a given day with the following two exceptions with associated requirements:

-Pain relief is incomplete following an adequately evaluated non-facet injection, and any potential residual effects from the first injection may be reliably known to have dissipated.

-Multiple anatomic pain generators are present, and diagnoses have been clearly documented, in a patient on anticoagulants and whose anticoagulation therapy must be discontinued prior to block.

• Monitored anesthesia care (MAC) is usually not necessary for intraarticular facet joint injections or medial branch blocks or facet joint denervation and will therefore be denied as not medically necessary without supporting documentation.

• Non-thermal RF modalities for facet joint denervation including chemical, low grade thermal energy (<80 degrees Celsius), as well as pulsed RF are not covered.

•Intraarticular or extraarticular facet joint prolotherapy is not covered.

• Injections into the paravertebral musculature must not be billed as

intraarticular facet joint injections or medial branch nerve injections. These injections, at most, trigger point injections, and should be billed as such, if appropriate.

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Coding Information

Bill Type Codes:
Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

Revenue Codes:
Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

CPT/HCPCS Codes
GroupName

64493	INJECTION(S), DIAGNOSTIC OR THERAPEUTIC AGENT, PARAVERTEBRAL FACET (ZYGAPOPHYSEAL) JOINT (OR NERVES INNERVATING THAT JOINT) WITH IMAGE GUIDANCE (FLUOROSCOPY OR CT), LUMBAR OR SACRAL; SINGLE LEVEL
64494	INJECTION(S), DIAGNOSTIC OR THERAPEUTIC AGENT, PARAVERTEBRAL FACET (ZYGAPOPHYSEAL) JOINT (OR NERVES INNERVATING THAT JOINT) WITH IMAGE GUIDANCE (FLUOROSCOPY OR CT), LUMBAR OR SACRAL; SECOND LEVEL (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
64495	INJECTION(S), DIAGNOSTIC OR THERAPEUTIC AGENT, PARAVERTEBRAL FACET (ZYGAPOPHYSEAL) JOINT (OR NERVES INNERVATING THAT JOINT) WITH IMAGE GUIDANCE (FLUOROSCOPY OR CT), LUMBAR OR SACRAL; THIRD AND ANY ADDITIONAL LEVEL(S) (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
64622	DESTRUCTION BY NEUROLYTIC AGENT, PARAVERTEBRAL FACET JOINT NERVE; LUMBAR OR SACRAL, SINGLE LEVEL
64623	DESTRUCTION BY NEUROLYTIC AGENT, PARAVERTEBRAL FACET JOINT NERVE; LUMBAR OR SACRAL, EACH ADDITIONAL LEVEL (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)

ICD-9 Codes that Support Medical Necessity

721.3	LUMBOSACRAL SPONDYLOSIS WITHOUT MYELOPATHY
724.8*	OTHER SYMPTOMS REFERABLE TO BACK
733.82*	NONUNION OF FRACTURE

* Use 724.8 for FACET SYNDROME ONLY
** Use 733.82 for PSEUDOARTHROSIS ONLY

Diagnoses that Support Medical Necessity
See above list of ICD-9-CM codes that support medical necessity and reasonableness.
ICD-9 Codes that DO NOT Support Medical Necessity
Any diagnosis codes other than those listed in the covered ICD-9-CM codes will be denied as not reasonable and necessary and will be denied provider liable unless a non-coverage notice has been issued to the beneficiary prior to the test. Screening diagnoses will be denied as routine services.

ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation

Diagnoses that DO NOT Support Medical Necessity

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General Information

Documentations Requirements
The patient's medical record should contain documentation that fully supports the medical necessity for paravertebral facet joint/nerve injections as they are covered by Medicare (please see "Indications and Limitations of Coverage and/or Medical Necessity"). This documentation includes, but is not limited to, relevant medical history, physical examination, results of pertinent diagnostic tests or procedures.

Medical documentation in the patient's medical record should substantiate the suspected diagnosis. As an example, "The patient had primarily axial low back pain without a radicular component, no associated neurologic deficit, and the pain was aggravated by hyperextension of the spine with paravertebal tenderness present at L4-5 and L5-S1." Medical documentation should also demonstrate that the patient's pain has been refractory to conservative medical management. The following lists some specific criteria that should be documented in the medical record:

• Complete initial evaluation including history and a musculoskeletal and neurological physical examination;
• Functional history and assessment
• Description of indications and medical necessity, as follows:

o Suspected organic problem;
o Pain and disability of moderate-to-severe degree;
o No evidence of contraindications such as bleeding diasthesis or predominantly psychogenic pain;
o Non-responsiveness to conservative treatment; Repeating interventions only upon return of pain and deterioration in functional status following documented improvement with prior interventions

The drugs injected, the doses and volumes and concentrations used, the site of the injection and contrast flow patterns should be documented in the patient's medical record.

Pre and post-procedural pain scores (numeric or visual analogue) must be documented and compared. A post-procedural re-examination for tenderness and functional improvement should be performed at least 20-30 minutes after the procedure and include activities that would normally elicit or aggravate the patient's pain.

The standard of care for all facet joint/nerve injections requires that these procedures be performed under fluoroscopic- or CT-guided imaging. A hard (plain radiograph with conventional film or specialized paper) or digital copy image or images which adequately documents the needle position and contrast medium flow (excluding those cases in which using contrast is contra-indicated, such as patients with documented contrast allergies), must be obtained whenever a substance is injected. This image or images must be made available on request. Providers are urged to limit the patient's exposure to ionizing radiation.

The medical record must be made available to Medicare upon request.

The HCPCS/CPT code(s) may be subject to Correct Coding Initiative (CCI) edits. This policy does not take precedence over CCI edits. Please refer to the CCI for correct coding guidelines and specific applicable code combinations prior to billing Medicare.

When the documentation does not meet the criteria for the service rendered or the documentation does not establish the medical necessity for the services, such services will be denied as not reasonable and necessary under Section 1862(a)(1) of the Social Security Act.

When requesting a written redetermination (formerly appeal), providers must include all relevant documentation with the appeal request.

Appendices

Utilization Guidelines See Indications & Limitations

Sources of Information and Basis for Decision

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This LCD was presented at the Open Door Coverage Meeting in February 2010 & the Open Public Meeting May 11, 2010. It was again discussed at the following Carrier Advisory Committee meetings on the following dates:

Alaska 06/24/2010
Oregon 06/19/2010
Washington 05/25/2010

All comments, literature and outcomes information submitted on the proposed non-coverage of the facet intervention procedure codes (Draft Lumbar Facet Blockade LCD [Part A-DL30813, DL30819, DL30821, and DL3082; Part B-DL30807 and DL30809] were reviewed and considered during the development of the current coverage document.

Comment: Several commenters, including some specialty societies, requested a reorganization of the LCD to emphasize the common requirements for any type of facet block intervention and more clearly represent any differences.

Response: The LCD was re-organized in accordance with the suggestion to the extent possible. While information is presented under different headings or in a different order, with the exception of modifications made in response to comments, the information is the same.

Comment: Several commenters reminded Noridian of the dearth of literature support for the use of intraarticular blocks (IA), especially in the diagnosis of facet-mediated pain and requested additional clarification that IA blocks may not be used to establish a diagnosis.

Response: Noridian is cognizant of the literature and made additional clarifications in the LCD, indicating that only Medial Branch Blocks (MBB) will be reimbursed for diagnostic purposes; consistent with the requirement for diagnosis and pain relief with MBBs prior to thermal RF ablation.

Comment: Commenters were concerned the requirement for dual comparative MBBs with differential response imposed an inappropriate restriction on the establishment of facet-mediated pain given the variability in response to LAs, even in the same patient.

Response: Noridian agrees and has replaced the requirement with "dual MBBs at separate injection sessions". Please note t here are other requirements that must be met to establish a positive response for diagnostic purposes.

Comment: Some Specialty Societies were concerned that coverage of the facet blocks was predicated on development of registries and analysis of outcomes information; especially as the collection of useful information might exceed the 5-year timeframe set by Noridian for determination of ongoing facet procedure coverage. The Societies asked for clarification of Noridian's coverage position.

Response: Regardless of any Society's registry functionality, Noridian will re-open our coverage policy on lumbar facet blocks in five years' time. If the peer-reviewed literature does not support the efficacy of the blocks and/or outcomes analyses are not obtainable, ongoing coverage would be difficult to defend. This is especially true in light of the collaborative national delineation of block techniques and patient population(s) most likely to show demonstrable benefit – if outcomes are assessed by random controlled trials (RCTs), registries, progress notes, or other. We will review all information available to us and in whatever forms it is submitted, but we must have solid evidence of efficacy. All physicians should document outcomes of interventions and the LCD requires both assessment in the immediate post-procedural period as well as assessment prior to any subsequent block.

Comment: Use of a numerical rating scale for pain was objected to on the grounds of inter-subject variability and facility with any scale devised.

Response: Noridian concurs and has modified the requirement to reflect patient functionality, stipulating moderate to severe pain that causes functional impairment, limiting ADLs.

Comment: The LCD requires documentation of inadequate response to conservative therapy for "three months" prior to blockade. Commenters requested clarification of timeframe and conservative therapy.

Response: Points well-taken and clarifications made. Patients must have experienced pain for at least three months and have failed conservative (non-invasive) therapies to include a minimum of six active exercise-centered PT sessions.

Comment: One commenter objected to the requirement for a physical examination prior to block.

Response: The commenter correctly points out the need for an appropriate examination and LCD has been modified to specify "a detailed musculoskeletal/neurological" PE with additional detail given in the LCD.

Comment: One comment objected to the requirement for a radiological examination prior to the block as cost-ineffective versus PE and history alone.

Response: Noridian has substituted "Plain films" to rule out more significant pathology. Based on our review of claims, we believe this requirement is indicated.

Comment: Several commenters expressed concerns about the excessive use of steroids and exposure to radiation.

Response: Noridian shares these concerns. The General section now includes a cautionary statement and the amount of steroid determined to be medically appropriate per block is specified in the LCD in accordance with the consensus determination of multiple Specialty Societies queried.

Comment: The requirement for contrast confirmation was deemed unnecessary given the use of fluoroscopy and aspiration.

Response: The literature documents a 6-8% rate of vascular uptake with MBBs. Additionally, the validating literature (Dreyfus) used contrast to assure appropriate flow and lack of uptake before the block was considered adequate. There is no literature that demonstrates the utility of MBBs without contrast.

Comment: Commenters including one Pain Society objected to the use of a pain diary for a variety of reasons, primarily non-compliance and undocumented utility. In addition, while 80% reduction in pain in the immediate post-procedure period was acceptable, the same commenters indicated that a sustained 50% reduction was sufficient to allow a second block.

Response: Noridian agrees. The requirement has been changed to a physician post-procedural assessment with details in the LCD and sustained 50 % relief.

Comment: The requirement for 80% pain reduction in the immediate post-procedure period was deemed excessive based on a paper documenting significant improvements in eight domains of the DF36 among patients with 50% pain relief.

Response: The study addresses patients with fibromyalgia and treatment effect, not 50% relief as a diagnostic threshold (sensitivity vs. specificity). The outcomes literature is clear on this point: 80% vs. 50% relief from MBBs produces better and longer lasting pain relief and/or function.

Comment: Commenters requested a reduction in duration of pain relief following RF from nine months to six months due to different rates of regeneration among patients.

Response: Noridian agrees. The effects of appropriately performed denervation should last at least six months or more and, in some cases, are permanent. Repeat denervation procedures of the same joint will be considered medically necessary only when the patient had at least 50% reduction in pain and functional improvement for at least six months.

Comment: Several commenters asked for clarification of the total number of interventions and total number of ablations that may, under the worst of circumstances, be reimbursable in one years' time.

Response: Noridian has tried to make this clear throughout the LCD, in several of the requirements. In addition, bullets were added at the end of the General and RF sections, indicating maximum numbers, 4 total interventions per year with a maximum of 2 ablations. Totals were based on both the literature and the consensus opinion of several Specialty Societies.

Comment: Several commenters suggested we use only one diagnostic code to describe medical necessity for the interventions while others suggested only deletion of the nonspecific codes, 716.98 (unspecified arthropathy) and 724.2 (lumbago). We received many requests for the addition of 721.3 (Spondylosis).

Response: Noridian will eliminate the non-specific codes and add 721.3.
Comment: One provider, citing a recent study by Cohen et al*, suggested that Medicare reimburse RF neurotomy without preceding blocks based solely on history and/or physical exam evidence of lumbar facet disease. The proposal was further suggested as cost-effective.

Response: Noridian rejects the request. Reimbursement for RF ablation will be made only when dual medial branch blocks provided ≥ 80% relief of the primary or index pain consistent with the expected physiological effects of the anesthetics utilized. Proceeding directly to RF ablation as in the Cohen study, produced pain relief no greater or longer-lasting than that produced with sham injection and/or dry needling, approximately 35%. The cost-effective procedure, then, is dry needling. On the other hand, however, ablation following dual MBBs and 50% immediate pain relief produced 50% pain relief persisting to 3 months in 64% of patients and when 80% immediate pain relief is employed following dual MBBs, 80-85% of patients have > 50% pain relief at 12 months, exceeding the results with either sham procedures or direct RF ablation, and medically reasonable. Noridian also reminds the commenter that the LCD establishes the conditions most likely to produce positive, measurable outcomes, a prerequisite for future coverage.

SP Cohen, Williams KA, Kurihara C, et al. Multicenter, randomized, comparative cost-effectiveness study comparing 0, 1, and 2 diagnostic medial branch (facet joint nerve) block treatment paradigms before lumbar facet radiofrequency denervation. Anesthesiology 2010; 113: 395-405.

The Section titled "Does the 'CPT 30% Rule' apply?" needs clarification. This rule comes from the AMA (American Medical Association), the organization that holds the copyrights for all CPT codes. The rule states that if, in a given section (e.g., surgery) or subsection (e.g., surgery, integumentary) of the CPT Manual, more than 30% of the codes are listed in the LCD, then the short descriptors must be used rather than the long descriptors found in the CPT Manual.

This policy is subject to the reasonable and necessary guidelines and the limitation of liability provision.

Start Date of Comment Period 05/11/2010

End Date of Comment Period 09/06/2010

Start Date of Notice Period 10/01/2010

Revision History Number

Revision History Explanation The date of the Alaska CAC was rescheduled to 07/15/2010 so the comment period was changed from 08/23/2010 to 09/06/2010 and the revision effective date was changed to the date of the Open Public Meeting, May 11, 2010.

B2010.01
10/01/2010-released to final.

Provider comments and NAS responses are added to section "Advisory Committee Meeting Notes".

See LCD for changes due to the comments received.

Reason for Change

Last Reviewed On Date

Related Documents
This LCD has no Related Documents.

LCD Attachments
There are no attachments for this LCD.

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All Versions

Updated on 04/20/2011 with effective dates 06/15/2011 - N/A
Updated on 10/07/2010 with effective dates 11/16/2010 - N/A
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