February 23, 2018

Division of Workers’ Compensation
State of California
PO Box 420603
San Francisco, CA 94142

Re: Adoption of ACOEM Guidelines on Low Back Disorders

To Whom It May Concern:

The Spine Intervention Society (SIS), a multi-specialty association of over 2,800 physicians dedicated to the development and promotion of the highest standards for the practice of interventional procedures in the diagnosis and treatment of spine pain, would like to take this opportunity to comment on your adoption of the ACOEM guidelines addressing low back disorders.

The Society’s membership includes many of the clinicians and academicians whose published literature provides the seminal references upon which the practice of evidence-informed interventional spine care is based. Our organization has a strong record of working to eliminate fraudulent, unproven, and inappropriate procedures. At the same time, we are equally committed to assuring that appropriate, effective, and responsible treatments are preserved so that patients do not have to suffer or undergo more invasive and often unnecessary surgical procedures.

While we offer several specific comments to assist in ensuring appropriate access to interventional pain procedures for appropriately selected patients, we are also attaching coverage policy recommendations on epidural steroid injections (ESI), facet joint interventions, and sacroiliac joint (SIJ) injections. These coverage policy recommendations were developed by the North American Spine Society and have been endorsed by SIS. The coverage policy recommendations were established as a result of a multidisciplinary, collaborative effort of healthcare leaders and experts in spine care, utilizing the best available evidence, while taking into account reasonable standard practices in the United States.

We offer the following recommendations for changes to be considered:

**Lumbar Epidural Steroid Injections**
1. We disagree including on the list of indications pain having been treated with NSAIDs prior to considering an ESI. There are many patients who are intolerant to NSAIDs and a clear medical consensus regarding the risks associated with NSAIDs. For this reason, we believe a trial of NSAIDs should not be required prior to an ESI.
2. We recommend the use of non-particulate steroid (dexamethasone) as a first-line injection for transforaminal epidural steroid injections. This would be consistent with the established safety guidelines (1).

3. We also disagree with the recommendation against the use of ESIs for spinal stenosis. While we agree about the limited utility of ESIs in treating axial back pain for the majority of patients with stenosis, evidence does support the effectiveness of ESIs in the treatment of radicular pain and neurogenic claudication which can both result from spinal stenosis (2-4).

Facet Interventions
With regard to the section on diagnostic and therapeutic facet joint procedures, we are in strong disagreement with the current guidelines. There is extensive high quality evidence regarding the use of medial branch blocks and radiofrequency neurotomy for the evaluation and treatment of lumbar spine pain as it arises from the facet joints. We are including a summary of extensive literature to this effect (attached) and wish to highlight two important studies for your reference (5, 6). We believe the current guidelines reflect a significant misunderstanding of the current literature and request that the evidence be carefully reviewed to ensure patients have access to invaluable treatment for their facet-mediated pain.

Sacroiliac Interventions
With regard to the section on sacroiliac joint interventions, we are also in strong disagreement with the indications stating that sacroiliac joint interventions should only be used in patients with a known cause of sacroiliitis, which is described as proven rheumatologic inflammatory arthritis involving the sacroiliac joints. This is too narrow an indication and once again is not consistent with the available literature (7-9). While we agree that the main indication for these procedures is sacroiliitis, we disagree that this only occurs in known rheumatologic conditions. This can certainly occur as a result of trauma.

We hope that this information, as well as any dialogue and collaboration between the California Division of Workers’ Compensation and the Spine Intervention Society, will lead to the establishment of reasonable coverage policies that will eliminate inappropriate utilization while preserving access in appropriately selected patients. We offer our ongoing input and expertise in this matter. If we may answer any questions or provide any assistance, please feel free to contact Belinda Duszynski, Senior Director of Policy and Practice at bduszynski@SpineIntervention.org.

Sincerely,

Timothy Maus, MD
President
Spine Intervention Society
Attachments:


References:


Lumbar Epidural Injections

DEFINING APPROPRIATE COVERAGE POSITIONS

Endorsed by:

North American Spine Society  7075 Veterans Blvd.  Burr Ridge, IL 60527
Introduction
North American Spine Society (NASS) coverage policy recommendations are intended to assist payers and members by proactively defining appropriate coverage positions. Historically, NASS has provided comment on payer coverage policy upon request. However, in considering coverage policies received by the organization, NASS believes proactively examining medical evidence and recommending credible and reasonable positions may be to the benefit of both payers and members in helping achieve consensus on coverage before it becomes a matter of controversy. This coverage recommendation reflects the best available data as of 3/20/2013; information and data available after 3/20/2013 is thus not reflected in this recommendation and may warrant deviations from this recommendation, if appropriate.

Methodology
The coverage policies put forth by NASS use an evidence-based approach to spinal care when possible. In the absence of strict evidence-based criteria, policies reflect the multidisciplinary and non-conflicted experience and expertise of the authors in order to reflect reasonable standard practice indications in the United States.

NASS Coverage Policy Methodology

Background Information
Lumbar epidural steroid injections can be performed via an interlaminar or caudal approach or a transforaminal approach that includes the use of fluoroscopic or CT-guidance, which is bundled into the procedure. Fluoroscopic-guidance is not bundled into the procedure and can be billed separately when performed with an interlaminar epidural steroid injection. Interlaminar and transforaminal epidural steroid injections using ultrasound guidance are not recommended for coverage by NASS.

Scope and Clinical Indications
Therapeutic lumbar epidural steroid injections (ESIs) are indicated for the following diagnoses with qualifying criteria, when appropriate.

1. **Lumbar radicular pain** in which the following criteria are met:
   a. the pain is severe enough to cause some degree of functional deficit
   b. failure of at least four weeks of noninvasive care (see below*)
   c. imaging demonstrating a correlative region of nerve impingement

2. **Neurogenic claudication** in which the following criteria are met:
   a. the pain is severe enough to cause some degree of functional deficit
   b. failure of at least four weeks of noninvasive care (see below*)
   c. imaging demonstrating a correlative region of nerve impingement

3. **Low back pain** without lower extremities symptoms ONLY in the following clinical scenarios:
   a. High-level athletes during a competitive season
   b. Pregnant women with intractable low back pain unresponsive to other treatments

*It is known that the majority of back and radicular pain will improve over 4 weeks. It is therefore reasonable to recommend failure of four weeks of non-surgical, noninvasive care. Appropriate nonsurgical, noninjection treatments should be considered along with a rationale for interventional treatment. Exceptions to waiting 4 weeks can exist but should be carefully documented and should be reviewed on a case-by-case basis. These include, but are not limited to:

1. At least moderate pain with significant functional loss at work and/or home
2. Severe pain unresponsive to outpatient medical management
3. Inability to tolerate non-surgical, non-injection care due to co-existing medical condition(s) (e.g. cardiac disease)
4. Prior successful ESI for the same condition

Diagnostic selective nerve root blocks (DSNRBs) use a small amount of anesthetic via a transforaminal approach to anesthetize a specific spinal nerve and share the same CPT codes as therapeutic transforaminal ESIs. DSNRBs are used to evaluate a patient’s anatomical level and/or source of radicular pain and are often used in surgical planning and decision-making. **Post-injection assessment**

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of the percentage of pain relief and/or change in visual or numerical analog score (VAS/NAS) must be documented.

Contraindications to Lumbar Epidural Injections and DSNRBs
Lumbar ESIs and DSNRBs are NOT indicated in cases that do not fulfill the above criteria. Of note, lumbar epidural steroid injections are not indicated in the following scenarios:

1. **Cancer:**
   a. New onset low back pain with a history of cancer, multiple risk factors for cancer, or strong clinical suspicion for cancer in the absence of advanced imaging studies (to rule out local cancer involvement)
   b. Epidural injections may be considered if cancer is ruled-out or if the patient’s pain is felt to be unrelated to their cancer AND they meet one of the above criteria lists (Items 1, 2, or 3)

2. **Infection:**
   a. New onset of low back pain with fever in the absence of advanced imaging studies (to rule out local infection)
   b. History of active intravenous drug use
   c. History of recent or ongoing systemic bacterial or fungal infection
   d. Immunosuppression

3. **Cauda equina syndrome**
   a. New onset urinary retention, fecal incontinence, or saddle anesthesia
   b. Rapidly progressing (or other) neurological deficits

4. **Axial Low Back Pain without lower extremity symptoms**

5. **Co-existing medical conditions** that would preclude the safe performance of the injection or be a contraindication to the intervention (eg, bleeding disorder, presence of an epidural mass, or central nerve system (CNS) disorders † such as transverse myelitis or other demyelinating disorder)

†**Note that if a CNS process is present, but the pain or neurologic deficit is clearly unrelated, an ESI may still be indicated if the patient meets one of the above criteria lists (Items 1, 2, or 3)**

Procedural Requirements, Utilization, and Restrictions:
Lumbar epidural steroid injections, regardless of approach or indication, are subject to the following requirements and restrictions:

1. **Contrast enhanced fluoroscopy or CT guidance.**
   a. For transforaminal ESIs, live contrast-enhanced fluoroscopy or digital subtraction angiography is preferred, though contrast-enhanced CT guidance may be performed with the understanding that this form of visualization might not detect intravascular flow leading to potential complications, especially if particulate steroids are used.
   b. Exceptions to the use of contrast are considered in patients who have a significant history and/or are at high risk for an adverse event if contrast material is used (eg, contrast allergy).
      i. In these cases, physicians should consider using a test-dose injection prior to injecting any particulate steroids and/or use only non-particulate steroid solutions.
      ii. The reasons for not using contrast should be documented in the procedure report.

2. Injections are performed independently based on the patients’ symptoms and response to prior injections and approach (if performed). There is no role for a routine “series of 3” ESIs.

3. If a prior lumbar ESI provided no relief, a second ESI is allowed following reassessment of the patient, injection technique and/or medication used.

4. No more than 3 lumbar ESIs and/or DSNRBs may be performed in a 6 month time period.

5. No more than 6 lumbar ESIs and/or DSNRBs may be performed in a 12 month time period regardless of the number of levels involved.

6. Films that adequately document final needle position and injectate flow must be retained and made available upon request.

7. No more than 2 transforaminal injections may be performed at a single setting (eg, single level bilaterally or two levels)

8. For caudal or lumbar interlaminar injections, only one per session may be performed and NOT in conjunction with a transforaminal injection.

9. For each session, no more than 80 mg of triamcinolone, 80 mg of methylprednisolone, 12 mg of betamethasone, 15 mg of dexamethasone or equivalent corticosteroid dosing should be used.
10. Given the recent RCT evidence\textsuperscript{2,3} for the therapeutic equivalency of dexamethasone to particulate steroid, particulate-free steroid, such as dexamethasone, should be used as the first line drug in all transforaminal ESIs. Particulate steroid should be used only after failure of particulate-free steroid and with appropriate patient counseling and safeguards, such as digital subtraction imaging.

11. Local anesthesia is usually sufficient for a majority of lumbar ESIs though on occasion minimal to moderate conscious sedation is an appropriate option

12. If monitored anesthesia care is utilized, the need for such sedation should be clearly documented in the medical records.

**Rationale**

Lumbar epidural steroid injections are one of the most commonly performed injection procedures in the treatment of spine-related pain. The Coverage Policy (also known as the “Policy”) put forth by the North American Spine Society utilizes an evidence-based approach to spinal care when possible. In the absence of strict evidence-based criteria, the Policy utilizes the multidisciplinary and nonconflicted experience and expertise of the task force in order to reflect reasonable standard practice indications in the United States.

**For lumbar radicular pain,** the rationale for coverage is based on high-level evidence and what most practitioners would consider to be accepted practice patterns. Lumbar radicular pain may be caused by a myriad of pathologic conditions including, but not limited to lumbar disc herniation, lumbar stenosis (central or foraminal), lumbar spondylolisthesis, postoperative perineural fibrosis, or failed low back surgery syndrome. Multiple randomized-controlled trials have demonstrated that ESIs are effective in the treatment of lumbar radiculitis caused by disc herniation.\textsuperscript{2,3} With adequate literature to suggest that at least a trial of ESI’s for radicular pain caused by conditions other than disc herniation is appropriate prior to considering surgical intervention,\textsuperscript{3,4}

**For neurogenic claudication,** the rationale for coverage is based on what most practitioners would consider to be accepted practice patterns. Neurogenic claudication is caused by spinal stenosis, either degenerative or ischemic. There is literature to suggest that ESIs are effective in reducing pain in this patient population\textsuperscript{5,6} though this treatment seems to be less effective in this group than in patients with herniated discs.\textsuperscript{7,8} In addition, there is data shows that the injection of epidural steroid is equivalent to epidural local anesthetic.\textsuperscript{9,10} It should be noted that epidural injection of local anesthetic has been clearly demonstrated to be more effective than a placebo.\textsuperscript{10} Based on these data, it is felt that a trial of epidural injections is reasonable prior to the consideration of surgical intervention for neurogenic claudication associated with lumbar spinal stenosis.

**For selected cases of LBP,** the rationale for coverage is based on what most practitioners would consider to be accepted practice patterns. While epidural injections are not typically considered an effective treatment for isolated, non-specific low back pain, they can be helpful in certain circumstances as described above. It is acknowledged that there is a paucity of data on this topic. In the absence of quality data, this coverage recommendation is guided by what appears to be reasonable and accepted practice patterns.

The rationale for the procedural requirements, utilization and restrictions is based on what most practitioners would consider to be accepted practice patterns. In addition, there are a number of reports of complications associated with epidural injections\textsuperscript{11-13} that have occurred primarily as a result of intravascular injection. The use of live, contrast-enhanced fluoroscopy, digital subtraction, and the use of nonparticulate steroids minimizes these risks.

As the potential risks with ESIs are both local from the procedure itself and systemic from the medications injected (specifically steroids), it is reasonable to place limits on the number of injections that should be administered in a given time. Currently, there are no data to support performing a predetermined "series" of injections. The determination to perform more than one injection should be based on the patient's response to the prior injection, the approach/location it was administered, the patient's symptoms, the medications used, and the imaging findings. This evaluation needs to be done via a face-to-face encounter and the reasons for repeating the injection clearly documented.

**References**


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Financial Statement
These Coverage Recommendations were developed in their entirety by the North American Spine Society (NASS). All participating authors have disclosed potential conflicts of interest consistent with NASS’ disclosure policy.

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Comments

Comments regarding the coverage recommendations may be submitted to coverage@spine.org and will be considered in development of future revisions of the work.

Disclosure Key

Direct or indirect remuneration: royalties, stock ownership, private investments, consulting, speaking and/or teaching arrangements, trips/travel.

Position held in a company: board of directors, scientific advisory board, other office.

Support from sponsors: endowments, research–investigator salary, research–staff and/or materials, grants, fellowship support.

Other

Degree of support:

Level A. $100 to $1000
Level B. $1,001 to $10,000
Level C. $10,001 to $25,000
Level D. $25,001 to $50,000
Level E. $50,001 to $100,000
Level F. $100,001 to $500,000
Level G. $500,001 to $1M
Level H. $1,000,001 to $2.5M
Level I. greater than $2.5M

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NASS Coverage Policy Recommendations | Lumbar Epidural Injections

05/2014

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Comments

Comments regarding the coverage recommendations may be submitted to coverage@spine.org and will be considered in development of future revisions of the work.
NASS Coverage Recommendations Methodology

Topic Selection:
Coverage Recommendations topic lists are developed and approved by the Coverage Committee. Topics include both therapeutic and diagnostic procedures and treatments as well as nonoperative, interventional, and surgical procedures and treatments. The breadth of the topics attempts to represent all facets of spinal care. Topics are selected based on frequency of use in spine care and will attempt to represent the full breadth of procedures, diagnostics, and interventions.

Author Assignment:
The Coverage Committee members rank their preferences (1, 2, or 3) for topic assignment. The Chair matches topics to the members’ preferences as much as possible. Active consideration is given to avoiding conflicts of interest, whether financial or otherwise, between members and the topics assigned. All authors disclose any conflicts of interest in accordance with the NASS disclosure policy.

Background Data Review:
For each topic, authors coordinate a literature search with the help of a research librarian/NASS staff member.

A literature search using PubMed, EMBASE, Web of Science and Cochrane is performed using search terms identified by the author specific to the topic assigned. Searches are limited to systematic reviews, meta-analyses, clinical guidelines, and most importantly, randomized controlled trials. The search produces a list of abstracts to be sent to the author for review and selection of appropriate articles for full review. Selected articles are then be sent to the Coverage Committee Chair for the approval to reduce any potential bias. The National Guidelines Clearinghouse is also be searched by NASS staff for appropriate clinical guidelines. Note that only full text, peer-reviewed articles published in English are eligible for review. Abstracts and non-published reports are not eligible for review.

In addition, NASS staff identify and retrieve any previously issued coverage policy on the topic, either by a private or public insurance provider.

Data Analysis:
The medical literature is analyzed with preference given to the highest quality literature available. Funding and other potential sources of bias are taken into consideration, as is consistency of the literature reviewed. In the absence of high-level data, coverage recommendations reflect the multi-disciplinary experience and expertise of the committee members in order to present reasonable standard practice indications in the United States.

Coverage Recommendations Formulation:
When trials, guidelines, or systematic reviews are available, the coverage recommendations should reflect the published data as much as possible. However, given the complexities of clinical care and the limitations of the medical literature in many circumstances, additional consideration is given to specific clinical scenarios and the currently available treatment options for those scenarios, including the potential risks and benefits of the alternative treatment options, prior to establishing a coverage decision. In summary, final determinations are made upon an evidence-based review of the existing data, an understanding of clinical care, and the NASS mission.

Individual coverage recommendations follow a standard format document approval: Once formulated, the coverage recommendations are reviewed and revised by the Coverage Committee Chair incorporating any new data if available since the document is developed and with modifications for format. The document is then sent to the senior reviewers of the Coverage Committee and subject-matter experts from the NASS’ Payor Policy Review Committee (PPRC) for review and comment. After review at this level, final modifications are made and author is advised. The proposed coverage document is sent to the NASS Executive Committee of the board directors for review and final approval before publication. The proposed coverage document is published on NASS’ website with a 30-day public comment period. At the end of the public comment period, comments are reviewed and considered by the NASS Coverage Committee. Where appropriate, the Committee makes edits and then publish the final document on NASS website.
NASS coverage recommendations should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution. The coverage recommendations do not represent a “standard of care,” nor are they intended as a fixed treatment protocol. It is anticipated that there will be patients who will require less or more treatment than the average. It is also acknowledged that in atypical cases, treatment falling outside these criteria will sometimes be necessary. This document should not be seen as prescribing the type, frequency or duration of intervention. Treatment and accompanying payment should be based on this information in addition to an individual patient’s needs as well as the doctor’s professional judgment and experience. This document is designed to function as a guide and should not be used as the sole reason for denial of treatment and services. It is not intended to supersede applicable ethical standards or provisions of law. This is not a legal document.
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NASS Coverage Policy Methodology

Background Information
Published, peer-reviewed studies have established prevalence estimates for cervical and lumbar facet joint pain in chronic neck (CNP) and low back pain (CLBP) subjects, respectively. Lumbar facet joint pain occurs in 15-32% of CLBP patients with patients over age 55 years most commonly affected. In the lumbar spine, L5-S1 is the level most commonly responsible for pain followed by L4-5. Cervical facet joint pain occurs in 55-69% of CNP patients and increases after whiplash injuries. In the cervical spine, C2-3 has been found to be the level most commonly responsible for upper neck and headache pain while low neck pain has been found to associated more often with C5-6. In most cases, a single joint is the source of symptoms. The prevalence of thoracic facet involvement in chronic thoracic pain has been estimated to be as high as 48%.

Facet Joint Interventions: Diagnostic and Therapeutic Scope and Clinical Indications
Injections involving the zygapophysial joints (Z-joints) can be indicated for diagnostic or therapeutic purposes. Therapeutic injections typically involve administration of corticosteroids, with or without local anesthetics, while diagnostic injections use anesthetic alone. This document will cover the diagnostic uses and therapeutic uses of intraarticular Z-joint injections and of diagnostic medial branch blocks.

The pain referral patterns of the cervical Z-joints are described and can include pain in the neck, and/or the head, and/or the periscapular and shoulder region. The pain referral patterns of the lumbar Z-joints are similarly described and can include pain in the back, gluteal area and leg. For patients with such pain, the procedures covered in this report may be considered when ALL of the following criteria are met:

1. The patient’s pain is severe enough to cause some degree of functional deficit.
2. Failure of at least 4 weeks of noninvasive care (see below*).
3. There is no other significant pathology that could explain the source of the patient’s pain, such as fracture, tumor, infection or significant extraspinal lesion.
4. Pain is predominantly axial, within the locations described above, and not associated with radiculopathy or myelopathy.
5. Clinical assessment implicates the Z-joint as the putative source of pain.

* It is known that the majority of back and neck pain will improve over 4 weeks. It is therefore reasonable to recommend failure of 4 weeks of nonsurgical, noninvasive care. Appropriate nonsurgical, noninjection treatments should be considered along with a rationale for interventional treatment. Exceptions to waiting 4 weeks can exist but should be carefully documented and should be reviewed on a case-by-case basis. These include but are not limited to:
   a. At least moderate pain with significant functional loss at work and/or home.
   b. Severe pain unresponsive to outpatient medical management.

NASS coverage recommendations should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution. The coverage recommendations do not represent a “standard of care,” nor are they intended as a fixed treatment protocol. It is anticipated that there will be patients who will require less or more treatment than the average. It is also acknowledged that in atypical cases, treatment falling outside these criteria will sometimes be necessary. This document should not be seen as prescribing the type, frequency or duration of intervention. Treatment and accompanying payment should be based on this information in addition to an individual patient’s needs as well as the doctor’s professional judgment and experience. This document is designed to function as a guide and should not be used as the sole reason for denial of treatment and services. It is not intended to supersede applicable ethical standards or provisions of law. This is not a legal document.
If diagnostic IA Z-joint injections are performed, the following criteria apply:

1. Dual blocks, performed in the same location(s) on 2 separate occasions, are necessary to confirm the diagnosis due to the unacceptably high false positive rate of single diagnostic anesthetic injections in the spine.
2. A second confirmatory injection is indicated only if the first injections produce ≥80% relief of the primary (index) pain and the onset and minimum duration of relief is consistent with the agent employed. This confirmatory block confirms the tested joint as the source if the index pain is reduced by > 80%.
3. A second injection may also be performed at a different or additional level if the pain is believed to be arising from a different joint (and the pain relief from the initial block was <80%).

**Intervention 1: Diagnostic Medial Branch Blocks**

Zygapophysial joint medial branch blocks (MBBs) are a validated means to diagnose Z-joint related pain \(^5\), which can include pain in the back, neck, and/or the head and/or the periscapular and shoulder region. Notably, this also includes the third occipital nerve since it innervates the C2-C3 Z-joint. Medial branch blocks, properly conducted, will anesthetize the target Z-joint(s), including the intraarticular surfaces, the joint capsule and the adjacent tissues including the paravertebral muscle supplied by the medial branch of the cervical dorsal ramus. The primary utility of MBBs is to determine the suitability of the patient for a radiofrequency neurotomy of painful segmental levels identified by the diagnostic MBBs, in order to achieve long-term management of the patient’s pain.

When diagnostic MBBs are performed, the following criteria apply:

1. Dual blocks, performed in the same location(s) on 2 separate occasions, are necessary to confirm the diagnosis due to the unacceptably high false positive rate of single diagnostic anesthetic injections in the spine.
2. A second confirmatory injection is indicated only if the first injections produces ≥80% relief of the primary (index) pain and the onset and minimum duration of relief is consistent with the agent employed. This confirmatory block confirms the tested joint as the source if the index pain is reduced by > 80%.
3. A second injection may also be performed at a different or additional level if the pain is believed to be arising from a different joint (and the pain relief from the initial block was <80%).

**Intervention 2: Therapeutic Medial Branch Blocks**

Therapeutic MBBs are performed in the same manner as diagnostic MBBs, but the therapeutic blocks are intended to achieve long-term management of the patient’s pain.

While MBBs are valid and reliable diagnostic procedures, current evidence does not support their use as a therapeutic intervention. Currently published research shows that the number of therapeutic MBB injections required in a single year (4-5) exceeds the number of therapeutic injections recommended for routine use elsewhere in this report, and no benefits are observed when adding corticosteroids or other potentially therapeutic medications to traditional anesthetic MBBs. Therefore, therapeutic MBBs are not recommended in the treatment of back or neck pain.

**Intervention 3: Diagnostic Intraarticular Zygapophysial Joint Injections**

Unlike MBBs, intraarticular (IA) Z-joint injections have not be validated as a means to diagnose Z-joint related pain and should generally not be used in lieu of MBBs for the diagnosis of suspected Z-joint pain. IA anesthetic injections are capable of blocking only the articular joint surfaces and interior joint capsule. There have been no studies that have compared the diagnostic effectiveness of intraarticular Z-joint injections versus MBBs.

IA Z-joint blocks should not be used as a diagnostic test unless MBBs cannot be performed due to specific documented anatomic restrictions. For example, in the case of the occipitoatlantal and atlantoaxial joints, there is no medial branch or other innervation available to block reliably, so IA injections are the only means of arriving at a potential diagnosis of pain from these joints.

If diagnostic IA Z-joint injections are performed, the following criteria apply:

1. Dual IA injections are necessary to confirm the diagnosis due to the unacceptably high false positive rate of single diagnostic injections in the spine.
2. A second confirmatory injection is indicated only if the first injections produces ≥80% relief of the primary (index) pain and the onset and minimum duration of relief is consistent with the agent employed.
**Facet Joint Interventions** | NASS Coverage Policy Recommendations

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**Intervention 4: Therapeutic Intraarticular Zygaphophysial Joint Injections**

There is some evidence in the current medical literature of clinical efficacy of IA Z-joint injection techniques in the treatment of chronic low back pain, chronic neck pain and/or its associated headaches, periscapular and shoulder pain. There are 3 published RCTs along with multiple cohort studies demonstrating short to mid-term relief of pain following intraarticular steroid injections, though when compared with RFA, RFA offers longer term relief in patients with chronic pain. Long-term outcomes have not been reported in adequately designed studies. Thus, utility has not been well established in the medical literature. As a result, the use of therapeutic IA Z-joint injections is an empiric practice, related to past experience and extrapolation of the presumed benefits of steroid injections from their use in other synovial joints.

- Therapeutic IA injections should be repeated no more than three times annually and only if the initial injection results in significant pain relief (> 50%) for at least 3 months.

There is a unique subset of patients that suffer from lumbar radicular pain due to facet joint pathology. In these cases, facet synovial cysts may cause nerve root compression or irritation with associated radicular pain similar to other neuro-compressive lesions. A number of interventional treatments for symptomatic Z-joint cysts has been described including intraarticular aspiration, rupture and direct cyst puncture. Each of these treatments require direct access into the Z-joint under fluoroscopic or CT guidance. In addition, it is appropriate and indicated to perform a transforaminal epidural steroid injection (one or two level) in combination with the above techniques to treat the associated radiculitis. These are distinct and separate procedures used to treat two separate and distinct but associated pathologies and diagnoses.

For the treatment of Z-joint synovial cysts with Z-joint aspiration/injection/rupture or direct puncture, the following criteria apply:

- The procedure should not be repeated more than two times on the same joint annually and only if the initial procedure results in significant pain relief (> 50%) for at least three months.

**Intervention 5: Therapeutic Medial Branch Radiofrequency Neurotomy**

Therapeutic medial branch RFN is a validated treatment for Z-joint pain. Long-term follow-up demonstrates that treatment effects are durable and reproducible if symptoms return. Success rates for initial treatment are high when patients are selected based on dual confirmatory diagnostic MBB. If symptoms return, repeat treatment shares an equally high success rate if response to the prior RFN lasted at least three months.

If therapeutic medial branch RFN is performed, the following criteria apply:

1. RFN is offered to patients only if dual diagnostic MBB injections each produce ≥ 80% relief of the primary (index) pain and the onset and minimum duration of relief is consistent with the agent employed.
2. RFN should be performed using a 20-gauge or larger needle with ≥ 10 mm active tip in lumbar spine and at least 5 mm active tip in the cervical spine. Heating must be performed to at least 80 degrees Celsius for 90 seconds in the lumbar and cervical spine. Repositioning and multiple lesions may be required to achieve appropriate denervation.
3. The patient should have pain that has been present for at least 3 months despite other treatments.
4. RFN should be performed at the same level no more than twice annually and only if the initial radiofrequency lesion results in significant pain relief (> 50%) for at least 6 months. In those situations, a repeat procedure in that year is appropriate.

**Rationale**

The proposed policy utilizes an evidence-based approach to care, where such evidence exists. In the absence of strict evidence-based criteria, the policy utilizes the multidisciplinary and non-conflicted experience and expertise of the committee in order to reflect reasonable standard practice indications in the United States.

Image guidance is considered mandatory for successful needle placement for both IA and MBBs. The vast majority of studies have used fluoroscopy during needle placement. Ultrasound is experiencing increasing popularity in the cervical spine due to the proximity of the target structures to the skin and thus the ability to visualize these structures; however, at the time of this publication, the use of ultrasound to perform any of these procedures is considered experimental, and NASS does not recommend coverage at this time. CT
guidance has also been used to direct needle placement, particularly for intraarticular injections.

**Medial Branch Blocks**

As described in Intervention 1, there are no valid historical physical exam findings, imaging studies or tissue examinations that can identify the cervical facets joints as the source of a patient’s neck pain, headaches or shoulder girdle pain. The rationale for using diagnostic cervical MBBs is that pain relief during the anesthetic nerve block provides prima facie evidence that the patient’s pain is caused by structures innervated by the target nerves.44-40 In addition to determining the possible cause of the patient’s pain, positive responses to diagnostic MBBs are an indication for a medial branch radiofrequency neurotomy. The effectiveness and long-term durability cervical medial branch radiofrequency neurotomy has been studied by multiple authors and is discussed elsewhere in this coverage document.

Since there is evidence of a significant false positive rate for diagnostic cervical medial branch blocks,41, 42 dual confirmatory (or “comparative”) blocks with local anesthetics of different expected durations of effect, administered on two separate occasions, are recommended to decrease the rate of false positive results. However, the increased specificity afforded by comparative blocks comes at the cost of decreased sensitivity, meaning that the number of false negative patients will increase, meaning some will be disqualified from potentially effective treatment.35,43

While the rate of false positives is lower with dual blocks, some have suggested that this practice is neither necessary nor cost effective.34 However, the study used to make this argument used provocation discography to identify false positives, when provocation discography is controversial specifically for its potential to produce false positive results.45 Placebo controls have also been advocated to further improve the specificity of MBBs.46 The decision to use placebo controls is felt by some to depend on whether or not absolute diagnostic certainty was critical, such as in the performance of an initial placebo controlled trial of treatment efficacy, in a medicolegal context or if surgery is contemplated based on the results of the testing.36 Still, no studies have used cervical IA or medial branch blocks to predict surgical outcomes. Thus, the primary indication for diagnostic cervical MBBs is to determine the suitability of the patient for a radiofrequency neurotomy of the painful segmental level(s) identified by the diagnostic MBBs, in order to achieve long-term management of the patient’s pain.

In Intervention 2, the rationale behind therapeutic MBBs is that compression or inflammation of the medial branch nerve may be responsible for Z-joint related pain or that injections of anesthetic and other potentially therapeutic substances may cause local nerve or central nervous system changes in pain transmission. However, these suggested mechanisms have never been demonstrated empirically.

Prospective randomized studies of therapeutic MBBs compared the standard anesthetic MBBs with blocks combining anesthetics and corticosteroids, showing no differences between groups in terms of pain relief, function, or number of required injection treatments.47,48 In these studies, patients in each group received an average of 4-5 injections per year for diagnosis and treatment.

Therapeutic cervical medial branch blocks showed short-term relief in an initial small case series published in 1986.49 Since then, nearly all research on therapeutic MBBs has come from a single center and includes a prospective case series and publications from a randomized controlled trial.50, 51 The outcomes documented in these studies involve patients who received between 4-5 injections in the first year of the trial. The repeated treatments were performed at various unspecified intervals, without reporting their timing relative to outcomes collection. Thus, it is impossible to determine the true duration of treatment effect. Furthermore, the publications from the randomized trial reveal no additional benefits when other potentially therapeutic medications, such as corticosteroids, are added to traditional anesthetic MBBs. There are no studies that have compared the effectiveness of therapeutic MBBs injections with medial branch radiofrequency neurotomy, a treatment known to provide effective long-term management of cervical Z-joint pain. Only one study has compared therapeutic MBBs to any other treatment, and this was in the lumbar spine. In this prospective, blinded, randomized trial patients were treated with the same combination of corticosteroids and anesthetics with MBBs vs. IA Z-joint injections.18 Statistically significant and clinically relevant improvements were observed in IA Z-joint injection group relative to the therapeutic MBB group.

**Intraarticular Injections**

As detailed in Item 3, cervical IA Z-joint injections have not been validated for diagnostic use. Thus, their false positive rate is not known. Lacking validity, they have limited utility in the diagnosis of Z-joint pain.52 There have been no studies that compare the ef-
fiveness of IA Z-joint injections vs. MBBs in the cervical spine. The use of diagnostic IA injections is thus reserved for those cases where MBBs are not anatomically possible, as is the case with occipitoatlantal and atlantoaxial joints.

In Item 4, the use of therapeutic IA Z-joint injections is placed into context. Corticosteroid injections for painful joint conditions outside the spine are a common practice, yet evidence is relatively lacking for these therapeutic joint injections – both within and outside the spine. Therefore, policy regarding the recommended indications and frequency of IA Z-joint injections is largely based on limited case series and anecdotes. Results of existing studies are conflicting. In controlled trials, benefits relative to other treatments are observed in some, but others fail to show significant short- or long-term benefits.

The negative trial, however, studied only patients with chronic pain following a whiplash injury, so it is unknown if similar results will occur when treating acute pain or pain related to inflammatory joint conditions. Accordingly, reviews addressing the treatment of chronic neck pain have found little or no evidence to support the use of therapeutic IA Z-joint injections in the management of chronic neck pain.

Cysts can arise from the facet joints, primarily in the lumbar spine, causing both mechanical and biochemical irritation of the adjacent nerves. These cysts most commonly arise from the L4-5 Z-joints and typically can be histologically divided into synovial and ganglion cysts. Ganglion cysts, the less common of the two, lack a synovial lining, are typically multiloculated and do not communicate with the adjacent Z-joint. Synovial cysts, which represent about 75% of Z-joint cysts, have a synovial lining and communicate with the Z-joint, making them amenable to fluoroscopic visualization and rupture though needle entry into the Z-joint. Z-joint injection and cyst rupture is performed to treat not only the Z-joint arthropathy and associated pain but also is performed to rupture the associated facet cyst, thereby decompressing the nerve root in an attempt to avoid the need for a more invasive, open surgical decompression.

The use of intraarticular injections for aspiration, steroid injection and rupture of synovial cysts arising from the lumbar facet joints is well described. These procedures are typically accompanied by transfemoral epidural steroid injections to treat the radicular pain component. However, the use of these procedures does not produce universally excellent results, and the cysts return after about half of the time, necessitating the need for surgical consideration. For this reason, it is recommended that the procedure not be repeated more than once and only if the first procedure produced satisfactory results.

**Medial Branch Radiofrequency Neurotomy**

The facet joints are dually innervated by medial branches emanating from the dorsal rami at the two adjacent levels in the cervical spine and superior levels in the lumbar spine. Surgical investigation has revealed intraarticular nerve endings as well as neurotransmitters associated with inflammation and pain, and animal studies have revealed the presence of mechanoreceptors. Joint provocation by intraarticular injection and capsule distension has produced clinically significant pain in asymptomatic individuals.

When cervical medical branch RFN is performed using appropriate anatomic technique and when the patients are selected based on response to dual confirmatory diagnostic MBB, there is consistent evidence of the treatment’s effectiveness in reducing pain and disability caused by cervical Z-joint pain. The most recent systematic review included eight primary studies. This systematic review found that a majority of patients, selected based on response to confirmatory MBB, were pain free at 6 months, with a number needed to treat of 2.

In the lumbar spine, an observational study of anatomically accurate RFA demonstrated that 80% of patients experienced at least 60% pain relief, and 60% of patients obtained at least 80% pain relief lasting 12 months after RFA. One randomized controlled trial employed a technique in which the RFA probes were positioned perpendicular to the medial branches. This is contrary to existing procedural recommendations as presumably only a short length of the nerve is lesioned using this approach. Indeed, the pain relief reported in the treatment arm was appreciable compared to the sham group, but as could be expected a diminishing number of patients had relief beyond 6 weeks after RFA. A randomized, controlled study of anatomically correct RFA in 40 patients revealed statistically significant improvement in back pain as well as functional outcome measures at 6 months. No serious adverse events or complications were reported in these trials when motor stimulation is performed prior to ablation and the patients remained awake.

When medial branch RFN is performed using appropriate anatomic technique and when the patients are selected based on response to dual confirmatory diagnostic MBB, there is consistent evidence of the treatment’s effectiveness in reducing pain and disability caused by Z-joint pain.
There is no literature addressing the use of IA injections for thoracic pain, and literature for the use of MBB or RFA for persistent pain in the thoracic spine is limited to lower level evidence from retrospective studies and case series. Empirically, studies have demonstrated that the thoracic facets are also innervated by medial branches, though the anatomical course of these nerves is more unpredictable and varies by the given anatomical level within the thoracic spine. Literature exists demonstrating efficacy of thoracic MBB and RFN, though this is limited to retrospective studies with relatively small study populations. However, there is no medical literature that suggests any other effective alternative therapy for this patient population. As such, we feel clinicians should weigh the risks and benefits of pursuing these interventions versus other palliative care in patients with thoracic spine pain who otherwise appear to have very limited remaining treatment options.

Another recent systematic reviews investigated the durability of the response and effectiveness of repeat RFA treatment in the cervical spine and lumbar spine. This review found durable treatment effects, averaging nine months in patients treated in the cervical spine. It also showed that benefits were reproducible with repeat treatment, provided that response to the prior RFN was at least 3 months. Thus, medial branch RFN is indicated in patients with a diagnosis of Z-joint pain based on response to dual diagnostic MBB injections. Repeat treatment is indicated in patients who experience a return of symptoms following at least three months’ relief from a previous RFN.

References

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Disclosure Key

Direct or indirect remuneration: royalties, stock ownership, private investments, consulting, speaking, and/or teaching arrangements, trips/travel.

Position held in a company: board of directors, scientific advisory board, other office. Support from sponsors: endowments, research-investigator salary, research-staff and/or materials, grants, fellowship support.

Degree of support:

- Level A: $100 to $1000
- Level B: $1,001 to $10,000
- Level C: $10,001 to $25,000
- Level D: $25,001 to $50,000
- Level E: $50,001 to $100,000
- Level F: $100,001 to $500,000
- Level G: $500,001 to $1M
- Level H: $1,000,001 to $2.5M
- Level I: greater than $2.5M

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Financial Statement

These Coverage Recommendations were developed in their entirety by the North American Spine Society (NASS). All participating authors have disclosed potential conflicts of interest consistent with NASS’ disclosure policy.

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Comments

Comments regarding the coverage recommendations may be submitted to coverage@spine.org and will be considered in development of future revisions of the work.
NASS Coverage Recommendations Methodology

**Topic Selection:**
Coverage Recommendations topic lists are developed and approved by the Coverage Committee. Topics include both therapeutic and diagnostic procedures and treatments as well as nonoperative, interventional, and surgical procedures and treatments. The breadth of the topics attempts to represent all facets of spinal care. Topics are selected based on frequency of use in spine care and will attempt to represent the full breadth of procedures, diagnostics, and interventions.

**Author Assignment:**
The Coverage Committee members rank their preferences (1, 2, or 3) for topic assignment. The Chair matches topics to the members’ preferences as much as possible. Active consideration is given to avoiding conflicts of interest, whether financial or otherwise, between members and the topics assigned. All authors disclose any conflicts of interest in accordance with the NASS disclosure policy.

**Background Data Review:**
For each topic, authors coordinate a literature search with the help of a research librarian/NASS staff member.

A literature search using PubMed, EMBASE, Web of Science and Cochrane is performed using search terms identified by the author specific to the topic assigned. Searches are limited to systematic reviews, meta-analyses, clinical guidelines, and most importantly, randomized controlled trials. The search produces a list of abstracts to be sent to the author for review and selection of appropriate articles for full review. Selected articles are then be sent to the Coverage Committee Chair for the approval to reduce any potential bias. The National Guidelines Clearinghouse is also be searched by NASS staff for appropriate clinical guidelines. Note that only full text, peer-reviewed articles published in English are eligible for review. Abstracts and non-published reports are not eligible for review.

In addition, NASS staff identify and retrieve any previously issued coverage policy on the topic, either by a private or public insurance provider.

**Data Analysis:**
The medical literature is analyzed with preference given to the highest quality literature available. Funding and other potential sources of bias are taken into consideration, as is consistency of the literature reviewed. In the absence of high-level data, coverage recommendations reflect the multi-disciplinary experience and expertise of the committee members in order to present reasonable standard practice indications in the United States.

**Coverage Recommendations Formulation:**
When trials, guidelines, or systematic reviews are available, the coverage recommendations should reflect the published data as much as possible. However, given the complexities of clinical care and the limitations of the medical literature in many circumstances, additional consideration is given to specific clinical scenarios and the currently available treatment options for those scenarios, including the potential risks and benefits of the alternative treatment options, prior to establishing a coverage decision. In summary, final determinations are made upon an evidence-based review of the existing data, an understanding of clinical care, and the NASS mission.

Individual coverage recommendations follow a standard format document approval: Once formulated, the coverage recommendations are reviewed and revised by the Coverage Committee Chair incorporating any new data if available since the document is developed and with modifications for format. The document is then sent to the senior reviewers of the Coverage Committee and subject-matter experts from the NASS’ Payor Policy Review Committee (PPRC) for review and comment. After review at this level, final modifications are made and author is advised. The proposed coverage document is sent to the NASS Executive Committee of the board directors for review and final approval before publication. The proposed coverage document is published on NASS’ website with a 30-day public comment period. At the end of the public comment period, comments are reviewed and considered by the NASS Coverage Committee. Where appropriate, the Committee makes edits and then publish the final document on NASS website.
Clinical Guidelines
Diagnosis and Treatment of Adult Isthmic Spondylolisthesis
Diagnosis and Treatment of Degenerative Spondylolisthesis (Revised 2014)
Diagnosis and Treatment of Lumbar Disc Herniation with Radiculopathy
Antibiotic Prophylaxis in Spine Surgery (Revised 2013)
Diagnosis and Treatment of Degenerative Lumbar Spinal Stenosis (Revised 2011)
Diagnosis and Treatment of Cervical Radiculopathy from Degenerative Disorders
Antithrombotic Therapies in Spine Surgery

Appropriate Use Criteria
Cervical Fusion

Coding FAQs (NASS Member Resource Only)

Patient Education Brochures (Complete Catalog)
Sacroiliac Joint Injections
Introduction
North American Spine Society (NASS) coverage policy recommendations are intended to assist payers and members by proactively defining appropriate coverage positions. Historically, NASS has provided comment on payer coverage policy upon request. However, in considering coverage policies received by the organization, NASS believes proactively examining medical evidence and recommending credible and reasonable positions may be to the benefit of both payers and members in helping achieve consensus on coverage before it becomes a matter of controversy. This coverage recommendation reflects the best available data as of 5/16/2013; information and data available after 5/16/2013 is thus not reflected in this recommendation and may warrant deviations from this recommendation, if appropriate.

Methodology
The coverage policies put forth by NASS use an evidence-based approach to spinal care when possible. In the absence of strict evidence-based criteria, policies reflect the multidisciplinary and non-conflicted experience and expertise of the authors in order to reflect reasonable standard practice indications in the United States.

NASS Coverage Policy Methodology

Scope and Clinical Indications
Management of chronic low back pain is a significant contributor to the national health care budget. When using comparative anesthetic blocks with a high degree of pain relief, the prevalence of sacroiliac joint pain likely ranges from 20% to 30% in patients with suspected SIJ pain based on history and physical examination. Sacroiliac (SI) joint injections have been used to diagnose and treat pain from this structure. Lateral branch blocks and radiofrequency ablation have similarly been used to diagnose and treat pain from the SI joint or from the posterior sacroiliac complex.

Pain from the SI joint may arise from a variety of disorders but most commonly is thought to be from degenerative or inflammatory arthritis. Certain conditions can increase the prevalence of SI joint pain, these include prior lumbar fusion6-9, older patient age10-12 and history of trauma.10,13

There is a known high false positive rate, at around 20% with SI joint injections.12,14,15 In order to increase the likelihood of the presence of this condition in patients whom an injection is considered, physical examination can be helpful. The literature has not demonstrated a single physical exam maneuver with a likelihood ratio greater than 1.3 for predicting a positive response to intra-articular anesthetic:2,16,17 However, other studies5,18,19 have reported that responses to at least three exam maneuvers (FABER, thigh thrust, Gaenslen’s, distraction, sacral thrust, and compression) were predictive of a positive response with a reported sensitivity of 78%.

Clinical Criteria for the Procedure

Item 1: Diagnostic SI Joint injections
Intraarticular SI joint injections are indicated to aid in the diagnostic work-up of low back pain when ALL of the listed criteria are met. Of note, any and all SIJ injections should be performed with some form of radiographic image guidance (eg, fluoroscopic, CT-guided). Further, volume of injectate should be limited to 2 mL.20-24 the inclusion of steroid with local anesthetic is not inappropriate. A diagnosis of SI joint pain is confirmed with at least 75% reduction of pain for the expected duration of the anesthetic used on 2 separate occasions.

1. Patient’s report of nonradicular, typically unilateral pain that is caudal to the lumbar spine (L5 vertebrae), localized over the posterior SIJ, and consistent with SIJ pain
2. A thorough physical examination demonstrating localized tenderness with palpation over the sacral sulcus (Fortin’s point, ie, at the insertion of the long dorsal ligament inferior to the posterior superior iliac spine or PSIS) in the absence of tenderness of similar severity elsewhere (eg, greater trochanter, lumbar spine, coccyx) and that other obvious sources for their pain do not exist.
3. Positive response to a cluster of three provocative tests (eg, thigh thrust test, compression test, Gaenslen’s test, distraction test, Patrick’s sign, posterior provocation test). Note that the thrust tests is not recommended in pregnant patients or those with connective tissue disorders.
Item 2: Therapeutic SI joint injections

Intraarticular SI joint injections of corticosteroid with or without local anesthetic are indicated for the treatment of low back pain when all of the listed criteria are met:

1. Patient’s report of nonradicular, typically unilateral pain that is caudal to the lumbar spine (L5 vertebrae), localized over the posterior SIJ, and consistent with SIJ pain.
2. A thorough physical examination demonstrating localized tenderness with palpation over the sacral sulcus (Fortin’s point, ie, at the insertion of the long dorsal ligament inferior to the posterior superior iliac spine or PSIS) in the absence of tenderness of similar severity elsewhere (eg, greater trochanter, lumbar spine, coccyx) and that other obvious sources for their pain do not exist.
3. Positive response to a cluster of three provocative tests (eg, thigh thrust test, compression test, Gaenslen’s test, distraction test, Patrick’s sign, posterior provocation test). Note that the thrust tests is not recommended in pregnant patients or those with connective tissue disorders.
4. SIJ pain has been confirmed with diagnostic SIJ injections.

Rationale

Item 1:

Image Guidance: Some form of image guidance is considered requisite for performing SI joint injections. In 2003, Hansen, in an observational study, showed that blind needle placement for sacroiliac joint injection was successful in only 12% of patients. He subsequently recommended image guidance. Rosenberg et al, in a prospective, double-blind study, showed intra-articular injections in only 22% of patients when no image guidance was used. Though multiple ultrasound-guided sacroiliac joint injection systems are available, Simopoulos et al found no systematic evaluations of ultrasound for SI joint injections. In most recent systematic reviews of SI joint interventions, fluoroscopic or CT guidance has been considered an inclusion criteria.

Physical Exam Findings: The utility of physical exam findings in the diagnosis of SI joint pain has been well-studied. In a systemic review by Szadek, meta-analysis of five individual provocation tests, compression, distraction, thigh thrust, Gaenslen’s test, and Patrick’s sign were evaluated. Analysis showed that positive thigh thrust test or compression tests are likely to have SI joint pain. Also, threshold of three positive tests had good diagnostic validity for SI joint pain. Joint injection with varying degree of pain relief (as low as 50%) was the gold standard. In contrast, Dreyfuss reviewed 20 physical examination tests, including thigh thrust, Gaenslen’s, Patrick’s, sacral thrust, and compression. This group showed that no single test or combination of tests was sufficiently useful in diagnosing sacroiliac joint pain. Of note, SI joint injection with high level of pain relief (>90%) was used as the gold standard. Three studies have reported that responses to at least three exam maneuvers (FABER, thigh thrust, Gaenslen’s, Patrick’s, sacral thrust, and compression) were predictive of a positive response with a reported sensitivity of 78%. Finally, a review by Hancock found that single manual tests for SI joint pain were uninformative, although combinations of test were helpful. Based on these available data, it seems reasonable to require documentation of at least three positive provocative physical examination maneuvers prior to consideration of a diagnostic or therapeutic injection.

Requirement of Radiographic Findings: Hansen reviewed the databases of EMBASE, MEDLINE and Cochrane reviews. This group concluded that MRI can detect abnormalities of the cartilaginous sacroiliac joint, early spondyloarthropathy, and inflammatory and destructive changes of the SI joint. Similar to literature about the lack of correlation between disc degeneration and back pain, this group found that radiological SI findings have not been found to be an accurate indicator of symptoms. Interestingly, Hancock, in a review of Medline, EMBASE, and CINAHL, found a positive bone scan may increase the probability of the SIJ being the source of pain, though a negative scan does not reduce the probability. In a more detailed analysis, Blum showed that MRI was more sensitive and specific than scintigraphy or radiography for sacroilitis. Simopoulos concluded that MRI appears to be useful for early sacroiliitis and to follow patients with spondyloarthropathy. Thus, imaging is considered be helpful in identifying patients who might benefit from further evaluations such as a diagnostic injection, though the absence of abnormalities on imaging does not negate the appropriateness of performing the procedure.

Utility of Diagnostic Injections: There have been 7 studies using controlled blocks to diagnose SI joint pain. Increasing the percentage of pain relief required for a positive block also decreases the reported prevalence of SIJ pain. Differences mainly arose when relaxing criteria from >75% to >50% pain relief (Table 1).
Single diagnostic injections have been used in multiple studies. When comparing controlled blocks with single diagnostic injections, the known false positive rate of injections is clearly demonstrated. Studies utilizing single blocks report rates of 29-63%, while studies utilizing dual blocks report rates between 10-33% (with only one study showing higher rates at 45%). For this reason, dual diagnostic blocks, with at least a 75% reduction in pain, are needed to confirm the diagnosis of SI joint pain.

**Item 2:**
Therapeutic SI joint injections: The utility of therapeutic SI joint injections has been well-studied. Hansen (2012) in a systematic review for therapy of SI joint pain found limited (or poor) evidence for intra-articular steroid injection and limited (or poor) evidence for peri-articular injection of local anesthetic and steroid or botulinum toxin. Hawkins (2009), in a retrospective audit of 155 patients, showed 77% of patients with short-term pain relief after one injection. Of those who showed pain relief, approximately 1/3 remained improved after one injection, and 2/3 remained improved after one or 2 injections. Of those who received 2 or more injections, the duration of relief averaged 9.3 months. Liliang (2009), in a prospective case series of sacroiliac joint pain determined by dual blocks, showed 66.7% patients with pain relief of more than 6 weeks. All patients required a second injection, which then had a mean duration of pain relief of 36.8 weeks. Interestingly, the 33.3% with a positive diagnostic injection but less than 6 weeks of pain relief had pain reduction mean of 4.4 weeks.

Luukkainen demonstrated in a non-blinded, randomized single injection study a significant decrease in VAS and pain index at four weeks in patients with peri-articular methyl-prednisolone acetate and lidocaine injection compared to sodium chloride and lidocaine injection. Borowsky showed in a retrospective review of two case series that injection of steroids in the SI joint and the posterior inter-osseous ligament and S1-3 lateral branches improved short-term (3 months) clinical outcomes when compared to sacroiliac joint alone, although both were suboptimal (12.5% vs. 31.25%). McKenzie-Brown in a systematic review that included spondyloarthopathy concluded that evidence for intra-articular sacroiliac joint injections was moderate for short-term relief and limited for long-term relief.

Based on these data, it seems reasonable to offer coverage of therapeutic SI joint injections in those cases that fulfill the listed criteria. It is acknowledged that there will likely not be high quality data to support the predictive value of each of these criteria. However, considering the available evidence discussed above in Item 1, it seems reasonable to apply these criteria to therapeutic SI joint injections.

### Table 1

<table>
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<th>Selection Based on Controlled Local Anesthetic Blocks</th>
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<td>20-46%</td>
<td>Laslett 2005</td>
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<td>At least 75% relief</td>
<td>26%</td>
<td>19-33%</td>
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<tr>
<td>At least 50% relief</td>
<td>33%</td>
<td>26-40%</td>
<td>Liliang 2011</td>
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</table>

### References

4. Laslett M, McDonald B, Tropp H, Aprill CN, Oberg B. Agreement between diagnoses reached by clinical examination and available reference
NASS Coverage Policy Recommendations | Sacroiliac Joint Injections


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These Coverage Recommendations were developed in their entirety by the North American Spine Society (NASS). All participating authors have disclosed potential conflicts of interest consistent with NASS’ disclosure policy.

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NASS coverage recommendations should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution. The coverage recommendations do not represent a “standard of care,” nor are they intended as a fixed treatment protocol. It is anticipated that there will be patients who will require less or more treatment than the average. It is also acknowledged that in atypical cases, treatment falling outside these criteria will sometimes be necessary. This document should not be seen as prescribing the type, frequency or duration of intervention. Treatment and accompanying payment should be based on this information in addition to an individual patient’s needs as well as the doctor’s professional judgment and experience. This document is designed to function as a guide and should not be used as the sole reason for denial of treatment and services. It is not intended to supersede applicable ethical standards or provisions of law. This is not a legal document.
NASS Coverage Policy Recommendations | Sacroiliac Joint Injections

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Comments
Comments regarding the coverage recommendations may be submitted to coverage@spine.org and will be considered in development of future revisions of the work.

Disclosure Key

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<td>(board of directors, scientific advisory board, other office)</td>
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Level F. $100,001 to $500,000  |
Level G. $500,001 to $1M  |
Level H. $1,000,001 to $2.5M  |
Level I. greater than $2.5M  |

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NASS Coverage Recommendations Methodology

**Topic Selection:**
Coverage Recommendations topic lists are developed and approved by the Coverage Committee. Topics include both therapeutic and diagnostic procedures and treatments as well as nonoperative, interventional, and surgical procedures and treatments. The breadth of the topics attempts to represent all facets of spinal care. Topics are selected based on frequency of use in spine care and will attempt to represent the full breadth of procedures, diagnostics, and interventions.

**Author Assignment:**
The Coverage Committee members rank their preferences (1, 2, or 3) for topic assignment. The Chair matches topics to the members’ preferences as much as possible. Active consideration is given to avoiding conflicts of interest, whether financial or otherwise, between members and the topics assigned. All authors disclose any conflicts of interest in accordance with the NASS disclosure policy.

**Background Data Review:**
For each topic, authors coordinate a literature search with the help of a research librarian/NASS staff member.

A literature search using PubMed, EMBASE, Web of Science and Cochrane is performed using search terms identified by the author specific to the topic assigned. Searches are limited to systematic reviews, meta-analyses, clinical guidelines, and most importantly, randomized controlled trials. The search produces a list of abstracts to be sent to the author for review and selection of appropriate articles for full review. Selected articles are then be sent to the Coverage Committee Chair for the approval to reduce any potential bias. The National Guidelines Clearinghouse is also be searched by NASS staff for appropriate clinical guidelines. Note that only full text, peer-reviewed articles published in English are eligible for review. Abstracts and non-published reports are not eligible for review.

In addition, NASS staff identify and retrieve any previously issued coverage policy on the topic, either by a private or public insurance provider.

**Data Analysis:**
The medical literature is analyzed with preference given to the highest quality literature available. Funding and other potential sources of bias are taken into consideration, as is consistency of the literature reviewed. In the absence of high-level data, coverage recommendations reflect the multi-disciplinary experience and expertise of the committee members in order to present reasonable standard practice indications in the United States.

**Coverage Recommendations Formulation:**
When trials, guidelines, or systematic reviews are available, the coverage recommendations should reflect the published data as much as possible. However, given the complexities of clinical care and the limitations of the medical literature in many circumstances, additional consideration is given to specific clinical scenarios and the currently available treatment options for those scenarios, including the potential risks and benefits of the alternative treatment options, prior to establishing a coverage decision. In summary, final determinations are made upon an evidence-based review of the existing data, an understanding of clinical care, and the NASS mission.

Individual coverage recommendations follow a standard format document approval: Once formulated, the coverage recommendations are reviewed and revised by the Coverage Committee Chair incorporating any new data if available since the document is developed and with modifications for format. The document is then sent to the senior reviewers of the Coverage Committee and subject-matter experts from the NASS’ Payor Policy Review Committee (PPRC) for review and comment. After review at this level, final modifications are made and author is advised. The proposed coverage document is sent to the NASS Executive Committee of the board directors for review and final approval before publication. The proposed coverage document is published on NASS’ website with a 30-day public comment period. At the end of the public comment period, comments are reviewed and considered by the NASS Coverage Committee. Where appropriate, the Committee makes edits and then publish the final document on NASS website.
Clinical Guidelines
Diagnosis and Treatment of Adult Isthmic Spondylolisthesis
Diagnosis and Treatment of Degenerative Spondylolisthesis (Revised 2014)
Diagnosis and Treatment of Lumbar Disc Herniation with Radiculopathy
Antibiotic Prophylaxis in Spine Surgery (Revised 2013)
Diagnosis and Treatment of Degenerative Lumbar Spinal Stenosis (Revised 2011)
Diagnosis and Treatment of Cervical Radiculopathy from Degenerative Disorders
Antithrombotic Therapies in Spine Surgery

Appropriate Use Criteria
Cervical Fusion

Coding FAQs (NASS Member Resource Only)

Patient Education Brochures (Complete Catalog)
February 23, 2018

Division of Workers’ Compensation via Email to: DWCforums@dir.ca.gov
State of California
PO Box 420603
San Francisco, CA 94142

Re: Multisociety Support for Coverage of Radiofrequency Neurotomy

To Whom It May Concern:

The undersigned medical specialty societies, comprising physicians who utilize and/or perform interventional spine procedures to accurately diagnose and treat patients suffering from spine pathologies, would like to take this opportunity to express our strong support for coverage of lumbar medial branch (facet) thermal radiofrequency neurotomy (RF neurotomy) and provide a detailed explanation for why you should too.

Our societies have a strong record of working to eliminate fraudulent, unproven, and inappropriate procedures. At the same time, we are equally committed to assuring that appropriate, effective, and responsible treatments are preserved so that patients do not have to suffer, or undergo more invasive surgical procedures, unnecessarily.

Payers are concerned about the increasing cost of facet RF neurotomy and its associated diagnostic medial branch blocks; and justifiably so. In seeking to limit costs, however, it is important to identify the root of the problem. The root of the problem lies not in the procedures, but rather in their inappropriate application. Literature assessing medial branch blocks and facet RF neurotomy shows how these procedures can be performed in a disciplined, responsible manner, in order to achieve desirable outcomes that are clinically, socially, and economically worthwhile 1,2.

Surely significant relief of pain, with greater restoration of function and return to work, as well as decreased utilization of other healthcare resources is an outcome that you do not want to deny patients. Those outcomes can be achieved by the responsible application of facet RF neurotomy. In order to address the true problem of the inappropriate application of these procedures, the following requirements should be applied:

- At least 80% relief of index pain from medial branch blocks should be recognized as a pretext for further investigation.
- Less than 80% relief of index pain should be regarded as non-positive; and further medial branch blocks at those levels should not be pursued.
- At least 80% relief of index pain following comparative or placebo-controlled blocks should become the only indication for facet RF neurotomy.

By adopting such measures, payers will greatly reduce the burden of cost by eliminating unproductive procedures from the portfolio, while preserving, respecting, and supporting conscientious practice for those patients who can benefit from these procedures.

SUMMARY OF RECOMMENDATIONS

Relative to the practice of facet RF neurotomy, we encourage payers to:

1. Recognize as valid only those procedures performed in accordance with techniques that have been validated. Optimal results have been achieved only when those techniques have been used. Results from the techniques described in the SIS guidelines include complete relief of back pain accompanied by restoration of function, return to work, and no need for further health care.

2. Adopt the SIS guidelines as the standard for the performance of medial branch blocks and facet RF neurotomy.

Furthermore, we recommend that payers regard as investigational any other techniques for facet RF neurotomy, or any other basis for the selection of patients for treatment by facet RF neurotomy.

By such measures payers can make available to suffering patients the best standard of care currently available, and avoid continuing to subsidize practices of lesser standard with substantially poorer outcomes.

DISCUSSION

Recently published systematic reviews and technology assessments poorly serve the needs of the payers or patients. While such reports adhere to the common requirements of systematic reviews, their depiction of the evidence is flawed due to lack of insight into the details – not of the data published – but of the practices inherent in the procedures being assessed. In formal terms, the reports suffer from lack of content expertise.

Imagine that the topic was “the effectiveness of antibiotics for cough”. Cough, similar to low back pain, is merely a symptom representing a variety of diseases. In the case of cough this could include: viral pneumonia, asthma, gastroesophageal reflux disease, heart failure, and even bacterial pneumonia. Without proper patient selection and stratification one may be tempted to say antibiotics are not effective for all patients suffering from a cough. This would clearly be a disservice to those with bacterial pneumonia. In addition to the lack of specificity in the diagnosis, this analogy is also similar in that like spine interventions not all antibiotics are the same. There are a variety of antibiotic types with differing efficacies
and routes of administration. The combination of these different treatments targeted at different diseases leads to the unfortunate misinterpretation of an effective treatment for a select group of patients as ineffective.

Armed with such information, a review would not pool all data and diseases indiscriminately, while simultaneously not distinguishing the effectiveness of oral antibiotics and intravenous antibiotics, full-strength antibiotics, or even diluted antibiotics. Yet, in the case of facet RF neurotomy this is what has been done in high profile studies and systematic reviews.

The literature on facet RF neurotomy must be meticulously stratified. That stratification can be applied in each of three domains: selection, technique, and outcome (Figure 1).

---

**FIGURE 1**

![Diagram](Figure 1)

*Figure 1.* A graphic representation of a structure for the stratification of literature on facet RF neurotomy.
For a variety of reasons, practitioners – whether those in clinical practice or those who publish – use different techniques, yet call their procedure by the same name. The reasons include:

- continuing to use older techniques that are not only out of date, but which have been disproven \(^6\)–\(^8\);
- preferring techniques according to their inventor or country of origin, such as the Dutch technique or the Australian technique \(^6\)–\(^8\);
- using personal adaptations or shortcuts in order to save time, because the published technique is labor-intensive and time-consuming, and not proportionately reimbursed;
- using smaller electrodes because physicians are more comfortable using them.

Correct technique is not defined by arbitrary, personal choice; nor is it defined by randomized controlled trials. Correct technique is defined by studies in basic science.

For facet RF neurotomy to have face validity the electrode must be accurately placed such that the lesion that it produces optimally captures the target nerve. If the electrode is not placed near the nerve, the validity of the technique lapses.

Somewhat contentious is whether electrodes can be placed perpendicular to the course of the target nerve or parallel to it. In both instances, the electrode may be sufficiently close to the nerve in order to capture it, but basic science studies indicate that perpendicular placements may fail to capture the entire diameter of the nerve, and that parallel placements are more likely both to capture a full thickness of the nerve and a substantial length of the nerve \(^1\),\(^9\),\(^10\),\(^11\). Therefore, the orientation of the electrode is likely to be pivotal to clinical outcome. Perpendicular placements could be successful, but are likely to have lower success rates and shorter durations of effect, whereas parallel placements are more likely to have greater success rates for longer periods. This, indeed, is borne out in the literature (see: OUTCOMES).

In light of these technical precepts, the literature can be stratified according to face validity of the technique used (Table 1).

The original technique for “facet denervation” described by Shealy was seriously flawed \(^1\),\(^12\). Electrodes were placed nowhere within reach of the target nerve. Therefore the procedure was tantamount to a sham procedure. Studies that used this disproven technique are, therefore, not representative of a correct technique. The clinical data that they provide might be of use to show what meager outcomes are obtained when flawed techniques are used, but they are inadmissible as evidence of the effectiveness or efficacy of facet RF neurotomy when correctly performed.

Inadmissible for this reason is the study of Gallagher, which explicitly stated that it used the Shealy technique \(^13\). Similarly, the study of Leclaire \(et\ al\) \(^14\) used a technique that was a
modified version of the Shealy technique. Therefore, that study also lapses as providing valid data on the efficacy of facet RF neurotomy if correctly performed. Indeed, Leclaire et al acknowledged this flaw in surgical anatomy, and effectively retracted their results.

The study of van Wijk et al illustrated the technique used. It is patently inaccurate as pointed out by a letter to the editor. Not only were electrodes placed perpendicular to the target nerve, but many placements were too far away from the nerve for the lesion made by the small electrodes used to be able to capture the nerve reliably and adequately. That controlled trial, therefore, pitted one sham procedure against another, thus it is not surprising that no statistically significant difference in outcome was found.
### TABLE 1

<table>
<thead>
<tr>
<th>Orientation of Electrode</th>
<th>Placement of Electrode in Relation to Target Nerve</th>
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Table 1. The stratification of studies of lumbar facet RF neurotomy according to whether the technique used placed the electrode within reach of the target nerve, and whether the electrode was placed perpendicular or parallel to the nerve.

The other studies that used perpendicular placements\(^{18-24}\) either illustrated their procedure or described their technique in sufficient detail to credit that their electrodes were placed within range of the target nerve. However, the perpendicular placement, as well as the use of small-gauge electrodes, constitutes a risk of bias against good outcomes, because the target nerves may have been incompletely coagulated – resulting in a lower than optimal success rate – or insufficiently coagulated – resulting in duration of relief less than the duration achievable by other techniques. Therefore, the clinical outcomes of these studies need to be interpreted carefully and with insight.
In the 2017 study by Juch et al.\textsuperscript{24}, the authors did not adequately describe or provide images to illustrate placement relative to the target nerve. They used small-gauge electrodes and did not mention parallel electrode placement, increasing the odds of incomplete or unaccomplished facet RF neurotomy.

In the case of one study that used perpendicular placement\textsuperscript{23} and which was also a controlled trial, the technical limitation may affect the success rate and durability of outcome, but it does not affect testing the technique against placebo, because the same placement was used in each arm.

Nine studies used what appears to be correct technique: placement of the electrode parallel to the target nerve\textsuperscript{25-34}. Of these, some provide evidence of outcomes\textsuperscript{25-29}; others provide data on repeat treatment\textsuperscript{26,29-31}; two are controlled trials\textsuperscript{32,33}; and one was a comparison study\textsuperscript{34}.

In light of this stratification of studies by face validity of technique used, certain corrections apply to the conclusions of the reports published to date on facet RF neurotomy.

**RF Neurotomy versus Sham Neurotomy: Efficacy in the Lumbar Spine**

The studies of Gallagher 1994, Leclaire 2001, and van Wijk 2005 do not qualify as providing evidence of efficacy because the techniques used for the active arm lacked face validity.\textsuperscript{13,14,16} Censoring these studies leaves only those of Nath 2008, Tekin 2007, and van Kleef 1999 eligible to provide evidence.\textsuperscript{32-34}

The study of Nath 2008 showed a difference in favor of facet RF neurotomy that was not significant for the relief of back pain at six months, but which was significant for relief of leg pain, global perceived effect, and consumption of analgesics.\textsuperscript{32} For the relief of back pain, the group data of van Kleef 1999 showed a difference in favor of RF neurotomy that was not significant statistically, but survival analysis showed a statistically significant greater success rate from three months to one year after facet RF neurotomy.\textsuperscript{34} Tekin 2007 showed statistically significant differences in favor of active RF neurotomy at six months and at one year, for group scores for back pain, and for disability, with a significantly greater proportion of patients reporting an excellent outcome.\textsuperscript{33}

No study provided data that contradicted the superiority of active treatment over sham treatment.
OUTCOMES

The outcomes of facet RF neurotomy can be quantified in several domains:

- success rate: the proportion of patients who achieve a successful outcome;
- degree of relief that constitutes a success;
- duration of that relief;
- corroboration of relief by improvements in critical domains such as restoration of function, return to work, and use of other health care.

To various extents, these criteria have been satisfied in various studies. Reviewers can choose which outcomes they consider to be worthwhile, or satisfactory.

The paradigm of facet RF neurotomy is that if patients obtain at least 80% relief of their index pain following controlled diagnostic blocks of one or more medial branches, then similar relief should be obtained if those nerves are successfully coagulated.

Two studies have provided benchmarks for the optimal outcomes of facet RF neurotomy. Each used optimal technique, as discussed above. The first reported, in essence, that 80% of patients could expect at least 60% relief of their back pain at 12 months, and that 60% could expect at least 80% relief. The second study reported the outcomes from two neighboring practices, in which 58% (44-72%) or 53% (40-66%) of patients respectively achieved complete relief of pain, accompanied by restoration of activities of daily living, return to work if applicable, and no need for further health care for their back pain.

The results of these two studies are statistically compatible with one another, and indicate what can be achieved by facet RF neurotomy if performed correctly, and in appropriately selected patients. In both instances the technique used for facet RF neurotomy was that recommended by the Spine Intervention Society, and patients were selected using comparative local anesthetic blocks.

A success rate of 55% may not seem impressive, but is compensated by the definition of success: complete relief of pain, restoration of function, and no other health care. The modest success rate, however, is mathematically consistent with the vicissitudes of diagnostic blocks (see: DIAGNOSIS). Because the prevalence of lumbar facet joint pain is low, the rate of false-positive diagnoses is high, even if controlled blocks are used.

Other studies that have used correct technique have reported lesser outcomes, such as 39% or 35% of patients achieving at least 50% relief of pain at six months. In each case, however, patients were selected for treatment using diagnostic blocks in a manner less rigorous than in the benchmark studies.
### DIAGNOSIS

It is not possible to diagnose facet joint pain by physical examination or by medical imaging. Diagnostic blocks are the only means of establishing a diagnosis, and providing an indication for treatment by facet RF neurotomy.

The acme of diagnostic blocks are placebo-controlled triple blocks \(^{35-37}\). These involve first administering an active agent, in order to find primum facie if anesthetizing the target nerves relieves the patient’s pain. In order to test the response, the patient subsequently undergoes repeat blocks, under double-blind conditions, in which a placebo and an active agent are randomly administered. A positive response is one in which pain is not relieved when the placebo is used, but is relieved each time that the active agent is used, and for a duration concordant with the expected duration of action of the agent used.

Although placebo-controlled, triple blocks have been used in research studies \(^{38}\), they are regarded by many as too consuming of resources to be practical in conventional practice. Meanwhile, payers appear to be averse to funding triple blocks on the grounds that they are expensive. Interestingly, however, triple blocks are cost-effective in jurisdictions such as those in Australia and New Zealand, where the reimbursement for facet RF neurotomy substantially exceeds that of a diagnostic block \(^{39}\).

A suitable alternative to placebo-controlled, triple blocks is comparative local anesthetic blocks. These involve administering, on a double-blind basis in random order, either a long-acting or a short-acting local anesthetic agent. A positive response is one in which the patient obtains at least 80% relief of the index pain on each occasion. A concordant positive response is one in which the duration of relief is concordant with the expected duration of action of each of the agents used. A discordant response is one in which one of the agents, usually lidocaine, has a longer than expected duration of effect \(^{35-37,40}\). When compared with placebo-controlled blocks, comparative local anesthetic blocks are a reasonably expedient clinical tool. Concordant responses have a sensitivity of 54% and a specificity of 88%, generating a positive likelihood ratio of 4.5 \(^{35,41}\). Discordant responses have a sensitivity of 100% but their specificity lapses to 65%, generating a positive likelihood ratio of 2.9.

Although numerically different, likelihood ratios of 2.9 and 4.5 make little appreciable difference to clinical practice. Discordant responses and concordant responses provide effectively the same diagnostic confidence (post-test likelihood). However, diagnostic confidence is critically dependent on the prevalence of the condition being diagnosed (Figure 2). For a condition with a high prevalence, e.g. 60%, the diagnostic confidence for a discordant response is 81% and that for a concordant response is 87%. However, for conditions with a prevalence below 30%, diagnostic confidence plummets \(^{35,37}\) (Figure 2).
Single diagnostic blocks, even if they provide complete relief, are not a dependable diagnostic tool, for they have an unacceptably high false-positive rate. Various, the false-positive rate has been measured as between 25% and 45\%. Such high values generate uncertainty as to whether a positive response is true or not.

The practical utility of comparative local anesthetic blocks, and their limitations, can be illustrated in the following figures.

Figure 3 shows the diagnostic confidence after single blocks, comparative blocks, and placebo-controlled blocks, for conditions of different prevalence. After a single positive block, the diagnostic confidence is barely greater than the prevalence of the condition. Diagnostic confidence increases markedly if comparative blocks are positive, with little difference between the confidence generated by discordant or concordant responses. However, throughout, diagnostic confidence is affected by prevalence. Only for common conditions is diagnostic confidence high.
**Figure 3.** A graph of the relationships between diagnostic confidence and prevalence after positive responses to no blocks, one diagnostic block, comparative blocks, and placebo-controlled blocks. The pairs of figures above comparative blocks are the confidence after discordant and concordant responses, respectively.

Figure 4 shows the numbers of patients who would undergo facet RF neurotomy depending on if the indication was response to no blocks, a single block, comparative blocks, or placebo-controlled blocks. The graph shows that if no blocks are used, all patients undergo treatment. Those numbers reduce little if single blocks are the sole indication for treatment. Substantial reductions occur in the number of patients being treated if comparative blocks are applied, with those reductions being greater the less prevalent the condition being diagnosed. This figure underscores the utility of making a diagnosis using comparative blocks. It protects substantial numbers of patients from undergoing unnecessary and futile treatment.
Figure 4. A graph showing the numbers of patients who would undergo facet RF neurotomy if the indication was a positive response to no blocks, one diagnostic block, comparative blocks, or placebo-controlled blocks. The pairs of figures above comparative blocks are the numbers of patients for whom discordant and concordant responses, respectively, would be the indication for treatment.

Figure 5 completes the sequence. It shows that the success rates of treatment increase substantially if comparative blocks (or placebo-controlled blocks) are used. Those success rates are greater in proportion to the prevalence of the condition diagnosed and treated. Conversely, success rates are adversely low if the prevalence is low.

These principles have significant implications for the use of comparative local anesthetic blocks for selecting patients for treatment by facet RF neurotomy.
Figure 5. A graph of the relationships between prevalence and the expected success rates of facet RF neurotomy if the indication for treatment is a positive response to no blocks, one diagnostic block, comparative blocks, or placebo-controlled blocks. The pairs of figures above comparative blocks are the success rates after discordant and concordant responses, respectively.

In both of the benchmark studies of lumbar facet RF neurotomy\textsuperscript{25,26} the singular indication was a positive response to comparative local anesthetic blocks. The earlier study used a relaxed criterion of 80% relief\textsuperscript{25}, whereas the later study required complete relief\textsuperscript{26}. Both studies achieved the best results heretofore reported in the literature. The earlier study reported 60% of patients maintaining at least 80% relief for 12 months\textsuperscript{25}. The later study reported complete relief of pain in 55% of patients, accompanied by restoration of function, return to work, and no need for other health care, for a median duration of 15 months per treatment\textsuperscript{26}.

In isolation, a success rate of 55% or 60% may not seem impressive. However, this figure arises in two contexts. The first is that it applies to complete relief of pain. The second is that no other intervention of any kind, for any form of back pain, provides either such success or such a success rate.
The reason for the modest success rate lies in the vicissitudes of comparative blocks for conditions of low prevalence (Figure 3). The prevalence of lumbar facet joint pain, based on complete relief of pain, is not known, but it appears to be low \(^6,^8\).

For a prevalence of 30\%, Figure 3 indicates that the diagnostic confidence of comparative blocks is only about 65\%, and Figure 5 indicates that the success rate of lumbar facet RF neurotomy should be of the order of 60\%. Greater diagnostic confidence and greater success rates cannot be achieved unless the prevalence of lumbar facet joint pain is much greater than currently estimated, or unless placebo-controlled blocks are used to make the diagnosis \(^35\). Under those conditions, comparative local anesthetic blocks are the best available, most practical means of establishing an indication for facet RF neurotomy, if complete relief of pain is the desired outcome.

No other study has shown that complete relief of pain can be achieved using any indication other than complete, or near complete (at least 80\%), relief of the index pain from comparative local anesthetic blocks.

**CONCLUSION**

The Spine Intervention Society has produced practice guidelines for the conduct of lumbar, thermal facet RF neurotomy \(^1\) as well as guidelines for the conduct of lumbar medial branch blocks \(^2\), by which patients are selected for treatment by facet RF neurotomy.

Based on the most rigorous studies using valid diagnostic techniques to select patients and using optimal techniques of facet RF neurotomy,

- Over 50\% of patients treated with lumbar facet RF neurotomy can expect to achieve complete relief of pain, accompanied by restoration of activities of daily living, resumption of work, and no need for other health care for their back pain, for a median duration of 15 months, with an interquartile range of 10-28 months \(^26\).

- In the event of recurrence of pain, complete relief can be reinstated by repeating the treatment \(^26\).

Such outcomes are unrivalled by any other intervention for back pain. No other intervention has been shown to be capable of achieving complete relief of pain, accompanied by restoration to normal life, and cessation of health care for the condition treated. The available literature shows that these outcomes can be achieved. It also shows how they can be achieved.

Surely payers would support practices that achieve such outcomes and would ensure that they are available to patients.
The undersigned societies appreciate the opportunity to provide these comments. If you have any questions or wish to discuss any of our suggestions, please contact Belinda Duszynski, SIS Senior Director of Policy and Practice, at bduszynski@SpineIntervention.org.

Sincerely,

American Academy of Pain Medicine
American Academy of Physical Medicine and Rehabilitation
North American Spine Society

Spine Intervention Society

References


