Re: Humana Medical Coverage Policy - Injections for Chronic Pain Conditions, revisions effective January 1, 2018

To Whom It May Concern:

On behalf of the Spine Intervention Society, a multi-specialty association of over 2,700 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, we would like to take this opportunity to comment on Humana’s updated medical policy regarding injections for chronic pain conditions, effective January 1, 2018.

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 and musculoskeletal 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.

We previously have reviewed and provided comments on the coverage policy that was implemented in January 2017 as well as the version effective September 28, 2017 and are disappointed to see that many of our areas of concern are still present in this new policy, effective January 2018. Below, please find our recommended comments and suggestions targeted at improving the policy to ensure that procedures are accessible to appropriately-selected patients.

Description of Epidural Injections (page 2)

- Although the terms selective nerve root blocks (SNRBs) and transforaminal epidural steroid injections are sometimes used interchangeably, properly performed diagnostic selective nerve root blocks (SNRBs) are not epidural injections and do not utilize steroid. Therefore, SNRBs should not be included in this section. There should be a separate section for Selective Nerve Root Blocks.
Description of Facet Joint Injections (page 3, line 1)

- In the first sentence, medial branch blocks should be included so that the line reads as “Facet injections, also known as facet blocks or medial branch blocks...”

Coverage Determination of Epidural Injections (page 5-6)

- Instead of stipulating 3 months of failed conservative treatment, we recommend 4 weeks of conservative treatment including, but not limited to, rest, systemic medications and/or physical therapy. We recommend this change because the natural time course for the resolution of acute low back pain is approximately 4 weeks, which when not treated appropriately, will then enter the chronic phase. In addition, there may be situations where patients will be in such severe pain, that they may not be able to tolerate or even participate in standard conservative treatments such as lifestyle/activity changes, medications, and physical therapy for such a period of time.

- When defining radicular, the definition should be changed to “low back pain, associated with pain and/or numbness that radiates to the pelvis, buttock, and/or lower extremity.” To strictly define lumbar radiculopathies as pain and/or numbness only going past the knee would exclude patients with upper lumbar radiculopathies, who typically will experience pain and/or numbness above (e.g. pelvic, buttock, groin, and/or thigh) and/or at the level of the knee.

- We strongly disagree with the requirement that a successful “diagnostic phase” be completed in order to perform a therapeutic epidural injection. There is no convincing evidence in the literature to support this policy. Epidural injections are often performed for both diagnostic and therapeutic purposes to help alleviate a patient’s pain, improve their function and quality of life, and to confirm their underlying pathology. In addition, it would be a waste of healthcare resources and delay timely care to patients to separate epidural injections into “diagnostic” and “therapeutic” phases.

- With respect to frequency, there is no good evidence to support that there must be at least a 2-month period between epidural injections.

Coverage Determination of Facet Joint Injections/Medial Branch Blocks (Pages 8-10)

- We recommend that the absence of radiculopathy should be excluded when recommending intra-articular facet joint injections and/or medial branch blocks because patients may often have more than one spinal pathology or condition co-existing simultaneously, which at times, may overlap in clinical presentation.

- As mentioned above in the coverage determination of epidural injections, we recommend coverage for procedures following a minimum of 4 weeks of failed conservative therapy rather than 3 months.

- In regard to the coverage determinations for both diagnostic and therapeutic facet joint injections/medial branch blocks, we strongly recommend that Humana follow the criteria set forth by the North American Spine Society’s coverage policy recommendations on facet joint interventions (please see attached).
Coverage Determination of Sacroiliac Joint Injections (Pages 11-13)

- As previously mentioned, we recommend coverage for procedures following a minimum of 4 weeks of failed conservative therapy rather than 3 months.
- In regard to the coverage policies for both diagnostic and therapeutic sacroiliac joint injections, we strongly recommend that Humana follow the criteria set forth by the North American Spine Society's coverage policy recommendations on sacroiliac joint interventions (please see attached).

The above recommendations and suggestions are consistent with the North American Spine Society's coverage policy recommendations, endorsed by the Spine Intervention Society, concerning cervical and lumbar epidural injections, sacroiliac joint injections, as well as facet joint interventions recommendations. The coverage policies’ recommendations (please see attached) 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.

Coverage Determination of Trigger Point Injections (Page 13-14)

- We strongly disagree that patients be required to undergo 3 months of conservative treatment prior to undergoing trigger point injection(s). This timeline is not supported by the literature and standard practice. When a patient’s history and physical exam are consistent with the clinical signs and features of a diagnosis of trigger points, then trigger point injections should be considered as a first line treatment and/or when noninvasive medical management (which includes but is not limited to, rest, systemic medications, activity modification, and/or physical therapy) is not successful. Please see the Medicare Pain Management LCD L28529 (Indications and Limitations for Specific Types of Injections: Trigger Point Injections) at https://apps.ngsmedicare.com/lcd/LCD_L28529.htm.
- There is no diagnostic phase for trigger point injections. Trigger point injections provide therapeutic relief of irritable trigger points in specific muscles.
- We disagree that trigger point injections with ultrasound guidance for needle placement is considered not medically necessary. There are certain situations when this easily available, dynamic, non-radiation-exposing imaging modality may be used to avoid injury near vital organs (for example, lung) and/or neurovascular bundles for trigger point injections such as the intercostal or anterior cervical muscles, respectively. Or it may be used if a specific muscle needs to be targeted that otherwise would not be easily differentiated and/or accessed by palpation alone (for example, upper trapezius versus levator scapulae muscles or a deeper muscles such as the subscapularis).

We hope that this information, as well as any dialogue and collaboration between Humana and the Spine Intervention Society, will lead to the establishment of a stronger, evidence-based and reasonable policy coverage program 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
Facet Joint Interventions
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, glutal 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.
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, 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 diagnose pain 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.
Intervention 4: Therapeutic Intraarticular Zygapophysial 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, periroyal 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 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. 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, 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.

While the rate of false positives is lower with dual blocks, some have suggested that this practice is neither necessary nor cost effective. 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. Placebo controls have also been advocated to further improve the specificity of MBBs. 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. 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. 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. 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. 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 trials 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. 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. There have been no studies that compare the ef-
fectiveness 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 transforaminal 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 use of IA Z-joint injections is thus reserved for those cases where MBBs are not anatomically possible, as is the case with occipitoatlantal and atlantoaxial joints.

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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.

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.
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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Facet Joint Interventions

Disclosure Key

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intervention Society (Treasurer), Association of Academic Physiatrists (Board of Directors - Chair of Membership Committee).
Kreiner, Scott: Stock Ownership: LDR Holdings (1%); Speaking and/or Teaching Arrangements: North American Spine Society (Travel expenses.); Trips/Travel: ISIS (Travel expenses).
Lapinsky, Anthony S.: Nothing to disclose.
Lebl, Darren R.: Speaking and/or Teaching Arrangements: Medtronic (B); Scientific Advisory Board: K2M MIS Advisory Team (B).
Matz, Paul G.: Speaking and/or teaching arrangements: AO Spine North America (B).
Mayer, E. Kano A.: Speaking and/or Teaching Arrangements: North American Spine Society (Travel expenses); Trips/Travel: North American Spine Society (B); Research Support - Staff and/or Materials: S-Bone (B, Paid directly to institution/employer).
O’Brien, David R.: Stock Ownership: OrthoCarolina (<1%), Transformant Healthcare Solutions (<1%), Arrowlytics (<1%); Trips/Travel: North American Spine Society (B); Board of Directors: North American Spine Society (Health Policy Council Director); Speaking and/or Teaching Arrangements: SIS (Travel expenses).
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Reiter, Mitchell F.: Private Investments: CreOsso (4%).
Reitman, Charles A.: Trips/Travel: North American Spine Society (Travel expenses); Board of Directors: North American Spine Society (Research Council Director); Scientific Advisory Board: Clinical Orthopedics and Related Research (B, Deputy Editor, Paid directly to institution/employer).
Sanford, Timothy: Nothing to disclose.
Seldomridge, Alex: Nothing to disclose.
Sharan, Alok D.: Consulting: Paradigm Spine (B); Other: Jaypee Brothers (A).
Smuck, Matthew: Stock Ownership: NuSpine (1%), BlueJay Mobile-Health (1%); Private Investments: Vivametrica/Sikoya (20%, Founding partner); Trips/Travel: SIS (B), North American Spine Society (B); Board of Directors: Vivametrica/Sikoya (None), SIS (None), North American Spine Society (Stock options); Scientific Advisory Board: NuSpine (Stock options), Lumo Body Tech (Stock options), BlueJay Mobile-Health (Stock options); Other Office: The Spine Journal (Deputy Editor), SIS (Board of Directors), North American Spine Society (Board of Directors); Other: Expert witness - State Farm (F), Expert witness - Kaiser Permanente (C); Relationships Outside the One-Year Requirement: Cytonics, Inc. (Research Support: Staff and/or Materials, F, dissolves in 2011).
Summers, Jeffrey T.: Stock Ownership: NEVRO (1%); Board of Directors: First Choice Insurance (Representative for Pain Management), SIS (Board Member and Past President, Travel expenses).
Tontz, William L.: Device or Biologic Distributorship (Physician-Owned Distributorship): Aliphatic (A, Paid directly to institution/employer), Stock Ownership: Phygen (<1%, Paid directly to institution/employer); Consulting: Medtronic (B, Paid directly to institution/employer); Speaking and/or Teaching Arrangements: SpineArt (A); Trips/Travel: Stryker (B); Scientific Advisory Board: Medtronic (Consulting Disclosed Above).
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Truumees, Eeric: Royalties: Stryker Spine (B); Board of Directors: North American Spine Society (Administration and Development Council Director); Other Office: AAOS Communications Cabinet (Incoming Editor-in-Chief of AAOS Now, AAOS Communications Cabinet member, Travel expenses, Monthly stipend.); Research Support - Investigator Salary: Relievant (B, Paid directly to institution/employer); Relationships Outside the One-Year Requirement: Research Support - Staff and/or Materials: Globus (B, Paid directly to institution/employer, Dissolved 2013).

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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)
NASS Coverage
Policy Recommendations

North American Spine Society
7075 Veterans Boulevard
Burr Ridge, IL 60527
(630) 230-3600
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.1-5 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.1,2,14,15 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.2,6-13 However, other studies14-16 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.

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**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, i.e., 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 (e.g., 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 (e.g., 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 spondyloarthopathy, 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 sacroiliitis. Simopoulos concluded that MRI appears to be useful for early sacroiliitis and to follow patients with spondyloarthopathy. 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 studies3,11,14,16,17,22,23,34-40. 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.26 Hawkins (2009), in a retrospective audit of 155 patients, showed 77% of patients with short-term pain relief after one injection.31 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.5 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.28 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%).34 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.28

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.

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<th>Selection Based on Controlled Local Anesthetic Blocks</th>
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<td>At least 50% relief</td>
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<td>At least 50% relief</td>
<td>27%</td>
<td>20-34%</td>
<td>Irwin 2007</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

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Sacroiliac Joint Injections

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.

Author Disclosures

Baisden, Jamie L.: Nothing to Disclose.
Baker, Ray M.: Stock Ownership: Relievant (<1%); Private Investments: Nocimed (1.78%), Laurimed (<1%); Consulting: Medtronic (B), UnitedHealthcare (B), Mesoblast (B); Board of Directors: ISIS (Immediate Past President); Scientific Advisory Board: Collaborative Spine Research Foundation (Board Member), Spine-Health.com (B).
Biyani, Ashok: Royalties: Globus Medical (E), Custom Spine (C); Consulting: K2M (B).
Boakye, Maxwell: Nothing to Disclose.
Cho, Charles: Board of Directors: North American Spine Society (Evidence Compilation and Analysis Chair, Travel expenses); Other Office: American Society of Neuroradiology (Finance Management Committee Co-Chair).
Cowan, R.S.: Relationships Outside the One Year Requirement: LDR (A, dissolved 2010).
DePalma, Michael J.: Consulting: VertiFlex, Inc. (Amount not disclosed, Paid directly to institution/employer); Trips/Travel: Medtronic (Travel expenses); Board of Directors: ISIS (Travel expenses, Paid directly to institution/employer), Virginia Spine Research Institute, Inc. (Amount not disclosed, President and Director of Research, Paid directly to institution/employer); Scientific Advisory Board: Medtronic (Amount not disclosed), Halyard (Amount not disclosed, Paid directly to institution/employer); Research Support (Investigator Salary): Relievant (B, Paid directly to institution/employer), SI-Bone (B, Paid directly to institution/employer), Mesoblast, Inc. (B, Paid directly to institution/employer), VertiFlex (B, Paid directly to institution/employer); Research Support (Staff/Materials): Relievant (B, Paid directly to institution/employer), SI-Bone (B, Paid directly to institution/employer), Mesoblast (B, Paid directly to institution/employer), SI-Bone (B, Paid directly to institution/employer), VertiFlex (B, Paid directly to institution/employer); Relationships Outside the One Year Requirement: AOI Medical (None, dissolved 2010), Stryker Interventional Spine (B, dissolved 2010), St. Jude Medical (Amount not disclosed, dissolved 2010), Stryker Biotech (None, dissolved 2011), ATRM (None, dissolved 2011).
Dietze, Donald D.: Stock Ownership: Globus Medical (<1%; Paid directly to institution/employer); Consulting: Globus Medical (None, Paid directly to institution/employer).
Donelson, Ronald G.: Stock Ownership: Integrated Mechanical Care (4%); Consulting: The McKenzie Institute International (B); Other Office: Integrated Mechanical Care (Medical Director).
Easa, John E.: Stock Ownership: Janus Biotherapeutics (3%, Paid directly to institution/employer).

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Disclosure Key

Direct or indirect remuneration: royalties, stock ownership, private investments, consulting, speaking and/or teaching arrangements, trips/travel, support from sponsors: endowments, research-investigator salary, research-staff and/or materials, grants, fellowship support. Other

Comments

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Introduction
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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
Cervical epidural steroid injections (CESIs) and diagnostic spinal nerve blocks are commonly used to treat and evaluate patients suffering from various forms of neck and/or radicular pain. Therapeutic injections include interlaminar CESIs and transforaminal CESIs. Diagnostic injections include selective spinal nerve root blocks (SNRBs).

CESIs and SNRBs are indicated for the treatment and/or evaluation of radiculopathy or radicular pain. Suitable candidates may be treated with a maximum of 4 diagnostic and/or therapeutic injections within a 6 month period. Repeated therapeutic CESIs are only indicated in cases where there was a documented positive response with a previous CESI in treating that specific pain condition. All injections should be performed with fluoroscopic or computed tomography (CT) image guidance.

1. **CESIs**, either interlaminar or transforaminal, are indicated for the treatment of cervical radicular pain due to the following causes that meet the following criteria:
   a. Cervical disc herniations, disc protrusions, disc bulges (eg, disc osteophyte complexes), cervical spinal stenosis (central or foraminal stenosis) noted on an advanced imaging study (MRI or CT) that are consistent with and appear to be contributory to the patient’s symptoms.
   b. Failure of a course of supportive noninterventional care which can include observation, oral medications, physical therapy and/or activity modification

2. **Diagnostic SNRBs** are indicated in the evaluation and diagnostic work-up of radicular pain due to the following causes:
   a. Cervical disc herniations, disc protrusions, disc bulges (eg, disc osteophyte complexes), cervical spinal stenosis (central or foraminal stenosis) noted on an advanced imaging study (MRI or CT) that are consistent with and appear to be contributory to the patient’s symptoms.

3. **Diagnostic SNRBs** are indicated in the evaluation and diagnostic work-up of radicular pain for the following scenarios:
   a. As a diagnostic modality in order to determine or confirm the (or most) symptomatic level (ie, site of compression) in presence of multi-level involvement for which the primary symptomatic level is unclear
   b. Radiculopathy without imaging evidence of compression to confirm or rule out a symptomatic level when clinical findings and imaging studies are discordant

**CESIs and SNRBs** are NOT indicated in the following scenarios:
1. Patients with nonspecific neck pain without arm or radicular pain (ie, isolated axial neck pain)
2. Clinical evidence of myelopathy from cervical spinal cord compression
3. Patients who already have failed a trial (1-2 injections) of therapeutic CESIs for a specific episode of radicular pain.
**Rationale**

**Item 1**

There is extensive worldwide experience with CESIs of local anesthetic and corticosteroid for the treatment of cervical radiculopathy and cervical radicular pain. Historically, the earliest reports of CESIs are from Europe in the mid-20th century, which documented its use for the treatment of so-called cervicobrachial neuralgias. Its use in North America began in the 1980s.¹⁻³

The proposed mechanism of efficacy of CESIs is related to the inflammation associated with cervical radiculopathy. It is postulated that corticosteroids reduce inflammation (and subsequently pain) through inhibition of the synthesis or release of proinflammatory substances. Additionally, corticosteroids have been shown to have a temporary local anesthetic effect.⁴

There are a number of systematic reviews and society guidelines that have examined the utility of CESIs. In their 2010 Guideline for The Treatment of Cervical Radicular Pain, the World Institute of Pain issued a positive recommendation for interlaminar cervical epidural steroid injections for the treatment of cervical radicular pain.⁵ A systematic review by Abdi et al⁶ found moderate evidence that both transforaminal and interlaminar cervical epidural steroid injections provided short and long-term relief from cervical radicular pain. A systematic review by Benyamin et al⁷ reported that interlaminar cervical epidural steroid injections provide a significant effect in relieving short and long-term cervical radicular pain and cervical radiculopathy. The North American Spine Society Clinical Guidelines for The Diagnosis and Treatment of Cervical Radiculopathy from Degenerative Disorders⁸ recommended consideration of transformaminal epidural steroid injections for the treatment of cervical radiculopathy due to degenerative disorders. A North American Spine Society Review and Recommendation Statement⁹ concluded that cervical epidural steroid injections provide relief from cervical radiculitis in 60% to 70% of patients, and relief is maintained for greater than one year.

CESIs have been demonstrated to be more effective than controls in a number of studies. Stav et al¹⁰ performed a randomized control trial that showed cervical interlaminar epidural injections of local anesthetic and corticosteroid were more effective than trigger point injections of local anesthetic and corticosteroid into the posterior neck muscles (ie, control) for the treatment of cervical radicular pain. One week after the last injection, good or very good pain relief was reported in 76% of the epidural group versus 35.2% of the control group. One year after injection, good or very good relief was noted in 68% of the PCSI group versus 11.8% in the control group. At both one week and one year, the epidural group had statistically significant greater pain relief, recovery of capacity for work, and decreased daily consumption of analgesics compared to controls.

Dreyfuss et al¹¹ performed a randomized control trial comparing cervical transformaminal injections performed with dexamethasone or triamcinolone for the treatment of cervical radicular pain. At 4 weeks both groups had statistically and clinically significant improvements. There was no significant difference in cervical radicular pain between the two groups. There was, however, a strong correlation between pain relief and restoration of daily activities in the triamcinolone group that was not found in the group treated with dexamethasone.

Some studies have compared the results of CESIs and surgery for cervical radiculopathy. Lee et al¹² performed a prospective outcome study on 98 patients with cervical radiculopathy who were considered to be surgical candidates. All patients underwent a transformaminal and interlaminar cervical injection of steroid and local anesthetic. Seventy-nine of the patients (80.6%) avoided surgery at an average follow-up of 40.4 months after having undergone an average of 1.8 cervical injections (Group 1). Nineteen patients (19.4%) ultimately underwent surgery (Group 2). At final follow-up, there were no statistically significant differences in the Visual Analog Scale score for arm pain, the proportion of patients with a good or excellent Odom’s criteria score, or the average Neck Disability Index between Groups 1 and 2. Of note, however, statistically significant prognostic factors favoring surgery were previous episodes of cervical radiculopathy and greater intensity of arm pain before and after the cervical epidural steroid injection. There were no radiographic differences between the two groups, such as location of compression, grade of degeneration, and soft-to-hard disc ratio.

**Items 2 and 3**

The rationale for coverage of diagnostic selective nerve root blocks in patients with cervical radicular pain is that multilevel equivocal pathology may appear on cervical spine imaging studies. Positive findings on cervical MRI scans are known to occur in asymptomatic patients, and it is accepted that mechanical compression is not always associated with cervical radicular pain.¹³ Diagnostic cervical selective nerve root blocks provide additional information regarding the nerve root(s) responsible for the radicular pain. Sasso et al¹⁴ analyzed results of diagnostic SNRBs in 101 patients who underwent lumbar or cervical decompression for radiculopathy.
and compared to surgical outcome one year postoperatively. A comparison of surgical outcomes was examined between magnetic resonance imaging (MRI) and SNRB results. Ninety-one percent of the patients with a positive SNRB had good surgical outcomes, versus 60% of the patients with a negative SNRB. Of the patients with a positive MRI result, 87% had good surgical outcomes, whereas a similar percentage of the patients with a negative MRI (85%) had good surgical outcomes. When findings between SNRB and MRI differed (n = 20), surgery at the level consistent with the SNRB was more strongly associated with a good surgical outcome. Of the patients with a poor surgical outcome, surgery was most often performed at a level inconsistent with the SNRB finding. They concluded that a diagnostic SNRB can safely and accurately discern the presence or absence of cervical or lumbar radicular pain. A diagnostic SNRB can dissuade surgeons from operating on an initially suspicious, but incorrect, level of radiculopathy. When MRI findings are equivocal, present at multiple levels, or discordant with the patient’s symptoms, the result of a negative diagnostic SNRB is useful in predicting the absence of an offending (symptomatic) lesion.

Anderberg et al\textsuperscript{15} studied 30 consecutive patients with cervical radiculopathy and ipsilateral two-level MRI degeneration. Patients underwent diagnostic selective nerve blocks at both levels. Correlation between selective nerve root block results and the level with the most severe MRI degeneration was 60%. Correlation between the selective nerve root block results and the clinical findings was 28%. Twenty-two of the 30 patients were treated either surgically or with transforaminal epidural steroid injections on the basis of the diagnostic selective nerve root blocks. A good to excellent outcome was reported in 18 of the 22 treated patients.

Diagnostic selective nerve root block may be considered to determine the association between unilateral headache and ipsilateral pain in the neck, shoulder, and arm (cervical radicular pain). A prospective cohort of 161 patients with cervical radicular pain and corresponding degenerative MRI changes occurring in association with ipsilateral unilateral headache underwent a diagnostic selective nerve root block. There was a significant correlation (P < 0.0001) between reduction of headache pain and cervical radiculopathy. Of the 161 patients, 93 had greater than 50% relief from their headache; and 61 had 100% relief from their headache.\textsuperscript{16}

The North American Spine Society Clinical Guidelines for The Diagnosis and Treatment of Cervical Radiculopathy from Degenerative Disorders recommends consideration of diagnostic selective nerve root blocks with specific dosing and technique protocols in the evaluation of patients with compressive lesions at multiple levels on imaging studies.\textsuperscript{8} Additionally, selective nerve root block may be considered to confirm a symptomatic level in patients with discordant clinical symptoms and imaging findings.

References

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**Financial Statement**

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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.

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Cervical Epidural Injections and Diagnostic Spinal Nerve Blocks

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Lumbar Epidural Injections

DEFINING APPROPRIATE COVERAGE POSITIONS
Introduction
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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 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. There is sufficient 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.

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 isthmic. There is literature to suggest that ESIs are effective in reducing pain in this patient population though this treatment seems to be less effective in this group than in patients with herniated discs. In addition, there is data that shows that the injection of epidural steroid is equivalent to epidural local anesthetic. It should be noted that epidural injection of local anesthetic has been clearly demonstrated to be more effective than a placebo. 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 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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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.

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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.
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Degree of support:

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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.

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Diagnosis and Treatment of Lumbar Disc Herniation with Radiculopathy
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Diagnosis and Treatment of Degenerative Lumbar Spinal Stenosis (Revised 2011)
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