Minimally Invasive Sacroiliac Joint Fusion

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DEFINING APPROPRIATE COVERAGE POSITIONS

North American Spine Society 7075 Veterans Blvd. Burr Ridge, IL 60527
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COVERAGE COMMITTEE

NASS Coverage Policy Recommendations

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7075 Veterans Boulevard
Burr Ridge, IL 60527 USA
(630) 230-3600
www.spine.org

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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 October 24, 2019; information and data available after October 24, 2019, 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 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

Low back pain (LBP) is the leading cause of global disability.[1] The sacroiliac joint (SIJ) represents a specific and identifiable cause of LBP. The SIJ is the cause of chronic LBP in 15-30% of patients, with a higher prevalence in older patients, those with a history of lumbosacral fusion, trauma, spondyloarthropathy, and/or maximal pain below the L5 vertebra.[2-14] Although no single physical exam maneuver has a high predictive value for diagnosing SIJ pain[2,15,16] the following criteria predict a positive response to a diagnostic intra-articular anesthetic block in 70-80% of patients: maximal pain below L5 and positive findings on at least 3 of 6 provocation tests (1. Patrick's or FABER, 2. Gaenslen, 3. thigh thrust, 4. sacral thrust, 5. distraction, 6. compression).[17-20] With the exception of acute inflammatory sacroiliitis or advanced arthritis, most patients will not demonstrate imaging abnormalities.[21] The reference standard for the diagnosis of SIJ pain remains a positive response to a fluoroscopically-guided intra-articular injection of local anesthetic.

Fusion of the SIJ was initially described as a treatment option in 1925. Given the depth and anatomic location of the SIJ, significant morbidity was associated with open fusion approaches and limited usage of these procedures. Over the past few decades, techniques utilizing trans-iliac approaches to fuse the SIJ have been developed. Minimally invasive technology has been applied to these approaches and has resulted in the development of minimally invasive SIJ fusion procedures in recent years. This Coverage Recommendation is limited to the insertion of, usually more than one, structural device traversing the SIJ intended to fuse to the bone or lead to the fusion of the joint itself.

Minimally invasive SIJ fusion is indicated for the treatment of SIJ pain for patients with low back/buttock pain who meet ALL of the following criteria:

1. Have undergone and failed a minimum 6 months of intensive nonoperative treatment that must include medication optimization, activity modification, and active therapeutic exercise targeted at the lumbar spine, pelvis, SIJ and hip including a home exercise program.
2. Patient's report of nonradicular, typically unilateral, pain that is maximal below the L5 vertebrae, localized over the posterior SIJ, and consistent with SIJ pain.

3. A physical examination typically 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) or the absence of tenderness elsewhere (eg, greater trochanter, lumbar spine, coccyx) that would explain the patient's symptoms.

4. Positive response to a cluster of at least 3 provocative tests (1. Patrick's or FABER, 2. Gaenslen, 3. thigh thrust, 4. sacral thrust, 5. distraction, 6. compression). Note that the thrust tests may not be recommended in pregnant patients or those with connective tissue disorders.

5. Absence of generalized pain behavior (eg, somatoform disorder) or generalized pain disorders (eg, fibromyalgia).

6. At least 75% reduction of pain, documented by pain diary, for the expected duration of the anesthetic used following an image-guided, contrast-enhanced intra-articular SIJ injection on 2 separate occasions.

7. A trial of at least one therapeutic intra-articular SIJ injection (ie, corticosteroid injection). Please see *NASS Coverage Policy Recommendation Sacroiliac Joint Injections and Radiofrequency Ablation*.[22]

8. Diagnostic imaging studies that include ALL of the following:

    a. Imaging (plain radiographs and a CT or MRI) of the SIJ that excludes the presence of destructive lesions (eg, tumor, infection) or autoimmune arthropathy that would not be properly addressed by percutaneous SIJ fusion.

    b. Imaging of the pelvis (AP plain radiograph) to rule out concomitant hip pathology that would better explain the patient's symptoms.

    c. Imaging of the lumbar spine (CT or MRI) to rule out neural compression or other degenerative condition that, in combination with the patient's history, physical, and other testing would more likely be the source of their low back or buttock pain.

Minimally invasive SIJ fusion for SIJ pain is **NOT** indicated in ANY of the following scenarios:

1. Any case that does not fulfill ALL of the above criteria.

2. Presence of systemic arthropathy such as ankylosing spondylitis or rheumatoid arthritis.

3. Presence of generalized pain behavior (eg, somatoform disorder) or generalized pain disorder (eg, fibromyalgia).

4. Presence of infection or tumor.

Coverage Recommendation

The NASS Coverage Committee recommends coverage for minimally invasive SIJ fusions when **all** 8 criteria have been met. Minimally invasive SIJ Fusions have been shown to be relatively safe[23-27] with a minimal EBL, low infection rate, low complication rate, and low revision surgery rates.[28] Much of the literature is subjected to potential bias since there is a high rate of industry sponsored data, however, multiple SIJ fusion devices have shown similar results.[29] The clinical efficacy for SIJ Fusion in appropriately selected patients has been shown to be more effective than nonoperative care and more cost effective.

Rational for Coverage Recommendations

Patient Selection: The challenges associated with identifying patients with SIJ pain by history and physical exam alone has been well studied.[30] No single historical finding is diagnostic of SIJ pain, but the following are common: unilateral pain, maximal pain below the L5 vertebrae, pain aggravated with sitting and transitions from sitting to standing, history of trauma, referred pain to the buttock, groin, thigh and occasionally below the knee.[3] The utility of physical exam findings has been more extensively evaluated in multiple studies, reviews and meta-analyses.[2,17-21,31-34] Studies agree that no single physical exam maneuver is reliable for diagnosis of SIJ pain[2,17-21], but a combination of provocative maneuvers can achieve a PPV of 70-80% for predicting at least a 50% improvement on a diagnostic intra-articular SIJ injection.[17,19,21,35] No combination of tests can predict an 80% or greater response.[2,34] History and physical exam cannot effectively differentiate between pain from the SIJ itself versus pain from the dorsal ligaments or both.[36] Based on the available evidence, it is reasonable to select patients for all types of diagnostic SIJ procedures on the basis of having maximal pain below the L5 vertebrae and at least 3 positive provocation maneuvers (1. Patrick's or FABER, 2. Gaenslen, 3. thigh thrust, 4. sacral thrust, 5. distraction, 6. compression) and lack of a better explanation for symptoms (eg, discogenic and/or radicular pain).[17-21,32,37,38]

Value of Radiographic Findings: While various imaging modalities can identify structural abnormalities of the SIJ, imaging abnormalities are not needed for a diagnosis of SIJ pain or for responsiveness to SIJ injections.[39] Plain radiographs and CT can identify late stage sacroiliitis or SIJ arthropathy. A positive bone scan can increase the likelihood that the SIJ is the source of pain, but a negative bone scan does not reduce the probability.[21] An MRI is more sensitive than bone scan or plain radiographs for early detection of sacroiliitis and may be useful for monitoring treatment response in patients with inflammatory spondyloarthropathy.[37,40,41] However, in the nonspondyloarthropathy population that makes up the vast majority of patients with LBP, neither MRI, nor any other imaging modality, has proven better than clinical selection to predict responsiveness to diagnostic SIJ injections. Furthermore, imaging findings have not been shown to be better than diagnostic injections for predicting responsiveness to therapeutic SIJ procedures. Thus, imaging is considered to 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: History, physical exam and imaging studies are inadequate for confirmation of SIJ pain[31], at least in patients without spondyloarthropathy. Multiple studies and reviews have evaluated the utility of single and dual anesthetic blocks for the diagnosis of SIJ pain.[15,17,19,31-32,36-37,42,43] A single SIJ injection of anesthetic, with or without steroid, carries with it a false positive rate of 20-54%.[15,17,31,44] Due to the high false positive rates from a single injection and relatively low prevalence of SIJ pain, true confirmation of SIJ pain requires at least 75% improvement using comparative anesthetic blocks. While many of the studies on SIJ fusion have relied on 50% relief from a single diagnostic block as an indicator for fusion,[45-50] it is known that relaxing positive anesthetic block criteria from 75% down to 50% will significantly increase the observed prevalence of SIJ pain and increase treatment failures.

Minimally Invasive Fusion: Lorio and Rashbaum[29] reviewed minimally invasive SIJ fusions with different implants and different approaches and overall identified a high success rate with improved validated outcome scores, low revision rates, and low adverse events.

A systematic review and meta-analysis by Lingutla et al[43] revealed statistical and clinical improvement in all outcomes: VAS pain, SF-36 ODI, and Majeed scores with a mean follow up of 17.6 months using MIS and open techniques in both

prospective and retrospective fashion using a variety of surgical approaches. In total 276 studies were identified in this review and after strict inclusion strategies, 6 studies were included in the meta-analysis for a total of 407 patients.

A multicenter study using both open and minimally invasive SIJ fusions compiled data on 263 patients: 149 were treated with open SIJF and 114 patients with MIS SIJ fusion. The MIS patients on average were 10 years older than the open SIJF, but the MIS Group showed statistically significant improvement in operative EBL, operative time, and lower length of hospitalization. VAS scores at 12 months postoperative were 3.5 points lower in the MIS vs open SIJ fusion groups. Compared to open SIJ fusion, MIS SIJ fusion had significantly better pain relief and improved perioperative outcome measures.[51]

David Polly et al[49] looked at the 2-year randomized control trial of MIS SIJF compared to nonoperative management for a SIJ dysfunction. They determined that MIS SIJF with triangular titanium implants had a larger improvement in pain disability and quality of life compared to those treated nonoperatively, and that the improvements persisted to 24 months.[49]

A systematic literature review by Zaidi et al[28] found for MIS patients near 84% had excellent outcomes, reoperation rate was near 6% for MIS vs near 15% for open SIJ, with a major complication rate of 5-20% in the MIS group as compared to the open group.

Shamrock et al [27] reviewed 14 studies with 720 patients. A total of 99 patients had bilateral MIS SIJF. A surgical complication rate of 11.11% was identified with 25 adverse events due to implant placement (3.05%) with nerve root impingement being the most commonly observed device related complication.

MIS SIJ fusion was found to be cost effective compared to nonsurgical treatment. Cher et al[52] used data from 2 prospective RCT and looked to 5-year health quality and costs after MIS SIJF triangular titanium implants. MIS SIJF provided potential cost savings/quality gained compared to nonsurgical treatment after a treatment period of greater than 13 years.

Conclusion

Overall MIS SIJF in properly selected patients, despite a difficult diagnosis or selection effort, has shown clinical improvement, improved QOL, relatively safe and cost-effective treatment for long-term strategy in the treatment of SIJ pain and dysfunction.

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Authors

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Baisden, Jamie: Other: ASIA (Nonfinancial, Surgery Committee), Globus Medical (A, Outside 12-Month Requirement), LSRS (None, Membership Committee), SI-BONE (A, Outside 12-Month Requirement); Trips/Travel: Synthes (A, Outside 12-Month Requirement).

Blasier, R. Dale: Other: AAOS (Travel Expense Reimbursement, Member of Committee on Coding, Coverage and Reimbursement).

Bono, Christopher M.: Consulting: United Health Care (B); Other: The Spine Journal (NASS) (F); Royalties: Elsevier (B), Wolters Kluwer (A).

Bydon, Mohamad : Nothing to Disclose

Cowan, R. Scott: Speaking and/or Teaching Arrangements: LDR (A, Outside 12-Month Requirement), LDR (A, Outside 12-Month Requirement), LDR (A, Outside 12-Month Requirement), LDR (A, Outside 12-Month Requirement).
Dazley, Justin M.: Consulting: Clariance (C).
Dietze, Donald: Consulting: Joimax Spine (Future Compensation Expected), Osseus Fixation Devices (B).
Easa, John E: Nothing to Disclose
Friedrich, Jason: Consulting: MCG Health (B, Outside 12-Month Requirement).
Ghiselli, Gary: Board of Directors: Colorado Orthopedic Society (None); Consulting: Johnson & Johnson (C); Device or Biologic Distribution Group (Physician-Owned Distributorship): Impulse Neuromonitoring, Neurointerpretive Services (E), New Era Orthopedics (B).
Glaser, John A.: Nothing to Disclose
Haring, Sterling: Scientific Advisory Board: Centers For Disease Control And Prevention (A); Trips/Travel: American Association Of Medical Colleges (Travel Expense Reimbursement, Outside 12-Month Requirement).
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Hullinger, Heidi M.: Trips/Travel: AAOS (Travel Expense Reimbursement, Delegate to AMA).
Hwang, Steven W.: Board of Directors: Ronald McDonald House (None); Consulting: NuVasive (C); Speaking and/or Teaching Arrangements: Zimmer Biomet (C); Stock Ownership: Auctus (7.50%); Trips/Travel: NASS (A).
Kennedy, D.J.: Board of Directors: AAPM&R (Nonfinancial, Member at Large), Spine Intervention Society (Nonfinancial, Member at Large); Consulting: State Farm Auto Insurance (B); Speaking and/or Teaching Arrangements: Spine Intervention Society (Travel Expense Reimbursement); Trips/Travel: AAPM&R (Travel Expense Reimbursement), Spine Intervention Society (Travel Expense Reimbursement).
Khalsa, Kevin: Nothing to Disclose
Kreiner, Scott: Research Support (Staff and/or materials): Abbott (Future Compensation Expected, Paid directly to institution/employer); Speaking and/or Teaching Arrangements: Spine Intervention Society (Travel Expense Reimbursement).
Krishnaney, Ajit A.: Consulting: Stryker (C).
Lapinsky, Anthony S.: Device or Biologic Distribution Group (Physician-Owned Distributorship): RTI Surgical (C).
Massey, Michael : Nothing to Disclose
Matz, Paul G.: Consulting: Norcal Mutual Insurance Company (B); Private Investments: Alumni Ventures Group (F, It is a blind trust. A power-of-attorney is signed by me so that the fiduciaries of the investment fund do the vetting and investing.).
Mayer, E. Kano A.: Consulting: Turning Point (Future Compensation Expected); Other: Wharton, Levin, Ehrmantraut & Klein, P.A (B, Outside 12 month Requirement); Private Investments: Lanai Health Solutions (30.00%); Speaking and/or Teaching Arrangements: North America Spine Society (B); Stock Ownership: Infinite Orthopedics (1%); Trips/Travel: AMA (Travel Expense Reimbursement).
O'Brien, David Reese: Nothing to Disclose
Panchal, Sunil J.: Speaking and/or Teaching Arrangements: RTI (B), Stimwave (B).
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Reitman, Charles A.: Board of Directors: NASS (Travel Expense Reimbursement); Other: NASS (Nonfinancial, Committeee leadership); Scientific Advisory Board: Clinical Orthopaedics And Related Research (B, Paid directly to institution/employer).
Sanford, Timothy : Nothing to Disclose
Schneider, Byron J.: Consulting: AIM Specialty (B), State Farm (C); Grants: SIS (E, Paid directly to institution/employer); Speaking and/or Teaching Arrangements: AAPM (Travel Expense Reimbursement), NASS (A, Travel, Reimbursement, and Honorarium for speaking/teaching).
Sharma, Sunny : Nothing to Disclose
Smuck, Matthew: Board of Directors: Spine Intervention Society (None); Consulting: Consultant & expert witness - State Farm (F), Spine Biopharma (Future Compensation Expected); Grants: Relievant Medsystems (F, Paid directly to institution/employer), ReWalk (E, Paid directly to institution/employer); Private Investments: Vivametrica (15.00%); Scientific Advisory Board: BlueJay Mobile-Health (Stock options), NuSpine (Stock options); Stock Ownership: BlueJay Mobile-Health (<1%), NuSpine (<1%); Trips/Travel: Spine Intervention Society, Board of Directors (B, Travel Expenses).
Summers, Jeffrey T.: Consulting: First Choice (A, Paid directly to institution/employer), Newsouth Neurospine (A, Paid directly to institution/employer); Other Office: Biomerieux (Salary, Family Relationship); Trips/Travel: SIS (A, Travel Expense Reimbursement).
Tontz, William L.: Nothing to Disclose

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.*

Truumees, Eeric: Board of Directors: Seton Family of Doctors (None); Other Office: AAOS (Editor-in-Chief of AAOS Now); Research Support (Staff and/or materials): Medtronic (C, Paid directly to institution/employer), Pfizer (E, Outside 12-Month Requirement, Paid directly to institution/employer), Relievant (F, Paid directly to institution/employer), Seikagaku Corporation (C, Paid directly to institution/employer), Stryker Spine (B, Outside 12-Month Requirement, Paid directly to institution/employer), Vertex Pharma (D, Outside 12-Month Requirement, Paid directly to institution/employer); Trips/Travel: AAOS (Travel Reimbursement (B).
Xu, Thomas H.: Trips/Travel: Nevro (A).

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.