Washington State Health Care Authority

Health Technology Clinical Committee

Date: June 18, 2021
Time: 8:00 a.m. – 12:30 p.m.
Location: Zoom webinar
Adopted: Pending

Meeting materials and transcript are available on the **HTA website.**

HTCC Minutes

Members present: Larry Birger, MD; John Bramhall, MD, PhD; Clinton Daniels, DC, MS; Janna Friedly, MD; Conor Kleweno, MD; Chris Hearne, DNP, MPH; Christoph Lee, MD, MS, MBA; Laurie Mischley, ND, MPH, PhD; Sheila Rege, MD; Mika Sinanan, MD, PhD; Tony Yen, MD

Clinical expert: Randall M. Chesnut, MD

HTCC Formal Action

1. **Call to order:** Dr. Rege, chair, called the meeting to order; members present constituted a quorum.
2. **HTA program updates:** Josh Morse, program director, presented HTCC meeting protocols and guidelines, a high-level overview of the HTA program, how to participate in the HTCC process, and upcoming topics.
3. **Previous meeting business:**

   November 20, 2020 meeting minutes: Draft minutes reviewed. Motion made and seconded to approve the minutes as written.

   Action: Seven committee members approved the November 20, 2020 meeting minutes. Four members abstained.
4. **Sacroiliac joint fusion: rereview 2021:**

   Clinical expert: The chair introduced Randall Chesnut, MD, Professor, Department of Neurological Surgery, University of Washington Harborview Medical Center; Joint Professor, Dept of Orthopaedics and Sports Medicine, University of Washington Harborview Medical Center; Integra Endowed Professor of Neurotrauma, Department of Neurological Surgery, University of Washington Harborview Medical Center, University of Washington, Seattle, WA.

   Agency utilization and outcomes: Emily Transue, MD, MHA, Medical Director, Employee and Retiree Benefits, Health Care Authority, presented the state agency perspective on the sacroiliac joint fusion rereview 2021. Find the full presentation published with the June 18 meeting materials.

   Scheduled and open public comments: Chair called for public comments. Comments were provided by:

   - Peter Ameglio, MD, Ameglio Orthopedics, Fort Meyers, FL
   - Thomas Flory, Executive Director North Corner Neurosurgical Associates, Bellingham, WA

- Roland Kent, MD, Axis Spine Center, Post Falls, ID
- Morgan Lorio, MD, Orthopaedic and Laser Spine Surgery, Fort Myers, FL
- David Polly, Jr, MD, University of Minnesota, Minneapolis, MN
- Cheri Sommers, ARNP, Multicare, Spokane, WA

Vendor report/HTCC question and answers: Leila Kahwati, MD, MPH, Research Triangle Institute, Inc. presented the evidence review for Sacroiliac Joint Fusion. Find the full presentation published with the June 18 meeting materials.

HTCC coverage vote and formal action:

Committee decision

Based on the deliberations of key health outcomes the committee decided that it had the most complete information: a comprehensive and current evidence report with updated literature since 2018, public comments, and state agency utilization information. The committee decided that the current evidence on sacroiliac joint fusion was sufficient to make a determination, discussed and voted on the evidence for the use of sacroiliac joint fusion. The committee considered the evidence, public comment and expert input, and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Based on these findings, the committee voted to not cover minimally invasive or open sacroiliac joint fusion for sacroiliac chronic joint pain related to degenerative sacroiliitis and/or sacroiliac joint dysfunction for adults 18 years old and older. One committee member recused himself from the vote.

	Not covered	Covered under certain conditions	Covered unconditionally
Sacroiliac joint fusion	10	0	0

Discussion

The committee reviewed and discussed the available studies for use of sacroiliac joint fusion for chronic sacroiliac joint pain related to degenerative sacroiliitis and/or sacroiliac joint dysfunction. Details of study design, inclusion criteria, outcomes and other factors affecting study quality were discussed. A majority of committee members found the evidence sufficient to determine that use of sacroiliac joint fusion for chronic sacroiliac joint pain related to degenerative sacroiliitis and/or sacroiliac joint dysfunction to be unproven for being safer, more effective, or more cost-effective than comparators.

Limitations

N/A

Action

The committee checked for availability of a Centers for Medicare and Medicaid Services (CMS) national coverage decision (NCD). There is no Medicare NCD for sacroiliac joint fusion for sacroiliac joint pain

related to degenerative sacroiliitis and/or sacroiliac joint dysfunction at this time.

The committee discussed clinical guidelines identified for sacroiliac joint fusion from the following organizations:

- AIM Specialty Health *Musculoskeletal Program Clinical Appropriateness Guidelines: Sacroiliac Joint Fusion,* (2020)
- eviCore *Clinical Guidelines Spine Surgery,* (2020)
- International Society for the Advancement of Spine Surgery *International Society for the Advancement of Spine Surgery Policy 2020 Update—Minimally Invasive Surgical Sacroiliac Joint Fusion (for Chronic Sacroiliac Joint Pain): Coverage Indications, Limitations, and Medical Necessity,* (2020)
- North American Spine Society (NASS) *Diagnosis and Treatment of Low Back Pain,* (2020)
- National Institute for Health and Care Excellence (NICE) *iFuse for treating chronic sacroiliac joint pain,* (2018)
- National Institute for Health and Care Excellence (NICE) *Minimally invasive sacroiliac joint fusion surgery for chronic sacroiliac pain - Intervention Procedure Guidance 578,* (2017)

The committee's determination is not consistent with the noted guidelines. The HTCC determination included consideration of local, clinical expert considerations related to the complexities of revision surgeries, concerns related to diffusion, and uncertainty of evidence for safety and cost-effectiveness. The quality of evidence assessment was either not performed or not reported for these guidelines.

The committee chair directed HTA staff to prepare a findings and decision document on use of sacroiliac joint fusion for public comment to be followed by consideration for final approval at the next committee meeting.

Action

The chair directed agency staff to prepare a draft findings and decision for the sacroiliac joint fusion: rereview 2021 to be considered by the committee at the next meeting.

5. Meeting adjourned

Washington State Health Care Authority

Health Technology Clinical Committee
Findings and Decision

Topic: Sacroiliac joint fusion - rereview
Meeting date: June 18, 2021
Final adoption: **Pending**

Meeting materials and transcript are available on the HTA website.

Number and coverage topic:

20210618A – Sacroiliac joint fusion *

HTCC coverage determination:

In adults, 18 years old and older, with chronic sacroiliac joint pain related to degenerative sacroiliitis and/or sacroiliac joint dysfunction, minimally invasive and open sacroiliac joint fusion procedures are **not covered benefits.**

HTCC reimbursement determination:

Limitations of coverage: N/A

Non-covered indicators: N/A

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* The scope of this decision does not apply to the following:

- Low back pain of other etiology (e.g., radiculopathy, neurogenic claudication), sacroiliac joint pain related to recent major trauma or fracture, infection, cancer, or sacroiliitis associated with inflammatory arthropathies;
- Sacroiliac joint fusion revision surgery.

Agency contact information:

Agency	Phone Number
Labor and Industries	1-800-547-8367
Public and School Employees Health Plan	1-800-200-1004
Washington State Medicaid	1-800-562-3022

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Limitations

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Health Technology Clinical Committee Authority:

Washington State's legislature believes it is important to use a science-based, clinician-centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority (HCA), through its Health Technology Assessment (HTA) program, to engage in an evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company that takes public input at all stages.

Pursuant to RCW 70.14.110, a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State HTCC determines how selected health technologies are covered by several state agencies (RCW 70.14.080-140). These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases its decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Director.

Washington State Health Care Authority

Sacroiliac Joint Fusion: Rereview 2021

Draft findings and decision
Timeline, overview and comments

The Health Technology Assessment (HTA) program received comments in response to the posted Health Technology Clinical Committee (HTCC) draft findings and decision on Sacroiliac Joint Fusion: Rereview 2021.

Timeline

Phase	Date	Public Comment Days
Technology recommendations published	July 14, 2020	
Public comments	July 14 to July 28, 2020	**14**
Selected technologies published	August 11, 2020	
Public comments	August 11 to September 9, 2020	**30**
Draft key questions published	January 26, 2021	
Public comments	January 27 to February 11, 2021	**14**
Final key questions published	February 22, 2021	
Draft report published	April 2, 2021	
Public comments	April 2 to May 3, 2021	**32**
Final report published	May 19, 2021	
Public meeting	June 18, 2021	
Draft findings & decision published	June 23, 2021	
Public comments	June 23 to July 6, 2021	**14**
Total		**104**

Overview

Category	Comment Period June 23 to July 6, 2021	Cited Evidence
Patient, relative, and citizen	0	0
Legislator and public official	0	0
Health care professional	1	0
Industry & manufacturer	0	0
Professional society & advocacy organization	1	1
Total	**2**	**1**

Comments

		Respondents	Representing	Cited Evidence
☐	1.	Peter Ameglio, MD	Ameglio Orthopedics	No
☐	2.	Eeric Truumees, MD	President, North American Spine Society	Yes
		Christopher Kauffman, MD	Director, Health Policy Council	
		William Mitchell, MD	Chair, Payor Policy Review Committee	

From: Peter Ameglio <peter@peterameglio.com>
Sent: Friday, June 18, 2021 2:29 PM
To: Morse, Josiah (HCA) <josh.morse@hca.wa.gov>
Subject: Re: HTCC Meeting Comments

External Email

Dear Josiah:

Thank you very much for the opportunity to make a comment. I am a consultant for SI Bone. Sacroiliitis is a real diagnosis and it is not difficult to make. In my practice I inject the sacroiliac joint and can determine within 5 to 10 minutes whether the patient has sacroiliitis based on the response to the injection. Typically patients get a 90 to 100% response following the injection. Those patients that have that level of response see the same level of relief following the I fuse sacroiliac joint fusion. The relief is quick and lasting. The sacroiliac joint can mimic other conditions such as spinal stenosis, hip osteoarthritis. I have seen instances where patients that have a lumbar fusion or hip replacement continue with the same preoperative pain pattern because the initial diagnosis of sacroiliitis was missed. I have seen revision hip replacements done for sacroiliitis without any improvement of pain as expected. Patient's are also being treated with multiple injections to the spine, spinal cord stimulators, narcotics and continue with pain. Diagnosing and treating the primary source of pain is not only good for the patient's but also saves healthcare dollars.

kind regards,

Peter

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July 6, 2021

Washington HCA

Re: Sacroiliac Joint Fusion
PUBLC COMMENT PERIOD ENDING: July 6, 2021

Dear Washington HCA,

The North American Spine Society (NASS) is a global multidisciplinary medical organization dedicated to fostering the highest quality, evidence-based and value-based, ethical spine care by promoting education, research and advocacy. NASS is comprised of nearly 9,000 spine care providers from several disciplines including orthopedic surgery, neurosurgery, physiatry, neurology, radiology, anesthesiology, research and physical therapy.

NASS is aware that The Washington HCA recently announced a non-coverage decision for minimally invasive SIJ fusion for SIJ pain. As noted in the letter that NASS sent to the Washington HCA on January 4th, 2021, NASS has a positive coverage recommendation for this procedure. NASS has a robust evidence-based coverage recommendation process that is systematic and multidisciplinary. Our Minimally Invasive SIJ fusion coverage recommendation was recently updated and has now completed its public comment period. The revised document includes significant additional literature, including high level studies that have been published since the original 2015 NASS review. NASS's new coverage recommendation has incorporated the extensive recent literature and continues to endorse a positive coverage recommendation for percutaneous SIJ fusion with specific restrictions.

NASS was disappointed to see Washington HCA chose not to reference the NASS coverage recommendation in their decision and chose to instead reference NASS's Low Back Pain Guidelines. As mentioned in our previous letter, the NASS' evidence-based coverage recommendations have been developed with input from a multidisciplinary team of spine specialists that systematically reviews available scientific literature found by searching PubMed, EMBASE, Cochrane and other resources. These searches prioritize systematic reviews, meta-analyses, clinical guidelines and most importantly, randomized controlled trials. NASS reviewers are required to have training in evidence-based medicine and extensive precautions are taken to exclude reviewers with any conflicts of interest relevant to the topic. We hope this resource will be useful to you as you continue to develop and revise your coverage policies.

Based on our extensive review of all available literature on this topic, NASS feels that the minimally invasive SIJ fusion is indicated for the treatment of SIJ pain for patients with low back/buttock pain who meet the strict criteria noted in the attached coverage policy. The criteria include patients who have undergone and failed a minimum of six months of intensive non-operative treatment, have pain localized over the posterior SIJ, physical examination findings consistent with SIJ pain, and confirmation with two separate image-guided, contrast-enhanced SIJ injections that provide a minimum of a 75% reduction in their index pain. Additionally, patients should have absence of generalized pain behavior and have imaging of the SIJ and spine that exclude the presence of destructive pelvic lesions, hip osteoarthritis, or neural compression that would better explain the patient's pain. It is important to note that the procedure itself has proven to be relatively safe.

NASS hopes that Washington HCA will reconsider its decision not to cover percutaneous sacroiliac joint fusion for SIJ pain. NASS welcomes the opportunity to further elaborate on the comments provided herein and look forward to working with Washington HCA to improve patient outcomes and access to care. Please contact Shweta Trivedi, RHIA, Associate Executive Director of Health Policy at strivedi@spine.org if you have any questions or comments.

Sincerely,

Eeric Truumees, MD
President, North American Spine Society

Christopher Kauffman, MD
Director, Health Policy Council

William Mitchell, MD
Chair, Payor Policy Review Committee (PPRC)

Percutaneous Sacroiliac Joint Fusion

DEFINING APPROPRIATE COVERAGE POSITIONS

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

NASS Coverage Policy Recommendations

NASS Coverage Committee

North American Spine Society
Coverage Policy Recommendations
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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 4/10/2013; information and data available after 4/10/2013 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

While the reported incidence of pain arising from the sacroiliac joint (SIJ) varies depending on the diagnostic criteria utilized, the sacroiliac joint is an established source of chronic low back, buttock, groin, or lower extremity pain.[1, 2] Anatomic data has demonstrated nociceptive innervation of the sacroiliac joint by the dorsal rami of the distal lumbar nerve roots and the lateral branches of the sacral nerve roots. Pathologic conditions that may result in pain arising from the sacroiliac joint include degenerative and inflammatory arthritis, post-traumatic arthritis, post-partum instability, post-infectious arthritis, joint degeneration related to previous lumbar spinal fusion, joint damage from previous posterior iliac crest bone graft harvesting, and neoplastic processes affecting the sacroiliac joint.[3]

Studies have reported the source of chronic lower back and buttock pain is from disorders of the sacroiliac joint in 10% to 26% of cases.[4, 5] Unfortunately, there is no single clinical, imaging, or provocative test that definitively confirms the sacroiliac joint as a primary source of pain.[6] Physical examination should include a combination of several provocative maneuvers to help identify pain arising from the sacroiliac joint and exclude other sources of pain. Diagnostic imaging studies have not been shown to reliably predict pain arising from the SI joint, but are sometimes necessary to identify other pathologic conditions that may be the source of a patient's back pain. A critical step in confirming the sacroiliac joint as the source of pain involves diagnostic intra-articular injection of the sacroiliac joint with local anesthetic.[7] This must be performed under contrast-enhanced image guidance (fluoroscopy or CT) and with a relatively low volume (eg, 2mls) of injectate to minimize leakage onto surrounding structures. Intra-articular confirmation of contrast spread should be confirmed and hard copies or digital images saved in the medical records. A positive response is one in which a patient experiences a substantial reduction in his or her pain, defined as at least 75% pain reduction, while the anesthetic is in effect.[5,7] An hourly pain log should be kept by the patient and reviewed by the provider upon follow-up evaluation. The duration of pain relief should be consistent with the expected duration (ie, long-acting or short-acting) of the anesthetic used. The pain log should also be stored in the medical records. A negative response excludes an intra-articular source of sacroiliac pain. Due to a potential placebo effect, a second diagnostic injection is required to further confirm the diagnosis in patients who report substantial (albeit temporary) pain reduction from an initial injection.[8]

Previous work has evaluated the diagnostic validity of clusters of provocative maneuvers. One group recommended three specific criteria (developed by the International Association for the Study of Pain) for the diagnosis of SIJ pain.[9] From analysis of their data, one could reasonably support a diagnosis of SIJ-mediated pain in the presence of pain and tenderness with palpation of the sacral sulcus (Fortin's point), positive findings to a thrust test, compression test or 3 or more provocative tests (additionally including the Gaenslen test, Patrick test and compression test), and at least 50% pain reduction from diagnostic infiltration of the SIJ using contrast-enhanced anesthetic that lasts at least 1 to 4 hours on two separate occasions. Others have suggested that clusters of 3 or more different provocative maneuvers can be useful, but that the same 3 tests do not have to be used in all patients.[10,11] From these and other data, it seems reasonable to recommend that positive responses to 3 or more provocative tests be used as one of the diagnostic criteria to support the potential diagnosis of SIJ related pain. This information is important in determining which patients should proceed with a confirmatory, diagnostic SIJ injection.

Traditional care for the treatment of pain arising from the sacroiliac joint not due to an infectious or neoplastic process begins with

physical therapy and activity modification. Analgesic medication including NSAIDS, acetaminophen or opioids could be considered depending on each patient's medical history and symptom severity. Alternative treatments such as sacroiliac support belts and manual medicine may be considered as well. It is important to note that while these treatments are utilized routinely, no comparative effectiveness study has been published to establish their efficacy.

Fusion of the sacroiliac joint was initially described as a treatment option in 1925.[12] Given the depth and anatomic location of the SI joint, 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 sacroiliac joint have been developed. Minimally invasive technology has been applied to these approaches and has resulted in the development of percutaneous SIJ fusion procedures in recent years.

Percutaneous (also referred to as minimally invasive) SIJ fusion (eg, insertion of a metallic device across the SIJ that is intended to fuse to the bone or lead to fusion of the joint itself, in distinction from insertion of screws without bone graft across the SIJ which are intended to stabilize but not fuse the joint) 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, bracing and active therapeutic exercise targeted at the lumbar spine, pelvis, SIJ and hip including a home exercise program.
2. Patient's report of typically unilateral pain that is caudal to the lumbar spine (L5 vertebra), localized over the posterior SIJ, and consistent with SIJ pain.
3. 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.
4. Positive response to a cluster of 3 provocative tests (eg, thigh thrust test, compression test, Gaenslen's test, distraction test, Patrick's sign, posterior provocation test). *Note that the thrust test is not 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. Diagnostic imaging studies that include ALL of the following:
    a. Imaging (plain radiographs and a CT or MRI) of the SI joint that excludes the presence of destructive lesions (eg, tumor, infection) or inflammatory 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.
    c. Imaging of the lumbar spine (CT or MRI) to rule out neural compression or other degenerative condition that can be causing low back or buttock pain.
    d. Imaging of the SI joint that indicates evidence of injury and/or degeneration.
7. At least 75% reduction of pain for the expected duration of the anesthetic used following an image-guided, contrast-enhanced intra-articular SIJ injection on 2 separate occasions.
8. A trial of at least one therapeutic intra-articular SIJ injection (ie, corticosteroid injection).

Percutaneous 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, tumor, or fracture
5. Presence of acute, traumatic instability of the SIJ
6. Presence of neural compression as seen on an MRI or CT that correlates with the patient's symptoms or other more likely source for their pain.

Coverage Recommendations

Within the limits of a moderate body of evidence, the Coverage Committee **recommends coverage** for percutaneous SIJ fusion when the criteria outlined above are met. Due to the relatively moderate evidence, it is particularly critical that inclusion criteria are scrutinized and patient selection is executed with vigilance. The procedure itself has proven to be relatively safe. There is a valid concern for bias in that the overwhelming majority of the data produced so far has been industry-sponsored and generally composed of case

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

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series. However, some data on five-year outcomes demonstrate sustained benefit that does not appear to degrade from 1-year to 5-year time-points. The committee will revisit the quality of forthcoming evidence as it is produced in re-evaluations of the indications and coverage of this procedure.

Rationale

As percutaneous fusion techniques addressing the SIJ have become available, multiple clinical studies have evaluated the results of these procedures. A prospective study by Al-Khayer in 2008 reported results of nine patients undergoing percutaneous sacroiliac fusion using a hollow modular anchorage screw filled with demineralized bone matrix and local bone that was obtained during drilling.[13] The mean follow up was 40 months (range, 24 – 70 months). The mean ODI value dropped from 59 (range: 34 to 70) preoperatively to 45 (range: 28 to 60) postoperatively (P<0.005), which we would interpret as a modest clinical improvement. The mean VAS value also modestly dropped from 8.1 (range: 7 to 9) preoperatively to 4.6 (range: 3 to 7) postoperatively (P<0.002). All of the patients reported that they would have the procedure again given the same circumstances. The average estimated blood loss was less than 50 ml. There was one complication consisting of a deep wound infection that healed with debridement and intravenous antibiotics. At one-year follow up, no non-unions were identified on radiographs.

In 2009, Khurana prospectively reported on 15 consecutive patients treated with percutaneous fusion using hollow modular anchorage screws in combination with demineralized bone matrix.[14] The mean follow-up in this study was 17 months (range, 9 to 39 months). The mean SF-36 scores improved from 37 (23 to 51) to 80 (67 to 92) for physical function and from 53 (34 to 73) to 86 (70 to 98) for general health (p = 0.037). Thirteen of 15 patients reported "good to excellent" results. The authors reported that residual pain in these two patients was potentially due to concurrent lumbar pathology. The average estimated blood loss was less than 50ml and there were no complications. Fusion was obtained in all patients.

Wise and Dall published a prospective study in 2008 on 13 consecutive patients who underwent percutaneous SI fusion using threaded fusion cages filled with rhBMP-2.[15] The mean follow-up period for all 13 patients was 29.5 months (range, 24 to 35 months). Significant improvements were seen in final low back pain score on a visual analog scale with an average improvement of 4.9, (P<0.001). Leg pain improved an average of 2.4 points (P=0.013) and dyspareunia pain improved an average of 2.6 point (P=0.0028). The mean estimated blood loss was less than 100 ml; there were no infections or neurovascular complications. The overall fusion rate was 89% (17/19 joints) as assessed by postoperative CT scan obtained six months following the procedure. One patient was revised to an open arthrodesis secondary to nonunion and persistent pain.

In 2012, Rudolph reported a retrospective study of 50 consecutive patients who underwent percutaneous SI fusion using triangular, porous, plasma-coated, titanium implants.[16] The mean follow up was 40 months (range, 24 to 56 months). Outcomes were assessed using the SF-36 Health Survey and the Oswestry Disability Index. At the 3-, 6- and 12-month assessments, 78%, 85% and 71% of patients, respectively, had experienced clinically significant improvement in pain and function from this fusion procedure. At all postoperative assessments, significant improvements had occurred in the mean numerical rating scale scores of the functional assessment questionnaire for pain (P < 0.0001), light activities (P < 0.0001), moderate activities (P < 0.0001), vigorous activities (P = 0.0081), sleep (P < 0.0001), overall happiness (P = 0.0022) and pain effect on social interest (P < 0.0001). Satisfaction with this fusion procedure was reported by 91% of the patients at 3 months and 82% of the patients at 6 and 12 months.

There were 10 complications in Rudolph's series of 50 patients. Three patients had a superficial wound cellulitis that resolved following treatment with oral antibiotics. One patient developed a deep wound infection that was successfully treated with 6 weeks of intravenous antibiotics. Two patients had a large buttock hematoma that gradually resolved. Two patients had implant penetration of the sacral foramen discovered on postoperative CT scan associated with nerve root irritation and radicular pain without neurological deficits. In both cases the implants were retracted surgically with complete resolution of symptoms. In one patient an implant had been placed too cephalad resulting in L5 nerve compression. The implant was retracted surgically with complete resolution of symptoms. One patient had a nondisplaced fracture of the ilium adjacent to the sciatic notch at the edge of the lowest implant. The fracture healed without implant loosening. One late complication was reported. This involved recurrence of SI joint pain 3 years after surgery. CT scan identified that the 2 caudal implants were showing signs of motion and had been misplaced too posteriorly. Two additional implants were able to be placed anterior to the loosened implants with complete pain resolution.

Rudolf and Capobianco reported five-year outcomes of 17 patients.[17] It is unclear if these patients were part of the 2012 publication. In addition, it should be noted that there were a total of 21 consecutive patients, though only 17 were available for follow-up. One of

these patients was truly lost to follow-up, 2 had passed away and one had become quadriplegic after cervical trauma. The percentages of patients who achieved substantial clinical benefit were 77%, 82% and 88% at the 12-, 24- and 60-month time points. The authors used an unvalidated outcome score (termed SI joint survey instrument) which was comprised of parts of both the ODI and SF-36. Improvement was seen in 6 of 8 domains at final follow-up. Patient satisfaction was 82% at 1 and 5 years. Fusion was noted in 87% of cases. No intraoperative complications were noted, though the authors did report a case of hematoma, wound infection and 2 cases of cellulitis.

In 2012, McGuire retrospectively reviewed and reported on 37 consecutive patients treated with 38 minimally invasive elective SIJ fusions using dual fibular allografts filled with local autograft obtained during drilling.[18] Patients were followed-up for a mean of 52 months (range, 24–62 months). Visual Analog Scale (VAS) was used to monitor clinical pain improvement and fusion was deemed to be present when bone bridging trabeculae could be seen crossing the SIJ on either oblique X-rays or by computed tomographic scan. Thirty-four patients (89.5%) achieved a solid arthrodesis; this group had substantial improvement in mean VAS pain scores from preoperative 9.1 to postoperative 3.4 ($P < .001$). This improvement in VAS occurred over a 6-month period and was sustained with subsequent follow-up. Nonunion occurred in 4 patients (10.5%). All four nonunions were successfully treated by secondary autogenous bone grafting and compression screw fixation.

A retrospective study by Sachs and Capobianco in 2012 reported on 11 consecutive patients treated by a single surgeon with a percutaneous SI joint using triangular, porous, plasma-coated, titanium implants.[19] The baseline VAS pain score average was 7.9 (± 2.2) and the mean pain score average at the 12-month follow-up interval was 2.3 (±3.1), resulting in an average improvement of 6.2 points from baseline ($p=0.000$). Patient satisfaction was very high with 100% of patients indicating that they would have the same surgery again for the same result. The estimated blood loss was less than 50ml, there were no operative complications reported and no revision surgeries were needed.

In 2013, this same group published one year outcomes of 40 patients undergoing percutaneous SIJ fusion.[20] Again, it is unclear if this included patients from the 2012 report. The indications and inclusion criteria of this study resemble those outlined in the coverage recommendation above. All patients indicated they would have the surgery again. A clinically significant improvement in pain was noted in all but one patient.

To our knowledge, the largest series of patients undergoing percutaneous SIJ fusions was recently published in 2014 by Sachs et al.[21] This was a review of 144 patients who underwent the procedure with a mean follow-up of 16 months. Mean pain scores improved from 8.6 preoperatively to 2.7 postoperatively. Though there were no intraoperative complications noted, one patient presented with nerve root impingement from implant malposition that required revision surgery. It should be noted that the authors of this study had previously published multiple other case series on this subject in prior years. Although not clearly defined, it is likely that some of the patients in this study were included in the other published studies. It should also be noted that this study, as well as many of the studies listed above, have been co-authored by industry employees and paid consultant. This underscores the need to consider both industry and nonindustry sponsored studies on this topic as well as reserving the right to amend recommendations as future data evolves.

In a post-market analysis performed by one of the manufacturers (SI Bone, San Jose, CA, USA), co-authored by company employees, the safety profile of 5,319 patients who underwent the procedure was analyzed.[22] They noted complaints reported in 3.8% of patients. Pain, nerve impingement and recurrent SIJ pain were the most common. Improper device placement occurred in 72 cases (1.4%). There were 96 revision surgeries performed in 94 patients. Various other parameters were listed. What is unclear from the study is a comparison to a benchmark of safety and complication rates of other surgical procedures.

Comparison to Open SIJ Fusion

While current interest is clearly focused on percutaneous SI fusion techniques, in 2005 Buchowski et al reported a retrospective review of 20 patients undergoing open sacroiliac joint arthrodesis using a modified Smith Peterson approach with direct curettage of the joint.[23] Internal fixation was then applied using plates and screws. Preoperative and postoperative general health and function were assessed via the 36-item Short-Form (SF-36) Health Survey and the American Academy of Orthopaedic Surgeons (AAOS) Modems Instrument, which were collected prospectively. Medical records and plain radiographs were reviewed retrospectively to determine the clinical and radiographic outcome. The average estimated blood loss was 290ml and 17 patients (85%) achieved a solid fusion.

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The three nonunions required treatment with an open anterior sacroiliac joint fusion procedure. Fifteen patients (75%) completed preoperative and postoperative SF-36 forms. Significant ($p<.05$) improvement occurred in the following categories: physical functioning, role physical, bodily pain, vitality, social functioning, role emotional and neurogenic and pain indices. Improvement (not statistically significant) was also noted in general and mental health. Most patients (60%) indicated they would choose to have the surgery again and only one patient definitely would choose not to have the surgery again.

Smith et al (2013) compared results of open versus percutaneous SIJ fusions. Importantly, the open fusions were performed at different centers and by different surgeons than the percutaneous procedures. Though both groups seemed to improve, there was reportedly an average of 3.5 points less pain in the percutaneous group. With an attempt to match the patients for age, gender and other parameters, this difference decreased to 3 points.

Comparison to Nonoperative Care

Six month outcomes of an industry-sponsored, prospective, randomized controlled trial comparing minimally invasive SIJ fusion using triangular titanium implants to nonoperative care has been recently published by Whang et al.[23] Success, as measured by a composite of pain reduction, absence of serious adverse events or neurological worsening, and absence of repeat surgery, was found in 81.4% of operative patients and 24% of nonoperative patients. At least 15 point improvement in the ODI scores was found in 75% of operative patients and 27% of nonoperative patients. One- and two-year follow-up reports are planned.

In summary, the outcomes of SIJ fusion for non-infectious, non-traumatic related pain appear to be relatively consistent. Both open and percutaneous SIJ fusions seem to produce improvement in pain scores. Considering that percutaneous SIJ fusions seem to be associated with less blood loss and fewer complications than open fusions, which has been a previously covered procedure, it seems reasonable to extend coverage to percutaneous or minimally invasive procedures. The most contentious part of the procedure admitted by each of the papers reviewed is the reliability and accuracy of diagnosing SIJ mediated pain. Thus, in reviewing a number of source recommendations and evaluative study of the criteria for the diagnosis, we propose the above listed criteria for coverage. Currently, a diagnostic contrast-enhanced, image-guided (fluoroscopy or CT) intra-articular SIJ injection with a local anesthetic is standard to exclude and/or confirm whether or not the SIJ is a source of the patient's pain. As data continues to emerge with longer follow-up from prospective, randomized controlled trials, it will be important to maintain scrupulous adherence to strict indications for surgical management of these patients. Future research and analysis must continue in order to further understand and refine the indications for this procedure.

References

1. Fortin JD, Aprill CN, Ponthieux B, Pier J. Sacroiliac joint: pain referral maps upon applying a new injection/arthrography technique. Part II: Clinical evaluation. Spine. 1994 Jul 1;19:1483-9.
2. Fortin JD, Dwyer AP, West S, Pier J. joint: pain referral maps upon applying a new injection/arthrography technique. Part I. Asymptomatic volunteers. Spine. 1994 Jul 1;19:1475-82.
3. Yoshihara H. Sacroiliac joint pain after lumbar/lumbosacral fusion: current knowledge. Eur Spine J. 2012 Sep;21(9): 1788-1796.
4. DePalma MJ, Ketchum JM, Saullo TR. Etiology of chronic low back pain in patients having undergone lumbar fusion. Pain Med. 2011;12(5):732-739.
5. Liliang PC, Lu K, Liang CL, Tsai YD, Wang KW, Chen HJ. Sacroiliac joint pain after lumbar and lumbosacral fusion: findings using dual sacroiliac joint blocks. Pain Med. 2011;12(4):565-70.
6. Schofferman J, Reynolds J, Herzog R, Covington E, Dreyfuss P, O'neill C. Failed back surgery: etiology and diagnostic evaluation. Spine J. 2003;3(5):400-3.
7. Katz V, Schofferman J, Reynolds J. The sacroiliac joint: a potential cause of pain after lumbar fusion to the sacrum. J Spinal Disord Tech. 2003;16(1):96-9.
8. Liliang PC, Lu K, Weng HC, Liang CL, Tsai YD, Chen HJ. The therapeutic efficacy of sacroiliac joint blocks with triamcinolone acetonide in the treatment of sacroiliac joint dysfunction without spondyloarthropathy. Spine. 2009;34(9):896-900.
9. Szadek KM, van der Wurff P, van Tulder MW, Zuurmond WW, Perez RS. Diagnostic validity of criteria for sacroiliac joint pain: a systematic review. J Pain. 2009 Apr;10(4):354-368.
10. Laslett M. Evidence-based diagnosis and treatment of the painful sacroiliac joint. J Man Manip Ther. 2008. 16: 142-52.
11. Vleeming A, Albert HB, Ostgaard HC, Sturesson B, Stuge B. European guidelines for the diagnosis and treatment of pelvic girdle pain. Eur Spine J. 2008. 17: 794-819.
12. Smith-Petersen MN, Rogers WA. End-Result study of arthrodesis of the sacro-iliac joint for arthritis—traumatic and non-traumatic. J Bone Joint Surg Am. 1926 Jan;8(1):118-136.

13. Al-khayer A, Hegarty J, Hahn D, Grevitt MP. Percutaneous sacroiliac joint arthrodesis: a novel technique. J Spinal Disord Tech. 2008;21(5):359-63.
14. Khurana A, Guha AR, Mohanty K, Ahuja S. Percutaneous fusion of the sacroiliac joint with hollow modular anchorage screws: clinical and radiological outcome. J Bone Joint Surg Br. 2009;91(5):627-31.
15. Wise CL, Dall BE. Minimally invasive sacroiliac arthrodesis: outcomes of a new technique. J Spinal Disord Tech. 2008;21(8):579-84.
16. Rudolf L. Sacroiliac joint arthrodesis-MIS technique with titanium implants: Report of the first 50 patients and outcomes. Open Orthop J. 2012;6:495-502.
17. Rudolf L, Capobianco R. Five-year clinical and radiographic outcomes after minimally invasive sacroiliac joint fusion using triangular implants. Open Orthop J. 2014 Oct 17;8:375-83.
18. McGuire RA, Chen Z, Donahoe K. Dual fibular allograft technique for sacroiliac joint arthrodesis. Evid Based Spine Care J. 2012;3:21-8.
19. Sachs D, Capobianco R. One year successful outcomes for novel sacroiliac joint arthrodesis system. Ann Surg Innov Res. 2012;6(1):13.
20. Sachs D, Capobianco R. Minimally invasive sacroiliac joint fusion: one-year outcomes in 40 patients. Adv Orthop. 2013;2013:536128.
21. Sachs D, Capobianco R, Cher D, et al. One-year outcomes after minimally invasive sacroiliac joint fusion with a series of triangular implants: a multicenter, patient-level analysis. Med Devices (Auckl). 2014 Aug 28;7:299-304.
22. Miller LE, Reckling WC, Block JE. Analysis of postmarket complaints database for the iFuse SI Joint Fusion System®: a minimally invasive treatment for degenerative sacroiliitis and sacroiliac joint disruption. Med Devices (Auckl). 2013 May 29;6:77-84.
23. Buchowski JM, Kebaish KM, Sinkov V, Cohen DB, Sieber AN, Kostuik JP. Functional and radiographic outcome of sacroiliac arthrodesis for the disorders of the sacroiliac joint. Spine J. 2005;5(5):520-8.
24. Whang P, Cher D, Polly D, et al. Sacroiliac Joint Fusion Using Triangular Titanium Implants vs. Non-Surgical Management: Six-Month Outcomes from a Prospective Randomized Controlled Trial. Int J Spine Surg. 2015;9:6.

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

Degree of support:

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

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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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)

(From page 7 of decision aide)

Next step: Proposed findings and decision and public comment

At the next public meeting the committee will review the proposed findings and decision and consider any public comments as appropriate prior to a vote for final adoption of the determination.

- ☐ 1) Based on public comment was evidence overlooked in the process that should be considered?
- ☐ 2) Does the proposed findings and decision document clearly convey the intended coverage determination based on review and consideration of the evidence?

Next step: Final determination

Following review of the proposed findings and decision document and public comments:

Final vote

☐ Does the committee approve the Findings and Decisions document with any changes noted in discussion?

If yes, the process is concluded.

If no, or unclear outcome (i.e., tie), chair will lead discussion to determine next steps.