

International Society for the Advancement of Spine Surgery
Proposed Recommendations for “Coverage Criteria”
Minimally Invasive Sacroiliac Joint Fusion

Coverage Indications, Limitations, and/or Medical Necessity

Introduction

The sacroiliac joint (SIJ) is a cause of chronic lower back pain. SI joints are paired diarthrodial articulations of the sacrum and ilium. The SI joint serves as the biomechanical mediator between the spine and pelvis. The subchondral bone, capsule, and surrounding ligaments of the SIJ are innervated by spinal nerves.¹

Because SIJ pain can be confused with lumbar and hip pain, proper diagnosis of SIJ pain is key to appropriate patient management. Patients with SIJ pain typically report pain in the buttocks, with possible radiation into the groin or upper legs. Specific physical examination tests that stress the SIJ (e.g., distraction test, compression test, thigh thrust, FABER (Patrick's) test, Gaenslen's maneuver, sacral sulcus tenderness) are typically performed in the physician's office; in combination, these tests are thought to be predictive of SI joint pain.² Apart from ankylosing spondylitis, in which MRI can show edema consistent with inflammation, imaging of the SIJ typically does not provide valuable diagnostic information. Rather, imaging is used to ensure that the patient does not have alternative diagnoses that could mimic SIJ pain (e.g., hip osteoarthritis, occasionally L5/S1 spine degeneration). The diagnosis of SIJ pain is confirmed by performing a fluoroscopy guided percutaneous SI joint block with local anesthetic (e.g., lidocaine). An acute reduction in pain of 75%^{3,4} (using visual analog scale) or more compared to immediately prior to the block is diagnostic as a positive test and indicates that the injected joint is the pain generator based on published studies. A study of patients undergoing blinded injection of saline or local anesthetic showed markedly high responses to the latter, validating the test.⁵ Because other pathologic processes can coexist with SIJ pain, in order to assure that SI joint pain is the primary (or only) diagnosis, the physician should ensure that non-SIJ causes of pelvic or lower back pain are ruled out on the basis of history, physical exam and/or imaging; examples of alternative diagnoses include pelvic fracture, tumor, infection, skeletal deformity, hip arthritis, and degeneration of the L5/S1 disc or other base-of-spine pathologies.

Occasionally, bilateral SIJ pain can occur. Diagnosis of bilateral SI joint pain must be made on the basis of typical history, physical examination showing bilateral SIJ pain with maneuvers that stress the SIJ, and bilateral acute pain relief upon bilateral, fluoroscopy-guided SI joint block.

Multiple non-surgical treatments for SIJ pain are available, including pain medications (e.g., non-steroid anti-inflammatory agents, opioids), physical therapy, steroid injections into the SIJ, and radio frequency ablation of the SIJ. Most patients respond adequately to conservative treatment. However, a small number of patients do not have satisfactory pain relief and may be functionally disabled (e.g., cannot sit or stand for more than five minutes, cannot perform normal activities of daily living (ADLs) cannot walk up or down stairs, may require a wheelchair may require chronic opioid treatment). Patients with a diagnosis of SIJ pain who experience pain for a minimum of six months and who do not respond to an adequate course of non-surgical treatment may be considered for SIJ fusion.

Coverage Rationale for Open and Minimally Invasive SIJ Fusion

Open fusion of the SIJ can provide pain relief but recovery times are long and the complication rate is high.⁶⁻¹⁰ Patients can experience significant intraoperative bleeding and require prolonged postoperative rehabilitation. Therefore, open fusion of the SIJ is best performed on patients who are not candidates for minimally invasive SIJ fusion.¹¹

Minimally invasive fusion of the SIJ has been performed with several types of implants, including triangular, porous, titanium coated implants,¹²⁻¹⁴ hollow modular screws,¹⁵⁻¹⁷ titanium cages,¹⁸ and

allograft dowels.⁶ These devices are placed either inside or across the SIJ using a minimally invasive surgical approach. Minimally invasive SIJ fusion provides pain relief by acutely stabilizing the painful SI joint with subsequent fusion. In addition to publication of multiple retrospective case series,¹²⁻¹⁴ published results from a prospective multicenter trial of minimally invasive SIJ fusion have substantiated high rates of pain relief, improvement in functional measures (SF-36, ODI and EQ-5D) and a low rate of both revisions (<5%) and serious adverse events.¹⁹ In a multicenter retrospective review of 263 patients undergoing either open or minimally invasive SIJ fusion, the latter was associated with statistically significant and clinically marked decreases in operating room time (mean 163 minutes for open vs. 70 minutes for minimally invasive), decreased blood loss (mean 288 cc vs. 33 cc), and decreased length of stay (5.1 vs. 1.3 days) as well as improved relief of pain at 1 (-2.7 points on 0-10 scale vs. -6.2 points) and 2-year (-2.0 vs. -5.6 points) follow-up.²⁰ (All differences are statistically significant.)

The complication rate for minimally invasive SI joint fusion is low. Importantly, the rate of removal or revision is less than 2%.^{19,21} Revisions can be required in the immediate postoperative period or after many months. Early revisions may include the need to reposition an implant that is impinging on a sacral nerve or removal of an implant due to infection.

In cases of bilateral SI joint pain, bilateral SIJ fusion may occasionally be indicated and is usually performed serially to minimize the impact on rehabilitation (i.e., patients who undergo simultaneous bilateral fusion procedures may be wheelchair or bedbound for several weeks, possible slowing overall recovery).

Indications/Limitations of Coverage

Patients who have all of the following criteria may be eligible for minimally invasive SIJ fusion:

- Significant SIJ pain (e.g., pain rating at least 5 on the 0-10 numeric rating scale where 0 represents no pain and 10 represents worst imaginable pain) or significant limitations in activities of daily living;
- SIJ pain confirmed with at least 3 physical examination maneuvers that stress the SIJ and cause the patient's typical pain.²
- Confirmation of the SIJ as a pain generator with $\geq 75\%$ ^{3,4} acute decrease in pain upon fluoroscopically guided diagnostic intra-articular SIJ block using local anesthetic.
- Failure to respond to at least 6 months of non-surgical treatment consisting of non-steroidal anti-inflammatory drugs and/or opioids (if not contraindicated) and one or more of the following: rest, physical therapy, SIJ steroid injection. Failure to respond means continued pain that interferes with activities of daily living and/or results in functional disability;
- Additional or alternative diagnoses that could be responsible for the patient's ongoing pain or disability have been ruled out (e.g., L5/S1 compression, hip osteoarthritis).

Minimally invasive SIJ fusion is NOT indicated for patients with the following:

- Less than 6 months of back pain;
- Failure to pursue conservative treatment of the SIJ (unless contra-indicated);
- Pain not confirmed with a diagnostic SIJ block;
- Existence of other pathology that could explain the patient's pain.

In rare instances, bilateral SIJ pain can occur. Diagnosis of bilateral SI joint pain must be made on the basis of a history of bilateral pain, bilateral elicitation of pain on physical examination maneuvers that stress each SIJ, and acute bilateral decrease in pain upon fluoroscopically guided intra-articular SI joint block with local anesthetic.

Bilateral SIJ fusion is probably best performed serially to ensure that fusion of both joints is necessary (i.e., pain/disability continues after the first fusion in spite of conservative treatment and a nerve block of the unfused joint results in more than 75% reduction in pain). If bilateral fusion is performed at the same

operative session, the surgeon must document both medical necessity and why serial fusion is not indicated in the patient.

It is expected that a person would not undergo more than one SIJ fusion per side per lifetime except in the rare case that a revision is needed.

Coding

Minimally invasive SI joint fusion is coded using CPT code 0334T until January 1, 2015. CPT code 27280 may be recommended by payers at their individual discretion.

When bilateral fusions are performed, use CPT code 0334T until January 1, 2015 on two line items with the RT (right side) and LT (left side) modifiers on each line item to indicate bilateral fusion.

Revision and/or removal of the SI joint implant is coded using 22899 (unlisted procedure, spine) or 27299 (unlisted procedure, pelvis or hip joint) depending on the type of approach and procedure performed, whether within the global period of the fusion, or not.

ICD-9 codes that support medical necessity are shown below.

ICD-9 code	Description
720.2	Sacroiliitis not elsewhere classified; inflammation of sacroiliac joint NOS
721.3	Lumbosacral spondylosis without myelopathy
724.6	Disorders of sacrum
739.4	Nonallopathic lesions, not elsewhere classified in the sacral region; sacrococcygeal region or sacroiliac region
846.9	Sprains and strains of the sacroiliac region, unspecified site of sacroiliac region
847.3	Sprains and strains of sacrum

Documentation Requirements

For patients undergoing minimally invasive SI joint fusion, the following must be documented in the medical record and available upon request:

- A complete history and physical documenting the likely existence of SI joint pain;
- Performance of a fluoroscopically- guided SI joint block on the affected side (or both sides, see discussion above) which shows at least a 75% acute reduction in pain;
- A course of conservative treatment to include use of non-steroidal anti-inflammatory drugs and/or opioids (unless contraindicated) and one of the following: (1) an adequate period of rest, (2) an adequate course of physical therapy wherein the physical therapist specifically documents lack of response to treatment, (3) SI joint steroid injections into the affected joint with inadequate response or return of pain after weeks to months, or (4) radio frequency ablation of the affected SI joint with either inadequate response or return of pain after weeks to months;
- SI joint pain has continued for a minimum of six months;
- All other diagnoses that could be causing the patient's pain have been ruled out;
- Within one month after surgery, that the level of pain and/or functional disability is continuing and that in the surgeon's opinion the only treatment option that will provide long term relief is SI joint fusion

Surgeon Qualifications

- Minimally invasive SIJ fusion is a surgical procedure performed only by orthopedic or neurologic surgeons who have successfully completed a residency in that specialty as well as at least one

specialized training course in the procedure. Training should include device placement in cadavers under supervision of a surgeon experienced in the procedure.

- Surgeons performing minimally invasive SIJ fusion should be specifically credentialed and/or privileged by at least one hospital to perform the procedure.

REFERENCES

1. Szadek, K. M., Hoogland, P. V., Zuurmond, W. W., de Lange, J. J. & Perez, R. S. Nociceptive nerve fibers in the sacroiliac joint in humans. *Reg. Anesth. Pain Med.* **33**, 36–43 (2008).
2. Szadek, K. M., van der Wurff, P., van Tulder, M. W., Zuurmond, W. W. & Perez, R. S. G. M. Diagnostic validity of criteria for sacroiliac joint pain: a systematic review. *J. Pain* **10**, 354–368 (2009).
3. Dreyfuss, P., Dreyer, S.J., Cole, A., Mayo, K. Sacroiliac joint pain. *J. Am. Acad. Orthop. Surg.* **12**, 255–265 (2004).
4. Manchikanti, L. et al. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: Guidance and recommendations. *Pain Physician* **16**, S49–S283 (2013).
5. Broadhurst, N. A. & Bond, M. J. Pain provocation tests for the assessment of sacroiliac joint dysfunction. *J. Spinal Disord.* **11**, 341–345 (1998).
6. McGuire, R. A., Chen, Z. & Donahoe, K. Dual fibular allograft dowel technique for sacroiliac joint arthrodesis. *Evid.-Based Spine-Care J.* **3**, 21–28 (2012).
7. Buchowski, J. M. et al. Functional and radiographic outcome of sacroiliac arthrodesis for the disorders of the sacroiliac joint. *Spine J. Off. J. North Am. Spine Soc.* **5**, 520–528; discussion 529 (2005).
8. Belanger, T. A. & Dall, B. E. Sacroiliac arthrodesis using a posterior midline fascial splitting approach and pedicle screw instrumentation: a new technique. *J. Spinal Disord.* **14**, 118–124 (2001).
9. Waisbrod, H., Krainick, J. U. & Gerbershagen, H. U. Sacroiliac joint arthrodesis for chronic lower back pain. *Arch. Orthop. Trauma. Surg. Arch. Für Orthop. Unf.-Chir.* **106**, 238–240 (1987).
10. Moore, M. R. in *Mov. Stab. Low Back Pain Essent. Role Pelvis* 563–572 (Churchill Livingstone, 1997).
11. Lorio, M. et al. Utilization of Minimally Invasive Surgical Approach for Sacroiliac Joint Fusion in Surgeon Population of ISASS and SMISS Membership. *Open Orthop J.* **8**, 1–6 (2014)
12. Sachs, D. & Capobianco, R. Minimally invasive sacroiliac joint fusion: one-year outcomes in 40 patients. *Adv. Orthop.* **2013**, 536128 (2013).
13. Rudolf, L. MIS Sacroiliac (SI) Joint Fusion in the Context of Previous Lumbar Spine Fusion: 5 Patients with 24 Month Follow up. in *Int. Soc. Adv. Spine Surg.* 107 (2013).
14. Gaetani, P. et al. Percutaneous arthrodesis of sacro-iliac joint: a pilot study. *J. Neurosurg. Sci.* **57**, 297–301 (2013).
15. Al-Khayer, A., Hegarty, J., Hahn, D. & Grevitt, M. P. Percutaneous sacroiliac joint arthrodesis: a novel technique. *J. Spinal Disord. Tech.* **21**, 359–363 (2008).
16. Khurana, A., Guha, A. R., Mohanty, K. & Ahuja, S. Percutaneous fusion of the sacroiliac joint with hollow modular anchorage screws: clinical and radiological outcome. *J. Bone Joint Surg. Br.* **91**, 627–631 (2009).
17. Mason, L. W., Chopra, I. & Mohanty, K. The percutaneous stabilisation of the sacroiliac joint with hollow modular anchorage screws: a prospective outcome study. *Eur. Spine J.* (2013). doi:10.1007/s00586-013-2825-2
18. Wise, C. L. & Dall, B. E. Minimally invasive sacroiliac arthrodesis: outcomes of a new technique. *J. Spinal Disord. Tech.* **21**, 579–584 (2008).
19. Duhon, B. S. et al. Safety and 6-month effectiveness of minimally invasive sacroiliac joint fusion: a prospective study. *Med. Devices Auckl. NZ* **6**, 219–229 (2013).
20. Graham-Smith, A., Capobianco, R. A. & Cher, D. J. Open versus minimally invasive sacroiliac joint fusion: a multi-center comparison of perioperative measures and clinical outcomes. *Ann. Surg. Innov. Res.* **7**, 1–12

21. Miller, L., Reckling, W. C. & Block, J. E. 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 Evid. Res.* 77–84 (2013). doi:10.2147/MDER.S44690