

Clinical Policy: Sacroiliac Joint Fusion

Reference Number: LA.CP.MP.126

Date of Last Revision: 07/23

Coding Implications
Revision Log

See <u>Important Reminder</u> at the end of this policy for important regulatory and legal information.

Description

Sacroiliac joint (SIJ) fusion, or arthrodesis, is a surgical technique that fuses the iliac bone to the sacrum for stabilization. This procedure may be performed in a minimally invasive manner or as an open surgical procedure requiring a larger incision and subsequent increased recovery time.

Policy/Criteria

- **I.** It is the policy of Louisiana Healthcare Connections that open sacroiliac joint fusion is **medically necessary** for any of the following indications:
 - A. Stabilization of a traumatic, severe disruption, or fracture of the pelvic ring;
 - B. As an adjunct to sacrectomy or partial sacrectomy for the treatment of sacral tumors; or
 - C. As an adjunct to the medical treatment of sacroiliac joint infection or sepsis (e.g., osteomyelitis, pyogenic sacroiliitis);
 - D. During multi-segment spinal constructs (e.g., correction of deformity in scoliosis or kyphosis surgery, extending to the ilium).
- **II.** It is the policy of Louisiana Healthcare Connections that minimally invasive sacroiliac joint fusion is **medically necessary** for the treatment of low back/buttock pain when meeting all of the following:
 - A. Failure of at least six consecutive months of conservative treatment that includes all of the following:
 - 1. Medication optimization (unless contraindicated);
 - 2. Activity modification;
 - 3. At least four to six weeks of active therapeutic exercise targeted at the lumbar spine, pelvis, sacroiliac joint (SIJ) and hip, including a home exercise program or documentation of patient's inability to tolerate; and/or osteopathic or chiropractic manipulation;
 - B. Non-radiating, unilateral pain that is caudal to the lumbar spine (L5 vertebrae), localized over the posterior SIJ, and consistent with SIJ pain, that interferes with activities of daily living (ADLs);
 - C. Localized tenderness with palpation of the posterior SIJ in the absence of tenderness of similar severity elsewhere (e.g., greater trochanter, lumbar spine, coccyx) and other obvious sources of pain do not exist;
 - D. Positive response to the thigh thrust test or compression test and at least two of the following additional provocative tests (distraction, Gaenslen's, Patrick's test/FABER test);
 - E. Absence of generalized pain behavior (e.g., somatoform disorder) or generalized pain disorders (e.g., fibromyalgia);
 - F. Recent (within six months) diagnostic imaging studies that include all of the following:



- 1. Plain radiographs and CT or MRI of the SI joint that excludes the presence of destructive lesions (e.g., tumor, infection), fracture, traumatic SIJ instability, or inflammatory arthropathy;
- 2. Plain radiographs of the ipsilateral hip that excludes the presence of osteoarthritis;
- 3. CT or MRI of the lumbar spine that excludes neural compression or other degenerative conditions that can cause low back or buttock pain.
- G. At least 75% reduction in pain for the expected duration of the anesthetic used following an image guided, contrast-enhanced intra-articular (diagnostic) SIJ injection on two separate occasions, at least two weeks apart;
- H. A failure of at least one therapeutic intra-articular SIJ injection (i.e., corticosteroid injection), or a therapeutic injection is contraindicated;
- I. Procedure will be performed using the lateral transarticular approach.
- **III.** It is the policy of Louisiana Healthcare Connections that the long-term safety and effectiveness of sacroiliac joint fusion procedures, either open or minimally invasive has not been proven for all other indications, including but not limited to, treatment of mechanical or axial low back pain, radicular pain syndromes, sacral insufficiency fractures, and pelvic girdle pain, due to limited clinical evidence.
- **IV.** It is the policy of Louisiana Healthcare Connecttions that current evidence does not support sacroiliac joint fusion using implants other than those which are placed across the joint (transfixing) to promote fusion (e.g., allograft, nonmetallic implants).

Background

Low back pain affects approximately 84% of adults during their lives with the sacroiliac joint being the source of chronic low back pain in approximately 15% to 30% of patients. 3,11,17 When the sacroiliac joint is the source of this pain, and all appropriate conservative measures fail to relieve symptoms of trauma associated with fracture, infection/sepsis, tumors involving the sacrum, cancer, or spinal instability, treatment options may include fusion of this joint or implantation of devices that stabilize this joint with minimally invasive surgery. To stabilize the sacroiliac joint, the iliac crest bone and the sacrum are held together by plates and/or screws or an interbody fusion cage, until the two bones fuse. 3

There are a number of FDA-approved implants that have been proposed for sacroiliac joint disorders, but the majority of clinical trials and studies have been done on the iFuse implant system. This was initially called the SI Joint Fusion and received the original 510(k) clearance from the Food and Drug Administration in November 2008 for fracture fixation of long bones, large bone fragments of the pelvis and for conditions including sacroiliac joint disruptions and degenerative sacroilitis. Additional FDA clearances were given on April 21, 2011, and on April 17, 2015. The iFuse system involves the fluoroscopically guided insertion of titanium implants across the sacroiliac joint. Under general anesthesia, a two to three centimeter incision is created, and after determining the appropriate size of the implant, a cannulated delivery system is used to insert the implants into the proper position. While the number varies, most patients receive three implants to stabilize the joint.^{7,8}



Whang and Polly completed two randomized controlled trials with a six month and one year follow up, respectively, on sacroiliac joint fusion using iFuse versus non-surgical management. The iFuse led to better outcomes and similar safety compared with nonsurgical management, and to better operative outcomes and at least comparable efficacy compared with open surgery. However, uncertainty remains due to the lack of longer-term efficacy and safety follow-up with radiologic confirmation, and to the lack of comparisons with other minimally invasive approaches.^{5,14} There is additional evidence suggesting sacroiliac joint fusion with iFuse improves pain, enhances health-related quality of life, and decreases disability compared to non-surgical management.^{2,21,22}

The percutaneous placement of an intraarticular stabilization device into the sacroiliac joint (SIJ) differs from the established percutaneous arthrodesis of the SIJ with placement of a transfixing device. Examples of SIJ stabilization devices that do not involve transfixation are CornerLoc[™], TransFasten[®], and LinQ[™]. These allograft devices are placed directly to the SIJ via posterior approaches, therefore, and do not involve drilling through the ilium to the sacrum or insertion of hardware. Minimally invasive SIJ arthrodesis involves the placement of screws, cages, or allograft dowels percutaneously using lateral transarticular (i.e., through the ilium to the sacrum) or posterior approaches. Implantation of SIJ fusion devices via a posterior approach is less invasive and potentially safer than the lateral approach since neurovascular structures are avoided. Although there is preliminary evidence that supports pain reduction with minimum complications using the posterior approach, current medical literature supports the lateral approach. There is a paucity of evidence to support the posterior and posterior lateral oblique approach.

The sacroiliac joint remains a controversial source of primary low back pain, and surgery is rarely performed for sacroiliac joint dysfunction.¹¹ Minimally invasive sacroiliac joint fusion is becoming a more prevalent treatment for chronic refractory low back pain isolated to the sacroiliac joint with the development of various fusion devices over the past ten years. Additional randomized, controlled trials or comparison studies are needed to investigate different aspects of each device to identify unique features that may be of clinical benefit, as well as determine the impact on health outcomes and long-term efficacy and safety.^{11,24}

International Society for the Advancement of Spine Surgery (ISASS)

The ISASS outlines eligibility criteria and contraindications relative to minimally invasive surgical sacroiliac joint fusion (MIS SIJF), but does not endorse any specific MIS SIJ system. ^{17,25} A meta-analysis was conducted, and the results for patients following MIS SIJF demonstrated steadily and considerably lower SIJ pain scores and ODI (Oswestry Disability Index) scores when compared to baseline scores. Evidence from two random controlled trials and five multicenter prospective studies specifically demonstrated pain relief, disability reduction and improvement in QOL (quality of life) were significantly higher in patients treated with MIS SIJF when compared to nonsurgically treated patients. The ISASS concludes that MIS SIJF is "a recognized safe, predictable, and preferred surgical method for the management of intractable, debilitating primary or secondary SIJ pain disorders". ¹⁷ The ISASS noted a scarce amount of published literature on minimally invasive SIJ fusion using a posterior approach. The society concluded that the instrumentation utilized in a MIS SIJ procedure is the surgeon's preference. ²⁵

North American Spine Society (NASS)



NASS recommends percutaneous sacroiliac joint (SIJ) fusion for the treatment of sacroiliac joint pain for patients with low back/buttock pain who meet specific criteria.⁴

National Institute for Health and Care Excellence (NICE)

NICE recommends minimally invasive sacroiliac (SI) joint fusion surgery for treatment of chronic SI pain in patients with a confirmed diagnosis of unilateral or bilateral SI joint dysfunction due to degenerative sacroiliitis or SI joint disruption. The committee indicates that this procedure stabilizes the joint, but fusion of the joint does not happen in many cases. The NICE guidelines only describe the lateral transarticular approach. Additionally, NICE recommends iFuse implant system as an option for treating chronic sacroiliac joint pain for patients with a confirmed diagnosis of chronic sacroiliac joint pain that is inadequately controlled by non-surgical management. The confirmed diagnosis should be based on a clinical assessment and a positive response to a diagnostic injection of local anesthetic in the sacroiliac joint.

Tobacco cessation is recommended to improve the outcome of spinal fusion surgery. The success of fusion surgery is determined by the ability of the joints to heal into a solid unit; however, the fusion rate of smokers is significantly lower than non-smokers. ^{19,20} Smoking increases the rate of perioperative complications, especially pseudoarthrosis; therefore, smoking cessation for four weeks following surgery is recommended to reduce risks. ^{18,19} One study of patients undergoing spinal fusions in the lower back demonstrated an 80-85% success rate for non-smokers or patients who quit smoking following surgery, and < 73% success rate for smokers. ²⁰

Coding Implications

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NOTE: Coverage is subject to each requested code's inclusion on the corresponding LDH fee schedule. Non-covered codes are denoted (*) and are reviewed for Medical Necessity for members under 21 years of age on a per case basis. **Codes that support coverage criteria**

CPT® Codes	Description			
27279	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indir visualization), with image guidance, includes obtaining bone graft when perform and placement of transfixing device			
27280	Arthrodesis, open, sacroiliac joint, includes obtaining bone graft, including instrumentation, when performed			



Codes that do not support coverage criteria

CPT ®	Description			
Codes				
0775T*	Arthrodesis, sacroiliac joint, percutaneous, with image guidance, includes			
	placement of intra-articular implant(s) (e.g., bone allograft[s], synthetic device[s])			

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Converted corporate to local policy.	08/15/2020	Date
Annual review complete. References reviewed, updated and reformatted. Replaced all instances of member with member/enrollee. Background updated. Section I updated to indicate criteria specific to open SIJ fusion. New criteria added for section II, specific to minimally invasive SIJ fusion. Updated section III "experimental/investigational" verbiage: replaced with "long-term safety and effectiveness has not been proven" and removed reference to iFUSE and sacroiliac joint examples. Reviewed by specialist. Changed "review date" in the header to "last revision date; changed "date" in the revision log header to "revision date."	11/11/2021	3/26/22
Annual review completed. Added "at least four to six weeks" to II.A.3. and added option for inability to tolerate exercise program. Section II.F.1 updated to include "fracture, traumatic SIJ instability". Background updated with information regarding smoking cessation. References reviewed and updated.	8/22	
Annual review completed. Added Criteria II.I. describing procedure approach. Added criteria IV. to address sacroiliac fusion using implants other than those which are placed across the joint (transfixing) to promote fusion. Additional minor rewording with no clinical significance. Background updated. Created tables to convey codes that do/do not support coverage criteria. Added new CPT code 0775T to table that does not support coverage criteria. ICD-10 code table removed. References reviewed and updated. External specialist reviewed.	07/23	9/13/2023

References

- 1. Chou R, Loeser JD, Owens DK, et al. Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the American Pain Society. *Spine* (Phila Pa 1976). 2009;34(10):1066 to 1077. doi:10.1097/BRS.0b013e3181a1390d.
- 2. Medical Technology Directory. Minimally invasive sacroiliac joint fusion using triangular titanium implants (iFuse Implant System, SI-Bone Inc.). Hayes. www.hayesinc.com. Published March 3, 2014. (Retitled September 3, 2020-annual review September 22, 2022). Accessed May 1, 2023.



- 3. Ledonio CG, Polly DW Jr, Swiontkowski MF. Minimally invasive versus open sacroiliac joint fusion: are they similarly safe and effective? *Clin Orthop Relat Res.* 2014;472(6):1831 to 1838. doi:10.1007/s11999-014-3499-8.
- 4. North American Spine Society (NASS). Evidence-based clinical guidelines for multidisciplinary spine care: diagnosis and treatment of low back pain. https://www.spine.org/Portals/0/assets/downloads/ResearchClinicalCare/Guidelines/LowBackPain.pdf. Published 2020. Updated January 27, 2021. Accessed May 1, 2023.
- 5. Polly DW, Cher DJ, Wine KD, et al. Randomized Controlled Trial of Minimally Invasive Sacroiliac Joint Fusion Using Triangular Titanium Implants vs Nonsurgical Management for Sacroiliac Joint Dysfunction: 12-Month Outcomes. *Neurosurgery*. 2015;77(5):674 to 691. doi:10.1227/NEU.00000000000000988.
- 6. SI-BONE, Inc. Announces Medicare Palmetto Removes MIS SI Joint Fusion from Non-Coverage. Published February 25, 2014. https://www.prnewswire.com/news-releases/si-bone-inc-announces-medicare-palmetto-removes-mis-si-joint-fusion-from-non-coverage-247035941.html. Accessed May 1, 2023.
- 7. U.S. Food and Drug Administration (FDA) 510(k) Premarket Notification Database. iFuse SI Fusion System. No. K110838. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K110838. Published April 21, 2011. Accessed May 1, 2023.
- 8. U.S. Food and Drug Administration (FDA) 510(k) Premarket Notification Database. SI-BONE iFuse Implant System. No. K150714. April 17, 2015. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K150714. Published April 17, 2015. Accessed May 1, 2023.
- 9. Vanaclocha V, Herrera JM, Sáiz-Sapena N, Rivera-Paz M, Verdú-López F. Minimally Invasive Sacroiliac Joint Fusion, Radiofrequency Denervation, and Conservative Management for Sacroiliac Joint Pain: 6-Year Comparative Case Series. *Neurosurgery*. 2018 Jan 1;82(1):48 to 55. doi: 10.1093/neuros/nyx185. PMID: 28431026.
- 10. Whang P, Cher D, Polly D, Frank C, Lockstadt H, Glaser J, Limoni R, Sembrano J. 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 Mar 5;9:6. doi: 10.14444/2006. PMID: 25785242; PMCID: PMC4360612.
- 11. Wheeler SG, Wipf JE, Staiger TO, Deyo RA, Jarvik JG. Evaluation of low back pain in adults. UpToDate. www.uptodate.com. Updated May 26, 2022. Accessed May 1, 2023.
- 12. Zaidi HA, Montoure AJ, Dickman CA. Surgical and clinical efficacy of sacroiliac joint fusion: a systematic review of the literature. *J Neurosurg Spine*. 2015 Jul;23(1):59 to 66. doi: 10.3171/2014.10.SPINE14516. Epub 2015 Apr 3. PMID: 25840040.
- 13. Bornemann R, Roessler PP, Strauss AC, Sander K, Rommelspacher Y, Wirtz DC, Pflugmacher R, Frey SP. Two-year clinical results of patients with sacroiliac joint syndrome treated by arthrodesis using a triangular implant system. *Technol Health Care*. 2017;25(2):319 to 325. doi: 10.3233/THC-161272. PMID: 27858725.
- 14. Polly DW, Swofford J, Whang PG, et al. Two-Year Outcomes from a Randomized Controlled Trial of Minimally Invasive Sacroiliac Joint Fusion vs. Non-Surgical Management for Sacroiliac Joint Dysfunction. *Int J Spine Surg.* 2016;10:28. Published 2016 Aug 23. doi:10.14444/3028.
- 15. Local Coverage Determination: minimally-invasive surgical (MIS) fusion of the sacroiliac (SI) joint (L36494). Centers for Medicare and Medicaid Services (CMS).



- https://www.cms.gov/medicare-coverage-database/search.aspx Published February 01, 2016. Updated January 5, 2023. Accessed May 1, 2023.
- 16. National Institute for Health and Care Excellence (NICE). Minimally invasive sacroiliac joint fusion surgery for chronic sacroiliac pain. April 5, 2017. https://www.nice.org.uk/guidance/ipg578/chapter/1-Recommendations. Accessed May 1, 2023.
- 17. Lorio M, Kube R, Araghi A. 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. *Int J Spine Surg.* 2020;14(6):860 to 895. doi:10.14444/7156
- 18. Berman D, Oren JH, Bendo J, Spivak J. The Effect of Smoking on Spinal Fusion. *Int J Spine Surg.* 2017;11(4):29. Published 2017 Nov 28. doi:10.14444/4029
- 19. Li Y, Zheng LM, Zhang ZW, He CJ. The Effect of Smoking on the Fusion Rate of Spinal Fusion Surgery: A Systematic Review and Meta-Analysis. *World Neurosurg*. 2021;154:e222 to e235. doi:10.1016/j.wneu.2021.07.011
- 20. American Academy of Orthopaedic Surgeons (AAOS). Surgery and smoking: Research on smoking and orthopaedic procedures. Updated April 2019. https://www.orthoinfo.org/en/treatment/surgery-and-smoking/. Accessed May 1, 2023.
- 21. National Institute for Health and Care Excellence (NICE). iFuse for treating chronic sacroiliac joint pain. https://www.nice.org.uk/guidance/mtg39/chapter/1-Recommendations Published October 2, 2018 (updated August 30, 2022). Accessed May 1, 2023.
- 22. Chang E, Rains C, Ali R, Wines RC, Kahwati LC. Minimally invasive sacroiliac joint fusion for chronic sacroiliac joint pain: a systematic review. *Spine J.* 2022;22(8):1240 to 1253. doi:10.1016/j.spinee.2022.01.005
- 23. Matias CM, Velagapudi L, Montenegro TS, Heller JE. Minimally invasive sacroiliac fusion-a review. *Curr Pain Headache Rep.* 2022;26(3):173 to 182. doi:10.1007/s11916-022-01016-y
- 24. Himstead AS, Brown NJ, Shahrestani S, Tran K, Davies JL, Oh M. Trends in diagnosis and treatment of sacroiliac joint pathology over the past 10 years: review of scientific evidence for new devices for sacroiliac joint fusion. *Cureus*. 2021;13(6):e15415. Published 2021 Jun 3. doi:10.7759/cureus.15415
- 25. Medical Code Brief. 0775T Category III (T codes). Hayes. <u>www.hayesinc.com</u>. July 20, 2022. Accessed May 8, 2023.
- 26. Lee DW, Patterson DG, Sayed D. Review of Current Evidence for Minimally Invasive Posterior Sacroiliac Joint Fusion. *Int J Spine Surg.* 2021;15(3):514-524. doi:10.14444/8073

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.



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