

### Clinical Policy: Sacroiliac Joint Fusion

Reference Number: CP.MP.126 Date of Last Revision: 06/22 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 health plans affiliated with Centene Corporation<sup>®</sup> 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 multisegment spinal constructs (e.g., correction of deformity in scoliosis or kyphosis surgery, extending to the ilium).
- II. It is the policy of health plans affiliated with Centene Corporation 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 6 consecutive months of conservative treatment that includes all of the following:
    - 1. Medication optimization (unless contraindicated);
    - 2. Activity modification;
    - 3. At least 4-6 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:

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- 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.
- III. It is the policy of health plans affiliated with Centene Corporation 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.

#### **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 2-to-3-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 3 implants to stabilize the joint.<sup>7,8</sup>

Whang and Polly completed two randomized controlled trials with a six month and one year follow up, respectively, on sacroiliac joint fusion using iFuse verses 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

The sacroiliac joint remains a controversial source of primary low back pain, and surgery is rarely performed for sacroiliac joint dysfunction. Although there are ongoing published peer-reviewed studies, there is a paucity of long-term, scientific literature to support sacroiliac joint fusion for low back pain. Additional randomized, controlled trials or comparison studies are needed to compare sacroiliac joint fusion for low back pain to non-surgical treatments to determine the impact on health outcomes and long-term efficacy and safety.<sup>11</sup>

#### *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). 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 2 RCTS and 5 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".<sup>17</sup>

#### 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.<sup>4</sup>

#### 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. <sup>16</sup>

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. <sup>19,20</sup> Smoking increases the rate of perioperative complications, especially pseudoarthrosis; therefore, smoking cessation for four weeks following surgery is recommended to reduce risks. <sup>18,19</sup> 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. <sup>20</sup>

#### **Coding Implications**

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2020, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage.



Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

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

HCPCS	Description
N/A	

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

ICD 10 CM Code	Description
C41.4	Malignant neoplasm of pelvic bones, sacrum and coccyx
C79.51	Secondary malignant neoplasm of bone
D16.8	Benign neoplasm of pelvic bones, sacrum and coccyx
D48.0	Neoplasm of uncertain behavior of bone and articular cartilage
D49.2	Neoplasm of unspecified behavior of bone, soft tissue, and skin
M43.27-M43.28	Fusion of spine, lumbosacral to sacral and sacrococcygeal region
M46.1	Sacroiliitis, not elsewhere classified
M46.28	Osteomyelitis of vertebra, sacral and sacrococcygeal region
M46.38	Infection of intervertebral disc (pyogenic), sacral and
	sacrococcygeal region
M53.2X6-M53.2X8	Spinal instabilities, lumbar – sacral and sacrococcygeal region
M53.3	Sacrococcygeal disorders, not elsewhere classified
S32.810A-S32.811S	Multiple fractures of pelvis with stable disruption of pelvic ring

Reviews, Revisions, and Approvals		Approval
	Date	Date
New policy developed based off of Health Net policy NMP536		09/16
Sacroiliac Joint Fusion.		
References reviewed and updated. Codes reviewed and updated.	09/17	09/17
References reviewed and updated.	06/18	06/18
References reviewed and updated. Codes reviewed and updated. ICD-	05/19	06/19
10 codes added: C41.4, C79.51, D16.8, D48.0, D49.2, M46.28, M46.38,		
and S32.810A-S32.811S. Specialty review.		
Annual review completed. References reviewed and updated. Changed	05/20	06/20
ICD-10 code M53.2X7 to M53.2X6. Corrected numbering in Reference		
Section and applicable footnotes. Added clarification to section II., "that		
sacroiliac joint fusion procedures, either open or minimally invasive		



Reviews, Revisions, and Approvals	Revision Date	Approval Date
(e.g., iFuse), are investigational for all other indications, including but not limited to, treating treatment of"		
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."	06/21	06/21
Annual review completed. Added "at least 4-6 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.	06/22	06/22

#### 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):1066-1077. 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.hayes.com. Published March 3, 2014. (Retitled September 3, 2020-annual review October 5, 2021). Accessed April 28, 2022.
- 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):1831-1838. doi:10.1007/s11999-014-3499-8.
- 4. North American Spine Society (NASS). Coverage policy recommendations percutaneous sacroiliac joint fusion. June 2015.
- 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):674-691. doi:10.1227/NEU.0000000000000988.
- 6. SI-BONE, Inc. Announces Medicare Palmetto Removes MIS SI Joint Fusion from Non-Coverage. Published February 25, 2014. <a href="https://www.prnewswire.com/news-releases/si-bone-inc-announces-medicare-palmetto-removes-mis-si-joint-fusion-from-non-coverage-247035941.html">https://www.prnewswire.com/news-releases/si-bone-inc-announces-medicare-palmetto-removes-mis-si-joint-fusion-from-non-coverage-247035941.html</a>. Accessed April 28, 2022.
- 7. U.S. Food and Drug Administration (FDA) 510(k) Premarket Notification Database. iFuse SI Fusion System. No. K110838.

  <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K110838">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K110838</a>.

  Published April 21, 2011. Accessed April 28, 2022.

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- 8. U.S. Food and Drug Administration (FDA) 510(k) Premarket Notification Database. SI-BONE iFuse Implant System. No. K150714. April 17, 2015. <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K150714">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K150714</a>. Published April 17, 2015. Accessed April 28, 2022.
- 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):48-55. 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, et al. Evaluation of low back pain in adults. UpToDate. <a href="https://www.uptodate.com">www.uptodate.com</a>. Updated June 6, 2021. Accessed April 28, 2022.
- 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):59-66. 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):319-325. 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/new-search/search.aspx. Published February 01, 2016. Updated January 6, 2022. Accessed April 28, 2022.
- 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 3, 2022.
- 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):860-895. 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-e235. doi:10.1016/j.wneu.2021.07.011
- American Academy of Orthopaedic Surgeons (AAOS). Surgery and smoking: Research on smoking and orthopaedic procedures. Updated April 2019. <a href="https://www.orthoinfo.org/en/treatment/surgery-and-smoking/">https://www.orthoinfo.org/en/treatment/surgery-and-smoking/</a>. Accessed May 13, 2022.



#### **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. The Health Plan 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. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

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**Note:** For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

**Note: For Medicare members/enrollees,** to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed <u>prior to</u> applying the criteria set forth in this clinical policy. Refer to the CMS website at <a href="http://www.cms.gov">http://www.cms.gov</a> for additional information.

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