

Clinical Policy: Sacroiliac Joint Fusion

Reference Number: CP.MP.126 Date of Last Revision: 04/25 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 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® that open sacroiliac joint (SIJ) 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;
 - 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 spinal 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 SIJ 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, SIJ and hip, including a home exercise program or documentation of member/enrollee's inability to tolerate;
 - B. Non-radiating, typically 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 (sacral sulcus) 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 at least three provocative tests (thigh trust, compression, sacral thrust, 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 SIJ that excludes the presence of destructive lesions (e.g., tumor, infection), fracture, traumatic SIJ instability, or inflammatory arthropathy;

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- 2. Plain radiographs of the pelvis to exclude the presence of concomitant hip pathology;
- 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;
- H. A failure of at least one therapeutic intra-articular SIJ injection (i.e., corticosteroid injection), unless a therapeutic injection is contraindicated;
- I. Procedure will be performed using the lateral transarticular approach.
- III. It is the policy of health plans affiliated with Centene Corporation that the long-term safety and effectiveness of SIJ 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 health plans affiliated with Centene Corporation that current evidence does not support SIJ 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. ¹⁻⁴ When the sacroiliac joint (SIJ) 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.

A number of Food and Drug Administration (FDA)-approved implants have been proposed for SIJ 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 FDA in November 2008 for fracture fixation of long bones, large bone fragments of the pelvis, and for conditions including SIJ disruptions and degenerative sacroiliitis. Additional FDA clearances were given on April 21, 2011, and on April 17, 2015. The iFuse system involves the fluoroscopically guided insertion of porous plasma spray coated titanium implants across the SIJ. 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.⁵⁻⁷

Polly, Swofford, Whang, et al. (2016) and Polly, Cher, Wine, et al. (2015) completed two randomized controlled trials with a six-month and one-year follow-up, respectively, on SIJ fusion using iFuse versus non-surgical management. Compared with nonsurgical management, the iFuse was more effective in pain reduction, improving quality of life, and improving function. 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.^{7,8} Additional evidence suggests SIJ fusion with iFuse improves pain, enhances health-related quality of life, and decreases disability compared to non-surgical management.^{9,10,11}

The percutaneous placement of an intraarticular stabilization device into the 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 and, 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.

Fusion can be performed by three approaches: a lateral approach, a posterior approach, and a posterior oblique approach. 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. ¹³

The SIJ remains a controversial source of primary low back pain, and surgery is rarely performed for sacroiliac joint dysfunction, as this condition is difficult to diagnose due to the lack of an agreed-upon "gold standard". However, minimally invasive SIJ fusion is becoming a more prevalent treatment for chronic refractory low back pain isolated to the SIJ 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. ^{2,14}

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. Smoking increases the rate of perioperative complications, especially pseudoarthrosis; therefore, smoking cessation for four weeks following surgery is recommended to reduce risks. Smoking of patients undergoing spinal fusions in the lower back demonstrated an 80 to 85% success rate for non-smokers or patients who quit smoking following surgery and less than 73% success rate for smokers. Smokers.

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 SIJF system.³ A meta-analysis was conducted, and the results for patients following MIS SIJF demonstrated steadily and considerably lower SIJ pain scores and 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 quality of life were significantly higher in patients treated with MIS SIJF when compared to



nonsurgically treated patients. The ISASS concludes that lateral MIS SIJF is "a recognized safe, predictable, and preferred surgical method for the management of intractable, debilitating primary or secondary SIJ pain disorders." The ISASS noted a scarce amount of published literature on MIS SIJF using a posterior approach. The society concluded that the instrumentation utilized in a MIS SIJ procedure is the surgeon's preference.³

North American Spine Society (NASS)

In 2021, NASS updated their coverage recommendations for minimally invasive sacroiliac joint (SIJ) fusion. ¹⁵ NASS recommends minimally invasive SIJ fusion for the treatment of SIJ pain for patients with low back/buttock pain who meet specific criteria. ¹⁶

National Institute for Health and Care Excellence (NICE)

NICE recommends minimally invasive sacroiliac joint (SIJ) fusion surgery for treatment of chronic sacroiliac pain in patients with a confirmed diagnosis of unilateral or bilateral SIJ dysfunction due to degenerative sacroiliitis or SIJ disruption. The committee indicates that this procedure stabilizes the joint, but there was evidence that 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 SIJ 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 SIJ. To

Coding Implications

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Codes that support coverage criteria

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



Codes that do not support coverage criteria

CPT® Codes	Description
27278	Arthrodesis, sacroiliac joint, percutaneous, with image guidance, including placement of intra-articular implant(s) (eg, bone allograft[s], synthetic device[s]), without placement of transfixation device.

Reviews, Revisions, and Approvals	Revision	Approval
	Date	Date
New policy developed based off of Health Net policy NMP536	09/16	09/16
Sacroiliac Joint Fusion.		
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 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.	06/22	06/22
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.	06/23	06/23
Annual review. Minor rewording in Criteria I.B. and Criteria I.D. Removed osteopathic or chiropractic manipulation from Criteria II.A.3. Added (sacral sulcus) to criteria II.C. Added clarifying verbiage to Criteria II.B. Updated Criteria II.D. to include a positive response to at least three provocative tests. Added clarifying language to Criteria II.F.2. Removed "at least two weeks apart" in Criteria II.G. regarding image guided, contrast-enhanced intra-articular (diagnostic) SIJ injection on two separate occasions. Added code 27278 to table of codes that do not support coverage. Background updated with no impact on criteria. References reviewed and updated.	05/24	05/24
Annual review. Description and background updated with no clinical significance. Minor rewording in criteria section with no clinical	04/25	04/25

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Reviews, Revisions, and Approvals	Revision Date	Approval Date
significance. Reviewed codes and descriptions. Removed deleted code 0775T from "Codes that do not support coverage criteria." References reviewed and updated. Internal specialists reviewed. External specialist reviewed.		

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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.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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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 http://www.cms.gov for additional information.

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