Medical Policy

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***Current Policy Effective Date: 3/1/25**
(See policy history boxes for previous effective dates)

Title: Sacroiliac Joint Fusion (Percutaneous or Minimally Invasive) for the Treatment of Low Back Pain

Description/Background

The sacroiliac joints connect the lower spine (sacrum) to the iliac bones that form the pelvic ring. The sacrum and iliac bones at the SI joints do not move, but are bound together by strong ligaments. The two sacroiliac joints move together as a single unit and are considered bicondylar joints (where the two joint surfaces move correlatively together). They are instrumental in transferring the load of the upper body to the lower body, supporting the entire weight of the upper body when erect, which in turn results in stress to this weight-bearing area of the pelvis and spine.

The sacroiliac joint, as a result of degenerative, arthritic or traumatic changes, can be a source of low back pain. Sacroiliac joint problems have been given various names, including sacroiliac joint dysfunction, sacroiliac joint inflammation, sacroiliac joint strain, and sacroiliac joint syndrome.

According to some estimates, the SI joint is the primary source of pain in 10 to 30% of patients with low back pain (LBP). There is uncertainty because there are no standard criteria by which to measure either prevalence or severity. Symptoms can occur in the setting of morphologically normal joints. There are no consistent, demonstrable radiographic or laboratory features. Pain can be felt throughout the lower lumbar region, buttocks, groin, thigh and/or leg and is often aggravated by any form of movement, including sitting, lifting, running or walking. Clinical tests for sacroiliac joint pain, in addition to the patient's description, may include various tests including movement, stress on the iliac bones and, palpation to detect tenderness. Further diagnostic difficulty exists because the posterior lumbar facet joints and discs may refer pain to the sacroiliac area. Injection of the sacroiliac joints using local anesthetic agents can be used as a diagnostic tool.

Sacral insufficiency fractures can occur when the sacrum becomes weak and too fragile to handle the stress of weight bearing. Sacral insufficiency fractures are usually located parallel to the spine, most often in the ala or "wings" of the sacrum, immediately adjacent to the sacroiliac

joint. A transverse fracture may also be present that connects an insufficiency fracture when it occurs on both sides of the sacrum. Sacral insufficiency fractures are more common in the elderly population, particularly in post-menopausal women, due to the presence of osteoporosis, and with no known history of trauma. Other risk factors for fracture include radiation to the pelvis (e.g. oncologic conditions), steroid use, rheumatoid arthritis, hyperparathyroidism, anorexia nervosa, liver transplantation, osteopenia, Paget's disease, hip joint replacement, and prior lumbosacral fusion. Sacral insufficiency fractures can also occur in pregnant or breastfeeding women due to temporary osteoporosis.

Sacroiliac joint fusion (arthrodesis) is a surgical technique that is intended to achieve bony fusion of the sacroiliac joint and stabilize it, thus reducing pain and disability. Sacroiliac joint fusion may be performed as a minimally invasive procedure or as an open surgical procedure. In the open procedure, bone grafts, obtained either from the patient or through the use of morselized bone product, may or may not be used. Percutaneous sacroiliac joint fusion is a minimally invasive approach in which pins screws or small bone-filled cages are placed percutaneously across the joint space on one or both sides in order to achieve fusion

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Regulatory Status:

A number of percutaneous or minimally invasive fixation/fusion devices have been cleared for marketing by the FDA through the 510(k) process. FDA product codes: OUR.

Table 1. Select Sacroiliac Fusion Devices

Device	Manufacturer	Features	Graft Compatible	Clearance	Date
Lateral Transiliac Approach					
iFuse®	SI Bone, Inc	Titanium triangular rod with conventional manufacturing	Y	K110838	2011
iFuse® 3D	SI Bone, Inc	Titanium triangular 3D printed porous rod	Y	K162733	2017
iFuse TORQ® Implant System	SI Bone, Inc	3D printed cannulated screw	Y	K222605, K241574	2022
iFuse TORQ TNT™ Implant System	SI-Bone, Inc	3D printed cannulated screw	Y	K241504	2024
iFuse Bedrock Granite® Implant System	SI-Bone, Inc	3D printed screw with porous graft windows	Y	K233508	2023
FIREBIRD SI Fusion System™	Orthofix	Cannulated screw	Y	K200696	2020
SambaScrew®	Orthofix	Cannulated screw	Y	K121148	2012

Silex Sacroiliac Joint Fusion®	X-Spine Systems	Cannulated screw	Y	K140079	2014
SI-LOK® Sacroiliac Joint Fixation System	Globus Medical	Cannulated screw	Y	K112028	2011
SImmetry® Sacroiliac Joint Fusion System	RTI	Cannulated screw	Y	K102907	2010
SImpact® Sacroiliac Joint Fixation System	Life Spine	Cannulated screw	Y	K180749	2018
SIros™	Genesys Spine	Cannulated screw	Y	K191748	2019
Triton SI Joint Fixation System™	Choice Spine	3D printed screw with porous graft windows	Y	K211449	2021
UNITY Sacroiliac Joint Fixation System	Dio Medical Corp.	Cannulated screw	Y	K222448	2022
T-FIX® 3DSI Joint Fusion System	Cutting Edge Spine, LLC	3D printed cannulated screw	Y	K214123	2023
PathLoc SI Joint Fusion System	L & K Biomed Co., Ltd.	Metalic fastener	Y	K231841, K240201	2023
SI-Cure Sacroiliac Joint Fusion System	Alevio, LLC	Metalic fastener	Y	K231951	2023
Integrity-SI® Fusion System	OsteoCentric Technologies	Cannulated screw	Y	K230226	2023
Sacrix® Sacroiliac Joint Fusion Device System	LESspine Innovations	Cannulated screw	Y	K232605	2023
TORPEDO Implant System®	Deltacor GmbH	Cannulated screw	Y	K230817	2024
Liberty SI Lateral Implant System	Spinal Simplicity LLC	Cannulated screw	Y	K231923	2023
Posterolateral Approach					
Rialto™ SI Joint Fusion System	Medtronic	Cannulated screw	Y	K161210	2016
SacroFuse®/ SIJFuse™	SpineFrontier	Solid or hollow-cored screw	Y	K150017	2015
SILO TFX MIS Sacroiliac Joint Fixation System	Aurora Spine, Inc	Solid or hollow-cored screw	Y	K221047	2022
Camber Sacroiliac (SI) Fixation System	Camber Spine Technologies	Cannulated screw	Y	K233972	2023

BowTie™ SI Joint Fusion System	SAIL Fusion, LLC	Solid or hollow-cored screw	Y	K232149	2024
Posterior Approach					
Catamaran™	Tenon Medical	Metal plug	Y	K180818	2018
CornerLoc™	Fusion Foundation Solutions	Bone allograft	N	HCT/P	N/A
LinQ™ SI Joint Stabilization	PainTEQ	Bone allograft	N	HCT/P	N/A
NADIA™ SI Fusion System (DIANA)	Ilion Medical	Metal plug	N	K190580	2020
PsiF™ Posterior Sacroiliac Fusion	Omnia Medical	Bone allograft	N	HCT/P	N/A
SIFix System®	NuTech	Bone allograft	N	HCT/P	N/A
TransFasten™	Captiva Spine	Bone allograft	N	HCT/P	N/A
CATAMARAN SI Joint Fusion System	Tenon Medical, Inc.	Metal plug	Y	K231944	2023
TiLink-P SI Joint Fusion System	Surgentec, LLC	Metal plug	Y	K230857, K240720; K242141	2023
Invictus® Spinal Fixation System	Alphatec Spine, Inc.	Cannulated screw	Y	K232275	2023
VyLink™ Spinal Screw System	Vy Spine, LLC	Cannulated screw	Y	K231744	2023
Patriot-SI Posterior Implant System	Spinal Simplicity LLC	Cannulated screw	Y	K232259	2024
Huvex Interspinous Fixation System	K&J Consulting Corporation	Cannulated screw	Y	K232877	2024
SI-DESIS® X™ Sacroiliac Joint Fusion System	SI-Technology, LLC	Cannulated screw	Y	K241813	2024

HCT/P: Human Cell and Tissue Product; N/A: not applicable; N: no; Y: yes.

Medical Policy Statement

Percutaneous minimally invasive sacroiliac joint fusion using placement of fixation/fusion devices are established. It is considered a useful therapeutic option when supporting documentation substantiates appropriate individual selection criteria listed under inclusionary guidelines.

Inclusionary and Exclusionary Guidelines

Inclusions:
This procedure is indicated for the treatment of sacroiliac joint pain for individuals with low back/buttock pain who meet **all** of the following criteria:

- Additional or alternative diagnoses that could be responsible for the individual's ongoing pain or disability have been ruled out (e.g., L5/S1 compression, hip osteoarthritis, tumors);
- Pain is caudal to the lumbar spine (L5 vertebra), localized over the posterior SIJ, and consistent with SIJ pain;
- Provocative tests with 3 or more positive responses (Patrick's sign, Gaenslen's test, posterior provocation test, distraction test, compression test, thigh thrust test)
- 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;
- SIJ pain confirmed with at least 3 physical examination maneuvers that stress the SIJ and cause the individual's typical pain;
- Controlled sacroiliac joint blocks, using local anesthetic agents of different duration of action for controlled comparison with or without placebo, are recommended to confirm the diagnosis when clinical findings are consistent with disabling sacroiliac joint pain. There is at least a 75% reduction in pain for the expected duration of the anesthetic used following an image-guided, contrast-enhanced intra-articular sacroiliac joint injection on 2 separate occasions.
- Radiographic imaging studies (plain radiographs and CT or MRI) that show **all** of the following:
    - Confirmed evidence of injury or degeneration of the SI joint by MRI or CT findings
    - Confirmation there is no presence of tumor, infection, other destructive lesions, or inflammatory arthropathy that would not be resolved by SI fusion
    - Concomitant hip pathology ruled out with plain AP radiograph of pelvis; if hip pathology is present that may correlate with symptoms, must have orthopedic surgeon consultation
    - Neural compression or other degenerative conditions that could cause low back or buttock pain are ruled out with advanced radiographic imaging (CT or MRI) of lumbar spine; if spine pathology is present that may correlate with symptoms, must have spine surgeon consultation

Exclusions:
This procedure is not indicated in the presence of:

- Less than 6 months of pain
- Failure to pursue conservative treatment
- Systemic arthropathy such as ankylosing spondylitis or rheumatoid arthritis
- Generalized pain behavior (e.g. somatoform disorder) or generalized pain disorder (e.g. fibromyalgia)
- Infection, tumor or fracture

- Neural compression as seen on MRI or CT that correlates with the individual's symptoms or other more likely source for their pain
- Presence of osteopenia or osteoporosis (t-score of less than -1.0)
- Acute, traumatic instability of SI joint
- Due to lack of sufficient evidence to establish safety and/or efficacy over other treatments, percutaneous posterior intra-articular fusion of the SI joint is considered investigational
- Smoking within 4 weeks prior to surgery; must also have documented commitment for smoking cessation for at least 4 weeks after surgery

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CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

27279 27280

Other codes (investigational, not medically necessary, etc.):

27278

Rationale

Treatment of Sacroiliac Joint (SIJ) Pain: SIJ Fusion/Fixation with a Transiliac Triangular Implant System

Clinical Context and Therapy Purpose
The purpose of SIJ fixation/fusion with a triangular implant is to provide a treatment option that is an alternative to or an improvement on existing therapies in patients with SIJ pain.

The question addressed in this evidence review is: Does the use of SIJ fixation/fusion with a triangular implant improve the net health outcome in individuals with SIJ pain?

The following **PICO** was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with SIJ pain.

Interventions
The therapy being considered is SIJ fixation/fusion with a triangular implant.
Comparators
The following therapy is currently being used to treat SIJ pain: conservative therapy.

Outcomes
The general outcomes of interest are symptoms (e.g., reductions in pain), functional outcomes, quality of life, reductions in medication use, and treatment-related morbidity. Follow-up from 1 to 5 years is of interest to monitor outcomes.

Study Selection Criteria
Methodologically credible studies were selected using the principles outlined in indication 2.

Review of Evidence

SYSTEMATIC REVIEWS

Ghaddaf et al (2024) published a meta-analysis of 3 randomized controlled trials (n=423) that compared minimally invasive SIJ fusion using triangular titanium implants to nonsurgical management for SIJ dysfunction.[22] At 6 months, the results showed statistically significant improvements with minimally invasive SIJ fusion in pain scores (standardized mean difference [SMD], -1.78 [95% CI, -2.46 to -1.11]; p<.00001; I2=90%), disability as measured by Oswestry Disability Index (ODI) score (SMD, -1.22 [95% CI, -1.47 to -0.96]; p<.00001; I2=43%), quality of life measures including 36-Item Short Form Health Survey (SF-36) Physical Component Summary (PCS) (SMD, 1.09 [95% CI, 0.90 to 1.28]; p<.00001; I2=0%), SF-36 Mental Component Summary (MCS) (SMD, 0.66 [95% CI, 0.30 to 1.01]; p=.0003; I2=66%), and EuroQol 5-Dimension (EQ-5D) (SMD, 1.09 [95% CI, 0.80 to 1.39]; p<.00001; I2=59%). The durability of the benefit persisted through 24 months; however, this long-term data was derived from only one trial for all outcomes. The study also reported improved patient satisfaction (Odds ratio [OR], 6.87 [95% CI, 3.73 to 12.64]; p<.00001; I2=1%) and reduced opioid use (OR,.43 [95% CI,.29 to.65]; p<.00001; I2=0%) with minimally invasive SIJ fusion compared to non-surgical management of SIJ dysfunction. No significant differences in adverse event rates were observed between groups.

RANDOMIZED CONTROLLED TRIALS

Investigation of Sacroiliac Fusion Treatment (INSITE)

Whang et al (2015) reported an industry-sponsored non-blinded RCT of the iFuse Implant System in 148 patients.[1] Twelve month follow-up to this RCT was reported by Polly et al (2015) [2] and 2-year follow-up was reported by Polly et al (2016).[3] However, by 12 months, almost all patients in the control group had crossed over to SIJ fusion, precluding comparison between groups. Trial inclusion was based on a determination of the SIJ as a pain generator from a combination of a history of SIJ-localized pain, positive provocative testing on at least 3 of 5 established physical tests, and at least a 50% decrease in SIJ pain after image-guided local anesthetic injection into the SIJ. The duration of pain before enrollment averaged 6.4 years (range, 0.47-40.7 years). A large proportion of subjects (37%) had previously undergone lumbar fusion, SIJ steroid injections (86%), and RFA (16%).

Patients were randomized 2:1 to minimally invasive SIJ fusion (n=102) or to nonsurgical management (n=46). Nonsurgical management included a stepwise progression of nonsurgical treatments, depending on individual patient choice. During follow-up, control patients received physical therapy (97.8%), intra-articular steroid injections (73.9%), and RFA of sacral nerve roots (45.7%). The primary outcome measure was 6-month success rate, defined as the proportion of treated subjects with a 20-mm improvement in SIJ pain in the absence of severe device-related or neurologic adverse events or surgical revision. Patients in the control arm could crossover to surgery after 6 months. Baseline scores indicated that the patients were severely disabled, with VAS pain scores averaging 82.3 out of 100, and ODI scores averaging 61.9 out of 100 (0=no disability, 100=maximum disability).

Characteristics and results of RCTs are shown in Tables 2 to 4. At 6 months, success rates were 23.9% in the control group vs. 81.4% in the surgical group (posterior probability of

superiority >0.999). A clinically important (≥15-point) improvement in ODI score was found in 27.3% of controls compared with 75.0% of fusion patients. Measures of quality of life (36-Item Short-Form Health Survey, EuroQol-5D) also improved to a greater extent in the surgery group. Of the 44 nonsurgical management patients still participating at 6 months, 35 (79.5%) crossed over to fusion. Compared with baseline, opioid use at 6 months decreased from 67.6% to 58% in the surgery group, and increased from 63% to 70.5% in the control group (p=0.082). At 12 months, opioid use was similar between groups (55% vs. 52%, p=0.61).

In 2016, Polly et al reported 2-year outcomes from the SIJ fusion arm of this RCT (see Table 2).[3] Of 102 subjects originally assigned to SIJ fusion and treated, 89 (87%) were evaluated at 2 years. In this report, clinical outcomes were based on the amount of improvement in SIJ pain and in ODI scores. Improvement was defined as a change of 20 points in SIJ pain score and 15 points in ODI score. Substantial improvement was defined as a change in 25 points in SIJ pain score or a score of 35 or less and an improvement of 18.8 points in ODI score. At 24 months, 83.1% had improvement in SIJ pain score, and 68.2% had improvement in ODI. By 24 months, the proportion taking opioids was reduced from 68.6% at baseline to 48.3%.

Three-year follow-up results of the INSITE and Sacroiliac Joint Fusion with iFuse Implant System trials were published by Darr et al (2018).[4] Of 103 patients with SIJ dysfunction who were treated with minimally invasive SIJ fusion with triangular titanium implants, 60 (72.3%) patients reported an improvement in ODI scores of at least 15 points from baseline to 3 years. The mean ODI score decreased from 56 to 28 for the same timeframe, an improvement of 28 points (p<0.001); similarly, the mean SIJ pain score decreased to 26.2, reflecting a decrease of 55 points (p<0.001). Over 3 years of follow-up, 168 adverse events were reported in 75 patients, although only 22 of these events involved the pelvis. The study was limited by its lack of long-term data from a control group not receiving surgical treatment.

iFuse Implant System Minimally Invasive Arthrodesis (iMIA)

In 2016 and 2017, the iMIA study group (Sturesson et al, Dengler et al) reported another industry-sponsored multicenter RCT of the iFuse Implant System in 103 patients.[5,6] Selection criteria were similar to those of the Whang trial, including at least 50% pain reduction on SIJ block. Mean pain duration was 4.5 years, and about half of the patients were not working due to lower back pain. Thirty-three percent of patients had undergone prior lumbar fusion. Nonsurgical management included physical therapy and exercises at least twice per week; interventional procedures (e.g., steroid injections, RFA) were not allowed. The primary outcome was change in VAS pain score at 6 months.

All patients assigned to iFuse underwent the procedure, and follow-up at 6 months was available for 49 of 51 patients in the control group and for all 52 patients in the iFuse group. Six-month results as reported by Sturesson et al (2016) are shown in Table 2.[5] At 6 months, VAS pain scores improved by 43.3 points in the iFuse group and by 5.7 points in the control group (p<.001). ODI scores improved by 25.5 points in the iFuse group and by 5.8 points in the control group (p<.001, between groups). An improvement in lower back pain by at least 20 VAS points (minimal clinically important difference [MCID]) was achieved in 78.8% of the SIJ fusion group vs. 22.4% of controls; p<.001). QOL outcomes showed a greater improvement in the iFuse group than in the control group. Changes in pain medication use are not reported. Patients in the conservative management group were allowed to cross over to SIJ fusion at 6 months.

Twelve and 24-month results from the iMIA trial were reported by Dengler et al (2017, 2019).[6,7] Twenty-one patients in the conservative management group had little or no improvement in symptoms and crossed over to SIJ fusion after the 6-month visit. Fourteen (56%) of the 25

patients who remained in the conservative management group had at least a 20-point improvement in VAS back pain score (22.4% of patients assigned to conservative management). At 12 months, low back pain had improved by 42 points (SD=27.0) on a 100-point VAS in the SIJ fusion group compared with 14 (SD=33.4) points in the conservative management group (p<.001). Mean ODI scores improved by 25 points in the SIJ fusion group compared with 8.7 points in controls (p<.001). At 24 months back pain had improved by 45 points compared to 11 points in the control group, with 79% (37 of 47) of SIJ fusion patients achieving at least a 20 point improvement compared to 24% (11 of 46) of controls. At 24 months there was an improvement of 26 points in ODI compared to 8 points in controls (p<.001). Improvement of at least 20 points was observed in 64% of the SIJ fusion group compared to 24% of the conservative management group.

Randers et al. (2024) conducted a double-blind randomized sham surgery-controlled trial comparing minimally invasive SIJ fusion using triangular titanium implants (iFuse, SI-BONE) to sham surgery in 63 patients with SIJ pain confirmed by diagnostic injection.[23] The surgical group received 3 implants inserted laterally through the ilium into the sacrum, while the sham group underwent a simulated procedure without implant placement. After 6 months, there was no statistically significant difference in the primary outcome between the SIJ fusion and sham groups. The mean reduction in SIJ pain was 2.6 points for the surgical group and 1.7 points (MD, -1.0; 95% CI: -2.2 to 0.3; p =.13) for the sham group on the Numeric Rating Scale (NRS). Secondary outcomes, including ODI and EuroQol 5-dimension 5-level EQ-5D, also showed similar results between groups. The study was limited by its short follow-up period.

Table 2. Summary of Key RCT Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	**Comparator**
Randers et al (2024)	Sweden and Norway	2	2018-2021	Patients 21 to 70 y with confirmed diagnosis of severe SIJ pain	32 randomized to SIJ fusion	31 randomized to nonsurgical
Whang et al (2015)[1]	U.S.	19	2013-2014	Patients 21-70 y with confirmed diagnosis of unilateral or bilateral SIJ dysfunction due to degenerative sacroiliitis and/or SIJ disruption	102 randomized to SIJ fusion	46 randomized to nonsurgical management
Sturesson et al (2017)[5]	EU (Belgium, Germany, Italy, Sweden)	9	2013-2015	Patients 21-70 y with LBP for >6 mo and diagnosed with SIJ as primary pain generator	52 randomized to SIJ fusion	51 randomized to conservative management

iMIA: iFuse Implant System Minimally Invasive Arthrodesis; INSITE: Investigation of Sacroiliac Fusion Treatment; LBP: low back pain; RCT: randomized controlled trial; SIJ: sacroiliac joint.
[a] The 3 criteria for diagnosis of SIJ pain were as follows: pain was present or near the posterior superior iliac spine; there were at least 3 positive findings on 5 provocative tests; at least a 50% pain reduction on fluoroscopically guided injection of local anesthetic into the joint.

Table 3. Summary of 6-Month iFuse

Results	VAS Score		Success End Point		ODI Score		SF-36 PCS Score		EQ-5D TTO Index	
	Ctl	iFuse	Ctl	iFuse	Ctl	iFuse	Ctl	iFuse	Ctl	iFuse
INSITE										
Baseline	82.2	82.3			61.1	62.2	30.8	30.2	0.47	0.44
Follow-up	40.4	29.8	23.9%	81.4%	56.4	31.9	32.0	42.8	0.52	0.72
Change	-12.1	-52.6[a]			-4.9	-30.3[a]	1.2	12.7	0.05	0.29
iMIA										
Baseline	73.0	77.7								
Follow-up	67.8	34.4								
Change	-5.7	-43.3			-5.8	-25.5			0.11	0.37
Randers et al (2024)	NRS score, operated SIJ						PGQ		EQ-5D-5L	
Baseline	7.7	7.9			53	51	74	70	61	63
Follow-up	6	5.0			50	47	68	64	66	65
Change	-1.7	-2.9			-3	-4	-6	-6	.05	.02
Mean difference (95% CI); p-value	-1.0 (-2.2 to 0.3); p =.13				-3 (-9 to 4); NS		−4 (−12 to 4); NS		-0.01 (-0.07 to 0.05); NS	

The success end point was defined as a reduction in VAS pain score of ≥20, absence of device-related events, absence of neurologic worsening, and absence of surgical intervention. Ctl: control; EQ-5D TTO index: EuroQol Time Tradeoff Index; iMIA: iFuse Implant System Minimally Invasive Arthrodesis; INSITE: Investigation of Sacroiliac Fusion Treatment; NRS: numeric rating scale; NS: not significant; ODI: Oswestry Disability Index; PGQ: pelvic girdle questionnaire; SF-36 PCS: 36-item Short Form Health Survey Physical Component Summary; VAS: visual analog scale.
[a] p<.001

Table 4. Extended Follow-Up From the INSITE and iMIA Trials

Outcome Measures	Baseline	6 Months (SD)	12 Months (SD)	24 Months (SD)
INSITE				
Sacroiliac joint fusion pain score	82.3	29.8		26.7
% >20 point improvement plan				83.1%
Sacroiliac joint fusion ODI score	57.2	31.9		28.7
% >15 point improvement ODI				68.2%
iMIA				
Low back pain				
Conservative management	73.0 (13.8)	67.8 (20.3)	58.9 (28.2)	
Sacroiliac joint fusion	77.7 (11.3)	34.4 (23.9)	35.2(25.5)	
Leg pain				
Conservative management	47.1 (31.1)	46.5 (31.4)	41.7 (32.4)	
Sacroiliac joint fusion	52.7 (31.5)	22.6 (25.1)	24.0 (27.8)	
ODI				
Conservative management	55.6 (13.7)	50.2 (17.2)	46.9 (20.8)	
Sacroiliac joint fusion	57.5 (14.4)	32.0 (18.4)	32.1 (19.9)	

Adapted from Dengler et al (2017)[5]
ODI: Oswestry Disability Index

Table 5. Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Whang et al (2015)[1] INSITE					
Sturesson et al (2017)[5] iMIA	1. Patients with other contributory sources of LBP might have been enrolled with SIJ-caused LBP patients				
Randers et al (2024)					1. Study limited to 6 month follow-up

iMIA: iFuse Implant System Minimally Invasive Arthrodesis; INSITE: Investigation of Sacroiliac Fusion Treatment; LBP: low back pain; SIJ: sacroiliac joint.
The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 6. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[d]	Data Completeness[e]	Power[d]	Statistical[f]
Whang et al (2015)[1]						
Sturesson et al (2017)[5] Randers et al (2024)		1. Intervention was unblinded				

The evidence limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4.Comparative treatment effects not calculated.

NONRANDOMIZED STUDIES

Prospective cohort studies with good follow-up rates are more likely to provide valid estimates of outcomes. Principal results of the studies at 2- to 5-year follow-up are shown in Table 7.

In 2016, results from a cohort of 172 patients undergoing SIJ fusion reported to 2 years were published by Duhon et al.[8-9] Patients were formally enrolled in a single-arm trial (NCT01640353) with planned follow-up for 24 months. Success was defined as a reduction of pain score of 20 mm on a 100-mm VAS, absence of device-related adverse events, absence of neurologic worsening, and absence of surgical reintervention. Enrolled patients had a mean VAS pain score of 79.8, a mean ODI score of 55.2, and a mean pain duration of 5.1 years. At 6 months, 136 (80.5%) of 169 patients met the success end point, which met the prespecified Bayesian probability of success rate. Mean VAS pain scores were 30.0 at 6 months and 30.4 at 12 months. Mean ODI scores were 32.5 at 6 months and 31.4 at 12 months. At 2 years, 149 (87%) of 172 patients were available for follow-up. The VAS pain score at 2 years was 26.0, and the ODI score was 30.9. Thus, 1-year outcomes were maintained at 2 years. Other outcomes (e.g., quality of life scores) showed similar maintenance or slight improvement compared with 1-year outcomes. Use of opioid analgesics decreased from 76.2% at baseline to 55% at 2 years. Over the 2-year follow-up, 8 (4.7%) patients required revision surgery.

Table 7. Two- to Five-Year Outcomes of the iFuse Implant

Studies and Outcomes	Mean Baseline Value	Mean 2-3 year value	Difference or % Achieving Outcome	3	4	5	P
Duhon et al (2016)							
N	172	149 (86.6%)					
Pain score (range, 0-100)	79.8	26.0	53.3				
Oswestry Disability Index score	55.2	30.9	24.5				
SF-36 score	31.7	40.7	8.9				
EQ-5D TTO score	0.43	0.71	0.27				
Whang et al (2019)							
N	103					93	

Pain score (range, 0-100)	81.5 (SD 12.7)				27.1 (29.4)	<0.001
Oswestry Disability Index score	56.3				29.9 (21.2)	<0.001
EQ-5D TTO score	0.45 (0.17)				0.75 (0.22)	<0.001
Opiod use	76.7%	53.9%	47.4%	42.6%	41.3%	
Not working due to back pain	16.5%				15.1%	

EQ-5D TTO Index: EuroQoL Time Tradeoff Index; INSITE: Investigation of Sacroiliac Fusion Treatment.; LOIS: Long Term Outcomes from INSITE and SIFI; SD: standard deviation; SF-36: 36-Item Short-Form Health Survey; SiFi: Sacroiliac Joint Fusion with iFuse Implant System; VAS: visual analog score.
[a] All differences between baseline and 2- to 3-year values were statistically significant.

In general, cohort studies and case series have shown improvements in VAS pain scores and other outcomes measures consistent in magnitude to the RCTs. The Long Term Outcomes from INSITE and SIFI (LOIS) trial was a prospective single-arm study that enrolled patients who had participated in 2 of the studies described above for evaluation at 3, 4, and 5 years.[10] The primary success outcome, a reduction in VAS of at least 20 points in the absence of a serious device-related adverse event, neurologic worsening, or surgical revision, was obtained in 81.7% (95% confidence interval 72.4 to 89.0%) of patients at 5 years. The improvements in other clinical outcomes were maintained out to 5 years. Opioid use decreased over time, although the contribution of the opioid use agreement cannot be determined. Fifteen percent of patients were no working due to back pain. Radiolucencies suggesting implant failure were observed in 5% of cases and were associated with incorrect placement. Bridging bone was observed in 45% of sides at 12 months, 71% at 24 months, and 88% at 60 months.

The Study of Bone Growth in the Sacroiliac Joint after Minimally Invasive Surgery with Titanium Implants (SALLY) is a 5 year multicenter study that will assess non-inferiority of outcomes with a 3-D printed triangular implant as compared to the traditionally manufactured titanium coated implant. Twelve month follow-up has been published for 46 of the 51 patients enrolled.[11] The 6-month change in ODI met the non-inferiority margin, and secondary outcomes of pain, disability, and QOL were similar to those obtained in the INSITE, iMIA, and SIFI trials. Independent radiographic analysis showed bridging bone in 70% and 77% of sides imaged at 6 and 12 months, respectively, compared to 45% bridging bone in prior studies with the solid titanium coated implants. No breakage, migration, or subsidence was detected. However, there was no evidence that the increase in bridging bone led to an improvement in pain or functional outcomes compared to the milled implant at 12 months. Follow-up is continuing.

Improved health outcomes are also supported by retrospective studies that compare SIJ fusion/fixation using a triangular implant with other treatments for SIJ pain.[12,13]These results are consistent with the medium-term durability of the treatment. Analysis of an insurance database reported an overall incidence of complications to be 16.4% at 6 months and the cumulative revision rate at 4years of 3.54%.[14] Spain and Holt (2017) reported a retrospective review of surgical revision rates following SIJ fixation with either surgical screws or the iFuse triangular implant.[13] Revision rates were lower with the iFuse device than observed with surgical screws.

Section Summary: SIJ Fusion/Fixation with a Transiliac Triangular Implant

The evidence on SIJ fusion/fixation with a triangular implant includes 1 meta-analysis, 1 blinded sham controlled trial, and 2 nonblinded RCTs of minimally invasive fusion and 2 case series with more than 85% follow-up at 2 to 3 years. Both RCTs reported superior short-term results for fusion, however, preferable design for assessing pain outcomes would be independent blinded assessment of outcomes or, when feasible, a sham-controlled trial. Longer term follow-up from these RCTs has indicated that the results obtained at 6 months persist to 2 years. An additional cohort study and case series with sample sizes ranging from 45 to 149 patients and low dropout rates (<15%) also showed reductions in pain and disability at 2 years. One small case series showed outcomes that persisted to 5 years. The cohort studies and case series are consistent with the durability of treatment benefits. The meta-analysis pooled data from 3 RCTs and found that SIJ fusion with triangular titanium implants resulted in statistically significant improvements in pain, disability, quality of life, and opioid use compared to nonsurgical management for SIJ dysfunction, with similar adverse event rates between groups, though long-term data beyond 12 months was limited to a single trial.

SIJ FUSION/FIXATION WITH AN IMPLANT OTHER THAN A TRANSILIAC TRIANGULAR IMPLANT

Clinical Context and Therapy Purpose
The purpose of SIJ fixation/fusion with a cylindrical threaded implant is to provide a treatment option that is an alternative to or an improvement on existing therapies in patients with SIJ pain.

The following **PICO** was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with SIJ pain.

Interventions
The therapy being considered is SIJ fixation/fusion with a cylindrical threaded implant.

Comparators
The following therapy is currently being used to treat SIJ pain: conservative therapy.

Outcomes
The general outcomes of interest are symptoms (e.g., reductions in pain), functional outcomes, quality of life, reductions in medication use, and treatment-related morbidity. Follow-up from 1 to 5 years is of interest to monitor outcomes.

Study Selection Criteria
Methodologically credible studies were selected using the principles outlined in indication 2.

Systematic Reviews
Tran et al (2019) published a systematic review comparing the effectiveness of minimally invasive joint fusion (i.e., utilizing the iFuse device) compared to screw-type surgeries.[15] A total of twenty studies was pooled to calculate a standardized mean difference (SMD) across pain, disability, and global/quality-of-life outcomes, including 14 studies evaluation the iFuse system and 7 studies evaluated cylindrical, threaded implants. Studies evaluating cylindrical, threaded implants consisted of case series and cohort studies. Patients receiving these implants experienced significantly worse pain outcomes (p=0.03) compared to patients receiving iFuse,

with SMD of 1.28 (95% CI: 0.47 to 2.09) and 2.04 (95% CI: 1.76 to 2.33), respectively. A statistically significant difference in disability scores was reported between screw-type and iFuse implant groups (0.26 [95% CI: -1.90 to 2.41] vs. 1.68 [95% CI: 1.43 to 1.94]; p=0.01), with improved outcomes in the iFuse population. For global/quality-of-life outcomes, a statistically significant difference in scores was reported between screw-type and iFuse implants groups (0.60 [95% CI: 0.33 to 0.88] vs. 0.99 [95% CI: 0.75 to 1.24]; p=0.04), with improved outcomes in the iFuse population.

A qualitative systematic review by Lorio et al (2020) for the International Society for the Advancement of Spine Surgery found evidence on the safety and effectiveness of distraction (posterior) SIJ fusion was limited to 1 prospective multicenter study (described below), no comparative studies, and a small number of case series. [16]

Prospective Studies

Rappoport et al (2017) reported on an industry-sponsored prospective study of SIJ fusion with a cylindrical threaded implant (SI-LOK).[17] The study included 32 patients with a diagnosis of SIJ dysfunction who had failed nonoperative treatment, including medication, physical therapy, and therapeutic injections. A diagnostic injection was performed to confirm the source of pain to the SIJ. The procedure included drilling to prepare for screw insertion and implantation of 3 screws, at least one of which was slotted. The slotted screws were packed with autogenous bone graft from the drill reamings. Pain and disability scores were reduced following device implantation (see Table 8), and revisions within the first 12 months of the study were low (n=2). At the 2 year follow-up, VAS scores remained low, although 4 (12.5%) did not return for follow-up and 2 patients required revision surgery; analysis did not count these as treatment failures.[18]

Fuchs and Ruhl (2018) published 2-year results of a prospective multi-center cohort of the posterior approach to arthrodesis of theSIJ.[21] A total of 171 patients from 20 hospitals in Germany were treated from 2011 to 2012 using a DIANA implant (marketed in the U.S. as the NADIA implant). The DIANA implant is a hollow, tapered dowel that comes in diameters of 13, 15, 17, or 19 mm. A distraction tool was used to determine the size of the implant, which is inserted between the ilium and sacrum under distraction. Allogeneic bone grafts were used in 66% of cases. Patients had partial weight bearing on the operated side for 6 to 8 weeks. At the 2year follow-up, VAS had decreased from 74 to 37, ODI improved from 51% to 33%, and the McGill Pain Questionnaire decreased from50% to 31% (all p<.001). Use of opioids decreased from 49.3% of patients to 30.3% at follow-up. In computed tomography (CT)scans, only 31% of patients showed SIJ fusion at 2 years.

Calodney et al (2024) reported results from SECURE, a multi-center, prospective, single-arm study evaluating a posterior SIJ fusion with the LinQ implant platform for sacroiliac joint stabilization and arthrodesis (NCT04423120).[20] The multi-center study included 159 patients treated from January 2020 to March 2022 who were followed for 12 months. Patients had a mean age of 59 years and had experienced SIJ pain for a mean of 5.8 years, with mean baseline VAS and ODI scores of 76.2 and 52.4, respectively. A total of 73 patients either withdrew consent or were lost to follow-up prior to 12 months of observation. At 12 months, 73.5% of participants (61/83) met the primary composite endpoint of ≥20 mm VAS improvement without serious adverse events or reintervention. Mean VAS scores improved from 76.2 at baseline to 32.6 at 12 months (43.3 point improvement, p<.0001). ODI scores improved by 25.3 points on average (p<.0001). Another endpoint investigated by the authors was the Patient-Reported Outcomes Measurement Information System (PROMIS-29 item) instrument, which showed significant (p<.001) improvements from baseline values in all 7

subscales (Pain interference, sleep disturbance, fatigue, anxiety, depression, ability to participate in social roles and activities, and physical functioning). Adverse events were infrequent, with only 5 total adverse events reported and 1 procedure-related serious adverse events (anesthesia aspiration). No implant-related serious adverse events occurred. This study's primary limitations include the absence of a control group and substantial participant attrition, with 47% of patients withdrawing or lost to follow-up before the 12-month mark.

Kucharzyk et al (2022) published interim results from a prospective cohort study evaluating pain and ODI outcomes for patients treated for SIJ pain with the SImmetry sacroiliac joint fusion system (NCT02074761). [21] A total of 250 participants were recruited from 23 centers in the U.S; of these 80.4% (n=201) were available for 1 year follow-up, although not all patients have each outcome reported due to incomplete follow-up. The mean age of the participants was 60.5 years of age, and each participant had SI joint pain for 6 months or greater, and most had prior treatment for SIJ pain, including some prior lumbar spinal procedures. The mean VAS score had decreased from 76.4 at baseline to 33 at 1 year after the procedure (p<.001), with 140 (72.2%) patients achieving minimal clinically important difference (≥20-point reduction). The mean ODI score likewise showed significant improvement from baseline to 1 year, decreasing from 54.4 to 30.5 (p<.001). Over half of the cohort (62.5% [n=120])achieved the minimal clinically important difference (15-point reduction) on the ODI. Before surgery, 62.7% (n=126) of the cohort were on opioids, decreasing to 26.9% (n=54) at the 1 year follow-up (p<.001). QOL was assessed with the EQ-5D: at baseline, the mean EQ-5D was 60.9, increasing to 72.8 after 1 year (p<.001). The authors reported 8 (3.2%) of patients had a serious adverse event, of which 5 were determined to be device-related (back pain, pain in the extremity, bilateral SI joint pain, device loosening, or device malposition). The main limitations of this study are a lack of comparison group and incomplete follow-up on all patients due to the interim nature of this analysis.

Splitt et al. (2023) compared two implant systems for SIJ fusion in a prospective study of 65 patients: the Deltacor Torpedo (n=30) and the SI-Bone iFuse (n=35).[24] At 12 months, both groups showed significant improvement in VAS pain scores (Torpedo: 80.6 to 21.9 mm; iFuse: 83.5 to 28 mm; p<.0001 for each group) and ODI scores (Torpedo: 62% reduction; iFuse: 58% reduction) from baseline values, with no significant differences between the two implant systems. The study was limited by its relatively small sample size with no power calculations, lack of blinding, and limited presentation of patient characteristics.

Davies et al. (2024) reported results from MAINSAIL, a prospective, single-arm, multi-center study evaluating the Catamaran SI Joint Fusion System.[25] The study included 33 patients with SIJ pain who had failed conservative treatment. At 6 months, 80% of patients met the primary composite endpoint of ≥20 mm VAS improvement without serious adverse events or reintervention. Mean VAS scores improved from 80.9 at baseline to 31.1 at 6 months (p<.001). Mean ODI scores improved from 51.9% at baseline to 29.6% at 6 months (p <.01). Patient satisfaction was high, with 93.3% reporting satisfaction at 6 months. No device-related serious adverse events or reoperation were reported. The study was limited by its relatively small sample size and lack of a comparison group.

Table 8. Pain and Disability Scores After Implantation with a Cylindrical Threaded Implant

Outcome Measures	Baseline	3 Months (SD)	6 Months (SD)	12 Months (SD)	24 Months (SD)	p
Low back pain	55.8 (26.7)	28.5 (21.6)	31.6 (26.9)	32.7 (27.4)	20.0 (18.4)	<.01

Left leg pain	40.6 (29.5)	19.5 (22.9)	16.4 (25.6)	12.5 (23.3)	5.8 (8.1)	<.01
Right leg pain	40.0 (34.1)	18.1 (26.3)	20.6 (25.4)	14.4 (21.1)	11.5 (20.1)	<.05
Oswestry Disability Index	55.6 (16.1)	33.3 (16.8)	33.0 (16.8)	34.6 (19.4)	27.5 (18.8)	<.01

Adapted from Rappoport et al (2017)[17]
SD: standard deviation.

Section Summary: SIJ Fusion/Fixation With an Implant Other Than a Transiliac Triangular Implant

The evidence on fusion of the SIJ with devices other than the triangular implant includes 6 prospective cohort studies, 3 were conducted with transiliac screws, and the 3 with a posterior approach. One cohort study compared SIJ fusion with the Torpedo device to iFuse (transiliac triangular implant) and found no differences in pain or function outcomes at 12 months between the two groups. No other controlled studies were identified. Meta-analyses of the available prospective and retrospective studies indicate improvement in subjective outcomes from before surgery to follow-up in these unblinded studies. The meta-analyses comparing outcomes from these cohorts with non-concurrent studies suggest a possible difference in outcomes between the more well-studied triangular transiliac implant and other implant designs and approaches. There is uncertainty in the health benefit of SIJ fusion/fixation with these various implant designs. Controlled studies with the different implant designs and approaches are needed to evaluate these devices.

SUMMARY OF EVIDENCE

For individuals who have SIJ pain who receive SIJ fixation/fusion with a transiliac triangular implant, the evidence includes 1 meta-analysis, 1 blinded sham controlled trial, 2 nonblinded RCTs of minimally invasive fusion, prospective cohorts with more than 85% follow-up, and case series. Relevant outcomes are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. The sham-controlled RCT found no significant difference in the primary outcome of pain reduction or in any secondary outcomes through 6 months of follow-up. Both nonblinded RCTs have reported outcomes past 6 months, after which crossover was allowed. Both studies reported significantly greater reductions in VAS pain scores and ODI scores in SIJ fusion patients than in control groups. The reductions in pain and disability observed in the SIJ fusion group at 6 months were maintained out to 1 year compared with controls who had not crossed over. The RCTs were nonblinded without a placebo or an active control group. Prospective cohorts and case series with sample sizes ranging from 45 to 149 patients and low dropout rates (<15%) also showed reductions in pain and disability out to 5 years. The cohort studies and case series are consistent with the durability of treatment benefit. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome. The meta-analysis pooled data from 3 RCTs and found that SIJ fusion with triangular titanium implants resulted in statistically significant improvements in pain, disability, quality of life, and opioid use compared to nonsurgical management for SIJ dysfunction, with similar adverse event rates between groups, though long-term data beyond 12 months was limited to a single trial.

For individuals who have SIJ pain who receive SIJ fusion/fixation with an implant other than a transiliac triangular implant, the evidence includes 6 prospective cohort studies and retrospective case series. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Three prospective cohorts were conducted with transiliac screws and the third with a device inserted through a posterior approach. One cohort study compared SIJ fusion with the Torpedo device to iFuse (transiliac

triangular implant) and found no differences in pain or function outcomes at 12 months between the two groups. No other controlled studies were identified. Meta-analyses of the available prospective and retrospective studies indicate improvement in subjective outcomes from before surgery to follow-up, but with a possible difference in outcomes between the more well studied triangular transiliac implant and other implant designs and approaches. There is uncertainty in the health benefit of SIJ fusion/fixation with these implant designs. Therefore, controlled studies with a larger number of patients and longer follow-up are needed to evaluate these devices. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

PRACTICE GUIDELINES AND POSITION STATEMENTS

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

North American Spine Society

The North American Spine Society (NASS) has developed appropriate use criteria for percutaneous SIJ fusion, SIJ injection, and radiofrequency ablation. These criteria can be accessed by payers through a registration process. For further information see: https://www.spine.org/Research-Clinical-Care/Quality-Improvement/Clinical-Guidelines.

International Society for the Advancement of Spine Surgery (ISASS)

In 2020, the International Society for the Advancement of Spine Surgery provided guidance on indications for minimally invasive SIJ fusion with placement of lateral transfixing devices.[16] The Society recommended that "patients who have all of the following criteria may be eligible for lateral MIS [minimally invasive surgical] SIJF with placement of lateral transfixing devices:

- "Chronic SIJ pain (pain lasting at least 6 months)
- Significant SIJ pain that impacts QOL [quality of life] or significantly limits activities of daily living
- SIJ pain confirmed with at least 3 physical examination maneuvers that stress the SIJ [list provided above] and reproduce the patient's typical pain
- Confirmation of the SIJ as a pain generator with > 50% acute decrease in pain upon fluoroscopically guided diagnostic intra-articular SIJ block using a small volume (< 2.5 mL) of local anesthetic.....
- Failure to respond to nonsurgical treatment consisting of NSAIDs [nonsteroidal anti-inflammatory drugs] and a reasonable course (4 to 6 weeks) of PT [physical therapy]. Failure to respond means continued pain that interferes with activities of daily living and/or results in functional disability"

It was recommended that intra-articular SIJ steroid injection and radiofrequency ablation (RFA) of the SIJ lateral branch nerves maybe considered but are not required.

Specifically not recommended were:

- Minimally invasive posterior (dorsal) SIJ fusion

- Repeat intra-articular steroid injection
- Repeat SIJ radiofrequency ablation

National Institute for Health and Care Excellence

National Institute for Health and Care Excellence guidance was published in April 2017 on minimally invasive SIJ fusion surgery for chronic sacroiliac pain.[26] The recommendations included:

> 1.1 "Current evidence on the safety and efficacy of minimally invasive sacroiliac (SI) joint fusion surgery for chronic SI pain is adequate to support the use of this procedure……
> 1.2 Patients having this procedure should have a confirmed diagnosis of unilateral or bilateral SI joint dysfunction due to degenerative sacroiliitis or SI joint disruption.
> 1.3 This technically challenging procedure should only be done by surgeons who regularly use image-guided surgery for implant placement. The surgeons should also have had specific training and expertise in minimally invasive SI joint fusion surgery for chronic SI pain."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this policy are listed in Table 9.

Table 9. Summary of Key Trial

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04423120[a]	A Single Arm, Multicenter, Prospective, Clinical Study on a Novel Minimally Invasive Posterior Sacroiliac Fusion Device	100	Mar 2026
NCT04062630[a]	Sacroiliac Joint Stabilization in Long Fusion to the Pelvis: Randomized Controlled Trial (SILVIA)	213	Dec 202
NCT05870488[a]	iFuse TORQ for the Treatment of Sacroiliac Joint Dysfunction	110	May 2026
NCT03507049	Sacroiliac Joint Fusion Versus Sham Operation for Treatment of Sacroiliac Joint Pain (SIFSO)	63	May 2030
NCT06487936[a]	Real-World Registry Study on Patient Satisfaction With TransLoc 3D SI Joint Fusion	120	Dec 2024
NCT05633888[a]	Prospective, Multi-Center, Single Arm Post-Market Feasibility Study of the Tenon Medical CATAMARAN™ SI Joint Fusion System	50	Jan 2026
NCT05276024[a]	Evaluation of the iFuse Bedrock Technique in Association With Posterior Lumbosacral Fusion With Iliac Fixation.	50	Apr 2025
Unpublished			
NCT01861899[a]	Treatment of Sacroiliac Dysfunction With SI-LOK® Sacroiliac Joint Fixation System	46	Apr 2019

NCT02074761[a]	Evolution study using the Zyga SImmetry Sacroiliac Joint Fusion System	250	Nov 2020
NCT04218838[a]	A Prospective, Multi-Center, Bi-Phasic Randomized Design to Compare Outcomes of the CornerLoc™ SI Joint Stabilization System and Intra-Articular Sacroiliac Joint Steroid Injection in Patients With Refractory Sacroiliac Joint Dysfunction	120	Jul 2023 (Terminated, enrollment difficulties)

NCT: national clinical trial
[a] Denotes industry-sponsored or cosponsored trial

Government Regulations

National:

There is no national coverage determination on this topic. CMS does have a fee schedule for 27279 and 27280.

Local:

WPS LCD L36000, Percutaneous minimally invasive fusion/stabilization of the sacroiliac joint for the treatment of back pain. Effective December 17, 2015. For services performed on or 06/27/2024.

Percutaneous minimally invasive fusion/stabilization of the sacroiliac joint for the treatment of back pain is indicated for the treatment of SIJ pain for patients with low back/buttock pain who meet all of the following criteria:

a) Have undergone and failed a minimum six months of intensive non-operative treatment that must include medication optimization, activity modification, and active physical therapy;
b) Patient's report of non-radiating, unilateral pain that is caudal to the lumbar spine (L5 vertebrae), localized over the posterior SIJ, and consistent with SIJ pain;
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 for their pain do not exist;
d) Positive response to the thigh thrust test OR compression test AND 2 of the following additional provocative tests: Gaenslen's test, distraction test, Patrick's sign;
e) Absence of generalized pain behavior (e.g. somatoform disorder) or generalized pain disorders (e.g. fibromyalgia);
f) Diagnostic imaging studies that include **ALL** of the following:
    1. imaging (plain radiographs and a CT or MRI) of the SI joint that excludes the presence of destructive lesions (e.g. tumor, infection) or inflammatory arthropathy that would not be properly addressed by percutaneous SIJ fusion;
    2. Imaging of the ipsilateral hip (plain radiographs) to rule out osteoarthritis;
    3. 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;

g) At least 75% reduction of pain for the expected duration of the anesthetic used following an image-guided, contrast-enhanced SIJ injection on two separate occasions.

Limitations: Percutaneous SIJ fusion for SIJ pain is not indicated in the presence of:

- Systemic arthropathy such as ankylosing spondylitis or rheumatoid arthritis;
- Generalized pain behavior or generalized pain disorder;
- Infection, tumor or fracture;
- Acute, traumatic instability of the SIJ;
- Neural compression as seen on an MRI or CT that correlates with the patient's symptoms or other more likely source for their pain.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Spinal Surgery-Minimally Invasive Lumbar Interbody Fusion (-LIF)

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through November 2024, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
7/1/14	4/8/14	4/21/14	Joint policy established
1/1/15	10/24/14	11/3/14	Code 27279 added to policy. No change in policy status.
3/1/16	12/10/15	1/19/16	Routine policy maintenance. References updated. Policy status change to established with criteria. Medicare LCD guidelines added.
3/1/17	12/13/16	12/13/16	Routine policy maintenance updated rationale and added references 16, 17, 20, 20-24, 28 and 29.
3/1/18	12/12/17	12/12/17	Updated rational section, references 11-13 added. Several outdated studies deleted. No change in policy status.
3/1/19	12/11/18		Routine policy maintenance, added references #14-16. No change in policy status.
3/1/20	12/17/19		Routine policy maintenance, added references 19-23. No change in policy status.
3/1/21	12/15/20		Routine policy maintenance, added reference #24 and #25. No change in policy status.
3/1/22	12/14/21		Routine policy maintenance. No change in policy status.
3/1/23	12/6/22		Routine policy maintenance. No change in policy status. (ky)
3/1/24	12/19/23		• Updated the MPS - the word exclusionary was removed from the MPS. Updated MPS to include placement of fixation/fusion devices to mimic BCBSA's statement under their Policy section: (Minimally invasive fixation/fusion of the SIJ using transiliac placement of a titanium triangular implant (eg, iFuse) may be considered medically necessary when ALL of the following criteria have been met).

			○ The safety and effectiveness of minimally invasive sacroiliac joint fusion using placement of fixation/fusion devices have been established. It may be considered a useful therapeutic option when supporting documentation substantiates appropriate patient selection criteria listed under inclusionary guidelines. • Updated and moved the 5th bullet under Inclusions to: there is at least a 75% reduction in pain for the expected duration of the anesthetic used following an image-guided, contrast-enhanced intra-articular sacroiliac joint injection on 2 separate occasions to the 4th bullet. • Per code update added code 27278 under E/I. • Title changed **to** Sacroiliac Joint Fusion (Percutaneous or Minimally Invasive) for the Treatment of Low Back Pain **from** Sacroiliac Joint Fusion for the Treatment of Low Back Pain. • Vendor: TurningPoint policy OR-1009.23 Sacroiliac Joint Fusion (ky)
3/1/25	12/17/24		• Routine maintenance • Updated MPS. • Updated Inclusions/Exclusions section based on TP and BCBSA. • Vendor: TP policy OR-1009.24 Sacroiliac Joint Fusion Post JUMP Comments: • Updates made to inclusion/exclusion based on Jump committee input. Under the Inclusions section – the last bullet starting with Radiographic imaging: updated **one** to **all.** Under Exclusions - added the below bullet:

			• Smoking within 4 weeks prior to surgery; must also have documented commitment for smoking cessation for at least 4 weeks after surgery (ky)

Next Review Date: 4th Qtr. 2025

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: SACROILIAC JOINT FUSION (PERCUTANEOUS OR MINIMALLY INVASIVE) FOR THE TREATMENT OF LOW BACK PAIN

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered, policy guidelines apply.
BCNA (Medicare Advantage)	See government section
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

N/A