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Minimally Invasive Fixation/Fusion of the Sacroiliac Joint

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

Minimally invasive fixation/fusion of the sacroiliac joint (SIJ) using transiliac placement of a titanium triangular implant (e.g., iFuse) **may be considered medically necessary** when meeting **ALL** of the following criteria:

- Pain is at least 5 on a 0 to 10 numeric pain rating scale that impacts quality of life or limits activities of daily living; AND
- Absence of generalized pain behavior (e.g., somatoform disorder) or generalized pain disorders (e.g., fibromyalgia); AND
- Have undergone and failed a minimum of 6 months of intensive nonoperative treatment that must include medication optimization, activity modification, and active therapeutic exercise targeted at the lumbar spine, pelvis, SIJ and hip, including a home exercise program; AND
- Nonradicular, typically unilateral, pain that is maximal below the L5 vertebra, localized over the posterior SIJ, and consistent with SIJ pain; AND
- A thorough physical examination demonstrates localized tenderness with palpation over the sacral sulcus (Fortin's point) in the absence of tenderness of similar severity elsewhere

(e.g., greater trochanter, lumbar spine, coccyx) that would explain the patient's symptoms;
AND

- Positive response to a cluster of 3 provocative tests (e.g., thigh or sacral thrust tests [see **NOTE 1**], compression test, Gaenslen's maneuver, distraction test, FABER/Patrick's sign);
AND
- Diagnostic imaging studies include **ALL** of the following:
 - a. Imaging (plain radiographs and computed tomography or magnetic resonance imaging) of the SIJ excludes the presence of destructive lesions (e.g., tumor, infection) or inflammatory arthropathy of the SIJ; and
 - b. Imaging of the pelvis (anteroposterior plain radiograph) rules out concomitant hip pathology; and
 - c. Imaging of the lumbar spine (computed tomography or magnetic resonance imaging) is performed to rule out neural compression or other degenerative condition that can be causing low back or buttock pain; AND
- At least 75% reduction of pain for the expected duration of the anesthetic used following an image-guided contrast-enhanced intra-articular SIJ injection on two separate occasions;
AND
- A trial of a therapeutic SIJ injection (i.e., corticosteroid injection) has been performed at least once.

NOTE 1: The thrust tests may not be recommended in pregnant patients or those with connective tissue disorders.

Minimally invasive fixation/fusion of the SIJ for the treatment of back pain presumed to originate from the SIJ **is considered experimental, investigational and/or unproven** under all other conditions and with any other devices not listed above.

Policy Guidelines

This policy does not address the treatment of sacroiliac joint (SIJ) pain due to infection, trauma, or neoplasm.

This technically demanding procedure should only be done by surgeons who have specific training and expertise in minimally invasive SIJ fusion surgery for chronic SIJ pain and who regularly use image-guidance for implant placement.

Conservative nonsurgical therapy for the duration specified should include the following:

- Use of prescription strength analgesics for several weeks at a dose sufficient to induce a therapeutic response:
 - Analgesics should include anti-inflammatory medications (NSAIDs) with or without adjunctive medications such as nerve membrane stabilizers or muscle relaxants;
- Participation in at least 6 weeks of physical therapy (including active exercise) or documentation of why the patient could not tolerate physical therapy;

- Evaluation and appropriate management of associated cognitive, behavioral, or addiction issues; and
- Documentation of individual compliance with the preceding criteria.

Description

Sacroiliac Joint Pain

Similar to other structures in the spine, it is assumed the sacroiliac joint (SIJ) may be a source of low back pain. In fact, before 1928, the SIJ was thought to be the most common cause of sciatica. In 1928, the role of the intervertebral disc was elucidated, and from that point forward, the SIJ received less research attention.

Diagnosis

Research into SIJ pain has been plagued by a lack of a criterion standard to measure its prevalence and against which various clinical examinations can be validated. For example, SIJ pain typically presents without any consistent, demonstrable radiographic or laboratory features and most commonly exists in the setting of morphologically normal joints. Clinical tests for SIJ pain may include various movement tests, palpation to detect tenderness, and pain descriptions by the patient. Further confounding the study of the SIJ is that multiple structures, (e.g., posterior facet joints, lumbar discs) may refer pain to the area surrounding the SIJ. Because of inconsistent information obtained from history and physical examination, some have proposed the use of image-guided anesthetic injection into the SIJ for the diagnosis of SIJ pain.

Treatment

Treatments being investigated for SIJ pain include prolotherapy, corticosteroid injection, radiofrequency ablation, stabilization, and arthrodesis. Some procedures have been referred to as SIJ fusion but may be more appropriately called fixation due to little to no bridging bone on radiographs. Devices for SIJ fixation/fusion that promote bone ingrowth to fixate the implants include a triangular implant (iFuse Implant System) and cylindrical threaded devices (e.g., Rialto, SImmetry, Silex, SambaScrew, SI-LOK). Some devices also have a slot in the middle where autologous or allogeneic bone can be inserted. This added bone is intended to promote the fusion of the SIJ.

A 2021 review identified 33 different devices that could be implanted using either a lateral transiliac approach (n=21), posterior allograft approach (n=6), posterolateral approach (n=3), or a combination of the approaches (n=3). (1) The iliosacral and posterolateral approaches use up to 3 implants that pass through the ilium, while the posterior approach involves inserting implants directly into the SIJ. Many of the devices are intended to be used with allograft bone. Implants composed entirely of allograft bone are typically inserted through a posterior approach. The authors found no published evidence for 23 of the 33 devices identified.

Regulatory Status

A number of percutaneous or minimally invasive fixation/fusion devices have been cleared for marketing by the U. S. Food and Drug Administration (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 cannulated screw	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 Fixation System	RTI	Cannulated screw	Y	K102907	2010
Slimpact® 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	Y	K211449	2021

		porous graft windows			
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.	Metallic fastener	Y	K231841	2023
SI-Cure Sacroiliac Joint Fusion System	Alevio, LLC	Metallic fastener	Y	K231951	2023
Integrity-SI® Fusion System	OsteoCentric Technologies	Cannulated screw	Y	K230226	2023
Sacrix® Sacroiliac Joint Fusion Device System	LESpine 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	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.

Rationale

Medical policies assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life (QOL), and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Minimally Invasive Sacroiliac Joint 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 individuals with SIJ pain.

The following PICO was used to select literature to inform this policy.

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, QOL, 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 following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and AEs, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

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. (2) At 6 months, the results showed statistically significant improvements with minimally invasive SIJ fusion in pain scores (standardized mean difference [SMD], -1.78 [95% confidence interval {CI}, -2.46 to -1.11]; $p<.00001$; $I^2=90\%$), disability as measured by Oswestry Disability Index (ODI) score (SMD, -1.22 [95% CI, -1.47 to -0.96]; $p<.00001$; $I^2=43\%$), 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]; $p<.00001$; $I^2=0\%$), SF-36 Mental Component Summary (MCS) (SMD, 0.66 [95% CI, 0.30 to 1.01]; $p=.0003$; $I^2=66\%$), and EuroQol 5-Dimension (EQ-5D) (SMD, 1.09 [95% CI, 0.80 to 1.39]; $p<.00001$; $I^2=59\%$). 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]; $p<.00001$; $I^2=1\%$) and reduced opioid use (OR, .43 [95% CI, .29 to .65]; $p<.00001$; $I^2=0\%$) 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

Characteristics and results of RCTs are shown in Tables 2 to 4.

Investigation of Sacroiliac Fusion Treatment (INSITE)

Whang et al. (2015) reported an industry-sponsored nonblinded RCT, Investigation of Sacroiliac Fusion Treatment (INSITE) of the iFuse Implant System in 148 patients. (3) The 12-month follow-up to this RCT was reported by Polly et al. (2015), (4) and a 2-year follow-up was reported by Polly et al. (2016). (5) However, by 12 months, almost all patients in the control group had crossed over to SIJ fusion, precluding a 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 to 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 the 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 AEs 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).

At 6 months, success rates were 23.9% in the control group versus 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 QOL (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 ($p=.082$). At 12 months, opioid use was similar between groups (55% vs 52%, $p=.61$).

Polly et al. (2016) reported 2-year outcomes from the SIJ fusion arm of this RCT. (5) 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. The improvement was defined as a change of 20 points in the SIJ pain score and 15 points in the ODI score. Substantial improvement was defined as a change of 25 points in SIJ pain score-or an SIJ pain score of 35 or less-and an improvement of 18.8 points in the ODI score. At 24 months, 83.1% had improvements in SIJ pain score, and 68.2% had improvements in ODI scores. 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 (SiFi) trials were published by Darr et al. (2018). (6) 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 ≥ 15 points from baseline to 3 years. The mean ODI score decreased from 56 to 28 for the same time frame, an improvement of 28 points ($p < .001$); similarly, the mean SIJ pain score decreased to 26.2, reflecting a decrease of 55 points ($p < .001$). Over 3 years of follow-up, 168 AEs 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 iFuse Implant System Minimally Invasive Arthrodesis (iMIA) study group reported another industry-sponsored multicenter RCT of the iFuse Implant System in 103 patients. (7, 8) Selection criteria were similar to those of the trial by Whang et al. (2015), including at least a 50% pain reduction on SIJ block. The mean pain duration was 4.5 years, and about half of the patients were not working due to lower back pain. Additionally, 33% 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 the 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 Stureson et al. (2016) are shown in Table 2. (7) 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 (a minimal clinically important difference) was achieved in 78.8% of the SIJ fusion group versus 22.4% of controls ($p < 0.001$). Quality of life outcomes showed a greater improvement in the iFuse group than in the control group. Changes in pain medication use were 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). (9, 10) 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. These were

analyzed with the last observation prior to crossover carried forward. At 12 months, low back pain had improved by 42 points (standard deviation [SD], 27.0) on a 100-point VAS in the SIJ fusion group compared with 14 points (SD=33.4) in the conservative management group ($p<.001$). 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. (11) 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; Trial	Countries	Sites	Dates	Participants	Interventions	
					<i>Active</i>	<i>Comparator</i>
Randers et al. (2024) (11)	Sweden and Norway	2	2018-2021	Patients 21 to 70 years with confirmed diagnosis of severe SIJ pain	32 randomized to SIJ fusion	31 randomized to nonsurgical
Whang et al. (2015) (3); INSITE	U.S.	19	2013-2014	Patients 21-70 years 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) (7); iMIA	EU (Belgium, Germany, Italy, Sweden)	9	2013-2015	Patients 21-70 years with LBP for >6 months and diagnosed with SIJ as primary pain generator ^a	52 randomized to SIJ fusion	51 randomized to conservative management

EU: European Union; 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 Six-Month iFuse Results

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 (3)										
Baseline	82.2	82.3			61.1	62.2	30.8	30.2	0.47	0.44
Follow-up	70.4	29.8	23.9%	81.4% ^a	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 (7)										
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) (11)	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	

Adapted from Whang et al. (2015) (3) and Stureson et al. (2015) (7). The success endpoint 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 5L: EuroQol 5-dimension 5-level; 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 (SD)	6 Months (SD)	12 Months (SD)	24 Months (SD)
INSITE (3)				
SIJ fusion pain score	82.3	29.8		26.7
Percent ≥ 20 -point improvement pain				83.1%
SIJ fusion ODI score	57.2	31.9		28.7

Percent ≥15-point improvement ODI				68.2%
iMIA (7, 9, 10)				Mean Improvement (95% CI)
Back pain				
• <i>Conservative management</i>	73.0 (13.8)	67.8 (20.3)	58.9 (28.2)	11.0
• <i>SIJ fusion</i>	77.7 (11.3)	34.4 (23.9)	35.2 (25.5)	45.3 (37 to 54)
Leg pain				
• <i>Conservative management</i>	47.1 (31.1)	46.5 (31.4)	41.7 (32.4)	7.7
• <i>SIJ fusion</i>	52.7 (31.5)	22.6 (25.1)	24.0 (27.8)	32.0
ODI				
• <i>Conservative management</i>	55.6 (13.7)	50.2 (17.2)	46.9 (20.8)	8 (2 to 14)
• <i>SIJ fusion</i>	57.5 (14.4)	32.0 (18.4)	32.1 (19.9)	26 (21 to 32)

Adapted from Dengler et al. (2017). (9)

CI: confidence interval; iMIA: iFuse Implant System Minimally Invasive Arthrodesis; INSITE: Investigation of Sacroiliac Fusion Treatment; ODI: Oswestry Disability Index; SIJ: sacroiliac joint; SD: standard deviation.

Tables 5 and 6 display notable limitations identified in each study.

Table 5. Study Relevance Limitations

Study; Trial	Population ^a	Intervention ^b	Comparator ^c	Outcomes ^d	Follow-Up ^e
Whang et al. (2015) (3); INSITE					
Sturesson et al. (2017) (7); iMIA	1. Patients with other contributory sources of LBP might have been enrolled with SIJ-caused LBP patients.				
Randers et al. (2024) (11)					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. Clinically significant difference not prespecified; 6. Clinically 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; Trial	Allocation^a	Blinding^b	Selective Reporting^c	Data Completeness^d	Power^e	Statistical^f
Whang et al. (2015) (3); INSITE						
Sturesson et al. (2017) (7); iMIA		1. Intervention was unblinded				
Randers et al. (2024) (11)						

iMIA: iFuse Implant System Minimally Invasive Arthrodesis; INSITE: Investigation of Sacroiliac Fusion Treatment.

The study 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.

Results from a cohort of 172 patients undergoing SIJ fusion reported to 2 years were published by Duhon et al. (2016). (12, 13) Patients were formally enrolled in a single-arm trial (SIFI 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 AEs, 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 endpoint, 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., QOL 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 & Outcomes	Mean Baseline Value	Mean 2- to 3- Year Value	Difference or % Achieving Outcome^a	3 Years	4 Years	5 Years	p Value
Duhon et al. (2016) (12, 13) SIFI							
N	172	149 (86.6%)					
Pain score (range, 0-100)	79.8	26.0	53.3				
ODI 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) (14) LOIS							
N	103					93	
VAS (range, 0-100)	81.5 (SD 12.7)					27.1 (29.4)	<0.001
ODI score	56.3					29.9 (21.2)	<0.001
EQ-5D TTO score	0.45 (0.17)					0.75 (0.22)	<0.001
Opioid use	76.7%	53.9%		47.4%	42.6%	41.3%	
Not working due to back pain	16.5%					15.1%	

EQ-5D TTO: EuroQoL Time Tradeoff Index; INSITE: Investigation of Sacroiliac Fusion Treatment; LOIS: Long Term Outcomes from INSITE and SIFI; ODI: Oswestry Disability Index; 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. (14) The primary success outcome, a reduction in VAS of ≥ 20 points in the absence of a serious device-related AE, neurologic worsening, or surgical revision, was obtained in 81.7% (95% CI: 72.4% to 89.0%) of patients at 5 years. The improvements in other clinical outcomes were maintained out to 5 years (Table 7). Opioid use decreased over time, although the contribution of the opioid use agreement cannot be determined. Fifteen percent of patients were not 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-dimensional (3D) 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 in the prospective cohort. (15) 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 at 24 months was available for 84% of patients, with the stability of subjective and objective outcomes and similar efficacy for the 3D-printed implant and the milled implant from the earlier trials. (15) Two patients had AEs related to the procedure and 2 had undergone revision. 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. (16, 17) 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 4 years of 3.54%. (18) Spain and Holt (2017) reported a retrospective review of surgical revision rates following SIJ fixation with either surgical screws or the iFuse triangular implant. (17) Revision rates were lower with the iFuse device than observed with surgical screws.

Section Summary: Sacroiliac Joint 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, prospective cohorts with more than 85% follow-up, and a case series. 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 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. In addition, pain has a significant subjective and psychological component, and cognitive-behavioral techniques to address pain were specifically excluded from the types of treatment that control subjects could obtain. As it relates to trial design, an independent assessment of pain outcomes would have been preferable. 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 that persist out 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.

Minimally Invasive Sacroiliac Joint Fixation/Fusion With an Implant Other Than a Transiliac Triangular Implant

Clinical Context and Therapy Purpose

The purpose of SIJ fixation/fusion with a SIJ implant is to provide a treatment option that is an alternative to or an improvement on existing therapies in individuals with SIJ pain.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with SIJ pain.

Interventions

The therapy being considered is SIJ fixation/fusion with an implant other than a transiliac triangular implant.

Numerous cannulated screws are marketed that use iliosacral and posterolateral approaches that pass through the ilium. Up to 3 implants may be used.

The posterior approach involves inserting implants into the ligamentous recess between the sacrum and ilium. The devices are intended to be used with allograft bone or are composed entirely of allograft bone. The posterior approach may be called distraction arthrodesis as the implants increase the joint space and create tension on the ligaments, repositioning the joint surfaces.

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, QOL, 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 following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and AEs, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews

Tran et al. (2019) published a systematic review comparing the effectiveness of minimally invasive joint fusion with a triangular implant (i.e., utilizing the iFuse device) compared to screw-type surgeries. (19) A total of 20 studies were pooled to calculate a standardized mean difference across pain, disability, and global/QOL outcomes, including 14 studies evaluating the iFuse system and 7 studies evaluating cylindrical, threaded implants. Studies evaluating cylindrical, threaded implants consisted of case series and cohort studies. Patients receiving these implants experienced significantly worse pain outcomes ($p=.03$) compared to patients receiving iFuse, with a standardized mean difference 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]; $p=.01$), with improved outcomes in the iFuse population. For global/QOL 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]; $p=.04$), 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. (20)

Prospective Cohort Studies

Rappoport et al. (2017) reported an industry-sponsored prospective study of SIJ fusion with a cylindrical threaded implant (SI-LOK). (21) The study included 32 patients using 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 1 of which was slotted. The slotted screws were packed with an 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. (22)

Fuchs and Ruhl (2018) published 2-year results of a prospective multi-center cohort of the posterior approach to arthrodesis of the SIJ. (23) 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 2-year follow-up, VAS had decreased from 74 to 37, ODI improved from 51% to 33%, and the McGill Pain Questionnaire decreased from 50% 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). (24) 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 event (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). (25) 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.

Spitt 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 ($n=35$). (26) 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. (27) 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)	p Value
Low back pain	55.8 (26.7)	28.5 (21.6)	31.6 (26.9)	32.7 (27.4)	<0.01
Left leg pain	40.6 (29.5)	19.5 (22.9)	16.4 (25.6)	12.5 (23.3)	<0.01
Right leg pain	40.0 (34.1)	18.1 (26.3)	20.6 (25.4)	14.4 (21.1)	<0.05
ODI	55.6 (16.1)	33.3 (16.8)	33.0 (16.8)	34.6 (19.4)	<0.01

Adapted from Rappoport et al. (21, 22)

ODI: Oswestry Disability Index. SD: standard deviation.

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

The evidence on the fusion of the SIJ with devices other than the triangular implant includes 6 prospective cohort studies; 3 were conducted with transiliac screws, and 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 visual analog scale pain scores and Oswestry Disability Index 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 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, QOL, medication use, and treatment-related morbidity. Three prospective cohorts were conducted with transiliac screws and the 3 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.

Practice Guidelines and Position Statements

North American Spine Society (NASS)

In 2021, the NASS published coverage recommendations for minimally invasive SIJ fusion. (28) NASS recommended coverage when ALL of the following criteria are met:

1. “[Patients] have undergone and failed a minimum 6 months of intensive nonoperative treatment that must include medication optimization, activity modification, and active therapeutic exercise targeted at the lumbar spine, pelvis, SIJ and hip including a home exercise program.
2. Patient’s report of nonradicular, typically unilateral, pain that is maximal below the L5 vertebra, localized over the posterior SIJ, and consistent with SIJ pain.
3. A physical examination demonstrating localized tenderness with palpation over the sacral sulcus (Fortin’s point, i.e., at the insertion of the long dorsal ligament inferior to the posterior superior iliac spine or PSIS) or the absence of tenderness elsewhere (e.g., greater trochanter, lumbar spine, coccyx) that would explain the patient’s symptoms.
4. Positive response to a cluster of 3 provocative tests (1. Patrick’s or FABER, 2. Gaenslen, 3. thigh thrust, 4. sacral thrust, 5. distraction, 6. compression). Note that the thrust tests may not be recommended in pregnant patients or those with connective tissue disorders.
5. Absence of generalized pain behavior (e.g., somatoform disorder) or generalized pain disorders (e.g., fibromyalgia).
6. At least 75% reduction of pain, documented by pain diary, for the expected duration of the anesthetic used following an image-guided, contrast-enhanced intra-articular SIJ injection on 2 separate occasions.
7. A trial of at least one therapeutic intra-articular SIJ injection (i.e., corticosteroid injection).
8. Diagnostic imaging studies that include ALL of the following:
 - a. Imaging (plain radiographs and a CT [computed tomography] or MRI [magnetic resonance imaging]) of the SI joint that excludes the presence of destructive lesions (e.g., tumor, infection) or autoimmune arthropathy that would not be properly addressed by percutaneous SIJ fusion.
 - b. Imaging of the pelvis (AP [anteroposterior] plain radiograph) to rule out concomitant hip pathology that would better explain the patient’s symptoms.
 - c. Imaging of the lumbar spine (CT or MRI) to rule out neural compression or other degenerative condition that, in combination with the patient’s history, physical, and other testing, would more likely be the source of their low back or buttock pain.”

NASS considers minimally invasive SIJ fusion in ANY of the following scenarios to NOT be indicated:

1. “Any case that does not fulfill ALL of the above criteria.

2. Presence of systemic arthropathy such as ankylosing spondylitis or rheumatoid arthritis.
3. Presence of generalized pain behavior (e.g., somatoform disorder) or generalized pain disorder (e.g., fibromyalgia).
4. Presence of infection or tumor.”

American Society of Interventional Pain Physicians

In 2013, the American Society of Interventional Pain Physicians guideline recommended the use of controlled SIJ blocks with placebo or controlled comparative local anesthetic block when indications are satisfied with suspicion of SIJ pain. (29) A positive response to a joint block is considered to be at least a 75% improvement in pain or in the ability to perform previously painful movements.

International Society for the Advancement of Spine Surgery

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. (20) The Society recommended that "patients who have all of the following criteria may be eligible for lateral MIS [minimally invasive surgical] SIJF [SIJ fusion] 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 $\geq 50\%$ 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 may be considered but are not required.

Specifically, not recommended were:

- Minimally invasive posterior (dorsal) SIJ fusion
- Repeat intra-articular steroid injection
- Repeat SIJ radiofrequency ablation

American Society of Pain and Neuroscience (ASPN)

In 2024, ASPN published guidance on the treatment of sacroiliac disorders. (30)

The following recommendations were provided concerning minimally invasive sacroiliac joint fixation:

- Best Practice Statements on Minimally Invasive Sacroiliac Fusion: Minimally invasive posterior SI stabilization with allograft is considered medically necessary when the appropriate clinical criteria have been met. (Grade, A; Level, I-B; Level of certainty, High)
 - Including:
 - A failure of conservative measures to at least include physical therapy and injections.
 - Pain persisting a minimum of 6 months that interferes with functional activities as documented by both a pain score of VAS/NRS of 5 or greater and an ODI of 30 or more.
 - Failure of at least one therapeutic sacroiliac joint injection (less than 50% pain relief for three months duration).
 - Predominant pain pattern consistent with sacroiliac joint pathology.
 - Positive response from at least three validated maneuvers for sacroiliac joint dysfunction.
 - Positive Fortin finger test.
 - Diagnostic imaging: either CT or MRI that excludes destructive lesions of the sacroiliac joint.
 - Diagnostic confirmation of the SI joint as the pain generator demonstrated by at least one image-guided (CT or fluoroscopy) intraarticular injection of the SI joint with 50% or greater pain relief for the expected duration of the local anesthetic.
 - Excluding:
 - Infection or fracture (unrelated to implant).
 - Tumor.
 - Acute traumatic instability.
- Minimally invasive SI fusion with lateral transfixing devices is considered medically necessary when the appropriate clinical criteria have been met (as above). (Grade, A; Level, I-A; Level of certainty, High)
- Minimally invasive SI fusion implants should be used according to FDA labeling. (Grade, A; Level, I-A; Level of certainty, High)
- The use of implants composed of human cell and tissue products for sacroiliac fusion is considered medically necessary only if the guidelines set forth by the FDA Regulation of Human Cells and Tissue is followed and should be registered in the FDA Human Cell and Tissue Establishment Registration. (Grade, A; Level, NA; Level of certainty, High)
- ASPN supports the utilization of sacroiliac fusion and stabilization devices with published, peer-reviewed, multi-center, prospective evidence of at least 6 months duration to assess efficacy and safety. (Grade, A; Level, I-A; Level of certainty, High)
- The current evidence is insufficient to determine the medical necessity of emerging techniques for minimally invasive sacroiliac fusion such as posterior-transfixing, and hybrid approaches. (Grade, I; Level, II; Level of certainty, Low)

National Institute for Health and Care Excellence (NICE)

In 2017, the National Institute for Health and Care Excellence guidance on minimally invasive SIJ fusion surgery for chronic sacroiliac pain included the following recommendations:

- 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." (31)

In 2022, NICE published medical technology guidance on using the iFuse implant system for treating chronic sacroiliac joint pain. It provided the following recommendations: (32)

- 1.1 iFuse implant system is recommended as an option for treating chronic sacroiliac joint pain.
- 1.2 iFuse should be considered for use in people with a confirmed diagnosis of chronic sacroiliac joint pain (based on clinical assessment and a positive response to a diagnostic injection of local anaesthetic in the sacroiliac joint) and whose pain is inadequately controlled by non-surgical management.

Ongoing and Unpublished Clinical Trials

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

Table 9. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
NCT04423120 ^a	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 2024
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. A Prospective Double Blinded Randomized Controlled Multicenter Trial.	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
NCT01861899 ^a	Treatment of Sacroiliac Dysfunction with SI-LOK® Sacroiliac Joint Fixation System	46	Apr 2019
NCT02074761 ^a	Evolusion Study Using the Zyga Symmetry 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 co-sponsored trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	27278, 27279
HCPCS Codes	C1737, [Deleted 1/2024: 0775T, 0809T]

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <<https://www.cms.hhs.gov>>.

Policy History/Revision	
Date	Description of Change
11/01/2025	Document updated. The following change was made to Coverage: Removed content related to open surgical fixation/fusion of the sacroiliac joint. Added references 29 and 30; others removed. Title changed from: "Sacroiliac Joint Fixation/Fusion".
11/15/2024	Document updated with literature review. Coverage unchanged. Added references 22, 23, 69-71, 74, 75 and 77.
08/01/2023	Document updated with literature review. The following change was made to Coverage: Removed "using bone grafting, without titanium triangular or cylindrical implant(s)" from open surgical fixation/fusion statement. Reference 67 added.
01/15/2023	Reviewed. No changes.
07/01/2022	Document updated with literature review. Multiple editorial changes without change to policy intent were made in Coverage, along with the following more significant changes: 1) Modified examples of provocative, physical examination maneuvers/tests, 2) Modified conservative, non-surgical treatment requirements, 3) Removed "Imaging of the SIJ that does not indicate evidence of injury and/or degeneration" from the imaging requirements, 4) Modified experimental, investigational and/or unproven statement for minimally invasive fixation/fusion to just have a comprehensive statement without an example listing, and 5) Added "transiliac placement" and "e.g., iFuse" to the medically necessary statement on sacroiliac joint fusion. Added/updated the following references: 1, 9, 12, 13, 18, 20, 22, and 68-70. Document title changed from: Sacroiliac Joint Fusion or Stabilization.
01/15/2021	Reviewed. No changes.
04/15/2020	Document updated with literature review. The following changes were made to Coverage: 1) Coverage statements reorganized, and 2) Experimental, investigational, and/or unproven statement for minimally invasive

	fusion/stabilization and open surgical fusion/stabilization split into two separate statements. The following references were added: 4 and 14.
09/01/2018	Document updated with literature review. The following coverage was added: Open surgical sacroiliac joint (SIJ) fusion or stabilization may be considered medically necessary when meeting specific criteria; otherwise, open surgical fusion or stabilization will be experimental, investigational and/or unproved. The intent of coverage remained unchanged for minimally invasive SIJ fusion, but an additional NOTE 2 was added regarding conservative nonsurgical therapy prior to proposed SIJ fusion. The following references were added: 5, 6, 8, 13, 14, 16-19, 63, and 69.
07/15/2017	Document updated with literature review. Coverage unchanged.
01/01/2017	Document updated with literature review. The coverage changed to the following: MI sacroiliac joint (SIJ) fusion or stabilization, using titanium triangular implants or devices, for the treatment of back pain presumed to originate from the SIJ may be considered medically necessary when meeting ALL of the criteria listed. The experimental, investigational and/or unproven statement was changed to include but not limited to the following indications: Use of MI or percutaneous SIJ fusion products other than titanium triangular implants/devices (e.g., iFuse implant system); Systemic arthropathy, e.g., ankylosing spondylitis or rheumatoid arthritis; Instability of the SIJ; Other pathology that would prevent deriving benefit from SIJ fusion; or When the medical necessity criteria has not been met.
09/01/2016	Document updated with literature review. Coverage unchanged. Rationale and References substantially reorganized and revised.
03/15/2016	Reviewed. No changes.
08/01/2015	Document updated with literature review. Coverage unchanged. The following NOTE was added: "This policy does not address treatment of the sacroiliac joint for infection, trauma, or neoplasm."
10/15/2014	Document updated with literature review. Coverage unchanged. Rationale and References substantially revised.
07/01/2013	New medical document. Sacroiliac joint (SIJ) fusion or stabilization for the treatment of back pain presumed to originate from the SIJ is considered experimental, investigational and unproven, including but not limited to percutaneous and MI techniques.