Policy Number	**SUR705.033**
Policy Effective Date	**11/15/2024**

Sacroiliac Joint Fixation/Fusion

Table of Contents

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
Minimally invasive fixation/fusion of the sacroiliac joint (SIJ) using transiliac placement of a titanium triangular implant (e.g., iFuse) for the treatment of back pain presumed to originate from the SIJ **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
- Additional or alternative diagnoses that could be responsible for the patient's ongoing pain or disability have been ruled out; AND
- Failure to respond to a minimum of 6 months of conservative, non-surgical treatment (see **NOTE 1**) consisting of medication optimization, activity modification, and active therapeutic exercise targeting 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 physical examination demonstrates localized tenderness with palpation over the sacral sulcus (Fortin's point) or 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, physical examination maneuvers/tests (e.g., thigh or sacral thrust tests [see **NOTE 2**], compression test, Gaenslen's maneuver, distraction test, Faber/Patrick's sign) that stresses the SIJ and reproduces the patient's typical pain; 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 block using local anesthetic on two separate occasions; AND
- A trial of a therapeutic SIJ injection (i.e., corticosteroid injection) has been performed at least once.

NOTE 1: 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:
  a. 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 patient compliance with the preceding criteria.

NOTE 2: 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.

Open Surgical Fixation/Fusion of the Sacroiliac Joint

Open surgical fixation/fusion of the SIJ **may be considered medically necessary** for the following indications:

- Post-traumatic injury of the SIJ (e.g., following pelvic ring fracture);
- As an adjunctive treatment for SIJ infection or sepsis;
- Management of sacral tumor (e.g., partial sacrectomy); or
- When performed as part of multi-segmental long fusions for the correction of spinal deformity (e.g., idiopathic scoliosis, neuromuscular scoliosis).

Open surgical fixation/fusion of the SIJ that does not meet the criteria listed above **is considered experimental, investigational and/or unproven.**

Policy Guidelines

None.

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 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 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 (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 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 code: OUR.

Table 1. Select Sacroiliac Fusion Devices

Device	Manufacturer	Features	Graft Compatible	Clearance	Date
Lateral Transiliac Approach					
iFuse®	SI Bone	Titanium triangular rod with conventional manufacturing	Y	K110838	2011
iFuse® 3D	SI Bone	Titanium triangular 3D printed porous rod	Y	K162733	2017
iFuse TORQ® Implant System	SI Bone	3D printed cannulated screw	Y	K222605	2022
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 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.	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	LESspine Innovations	Cannulated screw	Y	K232605	2023
Posterolateral Approach					
Rialto™ SI Joint Fusion System	Medtronic	Cannulated screw	Y	K161210	2016
SacroFuse®/SIJFuse™	SpineFrontier	Solid or howwow-cored screw	Y	K150017	2015
SILO TFX MIS Sacroiliac Joint Fixation System	Aurora Spine, Inc	Solid or hollow-cored screw	Y	K221047	2022
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

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

Rationale

The policy was created in February 2013 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through September 13, 2023.

Medical policies assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the 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 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 technology, two domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one or more intended clinical uses 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. RCTs 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.

Sacroiliac Joint (SIJ) Fixation/Fusion 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 one to five 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 adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Randomized Controlled Trials (RCTs)
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, INSITE of the iFuse® Implant System in 148 patients. (2) The twelve-month follow-up to this RCT was reported by Polly et al. (2015), (3) and a 2-year follow-up was reported by Polly et al. (2016). (4) 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 to 40.7 years). A large proportion of subjects (37%) had previously undergone lumbar fusion, SIJ steroid injections (86%), and radiofrequency ablation (RFA) (16%).

Patients were randomized 2:1 to MI 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 (PT) (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 (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 Visual Analog Scale (VAS) pain scores averaging 82.3 out of 100, and Oswestry Disability Index (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=0.082). At 12 months, opioid use was similar between groups (55% versus 52%, p=0.61).

Polly et al. (2016) reported 2-year outcomes from the SIJ fusion arm of this RCT. (4) 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). (5) 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 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 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 iMIA study group reported another industry-sponsored multicenter RCT of the iFuse® Implant System in 103 patients. (6, 7) Selection criteria were similar to those of the trial by Whang (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 PT 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 below in Table 3. (6) 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<0.001). ODI scores improved by 25.5 points in the iFuse® group and by 5.8 points in the control group (p<0.001, 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 versus 22.4% of controls; p<0.001). QOL 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). (8, 9) 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<0.001). 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<0.001). Improvement of at least 20 points was observed in 64% of the SIJ fusion group compared to 24% of the conservative management group.

Table 2. Summary of Key RCT Characteristics

Study; Trial	**Countries**	**Sites**	**Dates**	**Participants**	**Interventions**	
					Active	***Comparator***
Whang et al. (2015) (2); 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) (6); 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 from INSITE and iMIA

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 (2)										
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 (6)										
Baseline	73.0	77.7								
Follow-up	67.8	34.4								
Change	-5.7	-43.3			-5.8	-25.5			0.11	0.37

Adapted from Whang et al. (2015) (2) and Sturesson et al. (2015) (6). 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 TTO: EuroQoL (quality of life) Time Tradeoff Index; ODI: Oswestry Disability Index; SF-36 PCS: 36-Item Short-Form Health Survey Physical Component Summary score; VAS: Visual Analog Scale; INSITE: Investigation of Sacroiliac Fusion Treatment; iMIA: iFuse Implant System Minimally Invasive Arthrodesis.

[a:] $p<0.001$.

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 (2)				
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 (6, 8, 9)				***Mean Improvement (95% CI)***
Back pain				
• *Conservative management*	73.0 (13.8)	67.8 (20.3)	58.9 (28.2)	11.0
• *SIJ fusion*	77.7 (11.3)	34.4 (23.9)	35.2 (25.5)	45.3 (37 to 54)
Leg pain				

• *Conservative management*	47.1 (31.1)	46.5 (31.4)	41.7 (32.4)	7.7
• *SIJ fusion*	52.7 (31.5)	22.6 (25.1)	24.0 (27.8)	32.0
ODI				
• *Conservative management*	55.6 (13.7)	50.2 (17.2)	46.9 (20.8)	8 (2 to 14)
• *SIJ fusion*	57.5 (14.4)	32.0 (18.4)	32.1 (19.9)	26 (21 to 32)

Adapted from Dengler et al. (2017). (8)
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) (2); INSITE					
Sturesson et al. (2017) (6); iMIA	1. Patients with other contributory sources of LBP might have been enrolled with SIJ-caused LBP patients.				

The study limitations stated in this table are those notable in the current literature review; this is not a comprehensive gaps assessment.
LBP: low back pain; SIJ: sacroiliac joint; iMIA: iFuse Implant System Minimally Invasive Arthrodesis; INSITE: Investigation of Sacroiliac Fusion Treatment.
[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; Trial	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]

Whang et al. (2015) (2); INSITE						
Sturesson et al. (2017) (6); iMIA		1. Intervention was unblinded				

The study limitations stated in this table are those notable in the current literature review; this is not a comprehensive gaps assessment; iMIA: iFuse Implant System Minimally Invasive Arthrodesis; INSITE: Investigation of Sacroiliac Fusion Treatment.

[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). (10, 11) 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 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 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	3 Years	4 Years	5 Years	p Value
Duhon et al. (2016) (10, 11) 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) (12) 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%	

All differences between baseline and 2- to 3-year values were statistically significant.
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.

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. (12) 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% confidence interval [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. (13) 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. (13). 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. (14, 15) 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%. (16) Spain and Holt (2017) reported a retrospective review of surgical revision rates following SIJ fixation with either surgical screws or the iFuse® triangular implant. (15) Revision rates were lower with the iFuse® device than observed with surgical screws.

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

The evidence on SIJ fixation/fusion with a triangular implant includes 2 nonblinded RCTs of MI fusion, prospective cohorts with more than 85% follow-up, and a case series. 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.

SIJ 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 one to five 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 adverse events, 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 (i.e., utilizing the iFuse device) compared to screw-type surgeries. (17) A total of twenty studies were pooled to calculate a standardized mean difference across pain, disability, and global/QOL outcomes, including 14 studies evaluation 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=0.03) 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=0.01), 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=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. (18)

Prospective Cohort Studies

Rappoport et al. (2017) reported on an industry-sponsored prospective study of SIJ fusion with a cylindrical threaded implant (SI-LOK®). (19) 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 below), 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. (20)

Fuchs and Ruhl (2018) published 2-year results of a prospective multi-center cohort of the posterior approach to arthrodesis of the SIJ. (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 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.

Caldoney et al. (2022) reported an interim analysis of a single-arm prospective study of posterior SIJ fusion with the LinQ implant platform for sacroiliac joint stabilization and arthrodesis. (22) The multi-center study included 77 patients treated from January 2020 to March 2022 who were followed for 6 months (n=69); the trial aims to enroll 159 participants. Patients had a mean age of 60.3 years and had experienced SIJ pain for a mean of 4.9 years, with mean baseline VAS and ODI scores of 74.6 and 51, respectively. The average VAS

improvement from baseline was 34.9 (SD, 28.9; p<.001) and 47 (68%) participants had a greater than 20 mm improvement on the VAS, and 52% showed>50% pain relief at 6-month follow-up. ODI scores improved by a mean of 17.7 (SD, 18.8; p<.001), and 39 (57%) of participants had an improvement greater than 15 points. 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). A total of 2 adverse events, including 1 serious adverse event and 1 death, were reported through 6 months of follow-up, but none were determined as being related to the procedure. The main limitations of this study are a lack of a comparison group and the interim nature of the analysis, resulting in a lower number of participants and shorter duration of follow-up.

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). (23) 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.

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. (19, 20)
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 4 prospective cohort studies; 3 were conducted with transiliac screws, and the fourth with a posterior approach. No 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 fixation/fusion with these various implant designs. Controlled studies with the different implant designs and approaches are needed to evaluate these devices.

Further Discussions and Additional Studies for All Systems Used in MI SIJ Fusions

Numerous studies and publications were reviewed, some of them smaller with various designs, objectives, and study length; some of them are considered as literature reviews/meta-analysis. A summary of these studies follows below:

- Percutaneous fusion of the SIJ with hollow modular anchorage screws was reported by Mason et al. in 2013. (24) In this prospective single surgeon series, 73 patients underwent SIJ fusion, and 55 patients (75%) were available for follow-up. At a mean follow-up of 36 months (range, 12-84), VAS for pain had decreased from 8.1 preoperatively to 4.5. This finding is limited by the high loss to follow-up. Notably, outcomes were worse for patients who had SIJ pain after spine surgery (VAS score improvement, 1.76) compared with patients with degenerative SIJ pain (improvement, 4.85).
- The largest series identified was a multicenter retrospective comparison of open surgical versus MI SIJ in 263 patients. (25) Because all patients received fusion, this trial does not offer evidence on the comparative effectiveness of SI fusion versus alternative treatment approaches. This study had a pragmatic design that included 7 participating sites; 3 surgeons had performed open SIJ surgery (n=149), and 4 had performed MI fusion with the iFuse® Implant system (n=114). Patients who underwent MI fusion were an average of 10 years older and were more likely to have had prior lumbar fusion (47.4% versus 23.5%). Perioperatively, they had lower estimated blood loss (33 mL versus 288 mL), operating time (70 min versus 163 min), and length of hospitalization (1.3 days versus 5.1 days). At 12 months post-surgery, and after matching for age, sex, and history of prior lumbar fusion, pain scores were an average of 3 (of 10) points lower in the MI group (95% CI, 2.1 to 4.0; $p<0.001$). Implant repositioning was performed in 3.5% of patients in the MI group, while 44% of patients in the open surgical group underwent removal of spinal implants for pain. (NOTE: A 2012 survey by the International Society for the Advancement of Spinal Surgery [ISASS] found that nearly 90% of surgeons who replied to the survey used a MI technique to perform SIJ fusion).
- The same investigator group of Polly et al. published findings of a sub-group analysis, using the RCT study patients (n=148) compared to a case series of patients (n=172). (26) The study was designed as a reference study due to the lack of gold standards for the MI SIJ fusion technique. For both arms, patients were diagnosed with SIJ dysfunction by history,

physical examination, and a SIJ block/injection. A 50% reduction of pain at 30 or 60 minutes following the SIJ image-guided local anesthetic injection was considered confirmatory of SIJ dysfunction. Measurements of SIJ pain relief were assessed at 6 months and then again at 12 months following the SIJ implant fusion. The average pain relief during the first hour following the injection was 79.3% for the test groups. Following fusion at 6 months, the pain reduction score was 50.9 points. Reduction at 12 months was nearly identical to 6-month outcomes. Patients were examined in multiple ways, improvements in SIJ pain and ODI at 6 months and 12 months did not correlate with the SIJ intra-articular injections. The investigator group concluded that the degree of pain improvement during the SIJ intra-articular injection does not predict the degree of pain following SIJ MI fusion.

- Duhon et al. (2016) studied 172 patients. (10) This case series evaluated patients preoperatively and following a MI SIJ fusion at 1, 3, 6, and 12 months. The mean SIJ pain improved from 79.8 points at baseline to 30.0 and 30.4 points at 6 and 12 months respectively (mean improvements of 49.9 and 49.1 points, $p<0.0001$ each). Mean ODI improved from 55.2 at baseline to 32.5 and 31.4 at 6 and 12 months (improvements of 22.7 and 23.9 points, $p<0.0001$ each). The Short Form-36 (SF-36) physical component summary (PCS) improved from 31.7 at baseline to 40.2 and 40.3 at 6 and 13 months ($p<0.0001$). The authors concluded MI SIJ fusion resulted in improvements of pain, disability, and QOL patients with SIJ dysfunction due to degenerative sacroiliitis and SIJ disruption.
- Of the 172 patients discussed above, a subgroup of 100 women was studied as a single arm cohort by Capobianco et al. in 2015. (27) Of the 100 women, 80 did not experience post-partum back pain, leaving 20 patients with post-partum back pain who were younger (43.5 years) than those without (52.8 years). The length of study was at least 12 months. Study conclusion was that women with post-partum pain experienced pain improvement, improved function, and QOL improvements at 12 months following MI SIJ fusion. The results were the same for those patients who were not experiencing post-partum generated pain.
- In 2014, Ledonio et al. released 2 studies: a retrospective data-collection chart review and a retrospective cohort. (28, 29) The data-collection chart review evaluated the surgical experience and the postoperative pain experience of 63 patients, divided into 2 groups, open surgical fusion (n=36) and MI fusion (n=27). Regarding the surgical experience, blood loss was less, and surgical time was shorter in the MI SIJ group when compared to the open surgical fusion group. The length of hospital stay was shorter as well for the MI group. The postoperative pain scores were not different between the 2 groups. Unknown results were whether the MI fusion was as successful as the open surgical fusion. The second study of 144 patients, mean age of 58 years, 71% being female and 62% had a prior lumbar spinal fusion. Again, the surgical/hospital experience length of time was shorter, blood loss less, and operative time was shorter when compared to the open surgical procedure. Substantial pain decrease was by 2.5 points or a score of 3.5 or less, using their scoring method. This was achieved in 91.9% of the patients.
- An earlier 2013 prospective single arm cohort study, from New Zealand (Duhon et al.), (30) evaluated the safety and effectiveness of MI SIJ fusion. Ninety-four patients underwent structured assessments preoperatively, immediately following surgery, and again at 1, 3, and 6 months. At the time of publication, 32 patients had completed the 6-month

assessments. Pain improved by 49 points from the preoperative assessment to the 6-month evaluation. Ninety percent of the patients studied were able to ambulate fully by month 6. The median time to ambulation was 30 days. Patients surveyed were completely satisfied. It is unclear if these patients were included in the Duhon et al. study discussed above. (10)

- A 2013 retrospective review of 31 patients by a single surgeon reported 27 patients expressing satisfaction following a percutaneous fixation of the SIJ with porous coated triangular titanium implants. (31) Kim et al. followed patients for 12 months using medical charts, radiographs, and CT scans. Pain relief was noted to be complete in the charts of 16 patients. One patient required a revision. On 6 month postop CT scan, 18 of 19 patients had radiographic evidence of bone ingrowth and bone into or across the SIJ were evident in 8 or 19 patients. The authors concluded the results were promising.
- In 2013, Rudolf reported on a case series of 40 patients assessing pain at 3, 6, 12, and 24 months to determine if prior SIJ pain history and/or treatment affected patient outcomes following MI SIJ fusion. (32) Three patient groups were selected: having undergone prior lumbar spine fusion (PF); having no history of previous lumbar spine fusion and no concomitant symptomatic lumbar spine pathology (NF); and having no history of previous lumbar spine fusion with concomitant symptomatic lumbar spine pathology treated conservatively (LF). The mean age was 54 years. The NF cohort had a significant decrease of pain compared to the PF and LP cohorts. The overall satisfaction was 87%. Rudolf concludes that despite the prior history of lumbar spine fusion, there was significant improvement in pain scores following MI fusion. Rudolf states, “The presence of symptomatic lumbar spine pathology potentially confounds the treatment affect, as patients may not be able to discriminate between symptoms arising from the SIJ and the lumber spine. These patients expressed a lower satisfaction with surgery.” The LP cohort who had no prior lumbar spine fusion and tend to be younger experienced the greatest reduction in pain.
- A 2013 retrospective case series from Gaetani et al. of 12 female patients treated for SIJ disruption by MI SIJ arthrodesis was completed following review of medical records. (33) Factors reviewed included demographics, perioperative metrics, in addition to patient reported outcomes for pain, function, and QOL, surgical satisfaction, and image results. Follow up range was from 8 to 18 months. All patients showed initial fusion at 3 months using CT, and patient satisfaction was 100%.
- In 2013, Schroeder et al. reported on a 2-year retrospective study of 10 SIJ fusions in 6 patients who had failed conservative care following corrective scoliosis surgery in a single center. (34) Medical chart review of short-term complications, length of hospital stay, clinical and radiographic outcomes were assessed. The investigators reported no surgical or postoperative complications, discharge at second day postop, VAS of leg improved from 6.5 to 2.0, and back VAS decreased from 7.83 to 2.67. The ODI scores dropped from 22.2 to 10.5. Scoliosis Research Study (SRS) scores increased from 2.93 to 3.65. This therapeutic study was ranked as Level IV in Level of Evidence.
- Eighteen patients who were refractory to conservative care were followed postoperatively by Cummings et al. in 2013. (35) This anecdotal case series reporting MI SIJ fusion postoperative outcomes were measured at 3, 6, and 12 months using a series of triangular, titanium plasma spray coated implants. There were no intraoperative complications and only one explantation at 3 months for implant malposition. VAS improved by 6.6 points and

ODI improved by -37.5 points at 12 months. Ninety-five percent of patients reported satisfaction and physical improvements, and 89% indicated they would have the surgery again.

- A 2014 Vanaclocha-Vanaclocha et al. single arm cohort study followed 24 patients for a mean of 23.3 months (1- to 4.5-year time span). (36) Patients underwent MI SIJ arthrodesis after medical treatment failure and showing temporary relief following SIJ infiltration. Assessments were done at 1, 3, and 6 months, then at every 6-month intervals to the last evaluation at 4 years. Time returning to work averaged at 47.4 days (range of 30-67 days). Marked reduction in VAS and pain medication management: baseline at preop-8.7, 1 month postop-3.2, 3 months-2.8, 6 months-2.1, 12 months-1.7, 18 months-1.7, 2 years-1.9, 2.5 years-1.8, 3 and 3.5 years-2.1, and 4 years-2.1. Mean ODI scores improved from 54.1 preoperatively to 23.9, 21.2, 20.4, 14.3, and 15.1 at 1, 3, 6, 12 and 18 months respectively postoperatively; followed by 15.5, 15.8, 16.0, 16.1, and 16.3 at 2, 2.5, 3, 3.5, and 4 years respectively postoperatively. The authors concluded that percutaneous SIJ arthrodesis is effective and safe to treat chronic SIJ pain due to degenerative sacroiliitis or SIJ disruptions.
- In 2014, Scheyerer et al. reported the stability and bone ingrowth following placement of 10 iFuse® devices in 8 patients. (37) During a 12-month postoperative time period from 1 orthopedic surgeon, confirmation using radio-imaging was utilized to assess bony-ingrowth of the iFuse® device. The authors' primary focus of the study was the radio-imaging to direct the most beneficial way to assess the bony implant. Patient experience, mobility, pain, etc., were not evaluated; although patients were questioned regarding subjective pain reduction outcomes.
- In July 2016, Sachs et al. (38) published a retrospective study reviewing patient-based outcomes after SIJ fusion for chronic SIJ dysfunction 3 or more years following surgery. A consecutive study group of 107 patients were contacted by phone or email for questionnaire completion, along with a chart review and clinical course follow-up. The authors reported, "Mean preop pain score was 7.5. At 3.7 years, mean pain score improved to 2.6. The ODI was 28.2. Pts [patients] reported improved ability to perform activities commonly impaired by SIJ pain. Of the pts surveyed, 14 had contralateral surgery and 25.2% had additional spine or hip surgeries. In intermediate- to long-term follow-up, MI SIJ fusion was associated with improvements in low back pain and improvements in ADLs."
- Forty patients were retrospectively studied by Sachs et al. in 2013. (39) A chart review was completed of clinicians who were following the safety and effective of the MI SIJ arthrodesis using a series of triangular, porous plasma coated implants in patients' refractory to conservative care. Sachs et al. reported postoperative complications were minimal: 5% with trochanteric bursitis, 20% facet joint pain, and 2.5% new low back pain. Patient satisfaction was considered high, and reoperations were not warranted.
- Earlier in 2012, Sachs et al. (40) evaluated the safety and effectiveness of MI SIJ fusion via an ileo-sacral approach for patients' refractory to conservative care. This retrospective case series studied medical records from 11 patients from a single provider practice. Prior to surgery, the mean baseline pain score was 7.9. Following surgery, pain scores dropped to an average of 2.3 at 12 months. Patient satisfaction was 100% and all were willing to repeat the procedure due to positive outcomes. The authors agreed the study was too small, by

one provider at one center; therefore, they concluded that larger, multi-centered studies are needed.

- In 2015, Heiney et al. completed a systematic review and meta-analysis reviewing the operative measures and clinical outcomes of published MI SIJ fusions. (41) The studies had to have a minimum of 5 cases of MI SIJ fusions. A total of 18 published articles were reviewed from 4 countries, representing 432 patients. Pain scores dropped by 5.2 points at 6 months and 5.3 at 12 months. ODI decreased by 31 points at 12 months (baseline was 56.2), at 6 months the score was 30.7, and at 12 months the score was 25.1. There was variability in the types of implants used. The overall conclusion was clinical improvements in SIJ pain following MI SIJ fusion, in addition to patient reported improved QOL.
- Zaidi et al., in 2015, completed a literature review of SIJ fusion, which included 16 publications representing 430 patients having either MI SIJ fusion (n=299) compared to open surgical SIJ fusion (n=131). (42) Prior surgical interventions, actual surgical interventions, and radiographic confirmation of fusion success were elements of the review. Fusion success rate for open surgery was 20 to 90% compared to 13 to 100% for MI fusion. Pain reduction was rated as excellent. Mean QOL improvement was 54%. Mean for reoperation rate was 15% for open fusion versus 6% for MI. Outcomes were affected by the difficulty in accurate diagnosis, serious consideration of the pain cause or generator, and the need for alternate treatments prior to performing any surgical intervention.
- In 2010, Ashman et al. conducted a systematic review to compare fusion versus denervation for chronic SI pain. (43) Six articles on fusion (95 patients) and 5 on denervation (68 patients) were included in the review. All studies on fusion were case series evaluating a single treatment. There were 2 small RCTs on radiofrequency denervation; one by Cohen et al. (44) and another from Patel et al. that had only 9 patients. (45) The strength of the evidence was considered to be very low to low, preventing conclusions on the comparative efficacy of the treatments.
- A 2012 systematic review found that the quality of evidence for surgical treatment (débridement, fusion) versus injection treatment (corticosteroid, botulinum toxin, prolotherapy) for chronic SI pain was very low. (46) Seven case series on surgical treatment and 5 on injection treatment met their selection criteria. Although most studies reported more than 40% improvement in pain and more than 20% improvement in functionality, the literature was considered insufficient to evaluate the comparative effectiveness.
- A literature/editorial review from Rashbaum et al. was published in 2016, reporting that as many as 30% of patients presenting with low back pain, the pain origin comes from the SIJ. (47) Accuracy of diagnosis and treatment modalities is the key prior to surgical intervention. Additional statistical information from clinical trials was not provided.
- A database to record all iFuse® device patient-reported complaints was published in 2013 by Miller et al. (48) This prospective collection through spontaneous reporting from 204 patients of 5,319 implant surgeries was done in support of ongoing mandatory post-market surveillance. Of the complaints, the most common issue reported was pain by 119 respondents, which included nerve impingement and recurrent SIJ pain. Ninety-six revision procedures were done on 94 patients at a median time of 4 months, most often a result of a

malpositioned implant. Later postoperative procedures were performed for continued SIJ pain of unknown etiology.

- A 2014 in vitro study of 7 cadaveric specimens to investigate the effect of MIS SIJ fusion on the biomechanics of the SIJ before and after cyclic loading was reported by Lindsey et al. (49) The cadaveric specimens were tested under the following conditions: intact, posterior ligament, and pubic symphysis cut. Placement of 3 fusion devices followed by 5,000 cycles of flexion-extension movement was assessed. Lateral bending and axial rotation were not significantly altered. All posterior ligament/pubic symphysis cut and post-cyclic range of motions (ROMs) were observed as being larger than in the intact condition. The 5,000 flexion-extension cycles did not lead to a significant increase in any ROM.
- Lindsey et al. went on to study a finite element model of the lumbar spine and pelvis, which simulated a fusion of the SIJ using 3 laterally placed triangular implants (the iFuse® Implant System). (50) ROM access was flexion, extension, lateral bending, and axial rotation, which was reduced by 56.6%, 59.5%, 27.8%, and 53.3% respectively when compared to the intact condition. The stiffening of the SIJ resulted in an increase at the adjacent lumbar motion segment (L5-S1) for flexion, extension, lateral bending, and axial rotation of 3.0%, 3.7%, 1.1%, and 4.6% respectively. Outcomes revealed there was a significant reduction in ROM elements of the SIJ with minimal increases to the ROM elements in the lumbar spine. The authors recommended further investigation.
- A second cadaveric study was reported by Sorian-Baron et al. in 2015. (51) Seven cadaveric lumbosacral specimens were tested using a single leg stance following SIJ fusions. For all conditions, the ROM was tested in flexion-extension, lateral bending, and axial rotation positions. The posterior technique used significantly reduced the ROM by 27% (flexion-extension), 28% (lateral bending), and 32% (axial rotation). For the transarticular placement used, the ROM was significantly reduced by 41% (flexion-extension), 36% (lateral bending), and 36% (axial rotation). The study conclusion was posterior and transarticular implant placement stabilized the SIJ in all three motions tested.
- Three additional case series (Al-Khayer et al. [52], Ohtori et al. [53], and Wise and Dall [54]) were reviewed by ECRI, all having 20 patients or less. The average follow-up was either 2 or 2.5 years with the treatment of SIJ fusion with or without incorporating screw for stabilization/fixation. For each study, the pain scores improved, and the authors conclude SIJ fusion is a new technique that offers a safe and effective treatment for refractory low back pain.
- Multiple cost-effectiveness studies have been reported by Ackerman et al. in 2013 (55) and several in 2014 (56-58) evaluating MI SIJ fusion to medical non-surgical therapy, using the Medicare database or third-party payer claims. All studies reveal that non-surgical management of SIJ pain or disruption is costly, whether in the outpatient or in hospital setting.
- Polly et al. reported the costs of ignoring SIJ/chronic low back pain in 2016. (59) Their conclusion was that the preoperative workup for a patient presenting with chronic low back pain and finding a SIJ pain cause saves, when compared to treating a patient with a lumbar fusion. The authors believe the cost savings attributable to probability to accurate diagnosis and the probability of doing the correct surgical intervention.

- Cher et al. studied the health state utility following MI SIJ fusion using quality of life scoring and SF-36 of 198 patients (includes a subgroup of the 172 patients referenced earlier in the prospective clinical trial). (60) Patients completed surveys to quantify their burden of disease attributed to SIJ disruption. Baseline health state utility was significantly depressed in SIJ pain patients when compared to patients without SIJ pain, classified as normal individuals. In the SIJ cohort, all the measures improved by 6 months post fusion, and improvements were sustained at 12 months.
- A follow-up study published in 2015 by Cher et al. retrospectively reviewed the QOL and disability score of SIJ cohort studies compared to 3 spine surgical cohorts. (61) Patients with SIJ dysfunction considering surgery have decrements in QOL as more severe compared to patients with degenerative spondylolistheses, spinal stenosis, and intervertebral disc herniation. Again in 2016, Cher et al. reported the improved QOL years converted to costs in the United States, having come to the identical conclusion as other cost-saving studies targeting SIJ pain and treatments. (62)
- In 2016, Copay et al. assessed the validity of ODI to capture the disability caused by SIJ pain in the clinical outcome following MI SIJ fusion. (63) Patients (n=155) underwent baseline and follow-up assessments using ODI, VAS, SF-36, and EuroQOL-5D/EQ-5D (European Quality of Life), in addition to other questions pertaining to their pain prior and following surgery intervention. After the SIJ fusion, patients improved significantly on all measures – SIJ pain (48.8 points), ODI (23.8 points), EQ-5D (0.29 points), VAS (11.7 points), PCS (8.9 points), and mental component score (MCS) (9.2 points). Generally, each scoring methodology starts at zero to a higher score (some up to 100). The lower the score, the lesser the disability has affected the individual. Therefore, the ODI correlates to other generally used assessments to measure the changes in SIJ health.

ECRI

In 2013, ECRI released a review of SIJ fusion for treating chronic low back pain. (64) Their report comprised of controlled studies of any duration (1 study) and case series with at least 2 years' follow-up (4 studies). Of the 4-case series, Rudolf (32) has been summarized earlier in this Rationale. The nonrandomized controlled study included in the ECRI report was from Kibsgard et al. in 2013. (65) Seventy-eight patients participated with the diagnosis of severe pelvic girdle pain. Fifty of the 78 were treated with SIJ fusion, and the remaining 28 did not undergo SIJ fusion. At a mean of 23 years after surgery, mean ODI was 33 in the fusion group, and mean VAS pain score was 5.4 in a 1-10 scale. At the end of the long-term follow-up, no outcomes were different between the patient's receiving surgery and those not receiving surgery. The authors concluded, "Patients treated with SIJ fusion had moderate disability and pain 23 years after surgery, and the 1-year outcomes were sustained 23 years after surgery. Although many fused patients reported good outcomes, this did not differ from the comparable non-surgical group."

As a follow-up in 2016, ECRI published a product brief of the iFuse® Implant System for MI SIJ fusion. (66) Their summary stated, "Evidence from two retrospective comparison studies support the conclusions of the RCTs that iFuse® works to treat low-back pain associated with SI joint dysfunction." Earlier in 2016, they updated their 2013 review of SIJ fusion for treating

chronic low back pain. (67) This report was a review of 4 systematic reviews, 1 RCT, and 3 non-RCTs. They concluded, "Sacroiliac fusion surgery may work for reducing pain; however, the effects may diminish over time." This was based on the 23-year follow up that was cited in the 2013 review above.

In 2022, ECRI published a clinical evidence assessment updating the 2016 product brief. (68) Their summary states, "iFuse reduces SIJ pain and improves pain, patient functional status, and quality of life (QOL) compared with nonsurgical conservative management and screw-type implants, based on evidence from two systematic reviews. At four-year follow-up, iFuse revision surgery rates were 3.6%. How well iFuse works compared with MIS (e.g., Rialto) or open surgery cannot be determined from nonrandomized comparison and single-arm studies that provide very-low-quality evidence."

ECRI also released clinical evidence assessments (2022) on two non-transiliac triangular implants: the Rialto Sacroiliac Fusion System and the SI-LOK System. (69, 70) Both were considered to have "too few data on outcomes of interest", with only very-low-quality evidence or evidence with high risk of bias.

In May 2024, ECRI published a clinical evidence assessment on LinQ. (71) Early studies have shown improvement in pain and function at up to one year in patients with SIJ dysfunction. However, how the LinQ compares with other SIJ fusion techniques cannot be determined, as comparative data are not available. Large, randomized comparative studies with longer durations of follow-up are still needed.

Open Surgical (OS) SIJ Fusions

OS SIJ fusion has been performed since the 1920s. This technique has fallen out of favor with the introduction of MI SIJ fusion option; however, OS SIJ fusion is still being performed. In the last decade, MI SIJ fusion has shown to achieve the clinical effectiveness of the OS fusion, with lower operative morbidity and faster recovery. Though, patients may occasionally require an OS option, particularly for disease, trauma, or revisions. (72)

The OS SIJ fusion is done with a combination of screws and cages, compared to the implants used in the MI SIJ technique, which was discussed earlier in this rationale by Smith et al. (25), Ledonio et al. (28, 29), and Zaidi et al. (42) In these studies, the same inclusion criteria were generally used for each type of procedure (open versus MI). The primary aspect reviewed for each study was pain relief reported by the patients.

<u>Section Summary: Open Surgical (OS) SIJ Fusions</u>

Within the last decade in recent published literature, there is minimal evidence that OS SIJ fusion is still being performed by providers outside of select indications (e.g., trauma, infection, tumor). While there are advantages of the MI SIJ fusion procedure over the OS SIJ fusion, such as lower blood loss amounts and reduced recovery time, the OS method has been reported by patients, according to the literature, nearly the same pain relief scoring outcomes as the newer MI SIJ fusion. Reported studies outside of comparison to MI SIJ fusion have been scant.

Summary of Evidence

For individuals who have sacroiliac joint (SIJ) pain who receive SIJ fixation/fusion with a transiliac triangular implant, the evidence includes 2 nonblinded randomized controlled trials (RCTs) of minimally invasive fusion, prospective cohorts with more than 85% follow-up, and case series. Relevant outcomes are symptoms, functional outcomes, quality of life (QOL), medication use, and treatment-related morbidity. Both RCTs have reported outcomes past 6 months, after which crossover was allowed. Both studies reported significantly greater reductions in Visual Analog Scale (VAS) pain scores and Oswestry Disability Index (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.

For individuals who have SIJ pain who receive SIJ fusion/fixation with an implant other than a transiliac triangular implant, the evidence includes 4 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 fourth with a device inserted through a posterior approach. No 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.

For individuals who have SIJ pain who receive open surgical (OS) SIJ fusion, the evidence includes retrospective comparative studies with MI SIJ fusions. Relevant outcomes are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. Four retrospective cohort studies followed patients for a minimum of 12 months following the open repairs using screws and cages. In the comparative studies with MI SIJ fusions, blood loss amounts and recovery time were greater for the OS SIJ fusion; pain relief was nearly identical in most cases. The criteria for the OS fusion should be identical to that of the MI fusion but should only be performed in the case of trauma, neoplasm, disease, or when a MI fusion is not feasible. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Clinical Practice Guidelines and Position Statements

North American Spine Society (NASS)

In 2021, the NASS published coverage recommendations for minimally invasive SIJ fusion. (73) 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."

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. (74)

The Society recommended that "patients who have all of the following criteria may be eligible for lateral MIS SIJF [minimally invasive surgical sacroiliac joint fusion] with placement of lateral transfixing devices:

- "Chronic SIJ pain (pain lasting at least 6 months)
- Significant SIJ pain that impacts QOL 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 and a reasonable course (4–6 weeks) of PT. 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

In 2022, the American Society of Pain and Neuroscience published guidance on the treatment of lower back pain. (75) The following recommendation was provided concerning minimally invasive sacroiliac joint fixation:

- Minimally invasive sacroiliac fusion (Grade, A; Level, 1-A; Level of certainty, High)

National Institute for Health and Care Excellence (NICE)

In 2017, the NICE 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 MI sacroiliac (SI) joint fusion surgery for chronic SI pain is adequate to support the use of this procedure…. provided that standard arrangements are in place for clinical governance, consent and audit.
> 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 MI SI joint fusion surgery for chronic SI pain." (76)

In 2022, NICE published medical technology guidance on using the iFuse implant system for treating chronic sacroiliac joint pain. It provided the following recommendations: (77)

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 anesthetic 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
Ongoing			
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
Unpublished			
NCT01861899[a]	Treatment of Sacroiliac Dysfunction with SI-LOK® Sacroiliac Joint Fixation System	46	Apr 2019
NCT02074761[a]	Evolusion 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 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, 27280
HCPCS Codes	[Deleted 1/2024: 0775T, 0809T]

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

References

1. Himstead AS, Brown NJ, Shahrestani S, et al. Trends in diagnosis and treatment of sacroiliac joint pathology over the past 10 years: review of scientific evidence for new devices for sacroiliac joint fusion. Cureus. Jun 2021; 13(6):e15415. PMID 34249562
2. Whang P, Cher D, Polly D, et al. Sacroiliac joint fusion using triangular titanium implants versus non-surgical management: six-month outcomes from a prospective randomized controlled trial. Int J Spine Surg. 2015; 9:6. PMID 25785242
3. Polly DW, Cher DJ, Wine KD, et al. Randomized controlled trial of minimally invasive sacroiliac joint fusion using triangular titanium implants versus nonsurgical management for sacroiliac joint dysfunction: 12-month outcomes. Neurosurgery. Nov 2015; 77(5):674-691. PMID 26291338
4. Polly DW, Swofford J, Whang PG, et al. Two-year outcomes from a randomized controlled trial of minimally invasive sacroiliac joint fusion versus non-surgical management for sacroiliac joint dysfunction. Int J Spine Surg. 2016; 10:28. PMID 27652199
5. Darr E, Meyer SC, Whang PG, et al. Long-term prospective outcomes after minimally invasive trans-iliac sacroiliac joint fusion using triangular titanium implants. Med Devices (Auckl). Apr 2018; 11:113-121. PMID 29674852
6. Sturesson B, Kools D, Pflugmacher R, et al. Six-month outcomes from a randomized controlled trial of minimally invasive SI joint fusion with triangular titanium implants versus conservative management. Eur Spine J. May 2017; 26(3):708-719. PMID 27179664
7. Dengler J, Sturesson B, Kools D, et al. Referred leg pain originating from the sacroiliac joint: 6-month outcomes from the prospective randomized controlled iMIA trial. Acta Neurochir (Wien). Nov 2016; 158(11):2219-2224. PMID 27629371
8. Dengler JD, Kools D, Pflugmacher R, et al. 1-Year results of a randomized controlled trial of conservative management vs. minimally invasive surgical treatment for sacroiliac joint pain. Pain Physician. Sep 2017; 20(6):537-550. PMID 28934785
9. Dengler J, Kools D, Pflugmacher R, et al. Randomized trial of sacroiliac joint arthrodesis compared with conservative management for chronic low back pain attributed to the sacroiliac joint. J Bone Joint Surg Am. Mar 06 2019; 101(5):400-411. PMID 30845034
10. Duhon BS, Cher DJ, Wine KD, et al. Triangular titanium implants for minimally invasive sacroiliac joint fusion: a prospective study. Global Spine J. 2016; 6(3):257-269. PMID 27099817

11. Duhon BS, Bitan F, Lockstadt H, et al. Triangular titanium implants for minimally invasive sacroiliac joint fusion: 2-year follow-up from a prospective multicenter trial. Int J Spine Surg. May 2016; 10:13. PMID 27162715
12. Whang PG, Darr E, Meyer SC, et al. Long-term prospective clinical and radiographic outcomes after minimally invasive lateral transiliac sacroiliac joint fusion using triangular titanium implants. Med Devices (Auckl). 2019; 12:411-422. PMID 31576181
13. Patel V, Kovalsky D, Meyer SC, et al. Prospective trial of sacroiliac joint fusion using 3D-printed triangular titanium implants. Med Devices (Auckl). 2020; 13:173-182. PMID 32607011
14. Vanaclocha V, Herrera JM, Saiz-Sapena N, et al. Minimally invasive sacroiliac joint fusion, radiofrequency denervation, and conservative management for sacroiliac joint pain: 6-year comparative case series. Neurosurgery. Jan 2018; 82(1):48-55. PMID 28431026
15. Spain K, Holt T. Surgical revision after sacroiliac joint fixation or fusion. Int J Spine Surg. Jan 19 2017; 11(1):5. PMID 28377863
16. Schoell K, Buser Z, Jakoi A, et al. Postoperative complications in patients undergoing minimally invasive sacroiliac fusion. Spine J. Nov 2016; 16(11):1324-32. PMID 27349627
17. Tran ZV, Ivashchenko A, Brooks L. Sacroiliac joint fusion methodology - minimally invasive compared to screw-type surgeries: a systematic review and meta-analysis. Pain Physician. Jan 2019; 22(1):29-40. PMID 30700066
18. Lorio M, Kube R, Araghi A. International Society for the Advancement of Spine Surgery Policy 2020 Update-Minimally Invasive Surgical Sacroiliac Joint Fusion (for Chronic Sacroiliac Joint Pain): Coverage Indications, Limitations, and Medical Necessity. Int J Spine Surg. Dec 2020; 14(6):860-895. PMID 33560247
19. Rappoport LH, Luna IY, Joshua G. Minimally Invasive sacroiliac joint fusion using a novel hydroxyapatite-coated screw: preliminary 1-year clinical and radiographic results of a 2-year prospective study. World Neurosurg. May 2017; 101:493-497. PMID 28216399
20. Rappoport LH, Helsper K, Shirk T. Minimally invasive sacroiliac joint fusion using a novel hydroxyapatite-coated screw: final 2-year clinical and radiographic results. J Spine Surg. Jun 2021; 7(2):155-161. PMID 34296027
21. Fuchs V, Ruhl B. Distraction arthrodesis of the sacroiliac joint: 2-year results of a descriptive prospective multi-center cohort study in 171 patients. Eur Spine J. Jan 2018; 27(1):194-204. PMID 29058134
22. Calodney AK, Azeem N, Buchanan P, et al. Six Month Interim Outcomes from SECURE: A Single arm, Multicenter, Prospective, Clinical Study on a Novel Minimally Invasive Posterior Sacroiliac Fusion Device. Expert Rev Med Devices. May 2022; 19(5):451-461. PMID 35724479
23. Kucharzyk D, Colle K, Boone C, et al. Clinical Outcomes Following Minimally Invasive Sacroiliac Joint Fusion With Decortication: The EVoluSIon Clinical Study. Int J Spine Surg. Feb 2022; 16(1):168-175. PMID 35217586
24. Mason LW, Chopra I, Mohanty K. The percutaneous stabilization of the sacroiliac joint with hollow modular anchorage screws: a prospective outcome study. Eur Spine J. 2013; 22(10):2325-2331. PMID 23686478

25. Smith AG, Capobianco R, Cher D, et al. Open versus minimally invasive sacroiliac joint fusion: a multi-center comparison of perioperative measures and clinical outcomes. Ann Surg Innov Res. 2013; 7(1):14. PMID 24172188
26. Polly DW, Cher DJ, Whang PG, et al. Does level of response to SI joint block predict response to SI joint fusion? Int J Spine Surg. 2016; 10:4. PMID 26913224
27. Capobianco R, Cher DJ. Safety and effectiveness of minimally invasive sacroiliac joint fusion in women with persistent post-partum posterior pelvic girdle pain: 12-month outcomes from a prospective, multi-center trial. Springerplus. 2015; 4:570. PMID 26543705
28. Ledonio CG, Polly DW, Swiontkowski MF, et al. Comparative effectiveness of open versus minimally invasive sacroiliac joint fusion. Med Devices (Auckl). 2014; 7:187-193. PMID 24940087
29. Ledonio CG, Polly DW, Swiontkowski MF. Minimally invasive versus open sacroiliac joint fusion: are they similarly safe and effective? Clin Orthop Relat Res. Jun 2014; 472(6):1831-1838. PMID 24519569
30. Duhon BS, Cher DJ, Wine KD, et al. Safety and 6-month effectiveness of minimally invasive sacroiliac joint fusion: a prospective study. Med Devices (Auckl). 2013; 6:219-229. PMID 24363562
31. Kim JT, Rudolph LM, Glaser JA. Outcome of percutaneous sacroiliac joint fixation with porous plasma-coated triangular titanium implants: an independent review. The Open Orthop J. 2013; 7:51-56. PMID 23525073
32. Rudolf L. MIS fusion of the SI joint: does prior lumbar spinal fusion affect patient outcomes? The Open Orthop J. 2013; 7:163-168. PMID 23730380
33. Gaetani P, Miotti D, Risso A, et al. Percutaneous arthrodesis of sacroiliac joint: a pilot study. J Neurosurg Sci. Dec 2013; 57(4):297-301. PMID 24091432
34. Schroeder JE, Cunningham ME, Ross T. Early results of sacroiliac joint fixation following long fusion to the sacrum in adult spine deformity. HSS J. 2013; 10(1):1-3. Available at <https://www.hss.edu> (accessed June 24, 2014).
35. Cummings J, Capobianco R. Minimally invasive sacroiliac joint fusion: one-year outcomes in 18 patients. Ann Surg Innov Res. Jul 1 2013; 7:12-19. PMID 24040944
36. Vanaclocha-Vanaclocha V, Verdu-Lopez F, Sanchez-Pardo M, et al. Minimally invasive sacroiliac joint arthrodesis: experience in a prospective series of 24 patients. J Spine. Oct 8 2014; 3:5. Available at <https://www.sciencedirect.com> (accessed May 26, 2016).
37. Scheyerer MJ, Huller MW, Pietsch C, et al. Implant-bone interface of sacroiliac joint fusion using iFuse implant system. ISRN Min Inv Surg. 2014; (Article ID 571014):1-6. PMID 24057456
38. Sachs D, Kovalsky D, Redmond A, et al. Durable intermediate-to long-term outcomes after minimally invasive transiliac sacroiliac joint fusion using triangular titanium implants. Med Devices (Auckl). Jul 2016; 9:213-222. PMID 27471413
39. Sachs D, Capobianco R. Minimally invasive sacroiliac joint fusion: one-year outcomes in 40 patients. Adv Orthop. 2013; (Article ID 536128):1-5. PMID 25352932
40. Sachs D, Capobianco R. One-year successful outcomes for novel sacroiliac joint arthrodesis system. Ann Surg Innov Res. Jun 1 2012; 6(1):13-17. PMID 23270468

41. Heiney J, Capobianco R, Cher DJ. A systematic review of minimally invasive sacroiliac joint fusion utilizing a lateral transarticular technique. Int J Spine Surg. 2015; 9:40. PMID 26273558
42. Zaidi HA, Montoure AJ, Dickman CA. Surgical and clinical efficacy of sacroiliac joint fusion: a systematic review of the literature. J Neurosurg Spine. Jul 2015; 23(1):59-66. PMID 25840040
43. Ashman B, Norvell DC, Hermsmeyer JT. Chronic sacroiliac joint pain: fusion versus denervation as treatment options. Evid Based Spine Care J. 2010; 1(3):35-44. PMID 22956926
44. Cohen SP, Hurley RW, Buckenmaier CC, 3rd, et al. Randomized placebo-controlled study evaluating lateral branch radiofrequency denervation for sacroiliac joint pain. Anesth. 2008; 109(2):279-288. PMID 18648237
45. Patel N, Gross A, Brown L, et al. A randomized, placebo-controlled study to assess the efficacy of lateral branch neurotomy for chronic sacroiliac joint pain. Pain Med. 2012; 13(3):383-398. PMID 22299761
46. Spiker WR, Lawrence BD, Raich AL, et al. Surgical versus injection treatment for injection-confirmed chronic sacroiliac joint pain. Evid Based Spine Care J. 2012; 3(4):41-53. PMID 23526911
47. Rashbaum RF, Ohnmeiss DD, Lindley EM, et al. Sacroiliac joint pain and its treatment. Clin Spine Surg. Mar 2016; 29(2):42-48. PMID 26889985
48. Miller LE, Reckling WC, Block JE. Analysis of postmarket complaints database for the iFuse SI joint fusion system: a minimally invasive treatment for degenerative sacroiliitis and sacroiliac joint disruption. Med Dev (Auckl). 2013; 6:77-84. PMID 23761982
49. Lindsey DP, Perez-Orribo L, Rodriquez-Martinez N, et al. Evaluation of a minimally invasive procedure for sacroiliac joint fusion - an in vitro biomechanical analysis of initial and cycled properties. Med Dev (Auckl). 2014; 7:131-137. PMID 24868175
50. Lindsey DP, Kiapour A, Yerby SA, et al. Sacroiliac joint fusion minimally affects adjacent lumbar segment motion: a finite element study. Int J Spine Surg. 2015; 9:64. PMID 26767156
51. Soriano-Baron H, Lindsey DP, Rodriquez-Martinez N, et al. The effect of implant placement on sacroiliac joint range of motion: posterior versus transarticular. Spine. May 1 2015; 40(9):E525-E530. PMID 25705956
52. Al-Khayer A, Hegarty J, Hahn D, et al. Percutaneous sacroiliac joint arthrodesis: a novel technique. J Spinal Disord Tech. Jul 2008; 21(8):359-363. PMID 18600147
53. Ohtori S, Sainoh T, Takaso M, et al. Clinical incidence of sacroiliac joint arthritis and pain after sacropelvic fixation for spinal deformity. Yonsei Med J. Mar 2012; 53(2):416-421. PMID 22318832
54. Wise DL, Dall BE. Minimally invasive sacroiliac arthrodesis: outcomes of a new technique. J Spinal Disord Tech. Dec 2008; 21(8):579-584. PMID 19057252
55. Ackerman SJ, Polly DW, Knight T, et al. Comparison of the costs of nonoperative care to minimally invasive surgery for sacroiliac joint disruption and degenerative sacroiliitis in a United States commercial payer population: potential economic implications of a new minimally invasive technology. Clinicoecon Outcomes Res. 2014; 6:283-296. PMID 24904218

56. Ackerman SJ, Polly DW, Knight T, et al. Management of sacroiliac joint disruption and degenerative sacroiliitis with nonoperative care I medical resource-intensive and costly in a United States commercial payer population. Clinicoecon Outcomes Res. 2014; 6:63-74. PMID 24596468
57. Ackerman SJ, Polly DW, Knight T, et al. Comparison of the costs of nonoperative care to minimally invasive surgery for sacroiliac joint disruption and degenerative sacroiliitis in the United States Medicare population: potential economic implications of a new minimally invasive technology. Clinicoecon Outcomes Res. 2013; 5:575-587. PMID 24348055
58. Ackerman SJ, Polly DW, Knight T, et al. Nonoperative care to manage sacroiliac joint disruption and degenerative sacroiliitis: high costs and medical resource utilization in the United States Medicare population. J Neurosurg Spine. Apr 2014; 20(4):354-363. PMID 24527824
59. Polly DW, Cher D. Ignoring the sacroiliac joint in chronic low back pain is costly. Clinicoecon Outcomes Res. Jan 2016; 8:23-31. PMID 26855595
60. Cher DJ, Polly DW, Berven S. Sacroiliac joint pain: burden of disease. Med Devices (Auckl). 2014; 7:73-81. PMID 24748825
61. Cher DJ, Reckling WC. Quality of life in preoperative patients with sacroiliac joint dysfunction is at least as depressed as in other lumbar spinal conditions. Med Devices (Auckl). 2015; 8:395-403. PMID 26396547
62. Cher DJ, Polly DW. Improvement in health state utility after sacroiliac joint fusion: comparison to normal populations. Global Spine J. Mar 2016; 6(2):100-107. PMID 26933610
63. Copay AG, Cher DJ. Is the Oswestry Disability Index: a valid measure of response to sacroiliac joint treatment? Qual Life Res. Feb 2016; 25(2):283-292. PMID 26245709
64. ECRI Institute. Sacroiliac Joint Fusion for Treating Chronic Low-Back Pain. Plymouth Meeting (PA): ECRI Institute; 2013 Jan. 5 p. (Hotline Response).
65. Kibsgard TJ, Raise O, Sudman E, et al. Pelvic joint fusions in patients with chronic pelvic girdle pain: a 23-year follow-up. Eur Spine J. Apr 2013; 22(4):871-877. PMID 23001416
66. ECRI Institute. iFuse Implant System (SI-BONE, Inc.) for Minimally Invasive Sacroiliac Joint Fusion. Plymouth Meeting (PA): ECRI Institute; 2019 Sep. 18. (Custom Product Brief).
67. ECRI Institute. Sacroiliac Joint Fusion for Treating Chronic Low-Back Pain. Plymouth Meeting (PA): ECRI Institute; 2016 May. 13 p. (Hotline Response).
68. ECRI Institute. iFuse Implant System (SI-Bone, Inc.) for Minimally Invasive Sacroiliac Joint Fusion. Plymouth Meeting (PA): ECRI Institute; 2022 Nov. 22. (Clinical Evidence Assessment).
69. ECRI Institute. Rialto Sacroiliac Fusion System (Medtronic plc.) for Minimally Invasive Spinal Fusion. Plymouth Meeting (PA): ECRI Institute; 2022 Nov. 8. (Clinical Evidence Assessment).
70. ECRI Institute. SI-LOK System (Globus Medical) for Sacroiliac Fusion. Plymouth Meeting (PA): ECRI Institute; 2022 Nov. 9. (Clinical Evidence Assessment).
71. ECRI Institute. LinQ (PainTeq) for Sacroiliac Joint Fusion. Plymouth Meeting (PA): ECRI Institute; 2023 May 23. (Clinical Evidence Assessment).
72. MenMuir B, Fielding LC. Revision of minimally invasive sacroiliac joint fixation: technical considerations and case studies using decortication and threaded implant fixation. Int J Spine Surg. Feb 27 2017; 11:8. PMID 28377866

73. North American Spine Society (NASS). NASS coverage policy recommendations: Minimally invasive sacroiliac joint fusion (2021). Available at <https://www.spine.org> (accessed September 11, 2024).
74. Lorio M, Kube R, Araghi A. International Society for the Advancement of Spine Surgery Policy 2020 Update-Minimally Invasive Surgical Sacroiliac Joint Fusion (for Chronic Sacroiliac Joint Pain): Coverage Indications, Limitations, and Medical Necessity. Int J Spine Surg. Dec 2020; 14(6):860-895. PMID 33560247
75. Sayed D, Grider J, Strand N, et al. The American Society of Pain and Neuroscience (ASPN) Evidence-Based Clinical Guideline of Interventional Treatments for Low Back Pain. J Pain Res. 2022; 15:3729-3832. PMID 36510616
76. National Institute for Health and Care Excellence. Minimally invasive sacroiliac joint fusion surgery for chronic sacroiliac pain [IPG578] (2017). Available at <https://www.nice.org.uk> (accessed April 3, 2023).
77. National Institute for Health and Care Excellence. iFuse for treating chronic sacroiliac joint pain [MTG39]. 2022. Available at <https://www.nice.org.uk> (accessed October 4, 2023).

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
11/15/2024	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.