Medical Policy

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Title: Diagnosis and Treatment of Sacroiliac Joint Pain

Related Policies:	▪ *Percutaneous Vertebroplasty and Sacroplasty* ▪ *Facet Joint Denervation*

Professional / Institutional
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Populations	Interventions	Comparators	Outcomes
Individuals: • With suspected sacroiliac joint pain	Interventions of interest are: • Diagnostic sacroiliac joint block	Comparators of interest are: • Standard of care	Relevant outcomes include: • Test validity • Symptoms • Functional outcomes • Quality of life • Medication use • Treatment-related morbidity
Individuals: • With sacroiliac joint pain	Interventions of interest are:	Comparators of interest are: • Physical therapy	Relevant outcomes include: • Symptoms

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Populations	Interventions	Comparators	Outcomes
	• Therapeutic corticosteroid injections		• Functional outcomes • Quality of life • Medication use • Treatment-related morbidity
Individuals: • With sacroiliac joint pain	Interventions of interest are: • Radiofrequency ablation	Comparators of interest are: • Conservative therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use • Treatment-related morbidity
Individuals: • With sacroiliac joint pain	Interventions of interest are: • Sacroiliac joint fixation/fusion with a triangular implant	Comparators of interest are: • Conservative therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use • Treatment-related morbidity
Individuals: • With sacroiliac joint pain	Interventions of interest are: • Sacroiliac joint fixation/fusion with cylindrical threaded implant	Comparators of interest are: • Conservative therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use • Treatment-related morbidity

DESCRIPTION

Sacroiliac joint (SIJ) arthrography using fluoroscopic guidance with an injection of an anesthetic has been explored as a diagnostic test for SIJ pain. Duplication of the patient's pain pattern with the injection of contrast medium suggests a sacroiliac etiology, as does relief of chronic back pain with an injection of local anesthetic. Treatment of SIJ pain with corticosteroids, radiofrequency ablation (RFA), stabilization, or minimally invasive SIJ fusion has also been explored.

OBJECTIVE

The objective of this evidence review is to evaluate the diagnostic and therapeutic use of corticosteroid injections and minimally invasive methods (radiofrequency ablation, sacroiliac joint fixation/fusion) for the diagnosis and treatment of sacroiliac joint pain.

BACKGROUND

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.

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In 1928, the role of the intervertebral disc was elucidated, and from that point forward, the SIJ received less research attention.

Diagnosis

Research into SIJ pain has been plagued by a lack of a criterion standard to measure its prevalence and against which various clinical examinations can be validated. For example, SIJ pain typically presents without any consistent, demonstrable radiographic or laboratory features and most commonly exists in the setting of morphologically normal joints. Clinical tests for SIJ pain may include various movement tests, palpation to detect tenderness, and pain descriptions by the patient. Further confounding the study of the SIJ is that multiple structures, (eg, 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. 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 (eg, Rialto, SImmetry, Silex, SambaScrew, SI-LOK). Some devices also have a slot in the middle where autologous or allogeneic bone can be inserted. This added bone is intended to promote the fusion of the SIJ.

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

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POLICY

A. Injection of anesthetic for diagnosing SIJ pain may be considered **medically necessary** when **ALL** the following criteria have been met:
   1. Pain originates from the sacroiliac joint by evidence of 3 positive provocative test (see policy guidelines); **AND**
   2. Pain has failed to respond to 3 months of conservative management, which may consist of therapies such as nonsteroidal anti-inflammatory medications, acetaminophen, manipulation, physical therapy, and a home exercise program; **AND**
   3. Dual (controlled) diagnostic blocks with 2 anesthetic agents with differing duration of action are used (see policy guidelines); **And**
   4. The injections are performed under imaging guidance with documentation of contrast material throughout the sacroiliac joint. Ultrasound guidance is not considered adequate or accurate for sacroiliac joint injections.

B. Injection of corticosteroid may be considered **medically necessary** for the treatment of SIJ pain when **ALL** the following criteria have been met:
   1. ***Initial Injection***
      a. Pain originates from the sacroiliac joint by evidence of 3 positive provocative test (see policy guidelines); **AND**
      b. Pain has failed to respond to 3 months of conservative management, which may consist of therapies such as nonsteroidal anti-inflammatory medications, acetaminophen, manipulation, physical therapy, and a home exercise program; **AND**
      c. The injection is performed under imaging guidance with documentation of contrast material throughout the sacroiliac joint. Ultrasound guidance is not considered adequate or accurate for sacroiliac joint injections
   2. ***Repeat Injection***
      a. If individual has achieved substantial relief with previous injection, repeat injections are to be no more frequent than every 2 months with no more than 3 injections given in 1 year.
      b. Repeat injections extending beyond 12 months may be reviewed for continued medical necessity.

C. Sacroiliac injection is considered **experimental / investigational** for all other indications.

D. Arthrography of the sacroiliac joint is considered **experimental / investigational**.

E. Radiofrequency ablation of the sacroiliac joint or the nerves innervating the SI joint is considered **experimental / investigational**.

F. Minimally invasive fixation / fusion of the sacroiliac joint using transiliac placement of a titanium triangular implant (i.e., iFuse) may be considered **medically necessary** when **ALL** of the following criteria have been met:
   1. Average pain level is at least 5 on a 0 to 10 rating scale (see Policy Guidelines) that impacts quality of life or limits activities of daily living; **AND**
   2. There is an absence of generalized pain behavior (e.g., somatoform disorder) or generalized pain disorders (e.g., fibromyalgia); **AND**

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3. Individuals 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, sacroiliac joint, and hip, including a home exercise program; **AND**
4. Pain is caudal to the lumbar spine (L5 vertebra), localized over the posterior sacroiliac joint, and consistent with sacroiliac joint pain; **AND**
5. A thorough physical examination demonstrates localized tenderness with palpation over the sacral sulcus (Fortin's point) in the absence of tenderness of similar severity elsewhere; **AND**
6. There is a positive response to at least 3 provocative tests (see Policy Guidelines); **AND**
7. Diagnostic imaging studies include **ALL** of the following:
   a. Imaging (plain radiographs and computed tomography or magnetic resonance imaging) of the sacroiliac joint excludes the presence of destructive lesions (e.g., tumor, infection) or inflammatory arthropathy of the sacroiliac joint; **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.
8. There is at least a 75% reduction in pain for the expected duration of the anesthetic used following an image-guided, contrast-enhanced intra-articular sacroiliac joint injection on 2 separate occasions; **AND**
9. A trial of a therapeutic sacroiliac joint injection (i.e., corticosteroid injection) has been performed at least once.

G. Fixation / fusion of the sacroiliac joint for the treatment of back pain presumed to originate from the SI joint is considered **experimental / investigational** under all other conditions and with any other devices not listed above.

POLICY GUIDELINES

A. This policy does not address treatment of pain in the sacroiliac joint due to infection, trauma, or neoplasm.

B. Minimally invasive fusion / stabilization of the sacroiliac joint is a technically demanding procedure and should only be performed by physicians who have specific training and expertise in minimally invasive sacroiliac joint fusion surgery for chronic sacroiliac joint pain and who regularly use image guidance for implant placement.

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C. Pain may be defined as moderate (interferes significantly with ADLs) or severe (disabling; unable to perform ADLs).

Numeric Rating Scale (NRS 10)	
Rating	**Pain Level**
0	No pain
1-3	Mild pain
4-6	Moderate pain
7-10	Severe pain

D. Pain originating from the sacroiliac joint may be evidenced by provocation of pain in at least 3 out of 5 of the following tests:
1. Distraction
2. Thigh thrust
3. Patrick/FABER (Flexion, Abduction, External Rotation)
4. Compression
5. Gaenslen's

E. Conservative nonsurgical management should include the following:
1. Use of acetaminophen, nonsteroidal anti-inflammatory medications, or prescription strength analgesics at a dose sufficient to induce a therapeutic response
   a. Analgesics should include anti-inflammatory medications with or without adjunctive medications such as nerve membrane stabilizers or muscle relaxants, **AND**
2. Participation in at least 6 weeks of physical therapy (including active exercise) or manipulation or a home exercise program or documentation of why the individual could not tolerate physical therapy, manipulation, or a home exercise program, **AND**
3. Evaluation and appropriate management of associated cognitive, behavioral, or addiction issues, **AND**
4. Documentation of individual compliance with the preceding criteria.

F. A successful trial of controlled diagnostic lateral branch blocks consists of 2 separate positive blocks on different days with local anesthetic only (no steroids or other drugs), or a placebo-controlled series of blocks, under fluoroscopic guidance, that has resulted in a reduction in pain for the duration of the local anesthetic used (eg, 3 hours longer with bupivacaine than lidocaine). There is no consensus on whether a minimum of 50% or 75% reduction in pain would be required to be considered a successful diagnostic block, although evidence supported a criterion standard of 75% to 100% reduction in pain with dual blocks. No therapeutic intra-articular injections (ie, steroids, saline, other substances) should be administered for a period of at least 4 weeks before the diagnostic block. The diagnostic blocks should not be conducted under intravenous sedation unless specifically indicated (eg, the individual is unable to cooperate with the procedure).

G. Radiographic images used to perform SI joint injection should be digitally archived for retrieval at a later date. Records should be retained for not less than ten years after date of last film.

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REGULATORY STATUS

A number of radiofrequency generators and probes have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. In 2005, the SInergy® (Halyard; formerly Kimberly-Clark), a water-cooled single-use probe, was cleared by the FDA, listing the Baylis Pain Management Probe as a predicate device. The intended use is in conjunction with a radiofrequency generator to create radiofrequency lesions in nervous tissue.

FDA product codes: GXD, GXI.

Examples of types of commercially available SIJ fusion devices are listed in Table 1.

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

Bone allograft products that are regulated as Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) for homologous use may be marketed specifically for use in SIJ fusion.

Table 1. Select Sacroiliac Fusion Devices

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

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Device	Manufacturer	Features	Graft Compatible	Clearance	Date
SambaScrew®	Orthofix	Cannulated screw	Y	K121148	2012
Silex Sacroiliac Join Fusion®	X-Spine Systems	Cannulated screw	Y	K140079	2014
SI-LOK® Sacroiliac Joint Fixation Syste	Globus Medical	Cannulated screw	Y	K112028	2011
SImmetry® Sacroiliac Joint Fusion System	RTI	Cannulated screw	Y	K102907	2010
SImmetry+ System	SiVantage	Cannulated screw	Y	K250647	2025
SIimpact® Sacroilia Joint Fixation Syste	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 Syste	Dio Medical Corp.	Cannulated screw	Y	K222448	2022
T-FIX® 3DSI Joint Fusion System	Cutting Edge Spine, LLC	3D printed cannulated screw	Y	K214123	2023
PathLoc SI Joint Fusion System	L & K Biomed Co. Ltd.	Metalic fastener	Y	K231841, K240201	2023
SI-Cure Sacroiliac Joint Fusion System	Alevio, LLC	Metalic fastener	Y	K231951	2023
Integrity-SI® Fusio System	OsteoCentric Technologies	Cannulated screw	Y	K230226	2023
Sacrix® Sacroiliac Joint Fusion Device System	LESspine Innovations	Cannulated screw	Y	K232605	2023
TORPEDO Implant System®	Deltacor GmbH	Cannulated screw	Y	K230817	2024
Liberty SI Lateral Implant System	Spinal Simplicity, LLC	Cannulated screw	Y	K231923	2023
Eminent Spine SI Screw System	Eminent Spine, LL	Cannulated screw	Y	K240505	2025

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Device	Manufacturer	Features	Graft Compatible	Clearance	Date
ARx® SAI Implant System	Life Spine Inc.	Cannulated screw	Y	K241464	2024
DYNAMIS™ SI Scre System	Promethean Restorative LLC	Cannulated screw	Y	K243565	2025
NEXXT MATRIXX® SI System	Nexxt Spine, LLC	Cannulated screw	Y	K243838	2025
Posterolateral Approach					
Rialto™ SI Joint Fusion System	Medtronic	Cannulated screw	Y	K161210; K251395	2016
SacroFuse®/ SIJFuse™	SpineFrontier	Solid or hollow-cored screw	Y	K150017	2015
SILO TFX MIS Sacroiliac Joint Fixation System	Aurora Spine, Inc	Solid or hollow-cored screw	Y	K221047	2022
Camber Sacroiliac (SI) Fixation Systen	Camber Spine Technologies	Cannulated screw	Y	K233972	2023
BowTie™ SI Joint Fusion System	SAIL Fusion, LLC	Solid or hollow-cored screw	Y	K232149	2024
Omnia Medical PsiF DNA™ System	Omnia Medical, LLC	Cannulated screw	Y	K242431	2025
panaSIa SI Fusion System	Wenzel Spine, Inc	Cannulated screw	Y	K250247	2025
Posterior Approach					
Catamaran™	Tenon Medical	Metal plug	Y	K180818; K250403	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

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Device	Manufacturer	Features	Graft Compatible	Clearance	Date
SIFix System®	NuTech	Bone allograft	N	HCT/P	N/A
TransFasten™	Captiva Spine	Bone allograft	N	HCT/P	N/A
CATAMARAN SI Joi Fusion System	Tenon Medical, Inc.	Metal plug	Y	K231944	2023
TiLink-P SI Joint Fusion System	Surgentec, LLC	Metal plug	Y	K230857, K240720; K242141; K240720; K243835	2023
Invictus® Spinal Fixation System	Alphatec Spine, Inc.	Cannulated screw	Y	K232275	2023
VyLink™ Spinal Screw System	Vy Spine, LLC	Cannulated screw	Y	K231744	2023
Patriot-SI Posterior Implant System	Spinal Simplicity LLC	Cannulated screw	Y	K232259; K250001	2024
Huvex Interspinous Fixation System	K&J Consulting Corporation	Cannulated screw	Y	K232877	2024
SI-DESIS® X™ Sacroiliac Joint Fusion System	SI-Technology, LL	Cannulated screw	Y	K241813; K251525	2024

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

RATIONALE

This evidence review was created using searches of the PubMed database. The most recent literature update was performed through September 3, 2025.

Diagnosis of Sacroiliac Joint Pain

Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

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The use of diagnostic blocks to evaluate sacroiliac joint (SIJ) pain builds on the use of diagnostic blocks to evaluate pain in other joints. Blinded studies with placebo controls, although difficult to conduct when dealing with invasive procedures, are ideally required for scientific validation of SIJ blocks, particularly when dealing with pain relief well-known to respond to placebo controls. In the typical evaluation of a diagnostic test, the results of the sacroiliac diagnostic block would then be compared with a criterion standard. However, no current criterion standard for SIJ disease exists. In fact, some have positioned SIJ injection as the criterion standard against which other diagnostic tests and physical exam may be measured.[2,] Ultimately, the point of diagnosis is to select patients appropriately for treatment that improves outcomes. Diagnostic tests that differentiate patients who do or do not benefit from a particular treatment are clinically useful.

Clinical Context and Test Purpose
The purpose of diagnostic SIJ block in individuals who have suspected SIJ pain is to inform a decision whether to proceed to appropriate treatment.

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

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

Interventions
The test being considered is a diagnostic SIJ block. Sacroiliac blocks are administered under imaging guidance using a local anesthetic.

Comparators
The following practice is currently being used to diagnose SIJ pain: standard of care, which can include physical provocative tests to induce pain and diagnostic imaging. SIJ pain confirmed with at least 3 physical provocative tests and ≥50% acute decrease in pain upon SIJ diagnostic block following failed conservative management reflect typical criteria.

Outcomes
The general outcomes of interest are an accurate diagnosis, reductions in pain and medication usage, improvement in functional outcomes (eg, activities of daily living), improvement in the quality of life (QOL), and adverse events (AEs). A diagnostic result should be available within 1 to 2 hours postinjection.

Study Selection Criteria
For the evaluation of the clinical validity of a diagnostic SIJ block, studies that meet the following eligibility criteria were considered:

- Reported on the accuracy of the marketed version of the technology (including any algorithms used to calculate scores)
- Included a suitable reference standard (including a description of the reference standard)
- Patient/sample clinical characteristics were described
- Patient/sample selection criteria were described

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Clinically Valid
A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Systematic Reviews
Simopoulous et al (2015) conducted a systematic review evaluating 11 diagnostic accuracy studies.[3,] Studies were heterogeneous in patient selection, SIJ block procedure, assessment, and pain relief cutoff thresholds for diagnosis confirmation, which ranged from 50% to 90% reduction in pain. Four studies utilizing single blocks assessed at a cutoff threshold of at least a 75% decrease in pain score were found to have variable SIJ pain prevalence estimates of 10% to 64%. Eight studies utilizing dual blocks assessed at a cutoff threshold of at least a 70% decrease in pain score were found to have variable SIJ pain prevalence estimates of 10% to 40.4% with corresponding false-positive rates of 22% to 26%. The evidence for dual blocks was graded Level II.

Manchikanti et al (2013) updated an evidence review with guidelines on the diagnosis of SIJ pain for the American Society of Interventional Pain Physicians.[4,] Various studies evaluating diagnostic blocks were reviewed in which the criteria for a positive test varied from 50% to 100% relief from either single or dual blocks. The most stringent criterion (75% to 100% relief with dual blocks) was evaluated in 7 studies. The prevalence of a positive test in the 7 studies ranged from 10% to 44.4% in patients with suspected sacroiliac disease. The evidence for diagnostic sacroiliac intra-articular injections was considered to be good using 75% to 100% pain relief with single or dual blocks as the criterion standard.

Manchikanti et al (2010) published 2 systematic reviews for interventional techniques for treatment and diagnosis of low back pain.[5,6,] Evidence for diagnostic sacroiliac injections was considered to be fair to poor, and no additional literature was identified since a systematic review by Rupert et al (2009).[7,]

Chou et al (2009) conducted 2 systematic reviews at the Oregon Evidence-based Practice Center that informed practice guidelines from the American Pain Society.[8,9,] The systematic reviews concluded that no reliable evidence existed to evaluate the validity or utility of diagnostic SIJ block as a diagnostic procedure for low back pain with or without radiculopathy, with a resulting guideline recommendation of insufficient evidence. Data on SIJ steroid injection were limited to a small controlled trial, resulting in a recommendation of insufficient evidence for therapeutic injection of this joint.

Clinically Useful
A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence
Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials (RCTs).

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Direct evidence supporting the clinical utility of using diagnostic SIJ blocks in this population were not identified.

Chain of Evidence
Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

Because the clinical validity of diagnostic SIJ blocks has not been established, a chain of evidence cannot be constructed.

Section Summary: Diagnosis of Sacroiliac Joint Pain
Findings from systematic reviews assessing the utility of diagnostic SIJ blocks are conflicting. In addition, there is no independent reference standard for the diagnosis of SIJ pain.

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

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

TREATMENT OF SACROILIAC JOINT PAIN: THERAPEUTIC CORTICOSTEROID INJECTIONS

Clinical Context and Therapy Purpose
The purpose of therapeutic corticosteroid injections 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 review.

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

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Interventions
The therapy being considered is a therapeutic corticosteroid injection.

Comparators
The following therapy is currently being used to treat SIJ: conservative management, including physical therapy.

Outcomes
The general outcomes of interest are symptoms (eg, reductions in pain), functional outcomes, QOL, reductions in medication use, and treatment-related morbidity. Follow-up at 3 to 15 months is of interest to monitor outcomes.

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

REVIEW OF EVIDENCE

Systematic Reviews
Hansen et al (2012) published a systematic review of SIJ interventions. [10,] The primary outcomes were short-term (≤6 months) or long-term (>6 months) pain relief. Evidence quality was classified as good, fair, or limited/poor. Eleven studies (6 randomized, 5 nonrandomized trials) met the inclusion criteria. Reviewers found that evidence for intra-articular steroid injections was limited or poor, as was the evidence for periarticular injections (local anesthetic and steroid or botulinum toxin).

Randomized Controlled Trials
Tables 2 and 3 summarize the characteristics and results of select RCTs.

Patel et al (2022) randomized 72 patients with SIJ pain and sacroiliac joint dysfunction to fluoroscopy-guided intra-articular injection of corticosteroid and local anesthesia or a sham group consisting of fluoroscopy-guided anesthetic injection and distilled water injection.[11,] Diagnosis of sacroiliac joint dysfunction was based on the International Association for the Study of Pain criteria. All patients reported pain located over the SIJ. In a single-blinded assessment, pain (Numeric Rating Scale [NRS]) and disability (Oswestry Disability Index [ODI]) were significantly reduced at 4 weeks follow-up within each group (Table 3), but the corticosteroid injection group had a significantly greater magnitude for both outcomes ($p<.001$).

A trial by Visser et al (2013) randomized 51 patients with SIJ and leg pain to physical therapy, manual therapy, or intra-articular injection of corticosteroid.[12,] Diagnosis of SIJ pain was based on

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provocation tests and not SIJ injections. In a blinded assessment, 25 (56%) patients were considered to be successfully treated at the 12-week follow-up visit based on complete relief of pain and improvement in the visual analog scale (VAS) score for pain.

Kim et al (2010) reported a randomized, double-blind, controlled trial of intra-articular prolotherapy compared with steroid injection for SIJ pain.[13,] The trial included 48 patients with SIJ pain. Intra-articular dextrose water prolotherapy or steroid injections were administered under fluoroscopic guidance on a biweekly schedule, with a maximum of 3 injections. Injections were stopped when pain relief was 90% or greater, which required a mean of 2.7 prolotherapy injections and 1.5 steroid injections. Pain (NRS) and disability (ODI) scores were assessed at baseline, 2 weeks, and then monthly upon completing treatment. At the 2-week follow-up, pain and disability scores were significantly improved in both groups, with no significant difference between groups. The numeric rating scale pain score improved from 6.3 to 1.4 in the prolotherapy group and from 6.7 to 1.9 in the steroid group. At 6 months after treatment, 63.6% of patients in the prolotherapy group remained improved from baseline (≥50%), compared with 27.2% in the steroid group. At the 15-month follow-up, the cumulative incidence of sustained pain relief was 58.7% in the prolotherapy group compared with 10.2% in the steroid group. The median duration of the recurrence of severe SIJ pain was 3 months for the steroid group.

Table 2. Characteristics of Key RCTs Assessing Therapeutic Corticosteroid Injection

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	*Comparator*
Patel et al (2023)[11,]	India	1	NR	Diagnosed with sacroiliac joint dysfunction and pain located over the SIJ	36 fluoroscopy-guided corticosteroid and local anesthetic injection	36 fluoroscopy-guided distilled water and local anesthetic injection
Visser et al (2013)[12,]	NL	1	NR	Diagnosed with SIJ pain and/or leg pain between 4 wk and 1 in duration	18 patients randomized to IA injection	15 patients randomized to PT and 18 to manual therapy
Kim et al (2010)[1]	Korea	1	NR	Diagnosed with SIJ pain[a] who failed additional 1-mo treatment	26 patients randomized to steroid; 26 analyzed	24 patients randomized to IA prolotherapy; 23 analyzed

IA: intra-articular; NL: The Netherlands; NR: not reported; PT: physical therapy; RCT: randomized controlled trial; SIJ: sacroiliac joint.
[a] Confirmed by ≥50% improvement in response to a single local anesthetic block.

Table 3. Results of Key RCTs Assessing Therapeutic Corticosteroid Injection

Study	Pain Outcomes		Functional Outcomes	
Patel et al (2023)[11,]	NRS (SD)		ODI (SD)	
	Baseline	1 Month	Baseline	1 Month
IA Corticosteroid Injection	6.97 (0.878)	3.06 (1.567; p<.001 vs baseline)	35.94 (0.841)	18.14 (8.932; p<.001 baseline)

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Study	Pain Outcomes		Functional Outcomes	
Sham	7.28 (0.701)	5.17 (1.577; p<.001 vs baseline)	37.08 (0.729)	29.06 (8.003; p<.001 baseline)
p value (between group		<.001 favoring IA corticosteroid injection		<.001 favoring IA corticosteroid injection
Visser et al (2013)[12,]	VAS (SD)		RAND-36 Physical Functioning[1]	
	Baseline	3 Months	Baseline	3 Months
IA Corticosteroid Injection	5.7 (1.7)	5.0 (1.9)	45.3 (16.8)	37.9 (15.4)
Physical therapy	4.3 (1.2)	3.9 (1.4)	27.5 (6.5)	51.25 (28.7)
Manual therapy	5.2 (1.4)	3.3 (2.3)	30.0 (18.6)	60.5 (24.3)
Kim et al (2010)[13,]	NRS (SD)		ODI (SD)	
	Baseline	2 Weeks	Baseline	2 Weeks
Steroid	6.7 (1.0)	1.4 (1.1)	35.7 (20.4)	15.5 (10.7)
Prolotherapy	6.3 (1.1)	1.4 (1.1)	33.9 (15.5)	11.1 (10)

IA: intra-articular; NRS: Numerical Rating Scale; ODI: Oswestry Disability Index; RCT: randomized controlled trial; SD: standard deviation; VAS: Visual Analog Scale.
[1] Survey measures of health-related quality of life scored on a scale from 0 to 100, with 100 representing the highest level of functioning in a given category.

The purpose of the study relevance, conduct, and design limitations tables (see Tables 4 and 5) is to display notable limitations identified in each study. This information is synthesized as a summary of the body of evidence following each table and provides the conclusions on the sufficiency of the evidence supporting the position statement.

Table 4. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Patel et a (2023)[11,]				5. Clinical significant difference not prespecified; no definition of treatment success provided	1. Not sufficient duration for benefit 1 month follow-up only
Visser et al (2013)[12,]	4. Patients were recruite on the basis SIJ-related le pain with sho duration of signs and symptoms.	2. Unclear which if any patients received a second injection.		4-5. Definition of successful treatment did not utilize standard pain relief threshol cutoff of at least 50%.	
Kim et al (2010)[13,]					

SIJ: sacroiliac joint.
The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps

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assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 5. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Patel et a (2023)[11],		1. Trial was single-blinded; only participants were blinded to treatmer	1. Not registered.		1. Power calculations not reporte	
Visser et al (2013)[12],	3. Allocation not describe	1. Trial was single-blinde	1. Not registered.		2. Power nc calculated f primary outcome.	3. Confidenc intervals and/or p values not reported.
Kim et al (2010)[13],	3. Allocation not describe		1. Not registered.			

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. No 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.

Case Series

Case series studies evaluating corticosteroid injections, described in systematic reviews, have shown variable findings at generally short-term follow-up.[10,14,15,16,17,]

Section Summary: Therapeutic Corticosteroid Injections

Results from 3 trials are insufficient to permit conclusions on the effect of this procedure on health outcomes. While superior to a sham control in a single trial, steroid injections were not the most effective treatment in the 2 trials with active comparators. The degree of pain relief observed was also limited. Larger trials with rigorous designs and sufficient follow-up are needed to determine whether the treatment is effective.

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TREATMENT OF SACROILIAC JOINT PAIN: RADIOFREQUENCY ABLATION

Clinical Context and Therapy Purpose
The purpose of radiofrequency ablation (RFA) 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 review.

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

Interventions
The therapy being considered is RFA, also known as radiofrequency neurotomy. RFA involves heating a portion of a pain-transmitting nerve to create a heat lesion. The goal of the heat lesion is to functionally denervate the SIJ and prevent the transmission of pain signals to the brain. Several variations of RFA are available, including water-cooled, pulsed, and conventional continuous RFA. Water-cooled RFA produces larger lesions than the other 2 modalities, however, lesion size is also dependent on temperature, needles size, and procedure duration. Lateral branch RFA targets the SIJ nerves.

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

Outcomes
The general outcomes of interest are symptoms (eg, reductions in pain), functional outcomes, QOL, reductions in medication use, and treatment-related morbidity. Follow-up at 3 and 15 months is of interest to monitor outcomes.

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

REVIEW OF EVIDENCE

Systematic Reviews
Tables 6 and 7 summarize the characteristics and results of select systematic reviews.

Ciaffi et al (2024) conducted a meta-analysis on minimally invasive interventional procedures for osteoarthritis and inflammatory arthritis, including SIJ RFA.[18,] A total of 52 studies of SIJ RFA were identified, of which 33 (8 RCTs, 25 non-randomized studies [NRS]) were included in the

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quantitative synthesis. At 1 month, pooled RCT data (n=340) showed a mean VAS reduction of -3.18 (95% CI: -3.96 to -2.39; p<.001; I^2=93%), while NRS data (n=804) showed a larger reduction of -4.93 (95% CI: -5.58 to -4.28, p<.001; I^2=97%). Improvements persisted across 3, 6, and 12 months, though the magnitude diminished slightly over time (RCTs, -2.51; I^2=93% vs. NRS, -3.73; I^2=99% at 12 months). Functional outcomes on the Oswestry Disability Index also improved, with RCTs showing a mean decrease of -11.8 points (p<.001; I^2=65%) at 1 month and NRS a larger decrease of -21.1 points (p<.001; (p<.001; I^2=96%), with benefits maintained to 12 months. Heterogeneity across studies was high, especially among observational cohorts. Overall certainty of evidence was rated moderate for RCT pain outcomes and low for NRS, due to risk of bias and inconsistency in results.

Janapala et al (2024) conducted a meta-analysis on the effectiveness of RFA for SIJ pain.[19,] The review included 8 RCTs and 12 observational studies meeting inclusion criteria. Qualitative analysis, after downgrading based on GRADE criteria, resulted in Level III evidence with fair recommendation for RFA in managing sacroiliac joint pain. The meta-analysis included both dual-arm and single-arm analyses. A single-arm meta-analysis of 12 studies (including both RCTs and observational studies) showed a mean pain score reduction of 3.848 points at 3 months follow-up (95% CI: -4.552 to -3.145, p<.0001). Dual-arm analysis comparing RFA to non-active controls at 3 months showed a statistically significant difference in pain levels (standardized mean difference [SMD] -0.96, 95% CI: -1.73 to -0.19; p=.02). Functional improvement was variable but generally showed significant improvement across different time points. The authors suggest that while the evidence supports a Level III recommendation for RFA in managing sacroiliac joint pain, further high-quality research is needed to strengthen these findings.

Chou et al (2021) conducted a systematic review and meta-analysis on interventional treatments for acute and chronic pain for the Agency for Healthcare Research and Quality for use by the Centers for Medicare and Medicaid Services.[20,] The systematic review identified 2 trials (N=79) on cooled RFA versus sham for SIJ pain with results at 3 months, and 1 trial (N=28) on cooled RFA versus sham with results at 1 month. Meta-analysis indicated that cooled RFA is probably more effective for pain and function compared to sham at 1 and 3 months with moderate to large benefits. The strength of evidence was rated moderate for pain and function at 3 months and low for function at 1 month. When comparing cooled RFA to conventional RFA, 1 trial (N=43) showed no differences at 1 or 3-month follow-up and a small, nonstatistically significant reduction in pain at 6 months. The strength of evidence was rated as low.

Chappel et al (2020) performed a meta-analysis of RFA for chronic back pain.[21,]The review included 5 RCTs comparing RFA to sham or medical treatment in patients with chronic SIJ pain with follow-up from 1 to 3 months, and 1 study that had a follow-up to 12 months. This meta-analysis did not include pulsed RFA. Low-quality evidence indicated that RFA led to a modest reduction in pain at 1 to 3-month follow-up, but there was no significant reduction in pain in the single RCT (n=228) that had 6- and 12-month follow-up.[22,] The RCT by Juch et al (2017) with 12-month follow-up is described in greater detail below.

Chen et al (2019) performed a meta-analysis of 5 RCTs comparing RFA to sham or medical treatment in patients with chronic SIJ pain.[23,] Various RFA procedures were represented, including percutaneous, cooled, and palisade SIJ radiofrequency neurotomy. Pain outcomes from all RCTs were pooled for the meta-analysis. Disability outcomes were only available for 2 studies utilizing

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cooled RFA. While studies showed no significant heterogeneity for disability outcomes, heterogeneity was high for pain outcomes.

Table 6. Characteristics of Systematic Reviews

Study	Dates	Trials	Participants	N (Range)	Design	Duration, mo
Janapala et al (2024)[19]	Inception-2023	8 RCTs, 12 observation studies	Patients with chronic SIJ pain treated by various RFA procedures with or without sham control groups.	(17 to 22	RCTs ar single-arm studies	3
Chou et (2021)[20]	2007-2021	3	Patients with chronic SIJ pain treated by various RFA procedures compared to sham.	122 (28 t 51)	RCTs	1 to 3
Chappel al (2020)[21]	2008-2019	5	Patients with chronic SIJ pain treated by various RFA procedures compared to sham or medical treatment. One trial with 12 mo follow-up had 228 participants.	384	RCTs	3 to 12
Chen et (2019)[23]	2012-2018	5	Patients with chronic SIJ pain treated by various RFA procedures compared to sham or medical treatment	311 (28 t 155)	RCTs	3 to 6

SIJ: sacroiliac joint; RCT: randomized controlled trial; RFA: radiofrequency ablation.

Table 7. Results of Systematic Reviews

Study	Pain Score	Pain Score	ODI Score	GPE Score
Janapala et al (2024)[19]	3 mo (NRS)	6 mo (NRS)	3 mo	6 mo (ODI)
RFA vs active control, SMD (95% CI), p; I^2	-0.96 (-1.73 to -0.19 p=.02, I^2=89%	-1.17 (-1.70 to -0.65), p<.0001, I^2=66%	-6.971 (-8.729 to -5.212), p<.0001, I^2=75.5%	-2.285 (-2.482 to -2.088 p<.0001, I^2=0%
RFA vs non-activ control, SMD (95% CI), p; I^2	-0.97 (-1.53 to -0.42 p=.0005, I^2=71%		-0.47 (-1.07 to 0.13), p=.12, I^2=83%	
Single arm RFA, pooled MD (95% CI), p; I^2	-3.848 (-4.552 to -3.145), p<.0001, I^2=99.8%	-3.999 (-4.001 to 3.997), p<.0001 I^2=0%	-11.524 (-11.577 to -11.472), p<.0001, I^2=0%	-23.100 (-23.135 to -23.066), p<.0001, I^2=0%
Chou et al (2021)[20]	3 mo vs sham RFA (VAS)	6 mo vs conventional RFA (VAS)		
Total N	79			
Cooled RFA	-2.4	-3.8		
Sham or conventional RFA	-0.8	-3.0		

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Study	Pain Score	Pain Score	ODI Score	GPE Score
p	.04	.041		
Chappel et al (2020)[21,]	1 to 3 mo	6 mo		
Total N	5 studies[1]; n=384	1 study[1]; n=228		
MD (95% CI)	-1.53 (-2.62 to 0.45)	-0.28 (-1.00 to 0.44)		
p	.02			
I^2	83%	NA		
Chen et al (2019)[23,]Various RFA				
Total N	5 studies[1]; n=311	See NRS Score[1]	2 studies; n=79	1 study; n=60
MD (95% CI)	-2.13 (-3.4 to -0.87)		-8.91 (-16.44 to -1.38	0.60 (-0.09 to 1.29)
p	.001		.020	.090
I^2	82.3%		44.8%	NR

CI: confidence interval; GPE: Global Perceived Effect; MD: mean difference; NA: not applicable; NR: not reported; NRS: numerical rating scale; ODI: Oswestry Disability Index; RFA: radiofrequency ablation; VAS: visual analog score.
[1] All pain scores (NRS, VAS) utilizing an 11-point scoring system were pooled together for the meta-analysis.

Randomized Controlled Trials

Tables 8 and 9 summarize the characteristics and results of select RCTs.

Table 8. Characteristics of Key RCTs Assessing Radiofrequency Ablation

Study	Countries	Sites	Dates	Participants	Interventions	
Cohen et al (2023)[2]	U.S.	15	2018-2019	Patients with SIJ pain lasting 3 or more mos	Cooled RFA (n=105)	Medical management (n=105)
Mehta et al (2018)[21]	UK	1	2012-2015	Patients with SIJ pain confirmed by diagnostic intra-articular injection; only 17 of 30 enrolled patients were randomized due to results of interim analysis	Multi-probe strip lesion RFA (n=1	Sham (n=6) 4 patients crossed over t active group after 3-month endpoint
Juch et al (2017)[22,]	Netherlands	16	2013-2014	Patients with chronic low back pain related to th SIJ	RFA + exercise program (n=116 110 received RF 81 received Palisade radiofrequency	Exercise program (n=112) 69 completed program 18 did not

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Study	Countries	Sites	Dates	Participants	Interventions	
					treatment 23 received cooled RFA 6 received multi-probe strip lesion RFA	complete program 25 with unknown completion
Van Tilburg et al (2016)[26,]	Netherlands	NR	2012-2014	Patients with SIJ pain	Percutaneous RF to lateral branch and dorsal root primary ramus (n=30)	Sham (n=30)
Zheng et al (2014)[2]	China	1	2010-2012	Patients with ankylosing spondylitis and SIJ pain	PSRN with computed tomography guidance (n=82)	Celecoxib treatment (n=73)
Patel et al (2012; 2016)[28,29,]	U.S.	NR	2008-2010	Patients with SIJ pain	Lateral branch cooled RFA (n=34)	Sham (n=17)

NR: not reported; PSRN: palisade sacroiliac joint radiofrequency neurotomy; RFA: radiofrequency ablation; RCT: randomized controlled trial: SIJ: sacroiliac joint.

Table 9. Results of Key RCTs Assessing Radiofrequency Ablation

Study	Pain Outcomes		Functional Outcomes		Treatment Success	
Cohen et al (2023)[24,]	NRS at Baseline (SD	NRS at Mont 3 (SD)	ODI at Baseline (SD	ODI at Mon 3 (SD)	At Month 3 (%)	
Cooled RFA	6.3 (1.4)	3.8 (2.4)	40.7 (13.8)	29.7 (15.2)	52.3%	
Medical management	6.3 (1.4)	5.9 (1.7)	43.7 (13.9)	41.5 (13.6)	4.3%	
p Value	NR	<.0001	.27	<.0001	<.0001	
Mehta et al (2018)[25,]	NRS at Baseline (SD	NRS at Mont 3 (SD)	PCS[1] at Baseline (SD	PCS at Mon 3 (SD)	Treatment Success	
Strip lesion RFA	8.1 (0.8)	3.4 (2.0)	28.4 (7.1)	34.7 (10.8)	NR	
Sham	6.5 (2.0)	7.3 (0.8)	28.6 (5.0)	29.6 (5.6)	NR	
p Value	NR	<.001	NR	.0645	NR	
Juch et al (2017)[22,]	NRS at Mont 3 (95% CI)	NRS at Mont 12 (95% CI)	ODI at Mont 3 (95% CI)	ODI at Mon 12 (95% CI	At Month n/N (%)	At Mon 12, n/N (%)
RFA + exercise program	4.77 (4.31 t 5.24)	4.65 (4.16 t 5.13)	27.72 (24.5 to 30.95)	27.29 (23.8 to 30.69)	43/110 (39.10)	49/102 (48.03)
Exercise program	5.45 (4.94 t 5.95)	4.84 (4.30 t 5.38)	29.09 (25.47 to 2.71)	24.49 (20.7 to 28.23)	19/88 (21.59)	24/76 (31.78)

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Study	Pain Outcomes		Functional Outcomes		Treatment Success	
MD/RR (95% CI)	-0.71 (-1.35 to -0.06)	-0.07 (-0.74 to 0.60)	-4.20 (-8.39 to -0.00)	2.11 (-2.25 to 6.47)	1.87 (1.1 to 2.71)	1.46 (0.92 t 2.02)
p Value	.03	.83	.05	.34	.02	.10
Van Tilburg et al (2016)[26,]	Mean NRS a Baseline (SD	Mean NRS at Month 1 (SD	Mean GPE at Month 1 (SD	Mean GPE a Month 3 (SD	Treatment Success	
Percutaneous RFA	7.2 (1.4)	5.4 (1.7)	3.2 (1.1)	3.4 (1.6)	NR	
Sham	7.5 (1.2)	5.4 (1.9)	3.3 (1.0)	3.4 (1.5)	NR	
p Value	NR	NR	NR	NR	NR	
Zheng et al (2014)[27,]	VAS at Week 12 (95% CI)	VAS at Week 24 (95% CI)	Mean BASFI[2] at Baseline (95 CI)	BASFI at Week 24 (95% CI)	Treatment Success	
PSRN	2.5 (2.2 to 3.0)	2.8 (2.5 to 3.2)	5.4 (5.0 to 5.8)	3.1 (2.7 to 3.6)	NR	
Celecoxib	4.4 (4.0 to 4.9)	5.0 (4.6 to 5.3)	5.3 (4.8 to 5.8)	5.0 (4.5 to 5.5)	NR	
MD (95% CI)	-1.9 (-2.4 to 1.4)	-2.2 (-2.6 to 1.6)	NR	-1.9 (-2.5 to 1.2)	NR	
p Value	<.0001	<.0001	NR	<.0001	NR	
Patel et al (2012; 2016)[28,29,]	NRS at Baseline (SD	NRS at Mont 3 (SD)	ODI at Baseline (SD	ODI at Mon 9 (SD)	At Month n/N (%)	At Mon 6, n/N (%)
Cooled RFA	6.1 (1.3)	-2.4 (2.7)	37 (14)	-11 (17)	16/34 (47	13/34 (38)
Sham	5.8 (1.3)	-0.8 (2.4)	35 (10)	2 (6)	2/17 (12)	7/16 (44)[3]
p Value	.370	.035	.639	.011	.015	NR

BASFI: Bath Ankylosing Spondylitis Functional Index; CI; confidence interval; GPE: Global Perceived Effect; MD: mean difference; NR: not reported; NRS; Numeric Rating Scale; ODI: Oswestry Disability Index; PCS: Physical Component Score; RCT: randomized control trial; RFA: radiofrequency ablation; RR: relative risk; SD: standard deviation; VAS; Visual Analog Scale.

[1] Higher scores on the SF-12 Physical Component Score (PCS) indicate improved outcomes.

[2] The Bath Ankylosing Spondylitis Functional Index (BASFI) measures overall functional outcomes on a scale from 0 to 10 with 0 indicating best possible functioning.

[3] Patients assigned to the sham group were allowed to crossover to active treatment after the 3-month study endpoint.

Cohen et al (2023) reported results from a multi-center, single-blind, randomized, controlled trial assessing the efficacy of cooled RFA in patients with chronic SIJ pain compared to a control group of medical management alone.[25,] 210 enrolled patients were randomized to active (n=105) or control (n=105) treatment. Outcome assessors were blinded to treatment assignment. After the 3-

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month study endpoint, patients in the active group had significant improvements in the primary outcome of change in NRS score, and significantly more patients who reported ≥50% pain relief on the NRS (41.9% vs 6.5%; p<.0001) (Table 9). The secondary outcome ODI scores at 3 months significantly favored the cooled RFA group (p<.0001), as did SF-36 Physical component scores (40.2 vs 33 p<.0001), 5-level EuroQol-5D (EQ-5D-5L) scores (0.68 vs. 0.47; p<.0001), and the number of patients reporting improved Patient Global Impression of Change (PGIC) scores (65.5% vs 6.5%; p<.0001). Procedure-related adverse events were reported in 16 (15%) individuals who received cooled RFA, but none were considered severe. This study is limited by the short duration of follow-up as well as the single-blinded nature of the study, which could influence many of the self-reported outcomes. Additionally, participants continued their medical management during the study period, which may affect quality and functional outcome measurements.

Mehta et al (2018) published results from a double-blind, randomized, sham-controlled trial assessing the efficacy of radiofrequency neurotomy with a strip-lesioning device in patients with chronic SIJ pain.[25,] Seventeen of 30 enrolled patients were randomized to active (n=11) or sham (n=6) treatment. Recruitment was terminated after an interim analysis indicated a statistically significant difference in the pain outcome between groups. After the 3-month study endpoint, patients receiving sham treatment were allowed to crossover. While a statistically significant reduction in pain scores was reported at 3 months, there was no significant difference in functional outcome as measured by the Physical Component Score at 3 months. Due to the crossover design, it is difficult to gauge long-term outcomes and durability of the treatment.

Juch et al (2017) reported a nonblinded multicenter RCT of radiofrequency denervation in 228 of 2498 patients with suspected sacroiliac pain who were asked to participate in the trial.[22,]Patient selection criteria included body mass index (<35 kg/m^2), age (<70 years old), and pain reduction of at least 50% within 30 to 90 minutes of receiving a diagnostic sacroiliac block (n=228). An additional 202 patients had a negative diagnostic sacroiliac block; 1666 patients declined to participate in the trial. Patients meeting criteria were randomized to exercise plus radiofrequency denervation (n=116) or an exercise program alone (n=112) and were followed for a year. The RFA group had a modest improvement for the primary outcome at 3 months (-0.71; 95% confidence interval [CI]: -1.35 to -0.06), but the control group improved over time and there were no statistically significant differences between the groups for pain intensity score (p=.09) or in the number of patients who had more than a 30% reduction in pain intensity (p=.48) at 12 months. Limitations included the use of several techniques to achieve radiofrequency denervation, self-selection, lack of blinding, and a high dropout rate (31%) in the control group.

Van Tilburg et al (2016) reported a sham-controlled randomized trial of percutaneous RFA in 60 patients with SIJ pain.[26,]Patients selected had clinically suspected SIJ pain and a decrease of 2 or more points on a 10-point pain scale with a diagnostic sacroiliac block. At 3-month follow-up, there was no statistically significant difference in pain level over time between groups (group by period interaction, p=.56). Both groups improved over time (≥2 points out of 10; p-value for time, p<.001). In their discussion, trialists mentioned the criteria and method used for diagnosing SIJ pain might have resulted in the selection of some patients without SIJ pain.

Zheng et al (2014) reported on an RCT of palisade sacroiliac RFA in 155 patients with ankylosing spondylitis.[27,] Palisade RFA uses a row of radiofrequency cannulae perpendicular to the dorsal sacrum. Inclusion criteria were ages 18 to 75 years; diagnosis of ankylosing spondylitis; chronic

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low back pain for at least 3 months; axial pain below L5; no peripheral involvement; pain aggravation on manual pressing of the SIJ area; and at least 50% pain relief following fluoroscopically guided anesthetic injection into the joint. Patients who met the inclusion criteria were randomized to palisade RFA or celecoxib. Blinded evaluation to 24 weeks found that RFA (2.8) resulted in lower global VAS scores than celecoxib (5.0; p<.001) as well as improved scores for secondary outcome measures. This study lacked a sham control.

Patel et al (2012) reported a randomized, double-blind, placebo-controlled trial of lateral branch neurotomy with a cooled radiofrequency probe.[28,] Twelve-month follow-up was reported in 2016.[29,]Fifty-one patients who had a positive response to 2 lateral branch blocks were randomized 2:1 to lateral branch radiofrequency or to sham. At a 3-month follow-up, significant improvements were observed in pain levels (-2.4 vs -0.8), physical function (14 vs 3), disability (-11 vs 2), and QOL (0.09 vs 0.02) for radiofrequency treatment compared with controls (all respectively). With treatment success defined as a 50% or greater reduction in numeric rating scale score, 47% of radiofrequency-treated patients and 12% of sham-treated patients achieved treatment success. The treatment response was durable to 12 months in the 25 of 34 patients who completed all follow-up visits[29,]. Of the 9 patients who terminated study participation, 4 (12%) of 34 were considered treatment failures.

Tables 10 and 11 display notable relevance, design, and conduct limitations identified in each study.

Table 10. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Cohen et a (2023)[24,]			2. Not a sham control.		1. Not sufficient duration for benefit. Limited to 3 months follow-up.
Mehta et a (2019)[25,]				1. Disability outcomes were not reported.	
Juch et al (2017)[22,]	4. Patients older than 70 years were excluded.		2. Not a sham control.		
Van Tilburg et al (2016)[26,]					
Zheng et a (2014)[27,]	1. Patients were required to have a diagnosis of ankylosing spondylitis in addition to chroni low back pain related to the SI		2. Not a sham control.		
Patel et al (2012)[28,29,]					

SIJ: sacroiliac joint.
The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps

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assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not established 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 11. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Cohen et a (2023)[24,]		1. Not blinded to treatment assignment		1. 18% of the cooled RFA group and 13% of control group patients missed 3 mo follow-up		
Mehta et a (2019)[25,]				3. 66.6% of sham group patien crossed over to treatment grou at 3 mo	Other: Small study siz due to interim analysis	
Juch et al (2017)[22,]		1-2. Study was not blinded.				
Van Tilburg et al (2016)[26,]				3. 63.3% of sham group patien crossed over to the treatment group		
Zheng et a (2014)[27,]						
Patel et al (2012)[28,29,]				3. Patients in the sham group could cross over at 3 mo		

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

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Section Summary: Radiofrequency Ablation
Meta-analysis of available sham-controlled RCTs suggests that there may be a small effect of RFA on SIJ pain at short-term (1 to 3 months) follow-up. However, the randomized trials of RFA have methodologic limitations, and there is limited data on the duration of the treatment effect. The single RCT with 6 and 12-month follow-up showed no significant benefit of RFA compared to an exercise control group at these time points. In addition, heterogeneity of RFA treatment techniques precludes generalizing results across different studies.

TREATMENT OF SACROILIAC JOINT PAIN: SACROILIAC JOINT FUSION/FIXATION WITH A TRANSILIAC TRIANGULAR IMPLANT SYSTEM

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

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

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

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

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

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

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

REVIEW OF EVIDENCE

Systematic Reviews
Ghaddaf et al (2024) published a meta-analysis of 3 randomized controlled trials (n=423) that compared minimally invasive SIJ fusion using triangular titanium implants to nonsurgical

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management for SIJ dysfunction.[30,] At 6 months, the results showed statistically significant improvements with minimally invasive SIJ fusion in pain scores (standardized mean difference [SMD], -1.78 [95% CI, -2.46 to -1.11]; p<.00001; I^2=90%), disability as measured by Oswestry Disability Index (ODI) score (SMD, -1.22 [95% CI, -1.47 to -0.96]; p<.00001; I^2=43%), quality of life measures including 36-Item Short Form Health Survey (SF-36) Physical Component Summary (PCS) (SMD, 1.09 [95% CI, 0.90 to 1.28]; p<.00001; I^2=0%), SF-36 Mental Component Summary (MCS) (SMD, 0.66 [95% CI, 0.30 to 1.01]; p=.0003; I^2=66%), and EuroQol 5-Dimension (EQ-5D) (SMD, 1.09 [95% CI, 0.80 to 1.39]; p<.00001; I^2=59%). The durability of the benefit persisted through 24 months; however, this long-term data was derived from only one trial for all outcomes. The study also reported improved patient satisfaction (Odds ratio [OR], 6.87 [95% CI, 3.73 to 12.64]; p<.00001; I^2=1%) and reduced opioid use (OR,.43 [95% CI,.29 to.65]; p<.00001; I^2=0%) with minimally invasive SIJ fusion compared to non-surgical management of SIJ dysfunction. No significant differences in adverse event rates were observed between groups.

Randomized Controlled Trials
Characteristics and results of RCTs are shown in Tables 12 to 14.

Investigation of Sacroiliac Fusion Treatment (INSITE)
Whang et al (2015) reported an industry-sponsored nonblinded RCT, Investigation of Sacroiliac Fusion Treatment (INSITE) of the iFuse Implant System in 148 patients.[31,] The 12-month follow-up to this RCT was reported by Polly et al (2015),[32,] and a 2-year follow-up was reported by Polly et al (2016).[33,] However, by 12 months, almost all patients in the control group had crossed over to SIJ fusion, precluding a comparison between groups. Trial inclusion was based on a determination of the SIJ as a pain generator from a combination of a history of SIJ-localized pain, positive provocative testing on at least 3 of 5 established physical tests, and at least a 50% decrease in SIJ pain after image-guided local anesthetic injection into the SIJ. The duration of pain before enrollment averaged 6.4 years (range, 0.47 to 40.7 years). A large proportion of subjects (37%) had previously undergone lumbar fusion, SIJ steroid injections (86%), and RFA (16%).

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

At 6 months, success rates were 23.9% in the control group versus 81.4% in the surgical group (posterior probability of superiority >0.999). A clinically important (≥15-point) improvement in ODI score was found in 27.3% of controls compared with 75.0% of fusion patients. Measures of QOL (36-Item Short-Form Health Survey, EuroQol-5D) also improved to a greater extent in the surgery group. Of the 44 nonsurgical management patients still participating at 6 months, 35 (79.5%) crossed over to fusion. Compared with baseline, opioid use at 6 months decreased from 67.6% to

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58% in the surgery group and increased from 63% to 70.5% in the control group (p=.082). At 12 months, opioid use was similar between groups (55% vs 52%, p=.61).

Polly et al (2016) reported 2-year outcomes from the SIJ fusion arm of this RCT.[33,] 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).[34,] Of 103 patients with SIJ dysfunction who were treated with minimally invasive SIJ fusion with triangular titanium implants, 60 (72.3%) patients reported an improvement in ODI scores of ≥15 points from baseline to 3 years. The mean ODI score decreased from 56 to 28 for the same time frame, an improvement of 28 points (p<.001); similarly, the mean SIJ pain score decreased to 26.2, reflecting a decrease of 55 points (p<.001). Over 3 years of follow-up, 168 AEs were reported in 75 patients, although only 22 of these events involved the pelvis. The study was limited by its lack of long-term data from a control group not receiving surgical treatment.

iFuse Implant System Minimally Invasive Arthrodesis (iMIA)

In 2016 and 2017, the iFuse Implant System Minimally Invasive Arthrodesis (iMIA) study group reported another industry-sponsored multicenter RCT of the iFuse Implant System in 103 patients.[35,36,] Selection criteria were similar to those of the trial by Whang et al (2015), including at least a 50% pain reduction on SIJ block. The mean pain duration was 4.5 years, and about half of the patients were not working due to lower back pain. Additionally, 33% of patients had undergone prior lumbar fusion. Nonsurgical management included physical therapy and exercises at least twice per week; interventional procedures (eg, steroid injections, RFA) were not allowed. The primary outcome was change in the VAS pain score at 6 months.

All patients assigned to iFuse underwent the procedure, and follow-up at 6 months was available for 49 of 51 patients in the control group and for all 52 patients in the iFuse group. Six-month results as reported by Sturesson et al (2016) are shown in Table 12.[35,] At 6 months, VAS pain scores improved by 43.3 points in the iFuse group and by 5.7 points in the control group (p<.001). ODI scores improved by 25.5 points in the iFuse group and by 5.8 points in the control group (p<.001, between groups). An improvement in lower back pain by at least 20 VAS points (a minimal clinically important difference) was achieved in 78.8% of the SIJ fusion group versus 22.4% of controls (p<0.001). Quality of life outcomes showed a greater improvement in the iFuse group than in the control group. Changes in pain medication use were not reported. Patients in the conservative management group were allowed to cross over to SIJ fusion at 6 months.

Twelve and 24-month results from the iMIA trial were reported by Dengler et al (2017, 2019).[37,38,] 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

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

Randers et al. (2024) conducted a double-blind randomized sham surgery-controlled trial comparing minimally invasive SIJ fusion using triangular titanium implants (iFuse, SI-BONE) to sham surgery in 63 patients with SIJ pain confirmed by diagnostic injection.[39,] The surgical group received 3 implants inserted laterally through the ilium into the sacrum, while the sham group underwent a simulated procedure without implant placement. After 6 months, there was no statistically significant difference in the primary outcome between the SIJ fusion and sham groups. The mean reduction in SIJ pain was 2.6 points for the surgical group and 1.7 points (MD, -1.0; 95% CI: -2.2 to 0.3; p =.13) for the sham group on the Numeric Rating Scale (NRS). Secondary outcomes, including ODI and EuroQol 5-dimension 5-level EQ-5D, also showed similar results between groups. The study was limited by its short follow-up period.

Table 12. Summary of Key RCT Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	*Comparator*
Randers et al (2024)[39,]	Sweden and Norway	2	2018-2021	Patients 21 to 70 y with confirmed diagnosis of severe SIJ pain	32 randomize to SIJ fusion	31 randomized nonsurgical
Whang et al (2015)[31,]; INSITE	U.S.	19	2013-2014	Patients 21 to 70 y with confirmed diagnosis of unilateral or bilatera SIJ dysfunction due to degenerative sacroiliitis and/or SI disruption	102 randomized to SIJ fusion	46 randomized nonsurgical management
Sturesson et al (2017)[35,]; iMIA	EU (Belgium, Germany, Italy, Swede	9	2013-2015	Patients 21 to 70 y with LBP for >6 mo and diagnosed with SIJ as primary pain generator[a]	52 randomize to SIJ fusion	51 randomized conservative management

iMIA: iFuse Implant System Minimally Invasive Arthrodesis; INSITE: Investigation of Sacroiliac Fusion Treatment; LBP: low back pain; RCT: randomized controlled trial; SIJ: sacroiliac joint.

[a] The 3 criteria for diagnosis of SIJ pain were as follows: pain was present or near the posterior superior iliac spine; there were at least 3 positive findings on 5 provocative tests; at least a 50% pain reduction on fluoroscopically guided injection of local anesthetic into the joint.

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Table 13. Summary of Six-Month iFuse Results

Results	VAS Score		Success End Point		ODI Score		SF-36 PCS Scor		EQ-5D TTO Inde	
	Ctl	*iFuse*	*Ctl*	*iFuse*	*Ctl*	*iFuse*	*Ctl*	*iFuse*	*Ctl*	*iFuse*
INSITE[31,]										
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[35,]										
Baseline	73.0	77.7								
Follow-up	67.8	34.4								
Change	-5.7	-43.3			-5.8	-25.5			0.11	0.37
Randers et al (2024)[39,]	**NRS score, operated SIJ**						**PGQ**		**EQ-5D-5L**	
Baseline	7.7	7.9			53	51	74	70	.61	.63
Follow-up	6	5.0			50	47	68	64	.66	.65
Change	-1.7	-2.9			-3	-4	-6	-6	.05	.02
Mean differenc (95% CI); p-value	-1.0 (-2.2 to 0.3); p =.13				-3 (-9 to 4); NS		−4 (−12 to 4); N		-0.01 (-0.07 to 0.05); NS	

Adapted from Whang et al (2015)[31,] and Sturesson et al (2015).[35,]
The success endpoint was defined as a reduction in VAS pain score of ≥20, absence of device-related events, absence of neurologic worsening, and absence of surgical intervention.
Ctl: control;EQ-5D 5L: EuroQol 5-dimension 5-level; EQ-5D TTO Index: EuroQoL Time Tradeoff Index; iMIA: iFuse Implant System Minimally Invasive Arthrodesis; INSITE: Investigation of Sacroiliac Fusion Treatment; NRS: numeric rating scale; NS: not significant; ODI: Oswestry Disability Index; PGQ: pelvic girdle questionnaire; SF-36 PCS: 36-Item Short-Form Health Survey Physical Component Summary; VAS: visual analog scale.
[a] p<.001.

Table 14. Extended Follow-Up From the INSITE and iMIA Trials

Outcome Measures	Baseline (SD	6 Months (SI	12 Months (SD)	24 Months (SD)
INSITE[31,]				
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
% ≥15-point improvement ODI				68.2%

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Outcome Measures	Baseline (SD	6 Months (SD	12 Months (SD)	24 Months (SD)
iMIA[35,37,38,]				***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).[37,]
CI: confidence interval; iMIA: iFuse Implant System Minimally Invasive Arthrodesis; INSITE: Investigation of Sacroiliac Fusion Treatment; ODI: Oswestry Disability Index; SD: standard deviation; SIJ: sacroiliac joint.

Tables 15 and 16 display notable limitations identified in each study.

Table 15. Study Relevance Limitations

Study; Tri	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Whang et a (2015)[31,]; INSITE					
Sturesson e al (2017)[35,] iMIA	1. Patients with other contributory sources of LBP might have been enrolled with SIJ-caused LBP patients				
Randers et (2024)[39,]					1. Study limited to 6 month follow-up

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

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prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 16. 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)[31]; INSITE						
Sturesson et al (2017)[35]; iMIA		1. Intervention was nonblinde				
Randers et al (2024)[39]						

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

Nonrandomized Studies

Prospective cohort studies with good follow-up rates are more likely to provide valid estimates of outcomes. Principal results of the studies at 2- to 5-year follow-up are shown in Table 17.

Results from a cohort of 172 patients undergoing SIJ fusion reported to 2 years were published by Duhon et al (2016).[40,41] Patients were formally enrolled in a single-arm trial (SIFI NCT01640353) with planned follow-up for 24 months. Success was defined as a reduction of pain score of 20-mm on a 100-mm VAS, absence of device-related AEs, absence of neurologic worsening, and absence of surgical reintervention. Enrolled patients had a mean VAS pain score of 79.8, a mean ODI score of 55.2, and a mean pain duration of 5.1 years. At 6 months, 136 (80.5%) of 169 patients met the success endpoint, which met the prespecified Bayesian probability of success rate. Mean VAS pain scores were 30.0 at 6 months and 30.4 at 12 months. Mean ODI scores were 32.5 at 6 months and 31.4 at 12 months. At 2 years, 149 (87%) of 172 patients were available for follow-up. The VAS pain score at 2 years was 26.0, and the ODI score was 30.9. Thus, 1-year outcomes were maintained at 2 years. Other outcomes (eg, 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.

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Table 17. Two- to Five-Year Outcomes of the iFuse Implant

Studies and Outcomes	Mean Baseline Value	Mean 2 to 3-Year Value	Difference or % Achieving Outcome[a]	3	4	5	P
Duhon et al (2016)[40,41,] SIFI							
N	172	149 (86.6%)					
Pain score (range, 0 to 100)	79.8	26.0	53.3				
Oswestry Disability Index score	55.2	30.9	24.5				
SF-36 score	31.7	40.7	8.9				
EQ-5D TTO score	0.43	0.71	0.27				
Whang et al (2019)[42,] LOIS							
N	103					93	
VAS (range, 0 to 100)	81.5 (SD 12.7)					27.1 (29.4)	<.001
Oswestry Disability Index score	56.3					29.9 (21.2)	<.001
EQ-5D TTO score	0.45 (0.17					0.75 (0.22)	<.001
Opioid use	76.7%	53.9%		47.4%	42.6%	41.3%	
Not working due to back pain	16.5%					15.1%	

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

In general, cohort studies and case series have shown improvements in VAS pain scores and other outcomes measures consistent in magnitude to the RCTs. The Long Term Outcomes from INSITE and SIFI (LOIS) trial was a prospective single-arm study that enrolled patients who had participated in 2 of the studies described above for evaluation at 3, 4, and 5 years.[42,] The primary success outcome, a reduction in VAS of ≥20 points in the absence of a serious device-related AE, neurologic worsening, or surgical revision, was obtained in 81.7% (95% CI: 72.4% to 89.0%) of patients at 5 years. The improvements in other clinical outcomes were maintained out to 5 years (Table 17). 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

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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.[43,] 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.[43,] 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.[44,45,46,]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%.[47,] Spain and Holt (2017) reported a retrospective review of surgical revision rates following SIJ fixation with either surgical screws or the iFuse triangular implant.[45,] Revision rates were lower with the iFuse device than observed with surgical screws.

Section Summary: Sacroiliac Joint Fusion/Fixation With a Transiliac Triangular Implant
The evidence on SIJ fusion/fixation with a triangular implant includes 1 meta-analysis, 1 blinded sham controlled trial, and 2 nonblinded RCTs of minimally invasive fusion, prospective cohorts with more than 85% follow-up, and a case series. The sham-controlled RCT found no significant difference in the primary outcome of pain reduction or in any secondary outcomes through 6 months of follow-up. Both RCTs have reported outcomes past 6 months, after which crossover was allowed. Both studies reported significantly greater reductions in VAS pain scores and ODI scores in SIJ fusion patients than in control groups. The reductions in pain and disability observed in the SIJ fusion group at 6 months were maintained out to 1 year compared with controls who had not crossed over. The RCTs were nonblinded without a placebo or an active control group. In addition, pain has a significant subjective and psychological component, and cognitive-behavioral techniques to address pain were specifically excluded from the types of treatment that control subjects could obtain. As it relates to trial design, an independent assessment of pain outcomes would have been preferable. Prospective cohorts and case series with sample sizes ranging from 45 to 149 patients and low dropout rates (<15%) also showed reductions in pain and disability that persist out to 5 years. The cohort studies and case series are consistent with the durability of treatment benefits. The meta-analysis pooled data from 3 RCTs and found that SIJ fusion with triangular titanium implants resulted in statistically significant improvements in pain, disability, quality of life, and opioid use compared to nonsurgical management for SIJ dysfunction, with similar adverse event rates between groups, though long-term data beyond 12 months was limited to a single trial.

TREATMENT OF SACROILIAC JOINT PAIN: SACROILIAC JOINT FIXATION/FUSION WITH AN IMPLANT OTHER THAN A TRANSILIAC TRIANGULAR IMPLANT

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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 review.

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 (eg, reductions in pain), functional outcomes, QOL, reductions in medication use, and treatment-related morbidity. Follow-up from 1 to 5 years is of interest to monitor outcomes.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

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

REVIEW OF EVIDENCE

Systematic Reviews

Acevedo-Gonzalez et al (2025) conducted a systematic review and meta-analysis on minimally invasive SIJ fusion for low back pain.[48,] A total of 102 studies were included, and pooled quantitative analyses were performed across randomized, prospective, cohort, and retrospective designs. In RCTs, pooled results showed an overall effect size of 1.67 (95% CI: 1.00 to 2.44;

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I^2=72.47%). Prospective cohorts demonstrated larger pooled estimates of 3.84 (95% CI: 2.17 to 5.89; I^2=97.89%). Cohort studies yielded a pooled effect size of 2.45 (95% CI: 1.20 to 3.37; I^2=79.61%), while retrospective studies reported a pooled estimate of 4.34 (95% CI: 3.04 to 5.82; I^2=90.74%). Across pooled analyses by study design, minimally invasive SIJ fusion was associated with statistically significant and clinically meaningful reductions in pain and disability, although heterogeneity was high in all estimates, and variations in interventions varied (e.g., type of fixation screw and posterior, posterolateral, and transiliac approaches).

Tran et al (2019) published a systematic review comparing the effectiveness of minimally invasive joint fusion with a triangular implant (ie, utilizing the iFuse device) compared to screw-type surgeries.[49,]A total of 20 studies were pooled to calculate a standardized mean difference across pain, disability, and global/QOL outcomes, including 14 studies evaluating the iFuse system and 7 studies evaluating cylindrical, threaded implants. Studies evaluating cylindrical, threaded implants consisted of case series and cohort studies. Patients receiving these implants experienced significantly worse pain outcomes (p=.03) compared to patients receiving iFuse, with a standardized mean difference of 1.28 (95% CI: 0.47 to 2.09) and 2.04 (95% CI: 1.76 to 2.33), respectively. A statistically significant difference in disability scores was reported between screw-type and iFuse implant groups (0.26 [95% CI: -1.90 to 2.41] vs 1.68 [95% CI: 1.43 to 1.94]; p=.01), with improved outcomes in the iFuse population. For global/QOL outcomes, a statistically significant difference in scores was reported between screw-type and iFuse implants groups (0.60 [95% CI: 0.33 to 0.88] vs 0.99 [95% CI: 0.75 to 1.24]; p=.04), with improved outcomes in the iFuse population.

A qualitative systematic review by Lorio et al (2020) for the International Society for the Advancement of Spine Surgery found evidence on the safety and effectiveness of distraction (posterior) SIJ fusion was limited to 1 prospective multicenter study (described below), no comparative studies, and a small number of case series.[50,]

Prospective Cohort Studies

Rappoport et al (2017) reported an industry-sponsored prospective study of SIJ fusion with a cylindrical threaded implant (SI-LOK).[51,] The study included 32 patients using a diagnosis of SIJ dysfunction who had failed nonoperative treatment, including medication, physical therapy, and therapeutic injections. A diagnostic injection was performed to confirm the source of pain to the SIJ. The procedure included drilling to prepare for screw insertion and implantation of 3 screws, at least 1 of which was slotted. The slotted screws were packed with an autogenous bone graft from the drill reamings. Pain and disability scores were reduced following device implantation (see Table 18), 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.[52,].

Fuchs and Ruhl (2018) published 2-year results of a prospective multi-center cohort of the posterior approach to arthrodesis of the SIJ.[53,] 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

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decreased from 74 to 37, ODI improved from 51% to 33%, and the McGill Pain Questionnaire decreased from 50% to 31% (all p<.001). Use of opioids decreased from 49.3% of patients to 30.3% at follow-up. In computed tomography (CT) scans, only 31% of patients showed SIJ fusion at 2 years.

Calodney et al (2024) reported results from SECURE, a multi-center, prospective, single-arm study evaluating a posterior SIJ fusion with the LinQ implant platform for sacroiliac joint stabilization and arthrodesis (NCT04423120).[54,] The multi-center study included 159 patients treated from January 2020 to March 2022 who were followed for 12 months. Patients had a mean age of 59 years and had experienced SIJ pain for a mean of 5.8 years, with mean baseline VAS and ODI scores of 76.2 and 52.4, respectively. A total of 73 patients either withdrew consent or were lost to follow-up prior to 12 months of observation. At 12 months, 73.5% of participants (61/83) met the primary composite endpoint of ≥20 mm VAS improvement without serious adverse events or reintervention. Mean VAS scores improved from 76.2 at baseline to 32.6 at 12 months (43.3 point improvement, p<.0001). ODI scores improved by 25.3 points on average (p<.0001). Another endpoint investigated by the authors was the Patient-Reported Outcomes Measurement Information System (PROMIS-29 item) instrument, which showed significant (p<.001) improvements from baseline values in all 7 subscales (Pain interference, sleep disturbance, fatigue, anxiety, depression, ability to participate in social roles and activities, and physical functioning). Adverse events were infrequent, with only 5 total adverse events reported and 1 procedure-related serious adverse events (anesthesia aspiration). No implant-related serious adverse events occurred. This study's primary limitations include the absence of a control group and substantial participant attrition, with 47% of patients withdrawing or lost to follow-up before the 12-month mark.

Kucharzyk et al (2022) published interim results from a prospective cohort study evaluating pain and ODI outcomes for patients treated for SIJ pain with the SImmetry sacroiliac joint fusion system (NCT02074761).[55,] A total of 250 participants were recruited from 23 centers in the U.S; of these 80.4% (n=201) were available for 1 year follow-up, although not all patients have each outcome reported due to incomplete follow-up. The mean age of the participants was 60.5 years of age, and each participant had SI joint pain for 6 months or greater, and most had prior treatment for SIJ pain, including some prior lumbar spinal procedures. The mean VAS score had decreased from 76.4 at baseline to 33 at 1 year after the procedure (p<.001), with 140 (72.2%) patients achieving minimal clinically important difference (≥20-point reduction). The mean ODI score likewise showed significant improvement from baseline to 1 year, decreasing from 54.4 to 30.5 (p<.001). Over half of the cohort (62.5% [n=120]) achieved the minimal clinically important difference (15-point reduction) on the ODI. Before surgery, 62.7% (n=126) of the cohort were on opioids, decreasing to 26.9% (n=54) at the 1 year follow-up (p<.001). QOL was assessed with the EQ-5D: at baseline, the mean EQ-5D was 60.9, increasing to 72.8 after 1 year (p<.001). The authors reported 8 (3.2%) of patients had a serious adverse event, of which 5 were determined to be device-related (back pain, pain in the extremity, bilateral SI joint pain, device loosening, or device malposition). The main limitations of this study are a lack of comparison group and incomplete follow-up on all patients due to the interim nature of this analysis.

Splitt et al. (2023) compared two implant systems for SIJ fusion in a prospective study of 65 patients: the Deltacor Torpedo (n=30) and the SI-Bone iFuse (n=35).[56,] At 12 months, both groups showed significant improvement in VAS pain scores (Torpedo: 80.6 to 21.9 mm; iFuse: 83.5 to 28

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mm; p<.0001 for each group) and ODI scores (Torpedo: 62% reduction; iFuse: 58% reduction) from baseline values, with no significant differences between the two implant systems. The study was limited by its relatively small sample size with no power calculations, lack of blinding, and limited presentation of patient characteristics.

Davies et al. (2024) reported results from MAINSAIL, a prospective, single-arm, multi-center study evaluating the Catamaran SI Joint Fusion System.[57,]The study included 33 patients with SIJ pain who had failed conservative treatment. At 6 months, 80% of patients met the primary composite endpoint of ≥20 mm VAS improvement without serious adverse events or reintervention. Mean VAS scores improved from 80.9 at baseline to 31.1 at 6 months (p<.001). Mean ODI scores improved from 51.9% at baseline to 29.6% at 6 months (p <.01). Patient satisfaction was high, with 93.3% reporting satisfaction at 6 months. No device-related serious adverse events or reoperation were reported. The study was limited by its relatively small sample size and lack of a comparison group. A subsequent 12-month analysis of the same ongoing, prospective, multi-center MAINSAIL cohort (n=24 with 12-month data) reported composite success in 87.0% of evaluable subjects and independent CT-confirmed fusion in 82.6%. Mean VAS improved from 78.8 at baseline to 23.0 (p<.001) at 12 months and mean ODI from 51.6% to 20.8% (p<.001), with 83.3% of patients reporting satisfaction. No serious device or procedure-related adverse events or reinterventions occurred during the 12-month period.[58,]

Abbasi et al. (2025) reported results from a retrospective cohort study of 39 patients undergoing minimally invasive lateral SIJ fusion with the Trident™ screw system across 4 surgical sites, all performed by a single surgeon.[59,] All patients had failed conservative management, including ≥3 positive provocation tests and diagnostic injections. The cohort demonstrated a significant mean reduction in ODI at 6 or more months post-surgery of 13.7 points (p<.001), with improvements across nearly all ODI domains (pain intensity, personal care, lifting, walking, sitting, sleeping, social life, traveling, and employment; all p<.05), except for standing (p=.071). No intraoperative injuries were reported, and no major complications occurred. The study was limited by a potential lack of generalizability due to its single-surgeon design, the absence of a comparison group, and the short follow-up duration.

Table 18. Pain and Disability Scores After Implantation With a Cylindrical Threaded Implant

Outcome Measures	Baseline	3 Months (SD)	6 Months (SD)	12 Months (SD)	24 Months (SD)	p
Low back pain	55.8 (26.7)	28.5 (21.6)	31.6 (26.9)	32.7 (27.4)	20.0 (18.4)	<.01
Left leg pain	40.6 (29.5)	19.5 (22.9)	16.4 (25.6)	12.5 (23.3)	5.8 (8.1)	<.01
Right leg pain	40.0 (34.1)	18.1 (26.3)	20.6 (25.4)	14.4 (21.1)	11.5 (20.1)	<.05
Oswestry Disability Index	55.6 (16.1)	33.3 (16.8)	33.0 (16.8)	34.6 (19.4)	27.5 (18.8)	<.01

Adapted from Rappoport et al.[51,52,]
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 7 prospective cohort studies; 3 were conducted with transiliac screws, 1 with a lateral approach, and

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

SUMMARY OF EVIDENCE

Diagnostic

For individuals who have suspected SIJ pain who receive a diagnostic sacroiliac block, the evidence includes systematic reviews. Relevant outcomes are test validity, symptoms, functional outcomes, quality of life (QOL), medication use, and treatment-related morbidity. Current evidence is conflicting on the diagnostic utility of SIJ blocks. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Therapeutic

For individuals who have SIJ pain who receive therapeutic corticosteroid injections, the evidence includes systematic reviews, randomized controlled trials (RCTs), and case series. Relevant outcomes are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. In general, the literature on injection therapy of joints in the back is of poor quality. Results from 1 RCT showed superiority over a sham control group, but 2 RCTs showed that therapeutic SIJ steroid injections were not as effective as other active treatments. Larger trials with rigorous designs and sufficient follow-up, preferably using sham injections, are needed to determine that the technology improves the net health outcome. 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 RFA, the evidence includes 6 RCTs using different radiofrequency applications and case series. Relevant outcomes are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. Meta-analysis of available sham-controlled RCTs suggests that there may be a small effect of RFA on SIJ pain at short-term (1 to 6 months) follow-up. However, the RCTs of RFA have methodologic limitations, and there is limited data on the duration of the treatment effect. The single RCT with 6 and 12-month follow-up showed no significant benefit of RFA compared to an exercise control group at these time points. In addition, heterogeneity of RFA treatment techniques precludes generalizing results across different studies. For RFA with a cooled probe, 3 RCTs reported short-term benefits, but these are insufficient to determine the overall effect on health outcomes. An RCT on palisade RFA of the SIJ did not include a sham control. Another sham-controlled RCT showed no benefit from RFA. Further high-quality controlled trials are needed to compare this procedure in defined populations with sham control and alternative treatments. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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

For individuals who have SIJ pain who receive SIJ fusion/fixation with an implant other than a transiliac triangular implant, the evidence includes 7 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, 1 with a lateral approach, and the 3 with a device inserted through a posterior approach. One cohort study compared SIJ fusion with the Torpedo device to iFuse (transiliac triangular implant) and found no differences in pain or function outcomes at 12 months between the two groups. No other controlled studies were identified. Meta-analyses of the available prospective and retrospective studies indicate improvement in subjective outcomes from before surgery to follow-up, but with a possible difference in outcomes between the more well studied triangular transiliac implant and other implant designs and approaches. There is uncertainty in the health benefit of SIJ fusion/fixation with these implant designs. Therefore, controlled studies with a larger number of patients and longer follow-up are needed to evaluate these devices. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

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2017 Input
Clinical input was sought to help determine whether the use of sacroiliac joint (SIJ) fusion for individuals with SIJ pain would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, clinical input was received from 10 respondents, including 5 specialty society-level responses from 7 specialty societies (2 were joint society responses) and 5 physician-level responses from 4 academic centers while this policy was under review in 2017.

For carefully selected patients as outlined in statements from the North American Spine Society who have SIJ pain who receive percutaneous and minimally invasive techniques of SIJ fusion, the clinical input supports this use provides a clinically meaningful improvement in the net health outcome and is consistent with generally accepted medical practice.

Further details from clinical input are included in the Appendix.

2014 Input
In response to requests, input was received from 4 physician specialty societies and 4 academic medical centers (5 responses) while this policy was under review in 2014. Input was mixed on the use of arthrography, radiofrequency ablation, and fusion of the SIJ. Most reviewers considered injection for diagnostic purposes to be medically necessary when using controlled blocks with at least 75% pain relief, and for injection of corticosteroids for treatment purposes. Treatment with prolotherapy, periarticular corticosteroid, and periarticular botulinum toxin were considered investigational by most reviewers.

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

North American Spine Society
NASS posted a protocol for a forthcoming systematic review and guideline on SIJ pain, "Diagnosis and Treatment of Adults with Sacroiliac Joint Pain: A Protocol for a Systematic Review and Clinical Guideline by the North American Spine Society" in February, 2023.[60,] The review aims to provide evidence-based recommendations to address critical clinical questions surrounding diagnosing and treating adult patients with sacroiliac joint pain. No estimated date of publication was provided.

American Society of Interventional Pain Physicians
In 2013, the American Society of Interventional Pain Physicians guideline recommended the use of controlled SIJ blocks with placebo or controlled comparative local anesthetic block when indications are satisfied with suspicion of SIJ pain.[4,] A positive response to a joint block is considered to be at least a 75% improvement in pain or in the ability to perform previously painful movements. For therapeutic interventions, the only effective modality with fair evidence was cooled radiofrequency neurotomy, when used after the appropriate diagnosis was confirmed by diagnostic SIJ injections.

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American Society of Anesthesiologists & American Society of Regional Anesthesia and Pain Medicine

The American Society of Anesthesiologists and the American Society of Regional Anesthesia and Pain Medicine have a 2010 guideline for chronic pain management.[61,] The guideline recommends that "Diagnostic sacroiliac joint injections or lateral branch blocks may be considered for the evaluation of patients with suspected sacroiliac joint pain." Based on the opinions of consultants and society members, the guideline recommends that "Water-cooled radiofrequency ablation may be used for chronic sacroiliac joint pain."

International Society for the Advancement of Spine Surgery

In 2020, the International Society for the Advancement of Spine Surgery provided guidance on indications for minimally invasive SIJ fusion with placement of lateral transfixing devices.[50,]
The Society recommended that "patients who have all of the following criteria may be eligible for lateral MIS [minimally invasive surgical] SIJF with placement of lateral transfixing devices:

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

It was recommended that intra-articular SIJ steroid injection and radiofrequency ablation (RFA) of the SIJ lateral branch nerves 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 2021, the American Society of Pain and Neuroscience (ASPN) published practice a guideline on radiofrequency neurotomy.[62,] All of the workgroup members utilized radiofrequency neurotomy in clinical practice. A consensus statement, based on Grade II-1 evidence (well-designed, controlled, nonrandomized clinical trial), was that "lateral branch radiofrequency neurotomy may be used for the treatment of posterior sacral ligament and joint pain following positive response to appropriately placed diagnostic blocks."

In 2024, ASPN published guidance on the treatment of sacroiliac disorders.[63,]

The following recommendations were provided concerning SIJ injections, minimally invasive sacroiliac joint fixation and sacroiliac radiofrequency ablation:

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- Best Practice Statement on Diagnostic Intra-Articular Injection of the SIJ: The patient should experience greater than 50% relief when an appropriately performed local anesthetic only injection is completed that is consistent with duration of the local anesthetic utilized. A second confirmatory local anesthetic injection can be considered, but not mandatory, when using diagnostic injections to determine candidacy for surgical treatment.
- Best Practice Statement on Conservative Care: Appropriate conservative care should be considered and when acceptable attempted prior to interventional or surgical treatment of sacroiliac dysfunction.
- Best Practice Statement on Intra-Articular Corticosteroid Injections for SIJ Pain: Image-guided, intra-articular corticosteroid injections are recommended for persistent SIJ pain that has persisted despite conservative measures for 4 weeks. Fluoroscopic and CT guided injections are the preferred imaging modality of choice, although ultrasound guidance can be considered in situations where radiation exposure may be problematic.
- Best Practice Statement on Neuroablative Technique and Approach for SI Pain: RFA of the SIJ should be performed by an established and researched method and repeated no more than at six-month intervals when an improvement of 50% pain relief and functional improvement is seen.
- Best Practice Statement on Surgical Treatment for SIJ Pain: Minimally invasive surgical treatment can be considered when patients have failed 6 months of conservative treatment and the diagnosis has been confirmed via history, physical exam, and greater than 50% pain relief after a diagnostic, image guided, SIJ injection. Currently, there is no comparative evidence to claim superiority of one minimally invasive technique over another. The recommendation is to choose the safest approach with the greatest chance of clinical success. Approach and implants used should have peer reviewed prospective clinical evidence which demonstrate clinical efficacy and safety.
- Best Practice Statements on Minimally Invasive Sacroiliac Fusion: Minimally invasive posterior SI stabilization with allograft is considered medically necessary when the appropriate clinical criteria have been met. (Grade, A; Level, I-B; Level of certainty, High)
    - Including:
        - A failure of conservative measures to at least include physical therapy and injections.
        - Pain persisting a minimum of 6 months that interferes with functional activities as documented by both a pain score of VAS/NRS of 5 or greater and an ODI of 30 or more.
        - Failure of at least one therapeutic sacroiliac joint injection (less than 50% pain relief for three months duration).
        - Predominant pain pattern consistent with sacroiliac joint pathology.
        - Positive response from at least three validated maneuvers for sacroiliac joint dysfunction.
        - Positive Fortin finger test.
        - Diagnostic imaging: either CT or MRI that excludes destructive lesions of the sacroiliac joint.
        - Diagnostic confirmation of the SI joint as the pain generator demonstrated by at least one image-guided (CT or fluoroscopy) intraarticular injection of the SI joint with 50% or greater pain relief for the expected duration of the local anesthetic.

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    - Excluding:
        - Infection or fracture (unrelated to implant)
        - Tumor
        - Acute traumatic instability
- Minimally invasive SI fusion with lateral transfixing devices is considered medically necessary when the appropriate clinical criteria have been met (as above) (Grade, A; Level, I-A; Level of certainty, High)
- Minimally invasive SI fusion implants should be used according to FDA labeling (Grade, A; Level, I-A; Level of certainty, High)
- The use of implants composed of human cell and tissue products for sacroiliac fusion is considered medically necessary only if the guidelines set forth by the FDA Regulation of Human Cells and Tissue is followed and should be registered in the FDA Human Cell and Tissue Establishment Registration. (Grade, A; Level, NA; Level of certainty, High)
- ASPN supports the utilization of sacroiliac fusion and stabilization devices with published, peer-reviewed, multi-center, prospective evidence of at least 6 months duration to assess efficacy and safety. (Grade, A; Level, I-A; Level of certainty, High)
- The current evidence is insufficient to determine the medical necessity of emerging techniques for minimally invasive sacroiliac fusion such as posterior-transfixing, and hybrid approaches. (Grade, I; Level, II; Level of certainty, Low)

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

1.1 "Current evidence on the safety and efficacy of minimally invasive sacroiliac (SI) joint fusion surgery for chronic SI pain is adequate to support the use of this procedure....

1.2 Patients having this procedure should have a confirmed diagnosis of unilateral or bilateral SI joint dysfunction due to degenerative sacroiliitis or SI joint disruption.

1.3 This technically challenging procedure should only be done by surgeons who regularly use image-guided surgery for implant placement. The surgeons should also have had specific training and expertise in minimally invasive SI joint fusion surgery for chronic SI pain."[64,]

In 2022, NICE published medical technology guidance on using the iFuse implant system for treating chronic sacroiliac joint pain. It provided the following recommendations:[65,]

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.

U.S. Preventive Services Task Force Recommendations
Not applicable.

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Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in Table 19.

Table 19. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05409443	Conventional or Bipolar Radiofrequency Ablation for the Treatment of Sacroiliac Joint Pain? The COBRA-SIJ Study, a Double-blinded, Randomized, Comparative Trial.	116	Jun 2026
NCT04423120[a]	A Single Arm, Multicenter, Prospective, Clinical Study on a Novel Minimally Invasive Posterior Sacroiliac Fusion Device	100	Mar 2026 (completed)
NCT04062630[a]	Sacroiliac Joint Stabilization in Long Fusion to the Pelvis: Randomized Controlled Trial (SILVIA)	213	Dec 2024 (completed)
NCT05870488[a]	iFuse TORQ for the Treatment of Sacroiliac Joint Dysfunction	110	Nov 2027
NCT03507049	Sacroiliac Joint Fusion Versus Sham Operation for Treatment Sacroiliac Joint Pain. A Prospective Double Blinded Randomize Controlled Multicenter Trial.	63	May 2030
NCT06487936[a]	Real-World Registry Study on Patient Satisfaction With TransLoc 3D SI Joint Fusion	120	Dec 2024 (recruiting)
NCT05633888[a]	Prospective, Multi-Center, Single Arm Post-Market Feasibility Study of the Tenon Medical CATAMARAN™ SI Joint Fusion System	50	Jan 2026
NCT05276024[a]	Evaluation of the iFuse Bedrock Technique in Association With Posterior Lumbosacral Fusion With Iliac Fixation.	50	Apr 2026
Unpublished			
NCT01861899[a]	Treatment of Sacroiliac Dysfunction With SI-LOK® Sacroiliac Joint Fixation System	46	Apr 2019 (completed)
NCT02074761[a]	Evolusion Study Using the Zyga SImmetry Sacroiliac Joint Fusion System	250	Nov 2020 (unknown status)
NCT04218838[a]	A Prospective, Multi-Center, Bi-Phasic Randomized Design to Compare Outcomes of the CornerLoc™ SI Joint Stabilization System and Intra-Articular Sacroiliac Joint Steroid Injection in Patients With Refractory Sacroiliac Joint Dysfunction	120	Jul 2023 (Terminated, enrollment difficulties)

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

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CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. This may not be a comprehensive list of procedure codes applicable to this policy.

Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

The code(s) listed below are medically necessary ONLY if the procedure is performed according to the "Policy" section of this document.

CPT/HCPCS	
27096	Injection procedure for sacroiliac joint, anesthetic/steroid, with image guidance (fluoroscopy or CT) including arthrography when performed
27278	Arthrodesis, sacroiliac joint, percutaneous, or minimally invasive with image guidance, includes obtaining bone graft when performed, unilateral placement of intra-articular device(s), without cortical piercing
27279	Placement of transarticular device(s) and/or intra-articular device(s) piercing the lateral or medial cortices of the ilium and the lateral cortex of the sacrum
27280	Arthrodesis, open, sacroiliac joint, including obtaining bone graft, including instrumentation, when performed
64451	Injection anesthetic agent, nerves innervating the sacroiliac joint with image guidance
64625	Radiofrequency ablation, nerves innervating the sacroiliac joint, with image guidance (i.e., fluoroscopy or computed tomography)
64640	Destruction by neurolytic agent; other peripheral nerve or branch
C1737	Joint fusion and fixation device(s), sacroiliac and pelvis, including all system components (implantable)
G0259	Injection procedure for sacroiliac joint; arthrography
G0260	Injection procedure for sacroiliac joint; provision of anesthetic, steroid and/or other therapeutic agent, with or without arthrography

REVISIONS	
07-27-2011	Policy added to the bcbsks.com web site.
01-01-2012	In the Coding section: ▪ Revised CPT nomenclature for the following code: 27096 ▪ Added the following CPT guidelines: "27096 is to be used only with CT or fluoroscopic imaging confirmation of intra-articular needle positioning. If CT or fluoroscopic imaging is not performed, use 20552."
01-09-2012	Removed CPT code: 73542 (deleted code, effective 1/1/2012)
06-05-2012	Effective for Institutional providers 30 days after the Revision Date.
	Title revised from: "Sacroiliac Joint Arthrography and Injection" to: "Diagnosis and Treatment of Sacroiliac Joint Pain"
	Description section updated
	In Policy section:

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REVISIONS	
	▪ Added experimental / investigational language of: "D. Radiofrequency ablation of the sacroiliac joint is considered experimental / investigational."
	Rationale section updated
	In Coding section: ▪ Added CPT codes: 27299 ▪ Removed CPT code: 77003 ▪ Added Diagnosis codes: 720.2, 724.8, 724.9
	References updated
09-11-2014	Description section updated
	In Policy section: ▪ Added to Item A the criteria of "6. The injections are performed under radiographic guidance" ▪ Added experimental / investigational indication of, "Fusion / stabilization of the sacroiliac joint for the treatment of back pain presumed to originate from the SI joint is considered experimental / investigational, including but not limited to percutaneous and minimally invasive techniques."
	Rationale section updated
	In Coding section: ▪ Added CPT codes: 27280, 0334T ▪ Updated coding instructions ▪ Added ICD-10 Codes (Effective October 1, 2015)
	References updated
01-01-2015	In Coding section: ▪ Added CPT Code: 27279 (Effective January 1, 2015) ▪ Deleted CPT Code: 0334T (Effective January 1, 2015) ▪ Revised CPT Code: 27280 (Effective January 1, 2015)
09-18-2015	Updated Description section.
	In Policy section: ▪ In Item A 6, added "with documentation of contrast material throughout the sacroiliac joint" to read "The injections are performed under radiographic guidance with documentation of contrast material throughout the sacroiliac joint." Added "Note: Ultrasound guidance is not considered adequate or accurate for sacroiliac joint injections." ▪ In Item A Repeat Injections, 1, revised to read "If patient has achieved substantial relief with previous injection, repeat injections will be no more frequent than every 2 months." ▪ Added Policy Guidelines.
	Updated Rationale section.
	Updated References section.
11-18-2015	In Coding section: ▪ Removed notes from ICD-9 codes 724.02 and 724.03.
01-01-2017	Updated Description section.
	In Policy section: ▪ Removed previous Item A 2, "Duration of pain of at least 3 months; AND" ▪ Removed previous A 5, "Lack of obvious evidence for disc related or facet joint pain; AND" ▪ In new Item A 2, added (see Policy Guidelines)" to read, "Average pain level of ≥ 6 on a scale of 1 to 10 (see Policy Guidelines); AND" ▪ In new Item A 3, removed "3 months of more" and "including physical therapy and non-steroidal anti-inflammatory agents" and added "nonsurgical" and "therapies such as nonsteroidal anti-inflammatory medications, acetaminophen, manipulation, physical

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REVISIONS	
	therapy, and a home exercise program" to read, "Failure to respond to nonsurgical conservative management which should include therapies such as nonsteroidal anti-inflammatory medications, acetaminophen, manipulation, physical therapy, and a home exercise program; AND" ▪ Under Repeat Injections, Item 1, added "with no more than 3 injections given in one year" to read, "If patient has achieved substantial relief with previous injection, repeat injections are to be no more frequent than every 2 months with no more than 3 injections given in one year" ▪ In Policy Guidelines Item 2 a, removed "for several weeks" to read, "Use of prescription strength analgesics at a dose sufficient to induce a therapeutic response" ▪ In Policy Guidelines Item 3 b, removed "at least 6 weeks of" to read, "Participation in physical therapy (including active exercise) or documentation of why the patient could not tolerate physical therapy, AND" ▪ In Policy Guidelines, added Item 3, "Pain may be defined as moderate (interferes significantly with ADLs) or severe (disabling; unable to perform ADLs)." Along with table outlining the Numeric Rating Scale.
	Updated Rationale section.
	In Coding section: ▪ Added HCPCS codes G0259 and G0260.
	Updated References section.
04-12-2017	In Policy section: ▪ In Item A 3, removed "and" and added "and/or" to read, "Failure to respond to nonsurgical conservative management, which should include therapies such as nonsteroidal anti-inflammatory medications, acetaminophen, manipulation, physical therapy, and/or a home exercise program; AND" ▪ In Policy Guidelines Item 2, removed "for the duration specified" to read, "Conservative nonsurgical therapy should include the following:" ▪ In Policy Guidelines Item 2 a I, removed "AND" and added "OR" to read, "Analgesics should include anti-inflammatory medications with or without adjunctive medications such as nerve membrane stabilizers or muscle relaxants, OR" ▪ In Policy Guidelines Item 2 b, removed "AND" and added "or a home exercise program" and "OR" to read, "Participation in physical therapy (including active exercise) or a home exercise program or documentation of why the patient could not tolerate physical therapy or a home exercise program, OR" ▪ In Policy Guidelines Item 2 c, removed "AND" and added with "OR" to read, "Evaluation and appropriate management of associated cognitive, behavioral, or addiction issues, OR"
	Updated References section.
05-01-2018	Updated Description section.
	In Policy section: ▪ In Item A 3, removed "(see Policy Guidelines), which should include therapies such as nonsteroidal anti-inflammatory medications, acetaminophen, manipulation, physical therapy, and/or a home exercise program" and added "see NOTE below" to read, " Failure to respond to nonsurgical conservative management (see NOTE below)" ▪ In Item A 4, removed "Note:" and added parenthesis to read "… (Ultrasound guidance is not considered adequate or accurate for sacroiliac joint injections.)" ▪ In Item A, under NOTE: removed "therapy" and added "management" to read, "Conservative nonsurgical management should include the following:"

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	▪ In Item A, under NOTE: 1 i, removed "OR" and added "AND" to read, " Analgesics should include anti-inflammatory medications with or without adjunctive medications such as nerve membrane stabilizers or muscle relaxants, AND" ▪ In Item A, NOTE: 2, removed "OR" and added "manipulation" to read, " Participation in physical therapy (including active exercise) or manipulation or a home exercise program or documentation of why the patient could not tolerate physical therapy, manipulation, or a home exercise program, AND" ▪ In Item A, removed NOTE: "3. Manipulation, AND" ▪ In Item A, NOTE: 3 (previous Item A NOTE: 4), removed "OR" and added "AND" to read, Evaluation and appropriate management of associated cognitive, behavioral, or addiction issues, AND" ▪ Added new Item E, "Minimally invasive fusion/stabilization of the sacroiliac joint using a titanium triangular implant may be considered medically necessary when ALL of the following criteria have been met: 1. Average pain level of ≥6 on a scale of 1 to 10 (see Policy Guidelines) that impacts quality of life or limits activities of daily living; AND 2. There is an absence of generalized pain behavior (e.g., somatoform disorder) or generalized pain disorders (e.g., fibromyalgia); AND 3. Patients have undergone and failed a minimum 6 months of intensive nonoperative treatment that must include medication optimization, activity modification, bracing, and active therapeutic exercise targeted at the lumbar spine, pelvis, sacroiliac joint, and hip, including a home exercise program; AND 4. Pain is caudal to the lumbar spine (L5 vertebra), localized over the posterior sacroiliac joint, and consistent with sacroiliac joint pain; AND 5. A thorough physical examination demonstrates localized tenderness with palpation over the sacral sulcus (Fortin's point) in the absence of tenderness of similar severity elsewhere; AND 6. There is a positive response to at least 3 provocative tests (see Policy Guidelines); AND 7. Diagnostic imaging studies include ALL of the following: a) Imaging (plain radiographs and computed tomography or magnetic resonance imaging) of the sacroiliac joint excludes the presence of destructive lesions (e.g., tumor, infection) or inflammatory arthropathy of the sacroiliac joint; 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 d) Imaging of the sacroiliac joint indicates evidence of injury and/or degeneration; AND 8. There is at least a 75% reduction in pain for the expected duration of the anesthetic used following an image-guided, contrast-enhanced intra-articular sacroiliac joint injection on 2 separate occasions; AND 9. A trial of a therapeutic sacroiliac joint injection (i.e., corticosteroid injection) has been performed at least once. ▪ In new Item F (previous Item E), removed "including, but not limited to, percutaneous and minimally invasive techniques" and added "under all other conditions and with any other devices not listed above" to read, "Fusion / stabilization of the sacroiliac joint for the treatment of back pain presumed to originate from the SI joint is considered experimental / investigational under all other conditions and with any other devices not listed above." ▪ Updated Policy Guidelines.
	Updated Rationale section.
	In Coding section: ▪ Added CPT code: 64640. ▪ Removed ICD-9 codes. ▪ Added ICD-10 codes: M47.898, M47.899, M53.2X8, M54.18, M54.6, S33.2, S33.6.
	Updated References section.

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REVISIONS	
08-31-2018	Policy published to the bcbsks.com web site on 08-01-2018 with an effective date of 08-31-2018.
	In Policy section: ▪ In Item A 4, added "(see Policy Guidelines)" to read, "The injections are performed under radiographic guidance with documentation of contrast material throughout the sacroiliac joint (see Policy Guidelines). Ultrasound guidance is not considered adequate or accurate for sacroiliac joint injections." ▪ In Policy Guidelines, added new Item 2, "Radiographic images used to perform SI joint injection should be digitally archived for retrieval at a later date."
	Updated References section.
01-16-2019	Updated Description section.
	In Policy section: ▪ Updated Policy Guidelines.
	Updated Rationale section.
	In Coding section: ▪ Removed coding bullets.
	Updated References section.
09-13-2019	Policy published to the bcbsks.com website on August 14, 2019 with an effective date of September 13, 2019.
	In Policy section: ▪ Throughout policy language, references to Policy Guidelines were updated with the pertinent number for clarification. ▪ In Item A, the NOTE referring to conservative nonsurgical management was moved to Policy Guidelines 2. ▪ In Policy Guidelines, the items were renumbered to correspond with policy language. ▪ In Policy Guidelines 3, added "Records should be retained for not less than ten years after date of last film." ▪ In Policy Guidelines 4, added "Minimally invasive fusion / stabilization of the sacroiliac joint is a" and "physicians" and removed "surgeons" to read, "Minimally invasive fusion / stabilization of the sacroiliac joint is a technically demanding procedure and should only be performed by physicians who have specific training and expertise in minimally invasive sacroiliac joint fusion surgery for chronic sacroiliac joint pain and who regularly use image guidance for implant placement."
	Updated References section.
08-04-2020	Updated Description Section
	Updated Rationale Section
	Coding Section ▪ Removed CPT 27299
	Updated Reference Section
01-15-2021	In the policy section item D ▪ Added underlined portion: Radiofrequency ablation of the sacroiliac joint is <u>or the nerves innervating the SI joint</u> considered experimental / investigational.
	No other revisions
01-13-2022	Updated Description Section
	Updated Rationale Section
	Updated Codes Section ▪ Added ICD-10 code M54.6
	Updated References
	Added Appendix Section
12-29-2022	Updated Description Section

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REVISIONS	
	Updated Policy Guidelines ▪ Section F3 Added: "Patrick" to FABER
	Updated Rationale Section
	Updated Coding Section ▪ Added 0775T (eff. 01-01-2023) ▪ Updated nomenclature for 27280 (eff. 01-01-2023)
	Updated References
	Removed Appendix
07-03-2023	Updated Coding Section ▪ Added 0809T (eff. 07-01-2023) ▪ Removed ICD-10 Codes
01-05-2024	Updated Description Section
	Updated Policy Section ▪ Section E removed: "fusion / stabilization" changed to "fixation / fusion" Added "transiliac placement of" and "(eg, iFuse)" ▪ Section F removed: "fusion / stabilization" changed to "fixation / fusion"
	Update Rationale Section
	Updated Coding Section ▪ Removed Deleted Codes 0775T and 0809T (eff. 01-01-2024) ▪ Added 27278 (eff. 01-01-2024)
	Updated References Section
Posted 01-28-2025 Effective 02-27-2025	Updated Description Section
	Updated Policy Section ▪ Separated Section A into Section A and B A. Injection of anesthetic for diagnosing SIJ pain may be considered medically necessary when ALL the following criteria have been met: 1. Pain originates from the sacroiliac joint by evidence of 3 positive provocative test (see policy guidelines); AND 2. Pain has failed to respond to 3 months of conservative management, which may consist of therapies such as nonsteroidal anti-inflammatory medications, acetaminophen, manipulation, physical therapy, and a home exercise program; AND 3. Dual (controlled) diagnostic blocks with 2 anesthetic agents with differing duration of action are used (see policy guidelines); And 4. The injections are performed under imaging guidance with documentation of contrast material throughout the sacroiliac joint. Ultrasound guidance is not considered adequate or accurate for sacroiliac joint injections. B. Injection of corticosteroid may be considered medically necessary for the treatment of SIJ pain when ALL the following criteria have been met: 1. *Initial Injection* a. Pain originates from the sacroiliac joint by evidence of 3 positive provocative test (see policy guidelines); AND b. Pain has failed to respond to 3 months of conservative management, which may consist of therapies such as nonsteroidal anti-inflammatory medications, acetaminophen, manipulation, physical therapy, and a home exercise program; AND c. The injection is performed under imaging guidance with documentation of contrast material throughout the sacroiliac joint. Ultrasound guidance is not considered adequate or accurate for sacroiliac joint injections 2. *Repeat Injection* a. If individual has achieved substantial relief with previous injection, repeat injections are to be no more frequent than every 2 months with no more than 3 injections given in 1 year. b. Repeat injections extending beyond 12 months may be reviewed for continued medical necessity.

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REVISIONS	
	▪ Section F1: Changed Average pain level from ≥6 to " is at least 5 on a 0 to 10 rating" ▪ Section F3: Removed "bracing" as a nonoperative treatment ▪ Section F7d: Removed "Imaging of the sacroiliac joint indicates evidence of injury and/or degeneration; AND"
	Updated Policy Guideline Section ▪ Guideline E2: Added "at least 6 weeks of" to physical therapy ▪ Added Guideline F: F. "A successful trial of controlled diagnostic lateral branch blocks consists of 2 separate positive blocks on different days with local anesthetic only (no steroids or other drugs), or a placebo-controlled series of blocks, under fluoroscopic guidance, that has resulted in a reduction in pain for the duration of the local anesthetic used (eg, 3 hours longer with bupivacaine than lidocaine). There is no consensus on whether a minimum of 50% or 75% reduction in pain would be required to be considered a successful diagnostic block, although evidence supported a criterion standard of 75% to 100% reduction in pain with dual blocks. No therapeutic intra-articular injections (ie, steroids, saline, other substances) should be administered for a period of at least 4 weeks before the diagnostic block. The diagnostic blocks should not be conducted under intravenous sedation unless specifically indicated (eg, the individual is unable to cooperate with the procedure)."
	Update Rationale Section
	Updated Coding Section ▪ Added C1737 (eff. 01-01-2025)
	Updated References Section
01-13-2026	Updated Description Section
	Updated Rationale Section
	Updated Coding Section ▪ Updated nomenclature for 27278 and 27279 (eff. 01-01-2026)
	Updated Reference Section

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