Medical Policy

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Title: Diagnosis and Treatment of Sacroiliac Joint Pain

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

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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: • Therapeutic corticosteroid injections	Comparators of interest are: • Physical therapy	Relevant outcomes include: • Symptoms • 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. In 1928, the role of the intervertebral disc was elucidated, and from that point forward, the SIJ received less research attention.

Diagnosis

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

Because of inconsistent information obtained from history and physical examination, some have proposed the use of image-guided anesthetic injection into the SIJ for the diagnosis of SIJ pain. 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.

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	Titanium triangular rod with conventional manufacturing	Y	K110838	2011
iFuse® 3D	SI Bone	Titanium triangular 3D printed porous rod	Y	K162733	2017
FIREBIRD SI Fusion System™	Orthofix	Cannulated screw	Y	K200696	2020
SambaScrew®	Orthofix	Cannulated screw	Y	K121148	2012
Silex Sacroiliac Joint Fusion®	X-Spine Systems	Cannulated screw	Y	K140079	2014
SI-LOK® Sacroiliac Joint Fixation System	Globus Medical	Cannulated screw	Y	K112028	2011
SImmetry® Sacroiliac Joint Fusion System	RTI	Cannulated screw	Y	K102907	2010
SIimpact® Sacroiliac Joint Fixation System	Life Spine	Cannulated screw	Y	K180749	2018
SIros™	Genesys Spine	Cannulated screw	Y	K191748	2019
Triton SI Joint Fixation System™	Choice Spine	3D printed screw with porous graft windows	Y	K211449	2021
Posterolateral Approach					

Device	Manufacturer	Features	Graft Compatible	Clearance	Date
Rialto™ SI Joint Fusion System	Medtronic	Cannulated screw	Y	K161210	2016
SacroFuse®/ SIJFuse™	SpineFrontier	Solid or hollow-cored screw	Y	K150017	2015
Posterior Approach					
Catamaran™	Tenon Medical	Metal plug	Y	K180818	2018
CornerLoc™	Fusion Foundation Solutions	Bone allograft	N	HCT/P	N/A
LinQ™ SI Joint Stabilization	PainTEQ	Bone allograft	N	HCT/P	N/A
NADIA™ SI Fusion System (DIANA)	Ilion Medical	Metal plug	N	K190580	2020
PsiF™ Posterior Sacroiliac Fusion	Omnia Medical	Bone allograft	N	HCT/P	N/A
SIFix System®	NuTech	Bone allograft	N	HCT/P	N/A
TransFasten™	Captiva Spine	Bone allograft	N	HCT/P	N/A

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

POLICY

A. Injection into the sacroiliac joint for diagnostic or therapeutic purposes may be considered **medically necessary** when **ALL** of the following conditions are met:

1. Pain originates from the sacroiliac joint; **AND**
2. Average pain level of ≥ 6 on a scale of 1 to 10 (see Policy Guidelines); **AND**
3. Failure to respond to nonsurgical conservative management (see Policy Guidelines); **AND**
4. 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.

Repeat Injections:

1. 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 one year
2. Repeat injections extending beyond 12 months may be reviewed for continued medical necessity

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

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

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

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 (see Policy Guidelines):

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. Individuals 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.

F. 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.

POLICY GUIDELINES

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

Numeric Rating Scale (NRS-11)	
Rating	**Pain Level**
0	No pain
1-3	Mild pain
4-6	Moderate pain
7-10	Severe pain

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

C. 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
2. Analgesics should include anti-inflammatory medications with or without adjunctive medications such as nerve membrane stabilizers or muscle relaxants, **AND**
3. Participation in 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**
4. Evaluation and appropriate management of associated cognitive, behavioral, or addiction issues, **AND**
5. Documentation of individual compliance with the preceding criteria.

D. 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.

E. 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.

F. 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

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RATIONALE

This evidence review has been updated regularly with searches of the PubMed database. The most recent literature update was performed through October 4, 2022.

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.

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 patients who have suspected SIJ pain is to inform a decision whether to proceed to appropriate treatment.

The question addressed in this evidence review is: Does the use of a diagnostic SIJ block improve the net health outcome in patients who have suspected SIJ pain?

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 post injection.

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

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).

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 one 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 patients with SIJ pain.

The question addressed in this evidence review is: Does the use of therapeutic corticosteroid injections improve the net health outcome in individuals with SIJ pain?

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

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

Interventions
The therapy being considered is 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.

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.[11,] Diagnosis of SIJ pain was based on 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.[12,] 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 (numeric rating scale) and disability (Oswestry Disability Index [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*
Visser et al (2013)[11,]	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)[12]	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	
Visser et al (2013)[11,]	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)[12,]	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]
Visser et al (2013)[11,]	4. Patients were recruited on th basis of SIJ-related leg pain wit short duration of signs and symptoms.	2. Unclear whic if any patients received a second injection		4-5. Definitio of successful treatment di not utilize standard pai relief threshold cutoff of at least 50%.	
Kim et al (2010)[12,]					

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

Table 5. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Visser et al (2013)[11,]	3. Allocation not describe	1. Trial was single-blinded	1. Not registered.		2. Power not calculated for primar outcome.	3. Confidenc intervals and/or p values not reported.
Kim et al (2010)[12,]	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.[10,13,]

Section Summary: Therapeutic Corticosteroid Injections
Results from 2 small trials are insufficient to permit conclusions on the effect of this procedure on health outcomes. Steroid injections were not the most effective treatment in either trial and the degree of pain relief was limited. Larger trials with rigorous designs, preferably using sham injections, are needed to determine whether the treatment is effective.

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 patients with SIJ pain.

The question addressed in this evidence review is: Does the use of RFA improve the net health outcome in individuals with SIJ pain?

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

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

Interventions
The therapy being considered is 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.
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.[14,] 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.[15,]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.[16,] 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.[17,] 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 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
Chou et a (2021)[14,]	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)[15,]	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 22 participants.	384	RCTs	3 to 12

Study	Dates	Trials	Participants	N (Range)	Design	Duration, mo
Chen et a (2019)[17]	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
Chou et al (2021)[14]	3 mo vs sham RFA	6 mo vs conventional RFA		
Total N	79			
Cooled RFA	-2.4	-3.8		
Sham or conventional RFA	-0.8	-3.0		
p	.04	.041		
Chappel et al (2020)[15]	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 (p)	83%	NA		
Chen et al (2019)[17] 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 (p)	82.3% (NR)		44.8% (NR)	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	
					Active	Comparator
Mehta et al (2018)[18]	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 to active group after 3-month endpoint
Juch et al (2017)[16,]	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 treatment 23 received cooled RFA 6 received multi-probe strip lesion RFA	Exercise program (n=112) 69 completed program 18 did not complete program 25 with unknown completion
Van Tilburg et al (2016)[19,]	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)[21,22,]	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
Mehta et al (2018)[18,]	NRS at Baseline (SD	NRS at Mont 3 (SD)	PCS[1] at Baseline (SD	PCS at Mont 3 (SD)	Treatment Success
Strip lesion RFA	8.1 (0.8)	3.4 (2.0)	28.4 (7.1)	34.7 (10.8)	NR

Study	Pain Outcomes		Functional Outcomes		Treatment Success	
Sham	6.5 (2.0)	7.3 (0.8)	28.6 (5.0)	29.6 (5.6)	NR	
p Value	NR	<.001	NR	0.0645	NR	
Juch et al (2017)[16,]	NRS at Mont 3 (95% CI)	NRS at Mont 12 (95% CI)	ODI at Mont 3 (95% CI)	ODI at Mont 12 (95% CI	At Month 3, n/N (%	At Mont 12, n/N (%)
RFA + exercise program	4.77 (4.31 to 5.24)	4.65 (4.16 to 5.13)	27.72 (24.50 to 30.95)	27.29 (23.8 to 30.69)	43/110 (39.10)	49/102 (48.03)
Exercise program	5.45 (4.94 to 5.95)	4.84 (4.30 to 5.38)	29.09 (25.47 to 2.71)	24.49 (20.7 to 28.23)	19/88 (21.59)	24/76 (31.78)
MD/RR (95% CI)	-0.71 (-1.35 to -0.06)	-0.07 (-0.74 0.60)	-4.20 (-8.39 to -0.00)	2.11 (-2.25 6.47)	1.87 (1.1 to 2.71)	1.46 (0.92 to 2.02)
p Value	.03	.83	.05	.34	.02	.10
Van Tilburg et al (2016)[19,]	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)[20,]	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)[21,22,]	NRS at Baseline (SD	NRS at Mont 3 (SD)	ODI at Baseline (SD	ODI at Mont 9 (SD)	At Month 3, n/N (%	At Mont 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.

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.[18,] 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.[16,]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.[19,]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.[20,] Palisade RFA uses a row of radiofrequency cannula perpendicular to the dorsal sacrum. Inclusion criteria were ages 18 to 75 years; diagnosis of ankylosing spondylitis; chronic 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.[21,] Twelve-month follow-up was reported in 2016.[22,]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[22,]. 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]
Mehta et a (2019)[18,]				1. Disability outcomes we not reported.	
Juch et al (2017)[16,]	4. Patients older than 70 years were excluded.		2. Not a sham control.		
Van Tilburg et al (2016)[19,]					
Zheng et a (2014)[20,]	1. Patients were required to have a diagnosis of ankylosing spondylitis in addition to chronic low back pain related to the SIJ.		2. Not a sham control.		
Patel et al (2012)[21,22,]					

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 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]
Mehta et a (2019)[18,]				3. 66.6% of sham group patients crossed over to treatment group at mo	Other: Small study siz due to interim analysis	
Juch et al (2017)[16,]		1-2. Study was not blinded.				
Van Tilburg et al (2016)[19,]				3. 63.3% of sham group patients crossed over to the treatment group		
Zheng et a (2014)[20,]						
Patel et al (2012)[21,22,]				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.

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 patients with SIJ pain.

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

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

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

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

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

Outcomes
The general outcomes of interest are symptoms (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

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.[23,] The 12-month follow-up to this RCT was reported by Polly et al (2015),[24,] and a 2-year follow-up was reported by Polly et al (2016).[25,] However, by 12 months, almost all patients in the control group had crossed over to SIJ fusion, precluding a comparison between groups. Trial inclusion was based on a determination of the SIJ as a pain generator from a combination of a history of SIJ-localized pain, positive provocative testing on at least 3 of 5 established physical tests, and at least a 50% decrease in SIJ pain after image-guided local anesthetic injection into the SIJ. The duration of pain before

enrollment averaged 6.4 years (range, 0.47 to 40.7 years). A large proportion of subjects (37%) had previously undergone lumbar fusion, SIJ steroid injections (86%), and RFA (16%).

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

At 6 months, success rates were 23.9% in the control group versus 81.4% in the surgical group (posterior probability of superiority >0.999). A clinically important (≥15-point) improvement in ODI score was found in 27.3% of controls compared with 75.0% of fusion patients. Measures of QOL (36-Item Short-Form Health Survey, EuroQol-5D) also improved to a greater extent in the surgery group. Of the 44 nonsurgical management patients still participating at 6 months, 35 (79.5%) crossed over to fusion. Compared with baseline, opioid use at 6 months decreased from 67.6% to 58% in the surgery group and increased from 63% to 70.5% in the control group (p=.082). At 12 months, opioid use was similar between groups (55% vs 52%, p=.61).

Polly et al (2016) reported 2-year outcomes from the SIJ fusion arm of this RCT.[25,] 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).[26,] 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.[27,28,] 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.[27,] 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).[29,30,] Twenty-one patients in the conservative management group had little or no improvement in symptoms and crossed over to SIJ fusion after the 6-month visit. These were analyzed with the last observation prior to crossover carried forward. At 12 months, low back pain had improved by 42 points (standard deviation [SD], 27.0) on a 100-point VAS in the SIJ fusion group compared with 14 points (SD=33.4) in the conservative management group (p<.001). At 24 months back pain had improved by 45 points compared to 11 points in the control group, with 79% (37 of 47) of SIJ fusion patients achieving at least a 20 point improvement compared to 24% (11 of 46) of controls. At 24 months there was an improvement of 26 points in ODI compared to 8 points in controls (p<.001). Improvement of at least 20 points was observed in 64% of the SIJ fusion group compared to 24% of the conservative management group.

Table 12. Summary of Key RCT Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	*Comparator*
Whang et al (2015)[23,]; INSITE	U.S.	19	2013-2014	Patients 21 to 70 y with confirmed diagnosis of unilater or bilateral SIJ dysfunction due to degenerative sacroiliitis and/or SI disruption	102 randomized to SIJ fusion	46 randomized to nonsurgical management
Sturesson et al (2017)[27,]; iMIA	EU (Belgium, Germany, Italy, Sweder	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 to conservative management

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

[a] The 3 criteria for diagnosis of SIJ pain were as follows: pain was present or near the posterior superior iliac spine; there

were at least 3 positive findings on 5 provocative tests; at least a 50% pain reduction on fluoroscopically guided injection of local anesthetic into the joint.

Table 13. Summary of Six-Month iFuse Results From INSITE and iMIA

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[23,]										
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[27,]										
Baseline	73.0	77.7								
Follow-up	67.8	34.4								
Change	-5.7	-43.3			-5.8	-25.5			0.11	0.37

Adapted from Whang et al (2015)[23,] and Sturesson et al (2015).[27,]
The success endpoint was defined as a reduction in VAS pain score of ≥20, absence of device-related events, absence of neurologic worsening, and absence of surgical intervention.
Ctl: control; EQ-5D TTO Index: EuroQoL Time Tradeoff Index; iMIA: iFuse Implant System Minimally Invasive Arthrodesis; INSITE: Investigation of Sacroiliac Fusion Treatment; ODI: Oswestry Disability Index; 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 (SD	12 Months (SD)	24 Months (SD)
INSITE[23,]				
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%
iMIA[27,29,30,]				***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

Outcome Measures	Baseline (SD	6 Months (SD	12 Months (SD)	24 Months (SD)
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).[29,]
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; Trial	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Whang et al (2015)[23,]; INSITE					
Sturesson et a (2017)[27,]; iMIA	1. Patients with other contributory sources of LBP might have been enrolled with SIJ-caused LBP patients				

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

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

Table 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)[23,]; INSITE						
Sturesson et al (2017)[27,]; iMIA		1. Intervention was nonblinde				

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).[31,32,] 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.

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	3	4	5	P
Duhon et al (2016)[31,32,] 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)[33,] LOIS							
N	103					93	

Studies and Outcomes	Mean Baseline Value	Mean 2 to 3-Year Value	Difference or % Achieving Outcome	3	4	5	P
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%	

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

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.[33,] 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). Opiod use decreased over time, although the contribution of the opioid use agreement cannot be determined. Fifteen percent of patients were not working due to back pain. Radiolucencies suggesting implant failure were observed in 5% of cases and were associated with incorrect placement. Bridging bone was observed in 45% of sides at 12 months, 71% at 24 months, and 88% at 60 months.

The Study of Bone Growth in the Sacroiliac Joint after Minimally Invasive Surgery with Titanium Implants (SALLY) is a 5-year multicenter study that will assess non-inferiority of outcomes with a 3-dimensional (3D) printed triangular implant as compared to the traditionally manufactured titanium coated implant. Twelve-month follow-up has been published for 46 of the 51 patients enrolled in the prospective cohort.[34,] 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.[34,] 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.[35,36,]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%.[37,] Spain and Holt (2017) reported a retrospective review of surgical revision rates following SIJ fixation with either surgical screws or the iFuse triangular implant.[36,] 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 2 nonblinded RCTs of minimally invasive fusion, prospective cohorts with more than 85% follow-up, and a case series. Both RCTs have reported outcomes past 6 months, after which crossover was allowed. Both studies reported significantly greater reductions in VAS pain scores and ODI scores in SIJ fusion patients than in control groups. The reductions in pain and disability observed in the SIJ fusion group at 6 months were maintained out to 1 year compared with controls who had not crossed over. The RCTs were nonblinded without a placebo or an active control group. In addition, pain has a significant subjective and psychological component, and cognitive-behavioral techniques to address pain were specifically excluded from the types of treatment that control subjects could obtain. As it relates to trial design, an independent assessment of pain outcomes would have been preferable. Prospective cohorts and case series with sample sizes ranging from 45 to 149 patients and low dropout rates (<15%) also showed reductions in pain and disability that persist out to 5 years. The cohort studies and case series are consistent with the durability of treatment benefits.

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

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

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

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

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

Interventions
The therapy being considered is SIJ fixation/fusion with 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
Tran et al (2019) published a systematic review comparing the effectiveness of minimally invasive joint fusion with a triangular implant (i.e., utilizing the iFuse device) compared to screw-type surgeries.[38,]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.[39,]

Prospective Cohort Studies

Rappoport et al (2017) reported an industry-sponsored prospective study of SIJ fusion with a cylindrical threaded implant (SI-LOK).[40,] 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.[41,].

Araghi et al (2017) published interim results from an industry-sponsored prospective cohort study evaluating pain and ODI outcomes for patients treated for SIJ pain with the SImmetry system.[42,] For the 50 patients enrolled at the time of publication, the mean VAS score had decreased from 76.2 at baseline to 35.1 at 6 months after the procedure (p<.001), with 36 (72%) patients achieving minimal clinically important difference (≥20-point reduction). The mean ODI score likewise showed significant improvement from baseline to 6 months, decreasing from 55.5 to 35.3 (p<.001). Over half of the cohort (56% [n=28]) achieved the minimal clinically important difference (15-point reduction) on the ODI. Prior to surgery, 66% (n=33) of the cohort were on opioids, decreasing to 30% (n=15) at the 6-month follow-up (p<.001). QOL was assessed with the EQ-5D time trade-off index: at baseline, the mean EQ-5D was 0.51, decreasing to 0.69 after 6 months (p<.001). Likewise, improvements in the Physical and Mental Components Summary scores of the 36-Item Short-Form Health Survey were significantly improved at 6 months, compared with baseline. The strength of findings was limited by the small sample size and short follow-up; without full enrollment of 250 patients, the trial is underpowered to detect contributing factors to fusion and pain relief. Also, the trial does not have a control group.

Fuchs and Ruhl (2018) published 2-year results of a prospective multi-center cohort of the posterior approach to arthrodesis of the SIJ.[43,] A total of 171 patients from 20 hospitals in Germany were treated from 2011 to 2012 using a DIANA implant (marketed in the U.S. as the NADIA implant). The DIANA implant is a hollow, tapered dowel that comes in diameters of 13, 15, 17, or 19 mm. A distraction tool was used to determine the size of the implant, which is inserted between the ilium and sacrum under distraction. Allogeneic bone grafts were used in 66% of cases. Patients had partial weight bearing on the operated side for 6 to 8 weeks. At the 2 year follow-up, VAS had decreased from 74 to 37, ODI improved from 51% to 33%, and the McGill Pain Questionnaire decreased from 50% to 31% (all p<.001). Use of opioids decreased from 49.3% of patients to 30.3% at follow-up. In computed tomography (CT) scans, only 31% of patients showed SIJ fusion at 2 years.

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

Outcome Measures	Baseline	3 Months (SD	6 Months (SD)	12 Months (SD)	24 Months (SD)	p
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.[40,41,]
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 3 prospective cohort studies; 2 were conducted with transiliac screws, and the third with a posterior approach. No controlled studies were identified. Meta-analyses of the available prospective and retrospective studies indicate improvement in subjective outcomes from before surgery to follow-up in these unblinded studies. The meta-analyses comparing outcomes from these cohorts with non-concurrent studies suggest a possible difference in outcomes between the more well-studied triangular transiliac implant and other implant designs and approaches. There is uncertainty in the health benefit of SIJ 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, 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, small 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 2 small RCTs showed that therapeutic SIJ steroid injections were not as effective as other active treatments. Larger trials, preferably using sham injections, are needed to determine the degree of benefit of corticosteroid injections over placebo. 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 5 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 3 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, 2 small 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.

For individuals who have SIJ pain who receive SIJ fixation/fusion with a transiliac triangular implant, the evidence includes 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. 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. Prospective cohorts and case series with sample sizes ranging from 45 to 149 patients and low dropout rates (<15%) also showed reductions in pain and disability out to 5 years. The cohort studies and case series are consistent with the durability of treatment benefit. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have SIJ pain who receive SIJ fusion/fixation with an implant other than a transiliac triangular implant, the evidence includes 3 prospective cohort studies and retrospective case series. Relevant outcomes are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. Two prospective cohorts were conducted with transiliac screws and the third with a device inserted through a posterior approach. No controlled studies were identified. Meta-analyses of the available prospective and retrospective studies indicate improvement in subjective outcomes from before surgery to follow-up, but with a possible difference in outcomes between the more well studied triangular transiliac implant and other implant designs and approaches. There is uncertainty in the health benefit of SIJ fusion/fixation with these implant designs. Therefore, controlled studies with a larger number of patients and longer follow-up are needed to evaluate these devices. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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.

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.

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.

2010 Input
In response to requests, input was received from 4 physician specialty societies (6 responses) and 3 academic medical centers (5 responses) while this policy was under review in 2010. Input was mixed. There was general agreement that the evidence for SIJ injections is limited, although most reviewers considered sacroiliac injections to be the best available approach for diagnosis and treatment in defined situations.

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

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

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.

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.[44,] 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.[39,]
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 published practice a guideline on radiofrequency neurotomy.[45,] 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."

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."[46,]

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

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			
NCT04423120[a]	A Single Arm, Multicenter, Prospective, Clinical Study on a Novel Minimally Invasive Posterior Sacroiliac Fusion Device	100	Mar 2026
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
NCT03601949[a]	A Prospective, Multi-Center, Randomized, Assessor Blind, Controlled Study Comparing Lateral Branch Cooled Radiofrequency Denervation to Conservative Therapy as Treatment for Sacroiliac Joint Pain in a Military and Civilian Population	210	Jul 2022
NCT04062630[a]	Sacroiliac Joint Stabilization in Long Fusion to the Pelvis: Randomized Controlled Trial (SILVIA)	213	Dec 2024
NCT03507049	Sacroiliac Joint Fusion Versus Sham Operation for Treatment Sacroiliac Joint Pain. A Prospective Double Blinded Randomize Controlled Multicenter Trial.	63	May 2030
Unpublished			
NCT01861899[a]	Treatment of Sacroiliac Dysfunction With SI-LOK® Sacroiliac Joint Fixation System	46	Apr 2019
NCT02074761[a]	Evolusion Study Using the Zyga SImmetry Sacroiliac Joint Fusion System	250	Nov 2020

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

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
27279	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device
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
0775T	Arthrodesis, sacroiliac joint, percutaneous, with image guidance, includes placemen of intra-articular implant(s) (eg, bone allograft[s], synthetic device[s]) (eff 01/01/2023)
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

ICD-10 DIAGNOSES	
M46.1	Sacroiliitis, not elsewhere classified
M47.898	Other spondylosis, sacral and sacrococcygeal region
M47.899	Other spondylosis, site unspecified
M48.08	Spinal stenosis, sacral and sacrococcygeal region
M53.2X8	Spinal instabilities, sacral and sacrococcygeal region
M54.18	Radiculopathy, sacral and sacrococcygeal region
M54.31	Sciatica, right side
M54.32	Sciatica, left side
M54.41	Lumbago with sciatica, right side
M54.42	Lumbago with sciatica, left side
M54.5	Low back pain

ICD-10 DIAGNOSES	
M54.6	Pain in thoracic spine
S33.2	Dislocation of sacroiliac and sacrococcygeal joint
S33.6	Sprain of sacroiliac joint

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: ▪ 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:

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	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 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"

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	▪ 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:" ▪ 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

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	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.
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

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	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
	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

REFERENCES

1. Himstead AS, Brown NJ, Shahrestani S, et al. Trends in Diagnosis and Treatment of Sacroiliac Joint Pathology Over the Past 10 Years: Review of Scientific Evidence for New Devices for Sacroiliac Joint Fusion. Cureus. Jun 2021; 13(6): e15415. PMID 34249562
2. Dreyfuss P, Michaelsen M, Pauza K, et al. The value of medical history and physical examination in diagnosing sacroiliac joint pain. Spine (Phila Pa 1976). Nov 15 1996; 21(22): 2594-602. PMID 8961447
3. Simopoulos TT, Manchikanti L, Gupta S, et al. Systematic Review of the Diagnostic Accuracy and Therapeutic Effectiveness of Sacroiliac Joint Interventions. Pain Physician. Sep-Oct 2015; 18(5): E713-56. PMID 26431129
4. Manchikanti L, Abdi S, Atluri S, et al. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: guidance and recommendations. Pain Physician. Apr 2013; 16(2 Suppl): S49-283. PMID 23615883
5. Manchikanti L, Datta S, Derby R, et al. A critical review of the American Pain Society clinical practice guidelines for interventional techniques: part 1. Diagnostic interventions. Pain Physician. May-Jun 2010; 13(3): E141-74. PMID 20495596
6. Manchikanti L, Datta S, Gupta S, et al. A critical review of the American Pain Society clinical practice guidelines for interventional techniques: part 2. Therapeutic interventions. Pain Physician. Jul-Aug 2010; 13(4): E215-64. PMID 20648212

7. Rupert MP, Lee M, Manchikanti L, et al. Evaluation of sacroiliac joint interventions: a systematic appraisal of the literature. Pain Physician. Mar-Apr 2009; 12(2): 399-418. PMID 19305487
8. Chou R, Atlas SJ, Stanos SP, et al. Nonsurgical interventional therapies for low back pain: a review of the evidence for an American Pain Society clinical practice guideline. Spine (Phila Pa 1976). May 01 2009; 34(10): 1078-93. PMID 19363456
9. Chou R, Loeser JD, Owens DK, et al. Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the American Pain Society. Spine (Phila Pa 1976). May 01 2009; 34(10): 1066-77. PMID 19363457
10. Hansen H, Manchikanti L, Simopoulos TT, et al. A systematic evaluation of the therapeutic effectiveness of sacroiliac joint interventions. Pain Physician. May-Jun 2012; 15(3): E247-78. PMID 22622913
11. Visser LH, Woudenberg NP, de Bont J, et al. Treatment of the sacroiliac joint in patients with leg pain: a randomized-controlled trial. Eur Spine J. Oct 2013; 22(10): 2310-7. PMID 23720124
12. Kim WM, Lee HG, Jeong CW, et al. A randomized controlled trial of intra-articular prolotherapy versus steroid injection for sacroiliac joint pain. J Altern Complement Med. Dec 2010; 16(12): 1285-90. PMID 21138388
13. Kennedy DJ, Engel A, Kreiner DS, et al. Fluoroscopically Guided Diagnostic and Therapeutic Intra-Articular Sacroiliac Joint Injections: A Systematic Review. Pain Med. Aug 2015; 16(8): 1500-18. PMID 26178855
14. Chou R, Fu R, Dana T, Pappas M, Hart E, Mauer KM. Interventional Treatments for Acute and Chronic Pain: Systematic Review. Comparative Effectiveness Review No. 247. (Prepared by the Pacific Northwest Evidence-based Practice Center under Contract No. 75Q80120D00006.) AHRQ Publication No. 21-EHC030. Rockville, MD: Agency for Healthcare Research and Quality; September 2021. PMID: 34524764
15. Chappell ME, Lakshman R, Trotter P, et al. Radiofrequency denervation for chronic back pain: a systematic review and meta-analysis. BMJ Open. Jul 21 2020; 10(7): e035540. PMID 32699129
16. Juch JNS, Maas ET, Ostelo RWJG, et al. Effect of Radiofrequency Denervation on Pain Intensity Among Patients With Chronic Low Back Pain: The Mint Randomized Clinical Trials. JAMA. Jul 04 2017; 318(1): 68-81. PMID 28672319
17. Chen CH, Weng PW, Wu LC, et al. Radiofrequency neurotomy in chronic lumbar and sacroiliac joint pain: A meta-analysis. Medicine (Baltimore). Jun 2019; 98(26): e16230. PMID 31261580
18. Mehta V, Poply K, Husband M, et al. The Effects of Radiofrequency Neurotomy Using a Strip-Lesioning Device on Patients with Sacroiliac Joint Pain: Results from a Single-Center, Randomized, Sham-Controlled Trial. Pain Physician. Nov 2018; 21(6): 607-618. PMID 30508988
19. van Tilburg CW, Schuurmans FA, Stronks DL, et al. Randomized Sham-controlled Double-Blind Multicenter Clinical Trial to Ascertain the Effect of Percutaneous Radiofrequency Treatment for Sacroiliac Joint Pain: Three-month Results. Clin J Pain. Nov 2016; 32(11): 921-926. PMID 26889616
20. Zheng Y, Gu M, Shi D, et al. Tomography-guided palisade sacroiliac joint radiofrequency neurotomy versus celecoxib for ankylosing spondylitis: a open-label, randomized, and controlled trial. Rheumatol Int. Sep 2014; 34(9): 1195-202. PMID 24518967

21. Patel N, Gross A, Brown L, et al. A randomized, placebo-controlled study to assess the efficacy of lateral branch neurotomy for chronic sacroiliac joint pain. Pain Med. Mar 2012; 13(3): 383-98. PMID 22299761
22. Patel N. Twelve-Month Follow-Up of a Randomized Trial Assessing Cooled Radiofrequency Denervation as a Treatment for Sacroiliac Region Pain. Pain Pract. Feb 2016; 16(2): 154-67. PMID 25565322
23. Whang P, Cher D, Polly D, et al. Sacroiliac Joint Fusion Using Triangular Titanium Implants vs. Non-Surgical Management: Six-Month Outcomes from a Prospective Randomized Controlled Trial. Int J Spine Surg. 2015; 9: 6. PMID 25785242
24. Polly DW, Cher DJ, Wine KD, et al. Randomized Controlled Trial of Minimally Invasive Sacroiliac Joint Fusion Using Triangular Titanium Implants vs Nonsurgical Management for Sacroiliac Joint Dysfunction: 12-Month Outcomes. Neurosurgery. Nov 2015; 77(5): 674-90; discussion 690-1. PMID 26291338
25. Polly DW, Swofford J, Whang PG, et al. Two-Year Outcomes from a Randomized Controlled Trial of Minimally Invasive Sacroiliac Joint Fusion vs. Non-Surgical Management for Sacroiliac Joint Dysfunction. Int J Spine Surg. 2016; 10: 28. PMID 27652199
26. Darr E, Meyer SC, Whang PG, et al. Long-term prospective outcomes after minimally invasive trans-iliac sacroiliac joint fusion using triangular titanium implants. Med Devices (Auckl). 2018; 11: 113-121. PMID 29674852
27. Sturesson B, Kools D, Pflugmacher R, et al. Six-month outcomes from a randomized controlled trial of minimally invasive SI joint fusion with triangular titanium implants vs conservative management. Eur Spine J. Mar 2017; 26(3): 708-719. PMID 27179664
28. Dengler J, Sturesson B, Kools D, et al. Referred leg pain originating from the sacroiliac joint: 6-month outcomes from the prospective randomized controlled iMIA trial. Acta Neurochir (Wien). Nov 2016; 158(11): 2219-2224. PMID 27629371
29. Dengler JD, Kools D, Pflugmacher R, et al. 1-Year Results of a Randomized Controlled Trial of Conservative Management vs. Minimally Invasive Surgical Treatment for Sacroiliac Joint Pain. Pain Physician. Sep 2017; 20(6): 537-550. PMID 28934785
30. Dengler J, Kools D, Pflugmacher R, et al. Randomized Trial of Sacroiliac Joint Arthrodesis Compared with Conservative Management for Chronic Low Back Pain Attributed to the Sacroiliac Joint. J Bone Joint Surg Am. Mar 06 2019; 101(5): 400-411. PMID 30845034
31. Duhon BS, Cher DJ, Wine KD, et al. Triangular Titanium Implants for Minimally Invasive Sacroiliac Joint Fusion: A Prospective Study. Global Spine J. May 2016; 6(3): 257-69. PMID 27099817
32. Duhon BS, Bitan F, Lockstadt H, et al. Triangular Titanium Implants for Minimally Invasive Sacroiliac Joint Fusion: 2-Year Follow-Up from a Prospective Multicenter Trial. Int J Spine Surg. 2016; 10: 13. PMID 27162715
33. Whang PG, Darr E, Meyer SC, et al. Long-Term Prospective Clinical And Radiographic Outcomes After Minimally Invasive Lateral Transiliac Sacroiliac Joint Fusion Using Triangular Titanium Implants. Med Devices (Auckl). 2019; 12: 411-422. PMID 31576181
34. Patel V, Kovalsky D, Meyer SC, et al. Prospective Trial of Sacroiliac Joint Fusion Using 3D-Printed Triangular Titanium Implants. Med Devices (Auckl). 2020; 13: 173-182. PMID 32607011
35. Vanaclocha V, Herrera JM, Saiz-Sapena N, et al. Minimally Invasive Sacroiliac Joint Fusion, Radiofrequency Denervation, and Conservative Management for Sacroiliac Joint Pain: 6-Year Comparative Case Series. Neurosurgery. Jan 01 2018; 82(1): 48-55. PMID 28431026

36. Spain K, Holt T. Surgical Revision after Sacroiliac Joint Fixation or Fusion. Int J Spine Surg. 2017; 11: 5. PMID 28377863
37. Schoell K, Buser Z, Jakoi A, et al. Postoperative complications in patients undergoing minimally invasive sacroiliac fusion. Spine J. Nov 2016; 16(11): 1324-1332. PMID 27349627
38. Tran ZV, Ivashchenko A, Brooks L. Sacroiliac Joint Fusion Methodology - Minimally Invasive Compared to Screw-Type Surgeries: A Systematic Review and Meta-Analysis. Pain Physician. Jan 2019; 22(1): 29-40. PMID 30700066
39. Lorio M, Kube R, Araghi A. International Society for the Advancement of Spine Surgery Policy 2020 Update-Minimally Invasive Surgical Sacroiliac Joint Fusion (for Chronic Sacroiliac Joint Pain): Coverage Indications, Limitations, and Medical Necessity. Int J Spine Surg. Dec 2020; 14(6): 860-895. PMID 33560247
40. Rappoport LH, Luna IY, Joshua G. Minimally Invasive Sacroiliac Joint Fusion Using a Novel Hydroxyapatite-Coated Screw: Preliminary 1-Year Clinical and Radiographic Results of a 2-Year Prospective Study. World Neurosurg. May 2017; 101: 493-497. PMID 28216399
41. Rappoport LH, Helsper K, Shirk T. Minimally invasive sacroiliac joint fusion using a novel hydroxyapatite-coated screw: final 2-year clinical and radiographic results. J Spine Surg. Jun 2021; 7(2): 155-161. PMID 34296027
42. Araghi A, Woodruff R, Colle K, et al. Pain and Opioid use Outcomes Following Minimally Invasive Sacroiliac Joint Fusion with Decortication and Bone Grafting: The Evolusion Clinical Trial. Open Orthop J. 2017; 11: 1440-1448. PMID 29387289
43. Fuchs V, Ruhl B. Distraction arthrodesis of the sacroiliac joint: 2-year results of a descriptive prospective multi-center cohort study in 171 patients. Eur Spine J. Jan 2018; 27(1): 194-204. PMID 29058134
44. Benzon HT, Connis RT, De Leon-Casasola OA, et al. Practice guidelines for chronic pain management: an updated report by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine. Anesthesiology. Apr 2010; 112(4): 810-33. PMID 20124882
45. Lee DW, Pritzlaff S, Jung MJ, et al. Latest Evidence-Based Application for Radiofrequency Neurotomy (LEARN): Best Practice Guidelines from the American Society of Pain and Neuroscience (ASPN). J Pain Res. 2021; 14: 2807-2831. PMID 34526815
46. National Institute for Health and Care Excellence. Minimally invasive sacroiliac joint fusion surgery for chronic sacroiliac pain [IPG578]. 2017; https://www.nice.org.uk/guidance/ipg578. Accessed October 4, 2022.

OTHER REFERENCES

1. Blue Cross and Blue Shield of Kansas Anesthesiology Liaison Committee, May 2014; May 2015; July 2016; January 2017; May 2018; July 2019, May 2021.