Medical Policy

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Title: Diagnosis and Treatment of Sacroiliac Joint Pain

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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 fusion/fixation 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 fusion/fixation with a 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 sacroiliac joint 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 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 policy 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 is typically without any consistent, demonstrable radiographic or laboratory features and most commonly exists in the setting of morphologically normal joints. Clinical tests for SIJ pain may include various movement tests, palpation to detect tenderness, and pain descriptions by the patient. Further confounding the study of the SIJ is that multiple structures, (eg, posterior facet joints, lumbar discs) may refer pain to the area surrounding the SIJ.

Because of inconsistent information obtained from history and physical examination, some have proposed the use of image-guided anesthetic injection into the SIJ for the diagnosis of SIJ pain. Treatments being investigated for SIJ pain include prolotherapy (see evidence review 2.01.26), corticosteroid injection, radiofrequency ablation, stabilization, and arthrodesis. Some procedures have been referred to as SIJ fusion but may be more appropriately called fixation due to little to no bridging bone on radiographs. Devices for SIJ fixation/fusion that promote bone ingrowth to fixate the implants include a triangular implant (iFuse Implant System) and cylindrical threaded devices (Rialto, SImmetry, Silex, SambaScrew, SI-LOK). Some devices also have a slot in the middle where autologous or allogeneic bone can be inserted. This added bone is intended to promote the fusion of the SIJ.

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.

A number of percutaneous or minimally invasive fixation/fusion devices have been cleared for marketing by the FDA through the 510(k) process. They include the iFuse® Implant System (SI Bone), the Rialto™ SI Joint Fusion System (Medtronic), SIJ-Fuse (Spine Frontier), the SImmetry® Sacroiliac Joint Fusion System (Zyga Technologies), Silex™ Sacroiliac Joint Fusion System (XTANT Medical), SambaScrew® (Orthofix), and the SI-LOK® Sacroiliac Joint Fixation System (Globus Medical). FDA product code: OUR.

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.

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 1); AND
3. Failure to respond to nonsurgical conservative management (see Policy Guidelines 2); AND
4. The injections are performed under radiographic guidance with documentation of contrast material throughout the sacroiliac joint (see Policy Guidelines 3). Ultrasound guidance is not considered adequate or accurate for sacroiliac joint injections.

Repeat Injections:

1. 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
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 4):

1. Average pain level of ≥6 on a scale of 1 to 10 (see Policy Guidelines #4) that impacts quality of life or limits activities of daily living; AND
2. There is an absence of generalized pain behavior (eg, somatoform disorder) or generalized pain disorders (eg, 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 5); 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 (eg, 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 (ie, 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

1. 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

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

3. Conservative nonsurgical management should include the following:
    a. Use of acetaminophen, nonsteroidal anti-inflammatory medications, or prescription strength analgesics at a dose sufficient to induce a therapeutic response
        1) Analgesics should include anti-inflammatory medications with or without adjunctive medications such as nerve membrane stabilizers or muscle relaxants, AND
    b. 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
    c. Evaluation and appropriate management of associated cognitive, behavioral, or addiction issues, AND
    d. Documentation of patient compliance with the preceding criteria.
4. 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.
5. 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.
6. Pain originating from the sacroiliac joint may be evidenced by provocation of pain in at least 3 out of 5 of the following tests:
    a) Distraction
    b) Thigh thrust
    c) FABER (Flexion, Abduction, External Rotation)
    d) Compression
    e) Gaenslen's

RATIONALE

This evidence review is updated regularly with searches of the MEDLINE database. The most recent literature update was performed through August 28, 2019.

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.[1,] 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 PICOs were used to select literature to inform this review.

Patients

The relevant population of interest are 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 in an outpatient setting.

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. A diagnostic result should be available within one to two 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

Technically Reliable

Assessment of technical reliability focuses on specific tests and operators and requires a review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review and alternative sources exist. This evidence review focuses on the clinical validity and clinical utility.

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).

Simopoulous et al (2015) conducted a systematic review evaluating 11 diagnostic accuracy studies.[2,] 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.[3,] 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.[4,5,] 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).[6,]

Chou et al (2009) conducted 2 systematic reviews at the Oregon Evidence-based Practice Center that informed practice guidelines from the American Pain Society.[7,8,] 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 SIJ Pain

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

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, two domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one or more intended clinical 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. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Systematic Reviews

Hansen et al (2012) published a systematic review of SIJ interventions.[9,] The primary outcome was short-term (≤6 months) or long-term (>6 months) pain relief. Evidence was classified as good, fair, or limited/poor based on the quality of evidence. Eleven studies (six randomized, five 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). For radiofrequency neurotomy, the evidence for cooled radiofrequency was fair (two RCTs), while evidence for conventional radiofrequency or pulsed radiofrequency was limited or poor. The American Society of Interventional Pain Physicians' (2013) evidence review by Manchikanti et al (2013)[3,] found no additional studies on intra-articular or periarticular injections besides those identified by Hansen et al (2012).

Treatment of SIJ 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 PICOs were used to select literature to inform this review.

Patients

The relevant population of interest are 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 adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Randomized Controlled Trials

The available literature on therapeutic corticosteroid injections is limited, consisting of small RCTs and case series. Tables 1 and 2 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.[10,] 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 (see evidence review 2.01.26) compared with steroid injection for SIJ pain.[11,] 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, two weeks, and then monthly on completing treatment. At the two-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 three months for the steroid group.

Table 1. Characteristics of Key RCTs Assessing Therapeutic Corticosteroid Injection

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	*Comparator*
Visser et al (2013)[10,]	NL	1	NR	Diagnosed with SIJ pain and/or leg pain between 4 wk and 1 y in duration	18 patients randomized to IA injection	15 patients randomized to PT and 18 to manual therapy
Kim et al (2010)[11,]	Korea	1	NR	Diagnosed with SIJ pain[a] who failed additional 1-mo treatment	24 patients randomized to IA prolotherapy; 23 analyzed	26 patients randomized to steroid; 26 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 2. Results of Key RCTs Assessing Therapeutic Corticosteroid Injection

Study*	Pain Outcomes		Functional Outcomes	
Visser et al (2013)[10,]	VAS (SD)		RAND-36 Physical Functioning[1]	
	Baseline	3 Months	Baseline	3 Months
Intra-articular 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)[11,]	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)

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 3 and 4) 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 3. Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Visser et al (2013)[10,]	4. Patients were recruited on the basis of SIJ-related leg pain with short duration of signs and symptoms.	2. Unclear which if any patients received a second injection.		4-5. Definition of successful treatment did not utilize standard pain	

				relief threshold cutoff of at least 50%.	
Kim et al (2010)[11,]					

The study limitations stated in this table are those notable in the current review; this is not a comprehensive limitations 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 pre-specified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 4. Study Design and Conduct Limitations

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

The study limitations stated in this table are those notable in the current review; this is not a comprehensive limitations 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 non inferiority 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.[9,12,]

Section Summary: Therapeutic Corticosteroid Injections

Results from two 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 SIJ Pain: Radiofrequency Ablation

Clinical Context and Therapy Purpose
The purpose of 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 PICOs were used to select literature to inform this review.

Patients
The relevant population of interest are 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 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 two 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 principles outlined in indication 2.

Systematic Reviews
Chen et al (2019) performed a meta-analysis of 5 RCTs comparing RFA to sham or medical treatment in patients with chronic SIJ pain.[13,] Various RFA procedures were represented, including percutaneous, cooled, and palisade SIJ RF neurotomy. Pain outcomes from all RCTs were pooled for the meta-analysis. Disability outcomes were only available for two studies utilizing cooled RFA. While studies showed no significant heterogeneity for disability outcomes, heterogeneity was high for pain outcomes.

Sun et al (2018) published a meta-analysis of 7 studies that included patients with chronic SIJ pain who received treatment with cooled radiofrequency procedures.[14,]While overall outcomes were improved after treatment, there was heterogeneity across study

designs and patient selection, which limited the strength of the meta-analysis. Also, sample sizes in the selected studies were small.

Aydin et al (2010) published a meta-analysis of RFA for sacroiliac pain.[15,] Nine studies included reported the primary outcome measure of a reduction of pain of 50% or greater, including a randomized placebo-controlled study, 3 prospective observational studies, and 5 retrospective studies. All studies used an injection of a local anesthetic to determine if RFA was indicated for the patient. Seven studies reported follow-up to three months; six studies reported follow-up to six months. The meta-analysis indicated that at least 50% of patients who received RFA to the SIJ showed a reduction in their pain of 50% or more at 3 and 6 months. The analysis found no evidence of publication bias, but heterogeneity in studies was observed for the six-month follow-up. This meta-analysis included low-quality studies and lacked RCTs. In addition, as reviewers noted, no standards have been established for the specific nerves to ablate or type of technique.

No additional studies were identified in the American Society of Interventional Pain Physicians (2013) evidence review, which concluded that evidence was limited for conventional radiofrequency neurotomy, limited for pulsed radiofrequency neurotomy, and fair for cooled radiofrequency neurotomy.[5,]

Tables 5 and 6 summarize the characteristics and results of select systematic reviews.

Table 5. Characteristics of Systematic Reviews

Study	Dates	Trials	Participants[1]	N (Range)	Design	Duration, mo
Chen et al (2019)	2012-2018	5	Patients with chronic SIJ pain treated by various RFA procedures compared to sham or medical treatment	311 (28-155)	RCTs	3-6
Sun et al (2018)	2008-2017	7	Patients with chronic SIJ pain treated by cooled radiofrequency procedure followed at least 3 mo	240 (15-190)	4 retrospective observational, 2 RCTs 1 prospective observational	3-24

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

Table 6. Results of Systematic Reviews

Study	NRS Score	VAS Score	ODI Score	GPE Score
Chen et al (2019)[13,] 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	0.001		0.020	0.090
I^2 (p)	82.3% (NR)		44.8% (NR)	NR
Sun et al (2018)[14,] Cooled RFA				
Total N	4 studies; n=81	3 studies; n=150	5 studies; n=103	4 studies; n=75
MD (95% CI)	3.81 (3.29 to 4.33)	3.78 (3.31 to 4.23	18.20 (12.22 to 24.17)	OR=0.01 (0.00 to 0.05)
p	<0.001	<0.001	<0.001	<0.001

I^2 (p)	46% (0.13)	41% (0.16)	72% (<0.001)	0% (0.92)

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

Randomized Controlled Trials

Tables 7 and 8 summarize the characteristics and results of select RCTs.

Table 7. Characteristics of Key RCTs Assessing Radiofrequency Ablation

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Mehta et al (2018)[16,]	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=11)	Sham (n=6) 4 patients crossed over to active group after 3-month endpoint
Juch et al (2017)[17,]	Netherlands	16	2013-2014	Patients with chronic low back pain related to the SIJ	RFA + exercise program (n=116) 110 received RFA 81 received Palisade RF treatment 23 received cooled RFA 6 received multi-probe strip lesion RFA	Exercise progran (n=112) 69 completed program 18 did not complete program 25 with unknow completion
Van Tilburg et al (2016)[18,]	Netherlands	NR	2012-2014	Patients with SIJ pain	Percutaneous RFA to lateral branch and dorsal root primary ramus (n=30)	Sham(n=30)
Zheng et al (2014)[19,]	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)[20,21,]	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; RF: radiofrequency; RFA: radiofrequency ablation; RCT: randomized controlled trial: SIJ: sacroiliac joint.

Table 8. Results of Key RCTs Assessing Radiofrequency Ablation

Study	Pain Outcomes		Functional Outcomes		Treatment Success	
Mehta et al (2018)[16,]	NRS at Baseline (SD)	NRS at Month 3 (SD)	PCS[1] at Baseline (SD)	PCS at Month 3 (SD)	Treatment Success	
Strip lesion RFA	8.1 (0.8)	3.4 (2.0)	28.4 (7.1)	34.7 (10.8)	NR	
Sham	6.5 (2.0)	7.3 (0.8)	28.6 (5.0)	29.6 (5.6)	NR	
P-Value	NR	<0.001	NR	0.0645	NR	
Juch et al (2017)[17,]	NRS at Month 3 (95% CI)	NRS at Month 12 (95% CI)	ODI at Month 3 (95% CI)	ODI at Month 12 (95% CI)	At Month 3, n/N (%)	At Month 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 (23.89 to 30.69)	43/110 (39.10)	49/102 (48.03)

Study	Pain Outcomes		Functional Outcomes		Treatment Success	
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 (20.74 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 to 0.60)	-4.20 (-8.39 to -0.00)	2.11 (-2.25 to 6.47)	1.87 (1.13 to 2.71)	1.46 (0.92 to 2.02)
P-Value	0.03	0.83	0.05	0.34	0.02	0.10
Van Tilburg et al (2016)[18,]	Mean NRS at Baseline (SD)	Mean NRS at Month 1 (SD)	Mean GPE at Month 1 (SD)	Mean GPE at 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)[19,]	VAS at Week 1 (95% CI)	VAS at Week 2 (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	<0.0001	<0.0001	NR	<0.0001	NR	
Patel et al (2012; 2016)[20,21,]	NRS at Baseline (SD)	NRS at Month 3 (SD)	ODI at Baseline (SD)	ODI at Month 9 (SD)	At Month 3, n/N (%)	At Month 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	0.370	0.035	0.639	0.011	0.015	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 0-10 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 (2019) 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. 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 three-month study endpoint, patients receiving sham treatment were allowed to crossover. While a statistically significant reduction in pain scores was reported at three months, there was no significant difference in functional outcome as measured by the Physical Component Score at three 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 non-blinded multicenter RCT of radiofrequency denervation in 228 of 2498 patients with suspected sacroiliac pain who were asked to participate in the trial.[20,] 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% 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=0.09) or in the number of patients who had more than a 30% reduction in pain intensity (p=0.48) 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.[21,] Patients selected had clinically suspected SIJ pain and a decrease of two 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=0.56). Both groups improved over time (≈2 points out of 10; p-value for time, p<0.001). 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.[19,] Palisade RFA uses a row of radiofrequency cannulae perpendicular to the dorsal sacrum. Inclusion criteria were ages 18 to 75 years; diagnosis of ankylosing spondylitis; chronic 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<0.001) 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.[18,] Twelve-month follow-up was reported in 2016.[17,] Fifty-one patients who had a positive response to two 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.[17,] Of the 9 patients who terminated study participation, 4 (12%) of 34 were considered treatment failures.

Tables 9 and 10 display notable relevance, design, and conduct limitations identified in each study.

Table 9. Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Mehta et al (2019)[16,]	4. Female subjects of childbearing age were required to use a hormonal or implantable contraceptive agent in order to participate in the study.			1. Disability outcomes were not reported.	
Juch et al (2017)[17,]	4. Patients older than 70 years were excluded.		2. Not a sham control.		
Van Tilburg et al (2016)[18,]					
Zheng et al (2014)[19,]	1. Patients were required to have a diagnosis of ankylosing spondylitis in addition to chronic low back pain related to the sacroiliac joint.		2. Not a sham control.		
Patel et al (2012)[20,21,]					

The study limitations stated in this table are those notable in the current review; this is not a comprehensive limitations 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 10. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Mehta et al (2019)[16,]				3. 66.6% of sham group patients crossed over to treatment group at 3 mo	Other related: • Small study size due to interim analysis	•
Juch et al (2017)[17,]		1-2. Study was not blinded.				
Van Tilburg et al (2016)[18,]				3. 63.3% of sham group patients crossed over to treatment group		
Zheng et al (2014)[19,]						
Patel et al (2012)[20,21,]				3. Patients in 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 limitations 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 non-inferiority 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: RFA

The randomized trials of RFA have methodologic limitations; moreover, there is limited data on the duration of the treatment effect. Heterogeneity of RFA treatment techniques precludes generalizing results across different studies.

Treatment of SIJ Pain: SIJ Fusion/Fixation with a 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 PICOs were used to select literature to inform this review.

Patients

The relevant population of interest are 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 oneto one years is of interest to monitor outcomes.

Study Selection Criteria

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

Randomized Controlled Trials

INSITE

Whang et al (2015) reported an industry-sponsored non-blinded RCT, Investigation of Sacroiliac Fusion Treatment (INSITE) of the iFuse Implant System in 148 patients.[22,] The 12-month follow-up to this RCT was reported by Polly et al (2015),[23,] and a 2-year follow-up was reported by Polly et al (2016).[24,] 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. Trial characteristics are summarized in Table 11. The duration of pain before enrollment averaged 6.4 years (range, 0.47-40.7 years). A large proportion of subjects (37%) had previously undergone lumbar fusion, SIJ steroid injections (86%), and RFA (16%).

Patients were randomized 2:1 to minimally invasive SIJ fusion (n=102) or to nonsurgical management (n=46). Nonsurgical management included a stepwise progression of nonsurgical treatments, depending on individual patient choice. During follow-up, control patients received physical therapy (97.8%), intra-articular steroid injections (73.9%), and RFA of sacral nerve roots (45.7%). The primary outcome measure was 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 adverse events or surgical revision. Patients in the control arm could crossover to surgery after six 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).

Results from the INSITE trial are shown in Table 12. At 6 months, success rates were 23.9% in the control group vs 81.4% in the surgical group (posterior probability of superiority >0.999). A clinically important (≥15-point) improvement in ODI score was found in 27.3% of controls compared with 75.0% of fusion patients. Measures of QOL (36-Item Short-Form Health Survey, EuroQol-5D) also improved to a greater extent in the surgery group. Of the 44 nonsurgical management patients still participating at 6 months, 35 (79.5%) crossed over to fusion. Compared with baseline, opioid use at 6 months decreased from 67.6% to 58% in the surgery group and increased from 63% to 70.5% in the control group (p=0.082). At 12 months, opioid use was similar between groups (55% vs 52%, p=0.61).

Polly et al (2016) reported 2-year outcomes from the SIJ fusion arm of this RCT (see Table 13).[24,] 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 trials were published by Darr et al (2018).[25,] Of 103 patients with SIJ dysfunction who were treated with minimally invasive SIJ fusion with triangular titanium implants, 60

(72.3%) patients reported an improvement in ODI scores of at least 15 points from baseline to 3 years. The mean ODI score decreased from 56 to 28 for the same timeframe, an improvement of 28 points (p<0.001); similarly, the mean SIJ pain score decreased to 26.2, reflecting a decrease of 55 points (p<0.001). Over 3 years of follow-up, 168 adverse events were reported in 75 patients, although only 22 of these events involved the pelvis. The study was limited by its lack of long-term data from a control group not receiving surgical treatment.

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.[26,27,] 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 six 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.[26,] At 6 months, VAS pain scores improved by 43.3 points in the iFuse group and by 5.7 points in the control group (p<0.001). ODI scores improved by 25.5 points in the iFuse group and by 5.8 points in the control group (p<0.001, between groups). An improvement in lower back pain by at least 20 VAS points (a minimal clinically important difference) was achieved in 78.8% of the SIJ fusion group vs 22.4% of controls; p<0.001). QOL outcomes showed a greater improvement in the iFuse group than in the control group. Changes in pain medication use were not reported. Patients in the conservative management group were allowed to cross over to SIJ fusion at six months.

Twelve-month results from the iMIA trial were reported by Dengler et al (2017) (see Table 13).[28,] Twenty-one patients in the conservative management group had little or no improvement in symptoms and crossed over to SIJ fusion after the six-month visit. Fourteen (56%) of the 25 patients who remained in the conservative management group had at least a 20-point improvement in VAS back pain score (22.4% of patients assigned to conservative management). At 12 months, low back pain had improved by 42 points (standard deviation [SD], 27.0) on a 100-point VAS in the SIJ fusion group compared with 14 points (SD=33.4) in the conservative management group (p<0.001). Mean ODI scores improved by 25 points in the SIJ fusion group compared with 8.7 points in controls (p<0.001).

Table 11. Summary of Key RCT Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions

					Active	*Comparator*
Whang et al (2015)[22,]; INSITE	U.S.	19	2013-2014	Patients 21-70 y with confirmed diagnosis of unilateral or bilateral SIJ dysfunction due to degenerative sacroiliitis and/or SIJ disruption	102 randomized to SIJ fusion	46 randomized to nonsurgical management
Sturesson et al (2017)[26,]; iMIA	EU (Belgium, Germany, Italy, Sweden)	9	2013-2015	Patients 21-70 y with LBP for >6 mo and diagnosed with SIJ as primary pain generator[a]	52 randomized to SIJ fusion	51 randomized to conservative management

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

Results	VAS Score		Success End Point		ODI Score		SF-36 PCS Score		EQ-5D TTO Index	
	Ctl	*iFuse*	*Ctl*	*iFuse*	*Ctl*	*iFuse*	*Ctl*	*iFuse*	*Ctl*	*iFuse*
INSITE[22,]										
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[26,]										
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)[22,] and Sturesson et al (2015).[26,]
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; ODI: Oswestry Disability Index; SF-36 PCS: 36-Item Short-Form Health Survey Physical Component Summary; VAS: visual analog scale.
[a] p<0.001.

Table 13. Extended Follow-Up From the INSITE and iMIA Trials

Outcome Measures	Baseline (SD)	6 Months (SD)	12 Months (SD)	24 Months (SD)
INSITE[22,]				
Sacroiliac joint fusion pain score	82.3	29.8		26.7
Percent ≥20-point improvement pain				83.1%
Sacroiliac joint fusion ODI score	57.2	31.9		28.7
% ≥15-point improvement ODI				68.2%
iMIA[26,28,]				
Low back pain				
Conservative management	73.0 (13.8)	67.8 (20.3)	58.9 (28.2)	
Sacroiliac joint fusion	77.7 (11.3)	34.4 (23.9)	35.2 (25.5)	
Leg pain				
Conservative management	47.1 (31.1)	46.5 (31.4)	41.7 (32.4)	
Sacroiliac joint fusion	52.7 (31.5)	22.6 (25.1)	24.0 (27.8)	
ODI				
Conservative management	55.6 (13.7)	50.2 (17.2)	46.9 (20.8)	
Sacroiliac joint fusion	57.5 (14.4)	32.0 (18.4)	32.1 (19.9)	

Adapted from Dengler et al (2017).[28,]
ODI: Oswestry Disability Index; SD: standard deviation.

Tables 14 and 15 display notable limitations identified in each study.

Table 14. Relevance Limitations

Study; Trial	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up
Whang et al (2015)[22,]; INSITE					
Sturesson et al (2017)[26,]; iMIA	1. Patients with other contributory sources of LBP might have been enrolled with SIJ-caused LBP patients				

The study limitations stated in this table are those notable in the current review; this is not a comprehensive limitations assessment.
LBP: low back pain; SIJ: sacroiliac joint.
[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 15. 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)[22,]; INSITE						
Sturesson et al (2017)[26,]; iMIA		1. Intervention was unblinded				

The study limitations stated in this table are those notable in the current review; this is not a comprehensive limitations 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 non-inferiority 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.

Subsection Summary: Randomized Controlled Trials

Two RCTs have reported outcomes past six 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 six months were maintained out to one year compared with controls who had not crossed over. The RCTs were non-blinded without a placebo or an active control group. However, the pain has a significant subjective and psychologic component. Cognitive-behavioral techniques to address pain were specifically excluded from the types of treatment that control subjects could obtain. Thus, as relates

to trial design, an independent assessment of pain outcomes would have been preferable.

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 3-year follow-up are shown in Table 16.

Results from a cohort of 172 patients undergoing SIJ fusion reported to 2 years were published by Duhon et al (2016).[29,30,] Patients were formally enrolled in a single-arm trial (NCT01640353) with planned follow-up for 24 months. Success was defined as a reduction of pain score of 20-mm on a 100-mm VAS, absence of device-related adverse events, absence of neurologic worsening, and absence of surgical reintervention. Enrolled patients had a mean VAS pain score of 79.8, a mean ODI score of 55.2, and a mean pain duration of 5.1 years. At 6 months, 136 (80.5%) of 169 patients met the success 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, one-year outcomes were maintained at two years. Other outcomes (eg, QOL scores) showed similar maintenance or slight improvement compared with one-year outcomes. Use of opioid analgesics decreased from 76.2% at baseline to 55% at 2 years. Over the two-year follow-up, eight (4.7%) patients required revision surgery.

Table 16. Two- to Three-Year Outcomes of the iFuse Implant in Cohorts and Case Series

Studies and Outcomes	Mean Baseline Value	Mean 2- to 3-Year Value	Difference or % Achieving Outcome	Follow-Up Rate
Duhon et al (2016)[29,30,]				
Pain score (range, 0-100)	79.8	26.0	53.3	86.6% (149/172)
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	

All differences between baseline and 2- to 3-year values were statistically significant.
EQ-5D TTO Index: EuroQoL Time Tradeoff Index; SF-36: 36-Item Short-Form Health Survey.

Nonrandomized Comparative Studies

Two retrospective nonrandomized comparative studies have been published. Vanaclocha et al (2018) found greater pain relief with SIJ fusion than with conservative management or SIJ denervation.[31,] Spain and Holt (2017) reported a retrospective review of surgical revision rates following SIJ fixation with either surgical screws or the iFuse triangular implant.[32,] Revision rates were lower with the iFuse device than observed with surgical screws.

Subsection Summary: Nonrandomized Studies

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 subset of studies with good (>85%) follow-up rates generally showed that short-term outcomes were maintained. Two studies of reasonable sample size with good follow-up showed results maintained to two years.[30,33,] One study with small sample size and good follow-up showed results maintained to five years.[31,] Improved health outcomes are also supported by retrospective studies that compare SIJ fusion/fixation using a triangular implant with other treatments for SIJ pain.[31,32,]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%.[34,]

Section Summary: SIJ Fusion/Fixation With a Triangular Implant
The evidence on SIJ fusion/fixation with a triangular implant includes 2 non-blinded RCTs of minimally invasive fusion and 2 case series with more than 85% follow-up at 2 to 3 years. Both RCTs reported superior short-term results for fusion, however, a preferable design for assessing pain outcomes would be an independent blinded assessment of outcomes or, when feasible, a sham-controlled trial. Longer-term follow-up from these RCTs has indicated that the results obtained at six months persist to two years. An additional cohort study and case series with sample sizes ranging from 45 to 149 patients and low dropout rates (<15%) also showed reductions in pain and disability at 2 years. One small case series showed outcomes that persisted to five years. The cohort studies and case series are consistent with the durability of treatment benefit. 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%.

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

The question addressed in this evidence review is: Does the use of SIJ fixation/fusion with a cylindrical threaded implant improve the net health outcome in individuals with SIJ pain?
The following PICOs were used to select literature to inform this review.

Patients
The relevant population of interest are individuals with SIJ pain.

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

Comparators

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

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

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

Systematic Reviews
Tran et al (2019) published a systematic review comparing the effectiveness of minimally invasive joint fusion (ie, utilizing the iFuse device) compared to screw-type surgeries.[35,] A total of twenty studies was pooled to calculate a standardized mean difference across pain, disability, and global/quality-of-life outcomes, including 14 studies evaluation the iFuse system and 7 studies evaluated cylindrical, threaded implants. Studies evaluating cylindrical, threaded implants consisted of case series and cohort studies. Patients receiving these implants experienced significantly worse pain outcomes (p=0.03) compared to patients receiving iFuse, with a standardized mean difference of 1.28 (95% CI: 0.47 to 2.09) and 2.04 (95% CI: 1.76 to 2.33), respectively. A statistically significant difference in disability scores was reported between screw-type and iFuse implant groups (0.26 [95% CI: -1.90 to 2.41] vs 1.68 [95% CI: 1.43 to 1.94]; p=0.01), with improved outcomes in the iFuse population. For global/quality-of-life outcomes, a statistically significant difference in scores was reported between screw-type and iFuse implants groups (0.60 [95% CI: 0.33 to 0.88] vs 0.99 [95% CI: 0.75 to 1.24]; p=0.04), with improved outcomes in the iFuse population.

Prospective Studies
Rappoport et al (2017) reported on an industry-sponsored prospective study of SIJ fusion with a cylindrical threaded implant (SI-LOK).[36,] 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 one 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 17), and revisions within the first 12 months of the study were low (n=2). Follow-up will continue through two years.

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.[37,] 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<0.001), with 36 (72%) patients achieving minimal clinically important difference (at least a 20-point reduction). The mean ODI score likewise showed significant improvement from baseline to 6 months, decreasing from 55.5 to 35.3 (p<0.001). 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<0.001). 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<0.001). 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. Follow-up data will be published at one and two years.

Case Series

Cross et al (2018) published a case series of 19 patients from 3 centers who underwent minimally invasive SIJ fusion with decortication, placement of the bone graft, and fixation with threaded implants.[38,] At 12 months, bridging bone across the SIJ was observed in 79% (n=15) of patients, increasing to 94% (n=17 of 18 patients with data available) at 24 months. At 24 months post procedure, 88% (n=15) had fusion within the decorticated area, and the same percentage of patients (88% [n=15]) had solid fusion. While the study was not powered to detect associations between radiographic fusion and clinical outcomes, the authors reported a significant change in the mean numeric rating scale score for pain, from pre procedure to 24-month follow-up: patients showed an average 73% reduction in low back pain (7.9/10 decreased to 2.1/10, p<0.01; effect size, -2.9). The industry-sponsored study had a small sample size, but provided follow-up data at two years after SIJ fusion with a threaded implant, indicating a need for larger comparative studies to confirm the favorable radiographic fusion results suggested by the study.

Table 17. Pain and Disability Scores After Implantation With a Cylindrical Threaded Implant

Outcome Measures	Baseline	3 Months (SD)	6 Months (SD)	12 Months (SD)	p
Low back pain	55.8 (26.7)	28.5 (21.6)	31.6 (26.9)	32.7 (27.4)	<0.01
Left leg pain	40.6 (29.5)	19.5 (22.9)	16.4 (25.6)	12.5 (23.3)	<0.01
Right leg pain	40.0 (34.1)	18.1 (26.3)	20.6 (25.4)	14.4 (21.1)	<0.05
Oswestry Disability Index	55.6 (16.1)	33.3 (16.8)	33.0 (16.8)	34.6 (19.4)	<0.01

Adapted from Rappoport et al (2017).[36,]
SD: standard deviation.

Section Summary: SIJ Fixation/FusionWith Cylindrical Threaded Implant

There is limited evidence on the fusion of the SIJ with devices other than the triangular implant. One-year results from a prospective cohort of 32 patients who received a cylindrical slotted implant showed reductions in pain and disability similar to results obtained for the triangular implant. However, there is uncertainty in the health benefit of

SIJ fusion/fixation with this implant design. Therefore, controlled studies with a larger number of patients and longer follow-up are needed to evaluate this device.

Summary of Evidence

Diagnostic

For individuals who have suspected SIJ pain who receive a diagnostic sacroiliac block, the evidence includes systematic reviews. The 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 the effects of the technology on health outcomes.

Therapeutic

For individuals who have SIJ pain who receive therapeutic corticosteroid injections, the evidence includes small RCTs and case series. The 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 two 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 the effects of the technology on health outcomes.

For individuals who have SIJ pain who receive RFA, the evidence includes four small RCTs using different radiofrequency applications and case series. The relevant outcomes are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. For RFA with a cooled probe, the two small RCTs reported short-term benefits, but these are insufficient to determine the overall effect on health outcomes. The RCT on palisade RFA of the SIJ did not include a sham control. Another sham-controlled randomized trial 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 the effects of the technology on health outcomes.

For individuals who have SIJ pain who receive SIJ fixation/fusion with a triangular implant, the evidence includes 2 non-blinded RCTs of minimally invasive fusion and 2 case series with more than 85% follow-up at 2 to 3 years. The relevant outcomes are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. Both RCTs reported superior short-term results for fusion, however, a preferable design for assessing pain outcomes would be independent, blinded assessment of outcomes or, when feasible, a sham-controlled trial. Longer-term follow-up from these RCTs has indicated that the results obtained at six months persist to two years. An additional cohort study and case series, with sample sizes ranging from 45 to 149 patients and low dropout rates (<15%), have also shown reductions in pain and disability at 2 years. One small case series showed outcomes that persisted to five years. The cohort studies and case series are consistent with the durability of treatment benefit. 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%. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have SIJ pain who receive SIJ fusion/fixation with a cylindrical threaded implant, the evidence includes a prospective cohort. The relevant outcomes are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. The prospective cohort study will follow patients for two years following implantation of slotted screws filled with autologous bone. Results at one year are consistent with findings from the studies using a triangular implant. However, longer follow-up and controlled trials are needed to evaluate this type of implant. The evidence is insufficient to determine the effects of the technology on health outcomes.

Clinical Input
Objective
Clinical input is sought to help determine the appropriate use in the clinical practice of sacroiliac joint fusion for patients with sacroiliac joint pain.

Respondents*
Clinical input was provided by the following specialty societies and physician members identified by a specialty society or health system:

- American Association of Neurological Surgeons/Congress of Neurological Surgeons (AANS/CNS)
- American Pain Society (APS)
- American Society of Regional Anesthesia and Pain Medicine (ASRA)[a]
- International Society for the Advancement of Spine Surgery (ISASS)[b]
- North American Spine Society/American Academy of Orthopaedic Surgeons (NASS/AAOS)
- Neil Malhotra, MD, Assistant Professor of Neurosurgery, Perelman School of Medicine, University of Pennsylvania (identified by Hospital of the University of Pennsylvania)
- William Welch, MD, Vice Chair (Clinical) and Professor, Department of Neurosurgery, Perelman School of Medicine, University of Pennsylvania (identified by Hospital of the University of Pennsylvania)
- Zachary Gordon, MD, Assistant Professor, Department of Orthopaedics, Case Western Reserve University, identified by University Hospitals Cleveland Medical Center
- A. Alex Jahangir, MD, MMHC, Medical Director and Associate Professor of Orthopaedic Surgery, identified by Vanderbilt University Medical Center
- Anonymous, MD, Assistant Professor of Orthopaedics and Rehabilitation; identified by Oregon Health and Science University.

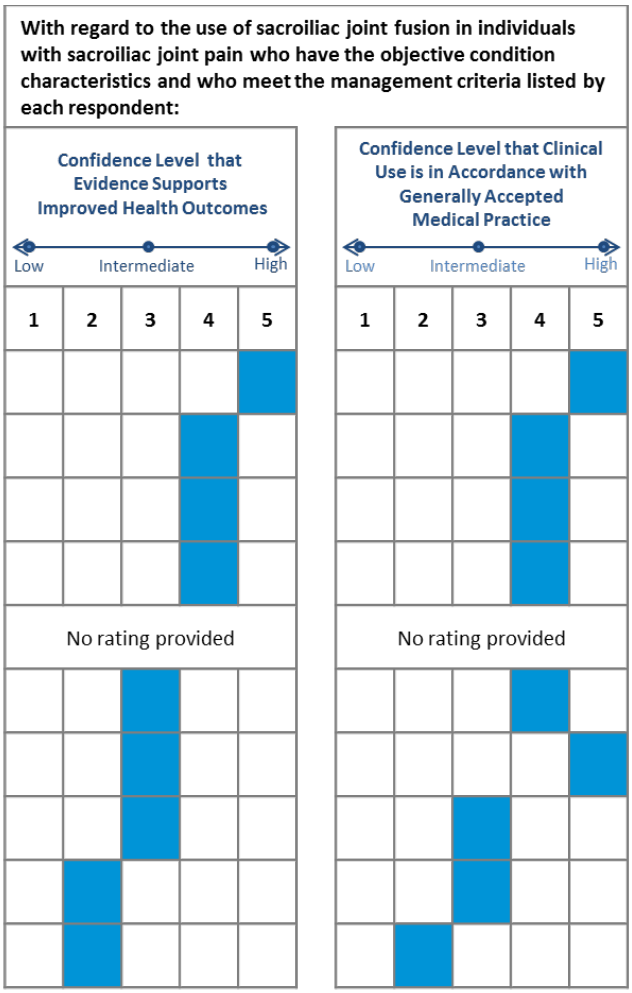
[a] Indicates that information was not provided regarding conflicts of interest related to the topic where clinical input is being sought.

[b] Indicates that conflicts of interest related to the topic where clinical input is being sought were identified by this respondent (see Appendix 1).

Clinical input provided by the specialty society at an aggregate level is attributed to the specialty society. Clinical input provided by a physician member designated by the specialty society or health system is attributed to the individual physician and is not a statement from the specialty society or health system. Specialty society and physician respondents participating in the Evidence Street® clinical input process provide a review, input, and feedback on topics being evaluated by Evidence Street. However, participation in the clinical input process by a special society and/or physician member designated by the specialty society or health system does not imply an endorsement or explicit agreement with the Evidence Opinion published by BCBSA or any Blue Plan.

Clinical Input Responses

Figure 1:



Clinical Indication	Respondent	Identified by
Per ISASS policy statement	ISASS**	
See response to Clinical Input Question 1 in Appendix	AANS/CNS	
Per NASS coverage recommendation	NASS/AAOS	
See response to Clinical Input Question 1 in Appendix	APS	
See response to Clinical Input Question 1 in Appendix	ASRA*	
Diagnostic and therapeutic injections	Dr. Malhotra	Hospital of Univ. Pennsylvania
Response to image-guided sacroiliac injections	Dr. Welch	Hospital of Univ. Pennsylvania
See response to Clinical Input Question 1 – NASS guideline	Anonymous	Oregon Health and Science Univ.
See response to Clinical Input Question 1 in Appendix	Dr. Jahangir	Vanderbilt University Med Ctr
See response to Clinical Input Question 1 in Appendix	Dr. Gordon	Univ. Hospitals Cleveland Med Ctr

* Indicates that information was not provided regarding conflicts of interest related to the topic where clinical input is being sought.
** Indicates that conflicts of interest related to the topic where clinical input is being sought were identified by this respondent (see Appendix).

Additional Comments

- "The evaluation of a patient for possible sacroiliac (SI) joint pain involves careful attention to a patient's history and physical examination. When a patient's symptoms and signs arouse sufficient clinical suspicion, additional tests are then required to confirm the diagnosis of SI joint dysfunction." (AANS/CNS)
- "Proper SIJ pain diagnosis is key to appropriate patient management. There is an accepted diagnostic algorithm for SIJ pain that combines medical history, physical examination and confirmatory diagnostic SIJ block." (ISASS)
- "The North American Spine Society's coverage recommendations on SI joint fusion provides evidence-based criteria for diagnosing SI joint pain and selection criteria for surgical intervention." (NASS/AAOS)
- "The North American Spine Society Criteria are the most respected and generally used criteria. Most patients with SI joint pain will respond to the conservative therapies listed. However, one criteria that I think should be added is a reduction in opioid use prior to the fusion." (APS)
- "SI fusion is currently acceptable therapy in patients in whom significant response is noted with injection. SI joint fusion as part of the inferior portion of extensive thoracolumbar fusion (IE SI joint and pelvis) is an accepted approach. Increasing literature on the topic will enhance the knowledge base on this topic." (Neil Malhotra, MD identified by Hospital of the University of Pennsylvania)
- "The only generally accepted objective criteria for the diagnosis of sacroiliac joint pain is response to image-guided sacroiliac injections. Patients who do not respond to the injections generally do not improve with directed therapies. Patients who do improve with the injections will usually respond to fusion therapies." (William Welch, MD identified by Hospital of the University of Pennsylvania)
- "Although criteria for the diagnosis of SI joint dysfunction is fairly well described, there is significant variability from study to study regarding the application of the diagnostic criteria. It is difficult to assess the efficacy of a treatment such as SI joint fusion when there is not a clearly defined and consistent manner of diagnosis from study to study. The vast majority of literature regarding outcomes following SI joint fusion surgery are low-quality retrospective studies, or small sample size prospective studies with limited follow-up." (Zachary Gordon, MD identified by University Hospitals Cleveland Medical Center)
- "While the evidence is low, I agree with the NASS recommendations as outlined in their report particularly focusing on the fact that a patient has undergone and failed a minimum 6 months of intensive non-operative treatments, the patient has a complaint and physical exam consistent with SIJ pain, imaging of the SI joint that excludes the presence of destructive lesions, at least 75% reduction of pain for the expected duration of the anesthetic used following an image-guided, contrast-enhanced intra-articular SIJ injection on 2 separate occasions and finally a successful trial of at least one therapeutic intra-articular SIJ injection with a corticosteroid." (A. Alex Jahangir, MD identified by Vanderbilt University Medical Center)
-

See Appendix 1 and 2 for details.

Supplemental Information

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

In response to requests, clinical input focused on sacroiliac joint (SIJ) fusion 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.

Based on the evidence and independent clinical input, the clinical input supports that the following indication provides a clinically meaningful improvement in the net health outcome and is consistent with generally accepted medical practice:

- Use of fusion/stabilization of the SIJ using percutaneous and minimally invasive techniques for carefully selected patients as outlined in statements from the North American Spine Society.

2015 Input

In response to requests, focused input on SIJ fusion was received from 5 physician specialty societies and 3 academic medical centers while this policy was under review in 2015. Most reviewers considered SIJ fusion to be investigational.

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

North American Spine Society

The NASS (2015) published coverage recommendations for percutaneous SIJfusion.[39,]The NASS indicated that there was relatively moderate evidence. In the absence of high-level data, NASS policies reflect the multidisciplinary experience and expertise of the committee members in order to present reasonable standard practice indications in the U. S. The NASS recommended coverage when *all* of the following criteria are met:

1. "[Patients] have undergone and failed a minimum 6 months of intensive nonoperative treatment that must include medication optimization, activity modification, bracing and active therapeutic exercise targeted at the lumbar spine, pelvis, SIJ, and hip including a home exercise program.
2. Patient's report of typically unilateral pain that is caudal to the lumbar spine (L5 vertebra), localized over the posterior SIJ, and consistent with SIJ pain.
3. A thorough physical examination demonstrating localized tenderness with palpation over the sacral sulcus (Fortin's point, ie, at the insertion of the long dorsal ligament inferior to the posterior superior iliac spine or PSIS) in the absence of tenderness of similar severity elsewhere (eg, greater trochanter, lumbar spine, coccyx) and that other obvious sources for their pain do not exist.
4. Positive response to a cluster of 3 provocative tests (eg, thigh thrust test, compression test, Gaenslen's test, distraction test, Patrick's sign, posterior provocation test). *Note that the thrust test is not recommended in pregnant patients or those with connective tissue disorders.*
5. Absence of generalized pain behavior (eg, somatoform disorder) or generalized pain disorders (eg, fibromyalgia).
6. Diagnostic imaging studies that include ALL of the following:
    a. Imaging (plain radiographs and a CT [computed tomography] or MRI [magnetic resonance imaging]) of the SI joint that excludes the presence of destructive lesions (eg, tumor, infection) or inflammatory arthropathy that would not be properly addressed by percutaneous SIJ fusion.
    b. Imaging of the pelvis (AP [anteroposterior] plain radiograph) to rule out concomitant hip pathology.
    c. Imaging of the lumbar spine (CT or MRI) to rule out neural compression or other degenerative condition that can be causing low back or buttock pain.
    d. Imaging of the SI joint that indicates evidence of injury and/or degeneration.
7. At least 75% reduction of pain for the expected duration of the anesthetic used following an image-guided, contrast-enhanced intra-articular SIJ injection on 2 separate occasions.
8. A trial of at least one therapeutic intra-articular SIJ injection (ie, corticosteroid injection)."

American Society of Interventional Pain Physicians

The American Society of Interventional Pain Physicians (2013) guidelines have been updated.[3,] The updated guidelines recommend the use of controlled SIJ blocks with placebo or controlled comparative local anesthetic block when indications are satisfied with suspicion of SIJ pain. 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 et al

The American Society of Anesthesiologists and the American Society of Regional Anesthesia and Pain Medicine (2010) updated their joint guidelines for chronic pain management.[40,] The guidelines recommended 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 guidelines recommend that "Water-cooled radiofrequency ablation may be used for chronic sacroiliac joint pain."

American Pain Society

The practice guidelines from the American Pain Society (2009) were based on a systematic review commissioned by the Society.[7,8,] The guidelines stated that there was insufficient evidence to evaluate the validity or utility of diagnostic SIJ block as a diagnostic procedure for low back pain with or without radiculopathy; the guidelines further stated that there was insufficient evidence to adequately evaluate the benefits of SIJ steroid injection for nonradicular low back pain.

International Society for the Advancement of Spine Surgery

The International Society for the Advancement of Spine Surgery (2014) updated its policy statement on minimally invasive SIJ fusion in 2016.[41,42,]Society recommendations indicated that patients who met all of the following criteria may be eligible for minimally invasive SIJ fusion:

- "Significant SI [sacroiliac] joint pain....or significantly limitations in activities of daily living because of pain from the SI joint(s).
- "SI joint pain confirmed with … at least 3 positive physical provocation examination maneuvers that stress the SI joint.
- "Confirmation of the SI joint as a pain generator with ≥ 75% acute decrease in pain immediately following fluoroscopically guided diagnostic intra-articular SI joint block using local anesthetic.
- "Failure to respond to at least 6 months of non-surgical treatment consisting of non-steroidal anti-inflammatory drugs and/or....one or more of the following:....physical therapy....Failure to respond means continued pain that interferes with activities of daily living and/or results in functional disability;

- "Additional or alternative diagnoses that could be responsible for the patient's ongoing pain or disability have been considered, investigated and ruled out."

National Institute for Health and Care Excellence
The National Institute for Health and Care Excellence (2017) 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."[43,]

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 18.

Table 18. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02074761[a]	Evolusion Study Using the Zyga SImmetry Sacroiliac Joint Fusion System	250	Aug 2020 (ongoing)
NCT03601949[a]	Lateral Branch Cooled Radiofrequency Denervation vs Conservative Therapy for Sacroiliac Joint Pain	208	Nov 2021 (recruiting)
NCT03507049	Sacroiliac Joint Fusion Versus Sham Operation for Treatment of Sacroiliac Joint Pain (SIFSO)	60	Apr 2023 (recruiting)
Unpublished			
NCT01861899[a]	Treatment of Sacroiliac Dysfunction With SI-LOK® Sacroiliac Join Fixation System	55	Nov 2018 (unknown)
NCT02270203[a]	LOIS: Long-Term Follow-Up in INSITE/SIFI	103	Dec 2019 (completed)

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. 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.

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	Anesthetic agent or steroid Injection; nerves innervating the sacroiliac joint
64625	Radiofrequency ablation, nerves innervating the sacroiliac joint, with image guidance (ie, fluoroscopy or computed tomography)
64640	Destruction by neurolytic agent; other peripheral nerve or branch
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
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: 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" ▪ 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 (eg, somatoform disorder) or generalized pain disorders (eg, 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 (eg, 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 (ie, 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 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

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