

Medical Policy



Title: Diagnosis and Treatment of Sacroiliac Joint Pain

Professional

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Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> With suspected sacroiliac joint pain 	Interventions of interest are: <ul style="list-style-type: none"> Diagnostic sacroiliac joint block 	Comparators of interest are: <ul style="list-style-type: none"> Standard of care 	Relevant outcomes include: <ul style="list-style-type: none"> Test validity Symptoms Functional outcomes Quality of life Medication use Treatment-related morbidity

Populations	Interventions	Comparators	Outcomes
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 that the sacroiliac joint may be a source of low back pain. In fact, prior to 1928, the sacroiliac joint 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 sacroiliac joint received less research attention.

Diagnosis

Research into sacroiliac joint pain has been thwarted by any criterion standard to measure its prevalence and against which various clinical examinations can be validated. For example, sacroiliac joint 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 sacroiliac joint pain may include various movement tests, palpation to detect tenderness, and pain descriptions by the patient. Further confounding study of the sacroiliac joint is that multiple structures, such as lower facet joints and lumbar discs, may refer pain to the area surrounding the sacroiliac joint.

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

REGULATORY STATUS

A number of radiofrequency generators and probes have been cleared for marketing through the U.S. Food and Drug Administration's (FDA) 510(k) process. One device, the SInergy® by Halyard (formerly Kimberly Clark), is a water-cooled single-use probe that received FDA clearance in 2005, 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 code: GXD.

Several percutaneous or minimally invasive fixation/fusion devices have received marketing clearance by the FDA through the 510(k) process. These 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); AND
 3. Failure to respond to nonsurgical conservative management (see NOTE below); AND
 4. The injections are performed under radiographic guidance with documentation of contrast material throughout the sacroiliac joint (see Policy Guidelines).
Ultrasound guidance is not considered adequate or accurate for sacroiliac joint injections.

NOTE:

Conservative nonsurgical management should include the following:

1. Use of acetaminophen, nonsteroidal anti-inflammatory medications, or prescription strength analgesics at a dose sufficient to induce a therapeutic response
 - i. Analgesics should include anti-inflammatory medications with or without adjunctive medications such as nerve membrane stabilizers or muscle relaxants, AND
2. 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
3. Evaluation and appropriate management of associated cognitive, behavioral, or addiction issues, AND
4. Documentation of patient compliance with the preceding criteria.

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 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:
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.
- 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. This policy does not address treatment of pain in the sacroiliac joint due to infection, trauma, or neoplasm.
2. Radiographic images used to perform SI joint injection should be digitally archived for retrieval at a later date.
3. 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
4. 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

5. This technically demanding procedure should only be performed by surgeons 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.

RATIONALE

This policy was updated with a literature review using MEDLINE; most recently through September 20, 2018. Following is a summary of key references to date.

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 SIJ pain is to inform a decision whether to proceed to an 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 SIJ pain?

The following PICOTS were used to select literature to inform this review.

Patients

The relevant population of interest is individuals with SIJ pain.

Interventions

The test being considered is a diagnostic SIJ block.

Comparators

The following practice is currently being used to diagnose SIJ pain: standard of care, which can include provocative tests to induce pain and diagnostic imaging.

Outcomes

The general outcomes of interest are an accurate diagnosis, reductions in pain and medication usage, and improvement in functional outcomes (eg, activities of daily living).

Timing

A diagnostic result should be available within 1 to 2 hours postinjection.

Setting

Sacroiliac blocks are administered under local anesthesia and imaging guidance in an outpatient setting.

Study Selection Criteria

For the evaluation of 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 (describe 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 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).

Manchikanti et al (2013) updated an evidence review with guidelines on the diagnosis of SIJ pain for the American Society of Interventional Pain Physicians.² 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.^{3,4} 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).⁵

Chou et al (2009) conducted 2 systematic reviews at the Oregon Evidence-based Practice Center that informed practice guidelines from the American Pain Society.^{6,7} 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 a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The RCT is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. 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.⁸ 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 (6 randomized, 5 nonrandomized trials) met 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 (2 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)² 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 Test 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 PICOTS were used to select literature to inform this review.

Patients

The relevant population of interest is individuals with SIJ pain.

Interventions

The therapy being considered is a therapeutic corticosteroid injection.

Comparators

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

Outcomes

The general outcomes of interest are symptoms (eg, reductions in pain), functional outcomes, quality of life, reductions in medication use, and treatment-related morbidity.

Timing

Follow-up at 3 to 15 months is of interest to monitor outcomes.

Setting

Patients with SIJ are actively managed by rheumatologists and primary care providers in an outpatient setting.

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 longer 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.⁹ Diagnosis of SIJ pain was based on provocation tests and not SIJ injections. In a blinded assessment, 25 (56%) patients were considered to be successfully treated at the 12-week follow-up visit based on complete relief of pain and improvement in the visual analog scale (VAS) score for pain.

Kim et al (2010) reported a randomized, double-blind, controlled trial of intra-articular prolotherapy compared with a steroid injection for SIJ pain.¹⁰ The trial included 48 patients with SIJ pain. Intra-articular dextrose water prolotherapy or steroid injections were administered under fluoroscopic guidance on a biweekly schedule, with a maximum of 3 injections. Injections were stopped when pain relief was 90% or greater, which required a mean of 2.7 prolotherapy injections and 1.5 steroid injections. Pain (numeric rating scale) and disability (Oswestry Disability

Index [ODI]) scores were assessed at baseline, 2 weeks, and then monthly on completing treatment. At the 2-week follow-up, pain and disability scores were significantly improved in both groups, with no significant difference between groups. The numeric rating scale pain score improved from 6.3 to 1.4 in the prolotherapy group and from 6.7 to 1.9 in the steroid group. At 6 months after treatment, 63.6% of patients in the prolotherapy group remained improved from baseline ($\geq 50\%$), 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 recurrence of severe SIJ pain was 3 months for the steroid group.

Table 1. Characteristics of Key RCTs Assessing Therapeutic Corticosteroid Injection

Study	Countries	Sites	Dates	Participants	Interventions
Visser et al (2013) ⁹	NL	1	NR	Diagnosed with SIJ pain and/or leg pain between 4 wk and 1 y in duration	Active 18 patients randomized to IA injection Comparator 15 patients randomized to PT and 18 to manual therapy
Kim et al (2010) ¹⁰	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; PT: physical therapy; RCT: randomized controlled trial; SIJ: sacroiliac joint.

^a Confirmed by $\geq 50\%$ improvement in response to a single local anesthetic block.

Table 2. Results of Key RCTs Assessing Therapeutic Corticosteroid Injection

Study	Successful Treatment, n/N (%) ^a	NRS Score	ODI Score	6-Month FU, %	15-Month FU (95% CI), %
Visser et al (2013) ⁹					
Overall	25/51 (56)				
Physical therapy	3/15 (20)				
Manual therapy	13/18 (72)				
Intra-articular injection	9/18 (50)				
Kim et al (2010) ¹⁰					
Baseline					
Prolotherapy		6.3	33.9		
Steroid		6.7	35.7		
2-wk FU					
Prolotherapy		1.4	11.1		
Steroid		1.9	15.5		
p			<0.001 for both groups		
Proportion sustaining $\geq 50\%$ improvement from baseline					
Prolotherapy				63.6	
Steroid				27.2	
Cumulative incidence of sustained pain relief					
Prolotherapy					58.7 (37.9 to 79.5)
Steroid					10.2 (6.7 to 27.1)

CI: confidence interval; FU: follow-up; NRS: numeric rating scale; ODI: Oswestry Disability Index; RCT: randomized controlled trial.

^a Based on complete relief of pain and improvement in visual analog scale score for pain.

The purpose of the gaps tables (see Tables 3 and 4) is to display notable gaps 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 evidence supporting the position statement.

Table 3. Relevance Gaps

Study	Population ^a	Intervention ^b	Comparator ^c	Outcomes ^d	Follow-Up ^e
Visser et al (2013) ⁹	4. Patients had additional leg pain with short duration of signs and symptoms				
Kim et al (2010) ¹⁰					

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

^b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.

^c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

^d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.

^e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 4. Study Design and Conduct Gaps

Study	Allocation ^a	Blinding ^b	Selective Reporting ^d	Data Completeness ^e	Power ^d	Statistical ^f
Visser et al (2013) ⁹		1. Trial was single-blinded				
Kim et al (2010) ¹⁰						

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

^b Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.

^c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

^d Follow-Up key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).

^e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

^f Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Case Series

Case series studies evaluating corticosteroid injections, described in systematic reviews, have shown variable findings at generally short-term follow-up.^{8,11}

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 Test Purpose

The purpose of radiofrequency ablation (RFA) is to provide a treatment option that is an alternative to or an improvement on existing therapies in patients with SIJ pain.

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

The following PICOTS were used to select literature to inform this review.

Patients

The relevant population of interest is individuals with SIJ pain.

Interventions

The therapy being considered is RFA.

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, quality of life, reductions in medication use, and treatment-related morbidity.

Timing

Follow-up at 3 and 15 months is of interest to monitor outcomes.

Setting

Patients with SIJ pain are actively managed by spine or musculoskeletal specialists, rheumatologists, and primary care providers in an outpatient setting.

Study Selection Criteria

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

Systematic Reviews

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.¹² 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.¹³ 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 local anesthetic to determine if RFA was indicated for the patient. Seven studies reported follow-up to 3 months; 6 studies reported follow-up to 6 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 6-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.²

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
Sun et al (2018) ¹²	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.

Table 6. Results of Systematic Reviews

Study	NRS Score	VAS Score	ODI Score	GPE Score
Sun et al (2018) ¹²				
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; MD: mean difference; NRS: numerical rating scale; ODI: Oswestry Disability Index; OR: odds ratio; VAS: visual analog scale.

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
Juch et al (2017) ¹⁴	Netherlands	16	2013-2014	Patients with chronic low back pain	Active RF denervation (n=125) Comparator Control group (n=126)
Van Tilburg et al (2016) ¹⁵	Netherlands	NR	2012-2014	Patients with SIJ pain	Percutaneous RF heat lesion (n=30) Sham group (n=30)
Zheng et al (2014) ¹⁶	China	1	2010-2012	Patients with SIJ pain	PSRN with computed tomography guidance (n=82) Celecoxib treatment (n=73)
Patel et al (2012) ¹⁷	U.S.	NR	2008-2010	Patients with SIJ pain	Lateral branch neurotomy (n=34) Sham group (n=17)
Patel et al (2016) ¹⁸	U.S.	NR	NR	Patients with SIJ pain	Lateral branch neurotomy (n=34) Sham group (n=17)

Study	Countries	Sites	Dates	Participants	Interventions
Cohen et al (2008) ¹⁹	U.S.	2	2005-2006	Patients with injection-diagnosed SIJ pain	L4-5 primary dorsal rami S1-3 lateral branch RF denervation after local anesthetic block (n=14) Local anesthetic block followed by placebo denervation (n=14)

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

Table 8. Results of Key RCTs Assessing Radiofrequency Ablation

Study	≥50% Pain Relief (at 1/3/6 mo), %	1-Year Continued Pain Relief, %	Treatment Success at 3 Months, %	Pain Reduction From Baseline (at 12/24 wk), %	Difference in Pain Level Over Time	Mean Decrease in NRS Score	Mean Decrease in ODI Score	Mean Difference in Pain Intensity (95% CI)
Juch et al (2017) ¹⁴								
FJ trial								-0.18 (-0.76 to 0.4)
SIJ trial								-0.71 (-1.35 to -0.06)
Combo trial								-0.99 (-1.73 to -0.25)
Van Tilburg et al (2016) ¹⁵					0.56			
Zheng et al (2014) ¹⁶								
PSRN				65.3/61.1				
Celecoxib				36.2/27.5				
p				<0.001				
Patel et al (2012) ¹⁷								
Neurotomy			47					
Sham			12					
p			0.015					
Patel et al (2016) ¹⁸						2.7 points	13.9	
Cohen et al (2008) ¹⁹								
RF denervation	79/64/57	14						
Placebo	14/0/0							
p	<0.001							

CI: confidence interval; Combo: Combination; FJ: facet joint; NRS: numeric rating scale; ODI: Oswestry Disability Index; PSRN: palisade sacroiliac joint radiofrequency neurotomy; RCT: randomized controlled trial; RF: radiofrequency; SIJ: sacroiliac joint.

Juch et al (2017) reported a nonblinded multicenter RCT of radiofrequency denervation in 228 of 2498 patients with suspected sacroiliac pain who were asked to participate in the trial.¹⁴ Patient selection criteria included body mass index (<35 kg/m²), 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 who had 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.¹⁵ Patients selected had clinically suspected SIJ pain and a decrease of 2 or more points on a 10-point pain scale with a diagnostic sacroiliac block. At 3-month follow-up, there was no statistically significant difference in pain level over time between groups (group by period interaction, $p=0.56$). 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.¹⁶ 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.¹⁷ Twelve-month follow-up was reported in 2016.¹⁸ Fifty-one patients who had a positive response to 2 lateral branch blocks were randomized 2:1 to lateral branch radiofrequency or to sham. At 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 quality of life (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.¹⁸ Of the 9 patients who terminated study participation, 4 (12%) of 34 were considered treatment failures.

The single RCT included in the Aydin meta-analysis was the trial by Cohen et al (2008), which examined the effect of lateral branch radiofrequency denervation with a cooled probe in 28 patients with injection-diagnosed SIJ pain.¹⁹ Two (14%) of 14 patients in the placebo-control group reported pain relief at 1-month follow-up. None reported benefit at 3-month follow-up. Of 14 patients treated with radiofrequency denervation, 11 (79%) reported pain relief at 1 month, 9 (64%) at 3 months, and 8 (57%) at 6 months.

Tables 9 and 10 display notable gaps identified in each study.

Table 9. Relevance Gaps

Study	Population ^a	Intervention ^b	Comparator ^c	Outcomes ^d	Follow-Up ^e
Juch et al (2017) ¹⁴					
Van Tilburg et al (2016) ¹⁵					
Zheng et al (2014) ¹⁶					
Patel et al (2012) ¹⁷					
Cohen et al (2008) ¹⁹					

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

^b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.

^c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

^d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.

^e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 10. Study Design and Conduct Gaps

Study	Allocation ^a	Blinding ^b	Selective Reporting ^d	Follow-Up ^e	Power ^d	Statistical ^f
Juch et al (2017) ¹⁴				1.- 3. Study was not blinded		
Van Tilburg et al (2016) ¹⁵				3. 63.3% of sham group patients crossed over to treatment group		
Zheng et al (2014) ¹⁶		1. Evaluator unaware of patient randomization				
Patel et al (2012) ¹⁷				3. Patients in sham group could cross over at 3 mo		
Cohen et al (2008) ¹⁹				3. Placebo-controlled patients treated with conventional denervation at 1-mo follow-up		

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

^b Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.

^c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

^d Follow-Up key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).

^e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

^f Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Section Summary: Radiofrequency Ablation

The randomized trials of RFA have methodologic limitations; moreover, there is limited data on duration of 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 Test Purpose

The purpose of SIJ fusion/fixation 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 PICOTS were used to select literature to inform this review.

Patients

The relevant population of interest is individuals with SIJ pain.

Interventions

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

Comparators

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

Outcomes

The general outcomes of interest are symptoms (eg, reductions in pain), functional outcomes, quality of life, reductions in medication use, and treatment-related morbidity.

Timing

Follow-up from 1 to 5 years is of interest to monitor outcomes.

Setting

Patients with SIJ pain are actively managed by spine or musculoskeletal specialists, rheumatologists, and primary care providers in an outpatient setting.

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 nonblinded RCT, Investigation of Sacroiliac Fusion Treatment (INSITE) of the iFuse Implant System in 148 patients.²⁰ The 12-month follow-up to this RCT was reported by Polly et al (2015),²¹ and 2-year follow-up was reported by Polly et al (2016).²² 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 6 months. Baseline scores indicated that the patients were severely disabled, with VAS pain scores averaging 82.3 out of 100, and ODI scores averaging 61.9 out of 100 (0=no disability, 100=maximum disability).

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 quality of life (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).²² 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 SIJ pain score and 15 points in 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 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).²³ 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.^{24,25} 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 VAS pain score at 6 months.

All patients assigned to iFuse underwent the procedure, and follow-up at 6 months was available for 49 of 51 patients in the control group and for all 52 patients in the iFuse group. Six-month results as reported by Stuesson et al (2016) are shown in Table 12.²⁴ At 6 months, VAS pain scores improved by 43.3 points in the iFuse group and by 5.7 points in the control group ($p < 0.001$). ODI scores improved by 25.5 points in the iFuse group and by 5.8 points in the control group ($p < 0.001$, between groups). An improvement in lower back pain by at least 20 VAS points (minimal clinically important difference) was achieved in 78.8% of the SIJ fusion group vs 22.4% of controls; $p < 0.001$). Quality of life outcomes showed a greater improvement in the iFuse group than in the control group. Changes in pain medication use were not reported. Patients in the conservative management group were allowed to cross over to SIJ fusion at 6 months.

Twelve-month results from the iMIA trial were reported by Dengler et al (2017) (see Table 13).²⁶ Twenty-one patients in the conservative management group had little or no improvement in symptoms and crossed over to SIJ fusion after the 6-month visit. 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) ²⁰ ; 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
Stuesson et al (2017) ²⁴ ; 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 6-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 ²⁰										
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

Results	VAS Score	Success End Point	ODI Score	SF-36 PCS Score	EQ-5D TTO Index
Change	-52.6 ^a 12.1		-4.9 -30.3 ^a	1.2 12.7	0.05 0.29
iMIA ²⁴					
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)²⁰ and Stuesson et al (2015).²⁴

The success end point 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				
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).²⁶

ODI: Oswestry Disability Index; SD: standard deviation.

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

Table 14. Relevance Gaps

Study; Trial	Population ^a	Intervention ^b	Comparator ^c	Outcomes ^d	Follow-Up ^e
Whang et al (2015) ²⁰ ; INSITE					
Stuesson et al (2017) ²⁴ ; iMIA	1. Patients with other contributory sources of LBP might have been enrolled with SIJ-caused LBP patients				

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps 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 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 15. Study Design and Conduct Gaps

Study; Trial	Allocation ^a	Blinding ^b	Selective Reporting ^d	Data Completeness ^e	Power ^d	Statistical ^f
Whang et al (2015) ²⁰ ; INSITE						
Sturesson et al (2017) ²⁴ ; iMIA		1. Intervention was unblinded				

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

^b Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.

^c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

^d Follow-Up key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).

^e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

^f Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Subsection Summary: Randomized Controlled Trials

Two RCTs have reported outcomes past 6 months, after which crossover was allowed. Both studies reported significantly greater reductions in VAS pain scores and ODI scores in SIJ fusion patients than in control groups. The reductions in pain and disability observed in the SIJ fusion group at 6 months were maintained out to 1 year compared with controls who had not crossed over. The RCTs were nonblinded without a placebo or an active control group. However, 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).^{27,28} 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 end point, which met the prespecified Bayesian probability of success rate. Mean VAS pain scores were 30.0 at 6 months and 30.4 at 12 months. Mean ODI scores were 32.5 at 6 months and 31.4 at 12 months. At 2 years, 149 (87%) of 172 patients were available for follow-up. The VAS pain score at 2 years was 26.0, and the ODI score was 30.9. Thus, 1-year outcomes were maintained at 2 years. Other outcomes (eg, quality of life scores) showed similar maintenance or slight improvement compared with 1-year outcomes. Use of opioid analgesics decreased from 76.2% at baseline to 55% at 2 years. Over the 2-year follow-up, 8 (4.7%) patients required revision surgery.

Table 16. Two- to 3-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) ²⁸				
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	
Sachs et al (2016) ²⁹				
Pain score (range 0-10)	7.5	2.5		
Oswestry Disability Index score		28.2		

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.³⁰ Spain and Holt (2017) reported a retrospective review of surgical revision rates following SIJ fixation with either surgical screws or the iFuse triangular implant.³¹ 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 2 years.^{28,32} One study with a small sample size and good follow-up showed results maintained to 5 years.^{30,33} Improved health outcomes are also supported by retrospective studies that compare SIJ fusion/fixation using a triangular implant with other treatments for SIJ pain.^{30,31} These results are consistent with the medium-term durability of treatment. Analysis of an insurance database reported an overall incidence of complications to be 16.4% at 6 months³⁴ and cumulative revision rate at 4 years of 3.54%.³⁵

Section Summary: SIJ Fusion/Fixation with a Triangular Implant

The evidence on SIJ fusion/fixation with a triangular implant includes 2 nonblinded 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 6 months persist to 2 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 5 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 Fusion/Fixation with a Cylindrical Threaded Implant

Clinical Context and Test 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 PICOTS were used to select literature to inform this review.

Patients

The relevant population of interest is 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, quality of life, reductions in medication use, and treatment-related morbidity.

Timing

Follow-up of 2 years is of interest to monitor outcomes.

Setting

Patients with SIJ pain are actively managed by spine or musculoskeletal specialists, rheumatologists, and primary care providers in an outpatient setting.

Study Selection Criteria

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

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 2 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 ($p < 0.001$). Quality of life 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 1 and 2 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 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 postprocedure, 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 preprocedure 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 2 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/Fusion with 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. Relevant outcomes are test validity, symptoms, functional

outcomes, quality of life, 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. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. In general, the literature on injection therapy of joints in the back is of poor quality. Results from 2 small RCTs showed that therapeutic SIJ steroid injections were not as effective as other active treatments. Larger trials, preferably using sham injections, are needed to determine the degree of benefit of corticosteroid injections over placebo. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have SIJ pain who receive RFA, the evidence includes 4 small RCTs using different radiofrequency applications and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. For RFA with a cooled probe, the 2 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 of 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 nonblinded RCTs of minimally invasive fusion and 2 case series with more than 85% follow-up at 2 to 3 years. Relevant outcomes are symptoms, functional outcomes, quality of life, 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 6 months persist to 2 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 5 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. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. The prospective cohort study will follow patients for 2 years following implantation of slotted screws filled with autologous bone. Results at 1 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 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 North American Spine Society (NASS; 2015) published coverage recommendations for percutaneous sacroiliac joint (SIJ) fusion.³⁹ 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 United States. 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.² 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

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.^{6,7} The guidelines stated that there was insufficient evidence to evaluate 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 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 $\geq 75\%$ 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 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			
NCT01861899 ^a	Treatment of Sacroiliac Dysfunction With SI-LOK® Sacroiliac Joint Fixation System	55	Nov 2018
NCT02270203 ^a	LOIS: Long-Term Follow-Up in INSITE/SIFI	103	Dec 2019
NCT02074761 ^a	Evolution Study Using the Zyga SImmetry Sacroiliac Joint Fusion System	250	Aug 2020
NCT03230279 ^a	Randomized Controlled Trial Of Minimally Invasive Sacroiliac Joint Fusion Compared To Radiofrequency Ablation For Sacroiliac Joint Dysfunction	84	Sep 2023 (withdrawn)

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
27299	Unlisted procedure, pelvis or hip joint
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
M54.6	Pain in thoracic spine

S33.2 Dislocation of sacroiliac and sacrococcygeal joint

S33.6 Sprain of sacroiliac joint

REVISIONS

07-27-2011	Policy added to the bcbsks.com web site.
01-01-2012	In the Coding section: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> Added experimental / investigational language of: "D. Radiofrequency ablation of the sacroiliac joint is considered experimental / investigational."
	Rationale section updated
	In Coding section: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> Added CPT codes: 27280, 0334T Updated coding instructions Added ICD-10 Codes (Effective October 1, 2015)
	References updated
01-01-2015	In Coding section: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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."

	<ul style="list-style-type: none"> ▪ Added Policy Guidelines.
	Updated Rationale section.
	Updated References section.
11-18-2015	<p>In Coding section:</p> <ul style="list-style-type: none"> ▪ Removed notes from ICD-9 codes 724.02 and 724.03.
01-01-2017	<p>Updated Description section.</p> <p>In Policy section:</p> <ul style="list-style-type: none"> ▪ 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.
	<p>In Coding section:</p> <ul style="list-style-type: none"> ▪ Added HCPCS codes G0259 and G0260.
	Updated References section.
04-12-2017	<p>In Policy section:</p> <ul style="list-style-type: none"> ▪ 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	<p>Updated Description section.</p> <p>In Policy section:</p> <ul style="list-style-type: none"> ▪ 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

	<p>experimental / investigational under all other conditions and with any other devices not listed above."</p> <ul style="list-style-type: none"> ▪ Updated Policy Guidelines.
	Updated Rationale section.
	<p>In Coding section:</p> <ul style="list-style-type: none"> ▪ 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	<p>Policy published to the bcbsks.com web site on 08-01-2018 with an effective date of 08-31-2018.</p> <p>In Policy section:</p> <ul style="list-style-type: none"> ▪ 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.
	<p>In Policy section:</p> <ul style="list-style-type: none"> ▪ Updated Policy Guidelines.
	Updated Rationale section.
	<p>In Coding section:</p> <ul style="list-style-type: none"> ▪ Removed coding bullets.
	Updated References section.

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