Diagnosis and Treatment of Sacroiliac Joint Pain

Policy Number: 6.01.23
Origination: 5/2013

Last Review: 7/2019
Next Review: 7/2020

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for diagnosis and treatment of sacroiliac joint when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered
Injection of anesthetic for diagnosing sacroiliac joint pain may be considered medically necessary when the following criteria have been met:

- Pain has failed to respond to 3 months of conservative management, which may consist of therapies such as nonsteroidal anti-inflammatory medications, acetaminophen, manipulation, physical therapy, and a home exercise program; AND
- Dual (controlled) diagnostic blocks with 2 anesthetic agents with differing duration of action are used; AND
- The injections are performed under imaging guidance

Injection of corticosteroid may be considered medically necessary for the treatment of sacroiliac joint pain when the following criteria have been met:

- Pain has failed to respond to 3 months of conservative management, which may consist of therapies such as nonsteroidal anti-inflammatory medications, acetaminophen, manipulation, physical therapy, and a home exercise program; AND
- The injection is performed under imaging guidance; AND
- No more than 3 injections are given in one year

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:

- Pain is at least 5 on a 0 to 10 rating scale that impacts quality of life or limits activities of daily living; AND
There is an absence of generalized pain behavior (eg, somatoform disorder) or generalized pain disorders (eg, fibromyalgia); AND

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

Pain is caudal to the lumbar spine (L5 vertebra), localized over the posterior sacroiliac joint, and consistent with sacroiliac joint pain; AND

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

There is a positive response to a cluster of 3 provocative tests (eg, thigh thrust test, compression test, Gaenslen sign, distraction test, Patrick test, posterior provocation test); AND

Diagnostic imaging studies include ALL of the following:
  o 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
  o Imaging of the pelvis (anteroposterior plain radiograph) rules out concomitant hip pathology; AND
  o 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
  o Imaging of the sacroiliac joint indicates evidence of injury and/or degeneration; AND

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

A trial of a therapeutic sacroiliac joint injection (ie, corticosteroid injection) has been performed on at least once.

When Policy Topic is not covered

Fusion/stabilization of the sacroiliac joint for the treatment of back pain presumed to originate from the SI joint is considered investigational, under all other conditions and with any other devices not listed above.

Radiofrequency denervation of the sacroiliac joint is considered investigational.

Arthrography of the sacroiliac joint is considered investigational.

Considerations

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

This technically demanding procedure should only be done 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.

Conservative nonsurgical therapy for the duration specified should include the following:

- Use of prescription strength analgesics for several weeks at a dose sufficient to induce a therapeutic response
  - Analgesics should include anti-inflammatory medications with or without adjunctive medications such as nerve membrane stabilizers or muscle relaxants AND
- Participation in at least 6 weeks of physical therapy (including active exercise) or documentation of why the patient could not tolerate physical therapy, AND
- Evaluation and appropriate management of associated cognitive, behavioral, or addiction issues
- Documentation of patient compliance with the preceding criteria.

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

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individuals: With suspected sacroiliac joint pain</td>
<td>Interventions of interest are: •Diagnostic sacroiliac joint block</td>
<td>Comparators of interest are: •Standard of care</td>
<td>Relevant outcomes include: •Test validity •Symptoms •Functional outcomes •Quality of life •Medication use •Treatment-related morbidity</td>
</tr>
<tr>
<td>Individuals: With sacroiliac joint pain</td>
<td>Interventions of interest are: •Therapeutic corticosteroid injections</td>
<td>Comparators of interest are: •Physical therapy</td>
<td>Relevant outcomes include: •Symptoms •Functional outcomes •Quality of life •Medication use •Treatment-related morbidity</td>
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<tr>
<td>Individuals: With sacroiliac joint pain</td>
<td>Interventions of interest are: •Radiofrequency ablation</td>
<td>Comparators of interest are: •Conservative therapy</td>
<td>Relevant outcomes include: •Symptoms •Functional outcomes •Quality of life •Medication use •Treatment-related morbidity</td>
</tr>
<tr>
<td>Individuals: With sacroiliac joint pain</td>
<td>Interventions of interest are: •Sacroiliac joint fixation/fusion with a triangular implant</td>
<td>Comparators of interest are: •Conservative therapy</td>
<td>Relevant outcomes include: •Symptoms •Functional outcomes •Quality of life •Medication use •Treatment-related morbidity</td>
</tr>
<tr>
<td>Individuals: With sacroiliac joint pain</td>
<td>Interventions of interest are: •Sacroiliac joint fixation/fusion with a cylindrical threaded implant</td>
<td>Comparators of interest are: •Conservative therapy</td>
<td>Relevant outcomes include: •Symptoms •Functional outcomes •Quality of life •Medication use •Treatment-related morbidity</td>
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</table>

### Summary

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

Clinical input obtained in 2014 supported the use of controlled diagnostic blocks with at least 75% pain reduction for diagnosis of sacroiliac pain. Based on clinical
input and the established use of injections to diagnose pain in other joints, controlled diagnostic (2 blocks with anesthetics of different duration) may be considered medically necessary for the diagnosis of SIJ pain.

**Therapeutic**

For individuals who have SIJ pain who receive therapeutic corticosteroid injections, the evidence includes small randomized controlled trials (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.

Clinical input obtained in 2014 supported the use of corticosteroids for the treatment of SIJ pain. Based on clinical input and the established use of injections to treat pain in other joints, therapeutic (corticosteroid) injections may be considered medically necessary for the treatment of SIJ pain.

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.

Clinical input obtained in 2017 supports that the following indication provides a clinically meaningful improvement in net health outcome and is consistent with generally accepted medical practice:

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

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.

**Background**

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.

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 posterior 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, radiofrequency ablation, 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, SiSymmetry, 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 by the U.S. Food and Drug Administration (FDA) through the 510(k) process. In 2005, the SInergy® (Halyard; formerly Kimberly-Clark), a water-cooled single-use probe, was cleared by the FDA, listing the Baylis Pain Management Probe as a predicate device. The intended use is in conjunction with a radiofrequency generator to create radiofrequency lesions in nervous tissue. FDA product code: GXD.

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

**Rationale**
This evidence review was created in February 2000 and has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through September 20, 2018.

**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. 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. 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. 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).

Chou et al (2009) conducted 2 systematic reviews at the Oregon Evidence-based Practice Center that informed practice guidelines from the American Pain Society. 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. 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) 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. Diagnosis of SIJ pain was based on provocation tests and not SIJ injections. In a blinded assessment, 25 (56%) patients were considered to be successfully treated at the 12-week follow-up visit based on complete relief of pain and improvement in the visual analog scale (VAS) score for pain.

Kim et al (2010) reported a randomized, double-blind, controlled trial of intra-articular prolotherapy (see evidence review 2.01.26) compared with a steroid injection for SIJ pain. 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 (≥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

<table>
<thead>
<tr>
<th>Study</th>
<th>Countries</th>
<th>Sites</th>
<th>Dates</th>
<th>Participants</th>
<th>Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visser et al</td>
<td>NL</td>
<td>1</td>
<td>NR</td>
<td>Diagnosed with SIJ pain and/or leg pain between 4 wk and 1 y in duration</td>
<td>18 patients randomized to IA injection; 15 patients randomized to PT and 18 to manual therapy</td>
</tr>
<tr>
<td>(2013)⁹</td>
<td></td>
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<tr>
<td>Kim et al</td>
<td>Korea</td>
<td>1</td>
<td>NR</td>
<td>Diagnosed with SIJ pain who failed additional 1-mo treatment</td>
<td>24 patients randomized to IA prolotherapy; 23 analyzed; 26 patients randomized to steroid; 26 analyzed</td>
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<tr>
<td>(2010)¹⁰</td>
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</tbody>
</table>

IA: intra-articular; NL: The Netherlands; PT: physical therapy; RCT: randomized controlled trial; SIJ: sacroiliac joint.

*Confirmed by ≥50% improvement in response to a single local anesthetic block.
### Table 2. Results of Key RCTs Assessing Therapeutic Corticosteroid Injection

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

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

<sup>a</sup> 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

<table>
<thead>
<tr>
<th>Study</th>
<th>Population&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Intervention&lt;sup&gt;b&lt;/sup&gt;</th>
<th>Comparator&lt;sup&gt;c&lt;/sup&gt;</th>
<th>Outcomes&lt;sup&gt;d&lt;/sup&gt;</th>
<th>Follow-Up&lt;sup&gt;e&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visser et al (2013)&lt;sup&gt;9&lt;/sup&gt;</td>
<td>4. Patients had additional leg pain with short duration of signs and symptoms</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kim et al (2010)&lt;sup&gt;10&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<sup>a</sup> 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.
Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.

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


Table 4. Study Design and Conduct Gaps

<table>
<thead>
<tr>
<th>Study</th>
<th>Allocation</th>
<th>Blinding</th>
<th>Selective Reporting</th>
<th>Data Completeness</th>
<th>Power</th>
<th>Statistical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visser et al (2013)</td>
<td></td>
<td>1. Trial was single-blinded</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kim et al (2010)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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


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).

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

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.\[^8\] [NA][^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. 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. 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

<table>
<thead>
<tr>
<th>Study</th>
<th>Dates</th>
<th>Trials</th>
<th>Participants</th>
<th>N (Range)</th>
<th>Design</th>
<th>Duration, mo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sun et al (2018)</td>
<td>2008-2017</td>
<td>7</td>
<td>Patients with chronic SIJ pain treated by cooled radiofrequency procedure, followed at least 3 mo</td>
<td>240 (15-190)</td>
<td>4 retrospective observational, 2 RCTs, 1 prospective observational</td>
<td>3-24</td>
</tr>
</tbody>
</table>

SIJ: sacroiliac joint; RCT: randomized controlled trial.

### Table 6. Results of Systematic Reviews

<table>
<thead>
<tr>
<th>Study</th>
<th>NRS Score</th>
<th>VAS Score</th>
<th>ODI Score</th>
<th>GPE Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sun et al (2018)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total N</td>
<td>4 studies; n=81</td>
<td>3 studies; n=150</td>
<td>5 studies; n=103</td>
<td>4 studies; n=75</td>
</tr>
<tr>
<td>MD (95% CI)</td>
<td>3.81 (3.29 to 4.33)</td>
<td>3.78 (3.31 to 4.23)</td>
<td>18.20 (12.22 to 24.17)</td>
<td>OR=0.01 (0.00 to 0.05)</td>
</tr>
<tr>
<td>p</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>I(^2) (p)</td>
<td>46% (0.13)</td>
<td>41% (0.16)</td>
<td>72% (&lt;0.001)</td>
<td>0% (0.92)</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Study</th>
<th>Countries</th>
<th>Sites</th>
<th>Dates</th>
<th>Participants</th>
<th>Interventions</th>
<th>Comparator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Juch et al (2017)</td>
<td>Netherlands</td>
<td>16</td>
<td>2013-2014</td>
<td>Patients with chronic low back pain</td>
<td>RF denervation (n=125)</td>
<td>Control group (n=126)</td>
</tr>
<tr>
<td>Van Tilburg et al</td>
<td>Netherlands</td>
<td>NR</td>
<td>2012-2014</td>
<td>Patients with SIJ pain</td>
<td>Percutaneous RF lesion (n=30)</td>
<td>Sham group (n=30)</td>
</tr>
<tr>
<td>Zheng et al (2014)</td>
<td>China</td>
<td>1</td>
<td>2010-2012</td>
<td>Patients with SIJ pain</td>
<td>PSRN with computed tomography guidance (n=82)</td>
<td>Celecoxib treatment (n=73)</td>
</tr>
<tr>
<td>Patel et al (2012)</td>
<td>U.S.</td>
<td>NR</td>
<td>2008-2010</td>
<td>Patients with SIJ pain</td>
<td>Lateral branch neurotomy (n=34)</td>
<td>Sham group (n=17)</td>
</tr>
<tr>
<td>Patel et al</td>
<td>U.S.</td>
<td>NR</td>
<td>NR</td>
<td>Patients</td>
<td>Lateral branch</td>
<td>Sham group (n=17)</td>
</tr>
<tr>
<td>Study</td>
<td>Pain Relief at 1/3/6 mo, %</td>
<td>Treatment Success at 3 Months, %</td>
<td>Pain Reduction From Baseline at 12/24 wk, %</td>
<td>Difference in Pain Level Over Time</td>
<td>Mean Decrease in NRS Score</td>
<td>Mean Decrease in ODI Score</td>
</tr>
<tr>
<td>---------------------------</td>
<td>----------------------------</td>
<td>---------------------------------</td>
<td>---------------------------------------------</td>
<td>-----------------------------------</td>
<td>---------------------------</td>
<td>---------------------------</td>
</tr>
<tr>
<td>Juch et al (2017)¹⁴</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FJ trial</td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>SIJ trial</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>Combo trial</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Van Tilburg et al (2016)¹⁵</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zheng et al (2014)¹⁶</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PSRN</td>
<td>65.3/61.1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Celecoxib</td>
<td>36.2/27.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patel et al (2012)¹⁷</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neurotomy</td>
<td>47</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sham</td>
<td>12</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patel et al (2016)¹⁸</td>
<td></td>
<td>0.015</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cohen et al (2008)¹⁹</td>
<td>79/64/5714</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RF denervation</td>
<td>14/0/0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Placebo</td>
<td></td>
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</tr>
</tbody>
</table>

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.\textsuperscript{14} Patient selection criteria included body mass index (<35 kg/m\textsuperscript{2}), age (<70 years old), and pain reduction of at least 50% within 30 to 90 minutes of receiving a diagnostic sacroiliac block (n=228). An additional 202 patients 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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{17} Twelve-month follow-up was reported in 2016.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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**

<table>
<thead>
<tr>
<th>Study</th>
<th>Population\textsuperscript{a}</th>
<th>Intervention\textsuperscript{b}</th>
<th>Comparator\textsuperscript{c}</th>
<th>Outcomes\textsuperscript{d}</th>
<th>Follow-Up\textsuperscript{e}</th>
</tr>
</thead>
<tbody>
<tr>
<td>Juch et al (2017)\textsuperscript{14}</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Van Tilburg et al (2016)\textsuperscript{15}</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Zheng et al (2014)\textsuperscript{16}</td>
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<td></td>
<td></td>
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<tr>
<td>Patel et al (2012)\textsuperscript{17}</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>Cohen et al (2008)\textsuperscript{19}</td>
<td></td>
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<td></td>
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</tr>
</tbody>
</table>

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

\textsuperscript{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.

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

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

\textsuperscript{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.

\textsuperscript{e} Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

**Table 10. Study Design and Conduct Gaps**

<table>
<thead>
<tr>
<th>Study</th>
<th>Allocation\textsuperscript{a}</th>
<th>Blinding\textsuperscript{b}</th>
<th>Selective Reporting\textsuperscript{c}</th>
<th>Follow-Up\textsuperscript{e}</th>
<th>Power\textsuperscript{f}</th>
<th>Statistical\textsuperscript{g}</th>
</tr>
</thead>
<tbody>
<tr>
<td>Juch et al (2017)\textsuperscript{14}</td>
<td></td>
<td></td>
<td></td>
<td>1.- 3. Study was not blinded</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Van Tilburg et al (2016)\textsuperscript{15}</td>
<td></td>
<td></td>
<td></td>
<td>3. 63.3% of sham group patients crossed over to treatment group</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patel et al (2012)\textsuperscript{17}</td>
<td></td>
<td></td>
<td></td>
<td>3. Patients in sham group could cross over at 3 mo</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cohen et al</td>
<td></td>
<td></td>
<td></td>
<td>3. Placebo-controlled patients</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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. The 12-month follow-up to this RCT was reported by Polly et al (2015), and 2-year follow-up was reported by Polly et al (2016). 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). 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). 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. 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 Sturesson et al (2016) are
shown in Table 12. 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). 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

<table>
<thead>
<tr>
<th>Study; Trial</th>
<th>Countries</th>
<th>Sites</th>
<th>Dates</th>
<th>Participants</th>
<th>Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whang et al (2015) ; INSITE</td>
<td>U.S.</td>
<td>19</td>
<td>2013-2014</td>
<td>Patients 21-70 y with confirmed diagnosis of unilateral or bilateral SIJ dysfunction due to degenerative sacroiliitis and/or SIJ disruption</td>
<td>102 randomized to SIJ fusion</td>
</tr>
<tr>
<td>Sturesson et al (2017) ; iMIA</td>
<td>EU (Belgium, Germany, Italy, Sweden)</td>
<td>9</td>
<td>2013-2015</td>
<td>Patients 21-70 y with LBP for &gt;6 mo and diagnosed with SIJ as primary pain generatora</td>
<td>52 randomized to SIJ fusion</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Results</th>
<th>VAS Score</th>
<th>Success End Point</th>
<th>ODI Score</th>
<th>SF-36 PCS Score</th>
<th>EQ-5D TTO Index</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ctl</td>
<td>iFuse</td>
<td>Ctl</td>
<td>iFuse</td>
<td>Ctl</td>
</tr>
<tr>
<td>INSITE</td>
<td>20</td>
<td>Baseline</td>
<td>82.2</td>
<td>82.3</td>
<td>61.1</td>
</tr>
<tr>
<td></td>
<td>Follow-up</td>
<td>70.4</td>
<td>29.8</td>
<td>23.9%</td>
<td>56.4</td>
</tr>
<tr>
<td></td>
<td>Change</td>
<td>-12.1</td>
<td>-52.6</td>
<td>81.4%a</td>
<td>-4.9</td>
</tr>
<tr>
<td>iMIA</td>
<td>24</td>
<td>Baseline</td>
<td>73.0</td>
<td>77.7</td>
<td>3.9</td>
</tr>
<tr>
<td></td>
<td>Follow-up</td>
<td>67.8</td>
<td>34.4</td>
<td>-24.1</td>
<td>56.9</td>
</tr>
</tbody>
</table>
Adapted from Whang et al (2015)\textsuperscript{20}, and Sturesson et al (2015).\textsuperscript{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.

\textsuperscript{a} p<0.001.

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

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

Adapted from Dengler et al (2017).\textsuperscript{26}

ODI: Oswestry Disability Index; SD: standard deviation.

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

### Table 14. Relevance Gaps

<table>
<thead>
<tr>
<th>Study; Trial</th>
<th>Population\textsuperscript{a}</th>
<th>Intervention\textsuperscript{b} Comparator\textsuperscript{c}</th>
<th>Outcomes\textsuperscript{d}</th>
<th>Follow-Up\textsuperscript{e}</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whang et al (2015)\textsuperscript{20}; INSITE</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sturesson et al (2017)\textsuperscript{24}; iMIA</td>
<td>1. Patients with other contributory sources of LBP might have been enrolled with SIJ-caused LBP patients</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.

\textsuperscript{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.

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

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

\textsuperscript{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.

\textsuperscript{e} Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.
### Table 15. Study Design and Conduct Gaps

<table>
<thead>
<tr>
<th>Study/Trial</th>
<th>Allocation</th>
<th>Blinding</th>
<th>Selective Reporting</th>
<th>Data Completeness</th>
<th>Power</th>
<th>Statistical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whang et al (2015)°; INSITE</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sturesson et al (2017)°; iMIA</td>
<td></td>
<td></td>
<td>1. Intervention was unblinded</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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


° 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).

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

° 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).° NA°. 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**

<table>
<thead>
<tr>
<th>Studies and Outcomes</th>
<th>Mean Baseline Value</th>
<th>Mean 2- to 3-Year Value</th>
<th>Difference or % Achieving Outcome</th>
<th>Follow-Up Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain score (range, 0-100)</td>
<td>79.8</td>
<td>26.0</td>
<td>53.3</td>
<td>86.6% (149/172)</td>
</tr>
<tr>
<td>Oswestry Disability Index score</td>
<td>55.2</td>
<td>30.9</td>
<td>24.5</td>
<td></td>
</tr>
<tr>
<td>SF-36 score</td>
<td>31.7</td>
<td>40.7</td>
<td>8.9</td>
<td></td>
</tr>
<tr>
<td>EQ-5D TTO score</td>
<td>0.43</td>
<td>0.71</td>
<td>0.27</td>
<td></td>
</tr>
<tr>
<td>Pain score (range 0-10)</td>
<td>7.5</td>
<td>2.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oswestry Disability Index score</td>
<td>28.2</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

**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,NA32. One study with a small sample size and good follow-up showed results maintained to 5 years.30,NA33. 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,NA31. 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). 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. 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. 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**

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


**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

Objective
Clinical input is sought to help determine the appropriate use in clinical practice of sacroiliac joint fusion for patients with sacroiliac joint pain.
Respondents
Clinical input was provided by the following specialty societies and physician members identified by a specialty society or health system:

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

\(^a\) Indicates that information was not provided regarding conflicts of interest related to the topic where clinical input is being sought.

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

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

Figure 1:

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

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

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

**Additional Comments**

- “The evaluation of a patient for possible sacroiliac (SI) joint pain involves careful attention to a patient’s history and physical examination. When a patient’s symptoms and signs arouse sufficient clinical suspicion, additional tests are then required to confirm the diagnosis of SI joint dysfunction.” (AANS/CNS)

- “Proper SIJ pain diagnosis is key to appropriate patient management. There is an accepted diagnostic algorithm for SIJ pain that combines medical history, physical examination and confirmatory diagnostic SIJ block.” (ISASS)

- “The North American Spine Society’s coverage recommendations on SI joint fusion provides evidence-based criteria for diagnosing SI joint pain and selection criteria for surgical intervention.” (NASS/AAOS)

- “The North American Spine Society Criteria are the most respected and generally used criteria. Most patients with SI joint pain will respond to the conservative therapies listed. However, one criteria that I think should be added is a reduction in opioid use prior to the fusion.” (APS)
“SI fusion is currently acceptable therapy in patients in whom significant response is noted with injection. SI joint fusion as part of the inferior portion of extensive thoracolumbar fusion (IE SI joint and pelvis) is an accepted approach. Increasing literature on the topic will enhance the knowledge base on this topic.” (Neil Malhotra, MD identified by Hospital of the University of Pennsylvania)

“The only generally accepted objective criteria for the diagnosis of sacroiliac joint pain is response to image-guided sacro-iliac injections. Patients who do not respond to the injections generally do not improve with directed therapies. Patients who do improve with the injections will usually respond to fusion therapies.” (William Welch, MD identified by Hospital of the University of Pennsylvania)

“Although criteria for the diagnosis of SI joint dysfunction is fairly well described, there is significant variability from study to study regarding the application of the diagnostic criteria. It is difficult to assess the efficacy of a treatment such as SI joint fusion when there is not a clearly defined and consistent manner of diagnosis from study to study. The vast majority of literature regarding outcomes following SI joint fusion surgery are low-quality retrospective studies, or small sample size prospective studies with limited follow-up.” (Zachary Gordon, MD identified by University Hospitals Cleveland Medical Center)

“While the evidence is low, I agree with the NASS recommendations as outlined in their report particularly focusing on the fact that a patient has undergone and failed a minimum 6 months of intensive nonoperative treatments, the patient has a complaint and physical exam consistent with SIJ pain, imaging of the SI joint that excludes the presence of destructive lesions, at least 75% reduction of pain for the expected duration of the anesthetic used following an image-guided, contrast-enhanced intra-articular SIJ injection on 2 separate occasions and finally a successful trial of at least one therapeutic intra-articular SIJ injection with a corticosteroid.” (A. Alex Jahangir, MD identified by Vanderbilt University Medical Center)

See Appendix 1 and 2 for details.

SUPPLEMENTAL INFORMATION

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

2017 Input
In response to requests, clinical input focused on sacroiliac joint (SIJ) fusion was received from 10 respondents, including 5 specialty society-level responses from 7
specialty societies (2 were joint society responses) and 5 physician-level responses from 4 academic centers while this policy was under review in 2017.

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

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

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

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

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

Practice Guidelines and Position Statements

North American Spine Society
The North American Spine Society (NASS; 2015) published coverage recommendations for percutaneous sacroiliac joint (SIJ) fusion. 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. 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. 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. 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. Society recommendations indicated that patients who met all of the following criteria may be eligible for minimally invasive SIJ fusion:

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

**National Institute for Health and Care Excellence**
The National Institute for Health and Care Excellence (2017) guidance on minimally invasive SIJ fusion surgery for chronic sacroiliac pain included the following recommendations:

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

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

1.3 This technically challenging procedure should only be done by surgeons who regularly use image-guided surgery for implant placement. The surgeons should
also have had specific training and expertise in minimally invasive SI joint fusion surgery for chronic SI pain."\(^{43}\).

**U.S. Preventive Services Task Force Recommendations**

Not applicable.

**Medicare National Coverage**

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this policy are listed in Table 18.

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCT01861899(^a)</td>
<td>Treatment of Sacroiliac Dysfunction With SI-LOK® Sacroiliac Joint Fixation System</td>
<td>55</td>
<td>Nov 2018</td>
</tr>
<tr>
<td>NCT02270203(^a)</td>
<td>LOIS: Long-Term Follow-Up in INSITE/SIFI</td>
<td>103</td>
<td>Dec 2019</td>
</tr>
<tr>
<td>NCT02074761(^a)</td>
<td>Evolusion Study Using the Zyga Simetry Sacroiliac Joint Fusion System</td>
<td>250</td>
<td>Aug 2020</td>
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<tr>
<td>NCT03230279(^a)</td>
<td>Randomized Controlled Trial Of Minimally Invasive Sacroiliac Joint Fusion Compared To Radiofrequency Ablation For Sacroiliac Joint Dysfunction</td>
<td>84</td>
<td>Sep 2023 (withdrawn)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

\(^a\) Denotes industry-sponsored or cosponsored trial.

**REFERENCES**


35. Cher DJ, Reckling WC, Capobianco RA. Implant survivorship analysis after minimally invasive sacroiliac joint fusion using the iFuse Implant System((R)). Med Devices (Auckl). Dec 2015;8:485-492. PMID 26648762


Billing Coding/Physician Documentation Information

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, sacroiliac joint (including obtaining graft)
Injection(s), anesthetic agent(s) and/or steroid; nerves innervating the sacroiliac joint, with image guidance (ie, fluoroscopy or computed tomography)

Radiofrequency ablation, nerves innervating the sacroiliac joint, with image guidance (ie, fluoroscopy or computed tomography)

Injection procedure for sacroiliac joint; arthrography

Injection procedure for sacroiliac joint; provision of anesthetic, steroid and/or other therapeutic agent, with or without arthrography

**ICD-10 Codes**

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
M54.30- Sciatica; code range
M54.32
M54.40- Lumbago with sciatica; code range
M54.42
M54.5 Lower back pain
M54.6 Pain in thoracic spine
S33.2 Dislocation of sacroiliac and sacrococcygeal joint
S33.6 Sprain of sacroiliac joint

The CPT code for injection into the sacroiliac joint is:

27096: Injection procedure for sacroiliac joint, anesthetic/steroid, with image guidance (fluoroscopy or CT) including arthrography when performed

Code 27096 is used only if the computed tomography or fluoroscopic imaging is used to confirm the intra-articular needle positioning.

There is no specific CPT code for radiofrequency ablation of the sacroiliac joint. Code 27299 – unlisted procedure, pelvis or hip joint – would likely be used.

There is a CPT category I code for percutaneous or minimally invasive stabilization:

27279: Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device.

Open sacroiliac joint arthrodesis would be reported with CPT code 27280 – Arthrodesis, open, sacroiliac joint, including obtaining bone graft, including instrumentation, when performed.
For both codes 27279 and 27280, if the procedure is performed bilaterally, the codes would be reported with a -50 modifier.

**Additional Policy Key Words**
N/A

**Policy Implementation/Update Information**

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
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<tr>
<td>5/1/13</td>
<td>New policy; considered investigational. Policy statement regarding sacroiliac joint fusion included from previous policy 7.01.509 Sacroiliac Joint Fusion for the Treatment of Low Back Pain.</td>
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<tr>
<td>5/1/14</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>3/1/15</td>
<td>Titled changed from Surgical Treatment for Sacroiliac Joint Pain to Diagnosis and Treatment of Sacroiliac Joint Pain. Added medically necessary policy statement for controlled diagnostic injections and for therapeutic injections with corticosteroid. Added investigational statement regarding Arthrography. CPT and HCPCS coding update.</td>
</tr>
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<td>7/1/15</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>7/1/16</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>7/1/17</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>2/1/18</td>
<td>SIJ fusion/stabilization with a titanium triangular implant is considered medically necessary under the specific conditions outlined by NASS.</td>
</tr>
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<td>7/1/18</td>
<td>No policy statement changes.</td>
</tr>
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<td>7/1/19</td>
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**APPENDIX**

**APPENDIX 1: CLINICAL INPUT**

**Appendix Table 1. Respondent Profile**

<table>
<thead>
<tr>
<th>Specialty Society</th>
<th>Name of Organization / Name of Organization</th>
<th>Clinical Specialty</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>American Association of Neurological Surgeons / Congress of Neurological Surgeons</td>
<td>Neurosurgery</td>
</tr>
<tr>
<td>2</td>
<td>International Society for the Advancement of Spine Surgery</td>
<td>Spine Surgery</td>
</tr>
<tr>
<td>4</td>
<td>American Society of Regional Anesthesia and Pain Medicine</td>
<td>Regional Anesthesia and Pain Medicine</td>
</tr>
<tr>
<td>5</td>
<td>American Pain Society</td>
<td>Pain Medicine</td>
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**Physician**

<table>
<thead>
<tr>
<th>No.</th>
<th>Name</th>
<th>Degree</th>
<th>Name of Organization</th>
<th>Clinical Specialty</th>
<th>Board Certification and Fellowship Training</th>
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</thead>
<tbody>
<tr>
<td>6</td>
<td>Neil R. Malhotra</td>
<td>MD</td>
<td>Hospital of the University of Pennsylvania</td>
<td>Neurosurgery</td>
<td>Neurosurgery</td>
</tr>
<tr>
<td>7</td>
<td>William Welch</td>
<td>MD</td>
<td>Hospital of the University of Pennsylvania</td>
<td>Neurosurgery</td>
<td>Neurosurgery, Spinal Surgery</td>
</tr>
<tr>
<td>8</td>
<td>Zachary L. Gordon</td>
<td>MD</td>
<td>University Hospitals Cleveland Medical Center</td>
<td>Spine Surgery</td>
<td>ABOS Certified, Fellowship Spine Surgery at University of Pittsburgh Medical Center</td>
</tr>
<tr>
<td>9</td>
<td>A. Alex Jahangir</td>
<td>MD</td>
<td>Vanderbilt University Medical</td>
<td>Orthopaedic Surgery</td>
<td>Orthopaedic Surgery / Orthopaedic Surgery</td>
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</table>
### Appendix Table 2. Respondent Conflict of Interest Disclosure

<table>
<thead>
<tr>
<th>No.</th>
<th>1. Research support related to the topic where clinical input is being sought</th>
<th>2. Positions, paid or unpaid, related to the topic where clinical input is being sought</th>
<th>3. Reportable, more than $1,000, health care–related assets or sources of income for myself, my spouse, or my dependent children related to the topic where clinical input is being sought</th>
<th>4. Reportable, more than $350, gifts or travel reimbursements for myself, my spouse, or my dependent children related to the topic where clinical input is being sought</th>
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</thead>
<tbody>
<tr>
<td>1</td>
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<td>No</td>
<td>No</td>
<td>No</td>
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<td>2</td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>Yes/No</td>
<td>Yes/No</td>
</tr>
<tr>
<td></td>
<td>Participated in INSITE, an SI-BONE sponsored randomized trials. Institution received support for trial but no personal support received. Designed and coauthored paper on the work intensity of MIS SIJ fusion organized by SI-Bone Inc., but received no remuneration. Institution is paid for a research study on MIS SIJ fusion.</td>
<td>Paid for teaching courses for Zyga.</td>
<td>Owns intellectual property in Transformer Spine.</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
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<table>
<thead>
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<th>No.</th>
<th>Conflicts of Interest Policy Statement</th>
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<tbody>
<tr>
<td>3</td>
<td>The North American Spine Society (NASS) employs rigorous checks and balances to ensure that its comments and recommendations on payors’ coverage policies/clinical evidence reports are scientifically sound and unbiased. These checks and balances include requiring all individuals involved in drafting, reviewing, revising and approving the comments to disclose any conflicts of interest he or she may have. Using an evidence-based approach when possible, the multi-disciplinary team works together to develop the comments which requires multiple levels of review. The individuals who provide the final reviews and approvals are further required to divest themselves of most financial interests in any medical industry-related concerns. For more information on NASS’ Level 1 disclosure policy, please visit NASS website.</td>
</tr>
</tbody>
</table>

Individual physician respondents answered at individual level. Specialty Society respondents provided aggregate information that may be relevant to the group of clinicians who provided input to the Society-level response.

NR: not reported.

### APPENDIX 2: CLINICAL INPUT RESPONSES

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

1. For individuals with sacroiliac joint pain, are there objective condition characteristics (ie, patient selection criteria) and management criteria (ie, regarding prior trial of standard treatment options) that would describe use of SIJ fusion that improves health outcomes and is considered in accordance with generally accepted medical practice? If Yes, please explain:

<table>
<thead>
<tr>
<th>No.</th>
<th>Yes/No</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Yes</td>
<td>Objective Condition Characteristics for SI Joint Fusion – The evaluation of a patient for possible sacroiliac (SI) joint pain involves careful attention to a patient’s history and physical examination. When a patient’s symptoms and signs arouse sufficient clinical suspicion, additional tests are then required to...</td>
</tr>
</tbody>
</table>
Diagnosis and Treatment of Sacroiliac Joint Pain 6.01.23

Several studies suggest that a history of lumbar or lumbosacral fusion may predispose a patient to develop SI joint pain. As such, a physician should consider a diagnosis of SI joint dysfunction in patients with new or persistent back pain complaints after a lumbar fusion. Analyzing a cohort of patients with SI joint pain after fusion, Maigne et al. found that these patients tended to have post-operative pain that had a different character from the pre-operative complaints and a pain-free interval of at least 3 months between surgery and the onset of new symptoms. Other studies analyzing a similar cohort of recurrent pain localized to the SI joint after lumbar fusion found that these patients tended to have inadequately restored lumbar lordosis (Shin et al.) and increased pelvic tilt with more significant retroversion of the pelvis compared to asymptomatic individuals (Cho et al.). Unoki et al. showed that fusion of multiple segments (at least 3) also had an increased risk for developing SI joint pain after lumbar surgery. Based on these studies, a history of lumbar fusion with recurrent pain complaints should arouse a healthy suspicion of SI joint dysfunction especially in patients with long-segment constructs or with suboptimal correction of spinopelvic parameters.

Lastly, it is important to conduct a thorough medical history to screen for conditions causing SI joint pathology that cause pain but are unlikely to respond to surgical stabilization of the joint (eg, inflammatory arthropathy, metastatic disease, residual pain from recent trauma).

Physical Examination

In addition to a convincing history of SI joint dysfunction, several findings on physical examination justify continued evaluation of the SI joint as a cause of back and leg pain. Recreation of a patient’s pain complaints during provocative maneuvers over the SI joint correlates closely with a diagnosis of SI joint dysfunction by SI block. Provocative maneuvers include Patrick test, iliac distraction, iliac compression, thigh thrust, and Gaenslen test. A positive response to three or more maneuvers is highly suggestive of SI joint pain that can be relieved by SI joint block. Additional physical examination findings suggestive of SI joint dysfunction include the Fortin finger test (in which the patient is asked to point to the location of most severe pain and identifies the sacral sulcus) and tenderness to palpation over the sacral sulcus.

Imaging:

No imaging studies have been shown to identify sacroiliac dysfunction reliably. X-rays, CT scans, and MRI scans of the SI joint often show a relatively normal appearance even in patients with diagnosed SI joint dysfunction. Nonetheless, X-rays and/or CT scans of the SI joint are important for ruling out confounding sources of pain (fracture, tumor, severe arthropathy, hip pathology). MRI of the lumbar spine is important to rule out spine pathology as a competing cause of back pain.

Response to SI Joint Block

Image-guided SI joint blockade using injection of local anesthetic is widely regarded as the gold standard for diagnosing SI joint dysfunction. This is supported in the fact that all randomized controlled studies on SI joint fusion and most case series use relief of pain with SI joint block as a major inclusion criterion. The majority of studies recommend pain relief of at least 75% after multiple SI joint blocks, and confirmed on repeat injection. Using this criterion as justification for performing SI joint fusion, the available literature shows a significant and durable relief of pain complaints after SI fusion. Nonetheless, an analysis by Polly et al. suggests that requiring a treatment effect of greater than 75% after an SI joint block to establish a diagnosis is too restrictive. In this study, patients experiencing only 50-75% relief of symptoms after a block have excellent outcomes with rates equivalent to the higher standard for treatment effect.


Management Criteria for SI Joint Fusion –

Prior to being a candidate for surgical intervention, patients must first attempt conservative management of their pain complaints. These non-surgical modalities are similar in many ways to the management of back pain thought to be caused by lumbar spondylosis. Patients must undergo a course of physical therapy and medical management with NSAIIDs. Patients should also be counseled about smoking cessation, as there is some evidence that smoking may exacerbate pain complaints as well as negatively impact response to SI fusion. Some patients receive benefit from pelvic belt stabilization and bracing. Generally non-surgical management for at least 6 months before considering surgical fusion is recommended.

There are two nonoperative interventional procedures available to patients experiencing SI joint dysfunction: SI joint steroid injections and radiofrequency ablation. SI joint injection with corticosteroids has been proposed and studied as a way to relieve pain from SI joint dysfunction. While there is not clear evidence to recommend steroid injections as the most effective or durable treatment for pain, it may help provide symptomatic relief during the interval of medical management. SI Joint radiofrequency ablation has also been well-studied for relief of SI joint pain. Studies indicate this treatment can offer a slightly greater durability of response compared to steroid injections but the effect is still transient for most patients. A study by Vanaclocha et al. compares these interventions and SI joint fusion and shows clear superiority of fusion over SI injection and nerve ablation for effective and durable pain relief. For these reasons, steroid injections and nerve ablations are not required in order to proceed with fusion but may offer relief to patients unwilling or unable to proceed with fusion.
**Diagnosis and Treatment of Sacroiliac Joint Pain** 6.01.23

### Indications/Limitations for MIS SIJ Fusion

Per the ISASS Policy Statement(7) on minimally invasive sacroiliac joint (MIS SIJ) fusion surgery, patients who have all of the following criteria may be eligible for MIS SIJ fusion:

- Significant SIJ pain that impacts quality of life or significantly limits activities of daily living;
- SIJ pain confirmed with at least 3 physical examination maneuvers that stress the SIJ (see list provided above) and reproduce the patient’s typical pain.
- Confirmation of the SIJ as a pain generator with ≥50% acute decrease in pain upon fluoroscopically-guided diagnostic intra-articular SIJ block using local anesthetic. Prospective trials have shown that patients with SIJ pain responses of 50-75% respond to MIS SIJ fusion as well as those with 75-100% acute responses. (There is no evidence that the SIJ block provides long-term pain relief and should be conducted for diagnostic, not therapeutic, purposes.)
- Failure to respond to at least 6 months of non-surgical treatment consisting of non-steroidal anti-inflammatory drugs and 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. Physicians should take into account that patients can have multiple pain generators and addressing just one pain generator may not adequately relieve disability or all back pain.

MIS SIJ fusion is NOT indicated for patients with the following:

- Less than 6 months of SIJ pain and/or functional impairment
- Failure to pursue conservative treatment of the SIJ (unless contra-indicated);
- Pain not confirmed with a diagnostic SIJ block;

---

**No.** | **Yes/No** | **Explanation**
---|---|---
2 | Yes | Reference numbers cited in parentheses refer to list of publications included in response to Question 4.

Proper SIJ pain diagnosis is key to appropriate patient management. There is an accepted diagnostic algorithm for SIJ pain that combines medical history, physical examination and confirmatory diagnostic SIJ block.

### Medical History

Patients with SIJ pain typically report pain in the buttock(s), with possible radiation into the groin or upper legs. The spectrum of pain and disability from SIJ dysfunction is wide. Patients may be affected mildly or may have substantial functional impairment (eg, cannot sit or stand for more than five minutes, cannot perform normal activities of daily living (ADLs), cannot walk up or down stairs, may require a wheelchair). Patients report the following activities to worsen pain: sitting on affected side; lying on affected side; rolling over in bed; ascending or descending stairs; getting in/out of a car. Patients with chronic SIJ dysfunction seeking surgical treatment have marked impairment of quality of life.(1) similar to that observed in other conditions commonly treated surgically.(2)

Patients often have a history of prior lumbar fusion, either because the condition was misdiagnosed (the wrong joint was operated on) or as a result of adjacent segment degeneration of the SI joint.

### Physical Examination

Specific physical examination tests that stress the SIJ (eg, distraction test, compression test, thigh thrust, FABER (Patrick's) test, Gaenslen's maneuver) are typically performed in the physician's office. A meta-analysis of physical examination tests suggests that having 3 or more positive tests is highly predictive of a positive diagnostic SI joint block.(3)

### Diagnostic SIJ Block

The diagnosis of SIJ pain is confirmed by performing a fluoroscopy-guided percutaneous SIJ block with local anesthetic (eg, lidocaine). An acute reduction in typical pain indicates a positive test, suggesting that the injected joint is a pain generator. A study of patients undergoing blinded injection of saline or local anesthetic showed markedly high responses to the latter, validating the test.(4) Because other pathologic processes can coexist with SIJ pain, physicians should discuss with patients the degree to which treatment of the SIJ may relieve overall pain and disability without addressing other pain generators.

While a marked response to SIJ block might be predicted to reassure the physician that treatment will produce larger responses to anatomic-based treatment, published data suggest little, if any, relationship. In two large prospective clinical trials of SIJ fusion, patients with suspected SIJ pain were included only if intra-articular SIJ block resulted in a 50% or greater amount of acute pain relief within 60 minutes after the block. The degree of improvement at 6 and 12 months after SIJ fusion was unrelated to the degree of acute pain relief during the block.(5)

### Imaging

Apart from ankylosing spondylitis, in which MRI can show edema consistent with inflammation, imaging of the SIJ typically does not provide valuable diagnostic information. In many cases, imaging can show non-specific findings in the SIJ.6 Rather, imaging is used to ensure that the patient does not have alternative diagnoses that could mimic SIJ pain (eg, hip osteoarthritis, occasionally L5/S1 spine degeneration).

### Bilateral SIJ Pain

Bilateral SIJ pain is not uncommon. Diagnosis of bilateral SIJ pain must be made on the basis of a history of bilateral pain, bilateral elicitation of pain on physical examination maneuvers that stress each SIJ, and acute bilateral decrease in pain upon CT or fluoroscopy-guided intra-articular SIJ block with local anesthetic. Bilateral SIJ fusion is probably best performed serially as successful treatment of one side may improve pain/disability to a degree acceptable by the patient. SIJ fusion of the contralateral side may be necessary if contralateral SIJ pain continues and disability is significant for the patient.

It is expected that a person would not undergo more than one SIJ fusion per side per lifetime except in the rare case that a revision is needed.

---

The North American Spine Society's coverage recommendations on SI joint fusion provides evidence-based criteria for diagnosing SI joint pain and selection criteria for surgical intervention. The excerpt below is from the NASS statement:

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. Patients report typically unilateral pain that is caudal to the lumbar spine (L5 vertebrae), 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 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. somatiform disorder) or generalized pain disorders (eg. fibromyalgia)
6. Diagnostic imaging studies that include ALL of the following:
   a. Imaging (plain radiographs and a CT or MRI) 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 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 percent reduction of pain for the expected duration of the anesthetic used following an image-guided, contrast-enhanced intra-articular SIJ injection on two separate occasions
8. A trial of at least one therapeutic intra-articular SIJ injection (ie, corticosteroid injection)

Reference numbers cited in parentheses refer to list of publications included in response to Question 4.

We have reviewed the BlueCross BlueShield Diagnosis and Treatment of Sacroiliac Joint Pain, Summary of Evidence. In general, this is a well-written, comprehensive review, but we have the following comments that should be considered.

**Diagnosis:** The document is correct in asserting that there is no other “reference standard” for identifying a painful sacroiliac (SI) joint besides a diagnostic injection. Many pain medicine organizations consider it to be “self-evident” that a positive response to a diagnostic block indicates a painful joint (eg. Spine Intervention Society, American Society of Interventional Pain Physicians), but we know from multiple studies performed for not only SI joint pain (references: 10, 14, 19, 18, 26, 15), but also lumbar and cervical facet pain, that there is a considerable false-positive rate for uncontrolled blocks. These studies have mostly considered failure of a 2nd block to provide adequate relief after a 1st block did provide relief to be evidence of a false-positive response, but without another reference standard, one cannot ascertain whether the positive block was a false-positive, or the negative block was a false-negative.

The authors also state that there is no reference standard besides injections, but multiple investigators have found a strong correlation (> 80% sensitivity and >75% specificity) between response to blocks and ≥ 3 positive provocation maneuvers (references: 25, 26, 14, 31, 2, 24). This provides indirect confirmatory evidence for the validity of diagnostic injections.

**iFuse:** This is a minimally-invasive surgical technique designed to treat degenerative SIJ arthritis and instability; it is not intended to treat extra-articular SI joint pain, which is the target population of radiofrequency ablation (the lateral branches innervate the SI joint capsule; reference 5). The SI joint is ligamented for stability and there is relatively little motion at the joint. Patients in the study were diagnosed via intra-articular injections, though the characteristics of those injections were not noted (the capacity of the SI joint is < 2.5 ml, so high volumes will anesthetize the ligaments or rupture the capsule). In two studies (references 29, 21), they considered patients with contrast extravasation during the injection as having “disruption”, and included them in the study. However, this is quite common (, and capsular disruption is different than “instability”, and is probably not a good indication for surgery (ie, how would fusion heal rupture of a fibrous capsule?). All RCTs reported outstanding results at > 1-year follow-up, which were much better than for non-industry RCTs that previously SIJ fusion (references: 22, 28, 3), and RCTs evaluating fusion surgery for lumbar degenerative conditions (reference 8) or cervical degenerative conditions (references 30, 9). These discrepancies may be due to either the rationale for iFuse (ie, fusion works, but people often do poorly because of the trauma associated with such a large operation) or methodological flaws inherent in randomized surgical trials (eg, inability to blind evaluators or patients, patients allocated to non-surgical therapy already failed non-surgical therapy, bias). In all studies, the large majority of patients were fused for degenerative conditions (which the authors termed “degenerative sacroiliitis”), rather than SIJ joint disruption or instability. Yet, it is not clear how active inflammation was identified, or why fusion might be an effective treatment for active inflammation. There was also considerable overlap between investigators in the 3 RCTs evaluating iFuse, which raises questions regarding generalizability.

In summary, SI joint pain is a common condition, and there are no long-term treatment options for either extra-articular SI joint pain or disruption. The evidence supporting fusion for other degenerative conditions is very weak, and most of the patients in the RCTs were fused for degenerative conditions. The reported results were extraordinary, much better than any RCT evaluating cervical or lumbar fusion, or SI joint fusion using an open surgical technique, but there were significant methodological flaws in the studies. There is little doubt that iFuse might be effective for individuals with true instability at the joint (ie, increased motion, rather than contrast extravasation indicating capsular disruption), and may provide some improvement for patients with degenerative joint pain, though these patients need to be better identified.

The North American Spine Society Criteria are the most respected and generally used criteria. Most patients with SI joint pain will respond to the conservative therapies listed. However, one criteria that I think should be added is a reduction in opioid use prior to the fusion. The literature does not show much reduction in opioids after fusion. This is because one must demonstrate that the patient can tolerate an opioid reduction before performing an advanced invasive procedure like percutaneous fusion. If the patient can tolerate at least a 50% reduction without aberrant behaviors, they are likely to be able to go off the opioid after the fusion. For those that show significant aberrant behaviors, psychosocial therapies should be the mainstay of therapy. Opioid taper take a lot of effort on the part of the patient and physician. If neither is willing, it will not be
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<td>Yes</td>
<td>Diagnostic and therapeutic injections.</td>
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<td>7</td>
<td>Yes</td>
<td>The only generally accepted objective criteria for the diagnosis of sacroiliac joint pain is response to image-guided sacro-iliac injections. Patients who do not respond to the injections generally do not improve with directed therapies. Patients who do improve with the injections will usually respond to fusion therapies.</td>
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<td>8</td>
<td>Yes</td>
<td>Diagnosis of SI joint pain/dysfunction is typically based on meeting a set of clinical criteria for location of pain, positive provocative maneuvers, and diagnostic injections.</td>
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<td>Yes</td>
<td>While the evidence is low, I agree with the NASS recommendations as outlined in their report particularly focusing on the fact that a patient has undergone and failed a minimum 6 months of intensive nonoperative treatments, the patient has a complaint and physical exam consistent with SIJ pain, Imaging of the SI joint that excludes the presence of destructive lesions, at least 75% reduction of pain for the expected duration of the anesthetic used following an image-guided, contrast-enhanced intra-articular SIJ injection on 2 separate occasions and finally a successful trial of at least one therapeutic intra-articular SIJ injection with a corticosteroid.</td>
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<td>Yes</td>
<td>I would agree with the NASS guidelines.</td>
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NR: no response.

2. For those who answered Yes to Question 1 regarding individuals with SIJ pain who have the objective condition characteristics and who meet the management criteria you listed and receive SIJ fusion,
   a. Use the 1 to 5 scale outlined below to indicate your level of confidence that there is adequate evidence supporting an improvement in health outcomes.

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b. Use the 1 to 5 scale outlined below to indicate your level of confidence that this clinical use is in accordance with generally accepted medical practice.

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3. Additional comments and/or any citations supporting your clinical input on the use of SIJ fusion for individuals with SIJ pain.

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<th>No.</th>
<th>Additional Comments</th>
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<tr>
<td>1</td>
<td>• Maigne J, Planchon C. Sacroiliac joint pain after lumbar fusion. A study with anesthetic blocks. Eur Spine J. 2005 Sep; 14(7):654-8. PMID 15761709. Patients experiencing persistent or recurrent pain after lumbar fusion underwent SI blocks. 35% had a positive result to SI block (&gt;75% improvement). Predictive criteria of response to SI block was pain different from pre-operative symptoms and those having a pain-free interval after lumbar fusion of &gt;3 months. • Shin M, Ryu K, Hur J, et al. Comparative study of lumbopelvic sagittal alignment between patients with and without sacroiliac joint</td>
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Diagnosis and Treatment of Sacroiliac Joint Pain 6.01.23

No.  Additional Comments


Higher rates of SI joint pain after lumbar fusion in patients with greater pelvic tilt and inadequately restored lordosis.


Patients with SI joint pain after lumbar fusion tended to have more pelvic retroversion than asymptomatic controls.


Fusion of multiple segments (>3) can increase the incidence of SI joint pain after lumbar or lumbosacral fusion.


Patients with low back pain after lumbar fusion had positive responses to injections to SI joint, fusion hardware, zygopophysial joint, or provocation discography. Of these different potential sources of back pain after lumbar fusion, SI joint was the most common source with 43% compared to 13% in patients with back pain without fusion.


Patients with lumbar/lumbosacral fusions were evaluated for SI joint pain with physical examination. 52 had positive response to at least three provocative tests and selected to receive diagnostic blocks. 40% had a positive response and the characteristics of these patients most likely to respond included unilateral pain complaints, more than 3 positive responses to provocative maneuvers, and post-operative pain characteristics different from pre-operative complaints.


This study is a subgroup analysis of INSITE and SIFI prospective SI joint fusion showing that the degree of pain relief from a SI joint block did not predict outcome after fusion. Successful outcomes from SI joint fusion were comparable in those patients experiencing >75% pain relief from SI block as those with 50-75% relief. This suggests that the higher 75% relief standard may be overly aggressive in discerning patients likely to benefit from SI joint fusion.


This study is a retrospective analysis of patients with SI joint pain and up to 6 years of follow up. Patients were managed with either conservative management, SI joint steroid injections, sacroiliac denervation, or SI joint fusion. Conservative management and injections showed no long-term improvement in pain or disability. SI joint denervation offered mild pain and disability improvements.

SI joint fusion offered better long-term pain relief compared to other treatments with lower opioid use and better work status.

2

Reference numbers cited in parentheses refer to list of publications included in response to Question 4.

After performing a thorough review of all available data and literature on the procedure, in March 2014, ISASS issued a comprehensive policy statement on MIS SIJ fusion and updated that policy in March 2015, December 2015 and July 2016.(7) The Policy Statement includes a discussion on the SIJ as a pain generator, information on diagnosing the SIJ as the primary source of pain, a discussion of non-surgical and surgical treatment options and recommended coverage criteria for MIS SIJ fusion. Please note, the ISASS Policy does not endorse any specific MIS SIJ fusion system. There are numerous devices available that have received FDA 510(k) clearance for use in MIS SIJ fusion surgery. ISASS maintains that the instrumentation utilized in a MIS SIJ fusion procedure is the purview of surgeon preference.

In 2008, the U.S. Food and Drug Administration approved the first minimally invasive device for sacroiliac joint fusion and MIS SIJ fusion surgery obtained a Category I CPT® code effective January 1, 2015. The body of literature on MIS SIJ fusion has grown substantially and continues to show positive outcomes for patients who receive the surgery. In addition to outcomes published of multiple retrospective case series(8-14) and comparative series(15-17), published results from two prospective, multi-center, randomized controlled trials of MIS SIJ fusion vs. non-surgical management (NSM)(18, 19) and a prospective multi-center single arm trial(20) have substantiated high rates of pain relief, improvement in functional measures (Oswestry Disability Index (ODI), SF-36, and EQ-5D) and a low rate of both revisions and serious adverse events.

In both prospective, multi-center, randomized controlled trials of MIS SIJ fusion vs. NSM,(18, 19) pain relief, disability reduction and improvement in quality of life were markedly higher in MIS SIJ fusion subjects compared to NSM subjects. Polly et al.(18) found in the MIS SIJ fusion group, mean SIJ pain improved rapidly and was sustained (mean improvement of 55.4 points, 0-100 scale) at month 24. The 6-month mean change in the NSM group (12.2 points on the 0-100 scale) was substantially smaller than that in the MIS SIJ fusion group (by 38.3 points, p<.0001 for superiority). By month 24, 83.1% and 82.0% received either clinical improvement or substantial clinical benefit in ODI score at month 24. In the MIS group, these proportions were 41% with non-surgical treatment only. Parallel changes were seen for EQ-5D and SF-36, with larger changes in the surgery group at 6 months compared to NSM. The rate of adverse events related to MIS SIJ fusion was low and only 3 subjects assigned to MIS SIJ fusion underwent revision surgery within the 24-month follow-up period. In the other randomized trial, Sturesson et al.(19) found mean self-rated low back pain improved by 43.3 points (0-100 scale) in the MIS SIJ fusion group and 5.7 points in the NSM group (difference of 38.1 points, p < 0.0001) at 6 months. Mean ODI improved by 26 points in the MIS SIJ fusion group and 5 points in the NSM group (p < 0.0001). Active straight leg raise test, EQ-5D-3L, walking distance and satisfaction were statistically superior in the MIS SIJ fusion group. The frequency of adverse events did not differ between groups.

Other relevant peer-reviewed published papers adding to the evidence base on MIS SIJ fusion include safety analyses,(21, 22) economic analyses,(23-25) cost analyses,(26, 27) a validation study,(28) burden of disease analyses,(29, 30) and a systematic review.(31)

A recently published 6-year case series(36) comparing MIS SIJ fusion, radiofrequency denervation and conservative management for SIJ pain showed very good patient outcomes (ie, improved pain and disability, decrease in opioid use and good final work status)
after MIS SIJ fusion and poor health outcomes (ie, worsening pain and disability, increased use of opioids and poor long-term work status) after conservative management. The poor long-term response, higher opioid use, and poor work status for conservative management contrasts significantly to improvements from MIS SIJ fusion.

In terms of bone growth and fusion rates for MIS SIJ fusion, independent analysis showed bonding of bone to the iFuse implant (SI-Bone Inc., San Jose, CA) in nearly 100% of cases. The surface's device design is similar to other orthopedic implants (eg, hip implants) where bone bonding has been shown. A 5-year study shows bridging bone across the SIJ in 87% of cases. (11) Kube and Muir demonstrated an analogous fusion rate of 88% bridging bone at 1 year using Simmetry (Zyga, Minnetonka, MN), a screw based technology.

Taken together, these studies represent a substantial amount of evidence supporting MIS SIJ fusion as a safe and effective treatment option. In addition, the National Institute for Health and Care Excellence (NICE) reviewed MIS SIJ fusion and concluded, “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 provided that standard arrangements are in place for clinical governance, consent and audit.”

Please see the following attachments to this form:

1. The ISASS Policy Statement on MIS SIJ Fusion (Available online at: https://www.isass.org/public-policy/isass-policy-statement-minimally-invasive-sacroiliac-joint-fusion-july-2016/); and
2. A letter submitted by ISASS to BCBSA Evidence Street on February 20, 2017 outlining additional concerns with the Evidence Review on the Diagnosis and Treatment of Sacroiliac Joint Pain (6.01.23).

It is the opinion of NASS that the peer reviewed published evidence supporting the efficacy of percutaneous SI joint fusion continues to accumulate. The BCBSA Evidence Street review identifies that there are now 2 randomized controlled trials as well as several well-designed case series and multiple other peer reviewed publications that all demonstrate the efficacy of percutaneous SI joint fusion. The magnitude of the effect in both RCTs was quite significant. At 6 month follow-up, Whang found a >15 point improvement in ODI in 75% of fusion patients vs 27% in controls. At 6 months, Sturesson found that VAS pain improved 43.4 points in the fusion group vs 6.7 points in the control group and that ODI improved 25.5 points in the fusion group vs 5.8 points in the control group. The results of both studies were also noted to be highly statistically significant. The longer-term follow-up studies demonstrate the durability of the results at 2 years. Adverse effects and revision rates have been reported and are consistent with those reported for other surgical interventions.

NASS would like to raise concerns regarding BCBSA’s criticism of the RCTs as being non-blinded. Patient blinding in surgery requires a sham procedure arm. Sham surgery, especially in the spine, exposes the patient to direct harm and risk. For this reason, many Institutional Review Boards will not accept sham-blinded studies. Even when accepted, patient enrollment is difficult and selection bias occurs in that patients with more severe symptoms will not participate. NASS is also perplexed by and disagrees with criticism of self-reported outcomes in the studies cited. Validated patient reported outcomes measures are the gold standard assessment tool for interventions designed to address a patient’s pain or functional limitations.

References (this list is not comprehensive and the studies were already identified in the Evidence Street Review):


Also see information in response to Question 1. Reference numbers cited in parentheses refer to list of publications included in response to Question 4.

Therapeutic value of sacroiliac joint injections: The sacroiliac joint is by far the largest “spinal joint”, and contains both extra- (eg, ligaments, muscles) and intra-articular portions. The extra-articular portion could also be classified into dorsal and ventral components, with the latter not amenable to blockade. When considering the evidence for blocks, we believe that the placebo-
No. | Additional Comments
--- | ---
5 | My confidence in the therapy is based on my comments in section one. It requires a high level of patient selection. For those that fail conservative therapy, a detailed psychosocial assessment is required. And for those on opioids, an opioid taper as described above.
6 | SI fusion is currently acceptable therapy in patients in whom significant response is noted with injection. SI joint fusion as part of the inferior portion of extensive thoracolumbar fusion (i.e., SI joint and pelvis) is an accepted approach. Increasing literature on the topic will enhance the knowledge base on this topic.
7 | No additional comments listed.
8 | Although criteria for the diagnosis of SI joint dysfunction is fairly well described, there is significant variability from study to study regarding the application of the diagnostic criteria. It is difficult to assess the efficacy of a treatment such as SI joint fusion when there is not a clearly defined and consistent manner of diagnosis from study to study. The vast majority of literature regarding outcomes following SI joint fusion surgery are low-quality retrospective studies, or small sample size prospective studies with limited follow-up.
9 | I believe the draft review of evidence is well written and highlights the challenge of the gathering high level clinical guidelines as there are minimal non industry supported studies for this intervention. This review also highlights the challenges present in conducting blinded high volume studies as this is not a common condition and fusion may help a selected group of patients.
10 | Overall, percutaneous SI joint fusion has more evidence than corticosteroid injections and RFA with proper patient selection.

### Is there any evidence missing from the attached draft review of evidence?

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<thead>
<tr>
<th>No.</th>
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<th>Citations of Missing Evidence</th>
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</table>
| 2   | Yes    | The literature review appears to be incomplete, with missing comparative studies, (15-17) missing case series, (6, 10, 12, 14, 33, 34, 35, 36) missing systematic reviews, (31, 39, 40) missing meta-analysis of prospective studies, (41) missing outcomes studies, (1, 28, 30, 42, 43, 44) missing economic studies, (23, 24, 25, 26, 27, 45) and missing biomechanical studies. (46, 47, 48) References
|     |        | 2. Cher DJ, Reckling WC. Quality of life in preoperative patients with sacroiliac joint dysfunction is at least as depressed as in other lumbar spinal conditions. Med Devices (Auckl). 2015 Sep 16; 8:395-403. PMID: 26396547.


41. Denger J, Duhon B, Whang P, et al; INSITE Study Group. Predictors of outcome in conservative and
No. | Yes/No | Citations of Missing Evidence
--- | --- | ---
3 | No | We have reviewed the BlueCross BlueShield Diagnosis and Treatment of Sacroiliac Joint Pain, Summary of Evidence. In general, this is a well-written, comprehensive review, but we have the following comments that should be considered also see responses included above in Questions 1 and 3.

Although this was not included in the evidence synthesis, and no randomized controlled trials have evaluated psychological interventions such as cognitive-behavioral therapy in individuals with SI joint pain, there is strong evidence supporting these treatments in individuals with nonspecific low back pain (Richmond H, Hall AM, Copsey B, et al. The effectiveness of cognitive behavioural treatment for non-specific low back pain: a systematic review and meta-analysis. PLoS One. 2015 Aug 5; 10(8):e0134192. PMID: 26244668), some of whom undoubtedly have SI joint pain. Therefore, incorporating these therapies, either before procedural interventions or in addition to interventions (ie, multimodal therapy), should be strongly considered.

Reference list for articles mentioned in the ASRA response to questions 1 and 3:
20. Maugars Y, Mathis C, Berthelot JM, et al. Assessment of the efficacy of sacroiliac corticosteroid injections in...
<table>
<thead>
<tr>
<th>No.</th>
<th>Yes/No</th>
<th>Citations of Missing Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Yes</td>
<td>See comment on the NICE review which complements your review</td>
</tr>
<tr>
<td>6</td>
<td>NR</td>
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</tbody>
</table>

NR: no response.

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