Medical Policy

Title: Diagnosis and Treatment of Sacroiliac Joint Pain

Professional
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Revision Date(s): January 1, 2012; January 9, 2012; June 5, 2012; September 11, 2014; January 1 2015; September 18, 2015; November 18, 2015; January 1, 2017; April 12, 2017; May 1, 2018; August 31, 2018
Current Effective Date: August 31, 2018

Institutional
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<td>Comparators of interest are: • Conservative therapy</td>
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**DESCRIPTION**

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

**OBJECTIVE**

The objective of this policy is to evaluate therapeutic corticosteroid injections and minimally invasive methods (radiofrequency ablation, sacroiliac joint fusion/stabilization) for the treatment of sacroiliac joint pain.

**BACKGROUND**

Sacroiliac Joint Pain
Similar to other structures in the spine, it is assumed that the sacroiliac joint may be a source of low back pain. In fact, prior to 1928, the sacroiliac joint was thought to be the most common cause of sciatica. In 1928, the role of the intervertebral disc was elucidated, and from that point forward the sacroiliac joint received less research attention.

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

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

**REGULATORY STATUS**

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

Several percutaneous or minimally invasive fixation/fusion devices have received marketing clearance by the FDA through the 510(k) process. These include the IFUSE® Implant System (SI Bone), the Rialto™ SI Joint Fusion System (Medtronic), SIJ-Fuse (Spine Frontier), the Symmetry® 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.
POLICY
A. Injection into the sacroiliac joint for diagnostic or therapeutic purposes may be considered **medically necessary** when ALL of the following conditions are met:

1. Pain originates from the sacroiliac joint; AND
2. Average pain level of ≥ 6 on a scale of 1 to 10 (see Policy Guidelines); AND
3. Failure to respond to nonsurgical conservative management (see NOTE below); AND
4. The injections are performed under radiographic guidance with documentation of contrast material throughout the sacroiliac joint (see Policy Guidelines). Ultrasound guidance is not considered adequate or accurate for sacroiliac joint injections.

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

Repeat Injections:  
1. If patient has achieved substantial relief with previous injection, repeat injections are to be no more frequent than every 2 months with no more than 3 injections given in one year
2. Repeat injections extending beyond 12 months may be reviewed for continued medical necessity

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

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

E. Minimally invasive fusion / stabilization of the sacroiliac joint using a titanium triangular implant may be considered medically necessary when ALL of the following criteria have been met:

1. Average pain level of ≥6 on a scale of 1 to 10 (see Policy Guidelines) that impacts quality of life or limits activities of daily living; AND
2. There is an absence of generalized pain behavior (eg, somatoform disorder) or generalized pain disorders (eg, fibromyalgia); AND
3. Patients have undergone and failed a minimum 6 months of intensive nonoperative treatment that must include medication optimization, activity modification, bracing, and active therapeutic exercise targeted at the lumbar spine, pelvis, sacroiliac joint, and hip, including a home exercise program; AND
4. Pain is caudal to the lumbar spine (L5 vertebra), localized over the posterior sacroiliac joint, and consistent with sacroiliac joint pain; AND
5. A thorough physical examination demonstrates localized tenderness with palpation over the sacral sulcus (Fortin’s point) in the absence of tenderness of similar severity elsewhere; AND
6. There is a positive response to at least 3 provocative tests (see Policy Guidelines); AND
7. Diagnostic imaging studies include ALL of the following:
   a) Imaging (plain radiographs and computed tomography or magnetic resonance imaging) of the sacroiliac joint excludes the presence of destructive lesions (eg, tumor, infection) or inflammatory arthropathy of the sacroiliac joint; AND
   b) Imaging of the pelvis (anteroposterior plain radiograph) rules out concomitant hip pathology; AND
   c) Imaging of the lumbar spine (computed tomography or magnetic resonance imaging) is performed to rule out neural compression or other degenerative condition that can be causing low back or buttock pain; AND
   d) Imaging of the sacroiliac joint indicates evidence of injury and/or degeneration; AND
8. There is at least a 75% reduction in pain for the expected duration of the anesthetic used following an image-guided, contrast-enhanced intra-articular sacroiliac joint injection on 2 separate occasions; AND
9. A trial of a therapeutic sacroiliac joint injection (ie, corticosteroid injection) has been performed at least once.

F. Fusion / stabilization of the sacroiliac joint for the treatment of back pain presumed to originate from the SI joint is considered experimental / investigational under all other conditions and with any other devices not listed above.
Policy Guidelines
1. This policy does not address treatment of pain in the sacroiliac joint due to infection, trauma, or neoplasm.
2. Radiographic images used to perform SI joint injection should be digitally archived for retrieval at a later date.
3. Pain originating from the sacroiliac joint may be evidenced by provocation of pain in at least 3 out of 5 of the following tests:
   a) Distraction
   b) Thigh thrust
   c) FABER (Flexion, Abduction, External Rotation)
   d) Compression
   e) Gaenslen's
4. Pain may be defined as moderate (interferes significantly with ADLs) or severe (disabling; unable to perform ADLs).

<table>
<thead>
<tr>
<th>Rating</th>
<th>Pain Level</th>
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<tbody>
<tr>
<td>0</td>
<td>No pain</td>
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<tr>
<td>1-3</td>
<td>Mild pain</td>
</tr>
<tr>
<td>4-6</td>
<td>Moderate pain</td>
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<tr>
<td>7-10</td>
<td>Severe pain</td>
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RATIONALE
This policy was updated with a literature review using MEDLINE; most recently through September 11, 2017. Following is a summary of key references to date.

Diagnosis of Sacroiliac Joint Pain
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 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.

Two 2009 practice guidelines from the American Pain Society were based on a systematic review commissioned by the Society and conducted at the Oregon Evidence-based Practice Center. 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. In 2010, Manchikanti et al published 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 2009 systematic review by Rupert et al.\(^6\)

In 2013, the American Society of Interventional Pain Physicians published an updated evidence review with guidelines on diagnosis of SIJ pain.\(^7\) 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.

Section Summary: Diagnosis of Sacroiliac Joint Pain

Although there is no independent reference standard for the diagnosis of SIJ pain, SIJ blocks are considered the reference standard for the condition. The utility of this test ultimately depends on its ability to identify patients who benefit from treatment.

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 randomized controlled trial (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 published a systematic review of SIJ interventions in 2012.\(^8\) The primary outcome was short-term (≤6 months) or long-term (>6 months) pain relief. Evidence was classified as good, fair, or limited/poor based on the quality of evidence. Eleven studies (6 randomized, 5 nonrandomized trials) met inclusion criteria. Reviewers found that evidence for intra-articular steroid injections is limited or poor, as was the evidence for periaricular injections (local anesthetic and steroid or botulinum toxin). For radiofrequency neurotomy, the evidence for cooled radiofrequency was found to be fair (2 randomized controlled trials [RCTs]), while evidence for conventional radiofrequency or pulsed radiofrequency was limited or poor. The 2013
American Society of Interventional Pain Physicians evidence review\(^7\) found no additional studies on intra-articular or periarticular injections besides those identified by Hansen.

**Therapeutic Corticosteroid Injections**

**Randomized Controlled Trials**

The available literature on therapeutic corticosteroid injections is limited, consisting of small RCTs and case series. Case series studies evaluating corticosteroid injections, described in systematic reviews, have shown variable findings at generally short-term follow-up.\(^8\)\(^9\)

A 2013 trial randomized 51 patients with SIJ and leg pain to physical therapy, manual therapy, or intra-articular injection of corticosteroid.\(^10\) Diagnosis of SIJ pain was based on provocation tests and not SIJ injections. In a blinded assessment, 25 (56\%) patients were considered to be successfully treated at the 12-week follow-up visit based on complete relief of pain and improvement in the visual analog scale (VAS) score for pain. Physical therapy was successful in 20\%, manual therapy in 72\%, and intra-articular injection in 50\%.

Kim et al reported a randomized, double-blind, controlled trial of intra-articular prolotherapy (see evidence review 2.01.26) compared with steroid injection for SIJ pain in 2010.\(^11\) The trial included 48 patients with SIJ pain, confirmed by 50\% or greater improvement in response to a single local anesthetic block, who had failed medical treatment. 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 scores (Oswestry Disability Index [ODI]) 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 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 three months for the steroid group.

**Section Summary: Therapeutic Corticosteroid Injections**

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

**Radiofrequency Ablation**

Evidence comparing radiofrequency ablation (RFA) of the SIJ with other treatments is limited. Two small RCTs using a cooled radiofrequency probe were identified. A third RCT used palisade SIJ radiofrequency neurotomy. Another RCT used a multi-electrode radiofrequency probe to perform the procedure.

**Systematic Reviews**

Aydin et al published a meta-analysis of RFA for sacroiliac pain in 2010.\(^12\) 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 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. 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 noted by reviewers, no standards have been established for the specific nerves to ablate or type of technique.

No additional studies were identified in the 2013 American Society of Interventional Pain Physicians evidence review, which concluded that evidence was limited for conventional radiofrequency neurotomy, limited for pulsed radiofrequency neurotomy, and fair for cooled radiofrequency neurotomy.7

**Randomized Controlled Trials**

The single RCT included in the Aydin meta-analysis was published in 2008.13 This trial by Cohen et al examined the effect of lateral branch radiofrequency denervation with a cooled probe in 28 patients with injection-diagnosed SIJ pain. 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.

In 2012, Patel et al reported a randomized, double-blind, placebo-controlled trial of lateral branch neurotomy with a cooled radiofrequency probe.14 Twelve-month follow-up was reported in 2016.15 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.15 Of the 9 patients who terminated study participation, 4 (12%) of 34 were considered treatment failures.

In 2014, Zheng et al reported an RCT of palisade sacroiliac RFA in 155 patients with ankylosing spondylitis.16 Palisade RFA uses a row of radiofrequency cannulae perpendicular to the dorsal sacrum. Inclusion criteria were ages 18 to 75 years; diagnosis of ankylosing spondylitis; chronic low back pain for at least 3 months; axial pain below L5; no peripheral involvement; pain aggravation on manual pressing of the SIJ area; and at least 50% pain relief following fluoroscopically guided anesthetic injection into the joint. Patients who met the inclusion criteria were randomized to palisade RFA or celecoxib. Blinded evaluation to 24 weeks found that RFA (2.8) resulted in lower global VAS scores than celecoxib (5.0; p<0.001) as well improved scores for secondary outcome measures. This study lacked a sham control.

In 2016, van Tilburg et al reported a sham-controlled randomized trial of percutaneous RFA in 60 patients with SIJ pain.17 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, authors mentioned that the criteria and method used for diagnosing SIJ pain may have resulted in selection some patients without SIJ pain.

In 2017, Kuch et al 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.\(^\text{18}\) Patient selection criteria included BMI (<35 kg/m²), age (<70 years old), and pain reduction of at least 50% within 30 to 90 minutes of receiving a diagnostic sacroiliac block (n=228). An additional 202 patients who had negative diagnostic sacroiliac block; 1666 patients declined to participate in the trial. Patients meeting criteria were randomized to exercise plus radiofrequency denervation (n=116) or an exercise program alone (n=112), and were followed for a year. The RFA group had a modest improvement for the primary outcome at 3 months (-0.71; 95% confidence interval [CI], -1.35 to -0.06), but the control group improved over time and there were no statistically significant differences between the groups for pain intensity score (p=0.09) or in the number of patients who had more than 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 high dropout rate (31%) in the control group.

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.

SIJ Fusion/Fixation with a Triangular Implant System
Randomized Controlled Trials
INSITE: In 2015, Whang et al reported an industry-sponsored nonblinded RCT (INSITE) of the iFuse Implant System in 148 patients.\(^\text{19}\) Twelve-month follow-up to this RCT was reported by Polly et al in 2015,\(^\text{20}\) and 2-year follow-up was reported by Polly et al in 2016.\(^\text{21}\) However, by 12 months, almost all patients in the control group had crossed over to SIJ fusion, precluding comparison between groups. Trial inclusion was based on a determination of the SIJ as a pain generator from a combination of a history of SIJ-localized pain, positive provocative testing on at least 3 of 5 established physical tests, and at least a 50% decrease in SIJ pain after image-guided local anesthetic injection into the SIJ. The duration of pain before enrollment averaged 6.4 years (range, 0.47-40.7 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 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 1. 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).

Table 1. 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>
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<tr>
<td></td>
<td>Baseline</td>
<td>Follow-up</td>
<td>Change</td>
<td>Ctl iFuse</td>
<td>Ctl iFuse</td>
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<td></td>
<td>82.2</td>
<td>70.4</td>
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<td>81.4%</td>
<td>61.1 62.2 30.8 30.2 0.47 0.44</td>
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<td></td>
<td>82.3</td>
<td>57.9</td>
<td>-52.6</td>
<td>61.4 31.9 32.0 42.8 0.52 0.72</td>
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<td></td>
<td>61.1</td>
<td>-4.9</td>
<td>-30.3</td>
<td>1.2 12.7 0.05 0.29</td>
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<tr>
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<td>Baseline</td>
<td>Follow-up</td>
<td>Change</td>
<td>Ctl iFuse</td>
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<td></td>
<td>73.0</td>
<td>67.8</td>
<td>-5.7</td>
<td>77.7 34.4 58.9 35.2 0.11 0.37</td>
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<tr>
<td></td>
<td>77.7</td>
<td>52.7</td>
<td>-25.5</td>
<td>35.2 24.0 0.11 0.37</td>
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</tr>
</tbody>
</table>

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.

In 2016, Polly et al reported 2-year outcomes from the SIJ fusion arm of this RCT (see Table 2).21 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. 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 in 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 improvement in SIJ pain score, and 68.2% had improvement in ODI. By 24 months, the proportion taking opioids was reduced from 68.6% at baseline to 48.3%.

Table 2. Extended Follow-Up from the INSITE and iMIA Trials

<table>
<thead>
<tr>
<th>Outcome Measures</th>
<th>Baseline</th>
<th>6 Months (SD)</th>
<th>12 Months (SD)</th>
<th>24 Months (SD)</th>
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<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>57.2</td>
<td>31.9</td>
<td>83.1%</td>
<td></td>
</tr>
<tr>
<td>Sacroiliac joint fusion ODI score</td>
<td>77.7</td>
<td>34.4</td>
<td>35.2</td>
<td>28.7</td>
</tr>
<tr>
<td>% ≥15-point improvement ODI</td>
<td>47.1</td>
<td>46.5</td>
<td>41.7</td>
<td>32.4</td>
</tr>
<tr>
<td>IMIA22</td>
<td></td>
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<tr>
<td>Low back pain</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Conservative management</td>
<td>73.0</td>
<td>67.8</td>
<td>58.9</td>
<td>58.9 (28.2)</td>
</tr>
<tr>
<td>Sacroiliac joint fusion</td>
<td>77.7</td>
<td>34.4</td>
<td>35.2</td>
<td>35.2 (25.5)</td>
</tr>
<tr>
<td>Leg pain</td>
<td></td>
<td></td>
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<tr>
<td>Conservative management</td>
<td>47.1</td>
<td>46.5</td>
<td>41.7</td>
<td>32.4</td>
</tr>
<tr>
<td>Sacroiliac joint fusion</td>
<td>52.7</td>
<td>22.6</td>
<td>24.0</td>
<td>24.0 (27.8)</td>
</tr>
<tr>
<td>ODI</td>
<td></td>
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### Outcome Measures

<table>
<thead>
<tr>
<th></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>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).<sup>23</sup>

ODI: Oswestry Disability Index.

iMIA: In 2016 and 2017, the iMIA study group (Sturesson et al, Dengler et al) reported another industry-sponsored multicenter RCT of the iFuse Implant System in 103 patients.<sup>22,24</sup> Selection criteria were similar to those of the Whang trial, including at least 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 are shown in Table 1. 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 [MCID]) 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 are 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 in 2017 (see Table 2).<sup>23</sup> 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 (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).

**Subsection Summary: Randomized Controlled Trials**

Two RCTs 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 when compared with controls who had not crossed over. The RCTs were nonblinded without a placebo or 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 3.

In 2016, results from a cohort of 172 patients undergoing SIJ fusion reported to 2 years were published by Duhon et al.25,26 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 3. 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>Rudolf (2012)27</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain score (range, 0-10)</td>
<td>7.59</td>
<td>2.0</td>
<td>5.59</td>
<td>90% (45/50)</td>
</tr>
<tr>
<td>&gt;2-point change in pain score</td>
<td>-</td>
<td>-</td>
<td>82%</td>
<td></td>
</tr>
<tr>
<td>Duhon et al (2016)26</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<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>Sachs et al (2016)28</td>
<td></td>
<td></td>
<td></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.

EQ-5D TTO Index: EuroQoL Time Tradeoff Index; SF-36: 36-Item Short-Form Health Survey.

Case Series: In 2012, Rudolf retrospectively analyzed his first 50 consecutive patients treated with the iFuse Implant System.27 There were 10 perioperative complications, including implant penetration into the sacral neural foramen (2 patients) and compression of the L5 nerve (1 patient); these 3 patients required surgical retraction of the implant. At 3 years postsurgery, a single patient required additional implants due to worsening symptoms. At a minimum of 24 months of follow-up (mean, 40 months), the treating surgeon was able to contact 45 patients. The mean pain score was 2 (1 to 10 scale), and 82% of patients had attained the minimal clinically important difference in pain score (defined as ≥2 of 10).

A 2014 report by Rudolph and Capobianco described 5-year follow-up for 17 of 21 consecutive patients treated at their institution between 2007 and 2009.29 Of the 4 patients lost to follow-up, two had died and one had become quadriplegic due to severe neck trauma. For the remaining patients, mean VAS score (range, 0-10) improved from 8.3 before surgery to 2.4 at 5 years; 88.2% of patients had substantial clinical benefit, which was defined as a 2.5-point decrease in
VAS score or a raw score less than 3.5. Mean ODI score at 5 years was 21.5. Imaging by radiograph and computed tomography showed intra-articular bridging in 87% of patients with no evidence of implant loosening or migration.

The 2014 case series (N=144) of Sachs et al, which did not report follow-up rates or study methodologies and did not permit calculation of the complete number of patients treated, will not be further discussed here.30

Nonrandomized Comparative Studies: Two retrospective nonrandomized comparative studies were published in 2017. Vanaclocha et al found greater pain relief with SIJ fusion than with conservative management or SIJ denervation.31 Spain and Holt reported a retrospective review of surgical revision rates following SIJ fixation with either surgical screws or the iFuse triangular implant.32 Revision rates were lower with the iFuse device than observed with surgical screws.

Database Analysis: Database analysis provides insight into treatment-related morbidity. A study by Cher et al (2015) reported rates of implant revision using the Humana insurance database of procedures.33 Between April 2009 and July 2014, 11,416 cases with the iFuse system took place. After minor adjustments of numbers to account for nonrecommended uses and inability to match revision cases, the cumulative revision rate at 4 years was 3.54%. Overall, 24% of revision surgeries occurred in the first month and 63% occurred within the first 12 months. One-year revision rates fell over time (9.7% to 1.4% from 2009 to 2014).

In 2016, Schoell et al analyzed postoperative complications tracked in an administrative database of minimally invasive SIJ fusions to determine complications coded in postoperative claims.34 Using the Humana insurance database, patients with complications were identified using ICD-9 codes corresponding to a surgical complication within 90 days or 6 months if the codes were used for the first time. Of 469 patients, the overall incidence of complications was 13.2% at 90 days and 16.4% at 6 months. For specific complications, the infection rate was 3.6% at 90 days and the rate of complications classified as nervous system complications was 4.3%. Authors noted that the infection rate observed was consistent with the infection rates reported by Polly et al (2015),20 but much higher than those reported for other types of minimally invasive spine procedures. The incidence of complications in this study may differ from those reported by registries. However, determining the true incidence of adverse events after procedures from either registries or insurance claims data can be difficult due to uncertainty about the completeness of reporting in registries and the accuracy of coded claims in claims databases.

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.26,27 One study with a small sample size and a good follow-up showed results maintained to 5 years.29,31 Improved health outcomes are also supported by retrospective studies that compare SIJ fusion/fixation using a triangular implant with other treatments for SIJ pain.31,32 These results are consistent with medium-term durability of treatment. Analysis of an insurance database reported overall incidence of complications to be 16.4% at 6 months34 and cumulative revision rate at 4 years of 3.54%.33
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, 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%) 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 overall incidence of complications to be 16.4% at 6 months and cumulative revision rate at 4 years of 3.54%.

SIJ Fusion/Fixation with Cylindrical Threaded Implant

Rappoport et al (2017) reported on an industry-sponsored prospective study of SIJ fusion with a cylindrical threaded implant (SI-LOK).35 The study included 32 patients with 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 autogenous bone graft from the drill reamings. Pain and disability scores were reduced following device implantation (see Table 4), and revisions within the first 12 months of the study were low (n=2). Follow-up will continue through 2 years.

Table 4. Pain and Disability Scores After Implantation With a Cylindrical Threaded Implant

<table>
<thead>
<tr>
<th>Outcome Measures</th>
<th>Baseline</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>

Adapted from Rappoport et al (2017).35

Section Summary: SIJ Fusion/Fixation with Cylindrical Threaded Implant

There is limited evidence on 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

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 that compare this procedure in defined populations with sham control and with alternative treatments. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who SIJ pain who receive SIJ fusion/fixation 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 cumulative revision rate at 4 years of 3.54%. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have SIJ pain who receive SIJ fusion/fixation with a cylindrical threaded implant, the evidence includes a prospective cohort. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. The prospective cohort study will follow patients for 2 years following implantation of slotted screws filled with autologous bone. Results at 1 year are consistent with findings from the studies using a triangular implant. However, longer follow-up and controlled trials are needed to evaluate this type of implant. The evidence is insufficient to determine the effects of the technology on health outcomes.

**CLINICAL INPUT FROM PHYSICIAN SPECIALTY SOCIETIES AND ACADEMIC MEDICAL CENTERS**

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

**2017 Input**

In response to requests, clinical input focused on sacroiliac joint (SIJ) fusion was received from 10 respondents, including 5 specialty society-level responses from 7 specialty societies (2 were joint society responses) and 5 physician-level responses from 4 academic centers while this policy
was under review in 2017. Based on the evidence and independent clinical input, the clinical input supports that the following indication provides a clinically meaningful improvement in the net health outcome and is consistent with generally accepted medical practice:

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

2015 Input
In response to requests, focused input on sacroiliac joint fusion was received from 5 physician specialty societies and 3 academic medical centers while this policy was under review in 2015. A majority of reviewers considered sacroiliac joint 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 concerning the use of arthrography, RFA, and fusion of the sacroiliac joint. 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. Clinical input was mixed. There was general agreement that the evidence for sacroiliac joint 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) published coverage recommendations for percutaneous sacroiliac joint fusion in 2015. NASS indicated that there was relatively moderate evidence. In the absence of high-level data, policies reflect the multi-disciplinary experience and expertise of the committee members in order to present reasonable standard practice indications in the United States. NASS recommends 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 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% 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
ASIPP Interventional Pain Management guidelines were updated in 2013.7 The updated guidelines recommend the use of controlled sacroiliac joint blocks with placebo or controlled comparative local anesthetic block when indications are satisfied with suspicion of sacroiliac joint 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 sacroiliac joint injections.

American Society of Anesthesiologists et al
In 2010, the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine Practice updated their guidelines for chronic pain management.37 The guidelines recommend 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 RFA may be used for chronic sacroiliac joint pain."

American Pain Society
The 2009 practice guidelines from the APS were based on a systematic review that was commissioned by the APS and conducted at the Oregon Evidence-based Practice Center.2,3 The APS guideline states that there is insufficient evidence to evaluate validity or utility of diagnostic sacroiliac joint block as a diagnostic procedure for low back pain with or without radiculopathy and that there is insufficient evidence to adequately evaluate benefits of sacroiliac joint steroid injection for nonradicular low back pain.

International Society for the Advancement of Spine Surgery
The International Society for the Advancement of Spine Surgery (ISASS) first published a policy statement on minimally invasive SIJ fusion in 2014.38 These recommendations were updated in a 2016 statement.34 ISASS recommendations state that patients who have all of the following criteria may be eligible for minimally invasive sacroiliac joint fusion:

- “Significant SI 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
National Institute for Health and Care Excellence guidance was published in 2017 on minimally invasive SIJ fusion surgery for chronic sacroiliac pain.40 The recommendations included:

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… provided that standard arrangements are in place for clinical governance, consent and audit.
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.”

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS
Not applicable

ONGOING AND UNPUBLISHED CLINICAL TRIALS
Some currently unpublished trials that might influence this policy are listed in Table 5.

Table 5. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
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</tr>
<tr>
<td>NCT01861899a</td>
<td>Treatment of Sacroiliac Dysfunction With SI-LOK® Sacroiliac Joint Fixation System</td>
<td>55</td>
<td>Aug 2018</td>
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<tr>
<td>NCT02270203a</td>
<td>LOIS: Long-Term Follow-Up in INSITE/SIFI</td>
<td>103</td>
<td>Dec 2019</td>
</tr>
<tr>
<td>NCT02074761a</td>
<td>Evolusion Study Using the Zyga SImetry Sacroiliac Joint Fusion System</td>
<td>250</td>
<td>Dec 2019</td>
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<tr>
<td>NCT03230279a</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</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

a Denotes industry-sponsored or cosponsored trial.
CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT/HCPCS

27096 Injection procedure for sacroiliac joint, anesthetic/steroid, with image guidance (fluoroscopy or CT) including arthrography when performed
27279 Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device
27280 Arthrodesis, open, sacroiliac joint, including obtaining bone graft, including instrumentation, when performed
27299 Unlisted procedure, pelvis or hip joint
64640 Destruction by neurolytic agent; other peripheral nerve or branch
G0259 Injection procedure for sacroiliac joint; arthrography
G0260 Injection procedure for sacroiliac joint; provision of anesthetic, steroid and/or other therapeutic agent, with or without arthrography

- The CPT code for injection into the sacroiliac joint is: 27096, used only if CT or fluoroscopic imaging is used to confirm the intra-articular needle position.
- There is no specific CPT code for radiofrequency ablation of the sacroiliac joint. Code 27299 would likely be used.
- There is a CPT category I code for percutaneous or minimally invasive stabilization: 27279.
- Open sacroiliac joint arthrodesis would be reported with CPT code 27280.
- For both codes 27279 and 27280, if the procedure is performed bilaterally, the codes would be reported with a -50 modifier.

ICD-10 Diagnoses

M46.1 Sacroiliitis, not elsewhere classified
M47.898 Other spondylosis, sacral and sacrococcygeal region
M47.899 Other spondylosis, site unspecified
M48.08 Spinal stenosis, sacral and sacrococcygeal region
M53.2X8 Spinal instabilities, sacral and sacrococcygeal region
M54.18 Radiculopathy, sacral and sacrococcygeal region
M54.31 Sciatica, right side
M54.32 Sciatica, left side
M54.41 Lumbago with sciatica, right side
M54.42 Lumbago with sciatica, left side
M54.5 Low back pain
M54.6 Pain in thoracic spine
S33.2 Dislocation of sacroiliac and sacrococcygeal joint
S33.6 Sprain of sacroiliac joint
**REVISIONS**

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
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<tbody>
<tr>
<td>07-27-2011</td>
<td>Policy added to the bcbksks.com web site.</td>
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</tbody>
</table>
| 01-01-2012 | In the Coding section:  
- Revised CPT nomenclature for the following code: 27096  
- Added the following CPT guidelines:  
  “27096 is to be used only with CT or fluoroscopic imaging confirmation of intra-articular needle positioning. If CT or fluoroscopic imaging is not performed, use 20552.” |
| 01-09-2012 | Removed CPT code: 73542 (deleted code, effective 1/1/2012)                  |
| 06-05-2012 | Effective for Institutional providers 30 days after the Revision Date.       |
|            | Title revised from: "Sacroiliac Joint Arthrography and Injection" to:  "Diagnosis and Treatment of Sacroiliac Joint Pain"  
- Description section updated  
- In Policy section:  
  - Added experimental / investigational language of: "D. Radiofrequency ablation of the sacroiliac joint is considered experimental / investigational."  
- Rationale section updated  
- In Coding section:  
  - Added CPT codes: 27299  
  - Removed CPT code: 77003  
  - Added Diagnosis codes: 720.2, 724.8, 724.9  
- References updated |
| 09-11-2014 | Description section updated  
- In Policy section:  
  - Added to Item A the criteria of "6. The injections are performed under radiographic guidance"  
  - Added experimental / investigational indication of, “Fusion / stabilization of the sacroiliac joint for the treatment of back pain presumed to originate from the SI joint is considered experimental / investigational, including but not limited to percutaneous and minimally invasive techniques.”  
- Rationale section updated  
- In Coding section:  
  - Added CPT codes: 27280, 0334T  
  - Updated coding instructions  
  - Added ICD-10 Codes (Effective October 1, 2015)  
- References updated |
| 01-01-2015 | In Coding section:  
- Added CPT Code: 27279 (Effective January 1, 2015)  
- Deleted CPT Code: 0334T (Effective January 1, 2015)  
- Revised CPT Code: 27280 (Effective January 1, 2015)  
- Updated Rationale section.  
- Updated References section. |
| 09-18-2015 | Updated Description section.  
- In Policy section:  
  - In Item A 6, added “with documentation of contrast material throughout the sacroiliac joint” to read "The injections are performed under radiographic guidance with documentation of contrast material throughout the sacroiliac joint." Added "Note: Ultrasound guidance is not considered adequate or accurate for sacroiliac joint injections."  
  - In Item A Repeat Injections, 1, revised to read "If patient has achieved substantial relief with previous injection, repeat injections will be no more frequent than every 2 months."  
- Added Policy Guidelines.  
- Updated Rationale section.  
- Updated References section. |
<p>| 11-18-2015 | In Coding section: |</p>
<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
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<tbody>
<tr>
<td>01-01-2017</td>
<td>Updated Description section.</td>
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<tr>
<td></td>
<td>In Policy section:</td>
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<tr>
<td></td>
<td>• Removed previous Item A 2, &quot;Duration of pain of at least 3 months; AND&quot;</td>
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<td></td>
<td>• Removed previous A 5, &quot;Lack of obvious evidence for disc related or facet joint pain; AND&quot;</td>
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<td>• In new Item A 2, added (see Policy Guidelines) to read, &quot;Average pain level of ≥ 6 on a scale of 1 to 10 (see Policy Guidelines); AND&quot;</td>
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<td>• In new Item A 3, removed &quot;3 months of more&quot; and &quot;including physical therapy and non-steroidal anti-inflammatory agents&quot; and added &quot;nonsurgical&quot; and &quot;therapies such as nonsteroidal anti-inflammatory medications, acetaminophen, manipulation, physical therapy, and a home exercise program&quot; to read, &quot;Failure to respond to nonsurgical conservative management which should include therapies such as nonsteroidal anti-inflammatory medications, acetaminophen, manipulation, physical therapy, and a home exercise program; AND&quot;</td>
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<td>• Under Repeat Injections, Item 1, added &quot;with no more than 3 injections given in one year&quot; to read, &quot;If patient has achieved substantial relief with previous injection, repeat injections are to be no more frequent than every 2 months with no more than 3 injections given in one year&quot;</td>
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<td>• In Policy Guidelines Item 2 a, removed &quot;for several weeks&quot; to read, &quot;Use of prescription strength analgesics at a dose sufficient to induce a therapeutic response&quot;</td>
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<td>• In Policy Guidelines Item 3 b, removed &quot;at least 6 weeks of&quot; to read, &quot;Participation in physical therapy (including active exercise) or documentation of why the patient could not tolerate physical therapy, AND&quot;</td>
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<td>• In Policy Guidelines, added Item 3, &quot;Pain may be defined as moderate (interferes significantly with ADLs) or severe (disabling; unable to perform ADLs).&quot; Along with table outlining the Numeric Rating Scale.</td>
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<tr>
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<td>Updated Rationale section.</td>
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<td>In Coding section:</td>
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<td>• Added HCPCS codes G0259 and G0260.</td>
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<td>Updated References section.</td>
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<tr>
<td>04-12-2017</td>
<td>In Policy section:</td>
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<tr>
<td></td>
<td>• In Item A 3, removed &quot;and&quot; and added &quot;and/or&quot; to read, &quot;Failure to respond to nonsurgical conservative management, which should include therapies such as nonsteroidal anti-inflammatory medications, acetaminophen, manipulation, physical therapy, and/or a home exercise program; AND&quot;</td>
</tr>
</tbody>
</table>
|            | • In Policy Guidelines Item 2 a, removed "for the duration specified" to read, "Conservative nonsurgical therapy should include the following:"
|            | • In Policy Guidelines Item 2 a 1, removed "AND" and added "OR" to read, "Analgesics should include anti-inflammatory medications with or without adjunctive medications such as nerve membrane stabilizers or muscle relaxants, OR" |
|            | • In Policy Guidelines Item 2 b, removed "AND" and added "OR" to read, "Participation in physical therapy (including active exercise) or a home exercise program or documentation of why the patient could not tolerate physical therapy or a home exercise program, OR" |
|            | • In Policy Guidelines Item 2 c, removed "AND" and added with "OR" to read, "Evaluation and appropriate management of associated cognitive, behavioral, or addiction issues, OR" |
|            | Updated References section. |
| 05-01-2018 | Updated Description section. |
|            | In Policy section: |
|            | • In Item A 3, removed "(see Policy Guidelines), which should include therapies such as nonsteroidal anti-inflammatory medications, acetaminophen, manipulation, physical |
therapy, and/or a home exercise program" and added "see NOTE below" to read, "Failure to respond to nonsurgical conservative management (see NOTE below)"

- In Item A 4, removed "Note:" and added parenthesis to read "... (Ultrasound guidance is not considered adequate or accurate for sacroiliac joint injections.)"

- In Item A, under NOTE: removed “therapy” and added “management” to read, "Conservative nonsurgical management should include the following:"

- In Item A, under NOTE: 1 i, removed "OR" and added "AND" to read, "Analgesics should include anti-inflammatory medications with or without adjunctive medications such as nerve membrane stabilizers or muscle relaxants, AND"

- In Item A, NOTE: 2, removed "OR" and added "manipulation" to read, "Participation in physical therapy (including active exercise) or manipulation or a home exercise program or documentation of why the patient could not tolerate physical therapy, manipulation, or a home exercise program, AND"

- In Item A, removed NOTE: "3. Manipulation, AND"

- In Item A, NOTE: 3 (previous Item A NOTE: 4), removed "OR" and added "AND" to read, Evaluation and appropriate management of associated cognitive, behavioral, or addiction issues, AND"

- Added new Item E, "Minimally invasive fusion/stabilization of the sacroiliac joint using a titanium triangular implant may be considered medically necessary when ALL of the following criteria have been met: 1. Average pain level of ≥6 on a scale of 1 to 10 (see Policy Guidelines) that impacts quality of life or limits activities of daily living; AND 2. There is an absence of generalized pain behavior (eg, somatoform disorder) or generalized pain disorders (eg, fibromyalgia); AND 3. Patients have undergone and failed a minimum 6 months of intensive nonoperative treatment that must include medication optimization, activity modification, bracing, and active therapeutic exercise targeted at the lumbar spine, pelvis, sacroiliac joint, and hip, including a home exercise program; AND 4. Pain is caudal to the lumbar spine (L5 vertebra), localized over the posterior sacroiliac joint, and consistent with sacroiliac joint pain; AND 5. A thorough physical examination demonstrates localized tenderness with palpation over the sacral sulcus (Fortin's point) in the absence of tenderness of similar severity elsewhere; AND 6. There is a positive response to at least 3 provocative tests (see Policy Guidelines); AND 7. Diagnostic imaging studies include ALL of the following: a) Imaging (plain radiographs and computed tomography or magnetic resonance imaging) of the sacroiliac joint excludes the presence of destructive lesions (eg, tumor, infection) or inflammatory arthropathy of the sacroiliac joint; AND b) Imaging of the pelvis (anteroposterior plain radiograph) rules out concomitant hip pathology; AND c) Imaging of the lumbar spine (computed tomography or magnetic resonance imaging) is performed to rule out neural compression or other degenerative condition that can be causing low back or buttock pain; AND d) Imaging of the sacroiliac joint indicates evidence of injury and/or degeneration; AND 8. There is at least a 75% reduction in pain for the expected duration of the anesthetic used following an image-guided, contrast-enhanced intra-articular sacroiliac joint injection on 2 separate occasions; AND 9. A trial of a therapeutic sacroiliac joint injection (ie, corticosteroid injection) has been performed at least once.

- In new Item F (previous Item E), removed "including, but not limited to, percutaneous and minimally invasive techniques" and added "under all other conditions and with any other devices not listed above" to read, "Fusion / stabilization of the sacroiliac joint for the treatment of back pain presumed to originate from the SI joint is considered experimental / investigational under all other conditions and with any other devices not listed above."

- Updated Policy Guidelines.

- Updated Rationale section.

- In Coding section:
- Added CPT code: 64640.
- Removed ICD-9 codes.
- Added ICD-10 codes: M47.898, M47.899, M53.2X8, M54.18, M54.6, S33.2, S33.6.

Updated References section.

08-31-2018 Policy published to the bcbsks.com web site on 08-01-2018 with an effective date of 08-31-2018.

In Policy section:
- In Item A 4, added "(see Policy Guidelines)" to read, "The injections are performed under radiographic guidance with documentation of contrast material throughout the sacroiliac joint (see Policy Guidelines). Ultrasound guidance is not considered adequate or accurate for sacroiliac joint injections."
- In Policy Guidelines, added new Item 2, "Radiographic images used to perform SI joint injection should be digitally archived for retrieval at a later date."

Updated References section.

REFERENCES


33. 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


**Other References**

1. Blue Cross and Blue Shield of Kansas Orthopedic Liaison Committee, February 2014; August 2017; February 2018.