Title: Diagnosis and Treatment of Sacroiliac Joint Pain

<table>
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<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
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<tbody>
<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>
</tr>
<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>
</tbody>
</table>
### Populations
- Individuals: With sacroiliac joint pain

### Interventions
- Interventions of interest are:
  - Sacroiliac joint fusion

### Comparators
- Comparators of interest are:
  - Conservative therapy

### Outcomes
- Relevant outcomes include:
  - Symptoms
  - Functional outcomes
  - Quality of life
  - Medication use
  - Treatment-related morbidity

### Description
Sacroiliac joint 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 sacroiliac joint pain with corticosteroids, radiofrequency ablation (RFA), stabilization, or minimally invasive arthrodesis has also been explored.

### 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 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.

### 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 SI-FIX Sacroiliac Joint Fusion System (Medtronic), the IFUSE® Implant System (SI Bone), the Simmetry® Sacroiliac Joint Fusion System (Zyga Technologies), Silex™ Sacroiliac Joint Fusion System (X-Spine Systems), 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 $\geq 6$ on a scale of 1 to 10 (see Policy Guidelines); AND
   3. 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
   4. The injections are performed under radiographic guidance with documentation of contrast material throughout the sacroiliac joint.

   Note: Ultrasound guidance is not considered adequate or accurate for sacroiliac joint injections.

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

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

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

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

E. 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.

**Policy Guidelines**

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

2. Conservative nonsurgical therapy should include the following:
   a) Use of 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, OR  
b) 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  
c) Evaluation and appropriate management of associated cognitive, behavioral, or addiction issues, OR  
d) Documentation of patient compliance with the preceding criteria.

3. 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>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No pain</td>
</tr>
<tr>
<td>1-3</td>
<td>Mild pain</td>
</tr>
<tr>
<td>4-6</td>
<td>Moderate pain</td>
</tr>
<tr>
<td>7-10</td>
<td>Severe pain</td>
</tr>
</tbody>
</table>

**RATIONALE**

This policy was updated with a literature review using MEDLINE; most recently through July 15, 2016. Following is a summary of key references to date.

**Diagnosis**

The use of diagnostic blocks to evaluate sacroiliac joint pain builds on the experience of use of diagnostic blocks in other joints to evaluate pain. Blinded studies with placebo controls (although difficult to conduct when dealing with invasive procedures) are ideally required for scientific validation of sacroiliac joint 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, there is no current criterion standard for sacroiliac joint injection. In fact, some authors have positioned sacroiliac joint injection as the criterion standard against which other diagnostic tests and physical exam may be measured. Ultimately, the point of diagnosis is to appropriately select patients 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 (APS) were based on a systematic review that was commissioned by APS and conducted at the Oregon Evidence-based Practice Center. The systematic review concluded that no reliable evidence existed to evaluate validity or utility of diagnostic sacroiliac joint block as a diagnostic procedure for low back pain with or without radiculopathy, with a resulting guideline recommendation of insufficient evidence. Data on sacroiliac joint steroid injection were limited to 1 small controlled trial, resulting in a recommendation of insufficient evidence for therapeutic injection of this joint. In 2010, Manchikanti et al published critical reviews of the APS guidelines for interventional techniques, including sacroiliac injections. 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 (ASIPP) published an updated evidence review and 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
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
Systemic Reviews of Different Treatments
Hansen et al published a systematic review of sacroiliac joint 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. A total of 11 studies (6 randomized, 5 nonrandomized trials) met inclusion criteria. Review found that evidence for intra-articular steroid injections is limited/poor, as is the evidence for periarticular 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/poor. The 2013 ASIPP evidence review found no additional studies on intra-articular or periarticular injections besides those identified by Hansen.7

Therapeutic Sacroiliac 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 study randomized 51 patients with sacroiliac joint and leg pain to physiotherapy, manual therapy, or intra-articular injection of corticosteroid.10 Diagnosis of sacroiliac joint pain was based on provocation tests and not sacroiliac joint injections. In a blinded assessment, 25 patients (56%) 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 score (VAS) 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 compared with steroid injection for sacroiliac joint pain in 2010.11 The study included 48 patients with sacroiliac joint 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 (numerical rating scale) and disability scores (Oswestry Disability Index) were assessed at baseline, 2 weeks, and monthly after completion of treatment. At 2-week follow-up, pain and disability scores were significantly improved in both groups, with no significant difference between the groups. Pain on the numerical rating scale 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 survival (recurrence of severe sacroiliac joint pain) was 3 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 to 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 and Meta-Analyses

Aydin et al published a meta-analysis of radiofrequency ablation (RFA) for sacroiliac pain in 2010.12 Nine studies were included that reported the primary outcome measure of a reduction of pain of 50% or greater, including 1 randomized placebo controlled study, 3 prospective observational studies, and 5 retrospective studies. All of the studies used injection of local anesthetic to determine if RFA was indicated for the patient. Seven studies reported follow-up to 3 months, and 6 studies reported follow-up to 6 months. Meta-analysis indicated that half or greater of the patients who received RFA to the sacroiliac joint 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 systematic review is limited by the low quality of included studies and lack of RCTs. In addition, as noted by the authors, no standards have been established for the specific nerves to ablate or type of technique.

No additional studies were identified in the 2013 ASIPP 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 systematic review was published in 2008.13 This study examined the effect of lateral branch radiofrequency denervation with a cooled probe in 28 patients with injection-diagnosed sacroiliac joint pain. Two of 14 patients (14%) 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.\textsuperscript{14} Twelve-month follow-up was reported in 2016.\textsuperscript{15} Fifty-one patients who had a positive response to 2 lateral branch blocks were randomized in a 2:1 ratio to lateral branch radiofrequency or sham. At 3-month follow-up, significant improvements in pain (-2.4 vs -0.8), physical function (14 vs 3), disability (-11 vs 2), and quality of life (0.09 vs 0.02) were observed for radiofrequency treatment compared with controls (all respectively). With treatment success defined as a 50% or greater reduction in the numerical rating scale (NRS), 47% of radiofrequency-treated patients and 12% of sham patients achieved treatment success. The treatment response was durable out to 12 months in the 25 of 34 patients who completed all follow-up visits.\textsuperscript{15} Of the 9 patients who terminated study participation, 4 were considered treatment failures (12% of 34).

In 2014, Zheng et al reported an RCT of palisade sacroiliac RFA in 155 patients with ankylosing spondylitis.\textsuperscript{22} Palisade RFA uses a row of radiofrequency cannulae perpendicular to the dorsal sacrum. Inclusion criteria were age 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/exclusion criteria were randomized to either palisade RFA or celecoxib. Blinded evaluation found that RFA resulted in lower global VAS scores compared with celecoxib (2.8 vs 5.0, respectively, p<0.001), as well improved scores for secondary outcome measures. This study is limited by the lack of a sham control.

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In 2016, van Tilburg et al reported a sham-controlled RCT of percutaneous RFA in 60 patients with SIJ pain.\textsuperscript{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.

Section Summary: Radiofrequency Ablation
The randomized trials of RFA have methodologic limitations and there is limited data on duration of treatment effect. Heterogeneity of RFA treatment techniques precludes generalizing results across different studies.
**SIJ Fusion**

The literature on minimally invasive SIJ fusion for SIJ pain includes 2 RCTs and a number of case series. Although open SIJ fusion has been used since the 1920s and case reports of outcomes exist, the open procedure is a rarely performed for this indication and hence clinical trials do not exist. Because RCT evidence for SIJ fusion only exists for the iFuse Implant system, this section of the evidence review will only evaluate RCTs and case series of fusion using this particular implant. Case series with high follow-up rates will be noted and emphasized, because they provide more valid estimates of outcomes. Case series with high follow-up rates and reporting longer term outcomes may allow conclusions on durability of treatment benefit, if such a benefit can be concluded from short-term RCTs.

**Randomized Controlled Trials**

In 2015, Whang et al reported an industry-sponsored non-blinded RCT (NCT01681004) of the iFuse Implant System in 148 patients. Twelve-month follow-up was reported by Polly et al in 2015. Inclusion in the study was based on the determination of the sacroiliac joint as a pain generator from a combination of a history of sacroiliac joint-localized pain, positive provocative testing on at least 3 of 5 established physical tests, and at least a 50% decrease in sacroiliac point pain after image-guided local anesthetic injection into the joint. The duration of pain before enrollment averaged 6.4 years (range, 0.47-40.7 years).

Patients were assigned in a 2:1 ratio to minimally invasive sacroiliac joint fusion (n=102) or to nonsurgical management (n=46). Nonsurgical management included a stepwise progression, depending on individual patient needs, of pain medications, physical therapy (98%), intra-articular steroid injections (73.9%), and RFA of sacral nerve roots (45.7%). The primary outcome measure was 6-month success rates, defined as the proportion of treated subjects with a 20-mm improvement in sacroiliac joint 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 of 100 and ODI scores averaging 61.9.

Six-month results of this study are shown in Table 1. At 6 months, success rates were 23.9% in the control group versus 81.4% in the surgical group (posterior probability of superiority >0.999). A clinically important (≥15 point) improvement in the ODI was found in 27.3% of controls compared with 75.0% of fusion patients. Measures of quality of life (SF-36, EQ-5D) also improved to a greater extent in the surgery group. Of the 44 nonsurgical management patients who were still participating at 6 months, 35 (79.5%) crossed over to fusion. Opioid use remained high in both groups at 6 months (70.5% for nonsurgical controls, 58.0% for fusion patients; p=0.082) and at 12 months (55% vs 52%, respectively, p=0.61). Although these results are generally positive, there is a high potential for bias in this nonblinded study with subjective outcome measures. Aside from nonblinding, the study was of high methodologic quality. Follow-up of all patients will continue through 24 months.

In 2016, Sturesson et al reported another industry-sponsored nonblinded RCT of the iFuse Implant System in 103 patients. Inclusion was based on similar criteria as the Whang trial, including at least 50% pain reduction on SIJ block. Mean pain duration was 4.5 years. 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.
Of 109 randomized subjects, 6 withdrew before any treatment. All patients assigned to iFuse underwent the procedure, and follow-up at 6 months was in 49 of 51 patients in the control group and in all 52 patients in the iFuse group. At 6 months, VAS pain scores improved by 43.3 points in the iFuse group and by 5.7 in the control group (p<0.001). ODI scores improved by 5.8 points in the control group and by 25.5 points in the iFuse group (p<0.001, between groups). Quality of life outcomes showed a greater improvement in the iFuse group than in the control group. Although these results favored fusion, with magnitudes of effect in a range similar to the RCT by Whang, this trial was also not blinded and lacked a sham control. Outcomes were only assessed to 6 months.

### Table 1. Summary of 6-Month iFuse Results From Whang et al and Sturesson et al

<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>Ctrl</td>
<td>iFuse</td>
<td>Ctrl</td>
<td>iFuse</td>
<td>Ctrl</td>
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<tr>
<td>Baseline</td>
<td>82.2</td>
<td>82.3</td>
<td>61.1</td>
<td>62.2</td>
<td>30.8</td>
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<tr>
<td>Follow-up</td>
<td>70.4</td>
<td>29.8</td>
<td>23.9%</td>
<td>81.4%a</td>
<td>56.4</td>
</tr>
<tr>
<td>Change</td>
<td>-52.6a</td>
<td>-4.9</td>
<td>-30.3a</td>
<td>1.2</td>
<td>12.7</td>
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<tr>
<td>Sturesson et al (2016)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>73.0</td>
<td>77.7</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Follow-up</td>
<td>67.8</td>
<td>34.4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change</td>
<td>-5.7</td>
<td>-43.3</td>
<td>-5.8</td>
<td>-25.5</td>
<td>0.11</td>
</tr>
</tbody>
</table>

The success end point was defined as a reduction in pain VAS score of ≥20, absence of device-related events, absence of neurologic worsening, and absence of surgical intervention.

Ctl: control; EQ-5D TTO: EuroQoL Time Tradeoff Index; ODI: Oswestry Disability Index; SF-36 PCS: 36-Item Short-Form Health Survey Physical Component Summary; VAS: visual analog scale.

a p<0.001.

### Case Series

In 2013, Smith et al reported a retrospective comparison of open versus minimally invasive SIJ fusion. Because all patients received fusion, this study should be interpreted as a case series, with attention paid to the minimally invasive fusion group. Only patients with medical records documenting 12- or 24-month pain scales were included, resulting in 114 patients selected for the minimally invasive group. Losses to follow-up could not be determined. At 12 months, VAS pain scores decreased to a mean of 2.3 from a baseline of 8.1. At 24 months, mean VAS pain score was 1.7, but data for only 38 patients were analyzed. These improvements in VAS pain score were greater than those for open fusion, but conclusions of comparative efficacy should not be made given this type of study. Implant repositioning was performed in 3.5% of patients in the minimally invasive group.

A large (N=144) industry-sponsored multicenter retrospective series was reported by Sachs et al in 2014. Consecutive patients from 6 sites were included in the study if preoperative and 12-month follow-up data were available. No information was provided on the total number of patients who were treated during the same time interval. The mean baseline pain score was 8.6. At a mean 16-month follow-up, VAS was 2.7, an improvement of 6.1 of 10. Ten percent of patients reported an improvement of 1 point or less. Substantial clinical benefit, defined as a decrease in pain by greater than 2.5 points or a score of 3.5 or less, was reported in 91.9% of patients.

In 2012, Rudolf reported a retrospective analysis of his first 50 consecutive patients treated with the iFuse Implant System. There were 10 perioperative complications, including implant
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penetration into the sacral neural foramen (2 patients) and compression of the L5 nerve (1 patient); these resolved with surgical retraction of the implant. 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, and 82% of patients had attained the minimum clinically important difference (defined as ≥2 of 10).

A 2014 report by Rudolph and Capobianco described 5-year follow-up from 17 of 21 consecutive patients treated at their institution between 2007 and 2009. Of the 4 patients lost to follow-up, 2 had died and 1 had become quadriplegic due to severe neck trauma. For the remaining patients, mean VAS 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 or a raw score less than 3.5. The 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.

In 2016, results from a case series of 172 patients undergoing SIJ fusion reported to 2 years were published by Duhon et al. Patients were formally enrolled in a single-arm trial (NCT01640353) with planned follow-up for 24 months. Success was defined as a reduction of VAS pain score of 20 mm (out of 100), 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 had 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. VAS pain score at 2 years was 26.0 and ODI score was 30.9. These 1-year outcomes were maintained at 2 years. Other outcomes (eg, quality of life scores) showed similar maintenance or slight improvement compared to 1-year outcomes. Use of opioid analgesics decreased from 76.2% at baseline to 55% at 2 years. Over the 2 years of follow-up, 8 (4.7%) patients required revision surgery.

In 2016, Sachs et al reported outcomes of 107 patients with a minimum follow-up of 3 years. The number of potentially eligible patients was not reported, so the follow-up rate is unknown. Pain scores improved from a mean of 7.5 at baseline to 2.5 at a mean follow-up time of 3.7 years. ODI score at follow-up was 28.2, indicating moderate residual disability. Satisfaction rate was 87.9% (67.3% very satisfied, 20.6% somewhat satisfied). Revision surgery was reported in 5 (4.7%) patients. Without knowing the number of eligible patients, the validity of this study cannot be determined.
In 2016, Schoell et al analyzed postoperative complications tracked in an administrative database of minimally invasive SIJ fusions. Although during the study there was no specific CPT code for minimally invasive sacroiliac fusion, CPT codes listed by a policy statement were used. 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%. The authors noted that the infection rate observed was consistent with the infection rates reported by Polly et al, but much higher than those reported for other types of minimally invasive spine procedures.

Case series in general showed improvements in VAS pain scores and other outcomes measures consistent in magnitude to the RCTs. The subset of studies with good 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. One study with a small sample size (17 of 21 followed) and a good follow-up showed results maintained to 5 years. If minimally invasive fusion is an effective treatment for SIJ pain, these results are consistent with medium-term durability of treatment.

Section Summary: SIJ Fusion
For SIJ fusion, the evidence includes 2 RCTs of minimally invasive fusion and a number of case series. Both nonblinded RCTs reported superior short-term results for fusion versus conservative management, but there is potential for bias because these trials lacked sham controls and used subjective outcome measures. Two case series of reasonable size and good follow-up showed that benefits obtained at 6 months persist to 2 years. One small case series showed good outcomes persist to 5 years.

Studies Comparing Different Treatments for SIJ Pain
Some investigators have analyzed studies comparing outcomes for different treatments for SIJ pain. In these studies, authors have compared case series of single treatments of studies to each other. Such analyses would not account for differences in patients between studies and differences in outcome assessment, and would be unlikely to provide valid comparisons between treatments.

ONGOING AND UNPUBLISHED CLINICAL TRIALS
Some currently unpublished trials that might influence this policy are listed in Table 2.

Table 2. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tr>
<td>Ongoing</td>
<td>Sacroiliac Joint Fusion With iFuse Implant System (SIFI)</td>
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<td>Dec 2015 (ongoing)</td>
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<tr>
<td>NCT01640353²⁹</td>
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<tr>
<td>NCT01861899²⁹</td>
<td>Treatment of Sacroiliac Dysfunction With SI-LOK® Sacroiliac Joint Fixation System</td>
<td>55</td>
<td>Aug 2017</td>
</tr>
</tbody>
</table>

²⁹ Some investigators have analyzed studies comparing outcomes for different treatments for SIJ pain. Some of these studies, authors have compared case series of single treatments of studies to each other. Such analyses would not account for differences in patients between studies and differences in outcome assessment, and would be unlikely to provide valid comparisons between treatments.
SUMMARY OF EVIDENCE

For individuals who have sacroiliac joint (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.

For individuals who have SIJ pain who receive RFA, the evidence includes 4 small RCTs using different techniques of applying radiofrequency 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 sacroiliac joint did not include a sham control. Another sham-controlled RCT 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 have SIJ pain who receive SIJ fusion, the evidence includes 2 RCTs of minimally invasive fusion and a number of case series. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Both nonblinded RCTs reported superior short-term results for fusion, but there is potential for bias because these trials lacked sham controls and used subjective outcome measures. Two case series of reasonable size and good follow-up showed that benefits obtained at 6 months persist to 2 years. One small case series showed good outcomes persist to 5 years. The case series are consistent with durability of treatment benefit, but only if there is a true benefit of treatment. 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.
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, periarthritis corticosteroid, and periarthritis 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, i.e., 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 (e.g., 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 (e.g., 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 (e.g., somatoform disorder) or generalized pain disorders (e.g., 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 (e.g., 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 (i.e., corticosteroid injection)."
- 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."

**U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS**

Not applicable

**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.

<table>
<thead>
<tr>
<th>CPT/HCPCS</th>
<th>Description</th>
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<tbody>
<tr>
<td>27096</td>
<td>Injection procedure for sacroiliac joint, anesthetic/steroid, with image guidance (fluoroscopy or CT) including arthrography when performed</td>
</tr>
<tr>
<td>27279</td>
<td>Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device</td>
</tr>
<tr>
<td>27280</td>
<td>Arthrodesis, open, sacroiliac joint, including obtaining bone graft, including instrumentation, when performed</td>
</tr>
<tr>
<td>27299</td>
<td>Unlisted procedure, pelvis or hip joint</td>
</tr>
<tr>
<td>G0259</td>
<td>Injection procedure for sacroiliac joint; arthrography</td>
</tr>
<tr>
<td>G0260</td>
<td>Injection procedure for sacroiliac joint; provision of anesthetic, steroid and/or other therapeutic agent, with or without arthrography</td>
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</table>

- The CPT code for injection into the sacroiliac joint is: 27096, used only if the 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-9 Diagnoses**

<table>
<thead>
<tr>
<th>Code</th>
<th>Diagnosis</th>
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<tbody>
<tr>
<td>720.2</td>
<td>Sacroiliitis, not elsewhere classified</td>
</tr>
<tr>
<td>724.00</td>
<td>Spinal stenosis, unspecified region other than cervical</td>
</tr>
<tr>
<td>724.01</td>
<td>Spinal stenosis of thoracic region</td>
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<tr>
<td>724.02</td>
<td>Spinal stenosis of lumbar region, without neurogenic claudication</td>
</tr>
</tbody>
</table>
724.03 Spinal stenosis of lumbar region, with neurogenic claudication
724.09 Spinal stenosis, other region other than cervical
724.1 Pain in thoracic spine
724.2 Lumbago
724.3 Sciatica
724.4 Thoracic or lumbosacral neuritis or radiculitis, unspecified
724.5 Unspecified backache
724.6 Disorders of sacrum
724.70 Unspecified disorder of coccyx
724.71 Hypermobility of coccyx
724.79 Other disorder of coccyx
724.8 Other symptoms referable to back
724.9 Other unspecified back disorders

ICD-10 Diagnoses (Effective October 1, 2015)
M46.1 Sacroiliitis, not elsewhere classified
M48.08 Spinal stenosis, 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

REVISIONS

<table>
<thead>
<tr>
<th>Date</th>
<th>Notes</th>
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<tbody>
<tr>
<td>07-27-2011</td>
<td>Policy added to the bcbsks.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: "Sacral 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

<table>
<thead>
<tr>
<th>Date</th>
<th>Coding Changes</th>
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</thead>
<tbody>
<tr>
<td>01-01-2015</td>
<td>Added CPT Code: 27279 (Effective January 1, 2015)</td>
</tr>
<tr>
<td></td>
<td>Deleted CPT Code: 0334T (Effective January 1, 2015)</td>
</tr>
<tr>
<td></td>
<td>Revised CPT Code 27280 (Effective January 1, 2015)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date</th>
<th>Coding Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>09-18-2015</td>
<td>Removed notes from ICD-9 codes 724.02 and 724.03.</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Date</th>
<th>Coding Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>11-18-2015</td>
<td>Removed previous Item A 2, &quot;Duration of pain of at least 3 months; AND&quot;</td>
</tr>
<tr>
<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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<tr>
<td></td>
<td>In new Item A 2, added (see Policy Guidelines)&quot; 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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<tr>
<td></td>
<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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<tr>
<td></td>
<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; AND&quot;</td>
</tr>
<tr>
<td></td>
<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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<tr>
<td></td>
<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>
</tr>
<tr>
<td></td>
<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</td>
</tr>
</tbody>
</table>
Updated Rationale section.

In Coding section:
- Added HCPCS codes G0259 and G0260.

Updated References section.

04-12-2017 In Policy section:
- In Item A 3, removed “and” and added “and/or” to read, “Failure to respond to nonsurgical conservative management, which should include therapies such as nonsteroidal anti-inflammatory medications, acetaminophen, manipulation, physical therapy, and/or a home exercise program; AND"
- In Policy Guidelines Item 2, removed “for the duration specified” to read, “Conservative nonsurgical therapy should include the following;”
- In Policy Guidelines Item 2 a I, removed “AND” and added “OR” to read, “Analgesics should include anti-inflammatory medications with or without adjunctive medications such as nerve membrane stabilizers or muscle relaxants, OR”
- In Policy Guidelines Item 2 b, removed “AND” and added “or a home exercise program” and “OR” to read, “Participation in physical therapy (including active exercise) or a home exercise program or documentation of why the patient could not tolerate physical therapy or a home exercise program, OR”
- In Policy Guidelines Item 2 c, removed “AND” and added with “OR” to read, “Evaluation and appropriate management of associated cognitive, behavioral, or addiction issues, OR”

Updated References section.

REFERENCES


Other References
1. Blue Cross and Blue Shield of Kansas Orthopedic Liaison Committee, February 2014.