Diagnosis and Treatment of Sacroiliac Joint Pain

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, 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, before 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 the study of the sacroiliac joint is that multiple structures, such as posterior facet joints and lumbar discs, may refer pain to the area surrounding the sacroiliac joint.

Because of inconsistent information obtained from history and physical examination, some have proposed the use of image-guided anesthetic injection into the sacroiliac joint for the diagnosis of sacroiliac joint pain. Treatments being investigated for sacroiliac joint pain include prolotherapy (see policy No. 2.01.26), corticosteroid injection, radiofrequency ablation, 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 Kimberly Clark/Baylis, 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. 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). Product Code: OUR.

Related Policies

2.01.26 Prolotherapy
6.01.25 Percutaneous Vertebroplasty and Sacroplasty
7.01.116 Facet Joint Denervation

Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Arthrography of the sacroiliac joint is considered investigational.

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

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

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

- Pain has failed to respond to 3 months of conservative management, which may consist of therapies such as nonsteroidal anti-inflammatory medications, acetaminophen, manipulation, physical therapy, and a home exercise program; AND
- The injection is performed under imaging guidance; AND
- No more than 3 injections are given in one year
Radiofrequency denervation of the sacroiliac joint is considered **not medically necessary**.

Fusion/stabilization of the sacroiliac joint for the treatment of back pain presumed to originate from the SI joint is considered **not medically necessary**, including but not limited to percutaneous and minimally invasive techniques.

**Policy Guidelines**

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

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

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

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

**Rationale**

**Diagnosis**

The use of diagnostic blocks to evaluate sacroiliac joint pain builds on the experience of use of diagnostic block 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 to 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. (1) Finally, one would like to
know how the results of a diagnostic test will be used in the management of the patient, and whether the subsequent treatment plan results in beneficial health outcomes.

The 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. (2,3) 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. (4,5) 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. (6-10) Seven studies met the inclusion criteria of 75% to 100% relief with dual blocks. The prevalence of sacroiliac joint pain ranged from 10% to 44.4% with false-positive rates ranging from 20% to 26%. The evidence for diagnostic sacroiliac intra-articular injections was considered to be good, with 75% to 100% pain relief as criterion standard with controlled local anesthetic or placebo blocks.

**Treatment**

Hansen et al published an updated systematic review of sacroiliac joint interventions in 2012. (11) 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 and 5 non-randomized) met inclusion criteria. Review found that evidence for intra-articular steroid injections is limited/poor, as is the evidence for periartricular 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 periartricular injections besides those identified by Hansen et al in 2012. (7)

**Therapeutic Sacroiliac Injections**

The available literature on therapeutic corticosteroid injections is limited, consisting of 1 small RCT that compared intra-articular injection with physical therapy or manual therapy, 1 small RCT that compared steroid injections with prolotherapy, 1 RCT with 10 patients that compared therapeutic sacroiliac injections with placebo, and case series. (11,12)

A 2013 study randomized 51 patients with sacroiliac joint and leg pain to physiotherapy, manual therapy, or intra-articular injection of corticosteroid. (13) 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 (see policy No. 2.01.26) compared with steroid injection for sacroiliac joint pain in 2010. (14) 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, ODI) 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.

Results from this small trial are insufficient to permit conclusions regarding the effect of this procedure on health outcomes. Comparisons to placebo, ideally using sham injections, are needed to determine the degree of benefit over placebo.

In 2007 Weksler et al reported results of diagnostic/therapeutic blocks in a series of patients who were referred for low back pain and disc herniation without claudication or neurologic abnormalities. (15) Fifty patients who had at least 3 positive pain provocation tests for sacroiliac joint dysfunction received sacroiliac injection of bupivacaine and betamethasone. Pain, assessed by visual analogue scores (VAS), improved from 7.8 to 1.3 at 30 minutes after the injection. At a 12-week follow-up, 46 patients (92%) reported VAS scores of 3 or less. Four patients required hospitalization for an unanticipated motor block.

Questions also remain about intra-articular versus periarticular sources of sacroiliac pain. For example, 1 prospective comparison found that peri-articular lidocaine injections (25/25 patients) were more effective than intra-articular injection (9 of 25 patients). (16,17)

**Radiofrequency Denervation**

The literature on radiofrequency denervation of the sacroiliac joint is limited. Two small RCTs using a cooled radiofrequency probe were identified. A third RCT used palisade sacroiliac joint radiofrequency neurotomy.

Aydin et al published a meta-analysis of radiofrequency ablation (RFA) for sacroiliac pain in 2010. (18) 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.

The single RCT included in the systematic review was published in 2008. (19) 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 the 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. (20) Twelve month follow-up was reported in 2015 (21) 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 to 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. (21) Of the 9 patients who terminated study participation, 4 were considered treatment failures (12% of 34).

No additional studies were identified in the 2013 ASIPP evidence review, which concluded that evidence is limited for conventional radiofrequency neurotomy, limited for pulsed radiofrequency neurotomy, and fair for cooled radiofrequency neurotomy. (7)

In 2014, Zheng et al reported an RCT of palisade sacroiliac RFA in 155 patients with ankylosing spondylitis (AS). (22) Palisade RFA uses a row of radiofrequency canulae perpendicular to the dorsal sacrum. Inclusion criteria were age 18 to 75 years; diagnosis of AS; chronic low back pain for at least 3 months; axial pain below L5; no peripheral involvement; pain aggravation upon manual pressing on the sacroiliac joint 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 to 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.

Arthrodesis

The literature on arthrodesis (open or minimally invasive) for sacroiliac joint pain includes 1 RCT on minimally invasive fusion, 1 cohort study comparing open and minimally invasive sacroiliac fusion, and a number of case series.

In 2015, Whang et al reported an industry-sponsored non-blinded RCT (INSITE, NCT01681004) of the iFuse Implant System in 148 patients. (23) Twelve-month follow-up was reported by Polly et al in 2015. (24) 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). Prior treatments in the control group included physical therapy (78.3% of subjects), intra-articular steroid injections (91.3%), and RFA of the sacroiliac nerve roots (8.7%). Patients were assigned in a 2:1 ratio to minimally invasive sacroiliac joint fusion (n=102) or to nonsurgical management (n=46). Non-surgical management included a step-wise progression, depending on individual patient needs, of pain medications, physical therapy (98% of patients), 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. Missing values were considered to be treatment failures, and the study was considered to meet its endpoint if there was a posterior probability for superiority of fusion of at least 0.975 by Bayesian analysis. Patients in the control arm could cross-over 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 Oswestry Disability Index (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.

Table 1. Summary of 6-Month Results from Whang et al (23)

<table>
<thead>
<tr>
<th>Results</th>
<th>VAS</th>
<th>At least 20 mm change in VAS</th>
<th>ODI</th>
<th>At least 15 pt. change in ODI</th>
<th>SF-36 PCS</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>
<td>iFuse</td>
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<tr>
<td>Baseline</td>
<td>82.2</td>
<td>82.3</td>
<td>23.9%*</td>
<td>81.4%*</td>
<td>61.1</td>
<td>62.2</td>
</tr>
<tr>
<td>Follow-up</td>
<td>70.4</td>
<td>29.8</td>
<td>-12.1</td>
<td>-52.6*</td>
<td>-4.9</td>
<td>-30.3*</td>
</tr>
<tr>
<td>Change</td>
<td>12.3</td>
<td>-53.0*</td>
<td>46.7%</td>
<td>-56.8%*</td>
<td>2.3</td>
<td>-27.1*</td>
</tr>
</tbody>
</table>

*p< 0.001; EQ-5D TTO: EuroQOL Time tradeoff index; ODI: Oswestry Disability Index; PCS: Physical Component Score; VAS: Visual analog scale

The largest study identified was a multicenter retrospective comparison of open versus minimally invasive sacroiliac joint fusion in 263 patients. (25) Because all patients received fusion, this trial does not offer evidence on the comparative effectiveness of SI fusion versus alternative treatment approaches. This study had a pragmatic design that included seven participating sites; 3 surgeons had performed open sacroiliac joint surgery (n=149) and 4 had performed minimally invasive fusion with the iFuse Implant system (n=114). Patients who underwent minimally invasive fusion were an average of 10 years older and were more likely to have had prior lumbar fusion (47.4% vs. 23.5%). Perioperatively, they had lower estimated blood loss (33 vs 288 cc), operating time (70 vs 163 min), and...
length of hospitalization (1.3 vs 5.1 days). At 12 months post-surgery, and after matching for age, gender, and history of prior lumbar fusion, pain scores were an average of 3 (of 10) points lower in the minimally invasive group (95% CI 2.1 to 4.0, p<0.001). Implant repositioning was performed in 3.5% of patients in the minimally invasive group, while 44% of patients in the open surgical group underwent removal of spinal implants for pain. (Note: A 2012 survey by the International Society for the Advancement of Spinal Surgery found that nearly 90% of surgeons who replied to the survey used a minimally invasive technique to perform sacroiliac joint fusion. (26))

A large (n=144) industry-sponsored multicenter retrospective series was reported by Sachs et al in 2014. (27) Consecutive patients from 6 sites were included in the study if pre-operative 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 out 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 Rudolf reported a retrospective analysis of his first 50 consecutive patients treated with the iFuse Implant System. (28) There were 10 perioperative complications, including implant 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’ follow-up (mean of 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 (MCID, defined as ≥2 out 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. (29) 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 or a raw score less than 3.5. The mean ODI score at 5 years was 21.5. Imaging by x-ray and CT showed intra-articular bridging in 87% of patients with no evidence of implant loosening or migration.

Percutaneous fusion of the sacroiliac joint with hollow modular anchorage screws was reported by Mason et al in 2013. (30) In this prospective single surgeon series, 73 patients underwent sacroiliac joint fusion and 55 patients (75%) were available for follow-up. At a mean follow-up of 36 months (range, 12-84), VAS for pain had decreased from 8.1 preoperatively to 4.5. This finding is limited by the high loss to follow-up. Notably, outcomes were worse for patients who had sacroiliac joint pain after spine surgery (VAS improvement of 1.76) compared to patients with degenerative sacroiliac joint pain (improvement of 4.85).

Comparative Studies

In 2010, Ashman et al conducted a systematic review to compare fusion vs denervation for chronic sacroiliac pain. (31) Six articles on fusion (95 patients) and 5 on denervation (68 patients) were included in the review. All studies on fusion were case series evaluating a single treatment. There were 2 small RCTs on radiofrequency denervation; one is described above, (19), and the other had only 9 patients. The strength of the evidence was considered to be very low to low, preventing conclusions regarding the comparative efficacy of the treatments.
A 2012 systematic review found that the quality of evidence for surgical treatment (debridement, fusion) vs injection treatment (corticosteroid, botulinum toxin, prolotherapy) for chronic sacroiliac pain was very low. (32) Seven case series on surgical treatment and 5 on injection treatment met their selection criteria. Although most studies reported over 40% improvement in pain and over 20% improvement in functionality, the literature was considered insufficient to evaluate the comparative effectiveness.

### Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this policy are listed in Table 1.

#### 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>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
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<tr>
<td>NCT01861899a</td>
<td>Treatment of Sacroiliac Dysfunction With SI-LOK® Sacroiliac Joint Fixation System</td>
<td>55</td>
<td>Dec 2016</td>
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<tr>
<td>Unpublished</td>
<td></td>
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<tr>
<td>NCT01104051</td>
<td>A Prospective, Single Center, Double Blind, Randomized, Sham Controlled, Crossover Study to Evaluate the Clinical Efficacy of Radiofrequency Nerve Ablation Using Simplicity III Versus Sham for the Treatment of Chronic Low Back Pain Associated With Sacroiliac Joint Dysfunction</td>
<td>39</td>
<td>Jan 2015</td>
</tr>
<tr>
<td>NCT01640353a</td>
<td>Sacroiliac Joint Fusion With iFuse Implant System (SIFI)</td>
<td>250</td>
<td>Dec 2015</td>
</tr>
</tbody>
</table>

NCT: national clinical trial

a Denotes industry-sponsored or cosponsored trial.

### Practice Guidelines, and Position Statements

The North American Spine Society (NASS) published coverage recommendations for percutaneous sacroiliac joint fusion in 2015. (33) 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).

The 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.

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. (34) 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 or sacroiliac joint injections may be used for chronic sacroiliac joint pain.

The 2009 practice guidelines from the American Pain Society (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.

The International Society for the Advancement of Spine Surgery (ISASS) published a policy statement on minimally invasive sacroiliac joint fusion in 2014. (35) ISASS states that patients who meet all of the following criteria may be eligible for minimally invasive sacroiliac joint fusion: significant sacroiliac joint pain or significant limitations in activities of daily living; pain confirmed on physical provocative examination maneuvers that stress the joint; confirmation of the sacroiliac joint as a pain generator with at least 75% acute decrease in pain immediately following fluoroscopically guided diagnostic joint block using local anesthetic; failure to respond to at least 6 months of non-surgical treatment; and additional or alternative diagnoses have been clearly considered, investigated and ruled out.
ISASS issued 2015 recommendations/coverage criteria for minimally invasive sacroiliac joint fusion, reiterating the recommendations in their 2014 policy statement.(35) ISASS recommendations state that patients who have all of the following criteria may be eligible for minimally invasive sacroiliac joint fusion:

- “Significant SIJ [sacroiliac joint fusion] pain (e.g., pain rating at least 5 on the 0-10 numeric rating scale where 0 represents no pain and 10 represents worst imaginable pain) or significant limitations in activities of daily living;
- “SIJ pain confirmed with at least 3 physical examination maneuvers that stress the SIJ and cause the patient’s typical pain.
- “Confirmation of the SIJ as a pain generator with ≥ 75% acute decrease in pain upon fluoroscopically guided diagnostic intra-articular SIJ 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 opioids (if not contraindicated) and one or more of the following: rest, physical therapy, SIJ steroid injection. 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 ruled out (e.g., L5/S1 compression, hip osteoarthritis).”

Minimally invasive sacroiliac joint fusion is not indicated for patients with the following:

- “Less than 6 months of back pain;
- “Failure to pursue conservative treatment of the SIJ (unless contra-indicated);
- “Pain not confirmed with a diagnostic SIJ block;
- Existence of other pathology that could explain the patient’s pain.”

U.S. Preventive Services Task Force Recommendations

Not applicable

Summary of Evidence

The evidence for therapeutic corticosteroid injections in patients who have sacroiliac joint pain includes small randomized controlled trials (RCTs). Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. In general, the literature regarding injection therapy on joints in the back is of poor quality. Results from the small trials on therapeutic sacroiliac joint injections are insufficient to permit conclusions on the effect of this procedure. Larger trials, preferably using sham injections, are needed to determine the degree of benefit over placebo. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for radiofrequency ablation in patients who have sacroiliac joint pain includes 2 small RCTs using a cooled radiofrequency probe and an RCT that used palisade sacroiliac joint radiofrequency neurotomy. 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 report short-term benefit, 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. Further high-quality controlled trials are needed that compare this procedure in defined populations with placebo and with
alternative treatments. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for sacroiliac joint fusion in patients who have sacroiliac joint pain includes 1 RCT on minimally invasive fusion, 1 cohort study comparing open and minimally invasive sacroiliac fusion, and a number of case series. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. The RCT reported superior short-term results for fusions, but there is a high potential for bias in this nonblinded study with subjective outcome measures. Follow-up of all patients will continue through 24 months. The evidence is insufficient to determine the effects of the technology on health outcomes.

Medicare National Coverage

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

References

31. Ashman B, Norvell DC, Hermesmeyer JT. Chronic sacroiliac joint pain: fusion versus denervation as treatment options. Evid Based Spine Care J. Dec 2010;1(3):35-44. PMID 22956926
Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>September 2011</td>
<td>New Policy</td>
<td>Policy updated with literature review and added references. Policy statement revised to include radio frequency ablation and fixation or fusions as not medically necessary.</td>
</tr>
<tr>
<td>June 2013</td>
<td>Update Policy</td>
<td>Policy updated with literature review; references 8, 14, 21-22, 24, and 27-28 added; policy changed to medically necessary for controlled diagnostic injections and for therapeutic injections with corticosteroids.</td>
</tr>
<tr>
<td>September 2014</td>
<td>Update Policy</td>
<td>Policy updated with literature review; references 8, 14, 21-23, 24, and 26-28 added; policy statements unchanged.</td>
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<tr>
<td>June 2015</td>
<td>Update Policy</td>
<td>Policy updated with literature review through October 22, 2015; references 17, 24, and 33 added. Policy statements unchanged.</td>
</tr>
<tr>
<td>June 2016</td>
<td>Update Policy</td>
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Keywords

Arthrography, Sacroiliac Joint
Sacroiliac Joint, Arthrodesis
Sacroiliac Joint, Arthrography
Sacroiliac Joint, Radiofrequency Ablation

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 24, 2016 and is effective July 15, 2016.

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