I. Policy

Sacroiliac Joint Arthrography
Arthrography of the sacroiliac joint is considered *investigational*. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Sacroiliac Joint Injections
Sacroiliac joint medication injections may be considered *medically necessary* for pain lasting more than three months despite appropriate conservative treatment. Documentation of fluoroscopy is required with each injection, to ensure correct needle placement. If successful (as documented by the usage of validated patient focused pain intensity assessment scales), it is reasonable to repeat the injection initially in two to four months. It is *not medically necessary* to perform sacroiliac injections more than four per twelve-month period, beginning with the date of the first injection.

Sacroiliac injections are considered *not medically necessary* for indications other than those listed above.

Radiofrequency Ablation
Radiofrequency ablation of the sacroiliac joint is considered *investigational*. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Fusion/stabilization of the Sacroiliac Joint
Fusion/stabilization of the sacroiliac joint for the treatment of back pain presumed to originate from the SI joint is considered *investigational*, including but not limited to percutaneous and minimally invasive techniques. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.
II. PRODUCT VARIATIONS

This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

BlueJourney HMO*  BlueJourney PPO*  FEP PPO**

*Refer to Novitas Solutions Local Coverage Determination (LCD) L34892 Transforaminal Epidural, Paravertebral Facet and Sacroiliac Joint Injections.

** For Sacroiliac Joint Arthrography and Injection refer to FEP Medical Policy Manual MP-6.01.23, Diagnosis and Treatment of Sacroiliac Joint Pain. The FEP Medical Policy Manual can be found at: www.fepblue.org.

III. DESCRIPTION/BACKGROUND

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.

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 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, 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 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) and the SI-LOK (Globus Medical). FDA Product Code: OUR.

IV. RATIONALE

The most recent literature review was performed 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, no current criterion standard for sacroiliac joint injection exists. In fact, some authors have positioned sacroiliac joint injection as the criterion standard against which other diagnostic tests and physical exam may be measured. 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. 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.
In 2013, the American Society of Interventional Pain Physicians (ASIPP) published an updated evidence review and guidelines on diagnosis of SIJ pain. 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**

**Systematic Reviews of Different Treatments**

Hansen et al published an systematic review of SIJ interventions in 2012. 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. The review found that evidence for intra-articular steroid injections is limited/poor, as was 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.

**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.

A 2013 trial randomized 51 patients with SIJ and leg pain to physical therapy, manual therapy, or intra-articular injection of corticosteroid. Diagnosis of SIJ pain was based on provocation tests and not SIJ injections. In a blinded assessment, 25 (56%) patients were considered to be successfully treated at the 12-week follow-up visit based on complete relief of pain and improvement in the visual analog scale (VAS) score for pain. 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. 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 [NRS]) and disability scores (Oswestry Disability Index [ODI]) were assessed at baseline, 2 weeks, and monthly after completing treatment. At 2-week follow-up, pain and disability scores were significantly improved in both groups, with no significant difference between groups. NRS 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 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 RFA for sacroiliac pain in 2010. Nine studies included 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 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. 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 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.

Randomized Controlled Trials
The single RCT included in the Aydin meta-analysis was published in 2008. 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. Twelve-month follow-up was reported in 2016. 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 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) were observed for radiofrequency treatment compared with controls (all respectively). With treatment success defined as a 50% or greater reduction in NRS 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. 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. 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 RCT of percutaneous RFA in 60 patients with SIJ pain. 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 nonblinded RCT of the iFuse Implant System in 148 patients.\(^1\) Twelve-month follow-up was reported by Polly et al in 2015.\(^2\) Trial inclusion was based on the 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 joint. The duration of pain before enrollment averaged 6.4 years (range, 0.47-40.7 years).

Patients were assigned 2:1 to minimally invasive SIJ 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 (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.

Six-month results 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 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. Opioid use remained high in both groups at 6 months (70.5% for controls vs 58.0% for fusion; p=0.082) and at 12 months (55% vs 52%, respectively, p=0.61). Although these results generally favored fusion and had high methodologic quality, the trial had a high potential for bias (nonblinded study, subjective outcome measures).

In 2016, Sturesson et al reported another industry-sponsored nonblinded RCT of the iFuse Implant System in 103 patients.\(^3\) 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 (e.g., 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 patient 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\textsuperscript{18} and Sturesson et al\textsuperscript{20}

<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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</thead>
<tbody>
<tr>
<td></td>
<td>Ctl</td>
<td>iFuse</td>
<td>Ctl</td>
<td>iFuse</td>
<td>Ctl</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%\textsuperscript{a}</td>
<td>56.4</td>
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<tr>
<td>Change</td>
<td>-12.1</td>
<td>-52.6\textsuperscript{a}</td>
<td>-4.9</td>
<td>-30.3\textsuperscript{a}</td>
<td>1.2</td>
</tr>
<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.

\textsuperscript{a} p<0.001.

Case Series

In 2013, Smith et al reported a retrospective comparison of open versus minimally invasive SIJ fusion.\textsuperscript{21} 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.\textsuperscript{22} Consecutive patients from 6 sites were included if preoperative and 12-month follow-up data were available. No information was provided on the total number of patients treated during the same time interval. The mean baseline pain score was 8.6. At a mean 16-month follow-up, VAS score 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 score by more 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.\textsuperscript{23} 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 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 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. 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 score 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. 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 (e.g., 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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<td>Sacroiliac Joint Fusion With iFuse Implant System (SIFI)</td>
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<td>NCT01861899a</td>
<td>Treatment of Sacroiliac Dysfunction With SI-LOK® Sacroiliac Joint Fixation System</td>
<td>55</td>
<td>Aug 2017</td>
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<tr>
<td>Unpublished</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>Jun 2015 (completed)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.
a Denotes industry-sponsored or cosponsored trial.

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 Received 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 SIJ 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 SIJ fusion to be investigational.

2014 Input

In response to requests, input was received from 4 physician specialty societies and 4 academic medical centers (5 responses) while this policy was under review in 2014. Input was mixed on the use of arthrography, RFA, and fusion of the SIJ. Most reviewers considered injection for diagnostic purposes to be medically necessary when using controlled blocks with at least 75% pain relief, and for injection of corticosteroids for treatment purposes. Treatment with prolotherapy, periarticular corticosteroid, and periarticular botulinum toxin were considered investigational by most reviewers.
2010 Input
In response to requests, input was received from 4 physician specialty societies (6 responses) and 3 academic medical centers (5 responses) while this policy was under review in 2010. Clinical input was mixed. There was general agreement that the evidence for SIJ injections is limited, although most reviewers considered sacroiliac injections to be the best available approach for diagnosis and treatment in defined situations.

Practice Guidelines and Position Statements

North American Spine Society
The North American Spine Society (NASS) published coverage recommendations for percutaneous SIJ fusion in 2015. NASS indicated that there was relatively moderate evidence. In the absence of high-level data, policies reflect the multidisciplinary experience and expertise of the committee members in order to present reasonable standard practice indications in the United States. NASS recommended coverage when ALL of the following criteria are met:

1. “[Patients] have undergone and failed a minimum 6 months of intensive nonoperative treatment that must include medication optimization, activity modification, bracing and active therapeutic exercise targeted at the lumbar spine, pelvis, SIJ and hip including a home exercise program.
2. Patient’s report of typically unilateral pain that is caudal to the lumbar spine (L5 vertebra), localized over the posterior SIJ, and consistent with SIJ pain.
3. A thorough physical examination demonstrating localized tenderness with palpation over the sacral sulcus (Fortin’s point, 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 [computed tomography] or MRI [magnetic resonance imaging]) 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 [anteroposterior] plain radiograph) to rule out concomitant hip pathology.
   c. Imaging of the lumbar spine (CT or MRI) to rule out neural compression or other degenerative condition that can be causing low back or buttock pain.
   d. Imaging of the SI joint that indicates evidence of injury and/or degeneration.
7. At least 75% reduction of pain for the expected duration of the anesthetic used following an image-guided, contrast-enhanced intra-articular SIJ injection on 2 separate occasions.
8. A trial of at least one therapeutic intra-articular SIJ injection (i.e., corticosteroid injection).”

American Society of Interventional Pain Physicians
American Society of Interventional Pain Physicians Interventional Pain Management guidelines were updated in 2013. 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 updated their guidelines for chronic pain management. The guidelines recommended that “Diagnostic sacroiliac joint injections or lateral branch blocks may be considered for the evaluation of patients with suspected sacroiliac joint pain.” Based on opinions of consultants and society members, the guidelines recommend that “Water-cooled radiofrequency ablation may be used for chronic sacroiliac joint pain.”

American Pain Society
The 2009 practice guidelines from the American Pain Society (APS) were based on a systematic review commissioned by APS. APS guidelines stated that there is insufficient evidence to evaluate validity or utility of diagnostic SIJ block as a diagnostic procedure for low back pain with or without radiculopathy and that there is insufficient evidence to adequately evaluate benefits of SIJ steroid injection for nonradicular low back pain.

International Society for the Advancement of Spine Surgery
The International Society for the Advancement of Spine Surgery (ISASS) first published a policy statement on minimally invasive SIJ fusion in 2014. These recommendations were updated in a 2016 statement. 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.”

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

Not applicable.

**Medicare National Coverage**

There is no national coverage determination (NCD).

V. **DEFINITIONS**

**ARTHROGRAPHY** is a diagnostic study that involves the injection of contrast media into a joint.

VI. **BENEFIT VARIATIONS**

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member’s individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member’s benefit information or contact Capital for benefit information.

VII. **DISCLAIMER**

*Capital’s medical policies are developed to assist in administering a member’s benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member’s benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.*
VIII. CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

**Considered investigational when used to bill for fusion/stabilization of the Sacroiliac joint; therefore not covered:**

| CPT Codes® | 27279 | 27280 |


**Considered investigational when used to bill for sacroiliac joint arthrography; therefore not covered:**

| CPT Codes® | 27096 |


<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>G0259</td>
<td>Injection procedure for sacroiliac joint; arthrography</td>
</tr>
</tbody>
</table>

**Investigational when billed for radiofrequency ablation of the sacroiliac joint; therefore not covered:**

| CPT Codes® | 64635 |


**Covered when medically necessary:**

| CPT Codes® | 27096 |


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<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<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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**ICD-10-CM**

<table>
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<tr>
<th>Description</th>
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Diagnosis Codes*  

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>M46.1</td>
<td>Sacroilitis, not elsewhere classified</td>
</tr>
<tr>
<td>M54.18</td>
<td>Radiculopathy, sacral and sacrococcygeal region</td>
</tr>
<tr>
<td>M54.31</td>
<td>Sciatica, right side</td>
</tr>
<tr>
<td>M54.32</td>
<td>Sciatica, left side</td>
</tr>
<tr>
<td>M54.41</td>
<td>Lumbago with sciatica, right side</td>
</tr>
<tr>
<td>M54.52</td>
<td>Lumbago with sciatica, left side</td>
</tr>
<tr>
<td>M54.5</td>
<td>Low back pain</td>
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* If applicable, please refer to the Medicare NCD or LCD for details.

VIII. REFERENCES


### MEDICAL POLICY

<table>
<thead>
<tr>
<th>POLICY TITLE</th>
<th>DIAGNOSIS AND TREATMENT OF SACROILIAC JOINT PAIN</th>
</tr>
</thead>
<tbody>
<tr>
<td>POLICY NUMBER</td>
<td>MP-5.048</td>
</tr>
</tbody>
</table>

**Other:**


**IX. POLICY HISTORY**

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>MP-5.048 CAC 11/22/11</td>
<td>New policy with criteria previously addressed in MP-4.014 Pain Control. BCBSA guidelines adopted. Arthrography of the sacroiliac joint remains investigational. Injection into the sacroiliac joint for treatment of pain previously considered medically necessary, is now considered investigational. FEP variation added. 2/9/12- Policy title changed to “Diagnosis and Treatment of Sacroiliac Joint Pain.” Radiofrequency ablation of the sacroiliac joint added as investigational.</td>
</tr>
<tr>
<td>3/22/12</td>
<td>Decision to adopt BCBSA revised. The revisions approved 11/22/11 were not posted. Will keep current policy criteria that were in the MP-4.014 Pain Control. The procedure for sacroiliac joint injection for treatment of pain will remain medically necessary.</td>
</tr>
<tr>
<td>04/22/13</td>
<td>Admin code review</td>
</tr>
<tr>
<td>CAC 7/30/13</td>
<td>Minor. Statement added indicating fusion/stabilization of the sacroiliac joint for the treatment of back pain presumed to originate from the SI joint is considered investigational, including but not limited to percutaneous and minimally invasive techniques. Policy coded</td>
</tr>
<tr>
<td>04/29/2014</td>
<td>Added 27280 as investigational</td>
</tr>
<tr>
<td>CAC 5/20/14</td>
<td>Consensus review. References updated. No changes to the policy statements. Rationale added. Codes reviewed.</td>
</tr>
<tr>
<td>8/12/2014</td>
<td>Admin error correction, code 27280 placed again with CPT codes in accordance with language noting as investigational as per CAC 7/30/13</td>
</tr>
<tr>
<td>01/2015</td>
<td>New 2015 CPT code added to policy.</td>
</tr>
<tr>
<td>CAC 6/2/15</td>
<td>Consensus review. No changes to the policy statements. References and rationale updated. Coding reviewed.</td>
</tr>
<tr>
<td>CAC 5/31/16</td>
<td>Consensus review. No change to the policy statements. References and rationale updated. LCD number changed from L27512 to L34892. Coding reviewed.</td>
</tr>
<tr>
<td>CAC 11/29/16</td>
<td>Consensus review. No change to the policy statements. FEP policy title updated. Variation reformatting completed. Description/Background, Rationale and Reference sections updated. Coding Reviewed.</td>
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<tr>
<td><strong>POLICY TITLE</strong></td>
<td><strong>DIAGNOSIS AND TREATMENT OF SACROILIAC JOINT PAIN</strong></td>
</tr>
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