Diagnosis and Treatment of Sacroiliac Joint Pain

**Policy**

Arthrography of the sacroiliac joint is considered **investigational**.

Injection of anesthetic 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 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 **investigational**.

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

### Related Policies

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<tr>
<th>Policy Number</th>
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<tr>
<td>2.01.26</td>
<td>Prolotherapy</td>
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<tr>
<td>7.01.551</td>
<td>Lumbar Spine Decompression Surgery: Discectomy, Foraminotomy, Laminotomy, Laminectomy</td>
</tr>
<tr>
<td>7.01.555</td>
<td>Facet Joint Denervation</td>
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</table>
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 (i.e., steroids, saline, other substances) should be administered for a period of at least 4 weeks before the diagnostic lateral branch block. The diagnostic blocks should not be conducted under intravenous sedation unless specifically indicated (e.g., the patient is unable to cooperate with the procedure).

### Coding

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<th>CPT</th>
<th>Description</th>
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<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 (new code effective 1/1/15)</td>
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<tr>
<td>27280</td>
<td>Arthrodesis, sacroiliac joint (including obtaining graft)</td>
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<td>64640</td>
<td>Destruction by neurolytic agent; other peripheral nerve or branch</td>
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### 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.

For individuals who have SIJ pain who receive therapeutic corticosteroid injections, the evidence includes small randomized controlled trials (RCTs) and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. In general, the literature on injection therapy of joints in the back is of poor quality. Results from 2 small RCTs showed that therapeutic SIJ steroid injections were not as effective as other active treatments. Larger trials, preferably using sham injections, are needed to determine the degree of benefit of corticosteroid injections over placebo. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

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 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 Related Policies), corticosteroid injection, radiofrequency ablation, stabilization, and arthrodesis.

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

Several percutaneous or minimally invasive fixation/fusion devices have been cleared for marketing by FDA. They 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.
Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

<table>
<thead>
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<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
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<td>Individuals:</td>
<td>Interventions of interest are:</td>
<td>Comparators of interest are:</td>
<td>Relevant outcomes include:</td>
</tr>
<tr>
<td>With sacroiliac joint pain</td>
<td>• Therapeutic corticosteroid injections</td>
<td>• Physical therapy</td>
<td>• Symptoms</td>
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<td></td>
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<td>• Functional outcomes</td>
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<td>• Medication use</td>
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<td>• Treatment-related morbidity</td>
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</table>

Individuals: With sacroiliac joint pain

Interventions of interest are:

Radiofrequency ablation

Comparators of interest are:

Conservative therapy

Relevant outcomes include:

Symptoms

Functional outcomes

Quality of life

Medication use

Treatment-related morbidity

Individuals: With sacroiliac joint pain

Interventions of interest are:

Sacroiliac joint fusion

Comparators of interest are:

Conservative therapy

Relevant outcomes include:

Symptoms

Functional outcomes

Quality of life

Medication use

Treatment-related morbidity

This policy was created in 2000 and has been updated periodically with searches of the MEDLINE database. 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.(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. 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.(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 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
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 updated 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 periarthritis injections (local anesthetic and steroid or botulinum toxin). For radiofrequency neurotomy, the evidence for cooled radiofrequency was found to be fair (2 RCTs), while evidence for conventional radiofrequency or pulsed radiofrequency was limited/poor. The 2013 ASIPP evidence review(7) found no additional studies on intra-articular or periarthritis injections besides those identified by Hansen.

Therapeutic Sacroiliac Injections

Randomized Controlled Trials
The available literature on therapeutic corticosteroid injections is limited, consisting of one 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.(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 (see Related Policies) 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 (numeric rating scale) and disability scores (Oswestry Disability Index [ODI]) were assessed at baseline, 2 weeks,
Section Summary
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. (12) 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. (7)

Randomized Controlled Trials
The single RCT included in the Aydin meta-analysis was published in 2008. (13) This trial by Cohen et al examined the effect of lateral branch radiofrequency denervation with a cooled probe in 28 patients with injection-diagnosed SIJ pain. Two (14%) of 14 patients in the placebo-control group reported pain relief at 1-month follow-up. None reported benefit at 3-month follow-up. Of 14 patients treated with radiofrequency denervation, 11 (79%) reported pain relief at 1 month, 9 (64%) at 3 months, and 8 (57%) at 6 months.

In 2012, Patel et al reported a randomized double-blind placebo-controlled trial of lateral branch neurotomy with a cooled radiofrequency probe. (14) Twelve-month follow-up was reported in 2016. (15) Fifty-one patients who had a positive response to 2 lateral branch blocks were randomized 2:1 to lateral branch radiofrequency or to sham. At 3-month follow-up, significant improvements 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. (15) Of the 9 patients who terminated study participation, 4 (12%) of 34 were considered treatment failures.

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

In 2016, van Tilburg et al reported a sham-controlled RCT of percutaneous RFA in 60 patients with SIJ pain. (17) Patients selected had clinically suspected SIJ pain and a decrease of 2 or more points on a 10-point pain scale with a diagnostic sacroiliac block. At 3-month follow-up, there was no statistically significant difference in pain level over time between groups (group by period interaction, p=0.56). Both groups improved over time (≥2 points out of 10; p value for time, p<0.001). In their discussion, authors mentioned that the criteria and method used for diagnosing SIJ pain may have resulted in selection some patients without SIJ pain.

Section Summary
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
SIJ fusion was evaluated with a Blue Cross Blue Shield Association Evidence Street Assessment in September 2016, which judged that for individuals with presumed sacroiliac joint pain who are treated with sacroiliac joint fusion, evidence is insufficient to determine the effects of the technology on health outcome.

Randomized Controlled Trials
In 2015, Whang et al reported an industry-sponsored nonblinded RCT of the iFuse Implant System in 148 patients. (18) Twelve-month follow-up to this RCT was reported by Polly et al in 2015. (19) However, by 12 months, almost all patients in the control group had crossed over to SIJ fusion. Two-year follow-up of this trial was reported by Polly et al in 2016. (20) This last publication will be discussed in the case series section of this report. Trial inclusion was based on a determination of the SIJ as a pain generator from a combination of a history of SIJ-localized pain, positive provocative testing on at least 3 of 5 established physical tests, and at least a 50% decrease in SIJ pain after image-guided local anesthetic injection into the SIJ. The duration of pain before enrollment averaged 6.4 years (range, 0.47-40.7 years). A large proportion of subjects (37%) had previously undergone lumbar fusion, steroid SI joint infections (86%), and RF ablation (16%).

Patients were assigned 2:1 to minimally invasive SIJ fusion (n=102) or to nonsurgical management (n=46). Nonsurgical management included a stepwise progression of nonsurgical treatments, depending on individual patient choice. During follow-up, control patients received physical therapy (97.8%), intra-articular steroid injections (73.9%), and radiofrequency ablation (RFA) of sacral nerve roots (45.7%). The primary outcome measure was 6-month success rate, defined as the proportion of treated subjects with a 20-mm improvement in SIJ pain in the absence of severe device-related or neurologic adverse events or surgical revision. Patients in the control arm could crossover to surgery after 6 months. Baseline scores indicated that the patients were severely disabled, with VAS pain scores averaging 82.3 out of 100 and ODI scores averaging 61.9 out of 100 (0=no disability, 100=maximum disability).

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. Compared to baseline, opioid use at 6 months decreased from 67.6% to 58% in the surgery group, and increased from 63 to 70.5% in the control group (p=0.082). At 12 months, opioid use was similar between groups (55% vs 52%, p=0.61). 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. (21) Selection criteria were similar to those of the Whang trial, including at least 50% pain reduction on SIJ block. Mean pain duration was 4.5 years. Thirty-three percent of patients had undergone prior lumbar fusion. Nonsurgical management included physical therapy and exercises at least twice per week; intervention
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 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 points in the control group (p<0.001). ODI scores improved by 25.5 points in the iFuse group and by 5.8 points in the control group (p<0.001, between groups). QOL outcomes showed a greater improvement in the iFuse group than in the control group. Changes in pain medication use are not reported. Although these results favored fusion, with magnitudes of effect in a range similar to the Whang RCT, this trial was also not blinded and lacked a sham control. Outcomes were only assessed to 6 months. Six-month results for the Whang and Sturesson trials are shown in Table 1.

Table 1. Summary of 6-Month iFuse Results From Whang et al(18) and Sturesson et al(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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<td>Ctrl</td>
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<td>81.4%</td>
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<td>Change</td>
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<td>-52.6a</td>
<td>-4.9</td>
<td>-30.3a</td>
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<td>Sturesson et al (2016)</td>
<td>Baseline</td>
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<td>77.7</td>
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<tr>
<td></td>
<td>Follow-up</td>
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<td>Change</td>
<td>-5.7</td>
<td>-34.3</td>
<td>-5.8</td>
<td>-25.5</td>
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</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.

Section Summary

Two fair quality RCTs report outcome to 6 months, after which crossover was allowed and comparisons between groups are no longer possible. Both studies report significantly greater improvements in VAS pain scores and ODI scores in SIJ fusion patients than the control groups. Studies were nonblinded without a placebo control. Pain has a significant subjective and psychologic component. Cognitive behavioral techniques to address pain were specifically excluded from the types of treatment that control subjects could obtain. The change in opioid use in surgical patients was less than would be expected from a procedure that reduced pain by the magnitude shown in the study and was not statistically significantly different than the control group.

Case Series With Good Reported Follow-Up Rates

Case series with good follow-up rates are more likely to provide valid estimates of outcomes. Series with good follow-up rates (>80%) are reported in this section and principal results of the studies at 2-year follow-up are shown in Table 2.

In 2012, Rudolf retrospectively analyzed his first 50 consecutive patients treated with the iFuse Implant System.(22) There were 10 perioperative complications, including implant penetration into the sacral neural foramen (2 patients) and compression of the L5 nerve (1 patient); these 3 patients required surgical retraction of the implant. At 3 years postsurgery, 1 patient required additional implants due to worsening symptoms. At a minimum of 24 months of follow-up (mean, 40 months), the treating surgeon was able to contact 45 patients. The mean pain score was 2 (1 to 10 scale), and 82% of patients had attained the minimal clinically important difference in pain score (defined as ≥2 of 10).

In 2016, results from a case series of 172 patients undergoing SIJ fusion reported to 2 years were published by Duhon et al.(23,24) 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 mm), 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. Thus, 1-year outcomes were maintained at 2 years. Other outcomes (e.g., QOL 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-year follow-up, 8 (4.7%) patients required revision surgery.

In 2016, Polly et al reported 2-year outcomes from the RCT of SIJ fusion. (20) When reported, without an untreated control group, the study was a case series. Of 102 subjects originally assigned to SIJ fusion and treated, 89 (87%) were evaluated at 2 years. Although the clinical trial used a different composite end point, in this report, clinical outcomes were based on the amount of improvement in SIJ pain and in ODI scores. Improvement was defined as a change of 20 points in SIJ pain score and 15 points in ODI score. Substantial improvement was defined as a change in in 25 points in SIJ pain score or a score of 35 or less and an improvement of 18.8 points in ODI score. At 24 months, 83.1% and 82% had improvement and substantial improvement in SIJ pain score, and 68.2% and 65.9% had improvement and substantial improvement in ODI. By 24 months, the proportion taking opioids was reduced from 68.6% at baseline to 48.3%.

### Table 2: Two-Year Outcomes of Case Series of SIJ Fusion With Good Follow-Up Rates

<table>
<thead>
<tr>
<th>Studies and Outcomes</th>
<th>Mean Baseline Value</th>
<th>Mean 2-Year Value</th>
<th>Difference or % Achieving Outcome</th>
<th>Follow-Up Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rudolf (2012)(22)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain score (range, 0-10)</td>
<td>7.59</td>
<td>2.0</td>
<td>5.59</td>
<td>90% (45/50)</td>
</tr>
<tr>
<td>&gt;2-pt change in pain score</td>
<td>-</td>
<td>-</td>
<td></td>
<td>82%</td>
</tr>
<tr>
<td>Duhon et al (2016)(24)</td>
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<td></td>
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<tr>
<td>Pain score (range, 0-100)</td>
<td>79.8</td>
<td>26.0</td>
<td>53.3</td>
<td>86.6% (149/172)</td>
</tr>
<tr>
<td>ODI score</td>
<td>55.2</td>
<td>30.9</td>
<td>24.5</td>
<td></td>
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<tr>
<td>SF-36 score</td>
<td>31.7</td>
<td>40.7</td>
<td>8.9</td>
<td></td>
</tr>
<tr>
<td>EQ-5D TTO score</td>
<td>0.43</td>
<td>0.71</td>
<td>0.27</td>
<td></td>
</tr>
<tr>
<td>Polly et al (2016)(20)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain score (range, 0-100)</td>
<td>82.3</td>
<td>26.7</td>
<td>55.4</td>
<td>87% (89/102)</td>
</tr>
<tr>
<td>ODI score</td>
<td>57.2</td>
<td>28.7</td>
<td>28.4</td>
<td></td>
</tr>
<tr>
<td>% ≥20-pt improvement pain score</td>
<td>-</td>
<td>-</td>
<td></td>
<td>83.1%</td>
</tr>
<tr>
<td>% ≥15-pt improvement ODI score</td>
<td>-</td>
<td>-</td>
<td></td>
<td>68.2%</td>
</tr>
</tbody>
</table>

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

EQ-5D TTO: EuroQol Time Tradeoff Index; ODI: Oswestry Disability Index; pt: point; SF-36: 36-Item Short-Form Health Survey; SIJ: sacroiliac joint.

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. (25) 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 (range, 0-10) improved from 8.3 before surgery to 2.4 at 5 years; 88.2% of patients had substantial clinical benefit, which was defined as a 2.5-point decrease in VAS score or a raw score less than 3.5. Mean ODI score at 5 years was 21.5. Imaging by radiograph and computed tomography showed intra-articular bridging in 87% of patients with no evidence of implant loosening or migration.

### Case Series With Unknown Follow-Up Rates

The following case series did not report follow-up rates or study methodologies did not permit calculation of the complete number of patients treated.

In 2013, Smith et al reported a retrospective comparison of open versus minimally invasive SIJ fusion. (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.(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 2016, Sachs et al reported outcomes of 107 patients with a minimum follow-up of 3 years.(28) 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. Overall 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.

**Case Series of Administrative Data**

In 2016, Schoell et al analyzed postoperative complications tracked in an administrative database of minimally invasive SIJ fusions.(29) 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.

**Section Summary**

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.(23,26) One study with a small sample size (17 of 21 followed) and a good follow-up showed results maintained to 5 years.(24) If minimally invasive fusion is an effective treatment for SIJ pain, these results are consistent with medium-term durability of treatment.

**Adverse Effects Monitoring**

From January 2010 through August 2016, we identified 438 MAUDE injury reports (product code OUR): 355 mentioned revision, 188 malposition, 32 radicular pain, 24 impingement or impingement, and 14 infection. One death due to vena cava rupture was recorded more than a week postoperatively after uneventful surgery in a patient with a Greenfield filter and morbid obesity (the death was not attributed to the device).

**Section Summary**

For individuals who have presumed sacroiliac joint (SIJ) pain who receive SIJ fusion, the evidence includes 2 randomized controlled trials (RCTs) of minimally invasive fusion 3 case series with long follow up. 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.

Three case series with sample sizes ranging from 45 to 149 and good follow-up (>85%) showed that benefits obtained at 6 months persisted to 2 years. One small case series showed good outcomes that persisted to 5 years. The case series are consistent with the durability of treatment benefit, but only if there is a true benefit of treatment.
Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this policy are listed in Table 3.

Table 3. 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>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01640353a</td>
<td>Sacroiliac Joint Fusion With iFuse Implant System (SIFI)</td>
<td>250</td>
<td>Dec 2015 (ongoing)</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>Aug 2017</td>
</tr>
<tr>
<td>Unpublished</td>
<td></td>
<td></td>
<td></td>
</tr>
<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.
* 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 presumed SIJ pain who receive SIJ fusion, the evidence includes 2 RCTs of minimally invasive fusion and 3 case series with long follow up. 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. Three case series with sample sizes ranging from 45 to 149 and good follow-up (>85%) 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 sacroiliac joint fusion was received from 5 physician specialty societies and 3 academic medical centers while this policy was under review in 2015. A majority of reviewers considered sacroiliac joint fusion to be investigational.

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

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

**Practice Guidelines and Position Statements**

**North American Spine Society**
The North American Spine Society (NASS) published coverage recommendations for percutaneous SIJ fusion in 2015. (30) 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, ie, at the insertion of the long dorsal ligament inferior to the posterior superior iliac spine or PSIS) in the absence of tenderness of similar severity elsewhere (eg, greater trochanter, lumbar spine, coccyx) and that other obvious sources for their pain do not exist.
4. Positive response to a cluster of 3 provocative tests (eg, thigh thrust test, compression test, Gaenslen’s test, distraction test, Patrick’s sign, posterior provocation test). Note that the thrust test is not recommended in pregnant patients or those with connective tissue disorders.
5. Absence of generalized pain behavior (eg, somatoform disorder) or generalized pain disorders (eg, fibromyalgia).
6. Diagnostic imaging studies that include ALL of the following:
   a. Imaging (plain radiographs and a CT [computed tomography] or MRI [magnetic resonance imaging]) of the SI joint that excludes the presence of destructive lesions (eg, tumor, infection) or inflammatory arthropathy that would not be properly addressed by percutaneous SIJ fusion.
   b. Imaging of the pelvis (AP [anteroposterior] plain radiograph) to rule out concomitant hip pathology.
   c. Imaging of the lumbar spine (CT or MRI) to rule out neural compression or other degenerative condition that can be causing low back or buttock pain.
   d. Imaging of the SI joint that indicates evidence of injury and/or degeneration.
7. At least 75% reduction of pain for the expected duration of the anesthetic used following an image-guided, contrast-enhanced intra-articular SIJ injection on 2 separate occasions.
8. A trial of at least one therapeutic intra-articular SIJ injection (ie, corticosteroid injection)."
American Society of Interventional Pain Physicians
American Society of Interventional Pain Physicians Interventional Pain Management guidelines were updated in 2013.(7) The updated guidelines recommend the use of controlled sacroiliac joint blocks with placebo or controlled comparative local anesthetic block when indications are satisfied with suspicion of sacroiliac joint pain. A positive response to a joint block is considered to be at least a 75% improvement in pain or in the ability to perform previously painful movements. For therapeutic interventions, the only effective modality with fair evidence was cooled radiofrequency neurotomy, when used after the appropriate diagnosis was confirmed by diagnostic sacroiliac joint injections.

American Society of Anesthesiologists et al
In 2010, the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine Practice updated their guidelines for chronic pain management.(31) 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.

American Pain Society
The 2009 practice guidelines from the American Pain Society (APS) were based on a systematic review commissioned by APS.(2,3) 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.(32) These recommendations were updated in a 2016 statement.(33) 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). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

References

1. Dreyfuss P, Michaelsen M, Pauza K, et al. The value of medical history and physical examination in
24. Duhon BS, Bitan F, Lockstadt H, et al. Triangular titanium implants for minimally invasive sacroiliac joint...

Appendix

N/A

History

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<tr>
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<td>New policy. Add to Radiology section. Considered investigational.</td>
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<tr>
<td>01/21/14</td>
<td>Update Related Policies. Add 7.01.551.</td>
</tr>
<tr>
<td>05/20/14</td>
<td>Update Related Policies. Remove 7.01.116 as it was deleted, and replace with 7.01.555</td>
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<tr>
<td>07/14/14</td>
<td>Annual Review. Policy updated with literature review through November 12, 2013; references 8, 14, 21-22, 24, and 27-28 added; clinical input reviewed; policy changed to medically necessary for controlled diagnostic injections and for therapeutic injections with corticosteroid. HPCPS code G0260 and CPT code 27096 each have been removed from the policy; these codes are no longer under review in support of changes to the policy as described above. ICD-9 and ICD-10 diagnosis and procedure codes removed from policy.</td>
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<tr>
<td>02/10/15</td>
<td>Coding update. CPT code 27279 added to policy; replaces 0334T which was deleted 12/31/14.</td>
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<tr>
<td>07/31/15</td>
<td>Coding correction: 0334T listed to replace 0344T which was listed in error.</td>
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<td>12/08/15</td>
<td>Annual Review. Policy updated with literature review through October 22, 2015; references 17, 24, and 32 added. Policy statement regarding arthrography as investigational inadvertently deleted from July 2014 update and has been reinstated. No other changes to policy statement.</td>
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<td>02/29/16</td>
<td>Coding Update. CPT codes: 64635, 64636 and 64640 were added to policy.</td>
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<tr>
<td>10/11/16</td>
<td>Annual Review. Policy updated with literature review through July 15, 2016; references 20, 23, 28-31, and 37 added. Some references removed. The word anesthetic added to the first medically necessary policy statement.</td>
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Interim review. Policy updated with literature review through September 2016: references added. Policy statements unchanged.

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200 Independence Avenue SW, Room S09F, HH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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Kreyòl ayisyen (Creole):

Deutsche (German):

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Tsbab ntwaw tjiaj no muaj cov ntxhib lus tseem ceeb. Tjae taum ntwaw nzej no cov ntxhib lus tseem ceeb borg koj dain ntxwv thov kip pab los yog koj dho kip pab cuam los ntxwv Premera Blue Cross. Tjae taum cov hnuv tseem ceeb cuam rau hauv dain ntxwv no. Tjae taum koj kip yuav tau uu qee yam uu peb koj um taas xab jung ntxwv no mas koj dhai yuav tau baas kip pab cuam koo hauv los yog kip pab them tej nqi kooj hauv ntxwv. Koj muaj cai kom lawv muab cov ntxhib lus no uas tau muab sau uu kip hon lus pub daaw rau koj. Hu rauu 800-722-1471 (TTY: 800-842-5357).

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Daytoy a Pakdaar ket naglaon ini Napateg nga Impormasion. Daytoy a pakdaar mabalin nga adda ket naglaon ini napateg nga impormasjon majaangep ngi aplikasyono weny coverage babaen iti Premera Blue Cross. Daytoy ket mabalin dagiti importante a pelsa iti daytoy a pakdaar. Mabalin nga adda rumbeng nga aramideng nga adda sakyay dagiti partikular a nakitaging nga adda tidap tapo mapagatalineyo nga coverage ti salun-atyo wenno tulong kadagiti gastos. Adda karbenganyo nga mangala iti daytoy nga impormasjon ken tulong iti bukodyo a pagasao nga awan ti bayadanyo. Tumawag ti numero nga 800-722-1471 (TTY: 800-842-5357).

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 Een waarschuwing of melding overheersende betekenis mag die stemming van de medische diagnostiek en behandeling afwijken van de stemming van de patiënt en andere medisch personeel.

Available in Dutch (Nederlands): Een waarschuwing of melding overheersende betekenis mag de stemming van de medische diagnostiek en behandeling afwijken van de stemming van de patiënt en andere medisch personeel.

Available in English (English): A warning or significant finding may affect the patient's or other medical personnel’s perception of the medical diagnosis and treatment.

Available in Indonesian (Bahasa Indonesia): Peringatan atau laporan yang mempunyai arti signifikan mungkin berpengaruh pada persepsi diagnosis dan penanganan medis dari pasien dan personel medis lainnya.

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Available in Polish (Polski): Oświadczenie może zawierać ważne informacje. Oświadczenie może mieć wpływ na diagnozę oraz na decyzję medyczną, a także na stopień zaangażowania pacjenta.

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Available in Spanish (Español): Un aviso o una observación con importancia puede influir en el diagnóstico y el tratamiento, así como en el nivel de participación del paciente.

Available in Ukrainian (Українська): Відмінно важливі висновки можуть вплинути на стадію діагностування та терапії, а також на рівень участі пацієнта.

Available in Vietnamese (Việt Nam): Thông báo cảnh báo có thể ảnh hưởng đến quan trọng của việc chăm sóc và điều trị bệnh, cũng như mức độ tham gia của bệnh nhân.