Surgical Treatment for Sacroiliac Joint Pain

Policy Number: 6.01.23  Last Review: 5/2014

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for surgical treatment of sacroiliac joint. This is considered investigational.

When Policy Topic is covered
Not Applicable

When Policy Topic is not covered
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.

Radiofrequency ablation of the sacroiliac joint is considered investigational.

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

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

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

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.

Several percutaneous or minimally invasive fixation/fusion devices have received marketing clearance by the FDA. These include the SI-FIX Sacroiliac Joint Fusion System (Medtronic), the IFUSE Implant System (SI Bone), the SImetry Sacroiliac Joint Fusion System (Zyga Technologies) and the SI-LOK (Globus Medical).

**Rationale**

**Treatment**

Hansen et al. published an updated systematic review of sacroiliac joint interventions in 2012. (12) The primary outcome was short-term (<6 months) or long-term (>6 months) pain relief. Evidence was classified as good, fair, or limited/poor based on the quality of evidence. A total of 11 studies (6 randomized and 5 non-randomized) met inclusion criteria. Review found that evidence for intra-articular steroid injections is limited/poor, as is the evidence for peri-articular 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.

**Radiofrequency Denervation**

Aydin et al. published a meta-analysis of radiofrequency ablation (RFA) for sacroiliac pain in 2010. (16) Nine studies were included that reported the primary outcome measure of a reduction of pain of 50% or greater, including 1 randomized placebo controlled study, 3 prospective observational studies, and 5 retrospective studies. All of the studies used injection of local anesthetic to determine if RFA was indicated for the patient. Seven studies reported follow-up to 3 months, and 6 studies reported follow-up to 6 months. Meta-analysis indicated that half or greater of the patients who received RFA to the sacroiliac joint showed a reduction in their pain of 50% or more at 3 and 6 months. Analysis found no evidence of publication bias, but heterogeneity in studies was observed for the 6-month follow-up. This systematic review is limited by the low quality of included studies and lack of RCTs. In addition, as noted by the authors, no standards have been established for the specific nerves to ablate or type of technique.

Two small RCTs were identified for this literature review. The first was published in 2008 and was the single RCT included in the systematic review. This study examined the effect of lateral branch radiofrequency denervation with a cooled probe in 28 patients with injection-diagnosed sacroiliac joint pain. (17) Two of 14 patients (14%) in the placebo-control group reported pain relief at 1-month follow-up. None reported benefit at 3-month follow-up. Of the 14 patients treated with radiofrequency denervation, 11 (79%) reported pain relief at 1 month, 9 (64%) at 3 months, and 8 (57%) at 6 months.

In 2012, Patel et al. reported a randomized double-blind placebo-controlled trial of lateral branch neurotomy with a cooled radiofrequency probe. (18) Fifty-one patients who had a positive response to 2 lateral branch blocks were randomized in a 2:1 ratio to lateral branch radiofrequency or sham. At 3-month follow-up, significant improvements in pain (-2.4 vs. -0.8), physical function (14 vs. 3), disability (-11 vs. 2), and quality of life (0.09 vs. 0.02) were observed for radiofrequency treatment compared to controls (all respectively). With treatment success defined as a 50% or greater reduction in the numerical rating scale (NRS), 47% of radiofrequency-treated patients and 12% of sham patients achieved treatment success. The treatment response was durable out to 9 months.

**Arthrodesis**

The literature on arthrodesis (open or minimally invasive) for sacroiliac joint pain consists of case series. No randomized trials were identified.

In 2010, Ashman et al. conducted a systematic review to compare fusion vs. denervation for chronic sacroiliac pain. (19) Six articles on fusion (95 patients) and 5 on denervation (68 patients) were included in the review. All studies on fusion were case series evaluating a single treatment. There were
2 small RCTs on radiofrequency denervation; one is described above, (17), and the other had only 9 patients. The strength of the evidence was considered to be very low to low, preventing conclusions regarding the comparative efficacy of the treatments.

In 2008, Wise and Dall reported a small prospective series of 13 consecutive patients (19 joints) with sacroiliac joint pain diagnosed by a single block and treated with percutaneously inserted fusion cages filled with bone morphogenetic protein (Medtronic). (20) At 6-month follow-up, radiographs showed a fusion rate of 89% (17/19). At 24-month follow-up, there were significant improvements in VAS for back pain (improvement of 4.9 out of 10), leg pain (2.4) and dyspareunia (2.6).

Two series were reported in 2012 on the iFuse Implant System for minimally-invasive fusion of the sacroiliac joint. A study by Sachs and Capobianco reported mean VAS for pain of 7.9 at baseline and 2.3 at 12-month follow-up for a series of 11 consecutive patients. (21) Rudolf reported a retrospective analysis of his first 50 consecutive patients. (22) There were 10 peri-operative complications, including implant penetration into the sacral neural foramen (2 patients) and compression of the L5 nerve (1 patient); these resolved with surgical retraction of the implant. At a minimum of 24 months’ follow-up (mean of 40 months), the treating surgeon was able to contact 45 patients. The mean pain score was 2, and 82% of patients had attained the minimum clinically important difference (MCID, defined as >2 out of 10).

Clinical Input Received through 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.

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 a majority of reviewers considered sacroiliac injections to be the best available approach for diagnosis and treatment in defined situations.

Summary
There is limited prospective or controlled evidence for sacroiliac joint arthrography, injection therapy, radiofrequency ablation (RFA) or fixation/fusion. For radiofrequency ablation, there are two small RCTs that report short-term benefit, but these are insufficient to determine the overall effect on health outcomes. Further high-quality controlled trials are needed that compare specific procedures in defined populations to placebo and to alternative treatments. Case series are inadequate evidence due to the variable natural history of back pain, the presence of confounders of outcome, and the potential for a placebo effect. In general, the literature regarding injection therapy on joints in the back is of poor quality. The current evidence on sacroiliac joint arthrography, injections, RFA, and fixation/fusion is insufficient to permit conclusions regarding the effect of these procedures on health outcomes. Therefore, these techniques are considered investigational for the diagnosis and treatment of sacroiliac joint pain.

Practice Guidelines and Position Statements
The ASIPP Interventional Pain Management guidelines were updated in 2009. The guidelines for diagnostic and therapeutic sacroiliac joint injections were based on the systematic review by Manchikanti et al. and Rupert et al. described earlier. (6, 7) Evidence for sacroiliac joint injections was considered to be level II-2 (evidence obtained from at least 1 properly designed small diagnostic accuracy study). The guidelines indicate that sacroiliac joint blocks appear to be the evaluation of choice to provide appropriate diagnosis, due to the inability to make the diagnosis of sacroiliac joint-mediated pain with non-invasive tests. Evidence was determined to be unavailable to establish efficacy of intra-articular sacroiliac joint injections for therapeutic purposes.
Common indications for sacroiliac joint injections were listed as follows:

- Somatic or nonradicular low back and lower extremity pain below the level of L5 vertebra.
- Duration of pain of at least 3 months.
- Average pain levels of >6 on a scale of 0 to 10.
- Intermittent or continuous pain causing functional disability.
- Failure to respond to more conservative management, including physical therapy modalities with exercises, chiropractic management, and non-steroidal anti-inflammatory agents.
- Lack of obvious evidence for disc-related or facet joint pain.
- No contraindications with understanding of consent, nature of the procedure, needle placement, or sedation.
- No history of allergy to contrast administration, local anesthetics, steroids, Sarapin, or other drugs potentially utilized.
- Contraindications or inability to undergo physical therapy, chiropractic management, or inability to tolerate non-steroidal anti-inflammatory drugs.
- For therapeutic sacroiliac joint interventions with intra-articular injections or radiofrequency neurotomy, the joint should have been positive utilizing controlled diagnostic blocks.

Recommended frequency of interventions was also described.

The 2009 practice guidelines from the APS were based on a systematic review that was commissioned by the APS and conducted at the Oregon Evidence-Based Practice Center. (8, 9) The APS guideline states that there is insufficient evidence to evaluate validity or utility of diagnostic sacroiliac joint block as a diagnostic procedure for low back pain with or without radiculopathy and that there is insufficient evidence to adequately evaluate benefits of sacroiliac joint steroid injection for nonradicular low back pain.

Medicare National Coverage
There is no national coverage determination.

References:


Billing Coding/Physician Documentation Information

27280 Arthrodesis, sacroiliac joint (including obtaining graft)
0334T Sacroiliac joint stabilization for arthrodesis, percutaneous or minimally invasive (indirect visualization), includes obtaining and applying autograft or allograft (structural or morselized), when performed, includes image guidance when performed (eg, CT or fluoroscopic). Effective 7/1/2013

There is no specific CPT code for radiofrequency ablation of the sacroiliac joint. Code 27299 – unlisted procedure, pelvis or hip joint – would likely be used.

Additional Policy Key Words

N/A

Policy Implementation/Update Information

5/1/13 New policy; considered investigational. Policy statement regarding sacroiliac joint fusion included from previous policy 7.01.509 Sacroiliac Joint Fusion for the Treatment of Low Back Pain.

5/1/14 No policy statement changes.

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