

Regence

Medical Policy Manual

Surgery, Policy No. 193

Sacroiliac Joint Fusion

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Last Review: August 2024

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

The sacroiliac (SI) joint is a strong weight bearing joint with a self-locking mechanism that provides stability with movement on the left and right side of the sacrum. Similar to other structures in the spine, it is assumed that the SI joint may be a source of low back pain but there are currently no reference standards for diagnosis. If conservative therapies fail to adequately treat symptoms, SI joint fusion may be used to stabilize the SI joint including open, percutaneous, and minimally invasive techniques.

MEDICAL POLICY CRITERIA

- I. Sacroiliac joint fusion performed by an open procedure may be considered **medically necessary** when one of the following criteria is met:
 - A. As an adjunct to sacrectomy or partial sacrectomy related to tumors involving the sacrum; or
 - B. As an adjunct to the medical treatment of sacroiliac joint infection (e.g., osteomyelitis, pyogenic sacroiliitis)/sepsis; or
 - C. As a treatment for severe traumatic injuries associated with pelvic ring fracture.
- II. Sacroiliac joint fusion performed by an open procedure, for any other indication not listed above in Criterion I. is considered **not medically necessary**.

- III. Minimally invasive fusion/stabilization of the sacroiliac joint may be considered **medically necessary** when ALL of the following criteria have been met:
- A. Request is for a titanium triangular implant; and
 - B. Request is for an FDA-approved device; and
 - C. Clinical documentation that pain limits activities of daily living (ADL). ADLs are defined as feeding, bathing, dressing, grooming, meal preparation, household chores, and occupational tasks that are required for daily functioning; and
 - D. Patients have undergone and failed a minimum 6 months of intensive physician-directed non-operative treatment that must include medication optimization, activity modification, and active therapeutic exercise targeted at the lumbar spine, pelvis, sacroiliac joint, and hip; and
 - E. There is at least 75% reduction of pain following an image-guided, contrast-enhanced intra-articular sacroiliac joint injection on 2 separate occasions; and
 - F. A trial of a therapeutic sacroiliac joint injection (i.e., corticosteroid injection) has been performed on at least one occasion (see Policy Guidelines); and
 - G. A thorough physical examination demonstrates findings consistent with sacroiliac joint disease including a positive response to a cluster of three provocative tests (e.g., thigh thrust test, compression test, Gaenslen's test, distraction test, Patrick's sign, posterior provocation test); and
 - H. Diagnostic imaging studies include ALL of the following:
 - 1. Imaging of the sacroiliac joint indicates evidence of injury and/or degeneration; and
 - 2. Imaging of the sacroiliac joint excludes the presence of destructive lesions (e.g., tumor, infection) or inflammatory arthropathy of the sacroiliac joint and rules out concomitant hip pathology; and
 - 3. Advanced imaging of the lumbar spine (CT or MRI) is performed to rule out neural compression or other degenerative conditions that can be causing low back or buttock pain and excludes the presence of destructive lesions or inflammatory arthropathy of the sacroiliac joint.
- IV. Minimally invasive fusion/stabilization of the sacroiliac joint for the treatment of back pain presumed to originate from the sacroiliac joint is considered **investigational** in all other scenarios including but not limited to when Criterion III is not met.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

POLICY GUIDELINES

A successful trial of controlled diagnostic SI joint or lateral branch blocks consists of two 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., three hours longer with bupivacaine than lidocaine). There is no 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 four weeks before the diagnostic 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).

LIST OF INFORMATION NEEDED FOR REVIEW

It is critical that the list of information below is submitted for review to determine if the policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

- History and Physical/Chart Notes
- Current Symptomology including indication for procedure (diagnostic or treatment of specific condition) and whether procedure will be open or minimally invasive
- Documentation of specific conservative pain management including length of time utilized including rheumatologic evaluation when indicated
- Documentation of diagnostic blocks including agents used, duration of action and if completed under imaging guidance
- If request is for minimally invasive fusion/stabilization with a titanium triangular implant provide the following; documentation of specifically how pain limits ADLs, failure of minimum of six months of specific nonoperative therapy attempted, percentage of pain reduction achieved using the specific image guided injections listed above on two separate occasions, trial of injection has been performed at least once, absence of generalized pain behavior/disorders, documentation of location of pain on spine/joint, documentation per physical exam of location of pain including tenderness, positive response to at least three provocative tests and diagnostic imaging studies/reports completed.
- Documentation of specific device being utilized if applicable

CROSS REFERENCES

1. [Percutaneous Vertebroplasty, Kyphoplasty, Sacroplasty, and Coccygeoplasty](#), Surgery, Policy No. 107
2. [Lumbar Spinal Fusion](#), Surgery Policy No. 187

BACKGROUND

The sacroiliac (SI) joint is a joint between the sacrum and ilium of the pelvis. The SI joint is a strong weight bearing joint with a self-locking mechanism that provides stability with movement on the left and right side of the sacrum. Similar to other structures in the spine, it is assumed that the SI joint may be a source of low back pain.

Currently, there are no reference standards for the diagnosis of SI joint pain. SI 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 SI joint pain may include various movement tests, palpation to detect tenderness, and pain descriptions by the patient. Research into sacroiliac joint pain has been inhibited by the lack of any criterion standard to measure its prevalence and against which various clinical examinations can be validated. Further confounding study of the SI joint is that multiple structures, such as posterior facet joints and lumbar discs, may refer pain to the area surrounding the SI joint.

There are many methods for the treatment of chronic SI joint pain including nonsurgical and surgical approaches. Conservative management may include nonsteroidal anti-inflammatory medications, prescription analgesics, spinal manipulation, physical therapy, a home exercise program, and evaluation and management of cognitive, psychological, or behavioral issues.

If conservative therapies fail to adequately treat symptoms, SI joint fusion may be used to stabilize the SI joint. Surgical approaches include open, percutaneous, and minimally invasive techniques. The open surgery technique involves the iliac crest bone and the sacrum being held together with plates and/or screws until fusion occurs between the two bones. The use of minimally invasive techniques to fuse the SI joint has increased over the last several years. Minimally invasive procedures use specially designed implants for the stabilization of the SI joint.

Some procedures have been referred to as SIJ fusion but may be more appropriately called fixation (this is because there is little to no bridging bone on radiographs). Devices for SIJ fixation/fusion that promote bone ingrowth to fixate the implants include a triangular implant (iFuse Implant System) and cylindrical threaded devices (Rialto, SImmetry, Silex, SambaScrew, SI-LOK). Some devices also have a slot in the middle where autologous or allogeneic bone can be inserted. This added bone is intended to promote fusion of the SIJ.

REGULATORY STATUS

Several percutaneous or minimally invasive fixation/fusion devices have received marketing clearance by the Food and Drug Administration. These include the Rialto™ SI Joint Fusion System (Medtronic), SIJ-Fuse (Spine Frontier), IFUSE® Implant Systems include the iFuse-3D, iFuse TORQ, and iFuse INTRA (SI Bone), SImmetry® Sacroiliac Joint Fusion System (Zyga Technologies), Silex™ Sacroiliac Joint Fusion System (XTANT Medical), SambaScrew® and FIREBIRD SI Fusion System (Orthofix), SIm pact Sacroiliac Joint Fixation System (Life Spine), and the SI-LOK® Sacroiliac Joint Fixation System (Globus Medical). FDA Product Code: OUR.

Note: This policy does not address percutaneous sacroplasty which is addressed in the *Percutaneous Vertebroplasty and Kyphoplasty* policy (SUR107).

EVIDENCE SUMMARY

SI joint fusion performed by open procedure is considered standard of care to stabilize the sacroiliac joint due to trauma, infection, and tumors involving the sacrum. Therefore, the focus of the literature review is on the use of diagnostic blocks for the diagnosis of SI joint pain and the use of percutaneous or minimally invasive fusion techniques.

Due to the volume of published literature regarding minimally invasive sacroiliac joint fusion with varying study design and quality, the following is a summary of key references published to date. It is important to note that many of the systematic reviews include similar studies in addition to those studies being summarized below.

DIAGNOSTIC BLOCKS

The use of diagnostic blocks to evaluate SI joint pain builds on the experience of diagnostic block use 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 SI diagnostic block would then be compared with a criterion standard. However, there is no current criterion standard for SI joint injection. A search for systematic reviews, randomized controlled trials, and comparative studies on diagnostic blocks was conducted and is summarized below.

Systematic Reviews

In 2013, the American Society of Interventional Pain Physicians published an updated evidence review with guidelines on diagnosis of SIJ pain.^[1] 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 seven studies. The prevalence of a positive test in the seven 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.

A 2012 systematic review^[2] evaluated the accuracy of diagnostic sacroiliac joint interventions. The methodological quality of the studies was evaluated and only the studies meeting at least 50% of the applicable appraisal inclusion criteria were included. A total of 17 studies met inclusion criteria with a range of diagnostic interventions and relief cutoff thresholds. Only one placebo-controlled study was identified with methodological limitations. The review concluded that there is good evidence for the use of controlled diagnostic local anesthetic blocks. Uncontrolled blocks had a false positive rate of approximately 20%. Overall, the systematic review concluded, based on what the authors determined to be good evidence, “there was no significant difference when 70% or greater relief is utilized as the criterion standard with dual blocks.” In addition, the systematic review concluded that “there is no evidence to support the use of ultrasound or landmark-guided injections for sacroiliac joint pain. These injections must be performed under fluoroscopic or radiologic guidance.” Limitations of this systematic review include the lack of high quality evidence, significant variation in interventions, and discrepancies in a gold standard to measure against.

A systematic review was commissioned by the American Pain Society and conducted by the Oregon Evidence-based Practice Center in 2009.^[3] The systematic review concluded that no studies were identified that evaluated validity or utility of diagnostic sacroiliac joint block as a diagnostic procedure for low back pain with or without radiculopathy.

Randomized Controlled Trials

No RCTs identified after the above SRs were published.

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. Sacroiliac Joint Fusion

SACROILIAC JOINT FUSION

Systematic Reviews

Whang (2023) published a systematic review of 2,851 patients evaluating the safety and efficacy of minimally invasive SI joint fusion using several techniques including lateral transiliac (LTI), posterolateral transiliac (PLTI), and posterior interpositional (PI) procedures.^[4] Results from the meta-analysis showed improvements in pain scores were highest for LTI (4.8 points [0-10 scale]), slightly lower for PLTI (4.2 points), and lowest for PI procedures (3.8 points, $P = 0.1533$). Mean improvements in ODI scores were highest for LTI (25.9 points), lowest for PLTI procedures (6.8 points), and intermediate for PI (16.3 points, $P = 0.0095$). For safety outcomes, acute symptomatic implant malposition was 0.43% for LTI, 0% for PLTI, and 0.2% for PI procedures. Wound infection was reported in 0.15% of LTI, 0% of PLTI, and 0% of PI procedures. Bleeding requiring surgical intervention was reported in 0.04% of LTI procedures and not reported for PLTI or PI. Most studies included in the review were retrospective case series and no prospective studies were available for the PLTI procedure. Only LTI included randomized trials and relied heavily on studies involving the iFuse titanium triangular implant. Prospective comparative data is very minimal for these different procedure types but is necessary to establish long-term durability and effectiveness.

Lingutla (2016) published a systematic review with meta-analysis evaluating SI joint fusion for low back pain where it has been determined that the cause of the pain is originating from the sacroiliac joint and not the lumbar spine.^[5] Six nonrandomized studies were included with a mean follow-up of 17.6 months. The authors concluded that all outcome measures showed a statistical improvement for alleviating pelvic girdle pain. However, the review consisted of nonrandomized studies with some methodological limitations. More research is needed for this patient population.

Zaidi (2015) conducted a systematic review of the evidence evaluating SI joint fusion interventions for treating SI joint pain or dysfunction.^[6] A comprehensive literature search was conducted and the authors included five case series, eight retrospective studies, and three prospective studies with at least two patients ($N=430$). The mean duration of follow-up was 60 months with the most common pathology being SI joint degeneration/arthrosis followed by SI joint dysfunction, postpartum instability among other less common pathologies. Study participants reported satisfaction after the procedures which varied widely. The rates of reoperation for open surgery were 5% to 65% (mean 15%) and for minimally invasive 0% to 17% (mean 6%). Major complications ranged from 5% to 20% with one study reporting a 56% adverse event rate. The authors concluded that surgical intervention is beneficial for a subset of patients and that serious consideration of alternatives should be considered prior to surgery.

A 2012 systematic review found that the quality of evidence for surgical treatment (debridement, fusion) compared to injection treatment (corticosteroid, botulinum toxin, prolotherapy) for chronic sacroiliac pain was very low.^[7] No studies were identified that directly compared surgery to injection therapy. Seven case series using a range of surgical techniques that evaluated a range of surgical treatments were included and summarized. The literature was considered heterogeneous and insufficient to evaluate the comparative effectiveness of surgical treatments compared to other treatments. Several surgical studies reported complications including but not limited to infections, nonunion, further surgery, and intraoperative fracture. Studies had small sample sizes and provided little information on determining successful fusion.

In 2010, Ashman^[8] conducted a systematic review comparing fusion to denervation for chronic SI joint pain. Six case series on fusion were identified that evaluated a single treatment. As a result, no conclusions could be drawn for the comparative efficacy of the treatments.

Randomized Controlled Trials

No RCTs identified after the above SRs were published.

SIJ FUSION/FIXATION WITH A TRIANGULAR IMPLANT SYSTEM

Systematic Reviews

Chang (2022) published a systematic review of forty studies evaluating the use of minimally invasive SI joint fusion.^[9] Minimally invasive SI joint fusion with the iFuse Implant System appeared to result in larger improvements in pain (two RCTs: MD for VAS -40.5 mm, 95% CI, -50.1 to -30.9; -38.1 mm, $p<.0001$) and larger improvements in physical function (mean difference in Oswestry Disability Index -25.4 points, 95% CI, -32.5 to -18.3; -19.8 points, $p<.0001$) compared to conservative management at six months. Improvements in pain and physical function for the RCTs appeared durable at one and two years of follow-up. Findings were similar in one CCS. The two RCTs also found significant improvements in QOL at six months and one year. AEs appeared higher in the fusion group at six months. The incidence of revision surgery varied by study; the highest was 3.8% at two years. Two CCSs compared the effectiveness of alternative minimally invasive fusion procedures. One CCS compared iFuse to the Rialto SI Fusion System and reported no differences in pain, function, QOL, and revision surgeries from six months to one year. One CCS compared iFuse to percutaneous screw fixation and reported significantly fewer revisions among iFuse participants (mean difference -61.0%, 95% CI, -78.4% to -43.5%).

Hermans (2022) published a systematic review comparing minimally invasive joint fusion using titanium implants to conservative management in patients with SI joint dysfunction.^[10] Three studies that included 388 patients were part of the review. The results from the pooled analysis showed that the fusion patients showed greater reduction in visual analog pain score and ODI outcomes compared to the ones who received conservative management. Adverse events reported across the studies were similar for both groups. The results of the study indicate that minimally invasive joint fusion is more effective than conservative management in patients with SIJ dysfunction.

Abbas (2022) published a systematic review evaluating the efficacy of SIJ fusion for low back pain caused by SIJ pathology.^[11] Six studies were included with a total of 564 patients who received either SIJ fusion or conservative management. The results showed that the SIJ fusion patients had greater reductions in VAS and ODI outcomes compared to those receiving conservative management.

Tran (2019) published a systematic review comparing the effectiveness of minimally invasive joint fusion (e.g. utilizing the iFuse device) compared to screw-type surgeries. A total of twenty studies was pooled to calculate a standardized mean difference across pain, disability, and global/quality-of-life outcomes, including 14 studies evaluation the iFuse system and 7 studies evaluated cylindrical, threaded implants. Studies evaluating cylindrical threaded implants consisted of case series and cohort studies. Patients receiving these implants experienced significantly worse pain outcomes ($p=0.03$) compared to patients receiving iFuse, with a standardized mean difference of 1.28 and 2.04, respectively. A statistically significant difference in disability scores was reported between screw-type and iFuse implant groups (0.26 vs 1.68), with improved outcomes in the iFuse population. For global/quality-of-life outcomes, a statistically significant difference in scores was reported between screw-type and iFuse implants groups (0.60 vs 0.99 with improved outcomes in the iFuse population).

Heiney (2015) evaluated clinical outcomes and operative measures of minimally invasive sacroiliac joint fusion utilizing a lateral transarticular technique.^[12] A total of 12 studies, including those for triangular implants were included. The authors concluded, for this particular technique, patients reported improvements in pain, disability, and quality of life scores.

Randomized Controlled Trials

Randers (2024) published a sham-controlled trial with 62 patients comparing minimally invasive SI joint fusion with titanium triangular implants compared to a sham surgery on pain reduction.^[13] The reduction in pain in the operated sacroiliac joint in the surgical group was 2.6 NRS points (95% CI, 1.5 to 3.7) and in the sham group 1.7 NRS points (95% CI 0.6 to 2.8) from baseline to six months postoperative. An improvement of 2 NRS points from baseline to 6 months postoperative was observed in 16 of 32 (50%) patients in the surgical group and in 13 of 31 (42%) in the sham group (OR 1.4; 95% CI 0.5 to 3.7; $p = 0.52$). Regarding self-reported treatment satisfaction 13 of 29 (45%) in the surgical group and 9 of 29 (31%) in the sham group reported themselves to be “much better” or “better” (OR 1.8; 95% CI 0.6 to 5.2; $p = 0.27$), and 11 of 29 (38%) in the surgical group and 8 of 29 (27%) in the sham group reported to be “worse” or “much worse” (OR 1.6; 95% CI 0.5 to 4.8; $p = 0.40$). The authors concluded that there were no statistically significant differences between the treatment and sham groups on the primary or secondary outcomes.

Whang (2015) reported an industry-sponsored nonblinded RCT of the iFuse Implant System in 148 patients.^[14] Twelve-month follow-up to this RCT was reported by Polly et al in 2015.^[15] However, by 12 months, almost all patients in the control group had crossed over to SI JOINT fusion. Two-year follow-up of this trial was reported by Polly et al in 2016.^[16] This last publication will be discussed in the case series section of this report. Trial inclusion was based on a determination of the SI JOINT as a pain generator from a combination of a history of SI JOINT-localized pain, positive provocative testing on at least three of five established physical tests, and at least a 50% decrease in SI JOINT pain after image-guided local anesthetic injection into the SI JOINT. 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 RFA (16%).

Patients were assigned 2:1 to minimally invasive SI joint 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 RFA of sacral nerve roots (45.7%). The primary outcome measure was six-month success rate, defined as the proportion of treated subjects with a 20-mm improvement in SI JOINT pain in the absence of severe device-related or neurologic adverse events or surgical revision. Patients in the control arm could crossover to surgery after six 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 six 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 QOL (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 six months, 35 (79.5%) crossed over to fusion. Compared to baseline, opioid

use at six 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, the trial is limited due to the high number of patients that crossed over from the control group to the fusion group. This limits the comparative long-term conclusions that can be drawn.

Sturesson (2016) reported another industry-sponsored nonblinded RCT of the iFuse Implant System in 103 patients.^[17] Selection criteria were similar to those of the Whang trial, including at least 50% pain reduction on SI JOINT 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; interventional procedures (eg, steroid injections, RFA) were not allowed. The primary outcome was change in VAS pain score at six months.

Of 109 randomized subjects, six withdrew before treatment. All patient assigned to iFuse underwent the procedure, and follow-up at six months was in 49 of 51 patients in the control group and in all 52 patients in the iFuse group. At six 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 six 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^[14] and Sturesson^[17]

Results	VAS Score		Success End Point		ODI Score		SF 36 PCS Score		EQ 5D TTO Index	
	Ctl	iFuse	Ctl	iFuse	Ctl	iFuse	Ctl	iFuse	Ctl	iFuse
Whang (2015)										
Baseline	82.2	82.3			61.1	62.2	30.8	30.2	0.47	0.44
Follow-up	70.4	29.8	23.9%	81.4% ^a	56.4	31.9	32.0	42.8	0.52	0.72
Change	-12.1	-52.6 ^a			-4.9	-30.3 ^a	1.2	12.7	0.05	0.29
Sturesson (2016)										
Baseline	73.0	77.7								
Follow-up	67.8	34.4								
Change	-5.7	-43.3			-5.8	-25.5			0.11	0.37

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.

Nonrandomized Studies

The Long Term Outcomes from INSITE and SIFI (LOIS) trial was a prospective single-arm study that enrolled patients who had participated in two of the studies described above for evaluation at three, four, and five years.^[18] The primary success outcome, a reduction in VAS of at least 20 points in the absence of a serious device-related adverse event, neurologic worsening, or surgical revision, was obtained in 81.7% of patients at five years. The improvements in other clinical outcomes were maintained out to 5 years. Opioid use decreased over time, although the contribution of the opioid use agreement cannot be determined. Fifteen percent of patients were no working due to back pain. Radiolucencies

suggesting implant failure were observed in 5% of cases and were associated with incorrect placement. Bridging bone was observed in 45% of sides at 12 months, 71% at 24 months, and 88% at 60 months.

The Study of Bone Growth in the Sacroiliac Joint after Minimally Invasive Surgery with Titanium Implants (SALLY) is a 5 year multicenter study that will assess non-inferiority of outcomes with a 3-D printed triangular implant as compared to the traditionally manufactured titanium coated implant.^[19] Twelve month follow-up has been published for 46 of the 51 patients enrolled. The 6-month change in ODI met the non-inferiority margin, and secondary outcomes of pain, disability, and QOL were similar to those obtained in the INSITE, iMIA, and SIFI trials. Independent radiographic analysis showed bridging bone in 70% and 77% of sides imaged at 6 and 12 months, respectively, compared to 45% bridging bone in prior studies with the solid titanium coated implants. No breakage, migration, or subsidence was detected. However, there was no evidence that the increase in bridging bone led to an improvement in pain or functional outcomes compared to the milled implant at 12 months.

Two retrospective nonrandomized comparative studies were published in 2017. Vanaclocha (2017) found greater pain relief with SIJ fusion than with conservative management or SIJ denervation.^[20] Spain and Holt (2017) reported a retrospective review of surgical revision rates following SIJ fixation with either surgical screws or the iFuse triangular implant.^[21] Revision rates were lower with the iFuse device than observed with surgical screws.

Twelve-month results from the iMIA trial were reported by Dengler (2017).^[22] Twenty-one patients in the conservative management group had little or no improvement in symptoms and crossed over to SIJ fusion after the 6-month visit. Fourteen (56%) of the 25 patients who remained in the conservative management group had at least a 20-point improvement in VAS back pain score (22.4% of patients assigned to conservative management). At 12 months, low back pain had improved by 42 points (SD=27.0) on a 100-point VAS in the SIJ fusion group compared with 14 (SD=33.4) points in the conservative management group (p<0.001). The authors noted that there were methodological limitations including lack of blinding and subjective assessments of outcomes.

At 24 months back pain had improved by 45 points compared to 11 points in the control group, with 79% (37 of 47) of SIJ fusion patients achieving at least a 20 point improvement compared to 24% (11 of 46) of controls.^[23] At 24 months there was an improvement of 26 points in ODI compared to 8 points in controls (p<0.001). Improvement of at least 20 points was observed in 64% of SIJ fusion group compared to 24% of the conservative management group.

Table 2. Extended Follow-Up From the INSITE and iMIA Trials

Outcome Measures	Baseline	6 Months (SD)	12 Months (SD)	24 Months (SD)
INSITE^[24]				
Sacroiliac joint fusion pain score	82.3	29.8		26.7
Percent ≥20-point improvement pain				83.1%
Sacroiliac joint fusion ODI score	57.2	31.9		28.7
% ≥15-point improvement ODI				68.2%
iMIA^[22]				
Low back pain				
Conservative management	73.0 (13.8)	67.8 (20.3)	58.9 (28.2)	
Sacroiliac joint fusion	77.7 (11.3)	34.4 (23.9)	35.2 (25.5)	
Leg pain				
Conservative management	47.1 (31.1)	46.5 (31.4)	41.7 (32.4)	
Sacroiliac joint fusion	52.7 (31.5)	22.6 (25.1)	24.0 (27.8)	

Outcome Measures	Baseline	6 Months (SD)	12 Months (SD)	24 Months (SD)
ODI				
Conservative management	55.6 (13.7)	50.2 (17.2)	46.9 (20.8)	
Sacroiliac joint fusion	57.5 (14.4)	32.0 (18.4)	32.1 (19.9)	

Adapted from Dengler et al (2017).^[22]

ODI: Oswestry Disability Index.

Case Series With Good Reported Follow-Up Rates

Case series with good follow-up rates are more likely to provide valid estimates of outcomes. Principal results of the studies at 2- to 3-year follow-up are shown in Table 3.

Polly (2016) reported two-year outcomes from the RCT of SI JOINT fusion.^[16] When reported, without an untreated control group, the study was a case series. Of 102 subjects originally assigned to SI JOINT fusion and treated, 89 (87%) were evaluated at two years. Although the clinical trial used a different composite end point, in this report, clinical outcomes were based on the amount of improvement in SI JOINT pain and in ODI scores. Improvement was defined as a change of 20 points in SI JOINT pain score and 15 points in ODI score. Substantial improvement was defined as a change in 25 points in SI JOINT 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 SI JOINT 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%.

Results from a case series of 172 patients undergoing SI JOINT fusion reported to two years were published by Duhon (2016).^[25, 26] 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 six 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 six months and 30.4 at 12 months. Mean ODI scores were 32.5 at six months and 31.4 at 12 months. At two years, 149 (87%) of 172 patients were available for follow-up. VAS pain score at two years was 26.0 and ODI score was 30.9. Thus, 1-year outcomes were maintained at two years. Other outcomes (eg, 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 two years. Over the 2-year follow-up, 8 (4.7%) patients required revision surgery.

Rudolph and Capobianco (2014) described 5-year follow-up for 17 of 21 consecutive patients treated at their institution between 2007 and 2009.^[27] Of the four patients lost to follow-up, two had died and one 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 five 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 five 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.

Rudolf (2012) retrospectively analyzed his first 50 consecutive patients treated with the iFuse Implant System.^[28] There were 10 perioperative complications, including implant penetration into the sacral neural foramen (two patients) and compression of the L5 nerve (1 patient);

these three patients required surgical retraction of the implant. At three 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 two (1 to 10 scale), and 82% of patients had attained the minimal clinically important difference in pain score (defined as ≥ 2 of 10).

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.

Smith (2013) retrospectively compared open with minimally invasive SI JOINT fusion. Because all patients received fusion, this study should be interpreted as a case series, with attention paid to the minimally invasive fusion group.^[29] 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.^[30] 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. Mean baseline pain score was 8.6. At a mean 16-month follow-up, VAS score was 2.7 (/10), an improvement of 6.1. 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.

Sachs (2016) reported outcomes of 107 patients with a minimum follow-up of 3 years.^[31] 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 five (4.7%) patients. Without knowing the number of eligible patients, the validity of this study cannot be determined.

Table 3. Two- to 3-Year Outcomes of the iFuse Implant in Cohorts and Case Series

Studies and Outcomes	Mean Baseline Value	Mean 2- to 3-Year Value	Difference or % Achieving Outcome	Follow-Up Rate
Rudolf (2012) ^[28]				
Pain score (range, 0-10)	7.59	2.0	5.59	90% (45/50)
>2-point change in pain score	-	-	82%	
Duhon et al (2016) ^[25]				
Pain score (range, 0-100)	79.8	26.0	53.3	86.6% (149/172)
Oswestry Disability Index score	55.2	30.9	24.5	
SF-36 score	31.7	40.7	8.9	
EQ-5D TTO score	0.43	0.71	0.27	
Sachs et al (2016) ^[31]				
Pain score (range 0-10)	7.5	2.5		

Studies and Outcomes	Mean Baseline Value	Mean 2- to 3-Year Value	Difference or % Achieving Outcome	Follow-Up Rate
Oswestry Disability Index score		28.2		

All differences between baseline and 2- to 3-year values were statistically significant.
EQ-5D TTO Index; EuroQoL Time Tradeoff Index; SF-36: 36-Item Short-Form Health Survey.

Database Analysis

Schoell (2016) analyzed postoperative complications tracked in an administrative database of minimally invasive SIJ fusions to determine complications coded in postoperative claims. 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%. Authors noted that the infection rate observed was consistent with the infection rates reported by Polly et al (2015), 20 but much higher than those reported for other types of minimally invasive spine procedures. The incidence of complications in this study may differ from those reported by registries. However, determining the true incidence of adverse events after procedures from either registries or insurance claims data can be difficult due to uncertainty about the completeness of reporting in registries and the accuracy of coded claims in claims databases.

Cher (2015) reported rates of implant revision using the Humana insurance database of procedures.^[32] Between April 2009 and July 2014, 11,416 cases with the iFuse system took place. After minor adjustments of numbers to account for non-recommended uses and inability to match revision cases, the cumulative revision rate at 4 years was 3.54%. Overall, 24% of revision surgeries occurred in the first month and 63% occurred within the first 12 months. One-year revision rates fell over time (9.7% to 1.4% from 2009 to 2014).

Adverse Events

From 9/1/2016 to 12/8/2017 a total of 47 MAUDE database injury reports were identified (product code OUR). Many reports were for revisions needed and/or user error/wrong placement e.g. too deep, wrong size device, with a few noting infection or hematoma.

From January 2010 through August 2016, a total of 438 MAUDE database injury reports were identified (product code OUR): 355 mentioned revision, 188 malposition, 32 radicular pain, 24 impingement or impingement, and 14 infection.

Summary

For individuals who SIJ pain who receive SIJ fusion/fixation with a triangular implant, the evidence includes two non-blinded RCTs of minimally invasive fusion and 2 case series with more than 85% follow-up at 2 to 3 years. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Both RCTs reported superior short-term results for fusion, however, a preferable design for assessing pain outcomes would be independent, blinded assessment of outcomes or, when feasible, a sham-controlled trial. Longer term follow-up from these RCTs indicated that the results obtained at six months persist to two years. Two additional cohort studies or case series, with sample sizes ranging from 45 to 149 patients and low dropout rates (<15%), have also shown reductions in pain and disability at two years. One small case series showed outcomes that

persisted to five years. The cohort studies and case series are consistent with the durability of treatment benefit. Analysis of an insurance database reported an overall incidence of complications to be 16.4% at six months and cumulative revision rate at four years of 3.54%. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

SIJ FUSION/FIXATION WITH A CYLINDRICAL THREADED IMPLANT

Systematic Reviews

No systematic reviews identified for SIJ Fusion/Fixation with a Cylindrical Threaded Implant that are not already addressed.

Randomized Controlled Trials

Rappoport (2017) reported on an industry-sponsored prospective study of SIJ fusion with a cylindrical threaded implant (SI-LOK).^[33] The study included 32 patients with a diagnosis of SIJ dysfunction who had failed nonoperative treatment, including medication, physical therapy, and therapeutic injections. A diagnostic injection was performed to confirm the source of pain to the SIJ. The procedure included drilling to prepare for screw insertion and implantation of three screws, at least one of which was slotted. The slotted screws were packed with autogenous bone graft from the drill reamings. Pain and disability scores were reduced following device implantation, and revisions within the first 12 months of the study were low (n=2). Follow-up will continue through two years.

Table 4. Pain and Disability Scores After Implantation With a Cylindrical Threaded Implant

Outcome Measures	Baseline	3 Months (SD)	6 Months (SD)	12 Months (SD)	p
Low back pain	55.8 (26.7)	28.5 (21.6)	31.6 (26.9)	32.7 (27.4)	<0.01
Left leg pain	40.6 (29.5)	19.5 (22.9)	16.4 (25.6)	12.5 (23.3)	<0.01
Right leg pain	40.0 (34.1)	18.1 (26.3)	20.6 (25.4)	14.4 (21.1)	<0.05
Oswestry Disability Index	55.6 (16.1)	33.3 (16.8)	33.0 (16.8)	34.6 (19.4)	<0.01

Adapted from Rappoport et al (2017).^[33]

Summary

There is limited evidence on fusion of the SIJ with devices other than the triangular implant. One-year results from a prospective cohort of 32 patients who received a cylindrical slotted implant showed reductions in pain and disability similar to results obtained for the triangular implant. However, there is uncertainty in the health benefit of SIJ fusion/fixation with this implant design. Therefore, controlled studies with a larger number of patients and longer follow-up are needed to evaluate this device.

PRACTICE GUIDELINE SUMMARY

NORTH AMERICAN SPINE SOCIETY

The North American Spine Society (NASS) published coverage recommendations for percutaneous sacroiliac joint fusion in 2015.^[34] 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, SI JOINT 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 SI JOINT, and consistent with SI JOINT 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 SI JOINT 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 SI JOINT injection on 2 separate occasions.
8. A trial of at least one therapeutic intra-articular SI JOINT injection (ie, corticosteroid injection).”

INTERNATIONAL SOCIETY FOR THE ADVANCEMENT OF SPINE SURGERY

The International Society for the Advancement of Spine Surgery (ISASS) published a policy statement on minimally invasive sacroiliac joint fusion. These recommendations were updated in 2016.^[35] ISASS lists criteria for determining a patient’s eligibility regarding minimally invasive SI joint fusion. However, the statement has several limitations including but not limited to the literature review methods are not transparent, there is no formal assessment of the quality of the evidence, and there is not a clear link between the recommendations and supporting evidence. ISASS recommendations state that patients who have all of the following criteria may be eligible for minimally invasive SI 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 three positive physical provocation examination maneuvers that stress the SI joint.
- “Confirmation of the SI joint as a pain generator with $\geq 75\%$ acute decrease in pain immediately following fluoroscopically guided diagnostic intra-articular SI joint block using local anesthetic.
- “Failure to respond to at least six 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.”

AMERICAN SOCIETY OF INTERVENTIONAL PAIN PHYSICIANS (ASIPP)

The ASIPP guidelines published in 2013 have a recommendation for diagnostic sacroiliac joint injections which were based on a systematic review of the evidence.^[1] The guideline indicates 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 noninvasive tests. The ASIPP guidelines conclude and recommend the following for diagnostic sacroiliac joint blocks:

- The evidence for diagnostic intraarticular sacroiliac joint injections is good with 75% to 100% pain relief as the criterion standard with controlled local anesthetic or placebo blocks, and fair due to the limitation of the number of studies with 50% to 74% relief with a dual block.
- Controlled sacroiliac joint blocks with placebo or controlled comparative local anesthetic blocks are recommended when indications are satisfied with suspicion of sacroiliac joint pain.

AMERICAN SOCIETY OF ANESTHESIOLOGISTS TASK FORCE ON CHRONIC PAIN MANAGEMENT AND THE AMERICAN SOCIETY OF REGIONAL ANESTHESIA AND PAIN MEDICINE PRACTICE

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.^[36] 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.

AMERICAN PAIN SOCIETY (APS)

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.^[3, 37] The APS guideline states that there is insufficient evidence to evaluate the validity or utility of diagnostic sacroiliac joint block as a diagnostic procedure for low back pain with or without radiculopathy.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE (NICE)

NICE guidance was published in April 2017 on minimally invasive SIJ fusion surgery for chronic sacroiliac pain.^[38] The recommendations included:

1.1 “Current evidence on the safety and efficacy of minimally invasive sacroiliac (SI) joint fusion surgery for chronic SI pain is adequate to support the use of this procedure.....

1.2 Patients having this procedure should have a confirmed diagnosis of unilateral or bilateral SI joint dysfunction due to degenerative sacroiliitis or SI joint disruption.

1.3 This technically challenging procedure should only be done by surgeons who regularly use image-guided surgery for implant placement. The surgeons should also have had specific training and expertise in minimally invasive SI joint fusion surgery for chronic SI pain.

SUMMARY

Sacroiliac joint fusion or fixation performed by open procedure is considered standard of care for traumatic injuries, tumors involving the sacrum, and SI joint infection/sepsis as outlined in the Medical Policy Criteria and therefore may be considered medically necessary. Sacroiliac joint fusion performed by an open procedure for any other indication is considered not medically necessary.

There is enough research to show that minimally invasive fusion/stabilization of the sacroiliac joint using an FDA-approved titanium triangular implant improves health outcomes. Additionally, clinical guidelines based on research recommend the use of minimally invasive fusion/stabilization of the sacroiliac joint using a titanium triangular implant. Therefore, minimally invasive fusion/stabilization of the sacroiliac joint using an FDA-approved titanium triangular implant may be considered medically necessary when policy criteria are met.

There is not enough research to show that minimally invasive fusion/stabilization of the sacroiliac joint using any other device or when policy criteria are not met improves health outcomes including but not limited to the use of a non-FDA approved device or a device that is not a titanium triangular implant. Therefore, minimally invasive fusion/stabilization of the sacroiliac joint using any other device including but not limited to a non-FDA approved device or a device that is not a titanium triangular implant or when policy criteria are not met is considered investigational.

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CODES

Codes	Number	Description
CPT	0775T	Arthrodesis, sacroiliac joint, percutaneous, with image guidance, includes placement of intra-articular implant(s) (eg, bone allograft[s], synthetic device[s]) (Deleted 01/01/2024)
	0809T	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, placement of transfixing device(s) and intraarticular implant(s), including allograft or synthetic device(s) (Deleted 01/01/2024)
	22899	Unlisted procedure, spine
	27096	Injection procedure for sacroiliac joint, anesthetic/steroid, with image guidance (fluoroscopy or CT) including arthrography when performed
	27278	Arthrodesis, sacroiliac joint, percutaneous, with image guidance, including placement of intra-articular implant(s) (eg, bone allograft[s], synthetic device[s]), without placement of transfixation device
	27279	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device
	27280	Arthrodesis, sacroiliac joint, open, including obtaining bone graft, including instrumentation, when performed
	27299	Unlisted procedure, pelvis or hip joint
HCPCS	None	

Date of Origin: December 2014