MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**SACROILIAC JOINT FUSION/STABILIZATION: OPEN AND PERCUTANEOUS METHODS**
Policy Number	**7.01.93**
Category	**Technology Assessment**
Effective Date	**12/15/16**
Revised Date	**06/21/18, 12/20/18, 07/18/19, 1/16/20**
Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.* • *If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.*

POLICY STATEMENT

I. Based on our criteria and assessment of the peer-reviewed literature, *minimally invasive* sacroiliac joint (SIJ) fusion using titanium triangular implants (SI-BONE iFuse Implant System®) for the treatment of lumbopelvic pain originating from the SIJ is considered **medically appropriate** when **ALL** of the following criteria are met:
   A. Performed by an orthopedic surgeon or neurosurgeon with specific training and expertise in percutaneous SIJ surgical techniques and who regularly uses image-guidance for placement of implants;
   B. Presence of non-radiating lumbopelvic pain caudal to L5, buttock, hip, and/or groin pain without radiation into the leg(s) that impairs physical activities;
   C. SIJ pain interfering with activities of daily living;
   D. Patient localizes posterior pain to the posterior superior iliac spine (Fortin's point);
   E. Localized tenderness to palpation over the sacral sulcus and posterior SIJ;
   F. Elicitation of typical pain on **THREE OR MORE** provocative physical examination maneuvers/tests that stress the SIJ:
      1. Thigh thrust test;
      2. Compression test;
      3. Gaenslen's maneuver;
      4. Distraction test;
      5. FABER/Patrick's sign; or
      6. Posterior provocation test;
   G. Absence of localized tenderness to palpation of similar severity to palpation of the sacral sulcus and posterior SIJ over the greater trochanter, lumbar spine, and coccyx;
   H. Diagnostic confirmation of the SIJ as a pain generator through 75% or greater reduction in pain for the expected duration of effect of the anesthetic agent used upon two separate contrast-enhanced fluoroscopically or CT-guided intra-articular SIJ blocks using a local anesthetic performed;
   I. Confirmation of the SIJ as a pain generator through at least a 75% reduction in pain for a minimum of two weeks following one contrast-enhanced fluoroscopically or CT-guided intra-articular SIJ injection using a corticosteroid;
   J. SIJ pain without minimal clinically important difference (MCID) from a minimum of a consecutive 6 months of conservative, non-surgical treatment including **ALL** of the following, unless contraindicated:
      1. Non-steroidal anti-inflammatory drugs (NSAIDs);
      2. Prescription medication optimization;
      3. Activity modification;

4. Physician supervised/prescribed active physical therapy (including home exercise program) targeting lumbopelvic (core) area; and
5. Chiropractic care;

K. Absence of generalized pain behavior (e.g., somatoform disorder) or generalized pain disorders (e.g., fibromyalgia);
L. Documentation of nicotine-free status with **EITHER** of the following:
1. Patient is a never-smoker; or
2. Patient has refrained from smoking, use of smokeless tobacco, and/or nicotine replacement therapy for at least 6 weeks prior to planned surgery as evidence by cotinine lab results of less than or equal to 10ng/mL;

M. Absence of unmanaged significant behavioral health disorders (e.g., major depressive disorder, chronic pain syndrome, secondary gain, drug and alcohol use disorders); and
N. Recent (within 6 months) diagnostic imaging studies that include **ALL** of the following:
1. Plain X-rays and/or cross sectional imaging (CT or MRI) that excludes the presence of destructive lesions (e.g., tumor, infection), acute fracture of inflammatory arthropathy that would not be properly addressed by SIJ fusion;
2. Plain X-rays of the pelvis including the ipsilateral hip to evaluate potential concomitant hip pathology; and
3. Cross-sectional imaging (e.g., CT or MRI) of the lumbar spine to evaluate potential concomitant neural compression or other degenerative conditions.

II. Based on our criteria and assessment of the peer-reviewed literature, *open* SIJ fusion is considered **medically necessary** when **ALL** of the following criteria are met:
A. Recent (within 6 months) plain X-rays and/or cross-sectional imaging (CT or MRI) demonstrate localized SIJ pathology; AND
B. Documentation of nicotine-free status with EITHER of the following:
1. Patient is a never-smoker; or
2. Patient has refrained from smoking, use of smokeless tobacco, and/or nicotine replacement therapy for at least 6 weeks prior to planned surgery as evidence by cotinine lab results of less than or equal to 10ng/mL.; AND

C. **ANY** of the following:
1. Post-traumatic injury of the SIJ (e.g., following pelvic ring fracture);
2. As an adjunctive treatment for SIJ infection;
3. Management of sacral tumor (e.g., partial sacrectomy);
4. When performed as part of a multisegmental long fusion construct for the correction of spinal deformity (e.g. idiopathic scoliosis, neuromuscular scoliosis); or
5. Failed prior percutaneous SIJ fusion.

III. Based on our criteria and assessment of the peer-reviewed literature, *minimally invasive* SIJ fusion or stabilization using titanium triangular implants has not been proven to be medically effective and, therefore, is considered **investigational** for any of the following, including but not limited to:
A. Any case that does not fulfill ALL of the above criteria;
B. Less than six months of SIJ pain and/or functional impairment;
C. Failure to pursue conservative treatment of the SIJ, unless contraindications are clearly documented;
D. Systemic arthropathy (e.g., ankylosing spondylitis, psoriatic arthritis, rheumatoid arthritis);
E. Generalized pain behavior (e.g., somatoform disorder) or generalized pain disorder (e.g., fibromyalgia);
F. Presence of infection, tumor, or fracture;
G. Acute traumatic instability of the SIJ;
H. Presence of neural compression, as seen on an MRI or CT, that correlates with the patient's symptoms or other more likely source for the patient's pain;
I. Any condition that would prevent insertion of the implants; or
J. Bilateral procedures on the same date of service.

IV. Based on our criteria and assessment of the peer-reviewed literature, the use of minimally invasive fusion products other than SI-BONE iFuse Implant System® (e.g., Rialto SI Fusion System, Symmetry SI Joint Fusion System, Silex

Sacroiliac Joint Fusion System, SiJoint Direct Posterior Fusion, Samba-Screw System, SI-LOK Sacroiliac Joint Fixation System) for minimally invasive SIJ fusion has not been proven to be medically effective and, therefore, is considered **investigational**.

V. Based on our criteria and assessment of the peer-reviewed literature, *open* SIJ fusion has not been proven to be medically effective and, therefore, is considered **investigational**, for ANY of the following indications:
   A. Mechanical low back pain;
   B. Sacroiliac joint syndrome;
   C. Degenerative sacroiliac joint; or
   D. Radicular pain syndrome.

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services.

POLICY GUIDELINES

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION

The sacroiliac joint, or SI joint (SIJ), is a large L-shaped synovial joint in the pelvis that connects the sacrum and the ilium of the pelvis. This joint is a strong, weight-bearing joint on both sides of the pelvis. These joints are supposed to move together as single unit. Sacroiliac joint pain is often from dysfunction from one of the two joints. When one joint does not move properly, pain may be felt as one-sided low back pain or midline "tailbone" pain. The joint can move too much (hypermobility) or too little (hypomobility) and can feel "locked-up." Pain can be dull or very sharp. When SI joint dysfunction is severe, this joint can refer pain to the hip, lower back, groin, buttocks, and even down the back of the thigh. The majority of patients can be treated non-operatively through anti-inflammatory medications, physical therapy, or SI joint injections. However, when conservative therapies have failed to improve symptoms, surgical intervention may be proposed. Within the past few years, as treatment options for SI joint dysfunction have advanced, there has been a resurgence in the recognition of the SI joint as a potential source of low back pain.

Open Sacroiliac (SI) joint fusion was an early technique used to stabilize the sacroiliac joint. However the open procedure has been associated with long intraoperative times, intraoperative bleeding and long rehabilitative times. Therefore, minimally invasive SIJ fusion techniques have been investigated. Minimally invasive fusion aims to permanently stabilize the SIJ but avoid the morbidity of the open procedure. Minimally invasive fusion of the SI joint has been performed with several types of implants, including triangular, porous, titanium-coated implants, hollow modular screws, titanium cages, and allograft dowels. Two surgical approaches are commonly used for minimally invasive SIJ fusion: a lateral transarticular approach, in which devices are placed across the SI joint from lateral to medial; and a posterior approach, in which devices are placed into the ligamentous portion of the joint via dissection of the multifidus muscle and removal of ligaments covering the outer posterior surface of the joint. In the posterior approach, a portion of the interosseous SIJ ligament is sometimes removed.

RATIONALE

Several percutaneous or minimally invasive fixation/fusion devices have been cleared for marketing by the federal Food and Drug Administration. 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 (Xtant Medical) and the SI-LOK® Sacroiliac Joint Fixation System (Globus Medical).

Although open SIJ fusion has been used since the 1920s, and case reports of outcomes exist, the open procedure is rarely performed and, hence, clinical trials do not exist. For individuals with SIJ pain who receive SIJ fusion, the evidence includes two 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 non-blinded 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 six months persist to two years. One small case series showed good outcomes persist to five years. The case series are consistent with durability of treatment benefit, but only if there is a true benefit of treatment.

In March of 2015, Whang, *et al*. reported the six-month follow-up of an industry-sponsored non-blinded RCT of the iFuse Implant System® in 148 patients. The 12-month follow-up was reported by Polly and colleagues in November of 2015. Trial inclusion was based on the determination of the SIJ as a pain generator from a combination of a history of SIJ-localized pain, positive provocative testing on at least 3 of 5 established physical tests, and at least a 50% decrease in SIJ pain after image-guided local anesthetic injection into the joint. The duration of pain before enrollment averaged 6.4 years (range, 0.47-40.7 years). Patients were assigned 2:1 to minimally invasive SIJ fusion (n=102) or to nonsurgical management (n=46). Nonsurgical management included a stepwise progression, depending on individual patient need for pain medications, physical therapy (97.8%), intra-articular steroid injections (73.9%), and RFA of sacral nerve roots (45.7%). The primary outcome measure was a six-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 cross over 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.
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 quality of life (36-Item Short-Form Health Survey, EuroQol-5D) also improved to a greater extent in the surgery group. Of the 44 nonsurgical management patients still participating at 6 months, 35 (79.5%) crossed over to fusion. Opioid use remained high in both groups at 6 months (70.5% for controls vs. 58.0% for fusion; p=0.082) and at 12 months (55% vs. 52%, respectively, p=0.61). Although these results generally favored fusion and had high methodologic quality, the trial had a high potential for bias (non-blinded study, subjective outcome measures).

In 2016, Sturesson and colleagues reported another industry-sponsored, non-blinded RCT of the iFuse Implant System® in 103 patients. Inclusion was based on similar criteria as the Whang trial, including at least 50% pain reduction on SIJ block. Mean pain duration was 4.5 years. Nonsurgical management included physical therapy and exercises at least twice per week; interventional procedures (e.g., steroid injections, RFA) were not allowed. The primary outcome was change in VAS pain score at 6 months. Of 109 randomized subjects, 6 withdrew before any treatment. All patient assigned to iFuse underwent the procedure, and follow-up at 6 months was in 49 of 51 patients in the control group and in all 52 patients in the iFuse group. At 6 months, VAS pain scores improved by 43.3 points in the iFuse group and by 5.7 in the control group ($p<0.001$). ODI scores improved by 5.8 points in the control group and by 25.5 points in the iFuse group ($p<0.001$, between groups). Quality of life outcomes showed a greater improvement in the iFuse group than in the control group. Although these results favored fusion, with magnitudes of effect in a range similar to the RCT by Whang, this trial was also not blinded and lacked a sham control. Outcomes were only assessed to 6 months.

Sachs, et al. (2016) reported outcomes of 107 patients with a minimum follow-up of 3 years. The number of potentially eligible patients was not reported, so the follow-up rate is unknown. Pain scores improved from a mean of 7.5 at baseline to 2.5 at a mean follow-up time of 3.7 years. ODI score at follow-up was 28.2, indicating moderate residual disability. Satisfaction rate was 87.9% (67.3% very satisfied, 20.6% somewhat satisfied). Revision surgery was reported in 5 (4.7%) patients. Without knowing the number of eligible patients, the validity of this study cannot be determined.

In 2016, Schoell and colleagues analyzed postoperative complications tracked in an administrative database of minimally invasive SIJ fusions. Although during the study there was no specific CPT code for minimally invasive sacroiliac fusion, CPT codes listed by a policy statement were used. Using the Humana insurance database, patients with complications were identified using ICD-9 codes corresponding to a surgical complication within 90 days or six 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 six 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.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*

CPT Codes

Code	Description
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, open, sacroiliac joint, including obtaining bone graft, including instrumentation, when performed

HCPCS Codes

Code	Description
No codes	

ICD10 Codes

Code	Description
M46.1	Sacroiliitis, not elsewhere classified
M47.898	Other spondylosis, sacral and sacrococcygeal region
M47.899	Other spondylosis, site unspecified
M48.08	Spinal stenosis, sacral and sacrococcygeal region
M53.2X8	Spinal instabilities, sacral and sacrococcygeal region
M54.18	Radiculopathy, sacral and sacrococcygeal region
M54.30-M54.32	Sciatica (code range)
M54.40-M54.42	Lumbago with sciatica (code range)
M54.5	Low back pain
S33.2XXA-S33.2XXS	Dislocation of sacroiliac and sacrococcygeal joint (code range)
S33.6XXA-S33.6XXS	Sprain of sacroiliac joint (code range)

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*Key Article

KEY WORDS

IFUSE® Implant System, SI-FIX, SImmetry® Sacroiliac Joint Fusion System, Silex™ Sacroiliac Joint Fusion System, SI-LOK® Sacroiliac Joint Fixation System

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a Local Coverage Determination (LCD) for minimally-invasive surgical (MIS) fusion of the sacroiliac joint (L36406). Please refer to the following LCD website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36406&ver=9&CntrctrSelected=298*1&Cntrctr=298&name=National+Government+Services%2c+Inc.+(13201%2c+A+and+B+and+HHH+MAC%2c+J+-+K)&s=All&DocType=Active&bc=AggAAAQBAAAA&