MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Sacroiliac Joint Fusion/Stabilization: Open and Percutaneous Methods**
Policy Number	**7.01.93**
Category	**Technology Assessment**
Original Effective Date	**12/15/16**
Committee Approval Date	**06/21/18, 12/20/18, 07/18/19, 1/16/20, 12/17/20, 12/16/21, 12/22/22, 05/18/23**
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Archived Date	**N/A**
Archive Review Date	**N/A**
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 or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) 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.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, minimally invasive sacroiliac joint (SIJ) fusion using titanium triangular implants (SI-BONE [iFuse Implant System or iFuse-3D Implant]) for the treatment of lumbopelvic pain originating from the SIJ has been medically proven to be effective and, therefore, is considered **medically appropriate**, when **ALL** of the following criteria have been met:

A. Procedure is performed by an orthopedic surgeon or neurosurgeon who has specific training and expertise in percutaneous SIJ surgical techniques and who regularly uses image guidance for placement of implants.
B. Patient has non-radiating lumbopelvic pain caudal to L5, buttock, hip, and/or groin pain without radiation into the leg(s) that impairs physical activities.
C. Patient has SIJ pain interfering with activities of daily living.
D. Patient localizes posterior pain to the posterior superior iliac spine (Fortin's point).
E. Patient has localized tenderness to palpation over the sacral sulcus and posterior SIJ.
F. Typical pain is elicited 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; and/or
   6. posterior provocation test.
G. Patient has no 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. The SIJ has been diagnostically confirmed to be a pain generator, in that the reduction in pain is 75% or greater for the expected duration of the effect of the local anesthetic agent used during two separate contrast-enhanced fluoroscopically or CT-guided intra-articular SIJ blocks.
I. Patient has experienced SIJ pain without minimal clinically important difference (MCID) from a minimum of a consecutive six months of conservative, non-surgical treatment that includes **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;
J. Patient has no generalized pain behavior (e.g., somatoform disorder) or generalized pain disorders (e.g., fibromyalgia).
K. Patient's medical record documents nicotine-free status, meaning **EITHER**:
   1. Patient is a never-smoker; or
   2. Patient has refrained from smoking, the use of smokeless tobacco, and/or nicotine replacement therapy for at least six weeks prior to planned surgery, as evidenced by cotinine lab results of less than or equal to 10ng/mL.
L. Patient has no unmanaged, significant mental and/or behavioral health disorders (e.g., major depressive disorder, chronic pain syndrome, secondary gain, opioid use or alcohol use disorders).
M. Recent (within six months) diagnostic imaging studies 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) or 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 upon our criteria and assessment of the peer-reviewed literature, open SIJ fusion has been medically proven to be effective and, therefore, is considered **medically appropriate**, when **ALL** of the following criteria have been met:

A. Recent (within six months) plain X-rays and/or cross-sectional imaging (CT or MRI) demonstrate localized SIJ pathology.
B. Patient's medical record documents nicotine-free status, meaning that **EITHER**:
   1. Patient is a never-smoker; or
   2. Patient has refrained from smoking, the use of smokeless tobacco, and/or nicotine replacement therapy for at least six weeks prior to planned surgery, as evidenced by cotinine lab results of less than or equal to 10ng/mL.
C. At least **ONE** of the following applies:
   1. Patient has post-traumatic injury of the SIJ (e.g., following pelvic ring fracture);
   2. The procedure is to be performed as an adjunctive treatment for SIJ infection;
   3. The procedure is to be performed for management of a sacral tumor (e.g., partial sacrectomy);
   4. The procedure is to be performed as part of a multi-segmental long fusion construct for the correction of spinal deformity (e.g., idiopathic scoliosis, neuromuscular scoliosis); or
   5. Prior percutaneous (minimally invasive) SIJ fusion has failed.

III. Based upon our criteria and assessment of the peer-reviewed literature, minimally invasive or percutaneous sacroiliac joint (SIJ) fusion or stabilization using *titanium triangular implants* is considered **not medically necessary** for the following indications:

A. Any case that does not fulfill ALL of the above criteria;
B. Performed with the presence of generalized pain behavior (e.g., somatoform disorder) or generalized pain disorder (e.g., fibromyalgia);

IV. Open sacroiliac joint (SIJ) fusion performed without meeting ALL of the above criteria is considered not medically necessary

V. Based upon 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** under circumstances that include, but are not limited to, the following:

A. Systemic arthropathy (e.g., ankylosing spondylitis, psoriatic arthritis, rheumatoid arthritis);
B. Presence of infection, tumor, or fracture;
C. Acute traumatic instability of the SIJ;
D. 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;
E. Any condition that would prevent insertion of the implants; or
F. Bilateral procedures on the same date of service.

VI. Based upon our criteria and assessment of the peer-reviewed literature, the use of minimally invasive fusion products/implants other than SI-BONE (iFuse Implant System or iFuse-3D Implant) for minimally invasive SIJ fusion have not been medically proven to be effective and, therefore, are considered **investigational**. Examples include, but are not be limited to, the following:

A. Rialto SI Joint Fusion System (Medtronic),
B. SImmetry Sacroiliac Joint Fusion System (RTI Surgical),
C. Firebird SI Fusion System (Orthofix),
D. SI-LOK Sacroiliac Joint Fixation System (Globus Medical),
E. SIJ-Fuse (Spine Frontier), and
F. SImpact Sacroiliac Joint Fixation System (Life Spine).

VII. Based upon our criteria and assessment of the peer-reviewed literature, open SIJ fusion has not been medically proven to be effective and, therefore, is considered **investigational**, for **ALL** of the following indications:

A. Mechanical low back pain;
B. Sacroiliac joint syndrome;
C. Degenerative sacroiliac joint; and
D. Radicular pain syndrome.

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

DESCRIPTION

The sacroiliac joints, or SI joints (SIJs), are large, L-shaped synovial joints on both sides of the pelvis that connect the sacrum and the ilium of the pelvis. These joints are strong and weight-bearing, and they are supposed to move together as single unit. SIJ pain is often from dysfunction of 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 joints can move too much (hypermobility) or too little (hypomobility) and can feel "locked-up." Pain can be dull or very sharp. When SIJ dysfunction is severe, pain can be referred 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 SIJ injections. However, when conservative therapies have failed to improve symptoms, surgical intervention may be proposed. Within the past few years, as treatment options for SIJ 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 SIJ. However, the open procedure had 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 SIJ 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 SIJ 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 (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), the 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 randomized, controlled trials (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 three of five 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 Oswestry Disability Index (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 six months, 35 (79.5%) crossed over to fusion. Opioid use remained high in both groups at six months (70.5% for controls versus 58.0% for fusion; p=0.082) and at 12 months (55% versus 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 six months. Of 109 randomized subjects, six withdrew before any treatment. All patient assigned to iFuse underwent the procedure, and follow-up at six months included 49 of 51 patients in the control group and 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 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 six months.

Sachs et al. (2016) reported outcomes of 107 patients with a minimum follow-up of three 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 five (4.7%) patients. Without knowing the number of eligible patients, the validity of this study cannot be determined.

In 2016, Schoell and colleagues analyzed post-operative complications tracked in an administrative database of minimally invasive SIJ fusions. Although, at the time of 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.

According to Lorio et al. (2020), bilateral SIJ fusion is generally best performed serially as successful treatment of one side may improve pain/disability to a degree acceptable to the patient. If contralateral SIJ pain continues and disability is significant for the patient, SIJ fusion of the contralateral side may be necessary. It is expected that patients would not require more than one SIJ fusion per side per lifetime unless a revision is required. Provider qualifications include orthopedic or neurologic surgeons who have successfully completed a residency in that specialty and at least one specialized training course in the procedure which includes device placement under the supervision of a surgeon experienced in the procedure.

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.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
27278 **(E/I)** Effective 01/01/24	Arthrodesis, sacroiliac joint, percutaneous, with image guidance, including placement of intra-articular implant(s) (e.g., bone allograft[s], synthetic device[s]), without placement of transfixation device *(effective 01/01/24) (Replacing code 0775T)*
0775T **(E/I)** Termed 12/31/23	Arthrodesis, sacroiliac joint, percutaneous, with image guidance, includes placement of intra-articular implant(s) (e.g., bone allograft[s], synthetic device[s]
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
M53.3	Sacrococcygeal disorders, not elsewhere classified
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&