SACROILIAC JOINT FUSION

Protocol: SUR054
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INSTRUCTIONS FOR USE
This protocol provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Evidence of Coverage (EOC)) may differ greatly. In the event of a conflict, the enrollee's specific benefit document supersedes this protocol. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Protocol. Other Protocols, Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Protocols, Policies and Guidelines as necessary. This protocol is provided for informational purposes. It does not constitute medical advice. This policy does not govern Medicare Group Retiree members.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

COMMERCIAL, MEDICARE & MEDICAID COVERAGE RATIONALE

Sacroiliac joint fusion is medically necessary for the following indications:
- Adjunctive to sacrectomy or partial sacrectomy for tumors involving the sacrum
- Adjunctive treatment for sacroiliac joint infection/sepsis;
- Severe traumatic SI joint injuries (pelvic ring fracture);
- During multisegmental correction of spinal deformities (e.g. scoliosis, kyphosis surgery) which extend to the ilium.

Sacroiliac joint fusion is not medically necessary for any other indication, including but not limited to:
- Mechanical low back pain,
• Sacroiliac joint syndrome,
• Degenerative sacroiliac joint disease,
• Radicular pain,
• Sacroiliac insufficiency fractures.

Minimally invasive and percutaneous sacroiliac joint fusion including the use of associated instrumentation/fixation devices (e.g. iFuse, Silex Sacroiliac Joint System, and SImmetry Sacroiliac Joint Fusion System, etc.) is **not medically necessary**.

For all indications not covered as medically necessary, there is insufficient clinical evidence to determine the safety and efficacy of sacroiliac joint fusion (open or minimally invasive). There is a lack of randomized controlled trials comparing sacroiliac joint fusion with conventional treatments.

Medicare does not have a National Coverage Determination or a Local Coverage Determination for Nevada specific to sacroiliac joint fusion. Accessed October 2018.

**Important Note:** Please also review local carrier Web sites in addition to the Medicare Coverage database on the Centers for Medicare and Medicaid Services’ Website.

### DESCRIPTION OF SERVICES

Sacroiliac joint fusion, (e.g. arthrodesis), is a surgical technique that involves bony fusion of the sacroiliac joint for stabilization. Sacroiliac joint fusion may be performed as a minimally invasive procedure or as an open surgical procedure requiring a larger incision and subsequent increased recovery time. Percutaneous sacroiliac joint fusion is a minimally invasive approach in which instrumentation involving cages or screws, with or without bone graft, are placed percutaneously in order to achieve a fusion.

### CLINICAL EVIDENCE

In a consecutive case-series study, Buchowski et al (2005) described the outcome of sacro-iliac joint (SIJ) arthrodesis for SIJ disorders, with the hypothesis that SIJ arthrodesis leads to improved post-operative function. The patient population consisted of 20 patients undergoing SIJ arthrodesis between December 1994 and December 2001. Patients undergoing concomitant procedures at the time of SIJ arthrodesis were excluded. The 3 men and 17 women in the study group had an average age of 45.1 years (range of 21.8 to 66.4 years), a mean duration of symptoms of 2.6 years (range of 0.5 to 8.0 years), and a mean follow-up period of 5.8 years (range of 2.0 to 9.0 years). Outcome measures included general health and function, clinical evaluation, and radiographic assessment. For all 20 patients, non-operative treatment had failed, and for all, the diagnosis was confirmed by pain relief with intra-articular SIJ injections under fluoroscopic guidance. Sacroiliac joint arthrodesis (via a modified Smith-Petersen technique) was recommended only when a positive response to the injection was noted, and patients had recurrence of symptoms after the initial positive response. Pre-operative and post-operative general health and function were assessed via the 36-item Short-Form (SF-36) Health Survey and American Academy of Orthopaedic Surgeons (AAOS) Modems Instrument, which were collected prospectively. Medical records and plain radiographs were reviewed retrospectively to determine the clinical and radiographic outcome. Multiple etiologies of sacroiliac symptoms were
observed: SIJ dysfunction (13 patients), osteoarthritis (5 patients), and spondyloarthropathy and SIJ instability (1 each). Seventeen patients (85%) had solid fusion. Fifteen patients (75%) completed pre-operative and post-operative SF-36 forms. Significant (p < 0.05) improvement occurred in the following categories: physical functioning, role physical, bodily pain, vitality, social functioning, role emotional, as well as neurogenic and pain indices. Improvement (not statistically significant) was also noted in general and mental health. The authors concluded that for carefully selected patients, SI arthrodesis appears to be a safe, well-tolerated, and successful procedure, leading to significant improvement in functional outcome and a high fusion rate. Limitations of this study were: (i) the 85% fusion rate may be an over-estimation because more precise methods (such as a CT scan) were not used to confirm successful arthrodesis, (ii) small number of patients (n = 20), and (iii) only 75% of patients were available for follow-up.

Wise and Dall (2008) compared efficacy and outcomes of a new technique for SI arthrodesis. This study described the radiographic and clinical outcomes of this procedure. A total of 13 consecutive patients underwent minimally invasive SI arthrodesis between February and December 2004 at a single teaching hospital and were prospectively followed. Six patients had bilateral fusions for a total of 19 joints. The average age was 53.1 (range of 45 to 62). Average body mass index was 31.2 (range of 21.9 to 46.9). Mean follow-up was 29.5 months (range of 24 to 35). Diagnosis was confirmed using fluoroscopically guided intra-articular injections of local anesthetic and corticosteroid when their pain was relieved 2 or more hours. Arthrodesis was only performed on patients with positive injections who subsequently had their symptoms recur. Outcome measurements included radiographic assessment for fusion and improvement in VAS for LBP, leg pain, and dyspareunia. Computed tomography scan to evaluate implant placement was performed post-operatively and again at 6 months to assess fusion. The overall fusion rate was 89% (17/19 joints). Significant improvements were seen in final LBP score on a VAS (0 to 10) (average improvement 4.9, p < 0.001). Leg pain improved an average of 2.4 (p = 0.013). Dyspareunia improved an average of 2.6 (p = 0.0028). One patient was revised to an open arthrodesis secondary to nonunion and persistent pain. There were no infections or neurovascular complications. The authors concluded that minimally invasive SI arthrodesis via a percutaneous posterior approach is a safe and efficacious procedure, leading to a high fusion rate and significant improvement in LBP, leg pain, and dyspareunia. Limitations of this study were its small sample size and the lack of a control group.

In a consecutive case-series study, Al-Khayer (2008) reported a new percutaneous SIJ arthrodesis technique utilizing a Hollow Modular Anchorage screw. Pre-operative and post-operative Oswestry Disability Index (ODI), VAS for pain, and post-operative subjective patients' satisfaction were assessed for all patients. Minimum 2 years follow-up was documented. A total of 9 patients underwent SIJ arthrodesis with the new technique. The mean ODI value dropped from 59 (range of 34 to 70) pre-operatively to 45 (range of 28 to 60) post-operatively (p < 0.005). The mean VAS value dropped from 8.1 (range of 7 to 9) pre-operatively to 4.6 (range of 3 to 7) post-operatively (p < 0.002). The mean patients' satisfaction was 6.8 (range of 5 to 8). The authors concluded that the new technique may offer a safe and effective treatment for intractable SIJ pain. Limitations of this study were its small sample size, lack of a control group, and despite the encouraging radiographic findings, the exact fusion status of SIJ arthrodesis cannot be determined by plain radiographs.

Khurana et al (2009) examined the effects of percutaneous fusion of the SIJ with hollow modular anchorage screws. These investigators reviewed 15 consecutive patients, 11 women and 4 men, with a
mean age of 48.7 years (37.3 to 62.6), who between July 2004 and August 2007 had undergone percutaneous SI fusion using hollow modular anchorage screws filled with demineralized bone matrix. Each patient was carefully assessed to exclude other conditions and underwent pre-operative CT and MR scans. The diagnosis of symptomatic SI disease was confirmed by an injection of local anesthetic and steroid under image intensifier control. The short form-36 questionnaire and Majeed's scoring system were used for pre- and post-operative functional evaluation. Post-operative radiological evaluation was performed using plain radiographs. Intra-operative blood loss was minimal and there were no post-operative clinical or radiological complications. The mean follow-up was for 17 months (9 to 39). The mean short form-36 scores improved from 37 (23 to 51) to 80 (67 to 92) for physical function and from 53 (34 to 73) to 86 (70 to 98) for general health (p = 0.037). The mean Majeed's score improved from 37 (18 to 54) pre-operatively to 79 (63 to 96) post-operatively (p = 0.014). There were 13 good to excellent results. The remaining 2 patients improved in short form-36 from a mean of 29 (26 to 35) to 48 (44 to 52). Their persistent pain was probably due to concurrent lumbar pathology. The authors concluded that percutaneous hollow modular anchorage screws are a satisfactory method of achieving SI fusion.

In a retrospective study, Rudolf (2012) evaluated the safety and effectiveness of minimally invasive SIJ fusion using a series of triangular, porous plasma spray coated titanium implants. A total of 50 consecutive patients were treated by a single orthopedic spine surgeon in private practice. Medical charts were reviewed for peri-operative metrics, complications, pain, quality of life and satisfaction with surgery. All patients were contacted at a 24 months post-op to assess SIJ pain, satisfaction with surgery and work status. An early and sustained statistically significant improvement in pain function was identified at all post-operative time points (ANOVA, p < 0.000). A clinically significant improvement (greater than 2 point change from baseline) was observed in 7 out of 9 domains of daily living. The complication rate was low and more than 80 % of patients would have the same surgery again. The authors concluded that minimally invasive SIJ fusion appears to be a safe and effective procedure for the treatment of SIJ disruption or degenerative sacroiliitis. The drawbacks of this study included its retrospective design, small sample size, a single surgeon’s experience, a non-standard outcomes measure, and the lack of a comparator group. Moreover, the author noted that prospective studies are currently underway to further evaluate this technology.

In a retrospective study, Sachs and Capobianco (2012) evaluated the safety and effectiveness of minimally invasive SIJ arthrodesis via an ileo-sacral approach in patients who were refractory to conservative care. These investigators reported on the first 11 consecutive patients treated with a novel minimally invasive SIJ fusion system by a single surgeon. Medical charts were reviewed for peri-operative metrics and baseline pain scores recorded using a 0 to 10 numerical rating scale. Ninety one percent (91 %) of patients were female and the average patient age was 65 years (range of 45 to 82). Mean baseline pain score (SD) was 7.9 (+/- 2.2). Mean pain score at the 12 month follow-up interval was 2.3 (+/- 3.1), resulting in an average improvement of 6.2 points from baseline, representing a clinically and statistically significant (p = 0.000) improvement. Patient satisfaction was very high with 100 % indicating that they would have the same surgery again for the same result. The authors concluded that the findings of this small case series illustrated the safety and effectiveness of minimally invasive SIJ fusion using a series of triangular porous plasma coated titanium implants in carefully selected patients. Moreover, they stated that larger multi-centered studies are needed.
Sachs and Capobianco (2013) performed a second retrospective case review of the first 40 consecutive individuals with 1-year follow-up data that underwent minimally invasive sacroiliac joint fusion with the iFuse Implant System. Nearly one-half (48%) of the individuals had a history of previous lumbar spine surgery that included: fusion at 1 or more levels (63%), decompression (16%), discectomy (10.5%) and 10.5% with nonspecific documented procedures. Medical record documentation was reviewed for demographics, perioperative metrics, complications, pain scores, and satisfaction with the procedure. Post-operative complications included transient trochanteric bursitis (n=2, 5%), facet joint pain (n=8, 20%), and new low back pain (n=1, 2.5%). There were no reoperations at 1 year. The mean pain score improved from 8.7 (± 1.5) at baseline to 0.9 (± 1.6) at 12 months, a 7.8-point improvement (p<0.001). Two individuals went on to have fusion surgery for significant degenerative disc disease or spinal stenosis. Limitations of this study include its retrospective design, lack of a comparator group, small sample size, and heterogeneous group of subjects (in terms of prior lumbar spine surgery procedures).

Miller et al (2013) stated that MIS SIJ arthrodesis was developed to minimize the risk of iatrogenic injury and to improve patient outcomes compared with open surgery. Between April 2009 and January 2013, a total of 5,319 patients were treated with the iFUSE SI Joint Fusion System® for conditions including SIJ disruption and degenerative sacroiliitis. A database was prospectively developed to record all complaints reported to the manufacturer in patients treated with the iFUSE device. Complaints were collected through spontaneous reporting mechanisms in support of ongoing mandatory post-market surveillance efforts. Complaints were reported in 204 (3.8 %) patients treated with the iFUSE system. Pain was the most commonly reported clinical complaint (n = 119, 2.2 %), with nerve impingement (n = 48, 0.9 %) and recurrent SIJ pain (n = 43, 0.8 %) most frequently cited. All other clinical complaints were rare (less than or equal to 0.2 %). Ninety-six revision surgeries were performed in 94 (1.8 %) patients at a median follow-up of 4 (range of 0 to 30) months. Revisions were typically performed in the early post-operative period for treatment of a symptomatic mal-positioned implant (n = 46, 0.9 %) or to correct an improperly sized implant in an asymptomatic patient (n = 10, 0.2 %). Revisions in the late post-operative period were performed to treat symptom recurrence (n = 34, 0.6 %) or for continued pain of undetermined etiology (n = 6, 0.1 %). The authors concluded that analysis of a post-market product complaints database demonstrated an overall low-risk of complaints with the iFUSE SIJ Fusion System in patients with degenerative sacroiliitis or SIJ disruption. The authors noted that the initial results are promising; however, clinical effectiveness outcomes were not assessed in this study.

The manufacturer of the iFuse implant for sacroiliac fusion has reported outcomes from an ongoing uncontrolled prospective clinical study that is sponsored by the manufacturer (Duhon, et al., 2013). Six month efficacy outcomes were available from 26 of 32 subjects enrolled in the efficacy cohort. Mean sacroiliac joint pain improved from a baseline score of 76 (±16.2) to a 6-month score of 29.3 (± 23.3, an improvement of 49 points, p<0.0001), mean ODI improved from 55.3 (±10.7) to 38.9 (±18.5, an improvement of 15.8 points, p<0.0001) and SF-36 PCS improved from 30.7 (±4.3) to 37.0 (±10.7, an improvement of 6.7 points, p=0.003).

Noting that there is minimal literature published on percutaneous fixation of the sacroiliac joint, Kim, et al. (2014) reported on a retrospective review of 31 patients operated on by a single surgeon. The investigators reported that 27 patients expressed satisfaction, 4 patients did not. Pain relief was noted to be Complete (16 patients), Excellent (5 patients), Good (9 patients), and Fair (1 patients). Four
patients had postoperative complications. These were infected hematoma (2), L5 nerve root irritation (1), and L5-S1 discitis (1). One patient required revision. On 6 month postop CT scan, 18/19 patients had radiographic evidence of bone ingrowth and bone into or across the SI joint was evident in 8/19 patients. Lucency was noted around at least one implant in 5/19 patients.

Duhon and colleagues (2013) reported interim results of an ongoing industry-sponsored, multicenter, prospective, single-arm clinical trial evaluating the early safety and 6-month effectiveness of the iFuse Implant System to relieve pain and improve quality of life in individuals with degeneration or disruption of the sacroiliac joint who have failed non-surgical care. The safety cohort included 94 subjects at 23 sites with chronic sacroiliac joint pain who met study eligibility criteria and underwent minimally invasive sacroiliac joint fusion between August 2012 and September 2013. Subjects underwent structured assessments preoperatively, immediately postoperatively, and at 1-, 3-, and 6 months postoperatively, including sacroiliac joint and back pain VAS, Oswestry Disability Index (ODI), Short Form-36 (SF-36), and EuroQoL-5D (EQ-5D). Satisfaction with surgery was also assessed at 6 months. Three implants were used in 80% of subjects; 2 subjects underwent staged bilateral implants. A total of 23 adverse events occurred within 1 month of surgery and 29 additional events occurred between 30 days and latest follow-up. Six adverse events were severe but none were device-related. The effectiveness cohort included 32 subjects, but only 26 remained in the cohort with reportable 6-month outcomes. In this cohort, mean sacroiliac joint pain improved from a baseline score of 76 (± 16.2) to a 6-month score of 29.3 (± 23.3), an improvement of 49 points, p<0.0001), mean ODI improved from 55.3 (± 10.7) to 38.9 (± 18.5), an improvement of 15.8 points; p<0.0001) and SF-36 PCS improved from 30.7 (± 4.3) to 37.0 (± 10.7), an improvement of 6.7 points; p=0.003). A total of 90% of subjects who were ambulatory at baseline regained full ambulation by month 6; median time to full ambulation was 30 days. Satisfaction with the procedure was high at 85%. Limitations of this trial include lack of an active control group and use of a non-standard outcome measure (that is, ODI) which is designed to evaluate lower back pain and not sacroiliac joint pain. Study enrollment is continuing and further results with long-term follow-up are needed.

Whang and colleagues (2015) noted that sacroiliac (SI) joint pain is a prevalent, under-diagnosed cause of lower back pain. SI joint fusion can relieve pain and improve quality of life in patients who have failed non-operative care. To-date, no study has concurrently compared surgical and non-surgical treatments for chronic SI joint dysfunction. These researchers conducted a prospective randomized controlled trial of 148 subjects with SI joint dysfunction due to degenerative sacroiliitis or sacroiliac joint disruptions who were assigned to either minimally invasive SI joint fusion with triangular titanium implants (n = 102) or non-surgical management (NSM, n = 46). SI joint pain scores, Oswestry Disability Index (ODI), Short-Form 36 (SF-36) and EuroQol-5D (EQ-5D) were collected at baseline and at 1, 3 and 6 months after treatment commencement. Six-month success rates, 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 SI joint-related adverse events or surgical revision, were compared using Bayesian methods. Subjects (mean age of 51, 70 % women) were highly debilitated at baseline (mean SI joint VAS pain score 82, mean ODI score 62). Six-month follow-up was obtained in 97.3 %. By 6 months, success rates were 81.4 % in the surgical group versus 23.9 % in the NSM group (difference of 56.6 %, 95 % posterior credible interval 41.4 to 70.0 %, posterior probability of superiority >0.999). Clinically important (greater than or equal to 15 point) ODI improvement at 6 months occurred in 75 % of surgery subjects versus 27.3 % of NSM subjects. At 6 months, quality of life improved more in the surgery group and satisfaction rates were high. The mean number of adverse events in the first 6
months was slightly higher in the surgical group compared to the non-surgical group (1.3 versus 1.0 events per subject, \( p = 0.1857 \)). The authors concluded that the 6-month follow-up from this level 1 study showed that minimally invasive SI joint fusion using triangular titanium implants was more effective than non-surgical management in relieving pain, improving function and improving quality of life in patients with SI joint dysfunction due to degenerative sacroiliitis or SI joint disruptions. This was a study with short-term follow-up (6 months); well-designed studies with long-term follow-up are needed to ascertain the clinical effectiveness of SI fusion.

Soriano-Baron et al (2015) stated that minimally invasive placement of SIJ fusion implants is a potential treatment for SIJ disruptions and degenerative sacroiliitis. Biomechanical studies of screw fixation within the sacrum have shown that placement and trajectory are important in the overall stability of the implant. Although clinical results have been promising, there is the possibility that a more optimal arrangement of implants may exist.

Zaidi et al (2015) stated that the SI joint (SIJ) and surgical intervention for treating SIJ pain or dysfunction has been a topic of much debate in recent years. There has been a resurgence in the implication of this joint as the pain generator for many patients experiencing low-back pain, and new surgical methods are gaining popularity within both the orthopedic and neurosurgical fields. There is no universally accepted gold standard for diagnosing or surgically treating SIJ pain. The authors systematically reviewed studies on SIJ fusion in the neurosurgical and orthopedic literature to investigate whether sufficient evidence exists to support its use. A literature search was performed using MEDLINE, Google Scholar, and OvidSP-Wolters Kluwer Health for all articles regarding SIJ fusion published from 2000 to 2014. Original, peer-reviewed, prospective or retrospective scientific papers with at least 2 patients were included in the study. Exclusion criteria included follow-up shorter than 1-year, non-surgical treatment, inadequate clinical data as determined by 2 independent reviewers, non-English manuscripts, and nonhuman subjects. A total of 16 peer-reviewed journal articles met the inclusion criteria: 5 consecutive case series, 8 retrospective studies, and 3 prospective cohort studies. A total of 430 patients were included, of whom 131 underwent open surgery and 299 underwent minimally invasive surgery (MIS) for SIJ fusion. The mean duration of follow-up was 60 months for open surgery and 21 months for MIS. SIJ degeneration/arthrosis was the most common pathology among patients undergoing surgical intervention (present in 257 patients [59.8%]), followed by SIJ dysfunction (79 [18.4%]), postpartum instability (31 [7.2%]), post-traumatic (28 [6.5%]), idiopathic (25 [5.8%]), pathological fractures (6 [1.4%]), and HLA-B27+/rheumatoid arthritis (4 [0.9%]). Radiographically confirmed fusion rates were 20% to 90% for open surgery and 13% to 100% for MIS. Rates of excellent satisfaction, determined by pain reduction, function, and quality of life, ranged from 18% to 100% with a mean of 54% in open surgical cases. For MIS patients, excellent outcome, judged by patients' stated satisfaction with the surgery, ranged from 56% to 100% (mean of 84%). The re-operation rate after open surgery ranged from 0% to 65% (mean of 15%). Re-operation rate after MIS ranged from 0% to 17% (mean of 6%). Major complication rates ranged from 5% to 20%, with 1 study that addressed safety reporting a 56% adverse event rate. The authors concluded that surgical intervention for SIJ pain is benefacicial in a subset of patients. However, with the difficulty in accurate diagnosis and evidence for the efficacy of SIJ fusion itself lacking, serious consideration of the cause of pain and alternative treatments should be given before performing the operation.
U.S. FOOD AND DRUG ADMINISTRATION (FDA)


APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Coverage Determination Guidelines may apply.

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<th>Description</th>
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<td>27279</td>
<td>Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device</td>
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<tr>
<td>27280</td>
<td>Arthrodesis, open, sacroiliac joint, including obtaining bone graft, including instrumentation, when performed</td>
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<tr>
<td>27299</td>
<td>Unlisted procedure, pelvis or hip joint</td>
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REFERENCES


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The foregoing Health Plan of Nevada/Sierra Health & Life Healthcare Operations protocol has been adopted from an existing UnitedHealthcare coverage determination guideline that was researched, developed and approved by the UnitedHealthcare Coverage Determination Committee.