Sacroiliac Joint Interventions

Policy Number: PAIN 025.5
Effective Date: January 1, 2023

Instructions for Use

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Related Policies

- Ablative Treatment for Spinal Pain
- Epidural Steroid Injections for Spinal Pain
- Facet Joint and Medial Branch Block Injections for Spinal Pain

Coverage Rationale

Note: This policy addresses intraarticular Sacroiliac Joint injections and fusion. This policy does not address radiofrequency ablation of the Sacroiliac Joint. For coverage criteria regarding radiofrequency ablation of the Sacroiliac Joint, refer to the Clinical Policy titled Ablative Treatment for Spinal Pain.

Sacroiliac Joint (SI) injections are proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® Client Defined, CP: Procedures, Sacroiliac (SI) Joint Interventions (Custom) – UHG.

Click here to view the InterQual® criteria.

Open Sacroiliac Joint fusion is proven and medically necessary for treating the following indications:

- Traumatic injuries (e.g., pelvic ring fracture, acetabular fracture, spinopelvic dissociation)
- Sacral tumors when used as an adjunct to sacrectomy or partial sacrectomy
- Sacroiliac Joint infection when used as an adjunct to the medical treatment
- As part of multisegment spinal constructs extending to the ilium
- Painful degenerative joint disease when the same criteria for Minimally Invasive Sacroiliac Joint Fusion are met

For medical necessity clinical coverage criteria, refer to the InterQual® Client Defined, CP: Procedures, Sacroiliac (SI) Joint Interventions (Custom) – UHG.

Click here to view the InterQual® criteria.

Minimally invasive joint fusion using a Titanium Triangular Implant for treating painful degenerative joint disease is proven and medically necessary when criteria are met. For medical necessity clinical coverage criteria, refer to the InterQual® Client Defined, CP: Procedures, Sacroiliac (SI) Joint Interventions (Custom) – UHG.

Click here to view the InterQual® criteria.

Open Sacroiliac Joint fusion is unproven and not medically necessary for all other indications not listed above due to insufficient evidence of efficacy.

Minimally invasive Sacroiliac Joint fusion is unproven and not medically necessary for all other conditions not listed above due to insufficient evidence of efficacy.

Documentation Requirements

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 documentation requirements outlined below are used to assess whether the member meets the clinical criteria for coverage but do not guarantee coverage of the service requested.

CPT Codes*	Required Clinical Information
Sacroiliac Joint Interventions	

27279
27280
64451
G0260
	For Sacroiliac Joint Fusion provide medical notes documenting the following, when applicable:
	• Condition requiring procedure
	• History and co-morbid medical condition(s), including presence or absence of somatoform disorder or generalized pain disorders
	• Member's symptoms including pain, location, and severity
	• Physical exam, including:
	  ○ Specific location of tenderness
	  ○ Results of at least three of these five tests:
	  ▪ Compression test
	  ▪ Distraction test
	  ▪ FABER test (also referred to as Patrick's test)
	  ▪ Gaenslen's test
	  ▪ Thigh thrust test (also referred to as posterior pelvic pain provocation)
	• Reports of all recent imaging studies and applicable diagnostics
	• Treatments tried, failed, or contraindicated; include the dates and reason for discontinuation
	• Results of the fluoroscopically guided diagnostic intra-articular SIJ block using local anesthetic

*For code descriptions, refer to the Applicable Codes section.

Definitions

Titanium Triangular Implant: A Sacroiliac Joint (SIJ) implant intended for Sacroiliac Joint fusion for conditions including Sacroiliac Joint disruptions and degenerative sacroiliitis. (https://si-bone.com/si-joint-pain-treatment/ifuse-implant-system)

Sacroiliac Joint: The joint or articulation between the sacrum and ilium. (Merriam-Webster)

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 Guidelines may apply.

CPT Code	Description
0775T	Arthrodesis, sacroiliac joint, percutaneous, with image guidance, includes placement of intra-articular implant(s) (eg, bone allograft[s], synthetic device[s])
27096	Injection procedure for sacroiliac joint, anesthetic/steroid, with image guidance (fluoroscopy or CT) including arthrography when performed

CPT 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, sacroiliac joint, open, includes obtaining bone graft, including instrumentation, when performed
64451	Injection(s), anesthetic agent(s) and/or steroid; nerves innervating the sacroiliac joint, with image guidance (i.e., fluoroscopy or computed tomography)

HCPCS Code	Description
G0260	Injection procedure for sacroiliac joint; provision of anesthetic, steroid and/or other therapeutic agent, with or without arthrography

Description of Services

Sacroiliac (SI) Joint Fusion is a surgical procedure, which fuses the iliac bone (pelvis) to the spine (sacrum) for stabilization. It is performed for a variety of conditions including trauma, infection, cancer, and spinal instability. 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. Fusion of the Sacroiliac Joint, combined with bone grafts and other metal implant devices, is an extensive procedure; it is generally considered a salvage procedure when all other measures have failed to provide relief of pain. Diagnosis of SIJ dysfunction is based on a combination of tests or provocative maneuvers during physical examination to help localize the pain to the SIJ. Imaging studies do not generally help to localize pain but can be used to exclude other diagnoses that may mimic SIJ pain (e.g., hip osteoarthritis, spine degeneration at the L5/S1 level, spinal stenosis). The physical examination may include Provocative tests (e.g., Gaenslen's maneuver, Patrick's test, thigh thrust, and compression and distraction tests) to stress the SIJ and reproduce the patient's pain. (Hayes, 2020, Foley and Buschbacher, 2006; Hooten and Cohen, 2015, Lorio, 2016)

Clinical Evidence

Sacroiliac Joint (SI) Injections

Cohen et al. (2022) evaluated patients in a multicenter study which looked at factors associated with treatment outcomes for low back pain injections. 346 participants were enrolled; 112 underwent lumbar facet blocks, 67 received SIJ injections and 167 underwent lumbar ESI. The participants were over 18 years of age, had more than six weeks of pain in the lumbosacral area or SI joint and had an average leg or low back pain score of greater than 4 out of 10 over a week. SI joint injections included 3 mL solution containing 1 mL of 40 mg/mL of depomethylprednisolone and 2 mL of 0.5% bupivacaine. It was considered a positive outcome if the patient received ≥ 50% pain reduction that lasted at least 3 hours; this was based on patient documentation from a pain diary with activity log. Follow-up occurred at one month and if the patient had a positive outcome from the procedure, they did not need to return until 3 months later. Participants with negative outcomes were allowed to exit from study and pursue other options. The authors found there was a significant decrease in pain overall and no significant differences amongst the groups. With the 139 successful patients, the mean reductions in the numerical rating scale (NRS) scores for facet interventions, SIJ injections and ESI were 4.0 ±1.5, 3.6 ±2.0, 3.6 ±1.9, respectively. Limitations included the combination of three different low back pain treatments which addressed different etiologies, the variability in radiologic and physical exam findings and less stringent inclusion criteria due to practice setting versus clinical trial setting.

Young et al. (2022) studied a cohort of 373 adults patients with a diagnosis of SIJ pain. In this retrospective study 354 patients received an intraarticular steroid (IAS) injection and 19 patients received lateral branch radiofrequency neurotomy (LBRFN). The main outcome was the self-report pain score, which was measured by the numeric rating scale (NRS). The secondary outcome was the functional score which was measured by the Eastern Cooperative Oncology Group (ECOG) performance scale. The mean score for the IAS injection was reduced from 6.77 to 2.72; the LBRFN mean score was reduced from 5.96 to 3.54 post procedure. The ECOG functional scores trended towards improvement for the cohort, however they were not statistically significant. The participants that received the IAS injections obtained 38 days of pain relief which was shorter in

duration when compared to those that received the LBRFN which experienced 82 days of pain relief. The authors concluded that SIJ pain can be effective for patients with either injections or LBRFN, however SIJ injections may give a shorter tenure of pain relief. Limitations included the disproportion of participants that received SIJ injections versus LBRFN, missing data, and sampling bias.

Chen et al. (2021) compared injections of intraarticular SI joint platelet rich plasma to that of intraarticular steroids on patients with SI joint pain. The 26 participants were randomized to either the group that underwent a fluoroscopically-guided intra-articular injection of steroid or a platelet rich plasma injection. Primary outcome was level of pain as scored by the 0- to 100-mm Numeric Pain Rating Scale and functional disability score using the Oswestry Disability Index (ODI). Patients were evaluated at 1-month, 3-months, and 6-months. The authors found while both groups had improvements with pain, the steroid group had a greater response.

Open Sacroiliac Joint Fusion

Surgical management of primary sacral tumors is challenging because of their size and location. Reconstruction is often required in individuals who require a radical resection with total sacrectomy for tumors such as chordoma, chondrosarcoma, Ewing sarcoma, and giant cell tumor of the sacrum. Sacroiliac joint fusion has been performed as an adjunct to en bloc sacrectomy or partial sacrectomy in the setting of sacral tumors. The evidence in the peer-reviewed literature to support the use of lumbar pedicle screws in combination with other surgical techniques involving the ilia in spinal pelvic reconstruction surgery (for example, Galveston rods, transiliac bar placement) consists of articles that review surgical techniques (Zhang, 2003) and small case series. (Gallia, 2005; Newman, 2009; Salehi, 2002)

Sacroiliac joint infection is an uncommon condition that generally responds to long-term antibiotics and occasionally requires drainage for abscess. Additional surgical treatment may involve debridement, decompression, and internal screw fixation when symptoms do not resolve with initial intravenous antibiotic therapy. The evidence in the peer-reviewed literature to support the use of sacroiliac joint fusion as an adjunct to the medical treatment of sacroiliac joint infection consists of single and small case series. (Davidson, 2003; Giannoudis, 2007; Sar, 2003)

Minimally Invasive Fusion of the Sacroiliac Joint

Chang et al. (2022) conducted a systematic review on the existing literature to assess the safety and efficacy of minimally invasive SI joint fusion. A search was conducted from 1987 through 2021 using PubMed, Embase, Cochrane and a clinical trial registry. A total of 40 studies were included for evaluation of SI joint pain; five studies (two RCTs and three controlled cohort studies (CCSs) provided evidence about effectiveness, and all 40 studies provided evidence about safety. Two RCTs and one CCS compared minimally invasive SI joint fusion with the iFuse Implant System to that of conservative management; two CCSs compared the effectiveness of alternative minimally invasive fusion procedures. The authors found the minimally invasive SI joint fusion appeared to improve pain, physical function, and QOL when compared to conservative treatment. Two of the CCSs evaluated alternative minimally invasive fusion procedures and one CCS compared the iFuse implant system to that of the Rialto SI Fusion System (a cylindrical threaded implant system). Pain was measured by visual analog scale (VAS) in both groups and the authors found improvements in pain for both groups but no significant difference between the two. However it was noted that the group receiving the Rialto system had an increase in revision rates when compared with those in the iFuse group. Limitations included small sample sizes and heterogeneity when reporting adverse effects, inconsistencies in the reported findings for the two RCTs, and only two studies that compared the iFuse implant system with that of another limiting the generalizability of findings to other devices.

For use of cylindrical threaded implants (CTIs) for SIJ fusion in adult patients, an updated 2021 Hayes health technology report reflects a very-low-quality body of evidence and is insufficient for drawing any conclusions regarding the efficacy and safety of this technology. There continues to be substantial uncertainty for this technology due to a small body of evidence and lack of comparative studies.

A Hayes technology assessment (2020) stated that there is moderate-quality evidence suggesting that minimally invasive sacroiliac joint (SIJ) fusion with the iFuse Implant System is efficacious for adult patients with SIJ dysfunction that is unresponsive to non-surgical management (NSM). iFuse implants are consistently associated with improved pain and disability from baseline without substantial safety concerns. Consistent evidence suggests that the use of the iFuse for the treatment of SIJ dysfunction may lead to clinically significant reductions in pain and disability. Comparative results suggest that SIJ fusion with iFuse is associated with better patient-reported outcomes.

ECRI (2020) conducted a literature search through October of 2020 and did not identify any relevant clinical studies regarding how well the Sacrofuse SIJFuse Sacroiliac Joint Fusion Device System worked when compared to other products; no published studies examined the safety and efficacy of the device for minimally invasive SI joint fusion.

Claus et al. (2020, included Chang et al., 2022 above) conducted a clinical outcome comparison of minimally invasive SI joint fusion between the iFuse (triangular dowel implant (TDI)) Implant system and the Rialto (cylindrical threaded implant (CTI)) system. A total of 156 patients were evaluated; 82 received the iFuse system and 74 patients received the Rialto system. The primary outcomes were postoperative visual analog scale (VAS), Oswestry Disability Index (ODI), and Short Form-12 evaluation at 6 months and 1 year; secondary outcomes included rate of surgery revision and time to revision. Both sets of cohorts experienced significant improvement in patient reported outcomes at six months when compared to their preoperative assessments. However, the authors found a significant difference in the length of the procedure between the two groups. The CTI procedure averaged 60 minutes in length, while the TDI averaged only 41.2 minutes. In addition, it should be noted that there was a 6.1% revision rate for the CTI cohort and only a 2.4% revision rate for the TDI patient group. While the authors found both the iFuse and Rialto SI joint fusion devices appear to suggest a significant improvement in pain, disability, and QoL, further attention should be allocated to the evaluation of the complication rates as they were found to be as high as 52% in the CTI system. Study limitations included the retrospective study design, small number of participants for each group, lack of randomization of participants and lack of long-term outcomes.

ECRI performed a literature review of the iFuse implant system for minimally invasive sacroiliac Joint fusion. The report stated that iFuse reduces SIJ pain and improves disability scores and quality of life (QOL) compared with nonsurgical conservative management (NCM) and screw-type implants. At four-year follow-up, revision surgery rates were 3.6%. The systematic review(SR) included mostly studies that did not directly compare iFuse with screw-based implants; therefore, the comparisons reported in the SR are indirect. Additionally, studies in the SR are at risk of bias because of small size, retrospective design, and lack of control groups and randomization. The RCTs are at risk of bias from use of subjective measures, (e.g., pain, QOL) and lack of blinding. The nonrandomized comparative studies are at risk of bias due to lack of randomization, blinding, and retrospective design. (ECRI, 2016; updated 2019)

In 2019, Whang et al., reported long-term (5-year) results from two prospective clinical trials (INSITE and SIFI; previously described) investigating the use of minimally invasive lateral transiliac SIJF using TTI (iFuse implant System, SI-BONE, Inc.) as a treatment for sacroiliac joint dysfunction. As previously described, a total of 103 participants were enrolled in the LOIS study with clinic visits at 3, 4, and 5 years and comparison of CT scans performed at 5 years to prior CT scans at 1 or 2 years. At the 5-year follow-up, the mean reported SIJ pain score had significantly reduced by 54.1 points, from 81.5 points at baseline to 27.1 points. A total of 77 (82.8%) study participants reported improvements of at least 20 points in SIJ pain scores. The study's primary outcome (VAS improvement of at least 20 points in the absence of severe device-related adverse event, neurologic adverse event, and revision surgery) was achieved in 76 participants at 5 years (81.7%, 95% CI, 72.4-89.0%). ODI was reduced from 56.3 points preoperatively to 29.9 points; a statistically significant improvement of 26.2 (21.6) points. Furthermore, an independent radiographic analysis exhibited a high rate of successful bone apposition to implants on both the sacral and iliac sides of the SI joint, a high rate of bony bridging, and a low rate of radiolucency's (98%, 87%, and 5%, respectively). Authors concluded that the 5-year data from the LOIS study establish the long-term safety and effectiveness of minimally invasive SIJF with TTI for SIJ dysfunction, demonstrated by improvement in pain, disability and QOL in conjunction with a low risk of complications and high rate of long-term durability.

Tran et al. (2019) published a systematic review comparing the effectiveness of minimally invasive joint fusion (i.e., utilizing the iFuse device) compared to screw-type surgeries. A total of twenty studies was pooled to calculate a standardized mean difference (SMD) 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 compared to patients receiving iFuse.

Darr et al. (2018b; LOIS [Long Term Outcomes from INSITE and SIFI]; NCT02270203) reported 3-year clinical and functional outcomes (including disability and quality of life) following minimally invasive sacroiliac joint fusion with the IFuse Implant System in 103 subjects from the INSITE and SIFI clinical trials. Subjects were evaluated in 12 study clinics at study start and at 3, 4, and 5 years. The primary efficacy endpoint was a composite of 3, 4, and 5 years defined as a reduction from preoperative VAS sacroiliac joint pain score of at least 20 points, absence of device-related serious adverse events, absence of neurological worsening, and absence of surgical revision. Other outcomes included improvements in VAS sacroiliac pain score, ODI, EQ-5D

score, proportion of non-working subjects who returned to work, and occurrence of serious adverse events. The mean (standard deviation) preoperative sacroiliac joint pain score was 81.5 and mean preoperative ODI was 56.3. At 3 years, the mean pain sacroiliac joint pain score decreased to 26.2 (a 55-point improvement from baseline; $p < 0.0001$) and the mean ODI was 28.2 (a 28-point improvement from baseline. A total of 82% of subjects were very satisfied with the procedure at 3 years. The proportion of subjects who would have the procedure again was lower at 3 years compared to earlier time points. Limitations of this study include lack of data from a control group that received only non-surgical treatment. Most INSITE study subjects in the non-surgical group who experienced inadequate pain relief crossed over to surgical care at month 6. The authors acknowledged that subjects at participating sites had slightly larger 24-month improvements in sacroiliac joint pain and ODI compared to those at non-participating sites as the calculated impact on 3-year pain scores was small, that is, approximately 4 points for VAS sacroiliac joint pain and 2.4 points for ODI.

Darr and colleagues (2018a; LOIS trial; NCT02270203) reported 4-year prospective follow-up in participants undergoing minimally invasive SIJF using triangular titanium implants (TTI) (iFuse Implant System, SI-BONE) for sacroiliac joint dysfunction. At 4 years follow-up clinical outcomes were similar to 3-year findings, the mean (standard deviation) preoperative sacroiliac joint pain score in 88.3% (n = 91) of participants had decreased by 54 points from baseline, disability ODI scores decreased by 26 points; and QOL rates improved by 0.3 points (0-1 scale). The LOIS study limitations were previously outlined above by Darr and colleagues (2018b).

Rappoport et al. (2017) reported on an industry-sponsored prospective study of SIJ fusion with a cylindrical threaded implant (SI-LOK).35 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 3 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. Follow-up will continue through 2 years. 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.

Two retrospective nonrandomized comparative studies were published in 2017. Vanaclocha et al. found greater pain relief with SIJ fusion than with conservative management or SIJ denervation. Spain and Holt reported a retrospective review of surgical revision rates following SIJ fixation with either surgical screws or the iFuse triangular implant.13 Revision rates were lower with the iFuse device than observed with surgical screws.

Duhon, et al. (2016) reported on a prospective uncontrolled industry sponsored study of subjects with SI joint dysfunction who underwent minimally invasive SI joint fusion with triangular titanium implants. One hundred ninety-four patients were enrolled between August 2012 and December 2013 at 26 sites. Of these, 10 withdrew prior to SI joint fusion and data from 12 subjects at a single site were eliminated due to the site's persistent non-compliance with the study protocol, leaving 172 subjects enrolled and treated. Two additional sites were terminated more than 1 year into the study for protocol non-compliance, resulting in 3 additional subjects not having 24-month study follow-up. Subjects underwent structured assessments preoperatively and at 1, 3, 6, 12, 18 and 24 months postoperatively, including SIJ pain ratings (0-100 visual analog scale), Oswestry Disability Index (ODI), Short Form-36 (SF-36), EuroQOL-5D (EQ-5D), and patient satisfaction. Adverse events were collected throughout follow-up. All participating patients underwent a high-resolution pelvic CT scan at 1 year. The primary study endpoint, evaluated at six months after the most recent SI joint fusion, was a binary success/failure composite endpoint. A subject was considered a success if all of the following were met: reduction from baseline VAS SI joint pain by at least 20 points, absence of device-related serious adverse events, absence of neurological worsening related to the sacral spine, and absence of surgical re-intervention (removal, revision, reoperation, or supplemental fixation) for SI joint pain. Of the 172 participants, 167 (97.1%) had 6-month follow-up, 157 (91.3%) had 12-month follow-up and 149 (86.6%) had 24-month follow-up. At month 6, 138 of 172 subjects met the study's success endpoint definition, for an intent-to-treat success rate of 80.2% (95% posterior credible interval 73.8-85.7%). Using available data only, the 12-month success rate was 127/159 (79.9%) and the 24-month success rate was 119/149 (79.9%). SIJ pain decreased from 79.8 at baseline to 30.4 at 12 months and 26.0 at 24 months. ODI decreased from 55.2 at baseline to 31.5 at 12 months and 30.9 at 24 months. The proportion of subjects taking opioids for SIJ or low back pain decreased from 76.2% at baseline to 55.0% at 24 months). The authors concluded that

minimally invasive SI joint fusion resulted in improvement of pain, disability, and quality of life in patients with SI joint dysfunction due to degenerative sacroiliitis and SI joint disruption.

Polly et al. (2016) reported 2-year outcomes from the randomized controlled trial (Polly, 2015; INSITE) of individuals treated with minimally invasive sacroiliac joint fusion for chronic sacroiliac joint dysfunction. Of the 102 participants originally treated with sacroiliac joint fusion, 89 (87%) were evaluated at 2 years. Although the clinical trial used a different composite endpoint, clinical outcomes in this report were based on the amount of improvement in sacroiliac joint pain and ODI scores. Improvement was defined as a change of 20 points in sacroiliac joint pain score and 15 points in ODI score. Substantial improvement was defined as a change of 25 points in sacroiliac 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% of participants had improvement and substantial improvement in sacroiliac joint pain score, and 68.2% and 65.9% had improvement and substantial improvement in ODI. In addition, the proportion of participants taking opioids was reduced from 68.6% at baseline to 48.3% (29.6% reduction; p = 0.0108 for change). A total of 22 (23%) adverse events related to device or procedure occurred in the sacroiliac joint fusion group (n = 102), including ipsilateral or contralateral sacroiliac joint pain and trochanteric bursitis (n = 9), surgical wound problems (n = 5), postoperative medical problems (n = 4, including nausea/vomiting, urinary retention, and atrial fibrillation), iliac fracture (n = 1), asymptomatic physical exam or radiographic findings (n = 2), and neuropathic symptoms (n = 1). Three participants assigned to sacroiliac joint fusion and 1 participant who underwent sacroiliac joint fusion as a crossover treatment underwent revision surgery within the 24-month follow-up period. Limitations of this study include lack of a sham comparator group and the high crossover rate to sacroiliac joint fusion at 6 months.

In 2016, Sturesson et al., reported another industry-sponsored nonblinded 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. ODI scores improved by 5.8 points in the control group and by 25.5 points in the iFuse group. 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. Patients were assigned 2:1 to minimally invasive SI joint fusion or to nonsurgical management. Nonsurgical management included a stepwise progression of nonsurgical treatments, depending on individual patient choice. The primary outcome measure was 6-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. 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. 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.

Whang et al. (2015) completed a comparison of surgical and non-surgical treatments for sacroiliac joint fusion in individuals who had failed nonoperative care for chronic sacroiliac joint dysfunction. The investigators conducted an industry-sponsored non-blinded randomized controlled trial (INSITE, Investigation of Sacroiliac Fusion Treatment; NCT01681004) of the iFuse Implant System in 148 subjects with sacroiliac joint dysfunction due to degenerative sacroiliitis or sacroiliac joint disruptions. Participants were included based on identification of the sacroiliac joint as the pain generator from a combination of a history of sacroiliac joint-localized pain, positive provocative testing on at least 3 of 5 established physical tests, and at least a 50% decrease in sacroiliac joint pain after image-guided local anesthetic injection into the joint. Participants were assigned in a 2:1 ratio to minimally invasive sacroiliac joint fusion or to nonsurgical management (NSM). Participants randomized to NSM received treatment in a stepwise progression (depending on the participant's needs) of pain medications, physical therapy (98%), intra-articular steroid injections (73.9%), and RFA of sacral nerve roots (45.7%). The primary outcome measure was comparison of 6-month success rates using Bayesian methods and defined as the proportion of treated subjects with a 20-mm

improvement in sacroiliac joint pain in the absence of severe device-related or neurologic adverse events or surgical revision. While the investigators suggest these results are positive, there is a high potential for bias in a nonblinded study with subjective outcome measures.

Clinical Practice Guidelines

American Society of Interventional Pain Physicians

In a comprehensive evidence-based guideline on interventional techniques for chronic spinal pain, the evidence for intraarticular injections and periarticular injections is limited for SI joint interventions. (Manchikanti et al., 2013)

North American Spine Society (NASS)

In the Evidence-Based Clinical Guidelines for Multidisciplinary Spine Care, NASS (2020) lists the following recommendation for the diagnosis and treatment of low back pain:

- Intra-articular steroid joint injections may be considered in patients with suspected SI joint pain (Grade of Recommendation: C (poor quality evidence (Level IV or V studies) for or against the recommending intervention))

In 2015, NASS published recommendations in a coverage committee document for therapeutic SI joint (SIJ) injections. The document states intraarticular SIJ injections of corticosteroid with or without local anesthetic are indicated for the treatment of low back pain when all of the listed criteria are met:

- Patient's report of nonradicular, typically unilateral pain that is caudal to the lumbar spine (L5 vertebrae), localized over the posterior SIJ, and consistent with SIJ pain.
- A thorough physical examination demonstrating localized tenderness with palpation over the sacral sulcus (Fortin's point, i.e., 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 (e.g., greater trochanter, lumbar spine, coccyx) and that other obvious sources for their pain do not exist.
- 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). Note that the thrust tests is not recommended in pregnant patients or those with connective tissue disorders.
- SIJ pain has been confirmed with diagnostic SIJ injections

NASS,(2015) published the following coverage policy recommendations on Percutaneous Sacroiliac Joint Fusion. The recommendations state "SIJ fusion...is indicated for the treatment of SIJ pain for patients with low back/buttock pain who meet all of the following criteria":

- 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, SIJ and hip including a home exercise program.
- Patient's report of typically unilateral pain that is caudal to the lumbar spine (L5 vertebra), localized over the posterior SIJ, and consistent with SIJ pain.
- A thorough physical examination demonstrating localized tenderness with palpation over the sacral sulcus (Fortin's point, i.e., 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 (e.g., greater trochanter, lumbar spine, coccyx) and that other obvious sources for their pain do not exist.
- Positive response to a cluster of 3 provocative tests (e.g., 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.
- Absence of generalized pain behavior (e.g., somatoform disorder) or generalized pain disorders (e.g., fibromyalgia).
- Diagnostic imaging studies that include all of the following:
    - Imaging (plain radiographs and a CT [computed tomography] or MRI [magnetic resonance imaging]) of the SI joint that excludes the presence of destructive lesions (e.g., tumor, infection) or inflammatory arthropathy that would not be properly addressed by percutaneous SIJ fusion. b. Imaging of the pelvis (AP [anteroposterior] plain radiograph) to rule out concomitant hip pathology.
    - 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.
    - Imaging of the SI joint that indicates evidence of injury and/or degeneration.

- At least 75% reduction of pain for the expected duration of the anesthetic used following an image-guided, contrast-enhanced intra-articular SIJ injection on 2 separate occasions.
- A trial of at least one therapeutic intra-articular SIJ injection (i.e., corticosteroid injection).

International Society for the Advancement of Spine Surgery (ISASS)

ISASS first published a policy statement on minimally invasive SIJ fusion in 2014 and updated it in 2020. ISASS recommends coverage for minimally invasive SIJ fusion when all of the following criteria are met:

- Significant SIJ [sacroiliac joint fusion] pain (e.g., pain rating at least 5 on the 0-10 numeric rating scale where 0 represents no pain and 10 represents worst imaginable pain) or significant limitations in activities of daily living;
- SIJ pain confirmed with at least 3 physical examination maneuvers that stress the SIJ and cause the patient's typical pain;
- Confirmation of the SIJ as a pain generator with ≥ 75% acute decrease in pain upon;
- fluoroscopically guided diagnostic intra-articular SIJ block using local anesthetic;
- Failure to respond to at least 6 months of non-surgical treatment consisting of non-steroidal anti-inflammatory drugs and/or opioids (if not contraindicated) and one or more of the following: rest, physical therapy, SIJ steroid injection. 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 ruled out (e.g., L5/S1 compression, hip osteoarthritis).

Minimally invasive SIJ fusion is not indicated for patients with the following:

- Less than 6 months of back pain;
- Failure to pursue conservative treatment of the SIJ (unless contra-indicated);
- Pain not confirmed with a diagnostic SIJ block;
- Existence of other pathology that could explain the patient's pain.

National Institute for Health and Care Excellence (NICE)

Medical technology guidance from NICE (2018) recommends the use of iFUSE in people with a confirmed diagnosis of chronic SI joint pain and pain that is inadequately controlled by non-surgical management.

NICE guidance was published in April 2017 on minimally invasive SIJ fusion surgery for chronic sacroiliac pain. The recommendations include: 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. Patients having this procedure should have a confirmed diagnosis of unilateral or bilateral SI joint dysfunction due to degenerative sacroiliitis or SI joint disruption. 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.

Department of Veterans Affairs (VA)/Department of Defense (DoD)

The 2022 guideline for the diagnosis and treatment of low back pain makes the following recommendations for patients with nonsurgical invasive therapy:

- For patients with low back pain, there is insufficient evidence to recommend for or against sacroiliac joint injections (Neither for nor against).

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

UHC medical policies are based on clinical evidence and do not represent an endorsement of any specific manufacturer's product.

Products used for Sacroiliac Joint fusion are numerous. Refer to the following website for more information and search by product name in device name section: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.
(Accessed May 9, 2022)

SIJ injection with corticosteroids and/or local anesthetics is a procedure and therefore not subject to FDA regulation. However, any medical devices, drugs, biologics, or tests used as a part of this procedure may be subject to FDA regulation. Refer to the following website for additional information: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed May 9, 2022)

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The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by UnitedHealthcare Medical Technology Assessment Committee. [*2022T0621D*]

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Policy History/Revision Information

Date	Summary of Changes

01/01/2023	**Documentation Requirements**
	• Added list of applicable CPT/HCPCS codes
	Applicable Codes
	• Updated list of applicable CPT codes to reflect annual edits:
	  ○ Added 0775T
	  ○ Revised description for 27280
	Supporting Information
	• Removed *Prior Authorization Requirements* section
	• Archived previous policy version PAIN 025.4 T2

Instructions for Use

This Clinical Policy provides assistance in interpreting UnitedHealthcare Oxford standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare Oxford reserves the right to modify its Policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice.

The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Oxford Clinical Policies 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.