07.01.91 Surgical Treatment of Sacroiliac Joint Pain

Wellmark Blue Cross and Blue Shield is an Independent Licensee of the Blue Cross and Blue Shield Association.

Original Effective Date: January 2010

Review Date: January 2026

Revised: January 2026

DISCLAIMER/INSTRUCTIONS FOR USE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations, or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

This Medical Policy document describes the status of medical technology at the time the document was developed. Since that time, new technology may have emerged, or new medical literature may have been published. This Medical Policy will be reviewed regularly and updated as scientific and medical literature becomes available; therefore, policies are subject to change without notice.

Related Policies:

- 02.01.18 Prolotherapy
- 07.01.58 Radiofrequency Ablation and Alternative Methods for Chronic Facet Joint Mediated Neck, Back and Sacroiliac Joint Pain*
- 07.01.75 Vertebral Augmentation

Summary

Description

Similar to other structures in the spine, it is assumed the sacroiliac joint (SIJ) may be a source of low back pain. Sacroiliac joint fusion/fixation, whether performed as an open or minimally invasive (percutaneous) surgical procedure, with or without bone grafts and other metal implant devices, has been proposed as a treatment for individuals who are unresponsive to or cannot tolerate other therapy for chronic low back pain due to sacroiliac joint (SIJ) syndrome and other pain-related sacroiliac conditions.

Summary of Evidence

For individuals who have SIJ pain who receive SIJ fixation/fusion with a transiliac triangular implant, the evidence includes 1 meta-analysis, 1 blinded sham controlled trial, 2 nonblinded randomized controlled trials (RCTs) of minimally invasive fusion, prospective cohorts with more than 85% follow-up, and case series. Relevant outcomes are symptoms, functional outcomes, quality of life (QOL), medication use, and treatment-related morbidity. The sham-controlled RCT found no significant difference in the primary outcome of pain reduction or in any secondary outcomes through 6 months of follow-up. Both nonblinded RCTs have reported outcomes past 6 months, after which crossover was allowed. Both studies reported significantly greater reductions in visual analog scale (VAS) pain scores and Oswestry Disability Index (ODI) scores in SIJ fusion patients than in control groups. The reductions in pain and disability observed in the SIJ fusion group at 6 months were maintained out to 1 year compared with controls who had not crossed over. The RCTs were nonblinded without a placebo or an active control group. Prospective cohorts and case series with sample sizes ranging from 45 to 149 patients and low dropout rates (<15%) also showed reductions in pain and disability out to 5 years. The cohort studies and case series are consistent with the durability of treatment benefit. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome. The meta-analysis pooled data from 3 RCTs and found that SIJ fusion with triangular titanium implants resulted in statistically significant improvements in pain, disability, QOL, and opioid use compared to nonsurgical management for SIJ dysfunction, with similar adverse event rates between groups, though long-term data beyond 12 months was limited to a single trial.

For individuals who have SIJ pain who receive SIJ fusion/fixation with an implant other than a transiliac triangular implant, the evidence includes 7 prospective cohort studies and retrospective case series. Relevant outcomes are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. Three prospective cohort studies were conducted with transiliac screws, 1 with a lateral approach, and the 3 with a device inserted through a posterior approach. One cohort study compared SIJ fusion with the Torpedo device to iFuse (transiliac triangular implant) and found no differences in pain or function outcomes at 12 months between the two groups. No other controlled studies were identified. Meta-analyses of the available prospective and retrospective studies indicate improvement in subjective outcomes from before surgery to follow-up, but with a possible difference in outcomes between the more well studied triangular transiliac implant and other implant designs and approaches. There is uncertainty in the health benefit of SIJ fusion/fixation with these implant designs. Therefore, controlled studies with a larger number of patients and longer follow-up are needed to evaluate these devices. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have SIJ pain associated with the following conditions: trauma (pelvic ring disruption fracture or dislocation), infection (osteomyelitis, pyogenic sacroiliitis, sepsis), cancer (sacral tumors), and corrections in spinal deformity during scoliosis or kyphosis surgery requiring multi-segment spinal constructs extending to the ilium who receive open sacroiliac joint fusion (SIJF) surgery the evidence includes retrospective single small case series and articles that review surgical techniques regarding open SIJF for these indications. Relevant outcomes are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. There is paucity of data in the peer-reviewed medical literature due to poor quality of evidence and lack of rigorous comparative studies. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome, however, based on society guidelines it is generally accepted that open SIJF surgery may be performed for structural support for these indications, see Practice Guideline and Position Statements. Therefore, open SIJF surgery will be considered medically necessary when the criteria is met, see Policy.

For individuals with chronic SIJ pain related to the following conditions: sacroiliac joint dysfunction, sacroiliac joint inflammation, sacroiliac joint strain, and sacroiliac joint syndrome, who receive open SIJF the evidence includes observational studies with majority of studies with retrospective data collection. Relevant outcomes are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. In Hayes Inc. Health Technology Assessment (July 2019) regarding open SIJF for unspecified SIJ dysfunction, this assessment included observational study designs with retrospective data collection in the majority of the studies. Six clinical studies in 7 publications (n=17-263 patients) evaluated open SIJ fusion for unspecified SIJ dysfunction with failed conservative management. These studies lacked active comparators and were of small sample size. Follow-up was limited to $\leq$ 24 months in the majority of studies. Additional limitations included potential for selection bias, high attrition and inconsistent and limited reporting of statistical analyses. Uncertainty exists due to the paucity of rigorous comparative evidence, poor-quality studies and inconsistent outcomes in this patient population. Additional studies are warranted to determine the safety and effectiveness of open SIJ fusion surgery for SIJ dysfunction compared to other surgeries to include non-minimally invasive SIJF surgery with larger sample sizes and longer follow-up to assess late adverse events (AEs). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information

2017 Input

Clinical input was sought to help determine whether the use of SIJ fusion for individuals with SIJ pain would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, clinical input was received from 10 respondents, including 5 specialty society-level responses from 7 specialty societies (2 were joint society responses) and 5 physician-level responses from 4 academic centers while this policy was under review in 2017.

For carefully selected patients as outlined in statements from the North American Spine Society who have SIJ pain who receive percutaneous and minimally invasive techniques of SIJ fusion, the clinical input supports that this use provides a clinically meaningful improvement in the net health outcome and is consistent with generally accepted medical practice.

Further details from clinical input are included in the Appendix.

OBJECTIVE

The objective of this evidence review is to evaluate the therapeutic use of minimally invasive method sacroiliac joint fixation/fusion and open sacroiliac joint fusion surgery for the treatment of sacroiliac joint pain.

PRIOR APPROVAL

Not applicable.

POLICY

Minimally Invasive

Minimally invasive fixation/fusion of the sacroiliac joint (SIJ) using transiliac placement of a titanium triangular implant (i.e., iFuse, see Policy Guidelines) may be considered **medically necessary** when **ALL** of the following criteria have been met:

- Pain is at least 5 on a 0 to 10 rating scale that impacts quality of life or limits activities of daily living;
- There is an absence of generalized pain behavior (e.g., somatoform disorder) or generalized pain disorders (e.g., fibromyalgia);
- Individuals have undergone and failed a minimum 6 months of intensive nonoperative treatment that must include medication optimization, activity modification, bracing, and active therapeutic exercise targeted at the lumbar spine, pelvis, SIJ, and hip, including a home exercise program;
- Pain is caudal to the lumbar spine (L5 vertebra), localized over the posterior SIJ, and consistent with SIJ pain;
- A thorough physical examination demonstrates localized tenderness with palpation over the sacral sulcus (Fortin's point) in the absence of tenderness of similar severity elsewhere;
- There is a positive response to a cluster of 3 provocative tests (e.g., thigh thrust test, compression test, Gaenslen sign, distraction test, Patrick test, posterior provocation test);
- Diagnostic imaging studies include **ALL** of the following:
    - Imaging (plain radiographs and computed tomography or magnetic resonance imaging) of the SIJ excludes the presence of destructive lesions (e.g., tumor, infection) or inflammatory arthropathy of the SIJ;
    - Imaging of the pelvis (anteroposterior plain radiograph) rules out concomitant hip pathology;
    - Imaging of the lumbar spine (computed tomography or magnetic resonance imaging) is performed to rule out neural compression or other degenerative conditions that can be causing low back or buttock pain;
    - Imaging of the SIJ indicates evidence of injury and/or degeneration;
- There is at least a 75% reduction in 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 a therapeutic SIJ injection (i.e., corticosteroid injection) has been performed at least once.

Minimally invasive fixation/fusion of the sacroiliac joint not meeting the above criteria is considered **investigational** to include any other devices not listed**.**

Open Sacroiliac Joint Fusion Surgery

Open Sacroiliac joint (SIJ) fusion is considered **medically necessary** for any of the following indications:

- As an adjunct to sacrectomy or partial sacrectomy related to tumors involving the sacrum;
- As an adjunct to the medical treatment of sacroiliac joint infection/sepsis;
- Severe traumatic injuries associated with pelvic ring disruption (fracture or dislocation);
- During multisegmented spinal constructs (for example, correction of deformity in scoliosis or kyphosis surgery) extending to the ilium.

Open sacroiliac joint fusion (SIJ) is considered **investigational** when the above criteria is not met and including, but not limited to the following because the evidence is insufficient to determine the effects of this technology on net health outcomes:

- Mechanical low back pain
- Sacroiliac joint syndrome
- Degenerative sacroiliac joint
- Radicular pain syndromes

POLICY GUIDELINES

Sacroiliac Fusion Devices

Note: *iFuse is the only FDA approved triangular hardware for minimally invasive fusion.*

Device	Manufacturer	Features	Graft Compatible
Lateral Transiliac Approach			
iFuse®	SI Bone, Inc	Titanium triangular rod with conventional manufacturing	Y
iFuse® 3D	SI Bone, Inc	Titanium triangular 3D printed porous rod	Y
iFuse TORQ® Implant System	SI Bone, Inc	3D printed cannulated screw	Y
iFuse TORQ TNT™ Implant System	SI-Bone Inc	3D printed cannulated screw	Y
iFuse Bedrock Granite® Implant System	SI Bone, Inc	3D printed screw with porous graft windows	Y
FIREBIRD SI Fusion System™	Orthofix	Cannulated screw	Y
SambaScrew®	Orthofix	Cannulated screw	Y
Silex Sacroiliac Joint Fusion®	X-Spine Systems	Cannulated screw	Y
SI-LOK® Sacroiliac Joint Fixation System	Globus Medical	Cannulated screw	Y
SImmetry® Sacroiliac Joint Fusion System	RTI	Cannulated screw	Y
SImmetry®+ System	SiVantage	Cannulated screw	Y
SIimpact® Sacroiliac Joint Fixation System	Life Spine	Cannulated screw	Y
SIros™	Genesys Spine	Cannulated screw	Y

Device	Manufacturer	Features	Graft Compatible
Triton SI Joint Fixation System™	Choice Spine	3D printed screw with porous graft windows	Y
UNITY Sacroiliac Joint Fixation System	Dio Medical Corp.	Cannulated screw	Y
T-FIX® 3DSI Joint Fusion System	Cutting Edge Spine, LLC	3D printed cannulated screw	Y
PathLoc SI Joint Fusion System	L & K Biomed Co., Ltd.	Metalic fastener	Y
SI-Cure Sacroiliac Joint Fusion System	Alevio, LLC	Metalic fastener	Y
Integrity-SI® Fusion System	OsteoCentric Technologies	Cannulated screw	Y
Sacrix® Sacroiliac Joint Fusion Device System	LESspine Innovations	Cannulated screw	Y
TORPEDO Implant System®	Deltacor GmbH	Cannulated screw	Y
Liberty SI Lateral Implant System	Spinal Simplicity LLC	Cannulated screw	Y
Eminent Spine SI Screw System	Eminent Spine, LLC	Cannulated screw	Y
ARx® SAI Implant System	Life Spine Inc.	Cannulated screw	Y
DYNAMIS™ SI Screw System	Promethean Restorative LLC	Cannulated screw	Y
NEXXT MATRIXX® SI System	Nexxt Spine, LLC	Cannulated screw	Y
Posterolateral Approach			
Rialto™ SI Joint Fusion System	Medtronic	Cannulated screw	Y
SacroFuse®/ SIJFuse™	SpineFrontier	Solid or hollow-cored screw	Y
SILO TFX MIS Sacroiliac Joint Fixation System	Aurora Spine, Inc	Solid or hollow-cored screw	Y
Camber Sacroiliac (SI) Fixation System	Camber Spine Technologies	Cannulated screw	Y
BowTie™ SI Joint Fusion System	SAIL Fusion, LLC	Solid or hollow-cored screw	Y
Omnia Medical PsiF DNA™ System	Omnia Medical, LLC	Cannulated screw	Y

Device	Manufacturer	Features	Graft Compatible
panaSIa SI Fusion System	Wenzel Spine, Inc	Cannulated screw	Y
Posterior Approach			
Catamaran™	Tenon Medical	Metal plug	Y
CornerLoc™	Fusion Foundation Solutions	Bone allograft	N
LinQ™ SI Joint Stabilization	PainTEQ	Bone allograft	N
NADIA™ SI Fusion System (DIANA)	Ilion Medical	Metal plug	N
PsiF™ Posterior Sacroiliac Fusion	Omnia Medical	Bone allograft	N
SIFix System®	NuTech	Bone allograft	N
TransFasten™	Captiva Spine	Bone allograft	N
CATAMARAN SI Joint Fusion System	Tenon Medical, Inc.	Metal plug	Y
TiLink-P SI Joint Fusion System	Surgentec, LLC	Metal plug	Y
Invictus® Spinal Fixation System	Alphatec Spine, Inc.	Cannulated screw	Y
VyLink™ Spinal Screw System	Vy Spine, LLC	Cannulated screw	Y
Patriot-SI Posterior Implant System	Spinal Simplicity LLC	Cannulated screw	Y
Huvex Interspinous Fixation System	K&J Consulting Corporation	Cannulated screw	Y
SI-DESIS® X™ Sacroiliac Joint Fusion System	SI-Technology, LLC	Cannulated screw	Y

HCT/P: Human Cell and Tissue Product; N/A: not applicable; N: no; Y: yes.

This technically demanding procedure should only be done by surgeons who have specific training and expertise in minimally invasive SIJ fusion surgery for chronic SIJ pain and who regularly use image-guidance for implant placement.

Conservative nonsurgical therapy for the duration specified should include the following:

- Use of prescription-strength analgesics for several weeks at a dose sufficient to induce a therapeutic response:
    - Analgesics should include anti-inflammatory medications with or without adjunctive medications such as nerve membrane stabilizers or muscle relaxants, and

- Participation in at least 6 weeks of physical therapy (including active exercise) or documentation of why the individual could not tolerate physical therapy, and
- Evaluation and appropriate management of associated cognitive, behavioral, or addiction issues, and
- Documentation of individual compliance with the preceding criteria.

Coding

See the Codes table for details.

BACKGROUND

Sacroiliac Joint Pain

Similar to other structures in the spine, it is assumed the sacroiliac joint (SIJ) may be a source of low back pain. In fact, before 1928, the SIJ was thought to be the most common cause of sciatica. In 1928, the role of the intervertebral disc was elucidated, and from that point forward, the SIJ received less research attention.

Diagnosis

Research into SIJ pain has been plagued by a lack of a criterion standard to measure its prevalence and against which various clinical examinations can be validated. For example, SIJ pain typically presents without any consistent, demonstrable radiographic or laboratory features and most commonly exists in the setting of morphologically normal joints. Clinical tests for SIJ pain may include various movement tests, palpation to detect tenderness, and pain descriptions by the individual. Further confounding the study of the SIJ is that multiple structures, (e.g., posterior facet joints, lumbar discs) may refer pain to the area surrounding the SIJ.

Because of inconsistent information obtained from history and physical examination, some have proposed the use of image-guided anesthetic injection into the SIJ for the diagnosis of SIJ pain. Treatments being investigated for SIJ pain include prolotherapy (see evidence review 02.01.18), corticosteroid injection, radiofrequency ablation (see evidence review 07.01.58), stabilization, and arthrodesis. Some procedures have been referred to as SIJ fusion but may be more appropriately called fixation due to little to no bridging bone on radiographs. Devices for SIJ fixation/fusion that promote bone ingrowth to fixate the implants include a triangular implant (iFuse Implant System) and cylindrical threaded devices (e.g., Rialto, SImmetry, Silex, SambaScrew, SI-LOK). Some devices also have a slot in the middle where autologous or allogeneic bone can be inserted. This added bone is intended to promote the fusion of the SIJ.

A 2021 review identified 33 different devices that could be implanted using either a lateral transiliac approach (n=21), posterior allograft approach (n=6), posterolateral approach (n=3), or a combination of the approaches (n=3). The iliosacral and posterolateral approaches use up to 3 implants that pass through the ilium, while the posterior approach involves inserting implants directly into the SIJ. Many of the devices are intended to be used with allograft bone. Implants composed entirely of allograft bone are typically inserted through a posterior approach. The authors found no published evidence for 23 of the 33 devices identified.

Regulatory Status

Examples of types of commercially available SIJ fusion devices are listed in Table 1.

A number of percutaneous or minimally invasive fixation/fusion devices have been cleared for marketing by the FDA through the 510(k) process. FDA product codes: OUR.

Bone allograft products that are regulated as Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) for homologous use may be marketed specifically for use in SIJ fusion.

Table 1. Select Sacroiliac Fusion Devices

Device	Manufacturer	Features	Graft Compatible	Clearance	Date
Lateral Transiliac Approach					
iFuse®	SI Bone, Inc	Titanium triangular rod with conventional manufacturing	Y	K110838	2011
iFuse® 3D	SI Bone, Inc	Titanium triangular 3D printed porous rod	Y	K162733	2017
iFuse TORQ® Implant System	SI Bone, Inc	3D printed cannulated screw	Y	K222605, K241574	2022
iFuse TORQ TNT™ Implant System	SI-Bone Inc	3D printed cannulated screw	Y	K241504	2024
iFuse Bedrock Granite® Implant System	SI Bone, Inc	3D printed screw with porous graft windows	Y	K233508	2023
FIREBIRD SI Fusion System™	Orthofix	Cannulated screw	Y	K200696	2020
SambaScrew®	Orthofix	Cannulated screw	Y	K121148	2012
Silex Sacroiliac Joint Fusion®	X-Spine Systems	Cannulated screw	Y	K140079	2014
SI-LOK® Sacroiliac Joint Fixation System	Globus Medical	Cannulated screw	Y	K112028	2011
SImmetry® Sacroiliac Joint Fusion System	RTI	Cannulated screw	Y	K102907	2010
SImmetry+ System	SiVantage	Cannulated screw	Y	K250647	2025
SIimpact® Sacroiliac Joint Fixation System	Life Spine	Cannulated screw	Y	K180749	2018
SIros™	Genesys Spine	Cannulated screw	Y	K191748	2019
Triton SI Joint Fixation System™	Choice Spine	3D printed screw with porous graft windows	Y	K211449	2021
UNITY Sacroiliac Joint Fixation System	Dio Medical Corp.	Cannulated screw	Y	K222448	2022

Device	Manufacturer	Features	Graft Compatible	Clearance	Date
T-FIX® 3DSI Joint Fusion System	Cutting Edge Spine, LLC	3D printed cannulated screw	Y	K214123	2023
PathLoc SI Joint Fusion System	L & K Biomed Co., Ltd.	Metalic fastener	Y	K231841, K240201	2023
SI-Cure Sacroiliac Joint Fusion System	Alevio, LLC	Metalic fastener	Y	K231951	2023
Integrity-SI® Fusion System	OsteoCentric Technologies	Cannulated screw	Y	K230226	2023
Sacrix® Sacroiliac Joint Fusion Device System	LESspine Innovations	Cannulated screw	Y	K232605	2023
TORPEDO Implant System®	Deltacor GmbH	Cannulated screw	Y	K230817	2024
Liberty SI Lateral Implant System	Spinal Simplicity LLC	Cannulated screw	Y	K231923	2023
Eminent Spine SI Screw System	Eminent Spine, LLC	Cannulated screw	Y	K240505	2025
ARx® SAI Implant System	Life Spine Inc.	Cannulated screw	Y	K241464	2024
DYNAMIS™ SI Screw System	Promethean Restorative LLC	Cannulated screw	Y	K243565	2025
NEXXT MATRIXX® SI System	Nexxt Spine, LLC	Cannulated screw	Y	K243838	2025
Posterolateral Approach					
Rialto™ SI Joint Fusion System	Medtronic	Cannulated screw	Y	K161210; K251395	2016
SacroFuse®/ SIJFuse™	SpineFrontier	Solid or hollow-cored screw	Y	K150017	2015
SILO TFX MIS Sacroiliac Joint Fixation System	Aurora Spine, Inc	Solid or hollow-cored screw	Y	K221047	2022
Camber Sacroiliac (SI) Fixation System	Camber Spine Technologies	Cannulated screw	Y	K233972	2023
BowTie™ SI Joint Fusion System	SAIL Fusion, LLC	Solid or hollow-cored screw	Y	K232149	2024
Omnia Medical PsiF DNA™ System	Omnia Medical, LLC	Cannulated screw	Y	K242431	2025
panaSIa SI Fusion System	Wenzel Spine, Inc	Cannulated screw	Y	K250247	2025
Posterior Approach					
Catamaran™	Tenon Medical	Metal plug	Y	K180818; K250403	2018

Device	Manufacturer	Features	Graft Compatible	Clearance	Date
CornerLoc™	Fusion Foundation Solutions	Bone allograft	N	HCT/P	N/A
LinQ™ SI Joint Stabilization	PainTEQ	Bone allograft	N	HCT/P	N/A
NADIA™ SI Fusion System (DIANA)	Ilion Medical	Metal plug	N	K190580	2020
PsiF™ Posterior Sacroiliac Fusion	Omnia Medical	Bone allograft	N	HCT/P	N/A
SIFix System®	NuTech	Bone allograft	N	HCT/P	N/A
TransFasten™	Captiva Spine	Bone allograft	N	HCT/P	N/A
CATAMARAN SI Joint Fusion System	Tenon Medical, Inc.	Metal plug	Y	K231944	2023
TiLink-P SI Joint Fusion System	Surgentec, LLC	Metal plug	Y	K230857, K240720; K242141; K243835	2023
Invictus® Spinal Fixation System	Alphatec Spine, Inc.	Cannulated screw	Y	K232275	2023
VyLink™ Spinal Screw System	Vy Spine, LLC	Cannulated screw	Y	K231744	2023
Patriot-SI Posterior Implant System	Spinal Simplicity LLC	Cannulated screw	Y	K232259; K250001	2024
Huvex Interspinous Fixation System	K&J Consulting Corporation	Cannulated screw	Y	K232877	2024
SI-DESIS® X™ Sacroiliac Joint Fusion System	SI-Technology, LLC	Cannulated screw	Y	K241813; K251525	2024

HCT/P: Human Cell and Tissue Product; N/A: not applicable; N: no; Y: yes.

RATIONALE

This evidence review was created in January 2010 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through January 2026.

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies

must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Treatment of Sacroiliac Joint Pain: Sacroiliac Joint Fusion/Fixation with a Transiliac Triangular Implant System

Clinical Context and Therapy Purpose

The purpose of SIJ fixation/fusion with a triangular implant is to provide a treatment option that is an alternative to or an improvement on existing therapies in individuals with SIJ pain.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with SIJ pain.

Interventions

The therapy being considered is SIJ fixation/fusion with a triangular implant.

Comparators

The following therapy is currently being used to treat SIJ pain: conservative therapy.

Outcomes

The general outcomes of interest are symptoms (e.g., reductions in pain), functional outcomes, QOL, reductions in medication use, and treatment-related morbidity. Follow-up from 1 to 5 years is of interest to monitor outcomes.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and AEs, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews

Ghaddaf et al (2024) published a meta-analysis of 3 randomized controlled trials (n=423) that compared minimally invasive SIJ fusion using triangular titanium implants to nonsurgical management for SIJ dysfunction. At 6 months, the results showed statistically significant improvements with minimally invasive SIJ fusion in pain scores (standardized mean difference [SMD], -1.78 [95% CI, -2.46 to -1.11]; p<.00001; I^2=90%), disability as measured by Oswestry Disability Index (ODI) score (SMD, -1.22 [95% CI, -1.47 to -0.96]; p<.00001; I^2=43%), quality of life measures including 36-Item Short Form Health Survey (SF-36) Physical Component Summary (PCS) (SMD, 1.09 [95% CI, 0.90 to 1.28]; p<.00001; I^2=0%), SF-36 Mental Component Summary (MCS) (SMD, 0.66 [95% CI, 0.30 to 1.01]; p=.0003; I^2=66%), and EuroQol 5-Dimension (EQ-5D) (SMD, 1.09 [95% CI, 0.80 to 1.39]; p<.00001; I^2=59%). The durability of the benefit persisted through 24 months; however, this long-term data was derived from only one trial for all outcomes. The study also reported improved patient satisfaction (Odds ratio [OR], 6.87 [95% CI, 3.73 to 12.64]; p<.00001; I^2=1%) and reduced opioid use (OR,.43 [95% CI,.29 to.65]; p<.00001; I^2=0%) with minimally invasive SIJ fusion compared to non-surgical management of SIJ dysfunction. No significant differences in adverse event rates were observed between groups.

Randomized Controlled Trials

Characteristics and results of RCTs are shown in Tables 2 to 4.

Investigation of Sacroiliac Fusion Treatment (INSITE)

Whang et al (2015) reported an industry-sponsored nonblinded RCT, Investigation of Sacroiliac Fusion Treatment (INSITE) of the iFuse Implant System in 148 patients.[23,] The 12-month follow-up to this RCT was reported by Polly et al (2015), and a 2-year follow-up was reported by Polly et al (2016).[25,] However, by 12 months, almost all patients in the control group had crossed over to SIJ fusion, precluding a comparison between groups. Trial inclusion was based on a determination of the SIJ as a pain generator from a combination of a history of SIJ-localized pain, positive provocative testing on at least 3 of 5 established physical tests, and at least a 50% decrease in SIJ pain after image-guided local anesthetic injection into the SIJ. The duration of pain before enrollment averaged 6.4 years (range, 0.47 to 40.7 years). A large proportion of subjects (37%) had previously undergone lumbar fusion, SIJ steroid injections (86%), and RFA (16%).

Patients were randomized 2:1 to minimally invasive SIJ fusion (n=102) or to nonsurgical management (n=46). Nonsurgical management included a stepwise progression of nonsurgical treatments, depending on individual patient choice. During follow-up, control patients received physical therapy (97.8%), intra-articular steroid injections (73.9%), and RFA of sacral nerve roots (45.7%). The primary outcome measure was the 6-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 AEs or surgical revision. Patients in the control arm could crossover to surgery after 6 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 6 months, success rates were 23.9% in the control group versus 81.4% in the surgical group (posterior probability of superiority >0.999). A clinically important (≥15-point) improvement in ODI score was found in 27.3% of controls compared with 75.0% of fusion patients. Measures of QOL (36-Item Short-Form

Health Survey, EuroQol-5D) also improved to a greater extent in the surgery group. Of the 44 nonsurgical management patients still participating at 6 months, 35 (79.5%) crossed over to fusion. Compared with baseline, opioid use at 6 months decreased from 67.6% to 58% in the surgery group and increased from 63% to 70.5% in the control group (p=.082). At 12 months, opioid use was similar between groups (55% vs 52%, p=.61).

Polly et al (2016) reported 2-year outcomes from the SIJ fusion arm of this RCT. Of 102 subjects originally assigned to SIJ fusion and treated, 89 (87%) were evaluated at 2 years. In this report, clinical outcomes were based on the amount of improvement in SIJ pain and in ODI scores. The improvement was defined as a change of 20 points in the SIJ pain score and 15 points in the ODI score. Substantial improvement was defined as a change of 25 points in SIJ pain score-or an SIJ pain score of 35 or less-and an improvement of 18.8 points in the ODI score. At 24 months, 83.1% had improvements in SIJ pain score, and 68.2% had improvements in ODI scores. By 24 months, the proportion taking opioids was reduced from 68.6% at baseline to 48.3%.

Three-year follow-up results of the INSITE and Sacroiliac Joint Fusion with iFuse Implant System (SiFi) trials were published by Darr et al (2018). Of 103 patients with SIJ dysfunction who were treated with minimally invasive SIJ fusion with triangular titanium implants, 60 (72.3%) patients reported an improvement in ODI scores of ≥15 points from baseline to 3 years. The mean ODI score decreased from 56 to 28 for the same time frame, an improvement of 28 points (p<.001); similarly, the mean SIJ pain score decreased to 26.2, reflecting a decrease of 55 points (p<.001). Over 3 years of follow-up, 168 AEs were reported in 75 patients, although only 22 of these events involved the pelvis. The study was limited by its lack of long-term data from a control group not receiving surgical treatment.

IFuse Implant System Minimally Invasive Arthrodesis (iMIA)

In 2016 and 2017, the iFuse Implant System Minimally Invasive Arthrodesis (iMIA) study group reported another industry sponsored multicenter RCT of the iFuse Implant System in 103 patients. Selection criteria were similar to those of the trial by Whang et al (2015), including at least a 50% pain reduction on SIJ block. The mean pain duration was 4.5 years, and about half of the patients were not working due to lower back pain. Additionally, 33% of patients had undergone prior lumbar fusion. 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 the VAS pain score at 6 months.

All patients assigned to iFuse underwent the procedure, and follow-up at 6 months was available for 49 of 51 patients in the control group and for all 52 patients in the iFuse group. Six-month results as reported by Sturesson et al (2016) are shown in Table 12. At 6 months, VAS pain scores improved by 43.3 points in the iFuse group and by 5.7 points in the control group (p<.001). ODI scores improved by 25.5 points in the iFuse group and by 5.8 points in the control group (p<.001, between groups). An improvement in lower back pain by at least 20 VAS points (a minimal clinically important difference) was achieved in 78.8% of the SIJ fusion group versus 22.4% of controls (p<0.001). Quality of life outcomes showed a greater improvement in the iFuse group than in the control group. Changes in pain medication use were not reported. Patients in the conservative management group were allowed to cross over to SIJ fusion at 6 months.

Twelve and 24-month results from the iMIA trial were reported by Dengler et al (2017, 2019). Twenty-one patients in the conservative management group had little or no improvement in symptoms and crossed over to SIJ fusion after the 6-month visit. These were analyzed with the last observation prior to crossover carried forward. At 12 months, low back pain had improved by 42 points (standard deviation [SD], 27.0)

on a 100-point VAS in the SIJ fusion group compared with 14 points (SD=33.4) in the conservative management group (p<.001). At 24 months back pain had improved by 45 points compared to 11 points in the control group, with 79% (37 of 47) of SIJ fusion patients achieving at least a 20-point improvement compared to 24% (11 of 46) of controls. At 24 months there was an improvement of 26 points in ODI compared to 8 points in controls (p<.001). Improvement of at least 20 points was observed in 64% of the SIJ fusion group compared to 24% of the conservative management group.

Randers et al. (2024) conducted a double-blind randomized sham surgery-controlled trial comparing minimally invasive SIJ fusion using triangular titanium implants (iFuse, SI-BONE) to sham surgery in 63 patients with SIJ pain confirmed by diagnostic injection. The surgical group received 3 implants inserted laterally through the ilium into the sacrum, while the sham group underwent a simulated procedure without implant placement. After 6 months, there was no statistically significant difference in the primary outcome between the SIJ fusion and sham groups. The mean reduction in SIJ pain was 2.6 points for the surgical group and 1.7 points (MD, -1.0; 95% CI: -2.2 to 0.3; p =.13) for the sham group on the Numeric Rating Scale (NRS). Secondary outcomes, including ODI and EuroQol 5-dimension 5-level EQ-5D, also showed similar results between groups. The study was limited by its short follow-up period.

Table 2. Summary of Key RCT Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	*Comparator*
Randers et al (2024)	Sweden and Norway	2	2018-2021	Patients 21 to 70 y with confirmed diagnosis of severe SIJ pain	32 randomized to SIJ fusion	31 randomized to nonsurgical
Whang et al (2015); INSITE	U.S.	19	2013-2014	Patients 21 to 70 y with confirmed diagnosis of unilateral or bilateral SIJ dysfunction due to degenerative sacroiliitis and/or SIJ disruption	102 randomized to SIJ fusion	46 randomized to nonsurgical management
Sturesson et al (2017); iMIA	EU (Belgium, Germany, Italy, Sweden)	9	2013-2015	Patients 21 to 70 y with LBP for >6 mo and diagnosed with SIJ as primary pain generator[a]	52 randomized to SIJ fusion	51 randomized to conservative management

iMIA: iFuse Implant System Minimally Invasive Arthrodesis; INSITE: Investigation of Sacroiliac Fusion Treatment; LBP: low back pain; RCT: randomized controlled trial; SIJ: sacroiliac joint.
[a] The 3 criteria for diagnosis of SIJ pain were as follows: pain was present or near the posterior superior iliac spine; there were at least 3 positive findings on 5 provocative tests; at least a 50% pain reduction on fluoroscopically guided injection of local anesthetic into the joint.

Table 3. Summary of Six-Moth IFuse Results

Results	VAS Score		Success End Point		ODI Score		SF-36 PCS Score		EQ-5D TTO Index	
	Ctl	*iFuse*	*Ctl*	*iFuse*	*Ctl*	*iFuse*	*Ctl*	*iFuse*	*Ctl*	*iFuse*
INSITE										
Baseline	82.2	82.3			61.1	62.2	30.8	30.2	0.47	0.44
Follow-up	70.4	29.8	23.9%	81.4%[a]	56.4	31.9	32.0	42.8	0.52	0.72
Change	-12.1	-52.6[a]			-4.9	-30.3[a]	1.2	12.7	0.05	0.29
iMIA										
Baseline	73.0	77.7								
Follow-up	67.8	34.4								

Change	-5.7	-43.3			-5.8	-25.5			0.11	0.37
Randers et al (2024)	NRS score , operated SIJ	NRS score , operated SIJ					PGQ	PGQ	EQ-5D-5L	EQ-5D-5L
Baseline	7.7	7.9			53	51	74	70	.61	.63
Follow-up	6	5.0			50	47	68	64	.66	.65
Change	-1.7	-2.9			-3	-4	-6	-6	.05	.02
Mean difference (95% CI); p-value	-1.0 (-2.2 to 0.3); p =.13	-1.0 (-2.2 to 0.3); p =.13			-3 (-9 to 4); NS	-3 (-9 to 4); NS	−4 (−12 to 4); NS	−4 (−12 to 4); NS	-0.01 (-0.07 to 0.05); NS	-0.01 (-0.07 to 0.05); NS

Adapted from Whang et al (2015), and Sturesson et al (2015).
The success endpoint was defined as a reduction in VAS pain score of ≥20, absence of device-related events, absence of neurologic worsening, and absence of surgical intervention.
Ctl: control; EQ-5D TTO Index: EuroQoL Time Tradeoff Index; iMIA: iFuse Implant System Minimally Invasive Arthrodesis; INSITE: Investigation of Sacroiliac Fusion Treatment; NRS: numeric rating scale; ODI: Oswestry Disability Index; PGQ: pelvic girdle questionnaire; SF-36 PCS: 36-Item Short-Form Health Survey Physical Component Summary; VAS: visual analog scale.
[a] p<.001.

Table 4. Extended Follow-up from the INSITE and iMIA Trials

Outcome Measures	Baseline (SD)	6 Months (SD)	12 Months (SD)	24 Months (SD)
INSITE				
SIJ fusion pain score	82.3	29.8		26.7
Percent ≥20-point improvement pain				83.1%
SIJ fusion ODI score	57.2	31.9		28.7
% ≥15-point improvement ODI				68.2%
iMIA				***Mean Improvement (95% CI)***
Back pain				
Conservative management	73.0 (13.8)	67.8 (20.3)	58.9 (28.2)	11.0
SIJ fusion	77.7 (11.3)	34.4 (23.9)	35.2 (25.5)	45.3 (37 to 54)
Leg pain				
Conservative management	47.1 (31.1)	46.5 (31.4)	41.7 (32.4)	7.7
SIJ fusion	52.7 (31.5)	22.6 (25.1)	24.0 (27.8)	32.0
ODI				
Conservative management	55.6 (13.7)	50.2 (17.2)	46.9 (20.8)	8 (2 to 14)
SIJ fusion	57.5 (14.4)	32.0 (18.4)	32.1 (19.9)	26 (21 to 32)

Adapted from Dengler et al (2017).
CI: confidence interval; iMIA: iFuse Implant System Minimally Invasive Arthrodesis; INSITE: Investigation of Sacroiliac Fusion Treatment; ODI: Oswestry Disability Index; SD: standard deviation; SIJ: sacroiliac joint.

Tables 5 and 6 display notable limitations identified in each study.

Table 5. Study Relevance Limitations

Study; Trial	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Whang et al (2015); INSITE					
Sturesson et al (2017); iMIA	1. Patients with other contributory sources of LBP might have been enrolled with SIJ-caused LBP patients				
Randers et al (2024)					1. Study limited to 6 month follow-up

iMIA: iFuse Implant System Minimally Invasive Arthrodesis; INSITE: Investigation of Sacroiliac Fusion Treatment; LBP: low back pain; SIJ: sacroiliac joint.
The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 6. Study Design and Conduct Limitations

Study; Trial	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Whang et al (2015); INSITE						
Sturesson et al (2017); iMIA		1. Intervention was nonblinded				
Randers et al (2024)						

iMIA: iFuse Implant System Minimally Invasive Arthrodesis; INSITE: Investigation of Sacroiliac Fusion Treatment.
The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4.Comparative treatment effects not calculated.

Nonrandomized Studies

Prospective cohort studies with good follow-up rates are more likely to provide valid estimates of outcomes. Principal results of the studies at 2- to 5-year follow-up are shown in Table 7.

Results from a cohort of 172 patients undergoing SIJ fusion reported to 2 years were published by Duhon et al (2016). Patients were formally enrolled in a single-arm trial (SIFI NCT01640353) with planned follow-up for 24 months. Success was defined as a reduction of pain score of 20-mm on a 100-mm VAS, absence of device-related AEs, absence of neurologic worsening, and absence of surgical reintervention. Enrolled patients had a mean VAS pain score of 79.8, a mean ODI score of 55.2, and a mean pain duration of 5.1 years. At 6 months, 136 (80.5%) of 169 patients met the success endpoint, which met the prespecified Bayesian probability of success rate. Mean VAS pain scores were 30.0 at 6 months and 30.4 at 12 months. Mean ODI scores were 32.5 at 6 months and 31.4 at 12 months. At 2 years, 149 (87%) of 172 patients were available for follow-up. The VAS pain score at 2 years was 26.0, and the ODI score was 30.9. Thus, 1-year outcomes were maintained at 2 years. Other outcomes (e.g., QOL scores) showed similar maintenance or slight improvement compared with 1-year outcomes. Use of opioid analgesics decreased from 76.2% at baseline to 55% at 2 years. Over the 2-year follow-up, 8 (4.7%) patients required revision surgery.

Table 7. Two- to Five-Year Outcomes of the IFuse implant

Studies and Outcomes	**Mean Baseline Value**	**Mean 2- to 3-Year Value**	**Difference or % Achieving Outcome**	3	4	5	P
Duhon et al (2016) SIFI							
N	172	149 (86.6%)					
Pain score (range, 0 to 100)	79.8	26.0	53.3				
Oswestry Disability Index score	55.2	30.9	24.5				
SF-36 score	31.7	40.7	8.9				
EQ-5D TTO score	0.43	0.71	0.27				
Whang et al (2019) LOIS							
N	103					93	
VAS (range, 0 to 100)	81.5 (SD 12.7)					27.1 (29.4)	<.001
Oswestry Disability Index score	56.3					29.9 (21.2)	<.001
EQ-5D TTO score	0.45 (0.17)					0.75 (0.22)	<.001
Opiod use	76.7%	53.9%		47.4%	42.6%	41.3%	
Not working due to back pain	16.5%					15.1%	

All differences between baseline and 2- to 3-year values were statistically significant.
EQ-5D TTO Index: EuroQoL Time Tradeoff Index; INSITE: Investigation of Sacroiliac Fusion Treatment.; LOIS: Long Term Outcomes from INSITE and SIFI; SD: standard deviation; SF-36: 36-Item Short-Form Health Survey; SiFi: Sacroiliac Joint Fusion with iFuse Implant System; VAS: visual analog score.

In general, cohort studies and case series have shown improvements in VAS pain scores and other outcomes measures consistent in magnitude to the RCTs. The Long-Term Outcomes from INSITE and SIFI (LOIS) trial was a prospective single-arm study that enrolled patients who had participated in 2 of the studies described above for evaluation at 3, 4, and 5 years. The primary success outcome, a reduction in VAS of ≥20 points in the absence of a serious device-related AE, neurologic worsening, or surgical

revision, was obtained in 81.7% (95% CI: 72.4% to 89.0%) of patients at 5 years. The improvements in other clinical outcomes were maintained out to 5 years (Table 7). Opioid use decreased over time, although the contribution of the opioid use agreement cannot be determined. Fifteen percent of patients were not working due to back pain. Radiolucencies suggesting implant failure were observed in 5% of cases and were associated with incorrect placement. Bridging bone was observed in 45% of sides at 12 months, 71% at 24 months, and 88% at 60 months.

The Study of Bone Growth in the Sacroiliac Joint after Minimally Invasive Surgery with Titanium Implants (SALLY) is a 5-year multicenter study that will assess non-inferiority of outcomes with a 3-dimensional (3D) printed triangular implant as compared to the traditionally manufactured titanium coated implant. Twelve-month follow-up has been published for 46 of the 51 patients enrolled in the prospective cohort. The 6-month change in ODI met the non-inferiority margin, and secondary outcomes of pain, disability, and QOL were similar to those obtained in the INSITE, iMIA, and SIFI trials. Independent radiographic analysis showed bridging bone in 70% and 77% of sides imaged at 6 and 12 months, respectively, compared to 45% bridging bone in prior studies with the solid titanium coated implants. No breakage, migration, or subsidence was detected. However, there was no evidence that the increase in bridging bone led to an improvement in pain or functional outcomes compared to the milled implant at 12 months. Follow-up at 24 months was available for 84% of patients, with the stability of subjective and objective outcomes and similar efficacy for the 3D-printed implant and the milled implant from the earlier trials. Two patients had AEs related to the procedure and 2 had undergone revision. Follow-up is continuing.

Improved health outcomes are also supported by retrospective studies that compare SIJ fusion/fixation using a triangular implant with other treatments for SIJ pain. These results are consistent with the medium-term durability of the treatment. Analysis of an insurance database reported an overall incidence of complications to be 16.4% at 6 months and the cumulative revision rate at 4 years of 3.54%. Spain and Holt (2017) reported a retrospective review of surgical revision rates following SIJ fixation with either surgical screws or the iFuse triangular implant. Revision rates were lower with the iFuse device than observed with surgical screws.

Section Summary: Sacroiliac Joint Fusion/Fixation with a Transiliac Triangular Implant

The evidence on SIJ fusion/fixation with a triangular implant includes 1 meta-analysis, 1 blinded sham controlled trial, and 2 nonblinded RCTs of minimally invasive fusion, prospective cohorts with more than 85% follow-up, and a case series. The sham-controlled RCT found no significant difference in the primary outcome of pain reduction or in any secondary outcomes through 6 months of follow-up. Both RCTs have reported outcomes past 6 months, after which crossover was allowed. Both studies reported significantly greater reductions in VAS pain scores and ODI scores in SIJ fusion patients than in control groups. The reductions in pain and disability observed in the SIJ fusion group at 6 months were maintained out to 1 year compared with controls who had not crossed over. The RCTs were nonblinded without a placebo or an active control group. In addition, pain has a significant subjective and psychological component, and cognitive-behavioral techniques to address pain were specifically excluded from the types of treatment that control subjects could obtain. As it relates to trial design, an independent assessment of pain outcomes would have been preferable. Prospective cohorts and case series with sample sizes ranging from 45 to 149 patients and low dropout rates (<15%) also showed reductions in pain and disability that persist out to 5 years. The cohort studies and case series are consistent with the durability of treatment benefits. The meta-analysis pooled data from 3 RCTs and found that SIJ fusion with triangular titanium implants resulted in statistically significant improvements in pain, disability, quality of life, and opioid use compared to nonsurgical management for SIJ dysfunction, with similar adverse event rates between groups, though long-term data beyond 12 months was limited to a single trial.

Treatment of Sacroiliac Joint Pain: Sacroiliac Joint Fixation/Fusion with an Implant Other than a Transiliac Triangular Implant

Clinical Context and Therapy Purpose

The purpose of SIJ fixation/fusion with a SIJ implant is to provide a treatment option that is an alternative to or an improvement on existing therapies in individuals with SIJ pain.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with SIJ pain.

Interventions

The therapy being considered is SIJ fixation/fusion with an implant other than a transiliac triangular implant.

Numerous cannulated screws are marketed that use iliosacral and posterolateral approaches that pass through the ilium. Up to 3 implants may be used.

The posterior approach involves inserting implants into the ligamentous recess between the sacrum and ilium. The devices are intended to be used with allograft bone or are composed entirely of allograft bone. The posterior approach may be called distraction arthrodesis as the implants increase the joint space and create tension on the ligaments, repositioning the joint surfaces.

Comparators

The following therapy is currently being used to treat SIJ pain: conservative therapy.

Outcomes

The general outcomes of interest are symptoms (e.g., reductions in pain), functional outcomes, QOL, reductions in medication use, and treatment-related morbidity. Follow-up from 1 to 5 years is of interest to monitor outcomes.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and AEs, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews

Acevedo-Gonzalez et al (2025) conducted a systematic review and meta-analysis on minimally invasive SIJ fusion for low back pain. A total of 102 studies were included, and pooled quantitative analyses were performed across randomized, prospective, cohort, and retrospective designs. In RCTs, pooled results showed an overall effect size of 1.67 (95% CI: 1.00 to 2.44; I^2=72.47%). Prospective cohorts demonstrated larger pooled estimates of 3.84 (95% CI: 2.17 to 5.89; I^2=97.89%). Cohort studies yielded a pooled effect size of 2.45 (95% CI: 1.20 to 3.37; I^2=79.61%), while retrospective studies reported a pooled estimate of 4.34 (95% CI: 3.04 to 5.82; I^2=90.74%). Across pooled analyses by study design, minimally invasive SIJ fusion was associated with statistically significant and clinically meaningful reductions in pain and disability, although heterogeneity was high in all estimates, and variations in interventions varied (e.g., type of fixation screw and posterior, posterolateral, and transiliac approaches).

Tran et al (2019) published a systematic review comparing the effectiveness of minimally invasive joint fusion with a triangular implant (i.e., utilizing the iFuse device) compared to screw-type surgeries. A total of 20 studies were pooled to calculate a standardized mean difference across pain, disability, and global/QOL outcomes, including 14 studies evaluating the iFuse system and 7 studies evaluating cylindrical, threaded implants. Studies evaluating cylindrical, threaded implants consisted of case series and cohort studies. Patients receiving these implants experienced significantly worse pain outcomes (p=.03) compared to patients receiving iFuse, with a standardized mean difference of 1.28 (95% CI: 0.47 to 2.09) and 2.04 (95% CI: 1.76 to 2.33), respectively. A statistically significant difference in disability scores was reported between screw-type and iFuse implant groups (0.26 [95% CI: -1.90 to 2.41] vs 1.68 [95% CI: 1.43 to 1.94]; p=.01), with improved outcomes in the iFuse population. For global/QOL outcomes, a statistically significant difference in scores was reported between screw-type and iFuse implants groups (0.60 [95% CI: 0.33 to 0.88] vs 0.99 [95% CI: 0.75 to 1.24]; p=.04), with improved outcomes in the iFuse population.

A qualitative systematic review by Lorio et al (2020) for the International Society for the Advancement of Spine Surgery found evidence on the safety and effectiveness of distraction (posterior) SIJ fusion was limited to 1 prospective multicenter study (described below), no comparative studies, and a small number of case series.

Prospective Cohort Studies

Rappoport et al (2017) reported an industry-sponsored prospective study of SIJ fusion with a cylindrical threaded implant (SI-LOK). The study included 32 patients using 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 1 of which was slotted. The slotted screws were packed with an autogenous bone graft from the drill reaming's. Pain and disability scores were reduced following device implantation (see Table 8), and revisions within the first 12 months of the study were low (n=2). At the 2-year follow-up, VAS scores remained low, although 4 (12.5%) did not return for follow-up and 2 patients required revision surgery; analysis did not count these as treatment failures.

Fuchs and Ruhl (2018) published 2-year results of a prospective multi-center cohort of the posterior approach to arthrodesis of the SIJ. A total of 171 patients from 20 hospitals in Germany were treated from

2011 to 2012 using a DIANA implant (marketed in the U.S. as the NADIA implant). The DIANA implant is a hollow, tapered dowel that comes in diameters of 13, 15, 17, or 19 mm. A distraction tool was used to determine the size of the implant, which is inserted between the ilium and sacrum under distraction. Allogeneic bone grafts were used in 66% of cases. Patients had partial weight bearing on the operated side for 6 to 8 weeks. At the 2-year follow-up, VAS had decreased from 74 to 37, ODI improved from 51% to 33%, and the McGill Pain Questionnaire decreased from 50% to 31% (all p<.001). Use of opioids decreased from 49.3% of patients to 30.3% at follow-up. In computed tomography (CT) scans, only 31% of patients showed SIJ fusion at 2 years.

Calodney et al (2024) reported results from SECURE, a multi-center, prospective, single-arm study evaluating a posterior SIJ fusion with the LinQ implant platform for sacroiliac joint stabilization and arthrodesis (NCT04423120). The multi-center study included 159 patients treated from January 2020 to March 2022 who were followed for 12 months. Patients had a mean age of 59 years and had experienced SIJ pain for a mean of 5.8 years, with mean baseline VAS and ODI scores of 76.2 and 52.4, respectively. A total of 73 patients either withdrew consent or were lost to follow-up prior to 12 months of observation. At 12 months, 73.5% of participants (61/83) met the primary composite endpoint of ≥20 mm VAS improvement without serious adverse events or reintervention. Mean VAS scores improved from 76.2 at baseline to 32.6 at 12 months (43.3 point improvement, p<.0001). ODI scores improved by 25.3 points on average (p<.0001). Another endpoint investigated by the authors was the Patient-Reported Outcomes Measurement Information System (PROMIS-29 item) instrument, which showed significant (p<.001) improvements from baseline values in all 7 subscales (Pain interference, sleep disturbance, fatigue, anxiety, depression, ability to participate in social roles and activities, and physical functioning). Adverse events were infrequent, with only 5 total adverse events reported and 1 procedure-related serious adverse events (anesthesia aspiration). No implant-related serious adverse events occurred. This study's primary limitations include the absence of a control group and substantial participant attrition, with 47% of patients withdrawing or lost to follow-up before the 12-month mark.

Kucharzyk et al (2022) published interim results from a prospective cohort study evaluating pain and ODI outcomes for patients treated for SIJ pain with the SImmetry sacroiliac joint fusion system (NCT02074761). A total of 250 participants were recruited from 23 centers in the U.S; of these 80.4% (n=201) were available for 1 year follow-up, although not all patients have each outcome reported due to incomplete follow-up. The mean age of the participants was 60.5 years of age, and each participant had SI joint pain for 6 months or greater, and most had prior treatment for SIJ pain, including some prior lumbar spinal procedures. The mean VAS score had decreased from 76.4 at baseline to 33 at 1 year after the procedure (p<.001), with 140 (72.2%) patients achieving minimal clinically important difference (≥20-point reduction). The mean ODI score likewise showed significant improvement from baseline to 1 year, decreasing from 54.4 to 30.5 (p<.001). Over half of the cohort (62.5% [n=120]) achieved the minimal clinically important difference (15-point reduction) on the ODI. Before surgery, 62.7% (n=126) of the cohort were on opioids, decreasing to 26.9% (n=54) at the 1-year follow-up (p<.001). QOL was assessed with the EQ-5D: at baseline, the mean EQ-5D was 60.9, increasing to 72.8 after 1 year (p<.001). The authors reported 8 (3.2%) of patients had a serious adverse event, of which 5 were determined to be device-related (back pain, pain in the extremity, bilateral SI joint pain, device loosening, or device malposition). The main limitations of this study are a lack of comparison group and incomplete follow-up on all patients due to the interim nature of this analysis.

Splitt et al. (2023) compared two implant systems for SIJ fusion in a prospective study of 65 patients: the Deltacor Torpedo (n=30) and the SI-Bone iFuse (n=35). At 12 months, both groups showed significant improvement in VAS pain scores (Torpedo: 80.6 to 21.9 mm; iFuse: 83.5 to 28 mm; p<.0001 for each group) and ODI scores (Torpedo: 62% reduction; iFuse: 58% reduction) from baseline values, with no significant differences between the two implant systems. The study was limited by its relatively small

sample size with no power calculations, lack of blinding, and limited presentation of patient characteristics.

Davies et al. (2024) reported results from MAINSAIL, a prospective, single-arm, multi-center study evaluating the Catamaran SI Joint Fusion System. The study included 33 patients with SIJ pain who had failed conservative treatment. At 6 months, 80% of patients met the primary composite endpoint of ≥20 mm VAS improvement without serious adverse events or reintervention. Mean VAS scores improved from 80.9 at baseline to 31.1 at 6 months (p<.001). Mean ODI scores improved from 51.9% at baseline to 29.6% at 6 months (p <.01). Patient satisfaction was high, with 93.3% reporting satisfaction at 6 months. No device-related serious adverse events or reoperation were reported. The study was limited by its relatively small sample size and lack of a comparison group. A subsequent 12-month analysis of the same ongoing, prospective, multi-center MAINSAIL cohort (n=24 with 12-month data) reported composite success in 87.0% of evaluable subjects and independent CT-confirmed fusion in 82.6%. Mean VAS improved from 78.8 at baseline to 23.0 (p<.001) at 12 months and mean ODI from 51.6% to 20.8% (p<.001), with 83.3% of patients reporting satisfaction. No serious device or procedure-related adverse events or reinterventions occurred during the 12-month period.

Abbasi et al. (2025) reported results from a retrospective cohort study of 39 patients undergoing minimally invasive lateral SIJ fusion with the Trident™ screw system across 4 surgical sites, all performed by a single surgeon. All patients had failed conservative management, including ≥3 positive provocation tests and diagnostic injections. The cohort demonstrated a significant mean reduction in ODI at 6 or more months post-surgery of 13.7 points (p<.001), with improvements across nearly all ODI domains (pain intensity, personal care, lifting, walking, sitting, sleeping, social life, traveling, and employment; all p<.05), except for standing (p=.071). No intraoperative injuries were reported, and no major complications occurred. The study was limited by a potential lack of generalizability due to its single-surgeon design, the absence of a comparison group, and the short follow-up duration.

Table 8. Pain and Disability Scores after Implantation with a Cylindrical Threaded Implant

Outcome Measures	Baseline	3 Months (SD)	6 Months (SD)	12 Months (SD)	24 Months (SD)	p
Low back pain	55.8 (26.7)	28.5 (21.6)	31.6 (26.9)	32.7 (27.4)	20.0 (18.4)	<.01
Left leg pain	40.6 (29.5)	19.5 (22.9)	16.4 (25.6)	12.5 (23.3)	5.8 (8.1)	<.01
Right leg pain	40.0 (34.1)	18.1 (26.3)	20.6 (25.4)	14.4 (21.1)	11.5 (20.1)	<.05
Oswestry Disability Index	55.6 (16.1)	33.3 (16.8)	33.0 (16.8)	34.6 (19.4)	27.5 (18.8)	<.01

Adapted from Rappoport et al.
SD: standard deviation.

Section Summary: SIJ Fixation/Fusion with an Implant Other than a Transiliac Triangular Implant

The evidence on the fusion of the SIJ with devices other than the triangular implant includes 7 prospective cohort studies; 3 were conducted with transiliac screws, 1 with a lateral approach, and 3 with a posterior approach. One cohort study compared SIJ fusion with the Torpedo device to iFuse (transiliac triangular implant) and found no differences in pain or function outcomes at 12 months between the two groups. No other controlled studies were identified. Meta-analyses of the available prospective and retrospective studies indicate improvement in subjective outcomes from before surgery to follow-up in these unblinded studies. The meta-analyses comparing outcomes from these cohorts with non-concurrent studies suggest a possible difference in outcomes between the more well-studied triangular transiliac implant and other implant designs and approaches. There is uncertainty in the health benefit of SIJ

fusion/fixation with these various implant designs. Controlled studies with the different implant designs and approaches are needed to evaluate these devices.

Open Sacral Joint Fusion

Clinical Context and Therapy Purpose

The purpose of open SIJ fusion is to provide a treatment option that is an alternative to or an improvement on existing therapies in individuals with SIJ pain related to variety of conditions including trauma (with fracture), infection, cancer, sacroiliac joint pain, and spinal instability.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with SIJ pain related to variety of conditions including trauma (with fracture), infection, cancer, sacroiliac joint pain, and spinal instability.

Interventions

The therapy being considered is open sacroiliac joint fusion (SIJF). Open SIJF is a surgical procedure that fuses the iliac bone (pelvis) to the spine (sacrum).

Comparators

The following therapy is currently being used to treat SIJ pain: conservative therapy; minimally invasive procedures.

Outcomes

The general outcomes of interest are symptoms (e.g., reductions in pain), functional outcomes, QOL, reductions in medication use, and treatment-related morbidity. Follow-up from 1 to 5 years is of interest to monitor outcomes.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and AEs, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Correction of Spinal Deformity

Spinal deformity surgery involving long fusions of the spine in adults with spinal diseases such as degenerative scoliosis and spondylolysis may result in a debilitating complication of failure of the lumbosacral (spinal-pelvic) junction resulting from nonunion, implant failure, or sacral fracture. As a result, individuals who experience continued pain, continued curve progression and deformity, and progressive sagittal imbalance may require reoperation. The addition of spinopelvic fixation at the caudal end of long segment fusions (constructs) has improved sacral fusion rates. Iliac wing screws have been successfully used in non-ambulatory individuals for the treatment of neuromuscular scoliosis, but concerns exist overuse in ambulatory individuals. Sacroiliac joint fusion has been performed in the setting of long segment fusions of the spine that end at the first sacral vertebra (S1) in adults with spinal deformity and persistent sacroiliac joint-related pain. The evidence in the peer-reviewed literature consists of retrospective case series (Tumialan et al 2008; n=20), the largest series involving 78 ambulatory adults with degenerative scoliosis and spondylolysis who underwent bilateral iliac wing fixation in long fusions to the pelvis (Kasten et al 2010). The operative indications for posterior spinal fusion in this case series were fixed sagittal imbalance spondylolysis (n=23), idiopathic scoliosis (n=22), degenerative scoliosis (n=15), pseudarthrosis below long fusions (n=13), and traumatic kyphosis (n=5). Postoperatively, 12 of 78 individuals (15.3%) developed pseudarthrosis with broken implants; however, only 5 of 78 (6.4%) nonunions occurred at the lumbosacral junction. Six of 78 individuals (7.7%) required removal of the iliac screws for pain or painful prominence. A total of 42 individuals had one or more complications with an overall complication rate of 54%. Based on responses to a satisfaction questionnaire, 78% of individuals reported good or excellent results with the procedure. A significant improvement was achieved in correction of sagittal balance and coronal deformity. On follow-up radiographs, there were no sacral fractures, sacral screw failures, or significant sacroiliac joint degeneration. Nonunions continued to be a problem, with a rate of 15.3%, however only 6.4% of nonunions were at the lumbosacral junction. Complications specific to iliac screw placement were reported as minimal. Despite the complication rates (similar to those reported in other articles) and the known problems that exist with the complexity of long segment spinal fusions, the use of iliac wing fixation appears to improve lumbosacral fusion rates by adding structural support to S1 screws in long-segment spinal fusions.

Sacral Fracture

Findings from 3 retrospective case series support the use of sacroiliac joint fusion procedures for unstable pelvic ring fracture or dislocation associated with traumatic injury (Schweitzer et al 2008, Hsu et al 2010, Rysavy et al 2010). However, additional studies are warranted to further determine the safety and effectiveness of open SIJ fusion surgery for unstable pelvic ring fracture or dislocation associated with traumatic injury.

Sacral Joint Infection

Sacroiliac joint infection (such as, osteomyelitis, pyogenic sacroiliitis, sepsis) is an uncommon condition that generally responds to long-term antibiotics and occasionally requires drainage for abscess. Single and small case series evidence in the peer-reviewed literature provides initial support of the use of open SIJF as an adjunct to failed medical treatment of sacroiliac joint infection; however, further prospective comparative studies are still needed to better clarify the safety and effectiveness of open SIJ fusion surgery for sacroiliac joint infection (Davidson et al 2003, Sar et al 2003, Giannoudis et al 2007).

Sacral Joint Pain

In Hayes Inc. Health Technology Assessment (July 2019) regarding open sacroiliac joint fusion for unspecified sacroiliac joint (SIJ) dysfunction, this assessment included observational study designs with retrospective data collection in the majority of the studies. Six clinical studies in 7 publications (n=17-263 patients) evaluated open SIJ fusion for unspecified SIJ dysfunction with failed conservative management. These studies lacked active comparators and were of small sample size. Follow-up was limited to ≤ 24 months in the majority of studies. Additional limitations included potential for selection bias, high attrition and inconsistent and limited reporting of statistical analyses. Uncertainty exists due to the paucity of rigorous comparative evidence, poor-quality studies and inconsistent outcomes in this patient population. Additional studies are warranted to determine the safety and effectiveness of open SIJ fusion surgery for SIJ dysfunction compared to other surgeries to include non-minimally invasive SIJ fusion surgery with larger sample sizes and longer follow-up to assess late adverse events (AEs).

Kibsgard et al (2014) evaluated physical function and pain after open-accessed unilateral anterior sacroiliac joint fusion and fusion of the pubic symphysis in a single-subject research design study of 9 individuals with severe pelvic girdle pain. Repeated outcome measures of Oswestry Disability Index (ODI), visual analogue scale (VAS), and Short Form-36 (SF-36) were assessed preoperatively and at 3, 6, and 12 months postoperatively. A total of 8 participants were evaluable and included in the 1-year analysis of outcomes. Significant reductions were reported in ODI (54 to 37) and VAS (82 to 57) scores after 1 year ($p<0.001$). At baseline, 7 out of 8 participants had bilateral SI joint symptoms. At the 1-year follow-up, only 2 participants experienced pain in the fused joint; however, 6 of the 7 participants reported discomfort in the contralateral side. A total of 7 participants had pain in the pubic symphysis before surgery, and 5 participants had persistent pain in this area at the 1-year follow-up. One year after surgery, there was a 20-point improvement in physical function and bodily pain ($p<0.001$), a 15-point improvement in social functioning ($p=0.008$) and a 6-point improvement in general health ($p=0.009$). There were 3 major complications reported: 1 infection, 1 complex regional pain syndrome with drop-foot, and 1 participant with loss of bladder sensation; in addition, 3 participants experienced transient sensitivity loss to the lateral femoral cutaneous nerve area. All participants reported high levels of postoperative pain and required epidural treatment for 5-7 days, were hospitalized for 7-10 days, and were discharged on opioids. Limitations of this small study include the short-term measurement of outcomes and the high incidence of adverse events and complications with the procedure. Additional studies are needed of larger populations measuring long-term outcomes to evaluate the clinical efficacy and safety of sacroiliac fusion of the pelvic joints for individuals with severe pelvic girdle pain.

Sacral Tumors

Surgical management of primary sacral tumors (chordoma, chondrosarcoma, Ewing sarcoma, and giant cell tumor of the sacrum) utilizing open SIJF has been performed as an adjunct to en bloc sacrectomy or partial sacrectomy in the setting of these tumors. Reconstruction is often required in individuals who require radical resection with total sacrectomy. Evidence from small case series provide initial support of the potential benefits of using lumbar pedicle screws in combination with other surgical techniques involving the ilia in spinal pelvic reconstruction surgery (for example, Galveston rods, transiliac bar placement) (Salehi et al 2002, Zhang et al 2003, Gallia et al 2005, Newman et al 2009).

Section Summary: Open Sacral Joint Fusion

For individuals with SIJ pain associated with the following conditions: trauma (pelvic ring disruption fracture or dislocation), infection (osteomyelitis, pyogenic sacroiliitis, sepsis), cancer (sacral tumors), and corrections in spinal deformity during scoliosis or kyphosis surgery requiring multi-segment spinal constructs extending to the ilium who have received open SIJF surgery the evidence includes retrospective single small case series and articles that review surgical techniques regarding open SIJF for

these indications. There is paucity of data in the peer-reviewed medical literature due to poor quality of evidence and lack of rigorous comparative studies.

For individuals with chronic SIJ pain which may be related to the following conditions: sacroiliac joint dysfunction, sacroiliac joint inflammation, sacroiliac joint strain, and sacroiliac joint syndrome, the evidence includes observational studies with majority of studies with retrospective data collection. In Hayes Inc. Health Technology Assessment (July 2019) regarding open SIJF for unspecified sacroiliac joint (SIJ) dysfunction, this assessment included observational study designs with retrospective data collection in the majority of the studies. Six clinical studies in 7 publications (n=17-263 patients) evaluated open SIJ fusion for unspecified SIJ dysfunction with failed conservative management. These studies lacked active comparators and were of small sample size. Follow-up was limited to $\leq$ 24 months in the majority of studies. Additional limitations included potential for selection bias, high attrition and inconsistent and limited reporting of statistical analyses. Uncertainty exists due to the paucity of rigorous comparative evidence, poor-quality studies and inconsistent outcomes in this patient population. Additional studies are warranted to determine the safety and effectiveness of open SIJ fusion surgery for SIJ dysfunction compared to other surgeries to include non-minimally invasive SIJ fusion surgery with larger sample sizes and longer follow-up to assess late adverse events (AEs).

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2017 Input

Clinical input was sought to help determine whether the use of sacroiliac joint (SIJ) fusion for individuals with SIJ pain would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, clinical input was received from 10 respondents, including 5 specialty society-level responses from 7 specialty societies (2 were joint society responses) and 5 physician-level responses from 4 academic centers while this policy was under review in 2017.

For carefully selected patients as outlined in statements from the North American Spine Society who have SIJ pain who receive percutaneous and minimally invasive techniques of SIJ fusion, the clinical input supports this use provides a clinically meaningful improvement in the net health outcome and is consistent with generally accepted medical practice.

Further details from clinical input are included in the Appendix.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Society of Pain and Neuroscience

In 2024, American Society of Pain and Neuroscience (ASPN) published guidance on the treatment of sacroiliac disorders.

The following recommendations were provided concerning minimally invasive sacroiliac joint fixation:

- Best Practice Statement on Surgical Treatment for SIJ Pain: Minimally invasive surgical treatment can be considered when patients have failed 6 months of conservative treatment and the diagnosis has been confirmed via history, physical exam, and greater than 50% pain relief after a diagnostic, image guided, SIJ injection. Currently, there is no comparative evidence to claim superiority of one minimally invasive technique over another. The recommendation is to choose the safest approach with the greatest chance of clinical success. Approach and implants used should have peer reviewed prospective clinical evidence which demonstrate clinical efficacy and safety.

- Best Practice Statement on Surgical Treatment for SIJ Pain: Minimally invasive surgical treatment can be considered when patients have failed 6 months of conservative treatment and the diagnosis has been confirmed via history, physical exam, and greater than 50% pain relief after a diagnostic, image guided, SIJ injection. Currently, there is no comparative evidence to claim superiority of one minimally invasive technique over another. The recommendation is to choose the safest approach with the greatest chance of clinical success. Approach and implants used should have peer reviewed prospective clinical evidence which demonstrate clinical efficacy and safety.

- Best Practice Statements on Minimally Invasive Sacroiliac Fusion: Minimally invasive posterior SI stabilization with allograft is considered medically necessary when the appropriate clinical criteria have been met. (Grade, A; Level, I-B; Level of certainty, High)

  Including:

  1.)A failure of conservative measures to at least include physical therapy and injections.
  2.) Pain persisting a minimum of 6 months that interferes with functional activities as documented by both a pain score of VAS/NRS of 5 or greater and an ODI of 30 or more.
  3.) Failure of at least one therapeutic sacroiliac joint injection (less than 50% pain relief for three months duration).
  4.) Predominant pain pattern consistent with sacroiliac joint pathology.
  5.) Positive response from at least three validated maneuvers for sacroiliac joint dysfunction.
  6.) Positive Fortin finger test.
  7.) Diagnostic imaging: either CT or MRI that excludes destructive lesions of the sacroiliac joint.
  8.) Diagnostic confirmation of the SI joint as the pain generator demonstrated by at least one image-guided (CT or fluoroscopy) intraarticular injection of the SI joint with 50% or greater pain relief for the expected duration of the local anesthetic.

  Excluding:

  - Infection or fracture (unrelated to implant)

- Tumor
- Acute traumatic instability

- Minimally invasive SI fusion with lateral transfixing devices is considered medically necessary when the appropriate clinical criteria have been met (as above) (Grade, A; Level, I-A; Level of certainty, High)

- Minimally invasive SI fusion implants should be used according to FDA labeling (Grade, A; Level, I-A; Level of certainty, High)

- The use of implants composed of human cell and tissue products for sacroiliac fusion is considered medically necessary only if the guidelines set forth by the FDA Regulation of Human Cells and Tissue is followed and should be registered in the FDA Human Cell and Tissue Establishment Registration. (Grade, A; Level, NA; Level of certainty, High)

- ASPN supports the utilization of sacroiliac fusion and stabilization devices with published, peer-reviewed, multi-center, prospective evidence of at least 6 months duration to assess efficacy and safety. (Grade, A; Level, I-A; Level of certainty, High)

- The current evidence is insufficient to determine the medical necessity of emerging techniques for minimally invasive sacroiliac fusion such as posterior-transfixing, and hybrid approaches. (Grade, I; Level, II; Level of certainty, Low)

International Society for the Advancement of Spine Surgery

In 2020, the International Society for the Advancement of Spine Surgery provided guidance on indications for minimally invasive SIJ fusion with placement of lateral transfixing devices.[1]

The Society recommended that "patients who have all of the following criteria may be eligible for lateral MIS [minimally invasive surgical] SIJF with placement of lateral transfixing devices:

- "Chronic SIJ pain (pain lasting at least 6 months)
- Significant SIJ pain that impacts QOL [quality of life] or significantly limits activities of daily living
- SIJ pain confirmed with at least 3 physical examination maneuvers that stress the SIJ [list provided above] and reproduce the patient's typical pain
- Confirmation of the SIJ as a pain generator with $\geq$ 50% acute decrease in pain upon fluoroscopically guided diagnostic intra-articular SIJ block using a small volume ($\leq$ 2.5 mL) of local anesthetic.....
- Failure to respond to nonsurgical treatment consisting of NSAIDs [nonsteroidal anti-inflammatory drugs] and a reasonable course (4 to 6 weeks) of PT [physical therapy]. Failure to respond means continued pain that interferes with activities of daily living and/or results in functional disability"

It was recommended that intra-articular SIJ steroid injection and radiofrequency ablation (RFA) of the SIJ lateral branch nerves may be considered but are not required.

Specifically, not recommended were:

- Minimally invasive posterior (dorsal) SIJ fusion
- Repeat intra-articular steroid injection

- Repeat SIJ radiofrequency ablation.

This guideline included the following regarding open SIJ fusion, the authors suggest the use of open SIJF "in certain cases, such as a acute trauma, tumor, infection, or for SIJF in conjunction with pelvic fixation in spinal deformity surgery."

National Institute for Health and Care Excellence

In 2017, the National Institute for Health and Care Excellence guidance on minimally invasive SIJ fusion surgery for chronic sacroiliac pain included the following recommendations:

> 1.1 "Current evidence on the safety and efficacy of minimally invasive sacroiliac (SI) joint fusion surgery for chronic SI pain is adequate to support the use of this procedure....
>
> 1.2 Patients having this procedure should have a confirmed diagnosis of unilateral or bilateral SI joint dysfunction due to degenerative sacroiliitis or SI joint disruption.
>
> 1.3 This technically challenging procedure should only be done by surgeons who regularly use image-guided surgery for implant placement. The surgeons should also have had specific training and expertise in minimally invasive SI joint fusion surgery for chronic SI pain.

In 2022, NICE published medical technology guidance on using the iFuse implant system for treating chronic sacroiliac joint pain. It provided the following recommendations:

1.1" iFuse implant system is recommended as an option for treating chronic sacroiliac joint pain.

1.2 iFuse should be considered for use in people with a confirmed diagnosis of chronic sacroiliac joint pain (based on clinical assessment and a positive response to a diagnostic injection of local anaesthetic in the sacroiliac joint) and whose pain is inadequately controlled by non-surgical management."

North American Spine Society

NASS posted a protocol for a forthcoming systematic review and guideline on SIJ pain, "Diagnosis and Treatment of Adults with Sacroiliac Joint Pain: A Protocol for a Systematic Review and Clinical Guideline by the North American Spine Society" in February 2023. The review aims to provide evidence-based recommendations to address critical clinical questions surrounding diagnosing and treating adult patients with sacroiliac joint pain. No estimated date of publication was provided.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review can be located at clinicaltrials.gov.

REFERENCES

1. Himstead AS, Brown NJ, Shahrestani S, et al. Trends in Diagnosis and Treatment of Sacroiliac Joint Pathology Over the Past 10 Years: Review of Scientific Evidence for New Devices for Sacroiliac Joint Fusion. Cureus. Jun 2021; 13(6): e15415. PMID 34249562
2. Dreyfuss P, Michaelsen M, Pauza K, et al. The value of medical history and physical examination in diagnosing sacroiliac joint pain. Spine (Phila Pa 1976). Nov 15 1996; 21(22): 2594-602. PMID 8961447
3. Simopoulos TT, Manchikanti L, Gupta S, et al. Systematic Review of the Diagnostic Accuracy and Therapeutic Effectiveness of Sacroiliac Joint Interventions. Pain Physician. Sep-Oct 2015; 18(5): E713-56. PMID 26431129
4. Chou R, Loeser JD, Owens DK, et al. Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the American Pain Society. Spine (Phila Pa 1976). May 01, 2009; 34(10): 1066-77. PMID 19363457
5. Whang P, Cher D, Polly D, et al. Sacroiliac Joint Fusion Using Triangular Titanium Implants vs. Non-Surgical Management: Six-Month Outcomes from a Prospective Randomized Controlled Trial. Int J Spine Surg. 2015; 9: 6. PMID 25785242
6. Polly DW, Cher DJ, Wine KD, et al. Randomized Controlled Trial of Minimally Invasive Sacroiliac Joint Fusion Using Triangular Titanium Implants vs Nonsurgical Management for Sacroiliac Joint Dysfunction: 12-Month Outcomes. Neurosurgery. Nov 2015; 77(5): 674-90; discussion 690-1. PMID 26291338
7. Polly DW, Swofford J, Whang PG, et al. Two-Year Outcomes from a Randomized Controlled Trial of Minimally Invasive Sacroiliac Joint Fusion vs. Non-Surgical Management for Sacroiliac Joint Dysfunction. Int J Spine Surg. 2016; 10: 28. PMID 27652199
8. Darr E, Meyer SC, Whang PG, et al. Long-term prospective outcomes after minimally invasive trans-iliac sacroiliac joint fusion using triangular titanium implants. Med Devices (Auckl). 2018; 11: 113-121. PMID 29674852
9. Sturesson B, Kools D, Pflugmacher R, et al. Six-month outcomes from a randomized controlled trial of minimally invasive SI joint fusion with triangular titanium implants vs conservative management. Eur Spine J. Mar 2017; 26(3): 708-719. PMID 27179664
10. Dengler J, Sturesson B, Kools D, et al. Referred leg pain originating from the sacroiliac joint: 6-month outcomes from the prospective randomized controlled iMIA trial. Acta Neurochir (Wien). Nov 2016; 158(11): 2219-2224. PMID 27629371
11. Dengler JD, Kools D, Pflugmacher R, et al. 1-Year Results of a Randomized Controlled Trial of Conservative Management vs. Minimally Invasive Surgical Treatment for Sacroiliac Joint Pain. Pain Physician. Sep 2017; 20(6): 537-550. PMID 28934785
12. Dengler J, Kools D, Pflugmacher R, et al. Randomized Trial of Sacroiliac Joint Arthrodesis Compared with Conservative Management for Chronic Low Back Pain Attributed to the Sacroiliac Joint. J Bone Joint Surg Am. Mar 06 2019; 101(5): 400-411. PMID 30845034
13. Duhon BS, Cher DJ, Wine KD, et al. Triangular Titanium Implants for Minimally Invasive Sacroiliac Joint Fusion: A Prospective Study. Global Spine J. May 2016; 6(3): 257-69. PMID 27099817
14. Duhon BS, Bitan F, Lockstadt H, et al. Triangular Titanium Implants for Minimally Invasive Sacroiliac Joint Fusion: 2-Year Follow-Up from a Prospective Multicenter Trial. Int J Spine Surg. 2016; 10: 13. PMID 27162715
15. Whang PG, Darr E, Meyer SC, et al. Long-Term Prospective Clinical And Radiographic Outcomes After Minimally Invasive Lateral Transiliac Sacroiliac Joint Fusion Using Triangular Titanium Implants. Med Devices (Auckl). 2019; 12: 411-422. PMID 31576181
16. Patel V, Kovalsky D, Meyer SC, et al. Prospective Trial of Sacroiliac Joint Fusion Using 3D-Printed Triangular Titanium Implants. Med Devices (Auckl). 2020; 13: 173-182. PMID 32607011
17. Vanaclocha V, Herrera JM, Saiz-Sapena N, et al. Minimally Invasive Sacroiliac Joint Fusion, Radiofrequency Denervation, and Conservative Management for Sacroiliac Joint Pain: 6-Year Comparative Case Series. Neurosurgery. Jan 01 2018; 82(1): 48-55. PMID 28431026

18. Spain K, Holt T. Surgical Revision after Sacroiliac Joint Fixation or Fusion. Int J Spine Surg. 2017; 11: 5. PMID 28377863
19. Schoell K, Buser Z, Jakoi A, et al. Postoperative complications in patients undergoing minimally invasive sacroiliac fusion. Spine J. Nov 2016; 16(11): 1324-1332. PMID 27349627
20. Tran ZV, Ivashchenko A, Brooks L. Sacroiliac Joint Fusion Methodology - Minimally Invasive Compared to Screw-Type Surgeries: A Systematic Review and Meta-Analysis. Pain Physician. Jan 2019; 22(1): 29-40. PMID 30700066
21. Lorio M, Kube R, Araghi A. International Society for the Advancement of Spine Surgery Policy 2020 Update-Minimally Invasive Surgical Sacroiliac Joint Fusion (for Chronic Sacroiliac Joint Pain): Coverage Indications, Limitations, and Medical Necessity. Int J Spine Surg. Dec 2020; 14(6): 860-895. PMID 33560247
22. Rappoport LH, Luna IY, Joshua G. Minimally Invasive Sacroiliac Joint Fusion Using a Novel Hydroxyapatite-Coated Screw: Preliminary 1-Year Clinical and Radiographic Results of a 2-Year Prospective Study. World Neurosurg. May 2017; 101: 493-497. PMID 28216399
23. Rappoport LH, Helsper K, Shirk T. Minimally invasive sacroiliac joint fusion using a novel hydroxyapatite-coated screw: final 2-year clinical and radiographic results. J Spine Surg. Jun 2021; 7(2): 155-161. PMID 34296027
24. Fuchs V, Ruhl B. Distraction arthrodesis of the sacroiliac joint: 2-year results of a descriptive prospective multi-center cohort study in 171 patients. Eur Spine J. Jan 2018; 27(1): 194-204. PMID 29058134
25. Benzon HT, Connis RT, De Leon-Casasola OA, et al. Practice guidelines for chronic pain management: an updated report by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine. Anesthesiology. Apr 2010; 112(4): 810-33. PMID 20124882
26. Lee DW, Pritzlaff S, Jung MJ, et al. Latest Evidence-Based Application for Radiofrequency Neurotomy (LEARN): Best Practice Guidelines from the American Society of Pain and Neuroscience (ASPN). J Pain Res. 2021; 14: 2807-2831. PMID 34526815
27. National Institute for Health and Care Excellence. Minimally invasive sacroiliac joint fusion surgery for chronic sacroiliac pain [IPG578]. 2017; https://www.nice.org.uk/guidance/ipg578
28. Hayes, a symplr company. Health Technology Assessment. Minimally Invasive Sacroiliac Joint Fusion using Triangular Titanium Implants (iFuse Implant System, SI-Bone Inc.) August 2023
29. Hayes, a symplr company . Evidence Analysis Research Brief. Minimally Invasive Posterior Sacroiliac Joint Fusin in the Management of Sacroiliac Joint Pain May 2023
30. Hayes, a symplr company. Medical Code Brief 0809T Category III (T-codes) January 11, 2023
31. Hayes, a symplr company. Health Technology Assessment. Minimally Invasive Sacroiliac Joint Fusion Using Cylindrical Threaded Implants. August 2023
32. Hayes, a symplr company. Health Technology Assessment Open Sacroiliac Joint Fusion for Unspecified Sacroiliac Joint Dysfunction. July 2019
33. Hayes, a symplr company . Evolving Evidence Review. Minimally Invasive Posterior Sacroiliac Joint Fusion Using a Bone Allograft for Management of Sacroiliac Joint Pain. March 2025
34. UpToDate. Subacute and chronic low back pain: Nonsurgical interventional treatment. Topic last updated April 29, 2025. Also available at https://www.uptodate.com
35. UpToDate. Subacute and chronic low back pain: Surgical treatment. Topic last updated October 2025. Also available at https://www.uptodate.com
36. Chang E, Rains C, Ali R, et al. Minimally invasive sacroiliac joint fusion for chronic sacroiliac joint pain: a systematic review. Spine J. 2022 Jan 10:S1529-9430(22)00005-5
37. Claus CF, Lytle E, Kaufmann A, et al. Minimally invasive sacroiliac joint fusion using triangular titanium versus cylindrical threaded implants: a comparison of patient-reported outcomes. World Neurosurg. 2020 Jan;133:e745-e750
38. Darr E, Cher D. Four-year outcomes after minimally invasive transiliac sacroiliac joint fusion with triangular titanium implants. Med Devices Evid Res. 2018a; 11:287-289

39. Darr E, Meyer SC, Whang PG, et al. Long-term prospective outcomes after minimally invasive trans-iliac sacroiliac joint fusion using triangular titanium implants. Med Devices (Auckl). 2018b; 11:113-121
40. Spain K, Holt T. Surgical revision after sacroiliac joint fixation or fusion. Int J Spine Surg. Apr 2017;11:5
41. Tran ZV, Ivashchenko A, Brooks L. Sacroiliac Joint Fusion Methodology - Minimally Invasive Compared to Screw-Type Surgeries: A Systematic Review and Meta-Analysis. Pain Physician, 2019 Feb 1;22(1)
42. Whang PG, Darr E, Meyer SC, et al. Long-term prospective clinical and radiographic outcomes after minimally invasive lateral transiliac sacroiliac joint fusion using triangular titanium implants. Medical Devices (Auckl). 2019; 12:411-422
43. Calodney AK, Azeem N, Buchanan P, et al. Six Month Interim Outcomes from SECURE: A Single arm, Multicenter, Prospective, Clinical Study on a Novel Minimally Invasive Posterior Sacroiliac Fusion Device. Expert Rev Med Devices. May 2022; 19(5): 451-461. PMID 35724479
44. Kucharzyk D, Colle K, Boone C, et al. Clinical Outcomes Following Minimally Invasive Sacroiliac Joint Fusion With Decortication: The EVoluSIon Clinical Study. Int J Spine Surg. Feb 2022; 16(1): 168-175. PMID 35217586
45. Sayed D, Grider J, Strand N, et al. The American Society of Pain and Neuroscience (ASPN) Evidence-Based Clinical Guideline of Interventional Treatments for Low Back Pain. J Pain Res. 2022; 15: 3729-3832. PMID 36510616
46. Gallia GL, Haque R, Garonzik I, et al. Spinal pelvic reconstruction after total sacrectomy for en bloc resection of a giant sacral chordoma. Technical note. J Neurosurg Spine. 2005; 3:501-506
47. Newman CB, Keshavarzi S, Aryan HE. En bloc sacrectomy and reconstruction: technique modification for pelvic fixation. Surg Neurol. 2009; 72(6):752-756
48. Salehi SA, McCafferty RR, Karahalios D, Ondra SL. Neural function preservation and early mobilization after resection of metastatic sacral tumors and lumbosacropelvic junction reconstruction. Report of three cases. J Neurosurg. 2002; 97(1 Suppl):88-93
49. Zhang HY, Thongtrangan I, Balabhadra RS, et al. Surgical techniques for total sacrectomy and spinopelvic reconstruction. Neurosurg Focus. 2003; 15(2):E5
50. Davidson D, Letts M, Khoshhal K. Pelvic osteomyelitis in children: a comparison of decades from 1980-1989 with 1990-2001. J Pediatr Orthop. 2003; 23(4):514-521
51. Sar C, Kilicoglu O. S1 pediculoiliac screw fixation in instabilities of the sacroiliac complex: biomechanical study and report of two cases. J Orthop Trauma. 2003; 17(4):262-270
52. Kibsgard TJ, Roise O, Stuge B. Pelvic joint fusion in patients with severe pelvic girdle pain - a prospective single-subject research design study. BMC Musculoskelet Disord. 2014; 15:85.
53. Hsu JR, Bear RR, Dickson KF. Open reduction internal fixation of displaced sacral fractures: technique and results. Orthopedics. 2010; 33(10):730
54. Rysavy M, Pavelka T, Khayarin M, Dzupa V. Iliosacral screw fixation of the unstable pelvic ring injuries. Acta Chir Orthop Traumatol Cech. 2010; 77(3):209-214
55. Peng KT, Huang KC, Chen MC, et al. Percutaneous placement of iliosacral screws for unstable pelvic ring injuries: comparison between one and two C-arm fluoroscopic techniques. J Trauma. 2006; 60(3):602-608
56. Ou-Yang DC, York PJ, Kleck CJ, Patel VV. Diagnosis and management of sacroiliac joint dysfunction. Journal of Bone and Joint Surgery - American Volume. 2017; 99(23):20272036
57. Giannoudis PV and Tsiridis E. A minimally-invasive technique for the treatment of pyogenic sacroiliitis. J Bone Joint Surg Br. 2007 Jan;89(1):112-4. PMID 17259428
58. Schweitzer D, Zylberberg A, Cardova M, et al. Closed reduction and iliosacral percutaneous fixation of unstable pelvic ring fractures. Injury 2008 aug;39(8):869-74. PMID 18621370
59. Becker's Spine Review. Advancing quality of life for patients with chronic low back pain: Safety and efficacy of lateral transiliac sacroiliac joint fusion. November 2023. Also available at https://www.bekersspine

60. Calodney A, Azeem N, Buchanan P, et. al. Safety, efficacy, and durability of outcomes: Results from SECURE: A single arm, multicenter, prospective, clinical study on a minimally invasive posterior sacroiliac fusion allograft implant. Journal of Pain Research 2024:17 1209-1222
61. Calodney A, Azeem N, Buchanan P, et al. Safety, Efficacy, and Durability of Outcomes: Results from SECURE: A Single Arm, Multicenter, Prospective, Clinical Study on a Minimally Invasive Posterior Sacroiliac Fusion Allograft Implant. J Pain Res. 2024; 17: 1209-1222. PMID 38524688
62. Davies M, Dreischarf M, Yusufbekov R. Catamaran SI Joint Fusion System (R) MAINSAIL TM Study: a prospective, single-arm, multi-center, post-market study of six-month clinical outcomes and twelve-month radiographic findings. Expert Rev Med Devices. Sep 2024; 21(9): 851-858. PMID 39161110
63. Ghaddaf AA, Alsharef JF, Alsharef NK, et al. Minimally invasive sacroiliac joint fusion using triangular titanium implants versus nonsurgical management for sacroiliac joint dysfunction: a systematic review and meta-analysis. Can J Surg. 2024; 67(1): E16-E26. PMID 38278549
64. Sayed D, Deer TR, Tieppo Francio V, et al. American Society of Pain and Neuroscience Best Practice (ASPN) Guideline for the Treatment of Sacroiliac Disorders. J Pain Res. 2024; 17: 1601-1638. PMID 38716038
65. Splitt T, Pflugmacher R, Soliman O, et al. Surgical Treatment of Patients with Sacroiliac Joint Syndrome: Comparative Study of Two Implants. Z Orthop Unfall. Nov 22 2023. PMID 37992733
66. Randers EM, Gerdhem P, Stuge B, et al. The effect of minimally invasive sacroiliac joint fusion compared to sham operation: a double-blind randomized placebo-controlled trial. EClinicalMedicine. Feb 2024; 68: 102438. PMID 38328752
67. Acevedo-Gonzalez JC, Lacouture-Silgado I. Utility of minimally invasive percutaneous arthrodesis of the sacroiliac joint for the treatment of low back pain: systematic review of the literature. Eur Spine J. Mar 2025; 34(3): 974-1003. PMID 39885048
68. Abbasi H, Moore D, Rusten MA, et al. Efficacy of Lateral Sacroiliac Joint Fusion With the Trident™ Screw System: A Retrospective Analysis. Cureus. Jan 2025; 17(1): e77793. PMID 39981446
69. Davies M, Christopher A, Edwards J, et al. Twelve-month clinical and radiographic outcomes following inferior-posterior sacroiliac joint fusion using the Catamaran SI Joint Fusion System: a prospective, multi-center evaluation. Expert Rev Med Devices. Aug 19 2025: 1-9. PMID 40773478

CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

Codes	Number	Description
CPT		
	27278	Arthrodesis, sacroiliac joint, percutaneous, or minimally invasive, with image guidance, includes obtaining bone graft when performed, unilateral placement of intra-articular devise(s), without cortical piercing
	27279	Arthrodesis, sacroiliac joint, percutaneous, or minimally invasive, with image guidance, includes obtaining bone graft when performed, unilateral placement of transarticular device(s) and/or intra-articular device(s) piercing the lateral or medial cortices of the ilium and the lateral cortex of the sacrum

	27280	Arthrodesis, sacroiliac joint, open, includes obtaining bone graft, including instrumentation, when performed
	27299	Unlisted procedure, pelvis, or hip joint
HCPCS		
	C1737	Joint fusion and fixation device(s), sacroiliac and pelvis, including all system components (implantable)
Type of Service	Surgery	
Place of Service	Outpatient/Inpatient	

POLICY HISTORY

Date	Action	Action
January	Annual Review	Policy Revised
July 2025	Annual Review	Policy Renewed
July 2024	Annual Review	Policy Renewed
July 2023	Annual Review	Policy Revised - content moved from retired policy “Miscellaneous Surgical Treatments of Back Pain”
January 2022	Interim Review	Policy Revised
July 2021	Annual Review	Policy Revised
July 2020	Annual Review	Policy Revised
October 2019	Interim Review	Policy Revised
July 2018	Annual Review	Policy Revised
July 2017	Annual Review	Policy Revised
July 2016	Annual Review	Policy Revised
July 2015	Annual Review	Policy Revised
October 2015	Interim Review	Policy Revised
August 2015	Annual Review	Policy Revised

Date	Action	Action
September 2014	Annual Review	Policy Revised
October 2013	Annual Review	Policy Revised
November 2012	Annual Review	Policy Renewed
November 2011	Annual Review	Policy Renewed
October 2010	Annual Review	Policy Renewed

Appendix

2017 Clinical Input

Clinical input was sought to help determine whether the use of sacroiliac joint (SIJ) fusion for individuals with SIJ pain would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice.

Respondents

Clinical input was provided by the following specialty societies and physician members identified by a specialty society or clinical health system:

- American Association of Neurological Surgeons/Congress of Neurological Surgeons (AANS/CNS)
- American Pain Society (APS)
- American Society of Regional Anesthesia and Pain Medicine (ASRA)[a]
- International Society for the Advancement of Spine Surgery (ISASS)[b]
- North American Spine Society/American Academy of Orthopaedic Surgeons (NASS/AAOS)
- Neil Malhotra, MD, Assistant Professor of Neurosurgery, Perelman School of Medicine, University of Pennsylvania (identified by Hospital of the University of Pennsylvania)
- William Welch, MD, Vice Chair (Clinical) and Professor, Department of Neurosurgery, Perelman School of Medicine, University of Pennsylvania (identified by Hospital of the University of Pennsylvania)
- Zachary Gordon, MD, Assistant Professor, Department of Orthopaedics, Case Western Reserve University, identified by University Hospitals Cleveland Medical Center
- A. Alex Jahangir, MD, MMHC, Medical Director and Associate Professor of Orthopaedic Surgery, identified by Vanderbilt University Medical Center
- Anonymous, MD, Assistant Professor of Orthopaedics and Rehabilitation; identified by Oregon Health and Science University.

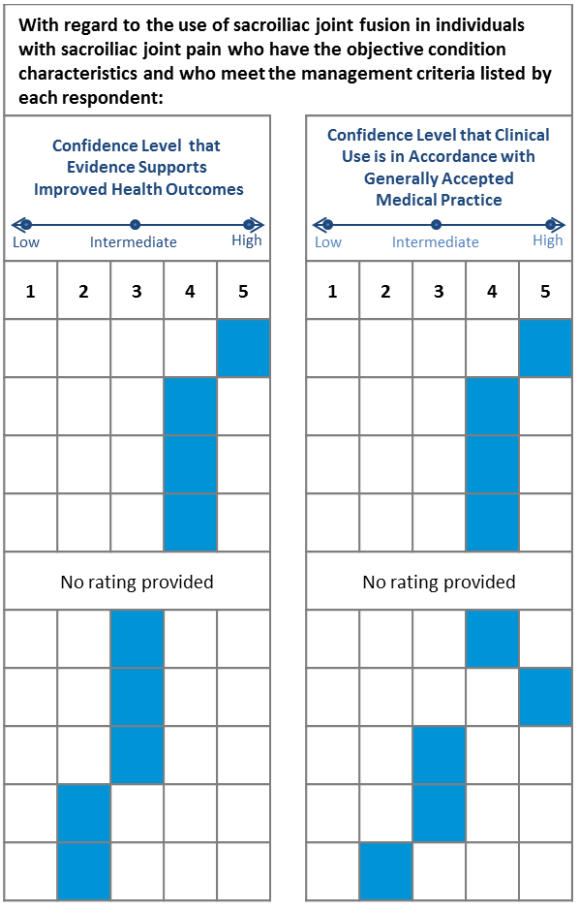
[a] Indicates that information was not provided regarding conflicts of interest related to the topic where clinical input is being sought. [b] Indicates that conflicts of interest related to the topic where clinical input is being sought were identified by this respondent.

Clinical input provided by the specialty society at an aggregate level is attributed to the specialty society. Clinical input provided by a physician member designated by the specialty society or health system is attributed to the individual physician and is not a statement from the specialty society or health system. Specialty society and physician respondents participating in the Evidence Street® clinical input process provide a review, input, and feedback on

topics being evaluated by Evidence Street. However, participation in the clinical input process by a special society and/or physician member designated by the specialty society or health system does not imply an endorsement or explicit agreement with the Evidence Opinion published by BCBSA or any Blue Plan.

Ratings

Clinical Indication	Respondent	Identified by
Per ISASS policy statement	ISASS**	
See response to Clinical Input Question 1 in Appendix	AANS/CNS	
Per NASS coverage recommendation	NASS/AAOS	
See response to Clinical Input Question 1 in Appendix	APS	
See response to Clinical Input Question 1 in Appendix	ASRA*	
Diagnostic and therapeutic injections	Dr. Malhotra	Hospital of Univ. Pennsylvania
Response to image-guided sacroiliac injections	Dr. Welch	Hospital of Univ. Pennsylvania
See response to Clinical Input Question 1 – NASS guideline	Anonymous	Oregon Health and Science Univ.
See response to Clinical Input Question 1 in Appendix	Dr. Jahangir	Vanderbilt University Med Ctr
See response to Clinical Input Question 1 in Appendix	Dr. Gordon	Univ. Hospitals Cleveland Med Ctr



* Indicates that information was not provided regarding conflicts of interest related to the topic where clinical input is being sought. ** Indicates that conflicts of interest related to the topic where clinical input is being sought were identified by this respondent.

Respondent Profile

	Specialty Society	
No.	**Name of Organization**	**Clinical Specialty**
1	American Association of Neurological Surgeons / Congress of Neurological Surgeons	Neurosurgery
2	International Society for the Advancement of Spine Surgery	Spine Surgery
3	North American Spine Society / American Academy of Orthopaedic Surgeons	Spine Surgery / Orthopaedic Surgery
4	American Society of Regional Anesthesia and Pain Medicine	Regional Anesthesia and Pain Medicine

	Specialty Society				
5	American Pain Society		Pain Medicine		
	Physician				
No.	Name	Degree	Name of Organization	Clinical Specialty	Board Certification and Fellowship Training
Identified by Hospital of the University of Pennsylvania					
6	Neil R. Malhotra	MD	Hospital of the University of Pennsylvania	Neurosurgery	Neurosurgery
7	William Welch	MD	Hospital of the University of Pennsylvania	Neurosurgery	Neurosurgery, Spinal Surgery
Identified by University Hospitals Cleveland Medical Center					
8	Zachary L. Gordon	MD	University Hospitals Cleveland Medical Center	Spine Surgery	ABOS Certified, Fellowship Spine Surgery at University of Pittsburgh Medical Center
Identified by Vanderbilt University Medical Center					
9	A. Alex Jahangir	MD	Vanderbilt University Medical Center	Orthopaedic Surgery	Orthopaedic Surgery / Orthopaedic Trauma
Identified by Oregon Health and Science University					
10	Anonymous	MD	Oregon Health and Science University	Orthopaedic Surgery	ABOS, AOSpine Fellowship

Respondent Conflict of Interest Disclosure

No.	**Research support related to the topic where clinical input is being sought**		**2. Positions, paid or unpaid, related to the topic where clinical input is being sought**		**3. Reportable, more than $1000, healthcare-relateda ssets or sources of income for myself, my spouse, or my dependent children related to the topic where clinical input is being sought**		**4. Reportable, more than $350, gifts or travel reimbursements for myself, my spouse, or my dependent children related to the topic where clinical input is being sought**	
	Yes/No	***Explanation***	***Yes/No***	***Explanation***	***Yes/No***	***Explanation***	***Yes/No***	***Explanation***
1	No		No		No		No	
2	3 Yes 2 No	Participated in INSITE, an SI-BONE sponsored randomized trials. Institution received support for trial but no personal support received.	1 Yes 4 No	Paid for teaching courses for Zyga.	1 Yes 4 No	Owns intellectual property in Transformer Spine.	5 No	

No.	Research support related to the topic where clinical input is being sought		2. Positions, paid or unpaid, related to the topic where clinical input is being sought		3. Reportable, more than $1000, healthcare-relateda ssets or sources of income for myself, my spouse, or my dependent children related to the topic where clinical input is being sought		4. Reportable, more than $350, gifts or travel reimbursements for myself, my spouse, or my dependent children related to the topic where clinical input is being sought	
		Designed and coauthored paper on the work intensity of MIS SIJ fusion organized by SI-Bone Inc., but received no remuneration. Institution is paid for a research study on MIS SIJ fusion.						
4	NR		NR		NR		NR	
5	No		No		No		No	
6	No		No		No		No	
7	No		No		No		NR	
8	No		No		No		No	
9	No		No		No		No	
10	No		No		No		No	
No.	Conflict of Interest Policy Statement							
3	The North American Spine Society (NASS) employs rigorous checks and balances to ensure that its comments and recommendations on payors' coverage policies/clinical evidence reports are scientifically sound and unbiased. These checks and balances include requiring all individuals involved in drafting, reviewing, revising and approving the comments to disclose any conflicts of interest he or she may have. Using an evidence-based approach when possible, the multi-disciplinary team works together to develop the comments which require multiple levels of review. The individuals who provide the final reviews and approvals are further required to divest themselves of most financial interests in any medical industry-related concerns. For more information on NASS' Level 1 disclosure policy, please visit NASS website.							

Individual physician respondents answered at individual level. Specialty Society respondents provided aggregate information that may be relevant to the group of clinicians who provided input to the Society-

level response.
NR: not reported.

Responses

For individuals with sacroiliac joint pain, are there objective condition characteristics (i.e., patient selection criteria) and management criteria (i.e., regarding prior trial of standard treatment options) that would describe use of SIJ fusion that improves health outcomes and is considered in accordance with generally accepted medical practice? If Yes, please explain:

No.	Yes/No	Explanation
1	Yes	Objective Condition Characteristics for SI Joint Fusion - The evaluation of a patient for possible sacroiliac (SI) joint pain involves careful attention to a patient's history and physical examination. When a patient's symptoms and signs arouse sufficient clinical suspicion, additional tests are then required to confirm the diagnosis of SI joint dysfunction. **History** The first step in identifying a patient with back or leg pain caused by the SI joint is to develop a clinical suspicion for this diagnosis based on their history. Patients with SI joint dysfunction will have a significant history of chronic back and/or leg pain unresponsive to other therapies and does not follow a dermatopic distribution. Patients usually report pain in the area medial to and below the posterior superior iliac spine (PSIS). Pain complaints can also be reported as radiating to the buttocks, posterior thigh, groin, or lower leg. Patients may describe an exacerbation of pain when transitioning from sitting to standing or sitting. Pain with extending periods of sitting may be relieved when shifting their weight shifted to the asymptomatic side. In order to warrant evaluation for surgery, pain should be intolerable and cause significant disability. Several studies suggest that a history of lumbar or lumbosacral fusion may predispose a patient to develop SI joint pain. As such, a physician should consider a diagnosis of SI joint dysfunction in patients with new or persistent back pain complaints after a lumbar fusion. Analyzing a cohort of patients with SI joint pain after fusion, Maigne et al. found that these patients tended to have post-operative pain that had a different character from the pre-operative complaints and a pain-free interval of at least 3 months between surgery and the onset of new symptoms. Other studies analyzing a similar cohort of recurrent pain localized to the SI joint after lumbar fusion found that these patients tended to have inadequately restored lumbar lordosis (Shin et al.) and increased pelvic tilt with more significant retroversion of the pelvis compared to asymptomatic individuals (Cho et al.). Unoki et al. showed that fusion of multiple segments (at least 3) also had an increased risk for developing SI joint pain after lumbar surgery. Based on these studies, a history of lumbar fusion with recurrent pain complaints should arouse a healthy suspicion of SI joint dysfunction especially in patients with long-segment constructs or with suboptimal correction of spinopelvic parameters. Lastly, it is important to conduct a thorough medical history to screen for conditions causing SI joint pathology that cause pain but are unlikely to respond to surgical stabilization of the joint (eg, inflammatory arthropathy, metastatic disease, residual pain from recent trauma). **Physical Examination** In addition to a convincing history of SI joint dysfunction, several findings on physical examination justify continued evaluation of the SI joint as a cause of back and leg pain. Recreation of a patient's pain complaints during provocative maneuvers over the SI joint correlates closely with a diagnosis of SI joint dysfunction by SI block. Provocative maneuvers include Patrick test, iliac distraction, iliac compression, thigh thrust, and Gaenslen test. A positive response to three or more maneuvers is highly suggestive of SI joint pain that can be relieved by SI joint block. Additional physical examination findings suggestive of SI joint dysfunction include the Fortin finger test (in which the patient is asked to point to the location of most severe pain and identifies the sacral sulcus) and tenderness to palpation over the sacral sulcus.

No.	Yes/No	Explanation
		Imaging No imaging studies have been shown to identify sacroiliac dysfunction reliably. X-rays, CT scans, and MRI scans of the SI joint often show a relatively normal appearance even in patients with diagnosed SI joint dysfunction. Nonetheless, X-rays and/or CT scans of the SI joint are important for ruling out confounding sources of pain (fracture, tumor, severe arthropathy, hip pathology). MRI of the lumbar spine is important to rule out spine pathology as a competing cause of back pain. **Response to SI Joint Block** Image-guided SI joint blockade using injection of local anesthetic is widely regarded as the gold standard for diagnosing SI joint dysfunction. This is supported in the fact that all randomized controlled studies on SI joint fusion and most case series use relief of pain with SI joint block as a major inclusion criterion. The majority of studies recommend pain relief of at least 75% after multiple SI joint blocks, and confirmed on repeat injection. Using this criterion as justification for performing SI joint fusion, the available literature shows a significant and durable relief of pain complaints after SI fusion. Nonetheless, an analysis by Polly et al. suggests that requiring a treatment effect of greater than 75% after an SI joint block to establish a diagnosis is too restrictive. In this study, patients experiencing only 50-75% relief of symptoms after a block have excellent outcomes with rates equivalent to the higher standard for treatment effect. • Polly D, Cher D, Whang PG, et al. Does Level of Response to SI Joint Block Predict Response to SI Joint Fusion? Int J Spine Surg. 2016;10:4. PMID 26913224 **Management Criteria for SI Joint Fusion** Prior to being a candidate for surgical intervention, patients must first attempt conservative management of their pain complaints. These non-surgical modalities are similar in many ways to the management of back pain thought to be caused by lumbar spondylosis. Patients must undergo a course of physical therapy and medical management with NSAIDs. Patients should also be counseled about smoking cessation, as there is some evidence that smoking may exacerbate pain complaints as well as negatively impact response to SI fusion. Some patients receive benefit from pelvic belt stabilization and bracing. Generally non-surgical management for at least 6 months before considering surgical fusion is recommended. There are two nonoperative interventional procedures available to patients experiencing SI joint dysfunction: SI joint steroid injections and radiofrequency ablation. SI joint injection with corticosteroids has been proposed and studied as a way to relieve pain from SI joint dysfunction. While there is no clear evidence to recommend steroid injections as the most effective or durable treatment for pain, it may help provide symptomatic relief during the interval of medical management. SI Joint radiofrequency ablation has also been well-studied for relief of SI joint pain. Studies indicate this treatment can offer a slightly greater durability of response compared to steroid injections but the effect is still transient for most patients. A study by Vanaclocha et al. compares these interventions and SI joint fusion and shows clear superiority of fusion over SI injection and nerve ablation for effective and durable pain relief. For these reasons, steroid injections and nerve ablations are not required in order to proceed with fusion but may offer relief to patients unwilling or unable to proceed with fusion. • Vanaclocha V, Herrera JM, Sáiz-Sapena N, et al. Minimally invasive sacroiliac joint fusion, radiofrequency denervation, and conservative management for sacroiliac joint pain: 6-year comparative case series. Neurosurgery. 2017 Apr 20. [Epub ahead of print] PMID: 28431026
2	Yes	Reference numbers cited in parentheses refer to list of publications included in response to Question 4.

No.	Yes/No	Explanation
		Proper SIJ pain diagnosis is key to appropriate patient management. There is an accepted diagnostic algorithm for SIJ pain that combines medical history, physical examination and confirmatory diagnostic SIJ block. **Medical History** Patients with SIJ pain typically report pain in the buttock(s), with possible radiation into the groin or upper legs. The spectrum of pain and disability from SIJ dysfunction is wide. Patients may be affected mildly or may have substantial functional impairment (eg, cannot sit or stand for more than five minutes, cannot perform normal activities of daily living (ADLs), cannot walk up or down stairs, may require a wheelchair). Patients report the following activities to worsen pain: sitting on affected side; lying on affected side; rolling over in bed; ascending or descending stairs; getting in/out of a car. Patients with chronic SIJ dysfunction seeking surgical treatment have marked impairment of quality of life,(1) similar to that observed in other conditions commonly treated surgically. (2) Patients often have a history of prior lumbar fusion, either because the condition was misdiagnosed (the wrong joint was operated on) or as a result of adjacent segment degeneration of the SI joint. **Physical Examination** Specific physical examination tests that stress the SIJ (e.g., distraction test, compression test, thigh thrust, FABER (Patrick's) test, Gaenslen's maneuver) are typically performed in the physician's office. A meta-analysis of physical examination tests suggests that having 3 or more positive tests is highly predictive of a positive diagnostic SI joint block. (3) **Diagnostic SIJ Block** The diagnosis of SIJ pain is confirmed by performing a fluoroscopy-guided percutaneous SIJ block with local anesthetic (e.g., lidocaine). An acute reduction in typical pain indicates a positive test, suggesting that the injected joint is a pain generator. A study of patients undergoing blinded injection of saline or local anesthetic showed markedly high responses to the latter, validating the test. (4) Because other pathologic processes can coexist with SIJ pain, physicians should discuss with patients the degree to which treatment of the SIJ may relieve overall pain and disability without addressing other pain generators. While a marked response to SIJ block might be predicted to reassure the physician that treatment will produce larger responses to anatomic-based treatment, published data suggest little, if any, relationship. In two large prospective clinical trials of SIJ fusion, patients with suspected SIJ pain were included only if intra-articular SIJ block resulted in a 50% or greater amount of acute pain relief within 60 minutes after the block. The degree of improvement at 6 and 12 months after SIJ fusion was unrelated to the degree of acute pain relief during the block. (5) **Imaging** Apart from ankylosing spondylitis, in which MRI can show edema consistent with inflammation, imaging of the SIJ typically does not provide valuable diagnostic information. In many cases, imaging can show non-specific findings in the SIJ.6 Rather, imaging is used to ensure that the patient does not have alternative diagnoses that could mimic SIJ pain (e.g., hip osteoarthritis, occasionally L5/S1 spine degeneration). **Bilateral SIJ Pain** Bilateral SIJ pain is not uncommon. Diagnosis of bilateral SIJ pain must be made on the basis of a history of bilateral pain, bilateral elicitation of pain on physical examination maneuvers that stress each SIJ, and acute bilateral decrease in pain upon CT or fluoroscopy-guided intra-articular SIJ block with local anesthetic. Bilateral SIJ fusion is probably best performed serially as successful treatment of one side may improve pain/disability to a degree acceptable by the patient. SIJ fusion of the contralateral side may be necessary if contralateral SIJ pain continues and disability is significant for the patient.

No.	Yes/No	Explanation
		It is expected that a person would not undergo more than one SIJ fusion per side per lifetime except in the rare case that a revision is needed. **Indications/Limitations for MIS SIJ Fusion** • Per the ISASS Policy Statement(7) on minimally invasive sacroiliac joint (MIS SIJ) fusion surgery, patients who have all of the following criteria may be eligible for MIS SIJ fusion: • Significant SIJ pain that impacts quality of life or significantly limits activities of daily living; • SIJ pain confirmed with at least 3 physical examination maneuvers that stress the SIJ (see list provided above) and reproduce the patient's typical pain. Confirmation of the SIJ as a pain generator with ≥50% acute decrease in pain upon fluoroscopically-guided diagnostic intra-articular SIJ block using local anesthetic. Prospective trials have shown that patients with SIJ pain responses of 50-75% respond to MIS SIJ fusion as well as those with 75-100% acute responses. (There is no evidence that the SIJ block provides long-term pain relief and should be conducted for diagnostic, not therapeutic, purposes.) • Failure to respond to at least 6 months of non-surgical treatment consisting of non-steroidal anti-inflammatory drugs and physical therapy. Failure to respond means continued pain that interferes with activities of daily living and/or results in functional disability; • Additional or alternative diagnoses that could be responsible for the patient's ongoing pain or disability have been considered. Physicians should take into account that patients can have multiple pain generators and addressing just one pain generator may not adequately relieve disability or all back pain. MIS SIJ fusion is NOT indicated for patients with the following: • Less than 6 months of SIJ pain and/or functional impairment • Failure to pursue conservative treatment of the SIJ (unless contra-indicated); • Pain not confirmed with a diagnostic SIJ block; • Presence of other pathology that would substantially prevent the patient from deriving benefit from SIJ fusion.
3	Yes	The North American Spine Society's coverage recommendations on SI joint fusion provides evidence-based criteria for diagnosing SI joint pain and selection criteria for surgical intervention. The excerpt below is from the NASS statement: 1. Patients have undergone and failed a minimum 6 months of intensive nonoperative treatment that must include medication optimization, activity modification, bracing and active therapeutic exercise targeted at the lumbar spine, pelvis, SIJ and hip including a home exercise program. 2. Patients report typically unilateral pain that is caudal to the lumbar spine (L5 vertebrae), localized over the posterior SIJ, and consistent with SIJ pain. 3. A thorough physical examination demonstrating localized tenderness with palpation over the sacral sulcus (Fortin's point, ie, at the insertion of the long dorsal ligament inferior to the posterior superior iliac spine or PSIS) in the absence of tenderness of similar severity elsewhere (e.g., greater trochanter, lumbar spine, coccyx) and other obvious sources for their pain do not exist. 4. 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.

No.	Yes/No	Explanation
		5. Absence of generalized pain behavior (e.g., somatoform disorder) or generalized pain disorders (e.g., fibromyalgia) 6. Diagnostic imaging studies that include ALL of the following: a. Imaging (plain radiographs and a CT or MRI) 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 plain radiograph) to rule out concomitant hip pathology c. Imaging of the lumbar spine (CT or MRI) to rule out neural compression or other degenerative condition that can be causing low back or buttock pain d. Imaging of the SI joint that indicates evidence of injury and/or degeneration 7. At least 75 percent reduction of pain for the expected duration of the anesthetic used following an image-guided, contrast-enhanced intra-articular SIJ injection on two separate occasions 8. A trial of at least one therapeutic intra-articular SIJ injection (ie, corticosteroid injection)
4	NR	Reference numbers cited in parentheses refer to list of publications included in response to Question 4. We have reviewed the BlueCross BlueShield Diagnosis and Treatment of Sacroiliac Joint Pain, Summary of Evidence. In general, this is a well-written, comprehensive review, but we have the following comments that should be considered. Diagnosis The document is correct in asserting that there is no other “reference standard” for identifying a painful sacroiliac (SI) joint besides a diagnostic injection. Many pain medicine organizations consider it to be “self-evident” that a positive response to a diagnostic block indicates a painful joint (eg, Spine Intervention Society, American Society of Interventional Pain Physicians), but we know from multiple studies performed for not only SI joint pain (references: 10, 14, 19, 18, 26, 15), but also lumbar and cervical facet pain, that there is a considerable false-positive rate for uncontrolled blocks. These studies have mostly considered failure of a 2nd block to provide adequate relief after a 1st block did provide relief to be evidence of a false-positive response, but without another reference standard, one cannot ascertain whether the positive block was a false-positive, or the negative block was a false-negative. The authors also state that there is no reference standard besides injections, but multiple investigators have found a strong correlation (> 80% sensitivity and >75% specificity) between response to blocks and $\geq$ 3 positive provocation maneuvers (references: 25, 26, 14, 31, 2, 24). This provides indirect confirmatory evidence for the validity of diagnostic injections. iFUse This is a minimally-invasive surgical technique designed to treat degenerative SIJ arthritis and instability; it is not intended to treat extra-articular SI joint pain, which is the target population of radiofrequency ablation (the lateral branches innervate the SI joint ligaments, not the joint capsule; reference 5). The SI joint is designed for stability and there is relatively little motion at the joint. Patients in the study were diagnosed via intra-

No.	Yes/No	Explanation
		articular injections, though the characteristics of those injections were not noted (the capacity of the SI joint is < 2.5 ml, so high volumes will anesthetize the ligaments or rupture the capsule). In two studies (references 29, 21), they considered patients with contrast extravasation during the injection as having “disruption”, and included them in the study. However, this is quite common (, and capsular disruption is different than “instability”, and is probably not a good indication for surgery (ie, how would fusion heal rupture of a fibrous capsule?). All RCTs reported outstanding results at > 1-year follow-up, which were much better than for non-industry RCTs that previously SIJ fusion (references: 22, 28, 3), and RCTs evaluating fusion surgery for lumbar degenerative conditions (reference 8) or cervical degenerative conditions (references 30, 9). These discrepancies may be due to either the rationale for iFuse (ie, fusion works, but people often do poorly because of the trauma associated with such a large operation) or methodological flaws inherent in randomized surgical trials (eg, inability to blind evaluators or patients, patients allocated to non-surgical therapy already failed non-surgical therapy, bias). In all studies, the large majority of patients were fused for degenerative conditions (which the authors termed “degenerative sacroiliitis), rather than SI joint disruption or instability. Yet, it is not clear how active inflammation was identified, or why fusion might be an effective treatment for active inflammation. There was also considerable overlap between investigators in the 3 RCTs evaluating iFuse, which raises questions regarding generalizability. In summary, SI joint pain is a common condition, and there are no long-term treatment options for either intra-articular SI joint pain or disruption. The evidence supporting fusion for other degenerative conditions is very weak, and most of the patients in the RCTs were fused for degenerative conditions. The reported results were extraordinary, much better than any RCT evaluating cervical or lumbar fusion, or SI joint fusion using an open surgical technique, but there were significant methodological flaws in the studies. There is little doubt that iFuse might be effective for individuals with true instability at the joint (ie, increased motion, rather than contrast extravasation indicating capsular disruption), and may provide some improvement for patients with degenerative joint pain, though these patients need to be better identified.
5	Yes	The North American Spine Society Criteria are the most respected and generally used criteria. Most patients with SI joint pain will respond to the conservative therapies listed. However, one criteria that I think should be added is a reduction in opioid use prior to the fusion. The literature does not show much reduction in opioids after fusion. This is because one must demonstrate that the patient can tolerate an opioid reduction before performing an advanced invasive procedure like percutaneous fusion. If the patient can tolerate at least a 50% reduction without aberrant behaviors, they are likely to be able to go off the opioid after the fusion. For those that show significant aberrant behaviors, psychosocial therapies should be the mainstay of therapy. Opioid taper takes a lot of effort on the part of the patient and physician. If neither is willing, it will not be successful.
6	Yes	Diagnostic and therapeutic injections.
7	Yes	The only generally accepted objective criteria for the diagnosis of sacroiliac joint pain is response to image-guided sacroiliac injections. Patients who do not respond to the injections generally do not improve with directed therapies. Patients who do improve with the injections will usually respond to fusion therapies.
8	Yes	Diagnosis of SI joint pain/dysfunction is typically based on meeting a set of clinical criteria for location of pain, positive provocative maneuvers, and diagnostic injections.
9	Yes	While the evidence is low, I agree with the NASS recommendations as outlined in their report particularly focusing on the fact that a patient has undergone and failed a minimum 6 months of intensive nonoperative treatments, the patient has a complaint and physical exam consistent with SIJ pain, Imaging of the SI joint that excludes the presence of destructive lesions, 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 and finally a successful trial of at least one therapeutic intra-articular SIJ injection with a corticosteroid

No.	Yes/No	Explanation
10	Yes	I would agree with the NASS guidelines.

NR: no response.

For those who answered Yes to Question 1 regarding individuals with SIJ pain who have the objective condition characteristics and who meet the management criteria you listed and receive SIJ fusion,

- Use the 1 to 5 scale outlined below to indicate your level of confidence that there is adequate evidence supporting an improvement in health outcomes.

No.	Low Confidence		Intermediate Confidence		High Confidence
	1	2	3	4	5
1				X	
2					X
3				X	
4	No response provided				
5				X	
6			X		
7			X		
8		X			
9		X			
10			X		

- Use the 1 to 5 scale outlined below to indicate your level of confidence that this clinical use is in accordance with generally accepted medical practice.

No.	Low Confidence		Intermediate Confidence		High Confidence
	1	2	3	4	5
1				X	
2					X
3				X	
4	No response provided				
5				X	
6				4	
7					X
8		X			
9			X		
10			3		

Additional comments and/or any citations supporting your clinical input on the use of SIJ fusion for individuals with SIJ pain.

No.	Additional Comments
1	• Maigne J, Planchon C. Sacroiliac joint pain after lumbar fusion. A study with anesthetic blocks. Eur Spine J. 2005 Sep; 14(7):654-8. PMID 15761709. Patients experiencing persistent or recurrent pain after lumbar fusion underwent SI blocks. 35% had a positive result to SI block (>75% improvement). Predictive criteria of response to SI block was pain different from pre-operative symptoms and those having a pain-free interval after lumbar fusion of >3 months. • Shin M, Ryu K, Hur J, et al. Comparative study of lumbopelvic sagittal alignment between patients with and without sacroiliac joint pain after lumbar interbody fusion. Spine (Phila PA 1976). 2013 Oct 1; 38(21):E1334-41. PMID 23797504. Higher rates of SI joint pain after lumbar fusion in patients with greater pelvic tilt and inadequately restored lumbar lordosis. • Cho D, Shin M, Hur J, et al. Sagittal sacropelvic morphology and balance in patients with sacroiliac joint pain following lumbar fusion surgery. J Korean Neurosurg Soc. 2013 Sep; 54(3):201-6. PMID 24278648. Patients with SI joint pain after lumbar fusion tended to have more pelvic retroversion than asymptomatic controls. • Unoki E, Abe E, Murai, H, et al. Fusion of multiple segments can increase the incidence of sacroiliac joint pain after lumbar or lumbosacral fusion. Spine (Phila PA 1976). 2016 Jun; 41(12):999-1005. PMID 26689576. Fusion of multiple segments (>3) can increase the incidence of SI joint pain after lumbar or lumbosacral fusion. • DePalma M, Ketchum J, Saulio T. Etiology of chronic low back pain in patients having undergone lumbar fusion. Pain Med. 2011 May; 12(5):732-9. PMID 21481166. Patients with low back pain after lumbar fusion had positive responses to injections to SI joint, fusion hardware, zygohypophyseal joint, or provocation discography. Of these different potential sources of back pain after lumbar fusion, SI joint was the most common source with 43% compared to 13% in patients with back pain without fusion. • Liliang P, Lu K, Liang C, et al. Sacroiliac joint pain after lumbar and lumbosacral fusion: findings using dual sacroiliac joint blocks. Pain Med. 2011 Apr; 12(4):565-70. PMID 21463470. Patients with lumbar/lumbosacral fusions were evaluated for SI joint pain with physical examination. 52 had positive response to at least three provocative tests and selected to receive diagnostic blocks. 40% had a positive response and the characteristics of these patients most likely to response included unilateral pain complaints, more than 3 positive responses to provocative maneuvers, and post-operative pain characteristics different from pre-operative complaints. • Polly D, Cher D, Whang P, et al. Does level of response to SI joint block predict response to SI joint fusion? Int J Spine Surg. 2016 Jan 21; 10:4. PMID 26913224. This study is a subgroup analysis of INSITE and SIFI prospective SI joint fusion showing that the degree of pain relief from a SI joint block did not predict outcome after fusion. Successful outcomes from SI joint fusion were comparable in those patients experiencing >75% pain relief from SI block as those with 50-75% relief. This suggests that the higher 75% relief standard may be overly aggressive in discerning patients likely to benefit from SI joint fusion.

No.	Additional Comments
	• Vanaclocha V, Herrera J, Saiz-Sapena N, et al. Minimally invasive sacroiliac joint fusion, radiofrequency denervation, and conservative management for sacroiliac joint pain: 6-year comparative case series. Neurosurgery. 2017 Apr 20. [Epub ahead of print]. PMID: 28431026. This study is a retrospective analysis of patients with SI joint pain and up to 6 years of follow up. Patients were managed with either conservative management, SI joint steroid injections, sacroiliac denervation, or SI joint fusion. Conservative management and injections showed no long-term improvement in pain or disability. SI joint denervation offered mild pain and disability improvements. SI joint fusion offered better long-term pain relief compared to all other treatments with lower opioid use and better work status.
2	Reference numbers cited in parentheses refer to list of publications included in response to Question 4. After performing a thorough review of all available data and literature on the procedure, in March 2014, ISASS issued a comprehensive policy statement on MIS SIJ fusion and updated that policy in March 2015, December 2015 and July 2016.(7) The Policy Statement includes a discussion on the SIJ as a pain generator, information on diagnosing the SIJ as the primary source of pain, a discussion of non-surgical and surgical treatment options and recommended coverage criteria for MIS SIJ fusion. Please note, the ISASS Policy does not endorse any specific MIS SIJ fusion system. There are numerous devices available that have received FDA 510(k) clearance for use in MIS SIJ fusion surgery. ISASS maintains that the instrumentation utilized in a MIS SIJ fusion procedure is the purview of surgeon preference. In 2008, the U.S. Food and Drug Administration approved the first minimally invasive device for sacroiliac joint fusion and MIS SIJ fusion surgery obtained a Category I CPT® code effective January 1, 2015. The body of literature on MIS SIJ fusion has grown substantially and continues to show positive outcomes for patients who receive the surgery. In addition to outcomes published of multiple retrospective case series(8-14) and comparative series(15-17), published results from two prospective, multi-center, randomized controlled trials of MIS SIJ fusion vs non-surgical management (NSM)(18, 19) and a prospective multi-center single-arm trial(20) have substantiated high rates of pain relief, improvement in functional measures (Oswestry Disability Index (ODI), SF-36, and EQ-5D) and a low rate of both revisions and serious adverse events. In both prospective, multi-center, randomized controlled trials of MIS SIJ fusion vs NSM,(18, 19) pain relief, disability reduction and improvement in quality of life were markedly higher in MIS SIJ fusion subjects compared to NSM subjects. Polly et al.(18) found in the MIS SIJ fusion group, mean SIJ pain improved rapidly and was sustained (mean improvement of 55.4 points, 0-100 scale) at month 24. The 6-month mean change in the NSM group (12.2 points on the 0-100 scale) was substantially smaller than that in the MIS SIJ fusion group (by 38.3 points, p<.0001 for superiority). By month 24, 83.1% and 82.0% received either clinical improvement or substantial clinical benefit in VAS SIJ pain score. Similarly, 68.2% and 65.9% had received clinical improvement or substantial clinical benefit in ODI score at month 24. In the NSM group, these proportions were <10% with non-surgical treatment only. Parallel changes were seen for EQ-5D and SF-36, with larger changes in the surgery group at 6 months compared to NSM. The rate of adverse events related to MIS SIJ fusion was low and only 3 subjects assigned to MIS SIJ fusion underwent revision surgery within the 24-month follow-up period. In the other randomized trial, Sturesson et al.(19) found mean self-rated low back pain improved by 43.3 points (0-100 scale) in the MIS SIJ fusion group and 5.7 points in the NSM group (difference of 38.1 points, p < 0.0001) at 6 months. Mean ODI improved by 26 points in the MIS SIJ fusion group and 6 points in the NSM group (p < 0.0001). Active straight leg raise test, EQ-5D-3L, walking distance and satisfaction were statistically superior in the MIS SIJ fusion group. The frequency of adverse events did not differ between groups. Other relevant peer-reviewed published papers adding to the evidence base on MIS SIJ fusion include safety analyses,(21, 22) economic analyses,(23-25) cost analyses,(26, 27) a validation study,(28) burden of disease analyses,(29, 30) and a systematic review.(31) A recently published 6-year case series(36) comparing MIS SIJ fusion, radiofrequency denervation and conservative management for SIJ pain showed very good patient outcomes (ie, improved pain and disability, decrease in opioid use and good final work status) after MIS SIJ fusion and poor health outcomes (ie, worsening pain and disability, increased use of opioids and poor long-term work status) after conservative management. The poor long-term response, higher opioid use, and poor work status for conservative management contrasts significantly to improvements from MIS SIJ fusion. In terms of bone growth and fusion rates for MIS SIJ fusion, independent analysis showed binding of bone to the iFuse implant (SI-Bone Inc., San

No.	Additional Comments
	Jose, CA) in nearly 100% of cases.(37) The surface's device design is similar to other orthopedic implants (eg, hip implants) where bone binding has been shown. A 5-year study shows bridging bone across the SIJ in 87% of cases.(11) Kube and Muir(38) demonstrated an analogous fusion rate of 88% bridging bone at 1 year using SImmetry (Zyga, Minnetonka, MN), a screw based technology. Taken together, these studies represent a substantial amount of evidence supporting MIS SIJ fusion as a safe and effective treatment option. In addition, the National Institute for Health and Care Excellence (NICE) reviewed MIS SIJ fusion and concluded, "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 provided that standard arrangements are in place for clinical governance, consent and audit." (https://www.nice.org.uk/guidance/IPG578/chapter/1-Recommendations) Please see the following attachments to this form: 1. The ISASS Policy Statement on MIS SIJ Fusion (Available online at https://www.isass.org/public-policy/isass-policy-statement-minimally-invasive-sacroiliac-joint-fusion-july-2016/); and 2. A letter submitted by ISASS to BCBSA Evidence Street on February 20, 2017 outlining additional concerns with the Evidence Review on the Diagnosis and Treatment of Sacroiliac Joint Pain (6.01.23).
3	It is the opinion of NASS that the peer-reviewed published evidence supporting the efficacy of percutaneous SI joint fusion continues to accumulate. The BCBSA Evidence Street review identifies that there are now 2 randomized controlled trials as well as several well-designed case series and multiple other peer-reviewed publications that all demonstrate the efficacy of percutaneous SI joint fusion. The magnitude of the effect in both RCTs was quite significant. At 6 month follow-up, Whang found a >15 point improvement in ODI in 75% of fusion patients vs 27% in controls. At 6 months, Sturesson found that VAS pain improved 43.4 points in the fusion group vs 5.7 points in the control group and that ODI improved 25.5 points in the fusion group vs 5.8 points in the control group. The results of both studies were also noted to be highly statistically significant. The longer-term follow-up studies demonstrate the durability of the results at 2 years. Adverse effects and revision rates have been reported and are consistent with those reported for other surgical interventions. NASS would like to raise concerns regarding BCBSA's criticism of the RCTs as being non-blinded. Patient blinding in surgery requires a sham procedure arm. Sham surgery, especially in the spine, exposes the patient to direct harm and risk. For this reason, many Institutional Review Boards will not accept sham-blinded studies. Even when accepted, patient enrollment is difficult and selection bias occurs in that patients with more severe symptoms will not participate. NASS is also perplexed by and disagrees with criticism of self-reported outcomes in the studies cited. Validated patient-reported outcomes measures are the gold standard assessment tool for interventions designed to address a patient's pain or functional limitations. References (this list is not comprehensive and the studies were already identified in the Evidence Street Review): 1. Whang P, Cher D, Polly D, et al. Sacroiliac joint fusion using triangular titanium implants vs non-surgical management: six-month outcomes from a prospective randomized controlled trial. Int J Spine Surg. 2015;9:6. PMID 25785242. 2. Polly DW, Cher DJ, Wine KD, et al. Randomized controlled trial of minimally invasive sacroiliac joint fusion using triangular titanium implants vs nonsurgical management for sacroiliac joint dysfunction: 12-month outcomes. Neurosurgery. Nov 2015;77(5):674-691. PMID 26291338. 3. Polly DW, Swofford J, Whang PG, et al. Two-year outcomes from a randomized controlled trial of minimally invasive sacroiliac joint fusion vs non-surgical management for sacroiliac joint dysfunction. Int J Spine Surg. 2016;10:28. PMID 27652199. 4. Sturesson B, Kools D, Pflugmacher R, et al. Six-month outcomes from a randomized controlled trial of minimally invasive SI joint fusion with triangular titanium implants vs conservative management. Eur Spine J. 2017 Mar;26(3):708-719. PMID 27179664. 5. Rudolf L. Sacroiliac joint arthrodesis-MIS technique with titanium implants: report of the first 50 patients and outcomes. Open Orthop J. 2012;6:495-502. PMID 23284593. 6. Duhon BS, Cher DJ, Wine KD, et al. Triangular titanium implants for minimally invasive sacroiliac joint fusion: a prospective study. Global Spine J. May 2016;6(3):257-69. PMID 27099817.

No.	Additional Comments
	7. Duhon BS, Bitan F, Lockstadt H, et al. Triangular titanium implants for minimally invasive sacroiliac joint fusion: 2-year follow-up from a prospective multicenter trial. Int J Spine Surg. 2016;10:13. PMID 27162715. 8. Rudolf L, Capobianco R. Five-year clinical and radiographic outcomes after minimally invasive sacroiliac joint fusion using triangular implants. Open Orthop J. 2014;8:375-83. PMID 25352932. 9. Miller LE, Reckling WC, Block JE. Analysis of post market complaints database for the iFuse SI Joint Fusion System(R): a minimally invasive treatment for degenerative sacroiliitis and sacroiliac joint disruption. Med Devices (Auckl). 2013;6:77-84. PMID 23761982. 10. Cher DJ, Reckling WC, Capobianco RA. Implant survivorship analysis after minimally invasive sacroiliac joint fusion using the iFuse Implant System((R)). Med Devices (Auckl). 2015;8:485-92. PMID 26648762. 11. Schoell K, Buser Z, Jakoi A, et al. Postoperative complications in patients undergoing minimally invasive sacroiliac fusion. Spine J. 2016 Nov; 16(11):1324-32. PMID: 27349627. 12. North American Spine Society (NASS). NASS coverage policy recommendations: Percutaneous sacroiliac joint fusion. 2015. Available online at:https://www.spine.org/PolicyPractice/CoverageRecommendations/CoverageRecommendations.aspx. Accessed November 16, 2015.
4	Also see information in response to Question 1. Reference numbers cited in parentheses refer to list of publications included in response to Question 4. **Therapeutic value of sacroiliac joint injections** The sacroiliac joint is by far the largest “spinal joint”, and contains both extra- (e.g., ligaments, muscles) and intra-articular portions. The extra-articular portion could also be classified into dorsal and ventral components, with the latter not amenable to blockade. When considering the evidence for blocks, we believe that the placebo-controlled trials showing benefit for steroid injections (in spondyloarthropathy patients [reference 20] in patients with and without spondyloarthropathy [references 16,17]) should be considered. The 2 Luukkainen et al. studies were included in the Hansen et al. systematic review cited in the summary of evidence (7), but the Maugars et al. study was not. Although spondyloarthropathy generally refers to a group of inflammatory rheumatic diseases (e.g., ankylosing spondylitis), many patients who present with signs and symptoms consistent with sacroiliac joint disease have evidence of inflammation (sacroiliitis). Whereas the small Hanly et al. study (6) followed individuals through 6 months and reported persistent benefit in over half of the patients, the 2 Luukainen et al. studies (16,17) followed patients for only 1 and 2 months and did not report secondary outcome measures. **Radiofrequency denervation** The Cohen et al. (4) study used intra-articular injections without prognostic lateral branch blocks to select patients for a treatment that targets extra-articular pain, though the high volume used likely anesthetized the SI joint ligaments as well. This study also treated L5-S1 facet joint pain (since the L4 and L5 nerves innervate the L5-S1 facet joint). The negative Tilburg et al. study evaluated a newer procedure which is essentially designed to significantly reduce the time required to perform the procedure (one cannula insertion to ablate multiple nerves), which comes at the expense of precision. The authors screened only 79 patients to enroll 60 subjects, and considering that 15%-30% of people with predominantly axial low back pain have the SI joint as their primary pain generator, it is likely that few patients enrolled actually had SI joint pain. The authors acknowledged enrolling patients with “sciatica”, which should not respond to any SI joint intervention. The screening test ($\geq$ 2-point decrease in pain following the diagnostic injection) also was insufficient, because even individuals without the index condition will often obtain some benefit from an injection (ie, higher placebo response rates for injections than pills (references 11,12,13), local anesthetic injected into the muscles (1), and extravasation of the injectate into other potential pain generators).
5	My confidence in the therapy is based on my comments in section one. It requires a high level of patient selection. For those that fail conservative therapy, a detailed psychosocial assessment is required. And for those on opioids, an opioid taper as described above. Also, there is too much emphasis on the need for blinded sham-controlled trials for interventional therapies. These are extremely challenging to do and because of this, we cannot ignore our clinical experience. Real-world observational studies are helpful in these situations. NICE recently published a thorough review of percutaneous SI joint fusion (April 5, 2017 - available online

No.	Additional Comments
	at https://www.nice.org.uk/guidance/ipg578/resources/minimally-invasive-sacroiliac-joint-fusion-surgery-for-chronic-sacroiliac-pain-pdf-1899872114909893). They included randomized controlled trials and systematic reviews which were very favorable. Overall, percutaneous SI joint fusion has more evidence than corticosteroid injections and RFA with proper patient selection.
6	SI fusion is currently acceptable therapy in patients in whom significant response is noted with injection. SI joint fusion as part of the inferior portion of extensive thoracolumbar fusion (i.e., SI joint and pelvis) is an accepted approach. Increasing literature on the topic will enhance the knowledge base on this topic.
7	No additional comments listed.
8	Although criteria for the diagnosis of SI joint dysfunction is fairly well described, there is significant variability from study to study regarding the application of the diagnostic criteria. It is difficult to assess the efficacy of a treatment such as SI joint fusion when there is not a clearly defined and consistent manner of diagnosis from study to study. The vast majority of literature regarding outcomes following SI joint fusion surgery are low-quality retrospective studies or small sample size prospective studies with limited follow-up.
9	I believe the draft review of evidence is well written and highlights the challenge of the gathering high-level clinical guidelines as there are minimal non-industry supported studies for this intervention. This review also highlights the challenges present in conducting blinded high volume studies as this is not a common condition and fusion may help a selected group of patients.
10	Lingutla, K.K., Pollock, R. & Ahuja, S. Sacroiliac joint fusion for low back pain: a systematic review and meta-analysis. *Eur Spine J.* Jun 2016;25(6):1924-1931. PMID 26957096.

- Is there any evidence missing from the attached draft review of evidence?

No.	Yes/No	Citations of Missing Evidence
1	NR	
2	Yes	The literature review appears to be incomplete, with missing comparative studies,(15-17) missing case series, (8, 10, 12, 14, 32, 33, 34, 35, 36) missing systematic reviews, (31, 39, 40) a missing meta-analysis of prospective studies, (41) missing outcomes studies, (1, 28, 30, 42, 43, 44) missing economic studies, (23, 24, 25, 26, 27, 45) and missing biomechanical studies. (46, 47, 48) **References** 1. Cher D, Polly D, Berven S. Sacroiliac joint pain: burden of disease. Med Devices (Auckl). 2014 Apr 12; 7:73-81. PMID: 24748825. 2. Cher DJ, Reckling WC. Quality of life in preoperative patients with sacroiliac joint dysfunction is at least as depressed as in other lumbar spinal conditions. Med Devices (Auckl). 2015 Sep 16; 8:395-403. PMID: 26396547. 3. Szadek KM, van der Wurff P, van Tulder MW, et al. Diagnostic validity of criteria for sacroiliac joint pain: a systematic review. J Pain. 2009 Apr; 10(4):354-68. PMID: 19101212. 4. Broadhurst NA, Bond MJ. Pain provocation tests for the assessment of sacroiliac joint dysfunction. J Spinal Disord. 1998 Aug; 11(4):341-5. PMID: 9726305. 5. Polly D, Cher D, Whang PG, et al; INSITE Study Group. Does level of response to SI joint block predict response to SI joint fusion? Int J Spine Surg. 2016 Jan 21; 10:4. PMID: 26913224. 6. Eno JJ, Boone CR, Bellino MJ, et al. The prevalence of sacroiliac joint degeneration in asymptomatic adults. J Bone Joint Surg Am. 2015 Jun 3; 97(11):932-6. PMID: 26041855. 7. Lorio MP. ISASS Policy 2016 Update - Minimally Invasive Sacroiliac Joint Fusion. Coverage indications, limitations, and/or medical necessity. (Available online at:http://www.isass.org/public-policy/isass-policy-statement-minimally-invasive-sacroiliac-joint-fusion-july-2016/). 8. Bornemann R, Roessler PP, Strauss AC, et al. Two-year clinical results of patients with sacroiliac joint syndrome treated by arthrodesis using a triangular implant system. Technol Health Care. 2017; 25(2):319-25. PMID: 27858725.

No.	Yes/No	Citations of Missing Evidence
		9. Sachs D, Capobianco R, Cher D, et al. One-year outcomes after minimally invasive sacroiliac joint fusion with a series of triangular implants: a multicenter, patient-level analysis. Med Devices (Auckl). 2014 Aug 28; 7:299-304. PMID: 25210479. 10. Gaetani P, Miotti D, Risso A, et al. Percutaneous arthrodesis of sacro-iliac joint: a pilot study. J Neurosurg Sci. 2013 Dec; 57(4):297-301. PMID: 24091432. 11. Rudolf L, Capobianco R. Five-year clinical and radiographic outcomes after minimally invasive sacroiliac joint fusion using triangular implants. Open Orthop J. 2014 Oct 17; 8:375-83. PMID: 25352932. 12. Sachs D, Capobianco R. Minimally invasive sacroiliac joint fusion: one-year outcomes in 40 patients. Adv Orthop. 2013; 2013:536128. PMID: 23997957. 13. Sachs D, Kovalsky D, Redmond A, et al. Durable intermediate-to long-term outcomes after minimally invasive transiliac sacroiliac joint fusion using triangular titanium implants. Med Devices (Auckl). 2016 Jul 13; 9:213-22. PMID: 27471413. 14. Vanaclocha VV, Verdú-López F, Sánchez-Pardo M, et al. Minimally invasive sacroiliac joint arthrodesis: experience in a prospective series with 24 patients. J Spine. 2014; 3:185. doi:10.4172/2165-7939.1000185 (Available online at https://www.omicsgroup.org/journals/minimally-invasive-sacroiliac-joint-arthrodesis-experience-in-a-prospective-series-with-patients-2165-7939-3-185.php?aid=33352). 15. Smith AG, Capobianco R, Cher D, et al. Open versus minimally invasive sacroiliac joint fusion: a multi-center comparison of perioperative measures and clinical outcomes. Ann Surg Innov Res. 2013 Oct 30; 7(1):14. PMID: 24172188. 16. Ledonio CG, Polly DW Jr, Swiontkowski MF. Minimally invasive versus open sacroiliac joint fusion: are they similarly safe and effective? Clin Orthop Relat Res. 2014 Jun; 472(6):1831-8. PMID: 24519569. 17. Ledonio CG, Polly DW Jr, Swiontkowski MF, et al. Comparative effectiveness of open versus minimally invasive sacroiliac joint fusion. Med Devices (Auckl). 2014 Jun 5; 7:187-93. PMID: 24940087. 18. Polly DW, Swofford J, Whang PG, et al; INSITE Study Group. Two-year outcomes from a randomized controlled trial of minimally invasive sacroiliac joint fusion vs non-surgical management for sacroiliac joint dysfunction. Int J Spine Surg. 2016 Aug 23; 10:28. PMID: 27652199. 19. Sturesson B, Kools D, Pflugmacher R, et al. Six-month outcomes from a randomized controlled trial of minimally invasive SI joint fusion with triangular titanium implants vs conservative management. Eur Spine J. 2017 Mar; 26(3):708-19. PMID: 27179664. 20. Duhon BS, Bitan F, Lockstadt H, et al; SIFI Study Group. Triangular titanium implants for minimally invasive sacroiliac joint fusion: 2-year follow-up from a prospective multicenter trial. Int J Spine Surg. 2016 Apr 20; 10:13. PMID: 27162715. 21. Miller LE, Reckling WC, Block JE. Analysis of postmarket complaints database for the iFuse SI Joint Fusion System®: a minimally invasive treatment for degenerative sacroiliitis and sacroiliac joint disruption. Med Devices (Auckl). 2013 May 29; 6:77-84. PMID: 23761982. 22. Cher DJ, Reckling WC, Capobianco RA. Implant survivorship analysis after minimally invasive sacroiliac joint fusion using the iFuse Implant System(®). Med Devices (Auckl). 2015 Nov 23; 8:485-92. PMID: 26648762. 23. Ackerman SJ, Polly DW Jr, Knight T, et al. Comparison of the costs of nonoperative care to minimally invasive surgery for sacroiliac joint disruption and degenerative sacroiliitis in a United States commercial payer population: potential economic implications of a new minimally invasive technology. Clinicoecon Outcomes Res. 2014 May 24; 6:283-96. PMID: 24904218. 24. Ackerman SJ, Polly DW Jr, Knight T, et al. Management of sacroiliac joint disruption and degenerative sacroiliitis with nonoperative care is medical resource-intensive and costly in a United States commercial payer population. Clinicoecon Outcomes Res. 2014 Feb 11; 6:63-74. PMID: 24596468. 25. Ackerman SJ, Polly DW Jr, Knight T, et al. Comparison of the costs of nonoperative care to minimally invasive surgery for sacroiliac joint disruption and degenerative sacroiliitis in a United States Medicare population: potential economic implications of a new minimally-invasive technology. Clinicoecon Outcomes Res. 2013 Nov 20; 5:575-87. PMID: 24348055. 26. Cher DJ, Frasco MA, Arnold RJ, et al. Cost-effectiveness of minimally invasive sacroiliac joint fusion. Clinicoecon Outcomes Res. 2015 Dec 18; 8:1-14. PMID: 26719717. 27. Polly DW, Cher D. Ignoring the sacroiliac joint in chronic low back pain is costly. Clinicoecon Outcomes Res. 2016 Jan 21; 8:23-31. PMID: 26855595.

No.	Yes/No	Citations of Missing Evidence
		28. Copay AG, Cher DJ. Is the Oswestry Disability Index a valid measure of response to sacroiliac joint treatment? Qual Life Res. 2016 Feb; 25(2):283-92. PMID: 26245709. 29. Cher D, Polly D, Berven S. Sacroiliac joint pain: burden of disease. Med Devices (Auckl). 2014 Apr 12; 7:73-81. PMID: 24748825. 30. Cher DJ, Polly DW. Improvement in health state utility after sacroiliac joint fusion: comparison to normal populations. Global Spine J. 2016 Mar; 6(2):100-7. PMID: 26933610. 31. Heiney J, Capobianco R, Cher D. A systematic review of minimally invasive sacroiliac joint fusion utilizing a lateral transarticular technique. Int J Spine Surg. 2015 Jul 22; 9:40. PMID: 26273558. 32. Sachs D, Capobianco R. One year successful outcomes for novel sacroiliac joint arthrodesis system. Ann Surg Innov Res. 2012 Dec 27; 6(1):13. PMID: 23270468. 33. Cummings J Jr, Capobianco RA. Minimally invasive sacroiliac joint fusion: one-year outcomes in 18 patients. Ann Surg Innov Res. 2013 Sep 16; 7(1):12. PMID: 24040944. 34. Schroeder JE, Cunningham ME, Ross T, et al. Early results of sacro-iliac joint fixation following long fusion to the sacrum in adult spine deformity. HSS J. 2014 Feb; 10(1):30-5. PMID: 24482619. 35. Kancherla VK, McGowan SM, Audley BN, et al. Patient reported outcomes from sacroiliac joint fusion. Asian Spine J. 2017 Feb; 11(1):120-6. PMID: 28243380. 36. Vanaclocha V, Herrera JM, Sáiz-Sapena N, et al. Minimally invasive sacroiliac joint fusion, radiofrequency denervation, and conservative management for sacroiliac joint pain: 6-year comparative case series. Neurosurgery. 2017 Apr 20. [Epub ahead of print] PMID: 28431026. 37. Duhon BS, Cher DJ, Wine KD, et al; SIFI Study Group. Triangular titanium implants for minimally invasive sacroiliac joint fusion: a prospective study. Global Spine J. 2016 May; 6(3):257-69. PMID: 27099817. 38. Kube RA, Muir JM. Sacroiliac joint fusion: one year clinical and radiographic results following minimally invasive sacroiliac joint fusion surgery. Open Orthop J. 2016 Nov 30; 10:679-89. PMID: 28144378. 39. Lingutla KK, Pollock R, Ahuja S. Sacroiliac joint fusion for low back pain: a systematic review and meta-analysis. Eur Spine J. 2016 Jun; 25(6):1924-31. PMID: 26957096. 40. Zaidi HA, Montoure AJ, Dickman CA. Surgical and clinical efficacy of sacroiliac joint fusion: a systematic review of the literature. J Neurosurg Spine. 2015 Jul; 23(1):59-66. PMID: 25840040. 41. Dengler J, Duhon B, Whang P, et al; INSITE, iMIA, SIFI study groups. Predictors of outcome in conservative and minimally invasive surgical management of pain originating from the sacroiliac joint: a pooled analysis. Spine (Phila Pa 1976). 2017 Mar 27. [Epub ahead of print] PMID: 28350586. 42. Dengler J, Sturesson B, Kools D, et al; and the iMIA study group. Referred leg pain originating from the sacroiliac joint: 6-month outcomes from the prospective randomized controlled iMIA trial. Acta Neurochir (Wien). 2016 Nov; 158(11):2219-24. PMID: 27629371. 43. Capobianco R, Cher D; SIFI Study Group. Safety and effectiveness of minimally invasive sacroiliac joint fusion in women with persistent post-partum posterior pelvic girdle pain: 12-month outcomes from a prospective, multi-center trial. Springerplus. 2015 Oct 5; 4:570. PMID: 26543705. 44. Spain K, Holt T. Surgical revision after sacroiliac joint fixation or fusion. Int J Spine Surg. 2017 Jan 19; 11:5. PMID: 28377863. 45. Saavoss JD, Koenig L, Cher DJ. Productivity benefits of minimally invasive surgery in patients with chronic sacroiliac joint dysfunction. Clinicoecon Outcomes Res. 2016 Apr 11;8:77-85. PMID: 27114712. 46. Lindsey DP, Kiapour A, Yerby SA, et al. Sacroiliac joint fusion minimally affects adjacent lumbar segment motion: a finite element study. Int J Spine Surg. 2015 Nov 13; 9:64. PMID: 26767156. 47. Lindsey DP, Perez-Orribo L, Rodriguez-Martinez N, et al. Evaluation of a minimally invasive procedure for sacroiliac joint fusion - an in vitro biomechanical analysis of initial and cycled properties. Med Devices (Auckl). 2014 May 15; 7:131-7. PMID: 24868175. 48. Soriano-Baron H, Lindsey DP, Rodriguez-Martinez N, et al. The effect of implant placement on sacroiliac joint range of motion: posterior versus transarticular. Spine (Phila Pa 1976). 2015 May 1; 40(9):E525-30. PMID: 25705956.
3	No	

No.	Yes/No	Citations of Missing Evidence
4	NR	We have reviewed the BlueCross BlueShield Diagnosis and Treatment of Sacroiliac Joint Pain, Summary of Evidence. In general, this is a well-written, comprehensive review, but we have the following comments that should be considered Also see responses included above in Questions 1 and 3. Although this was not included in the evidence synthesis, and no randomized controlled trials have evaluated psychological interventions such as cognitive-behavioral therapy in individuals with SI joint pain, there is strong evidence supporting these treatments in individuals with nonspecific low back pain (Richmond H, Hall AM, Copsey B, et al. The effectiveness of cognitive behavioural treatment for non-specific low back pain: a systematic review and meta-analysis. PLoS One. 2015 Aug 5; 10(8):e0134192. PMID: 26244668), some of whom undoubtedly have SI joint pain. Therefore, incorporating these therapies, either before procedural interventions or in addition to interventions (ie, multimodal therapy), should be strongly considered. Reference list for articles mentioned in the ASRA response to questions 1 and 3: 1. Ackerman WE, Munir MA, Zhang JM, et al. Are diagnostic lumbar facet injections influenced by pain of muscular origin? Pain Pract. 2004 Dec; 4(4):286-91. PMID: 17173609. 2. Broadhurst NA, Bond MJ. Pain provocation tests for the assessment of sacroiliac joint dysfunction. J Spinal Disord. 1998 Aug; 11(4):341-5. PMID: 9726305 3. Cohen SP, Hurley RW. The ability of diagnostic spinal injections to predict surgical outcomes. Anesth Analg. 2007 Dec; 105(6):1756-75. PMID: 18042881. 4. Cohen SP, Wenzell D, Hurley RW, et al. A double-blind, placebo-controlled, dose-response pilot study evaluating intradiscal etanercept in patients with chronic discogenic low back pain or lumbosacral radiculopathy. Anesthesiology. 2007 Jul; 107(1):99-105. PMID: 17585221. 5. Dreyfuss P, Henning T, Malladi N, et al. The ability of multi-site, multi-depth sacral lateral branch blocks to anesthetize the sacroiliac joint complex. Pain Med. 2009 May-Jun; 10(4):679-88. PMID: 19638143. 6. Hanly JG, Mitchell M, MacMillan L, et al. Efficacy of sacroiliac corticosteroid injections in patients with inflammatory spondyloarthropathy: results of a 6 month controlled study. J Rheumatol. 2000 Mar; 27(3):719-22. PMID: 10743815. 7. Hansen H, Manchikanti L, Simopoulos TT, et al. A systematic evaluation of the therapeutic effectiveness of sacroiliac joint interventions. Pain Physician. May-Jun 2012; 15(3): E247-278. PMID 22622913 8. Hedlund R, Johansson C, Hägg O, et al; Swedish Lumbar Spine Study Group. The long-term outcome of lumbar fusion in the Swedish lumbar spine study. Spine J. 2016 May; 16(5):579-87. PMID: 26363250. 9. Hu Y, Lv G, Ren S, et al. Mid- to long-term outcomes of cervical disc arthroplasty versus anterior cervical discectomy and fusion for treatment of symptomatic cervical disc disease: a systematic review and meta-analysis of eight prospective randomized controlled trials. PLoS One. 2016 Feb 12; 11(2):e0149312. PMID: 26872258. 10. Irwin RW, Watson T, Minick RP, et al. Age, body mass index, and gender differences in sacroiliac joint pathology. Am J Phys Med Rehabil. 2007 Jan; 86(1):37-44. PMID: 17304687. 11. Kaptchuk TJ, Goldman P, Stone DA, et al. Do medical devices have enhanced placebo effects? J Clin Epidemiol. 2000 Aug; 53(8):786-92. PMID: 10942860. 12. Kaptchuk TJ, Stason WB, Davis RB, et al. Sham device v inert pill: randomised controlled trial of two placebo treatments. BMJ. 2006 Feb 18; 332(7538):391-7. PMID: 16452103. 13. Kong J, Spaeth R, Cook A, et al. Are all placebo effects equal? Placebo pills, sham acupuncture, cue conditioning and their association. PLoS One. 2013 Jul 31; 8(7):e67485. PMID: 23935833. 14. Laslett M, Young SB, Aprill CN, et al. Diagnosing painful sacroiliac joints: a validity study of a McKenzie evaluation and sacroiliac provocation tests. Aust J Physiother. 2003; 49(2):89-97. PMID: 12775204. 15. Liliang PC, Lu K, Liang CL, et al. Sacroiliac joint pain after lumbar and lumbosacral fusion: findings using dual sacroiliac joint blocks. Pain Med. 2011 Apr; 12(4):565-70. PMID: 21463470.

No.	Yes/No	Citations of Missing Evidence
		16. Luukkainen R, Nissilä M, Asikainen E, et al. Periarticular corticosteroid treatment of the sacroiliac joint in patients with seronegative spondylarthropathy. Clin Exp Rheumatol. 1999 Jan-Feb; 17(1):88-90. PMID: 10084038. 17. Luukkainen RK, Wennerstrand PV, Kautiainen HH, et al. Efficacy of periarticular corticosteroid treatment of the sacroiliac joint in non-spondylarthropathic patients with chronic low back pain in the region of the sacroiliac joint. Clin Exp Rheumatol. 2002 Jan-Feb; 20(1):52-4. PMID:11892709. 18. Maigne JY, Aivaliklis A, Pfefer F. Results of sacroiliac joint double block and value of sacroiliac pain provocation tests in 54 patients with low back pain. Spine (Phila Pa 1976). 1996 Aug 15; 21(16):1889-92. PMID: 8875721. 19. Manchikanti L, Pampati V, Bakhit CE, et al. Effectiveness of lumbar facet joint nerve blocks in chronic low back pain: a randomized clinical trial. Pain Physician. 2001 Jan; 4(1):101-17. PMID: 16906173. 20. Maugars Y, Mathis C, Berthelot JM, et al. Assessment of the efficacy of sacroiliac corticosteroid injections in spondylarthropathies: a double-blind study. Br J Rheumatol. 1996 Aug; 35(8):767-70. PMID: 8761190. 21. Polly D, Cher D, Whang P, et al. Does level of response to SI joint block predict response to SI joint fusion? Int J Spine Surg. 2016 Jan 21; 10:4. PMID 26913224. 22. Schütz U, Grob D. Poor outcome following bilateral sacroiliac joint fusion for degenerative sacroiliac joint syndrome. Acta Orthop Belg. 2006 Jun;72(3):296-308. PMID: 16889141. 23. Schwarzer AC, Aprill CN, Bogduk N. The sacroiliac joint in chronic low back pain. Spine (Phila Pa 1976). 1995 Jan 1; 20(1):31-7. PMID: 7709277. 24. Stanford G, Burnham RS. Is it useful to repeat sacroiliac joint provocative tests post-block? Pain Med. 2010 Dec; 11(12):1774-6. PMID: 21040430. 25. Szadek KM, van der Wurff P, van Tulder MW, et al. Diagnostic validity of criteria for sacroiliac joint pain: a systematic review. J Pain. 2009 Apr; 10(4):354-68. PMID: 19101212. 26. van der Wurff P, Buijs EJ, Groen GJ. A multitest regimen of pain provocation tests as an aid to reduce unnecessary minimally invasive sacroiliac joint procedures. Arch Phys Med Rehabil. 2006 Jan; 87(1):10-4. PMID: 16401431. 27. van Tilburg CW, Schuurmans FA, Stronks DL, et al. Randomized sham-controlled double-blind multicenter clinical trial to ascertain the effect of percutaneous radiofrequency treatment for sacroiliac joint pain: three-month results. Clin J Pain. Apr 1 2016; 32(11):921-926. PMID 26889616 28. Waisbrod H, Krainick JU, Gerbershagen HU. Sacroiliac joint arthrodesis for chronic lower back pain. Arch Orthop Trauma Surg. 1987; 106(4):238-40. PMID: 2956935. 29. Whang P, Cher D, Polly D, et al. Sacroiliac joint fusion using triangular titanium implants vs non-surgical management: six-month outcomes from a prospective randomized controlled trial. Int J Spine Surg. 2015 Mar 5; 9:6. PMID: 25785242 30. Xie L, Liu M, Ding F, et al. Cervical disc arthroplasty (CDA) versus anterior cervical discectomy and fusion (ACDF) in symptomatic cervical degenerative disc diseases (CDDDs): an updated meta-analysis of prospective randomized controlled trials (RCTs). Springerplus. 2016 Jul 27; 5(1):1188. PMID: 27516926. 31. Young S, Aprill C, Laslett M. Correlation of clinical examination characteristics with three sources of chronic low back pain. Spine J. 2003 Nov-Dec; 3(6):460-5. PMID: 14609690.
5	Yes	See comment on the NICE review which complements your review
6	NR	
7	NR	
8	No	
9	No	
10	Yes	Lingutla, K.K., Pollock, R. & Ahuja, S. Sacroiliac joint fusion for low back pain: a systematic review and meta-analysis. *Eur Spine J. Jun* 2016;25(6):1924-1931. PMID 26957096.

NR: no response

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
PO Box 9232
Des Moines, IA 50306-9232

*CPT® is a registered trademark of the American Medical Association.