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# MEDICAL POLICY – 6.01.527 Diagnosis and Treatment of Sacroiliac Joint Pain

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Effective Date:	Feb. 1, 2025	RELATED I	MEDICAL POLICIES:
Last Revised:	Jan. 13, 2025	2.01.26	Prolotherapy
Replaces:	6.01.524	6.01.25	Percutaneous Vertebroplasty and Sacroplasty
		7.01.542	Lumbar Spinal Fusion in Adults
		7.01.551	Lumbar Spine Decompression Surgery: Discectomy, Foraminotomy,
			Laminotomy, Laminectomy
		7.01.555	Facet Joint Denervation

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POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | APPENDIX | HISTORY

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### Introduction

The sacroiliac (SI) joints are between the lower spine and the pelvic bones. There is one on each side of the body. These joints transfer weight and the forces of the upper body to the hips and legs. Pain can develop in one or both of these joints and may be felt in the lower back, buttocks, or legs. One way to test if pain is coming from an SI joint is to inject a numbing solution. Imaging is used to guide and position the needle for the injection. If the numbing agent reduces pain, it is an indication that an SI joint is the cause. To relieve pain, steroids can be injected into the joint using the same type of imaging guidance. Another option for pain relief is minimally invasive fixation/fusion of the sacroiliac joint using a titanium triangular implant. This policy describes when minimally invasive fixation/fusion of the SI joint, and other certain treatments may be considered medically necessary to diagnose and treat SI joint pain. This policy also

**Note:** The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

# Policy Coverage Criteria

Service	Medical Necessity
Minimally invasive	Minimally invasive fixation/fusion of the sacroiliac joint using
fixation/fusion of the SIJ	transiliac placement of a titanium triangular implant (i.e.,
(27279)	iFuse) 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
	AND
	• There is an absence of generalized pain behavior (e.g.,
	somatoform disorder) or generalized pain disorders (e.g.,
	fibromyalgia)
	AND
	• 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,
	sacroiliac joint, and hip, including a home exercise program
	AND
	• Pain is caudal (posterior) to the lumbar spine (L5 vertebra),
	localized over the posterior sacroiliac joint, and consistent with
	sacroiliac joint pain
	AND
	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
	AND
	• There is a positive response to a cluster of 3 provocative tests,
	examples include (see Appendix):
	<ul> <li>Compression test</li> </ul>
	<ul> <li>Distraction test</li> </ul>
	<ul> <li>Gaenslen sign</li> </ul>
	<ul> <li>Patrick test (aka FABER test)</li> </ul>
	<ul> <li>Posterior provocation test</li> </ul>



Service	Medical Necessity
	<ul> <li>Thigh thrust test</li> </ul>
	AND
	<ul> <li>Diagnostic imaging studies include ALL of the following:         <ul> <li>Imaging (plain radiographs and computed tomography or magnetic resonance imaging) of the sacroiliac joint excludes the presence of destructive lesions (e.g., tumor, infection) or inflammatory arthropathy of the sacroiliac joint; and</li> <li>Imaging of the pelvis (anteroposterior plain radiograph) rules out concomitant hip pathology; and</li> <li>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; and</li> <li>Imaging of the sacroiliac joint indicates evidence of injury</li> </ul> </li> </ul>
	and/or degeneration
	AND
	<ul> <li>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 sacroiliac joint injection on 2 separate occasions</li> </ul>
	AND
	<ul> <li>A trial of a therapeutic sacroiliac joint injection (i.e., corticosteroid injection) has been performed at least once</li> </ul>
Open SIJ fusion (27280)	<ul> <li>Open sacroiliac joint fusion procedures may be considered medically necessary for any of the following indications:</li> <li>As an adjunct to sacrectomy or partial sacrectomy related to tumors involving the sacrum</li> <li>OR</li> <li>As an adjunct to the medical treatment of sacroiliac joint infection/sepsis</li> <li>OR</li> </ul>
	<ul> <li>As a treatment for severe traumatic injuries associated with pelvic ring fracture</li> </ul>

Service	Medical Necessity
	Sacroiliac joint fusion performed by an open procedure for any
	other indication, including, but not limited to, chronic low
	back pain is considered not medically necessary.

Service	Investigational
All other devices (27278)	Fixation/fusion of the sacroiliac joint for the treatment of back
	pain presumed to originate from the sacroiliac joint with any
	other devices other than a titanium triangular implant (i.e.,
	iFuse) is considered investigational. (See Table 2 for examples of
	other devices)
Arthrography (G0259)	Arthrography of the sacroiliac joint is considered
	investigational.
Radiofrequency	Radiofrequency denervation of the sacroiliac joint is
denervation (64625)	considered investigational.

#### **Documentation Requirements**

The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following: Office visit notes that contain the relevant history and physical.

- For minimally invasive fixation/fusion of the sacroiliac joint, provide documentation that ALL of the criteria above have been met plus copies of these diagnostic imaging studies:
  - Imaging (plain radiographs and computed tomography or magnetic resonance imaging) of the sacroiliac joint to exclude the presence of destructive lesions (e.g., tumor, infection) or inflammatory arthropathy of the sacroiliac joint; and
  - Imaging of the pelvis (anteroposterior plain radiograph) to rule out concomitant hip pathology; and
  - Imaging of the lumbar spine (computed tomography or magnetic resonance imaging) to rule out neural compression or other degenerative condition that can be causing low back or buttock pain; and
  - Imaging of the sacroiliac joint indicates evidence of injury and/or degeneration

# Coding

Code	Description
СРТ	
Reviewed for Medical N	Necessity
27279	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device (iFuse)
27280	Arthrodesis, sacroiliac joint, open, includes obtaining bone graft, including instrumentation, when performed
Investigational (Not Eli	gible for Coverage)
27278	Arthrodesis, sacroiliac joint, percutaneous, with image guidance, including placement of intra-articular implant(s) (e.g., bone allograft[s], synthetic device[s]), without placement of transfixation device
64625	Radiofrequency ablation, nerves innervating the sacroiliac joint, with image guidance (i.e, fluoroscopy or computed tomography)
HCPCS	
Investigational (Not Eli	gible for Coverage)
G0259	Injection procedure for sacroiliac joint; arthrography

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

# **Related Information**

This technically demanding procedure should only be done by surgeons who have specific training and expertise in minimally invasive sacroiliac joint fusion surgery for chronic sacroiliac joint 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 six 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.

A successful trial of controlled diagnostic lateral branch blocks consists of two separate positive blocks on different days with local anesthetic only (no steroids or other drugs), or a placebocontrolled series of blocks, under fluoroscopic guidance, that has resulted in a reduction in pain for the duration of the local anesthetic used (e.g., three hours longer with bupivacaine than lidocaine). There is no consensus on whether a minimum of 50% or 75% reduction in pain would be required to be considered a successful diagnostic block, although evidence that supported a criterion standard of 75% to 100% reduction in pain with dual blocks. No therapeutic intraarticular injections (i.e., steroids, saline, other substances) should be administered for a period of at least four weeks before the diagnostic block. The diagnostic blocks should not be conducted under intravenous sedation unless specifically indicated (e.g., the individual is unable to cooperate with the procedure).

#### **Evidence Review**

### Description

Sacroiliac joint (SIJ) arthrography using fluoroscopic guidance with an injection of an anesthetic has been explored as a diagnostic test for SIJ pain. Duplication of the individual's pain pattern with the injection of contrast medium suggests a sacroiliac etiology, as does relief of chronic back pain with an injection of local anesthetic. Treatment of SIJ pain with corticosteroids, radiofrequency ablation (RFA), stabilization, or minimally invasive SIJ fusion has also been explored.

# 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 sacroiliac joint 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 sacroiliac joint 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 **Related Policies**), corticosteroid injection, RFA, 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 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).<sup>1</sup> The iliosacral and posterolateral approaches use up to three 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.



# **Summary of Evidence**

# Diagnostic

For individuals who have suspected SIJ pain who receive a diagnostic sacroiliac block, the evidence includes systematic reviews. The relevant outcomes are test validity, symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Current evidence conflicts on the diagnostic utility of SIJ blocks. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

# Therapeutic

For individuals who have SIJ pain who receive therapeutic corticosteroid injections, the evidence includes systematic reviews, randomized controlled trials (RCTs) and case series. The relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. In general, the literature on injection therapy of joints in the back is of poor quality. Results from one RCT showed superiority over a sham control group, but two RCTs showed that therapeutic SIJ steroid injections were not as effective as other active treatments. Larger trials, with rigorous designs and sufficient follow-up, preferably using sham injections, are needed to determine that the technology improves the net health outcome. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have SIJ pain who receive RFA, the evidence includes six RCTs using different radiofrequency applications and case series. The relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Meta-analysis of available sham-controlled RCTs suggests that there may be a small effect of RFA on SIJ pain at short-term (one to six months) follow-up. However, the RCTs of RFA have methodologic limitations, and there is limited data on the duration of the treatment effect. The single RCT with 6- and 12-month follow-up showed no significant benefit of RFA compared to an exercise control group at these time points. In addition, heterogeneity of RFA treatment techniques precludes generalizing results across different studies. For RFA with a cooled probe, three RCTs reported short-term benefits, but these are insufficient to determine the overall effect on health outcomes. An RCT on palisade RFA of the SIJ did not include a sham control. Another sham-controlled RCT showed no benefit from RFA. Further high-quality controlled trials are needed to compare this procedure in defined populations with sham control and alternative treatments. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.



For individuals who have SIJ pain who receive SIJ fusion/fixation with a transiliac triangular implant, the evidence includes one meta-analysis, one blinded sham-controlled trial, two nonblinded RCTs of minimally invasive fusion, prospective cohorts with more than 85% followup, and case series. The relevant outcomes are symptoms, functional outcomes, quality of life, 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 six 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 six months were maintained out to one 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 individuals 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 three 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.

For individuals who have SIJ pain who receive SIJ fusion/fixation with an implant other than a transiliac triangular implant, the evidence includes six prospective cohort studies and retrospective case series. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Three prospective cohorts were conducted with transiliac screws and the three 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 individuals 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. (See **Clinical Input** below)

# Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in **Table 1**.

Table	1.	Summary	of	Key	Trials
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NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04423120ª	A Single Arm, Multicenter, Prospective, Clinical Study on a Novel Minimally Invasive Posterior Sacroiliac Fusion Device	100	Mar 2026
NCT04062630ª	Sacroiliac Joint Stabilization in Long Fusion to the Pelvis: Randomized Controlled Trial (SILVIA)	213	Dec 2024
NCT05870488ª	iFuse TORQ for the Treatment of Sacroiliac Joint Dysfunction	110	May 2026
NCT03507049	Sacroiliac Joint Fusion Versus Sham Operation for Treatment of Sacroiliac Joint Pain. A Prospective Double Blinded Randomized Controlled Multicenter Trial.	63	May 2030
NCT06487936ª	Real-World Registry Study on Patient Satisfaction With TransLoc 3D SI Joint Fusion	120	Dec 2024
NCT05633888ª	Prospective, Multi-Center, Single Arm Post-Market Feasibility Study of the Tenon Medical CATAMARAN™ SI Joint Fusion System	50	Jan 2026
NCT05276024ª	Evaluation of the iFuse Bedrock Technique in Association With Posterior Lumbosacral Fusion With Iliac Fixation.	50	Apr 2025
Unpublished			
NCT01861899ª	Treatment of Sacroiliac Dysfunction With SI-LOK Sacroiliac Joint Fixation System	46	Apr 2019
NCT02074761ª	Evolusion Study Using the Zyga SImmetry Sacroiliac Joint Fusion System	250	Nov 2020
NCT04218838ª	A Prospective, Multi-Center, Bi-Phasic Randomized Design to Compare Outcomes of the CornerLoc SI Joint Stabilization System and Intra-Articular Sacroiliac Joint Steroid Injection in Patients With Refractory Sacroiliac Joint Dysfunction	120	Jul 2023 (Terminated, enrollment difficulties)



# 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 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 five specialty society-level responses from seven specialty societies (two were joint society responses) and five physician-level responses from four academic centers while this policy was under review in 2017.

For carefully selected individuals as outlined in statements from the North American Spine Society (NASS) 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.

# 2014 Input

In response to requests, input was received from four physician specialty societies and four academic medical centers (five responses) while this policy was under review in 2014. Input was mixed on the use of arthrography, radiofrequency ablation, and fusion of the SIJ. Most reviewers considered injection for diagnostic purposes to be medically necessary when using controlled blocks with at least 75% pain relief, and for injection of corticosteroids for treatment purposes. Treatment with prolotherapy, periarticular corticosteroid, and periarticular botulinum toxin were considered investigational by most reviewers.

# **Practice Guidelines and Position Statements**

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

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or the 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.

# 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.<sup>55</sup> The review aims to provide evidence-based recommendations to address critical clinical questions surrounding diagnosing and treating adult individuals with sacroiliac joint pain. No estimated date of publication was provided.

# American Society of Interventional Pain Physicians

In 2013, the American Society of Interventional Pain Physicians guideline recommended the use of controlled SIJ blocks with placebo or controlled comparative local anesthetic block when indications are satisfied with suspicion of SIJ pain.<sup>4</sup> A positive response to a joint block is considered to be at least a 75% improvement in pain or in the ability to perform previously painful movements. For therapeutic interventions, the only effective modality with fair evidence was cooled radiofrequency neurotomy, when used after the appropriate diagnosis was confirmed by diagnostic SIJ injections.

# American Society of Anesthesiologists and American Society of Regional Anesthesia and Pain Medicine

The American Society of Anesthesiologists and the American Society of Regional Anesthesia and Pain Medicine have a 2010 guideline for chronic pain management.<sup>56</sup> The guideline



recommends that "Diagnostic sacroiliac joint injections or lateral branch blocks may be considered for the evaluation of patients with suspected sacroiliac joint pain." Based on the opinions of consultants and society members, the guideline recommends that "Water-cooled RFA may be used for chronic sacroiliac joint pain."

# 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.<sup>47</sup>

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

- "Chronic SIJ pain (pain lasting at least 6 months)
- Significant SIJ pain that impacts QOL 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 > 50% acute decrease in pain upon fluoroscopically guided diagnostic intra-articular SIJ block using a small volume (≤ 2.5 mL) of local anesthetic.....
- Failure to respond to nonsurgical treatment consisting of NSAIDs [nonsteroidal antiinflammatory drugs] and a reasonable course (4–6 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

# American Society of Pain and Neuroscience

In 2021, the American Society of Pain and Neuroscience (ASPN) published a practice guideline on radiofrequency neurotomy.<sup>57</sup> All of the workgroup members utilized radiofrequency neurotomy in clinical practice. A consensus statement, based on Grade II-1 evidence (welldesigned, controlled, nonrandomized clinical trial), was that "lateral branch radiofrequency neurotomy may be used for the treatment of posterior sacral ligament and joint pain following positive response to appropriately placed diagnostic blocks."

In 2024, ASPN published guidance on the treatment of sacroiliac disorders.<sup>58</sup>

The following recommendations were provided concerning SIJ injections, minimally invasive sacroiliac joint fixation and sacroiliac radiofrequency ablation:

- Best Practice Statement on Diagnostic Intra-Articular Injection of the SIJ: The patient should experience greater than 50% relief when an appropriately performed local anesthetic only injection is completed that is consistent with duration of the local anesthetic utilized. A second confirmatory local anesthetic injection can be considered, but not mandatory, when using diagnostic injections to determine candidacy for surgical treatment.
- Best Practice Statement on Conservative Care: Appropriate conservative care should be considered and when acceptable attempted prior to interventional or surgical treatment of sacroiliac dysfunction.
- Best Practice Statement on Intra-Articular Corticosteroid Injections for SIJ Pain: Imageguided, intra-articular corticosteroid injections are recommended for persistent SIJ pain that has persisted despite conservative measures for 4 weeks. Fluoroscopic and CT guided injections are the preferred imaging modality of choice, although ultrasound guidance can be considered in situations where radiation exposure may be problematic.
- Best Practice Statement on Neuroablative Technique and Approach for SI Pain: RFA of the SIJ should be performed by an established and researched method and repeated no more than at six-month intervals when an improvement of 50% pain relief and functional improvement is seen.
- 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. The 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:
    - A failure of conservative measures to at least include physical therapy and injections.
    - 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.
    - Failure of at least one therapeutic sacroiliac joint injection (less than 50% pain relief for three months duration).
    - Predominant pain pattern consistent with sacroiliac joint pathology.
    - Positive response from at least three validated maneuvers for sacroiliac joint dysfunction.
    - Positive Fortin finger test.
    - Diagnostic imaging: either CT or MRI that excludes destructive lesions of the sacroiliac joint.
    - 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)

# National Institute for Health and Care Excellence

In 2017, the National Institute for Health and Care Excellence (NICE) 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."<sup>59</sup>

In 2022, NICE published medical technology guidance on using the iFuse implant system for treating chronic sacroiliac joint pain. It provided the following recommendations:<sup>60</sup>

- 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.

## Medicare National Coverage

There is no national coverage determination.

# **Regulatory Status**

A number of radiofrequency generators and probes have been cleared for marketing by the US Food and Drug Administration (FDA) through the 510(k) process. In 2005, the SInergy (Halyard; formerly Kimberly-Clark), a water-cooled single-use probe, was cleared by the FDA, listing the Baylis Pain Management Probe as a predicate device. The intended use is in conjunction with a radiofrequency generator to create radiofrequency lesions in nervous tissue. FDA product codes: GXD, GXI.

Examples of types of commercially available SIJ fusion devices are listed in Table 2.

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 code: 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.

Device	Manufacturer	Features	Graft Compatible	Clearance	Date
Lateral Transili	ac Approach				
iFuse	SI Bone	Titanium triangular rod with conventional manufacturing	Y	K110838	2011
iFuse 3D	SI Bone	Titanium triangular 3D printed porous rod	Y	K162733	2017
iFuse TORQ Implant System	SI Bone	3D printed cannulated screw	Y	K222605, K241574	2022

# Table 2. Select Sacroiliac Fusion Devices



Device	Manufacturer	Features	Graft	Clearance	Date
			Compatible		
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
Slimpact 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
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.	Metallic fastener	Y	K231841, K240201	2023
SI-Cure Sacroiliac Joint Fusion System	Alevio, LLC	Metallic 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

Device	Manufacturer	Features	Graft	Clearance	Date
			Compatible		
TORPEDO Implant System	Deltacor GmbH	Cannulated screw	Y	K230817	2024
Liberty SI Lateral Implant System	Spinal Simplicity LLC	Cannulated screw	Y	K231923	2023
Posterolateral	Approach				
Rialto SI Joint Fusion System	Medtronic	Cannulated screw	Y	K161210	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
Posterior Appr	oach				
Catamaran	Tenon Medical	Metal plug	Y	K180818	2018
CornerLoc	Fusion Foundation Solutions	Bone allograft	N	НСТ/Р	N/A
LinQ SI Joint Stabilization	PainTEQ	Bone allograft	N	НСТ/Р	N/A
NADIA SI Fusion System (DIANA)	llion Medical	Metal plug	N	K190580	2020
PsiF Posterior Sacroiliac Fusion	Omnia Medical	Bone allograft	N	НСТ/Р	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	2023
Invictus Spinal Fixation System	Alphatec Spine, Inc.	Cannulated screw	Y	K232275	2023

Device	Manufacturer	Features	Graft	Clearance	Date
			Compatible		
VyLink Spinal Screw System	Vy Spine, LLC	Cannulated screw	Y	K231744	2023
Patriot-SI Posterior Implant System	Spinal Simplicity LLC	Cannulated screw	Y	K232259	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	2024

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

#### 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. 2015; 18(5): E713-56. PMID 26431129
- 4. Manchikanti L, Abdi S, Atluri S, et al. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: guidance and recommendations. Pain Physician. Apr 2013; 16(2 Suppl): S49-283. PMID 23615883
- 5. Manchikanti L, Datta S, Derby R, et al. A critical review of the American Pain Society clinical practice guidelines for interventional techniques: part 1. Diagnostic interventions. Pain Physician. 2010; 13(3): E141-74. PMID 20495596
- 6. Manchikanti L, Datta S, Gupta S, et al. A critical review of the American Pain Society clinical practice guidelines for interventional techniques: part 2. Therapeutic interventions. Pain Physician. 2010; 13(4): E215-64. PMID 20648212
- 7. Rupert MP, Lee M, Manchikanti L, et al. Evaluation of sacroiliac joint interventions: a systematic appraisal of the literature. Pain Physician. 2009; 12(2): 399-418. PMID 19305487
- 8. Chou R, Atlas SJ, Stanos SP, et al. Nonsurgical interventional therapies for low back pain: a review of the evidence for an American Pain Society clinical practice guideline. Spine (Phila Pa 1976). May 01 2009; 34(10): 1078-93. PMID 19363456
- 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
- 10. Hansen H, Manchikanti L, Simopoulos TT, et al. A systematic evaluation of the therapeutic effectiveness of sacroiliac joint interventions. Pain Physician. 2012; 15(3): E247-78. PMID 22622913
- 11. Patel A, Kumar D, Singh S, et al. Effect of Fluoroscopic-Guided Corticosteroid Injection in Patients With Sacroiliac Joint Dysfunction. Cureus. Mar 2023; 15(3): e36406. PMID 37090293



- 12. Visser LH, Woudenberg NP, de Bont J, et al. Treatment of the sacroiliac joint in patients with leg pain: a randomized-controlled trial. Eur Spine J. Oct 2013; 22(10): 2310-7. PMID 23720124
- 13. Kim WM, Lee HG, Jeong CW, et al. A randomized controlled trial of intra-articular prolotherapy versus steroid injection for sacroiliac joint pain. J Altern Complement Med. Dec 2010; 16(12): 1285-90. PMID 21138388
- 14. Kennedy DJ, Engel A, Kreiner DS, et al. Fluoroscopically Guided Diagnostic and Therapeutic Intra-Articular Sacroiliac Joint Injections: A Systematic Review. Pain Med. Aug 2015; 16(8): 1500-18. PMID 26178855
- 15. Ab Aziz SNF, Zakaria Mohamad Z, Karupiah RK, et al. Efficacy of Sacroiliac Joint Injection With Anesthetic and Corticosteroid: A Prospective Observational Study. Cureus. Apr 2022; 14(4): e24039. PMID 35547453
- 16. Al Khayyat SG, Fogliame G, Barbagli S, et al. Ultrasound guided corticosteroids sacroiliac joint injections (SIJIs) in the management of active sacroiliitis: a real-life prospective experience. J Ultrasound. Jun 2023; 26(2): 479-486. PMID 36229757
- 17. Chandrupatla RS, Shahidi B, Bruno K, et al. A Retrospective Study on Patient-Specific Predictors for Non-Response to Sacroiliac Joint Injections. Int J Environ Res Public Health. Nov 23 2022; 19(23). PMID 36497595
- 18. Janapala RN, Knezevic E, Knezevic NN, et al. Systematic Review and Meta-Analysis of the Effectiveness of Radiofrequency Ablation of the Sacroiliac Joint. Curr Pain Headache Rep. May 2024; 28(5): 335-372. PMID 38472618
- Chou R, Fu R, Dana T, Pappas M, Hart E, Mauer KM. Interventional Treatments for Acute and Chronic Pain: Systematic Review. Comparative Effectiveness Review No. 247. (Prepared by the Pacific Northwest Evidence-based Practice Center under Contract No. 75Q80120D00006.) AHRQ Publication No. 21-EHC030. Rockville, MD: Agency for Healthcare Research and Quality; September 2021. PMID: 34524764
- 20. Chappell ME, Lakshman R, Trotter P, et al. Radiofrequency denervation for chronic back pain: a systematic review and metaanalysis. BMJ Open. Jul 21 2020; 10(7): e035540. PMID 32699129
- 21. Juch JNS, Maas ET, Ostelo RWJG, et al. Effect of Radiofrequency Denervation on Pain Intensity Among Patients With Chronic Low Back Pain: The Mint Randomized Clinical Trials. JAMA. Jul 04 2017; 318(1): 68-81. PMID 28672319
- 22. Chen CH, Weng PW, Wu LC, et al. Radiofrequency neurotomy in chronic lumbar and sacroiliac joint pain: A meta-analysis. Medicine (Baltimore). Jun 2019; 98(26): e16230. PMID 31261580
- Cohen SP, Kapural L, Kohan L, et al. Cooled radiofrequency ablation versus standard medical management for chronic sacroiliac joint pain: a multicenter, randomized comparative effectiveness study. Reg Anesth Pain Med. Mar 04 2024; 49(3): 184-191.
   PMID 37407279
- Mehta V, Poply K, Husband M, et al. The Effects of Radiofrequency Neurotomy Using a Strip-Lesioning Device on Patients with Sacroiliac Joint Pain: Results from a Single-Center, Randomized, Sham-Controlled Trial. Pain Physician. Nov 2018; 21(6): 607-618. PMID 30508988
- 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. Nov 2016; 32(11): 921-926. PMID 26889616
- Zheng Y, Gu M, Shi D, et al. Tomography-guided palisade sacroiliac joint radiofrequency neurotomy versus celecoxib for ankylosing spondylitis: a open-label, randomized, and controlled trial. Rheumatol Int. Sep 2014; 34(9): 1195-202. PMID 24518967
- 27. Patel N, Gross A, Brown L, et al. A randomized, placebo-controlled study to assess the efficacy of lateral branch neurotomy for chronic sacroiliac joint pain. Pain Med. Mar 2012; 13(3): 383-98. PMID 22299761
- 28. Patel N. Twelve-Month Follow-Up of a Randomized Trial Assessing Cooled Radiofrequency Denervation as a Treatment for Sacroiliac Region Pain. Pain Pract. Feb 2016; 16(2): 154-67. PMID 25565322
- 29. 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



- 30. 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
- 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
- 32. 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
- 33. 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
- 34. 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
- 35. 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
- 36. 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
- 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
- 38. 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
- 39. 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
- 40. 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
- 41. 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
- 42. 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
- 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. Jan 01 2018; 82(1): 48-55. PMID 28431026
- 44. Spain K, Holt T. Surgical Revision after Sacroiliac Joint Fixation or Fusion. Int J Spine Surg. 2017; 11(1): 5. PMID 28377863
- 45. 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
- 46. 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
- 47. 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
- 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

- 49. Rappoport LH, Helsper K, Shirk T. Minimally invasive sacroiliac joint fusion using a novel hydroxyapatite-coated screw: final 2year clinical and radiographic results. J Spine Surg. Jun 2021; 7(2): 155-161. PMID 34296027
- 50. 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
- 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
- 52. 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
- 53. 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
- 54. 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
- 55. North American Spine Society. Diagnosis and Treatment of Adults with Sacroiliac Joint Pain: A Protocol for a Systematic Review and Clinical Guidelines by the North American Spine Society. n.d. https://www.spine.org/Portals/0/assets/downloads/ResearchClinicalCare/Guidelines/SacroiliacJointPain-Protocol.pdf. Accessed December 4, 2024.
- 56. 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
- 57. 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
- 58. 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
- 59. 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. Accessed October 4, 2024.
- 60. National Institute for Health and Care Excellence. iFuse for treating chronic sacroiliac joint pain [MTG39]. 2022; https://www.nice.org.uk/guidance/mtg39. Accessed December 4, 2024.

#### Appendix

"Tests that stress the SIJ in order to provoke familiar pain have acceptable inter-examiner reliability and have clinically useful validity against an acceptable reference standard. Three or more positive pain provocation SIJ tests have sensitivity and specificity of 91% and 78% respectively."

Figure 1 – The Distraction test



The distraction test (testing right and left SIJ simultaneously).

**Note:** Vertically oriented pressure is applied to the anterior superior iliac spinous processes directed posteriorly, distracting the sacroiliac joint.



# Figure 2 – Thigh thrust test



The **thigh thrust test** (aka posterior provocation test) (testing the right SIJ).

**Note:** The sacrum is fixated against the table with the left hand, and a vertically oriented force is applied through the line of the femur directed posteriorly, producing a posterior shearing force at the SIJ.

# Figure 3 – Gaenslen's test



Gaenslen's test (testing the right SIJ in posterior rotation and the left SIJ in anterior rotation).

**Note:** The pelvis is stressed with a torsion force by a superior/posterior force applied to the right knee and a posteriorly directed force applied to the left knee.

# Figure 4 – Compression test



The **compression test** (testing right and left SIJ).

**Note:** A vertically directed force is applied to the iliac crest directed towards the floor, i.e., transversely across the pelvis, compressing the SIJs.



# Figure 5 – Sacral thrust test

The sacral thrust test (testing right and left SIJ simultaneously).



**Note:** A vertically directed force is applied to the midline of the sacrum at the apex of the curve of the sacrum, directed anteriorly, producing a posterior shearing force at the SIJs with the sacrum nutated.

Source: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2582421/ Accessed December 15, 2024

FABER test stands for: Flexion, Abduction and External Rotation (aka Patrick's sign or test). These three movements combined result in a clinical pain provocation test to assist in diagnosis of pathologies at the SI region.

#### History

Date	Comments	
03/01/18	New policy (6.01.524), approved February 13, 2018. This policy replaces the previous policy 6.01.23. Diagnosis and treatment of sacroiliac joint pain are considered medically necessary when criteria are met. Arthrography and radiofrequency denervation of the sacroiliac joint are considered investigational. Open SIJ Fusion is medically necessary when criteria are met. Percutaneous and minimally invasive SIJ fusion/stabilization procedures are considered investigational.	
02/01/19	Annual Review, approved January 8, 2019, Policy updated with literature review through September 2018; references 12, 23, and 37-38 added. Policy statement added to indicate minimally invasive fixation/fusion of the SIJ using a titanium triangular implant is medically necessary when criteria are met.	
12/01/19	Interim Review, approved November 6, 2019. Medical necessity statements for minimally fixation/fusion of the SIJ reformatted with minor edits for greater clarity. Intent of the policy statements unchanged.	
01/01/20	Coding update, added CPT code 64625 (new code effective 1/1/20).	
02/01/20	Annual Review, approved January 9. 2020. Policy updated with literature review through August 2019; references added. Policy statements unchanged.	
07/01/20	New Policy, renumbered to 6.01.23 (from 6.01.524), approved June 9, 2020, effective July 1, 2020. This policy replaces policy 6.01.524 which is now deleted. Policy statements remain unchanged but have been reformatted; this is effectively a policy renumber.	
07/02/20	Coding update. Removed CPT codes 27280 and 64625.	
08/01/20	Coding update. Removed CPT codes 64635 and 64636.	



Date	Comments
02/01/21	Annual Review, approved January 6, 2021. Policy updated with literature review through September 22, 2020; references added. Policy statements unchanged. Added CPT codes 27280 and 64625 and HCPCS codes G0259 and G0260.
08/01/21	Interim Review, approved July 9, 2021.Removed policy statement for therapeutic corticosteroid injections for SI joint pain. Added CPT code 64451. Removed CPT codes 64640 and HCPCS G0260.
10/01/21	New policy (renumber), approved September 14, 2021. Policy renumbered from 6.01.23 Diagnosis and Treatment of Sacroiliac Joint Pain to 6.01.527 Diagnosis and Treatment of Sacroiliac Joint Pain. Removed policy statement for injection of anesthetic agent for diagnosing SI joint pain. Removed CPT code 64451.
02/01/22	Annual Review, approved January 10, 2022. Policy updated with literature review through September 27, 2021; references added. Minor edit "transiliac placement" added to the medically necessary statement on sacroiliac joint fusion.
03/01/22	Interim Review, approved February 21, 2022. Added policy statement that open SIJ fusion is medically necessary for the treatment of tumors, infection, or trauma.
02/01/23	Annual Review, approved January 23, 2023. Policy updated with literature review through October 4, 2022; no references added. Minor editorial refinements to policy statements; intent unchanged. Added Appendix section. Changed the wording from "patient" to "individual" throughout the policy for standardization. Updated coding description for CPT code 27280. Added CPT 0775T.
07/01/23	Coding update. Added new CPT code 0809T
09/14/23	Minor edit for clarification purposes only. Clarified in the policy section that FABER test is the same as the Patrick test as already noted in the Appendix section.
01/01/24	Coding update. Added new CPT code 27278 and added term dates to CPT codes 0775T and 0809T.
02/01/24	Annual Review, approved January 8, 2024. Policy updated with literature review through September 13, 2023; references added. Policy statements unchanged.
06/01/24	Interim Review, approved May 24, 2024. Minor editorial refinements made for clarity only; policy intent unchanged.
08/02/24	Minor update made to Policy Criteria section for clarity purposes. Policy intent unchanged.
12/01/24	Interim Review, approved November 11, 2024. Minor edits made to policy statements for greater clarity only, policy intent unchanged.
02/01/25	Annual Review, approved January 13, 2025. Policy updated with literature review through September 23, 2024; references added. Policy statements unchanged. Removed termed CPT codes 0775T and 0809T.

**Disclaimer**: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2025 Premera All Rights Reserved.

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