LifeWise
Health Plan of Washington

MEDICAL POLICY – 6.01.527

Diagnosis and Treatment of Sacroiliac Joint Pain

BCBSA Ref. Policy: 6.01.23

Effective Date:	June 1, 2024
Last Revised:	Aug. 2, 2024
Replaces:	6.01.524

RELATED MEDICAL POLICIES:

2.01.26	Prolotherapy
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 discusses investigational (unproven) techniques for diagnosing or treating SI pain.

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 fixation/fusion of the SIJ (27279)	**Minimally invasive fixation/fusion of the sacroiliac joint using transiliac placement of a titanium triangular implant (i.e., 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 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**):
	  ○ Thigh thrust test
	  ○ Compression test
	  ○ Gaenslen sign
	  ○ Distraction test
	  ○ Patrick test (aka FABER test)

Service	Medical Necessity
	○ posterior provocation test **AND** • Diagnostic imaging studies include ALL of the following: ○ Imaging (plain radiographs and computed tomography or magnetic resonance imaging) of the sacroiliac joint excludes the presence of destructive lesions (eg, tumor, infection) or inflammatory arthropathy of the sacroiliac joint; and ○ Imaging of the pelvis (anteroposterior plain radiograph) rules out concomitant hip pathology; and ○ 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 ○ Imaging of the sacroiliac joint indicates evidence of injury and/or degeneration **AND** • 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 **AND** • A trial of a therapeutic sacroiliac joint injection (i.e., corticosteroid injection) has been performed at least once
Open SIJ fusion (27280)	**Open sacroiliac joint fusion procedures may be considered medically necessary for any of the following indications:** • As an adjunct to sacrectomy or partial sacrectomy related to tumors involving the sacrum **OR** • As an adjunct to the medical treatment of sacroiliac joint infection/sepsis **OR** • As a treatment for severe traumatic injuries associated with pelvic ring fracture **Sacroiliac joint fusion performed by an open procedure for any other indication is considered not medically necessary.**

Service	Investigational
All other conditions and other devices (27278)	**Fixation/fusion of the sacroiliac joint for the treatment of back pain presumed to originate from the sacroiliac joint is considered investigational under all other conditions and with any other devices not listed above.** (See **Table 2** for other devices)
Arthrography (G0259)	**Arthrography of the sacroiliac joint is considered investigational.**
Radiofrequency denervation (64625)	**Radiofrequency denervation of the sacroiliac joint is 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
CPT	
Reviewed for Medical Necessity	

Code	Description
27279	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device (iFuse)
27280	Arthrodesis, sacroiliac joint, open, includes obtaining bone graft, including instrumentation, when performed
Investigational (Not Eligible for Coverage)	
0775T	Arthrodesis, sacroiliac joint, percutaneous, with image guidance, includes placement of intra-articular implant(s) (eg, bone allograft[s], synthetic device[s]) (code termed 1/1/2024)
0809T	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, placement of transfixing device(s) and intra-articular implant(s), including allograft or synthetic device(s) (code termed 01/01/2024)
27278	Arthrodesis, sacroiliac joint, percutaneous, with image guidance, including placement of intra-articular implant(s) (eg, bone allograft[s], synthetic device[s]), without placement of transfixation device (new code effective 01/01/2024)
64625	Radiofrequency ablation, nerves innervating the sacroiliac joint, with image guidance (i.e.., fluoroscopy or computed tomography)
HCPCS	
Investigational (Not Eligible for Coverage)	
G0259	Injection procedure for sacroiliac joint; arthrography

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 placebo-controlled 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 intra-articular 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).[1] 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 is conflicting 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, small 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 t 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 three 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 two nonblinded RCTs of minimally invasive fusion, prospective cohorts with more than 85% follow-up, and case series. The relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Both 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.

For individuals who have SIJ pain who receive SIJ fusion/fixation with an implant other than a transiliac triangular implant, the evidence includes four 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 third with a device inserted through a posterior approach. No 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.

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

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04423120[a]	A Single Arm, Multicenter, Prospective, Clinical Study on a Novel Minimally Invasive Posterior Sacroiliac Fusion Device	100	Mar 2026
NCT04062630[a]	Sacroiliac Joint Stabilization in Long Fusion to the Pelvis: Randomized Controlled Trial (SILVIA)	213	Dec 2024
NCT05870488[a]	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
Unpublished			
NCT01861899[a]	Treatment of Sacroiliac Dysfunction With SI-LOK Sacroiliac Joint Fixation System	46	Apr 2019
NCT02074761[a]	Evolusion Study Using the Zyga SImmetry Sacroiliac Joint Fusion System	250	Nov 2020
NCT04218838[a]	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)

NCT: national clinical trial

[a] Denotes industry-sponsored or cosponsored trial

Clinical Input from Physician Specialty Societies and Academic Medical Centers

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

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

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 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

The NASS has developed appropriate use criteria for percutaneous SIJ fusion, SIJ injection, and RFA. These criteria can be accessed by payers through a registration process. For further information see: **https://www.spine.org/Research-Clinical-Care/Quality-Improvement/Clinical-Guidelines** (accessed December 5, 2023).

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.

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.[4] 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.[50] 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.[44]

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 anti-inflammatory 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.[51] All of the workgroup members utilized radiofrequency neurotomy in clinical practice. A consensus statement, based on Grade II-1 evidence (well-

designed, 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 2022, ASPN published guidance on the treatment of lower back pain.[52]

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

- Sacroiliac joint injections have been associated with positive predictive value in the diagnosis of SIJ dysfunction (Grade, A; Level, I-A; Level of certainty, Strong)
- Sacroiliac joint injections demonstrate short term relief of SIJ dysfunction (Grade, B; Level, I-B; Level of certainty, Moderate)
- Minimally invasive sacroiliac fusion (Grade, A; Level, 1-A; Level of certainty, High)
- SI joint denervation/ablation is effective in treatment of SI joint dysfunction pain and is superior to sham in RCT (Grade, A; Level, I-A; Level of certainty, High)

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."[53]

In 2022, NICE published medical technology guidance on using the iFuse implant system for treating chronic sacroiliac joint pain. It provided the following recommendations:[54]

- 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 U.S. 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 code: 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.

Table 2. Select Sacroiliac Fusion Devices

Device	Manufacturer	Features	Graft Compatible	Clearance	Date
Lateral Transiliac 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

Device	Manufacturer	Features	Graft Compatible	Clearance	Date
iFuse TORQ Implant System	SI Bone	3D printed cannulated screw	Y	K222605	2022
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
SImpact 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	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
Posterolateral Approach					
Rialto SI Joint Fusion System	Medtronic	Cannulated screw	Y	K161210	2016

Device	Manufacturer	Features	Graft Compatible	Clearance	Date
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
Posterior Approach					
Catamaran	Tenon Medical	Metal plug	Y	K180818	2018
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	2023
Invictus Spinal Fixation System	Alphatec Spine, Inc.	Cannulated screw	Y	K232275	2023

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

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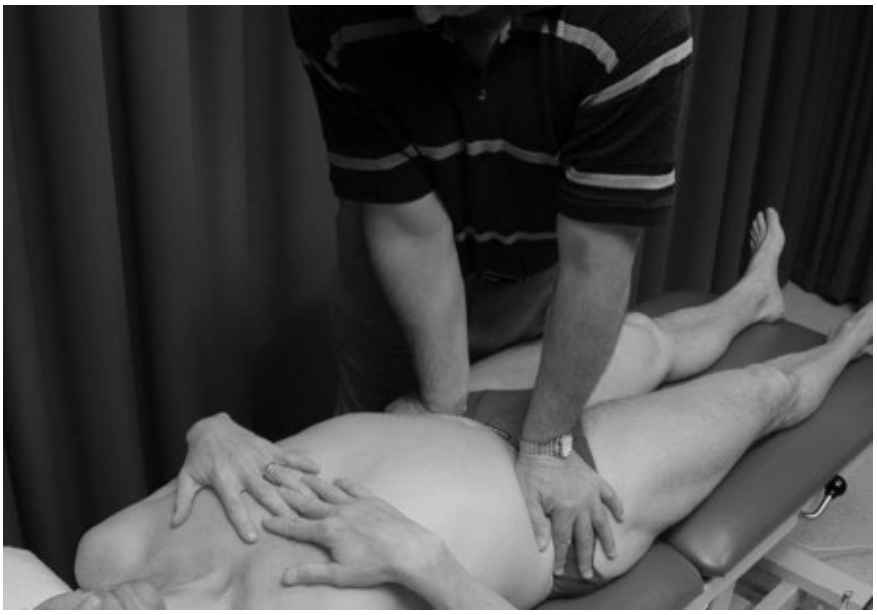
Appendix

"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."

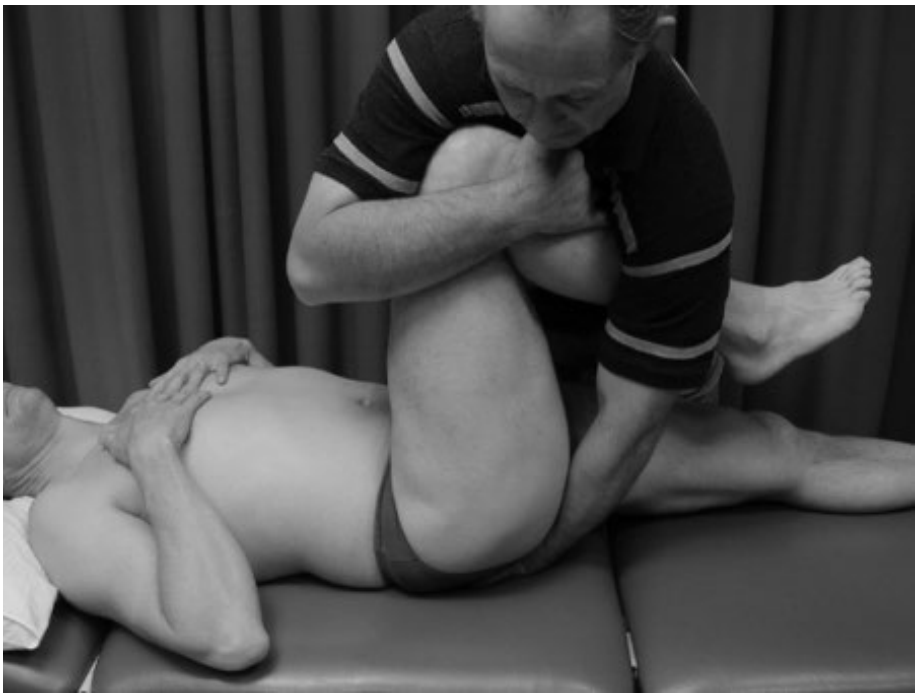
Figure 1 – The Distraction test



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.

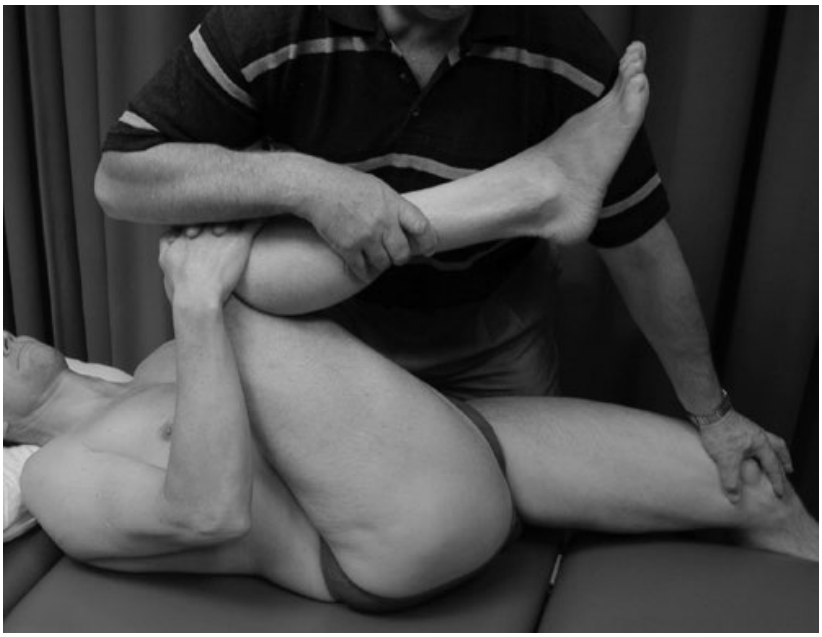
Figure 2 – Thigh thrust test



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.

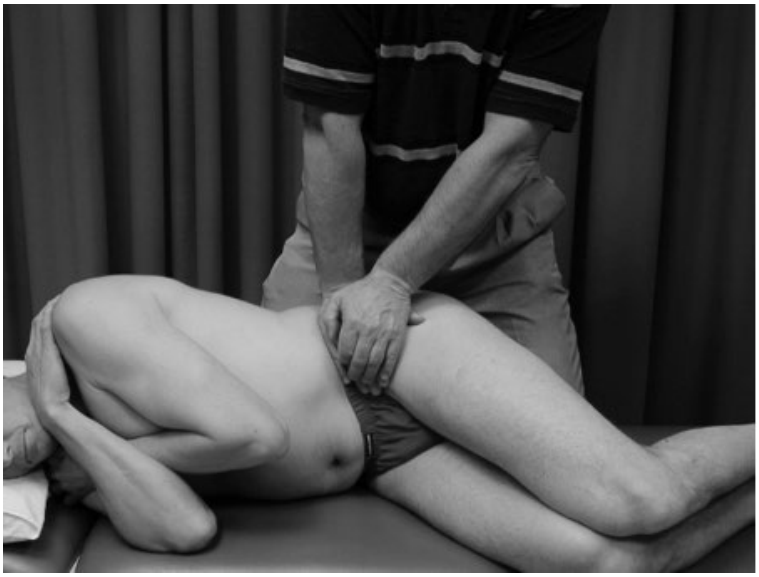
Figure 3 – Gaenslen's test



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.

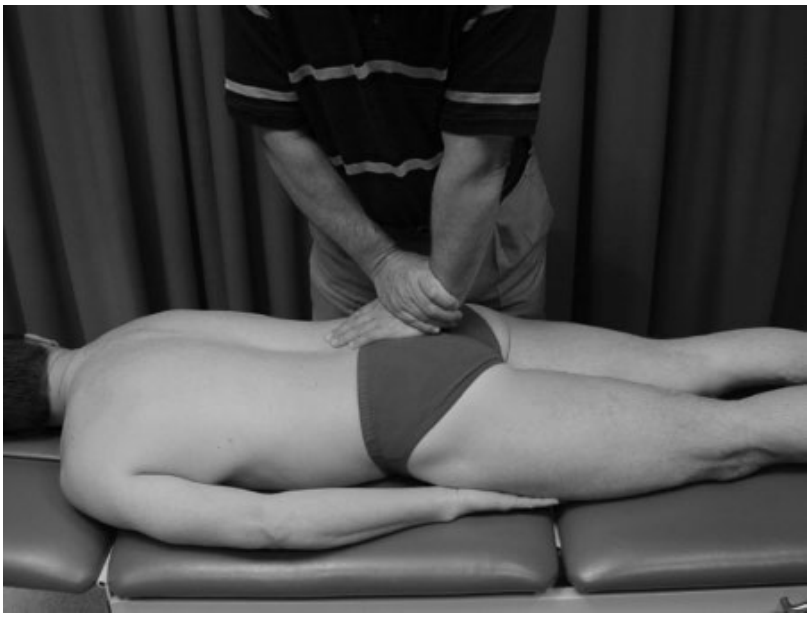
Figure 4 – Compression test



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, 2022

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.
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

Date	Comments
	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.

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ATENÇÃO: Se fala português, encontram-se disponíveis serviços linguísticos, grátis. Ligue para 800-817-3056 (TTY: 711).

ATTENZIONE: In caso la lingua parlata sia l'italiano, sono disponibili servizi di assistenza linguistica gratuiti. Chiamare il numero 800-817-3056 (TTY: 711).

توجه: اگر به زبان فارسی گفتگو می کنید، تسهیلات زبانی بصورت رایگان برای شما فراهم می باشد. با 800-817-3056 (TTY: 711) تماس بگیرید.