



Sacroiliac Joint Fusion (Percutaneous/Minimally Invasive Techniques)

Policy # 00558

Original Effective Date: 08/01/2017

Current Effective Date: 07/01/2023

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Percutaneous/Minimally invasive SI joint fusion

Based on review of available data, the Company may consider percutaneous/minimally invasive Sacroiliac (SI) joint fusion with FDA-approved structural fixation device[±] to be **eligible for coverage**.**

[±]Limited to the insertion of usually more than one structural device traversing the SI joint intended to fuse to the bone or lead to the fusion of the joint itself.

Patient Selection Criteria

Coverage eligibility for percutaneous/minimally invasive SI joint fusion will be considered when ALL of the following criteria are met:

- Pain persisting a minimum of six (6) months that interferes with functional activities as documented by both of the following: (See policy guidelines)
 - Pain score Visual Analogue Scale (VAS) of 5 or greater
 - Oswestry Disability Index (ODI) 30 or greater
- Failure of at least six (6) months of conservative management that includes a trial of at least one therapeutic intra-articular SI joint injection (i.e., corticosteroid injection) (See policy guidelines)
- Confirmation of the SI joint as a pain generator as demonstrated by ALL of the following:

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- Pain pattern consistent with SI joint pain (typically unilateral pain caudal to L5 vertebrae, localized over posterior SI joint); and
- Positive finger Fortin test (localized tenderness with palpation over the sacral sulcus); and
- Absence of tenderness of similar severity elsewhere in the pelvic region (e.g., greater trochanter, lumbar spine, coccyx); and
- Positive response from at least three (3) of the following provocative tests:
 - Long ligament test
 - Faber's test/Patrick's sign
 - Active straight leg raise
 - Compression test
 - Distraction test
 - Thigh thrust test (not recommended for those who are pregnant or those with connective tissue disorder)
 - Gaenslen's test
- Other sources of pain have been excluded as an etiology
- Diagnostic imaging studies that include ALL of the following:
 - Imaging (plain radiographs and a computerized tomography {CT}) or magnetic resonance imaging (MRI) of the SI joint that excludes the presence of destructive lesions (eg, tumor, infection) or inflammatory arthropathy that would not properly be addressed by percutaneous SI joint fusion; and
 - Imaging of pelvis (AP plain radiograph) to rule out concomitant hip pathology; and
 - Imaging of lumbar spine (CT or MRI) to rule out neural compression or other degenerative condition that can be causing low back or buttock pain; and
 - Imaging of SI joint that indicates evidence of injury and/or degeneration
- Diagnostic confirmation of the SI joint as the pain generator demonstrated by at least 75% reduction of pain for the expected duration of the anesthetic used following an image-guided, contrast-enhanced intra-articular SI joint injection (with anesthetic only) on two (2) separate occasions

Revision minimally invasive SI joint fusion

Based on review of available data, the Company may consider revision or replacement SI joint fusion to be **eligible for coverage**** when ANY of the following conditions are present:

- Symptomatic pseudarthrosis (nonunion); or

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- Symptomatic malposition (with impingement of foramen); or
- Infection; or
- Implant fracture/breakage/loosening

When Services Are Considered Not Medically Necessary

Fusion/ stabilization of the sacroiliac joint for the treatment of back pain presumed to originate from the SI joint using any other devices not listed above is considered **not medically necessary**.**

The use of percutaneous/Minimally Invasive SI Joint Fusion for indications other than those addressed in this policy including but not limited to the following is considered to be **not medically necessary**.**

- Presence of infection, tumor, or fracture
- Presence of acute, traumatic instability of the SI joint
- Presence of neural compression as seen on imaging that correlates with symptoms or other more likely source of pain
- Presence of generalized pain behavior (eg, somatoform disorder) or generalized pain disorders (eg, fibromyalgia)
- Presence of ankylosing spondylitis or rheumatoid arthritis
- Posterior (dorsal) minimally invasive surgical (MIS) SI joint fusion procedures using only intra-articular implant(s) (e.g., bone allograft[s], synthetic device[s]), and no internal fixation device

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers percutaneous or minimally invasive SI joint fusion procedures requiring placement of transfixing device(s) and intraarticular implants, including allograft or synthetic device(s) (e.g., Hybrid- SIros^{TM†} 3D Printed + SIrten^{TM†} Allograft, Catamaran^{TM†} SI Joint Fusion System, SiLO TFX^{TM†} Transfixing Si Joint Fusion System, TransLoc 3D^{TM†} SI Joint Fusion System, and VYRSA^{TM†} V1 implant) to be **investigational**.*

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Policy Guidelines

Documentation supporting medical necessity should be submitted at the time of the request and must include the following information:

- Symptom duration and severity
- Specific functional limitations related to symptoms
- Type and duration of all therapeutic measures provided. If conservative management is not appropriate, the reason must be clearly documented.

Conservative management¹ should include a combination of strategies to reduce inflammation, alleviate pain, and correct underlying dysfunction, including physical therapy AND at least one complementary conservative treatment strategy:

- Physical therapy requirement includes ANY of the following:
 - Physical therapy rendered by a qualified provider of physical therapy services
 - Supervised home treatment program that includes ALL of the following:
 - Participation in a patient-specific or tailored program
 - Initial active instruction by MD/DO/PT with redemonstration of patient ability to perform exercises
 - Compliance (documented or by clinician attestation on follow-up evaluation)
 - Exception to the physical therapy requirement in unusual circumstances (for instance, intractable pain so severe that physical therapy is not possible) when clearly documented in the medical record
- Complementary conservative treatment requirement includes ANY of the following:
 - Anti-inflammatory medications and analgesics¹
 - Adjunctive medications such as nerve membrane stabilizers or muscle relaxants¹
 - Intra-articular corticosteroid injection (in the absence of contraindications)¹
 - Sacroiliac support belt or other appropriate bracing
 - Alternative therapies such as acupuncture, chiropractic manipulation, massage therapy, activity modification, and/or a trial period of rest (e.g., from the aggravating/contributing factors) where applicable

¹In the absence of contraindications.



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Clinical reevaluation. In most cases, reevaluation should include a physical examination. Direct contact by other methods, such as telephone communication or electronic messaging, may substitute for in-person evaluation when circumstances preclude an office visit.

Failure of conservative management requires ALL of the following:

- Patient has completed a full course of conservative management (as defined above) for the current episode of care; and
- Worsening of or no significant improvement in signs and/or symptoms upon clinical reevaluation; and
- More invasive forms of therapy are being considered

Documentation of compliance with a plan of therapy that includes elements from these areas is required where conservative management is appropriate.

Reporting of symptom severity. Severity of pain and its associated impact on activities of daily living (ADLs) and instrumental ADLs (IADLs) are key factors in determining the need for intervention. For purposes of these criteria, significant pain and functional impairment refer to pain that is at least 3 out of 10 in intensity and is associated with inability to perform at least two (2) ADLs and/or IADLs.

General Recommendations

Tobacco Cessation. Adherence to a tobacco-cessation program resulting in abstinence from tobacco for at least 6 weeks prior to surgery is recommended.

Diabetes. It is recommended that a patient with history of diabetes maintain hemoglobin A1C 8% or less prior to any joint replacement surgery.

Body Mass Index (BMI). It is recommended that any patient with a BMI equal to or greater than 40 should attempt weight reduction prior to surgery.

Background/Overview

Low back pain is a global health issue and one of the top 3 causes of health degradation in highly developed countries. Goldwaith and Osgood first discussed the possibility that SI joint injury could cause low back pain as early as 1905. Since that time, there have been numerous studies looking at

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the prevalence of SI joint syndrome in persons with back pain, and the results vary widely. Recent studies have estimated that 15%–30% of chronic low back pain is of sacroiliac origin.

Identifying the SI joint as the pain generator is challenging due to the multifactorial nature of low back pain. Once confirmed, management may include physical or manual therapy with a focus on core and pelvic stability, external orthotics, periodic intra-articular injections, anti-inflammatory medications, and lifestyle changes including smoking cessation and weight loss.

SI joint fusion techniques were developed based on the assumption that movement across the joint was the primary source of pain. These techniques are not new, but their success has been limited by the extensive nature of the open fusion procedure and a lack of consistent outcome data. However, recent advances in minimally invasive techniques have shown some promise and are addressed here.

This policy address SI joint fusion when performed as an elective, non-emergent procedure and not as part of the care of a congenital condition, acute or traumatic event such as fracture (excluding fracture of implant and periprosthetic fracture), malignancy or infection.

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

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

FDA product codes: GXD, GXI.

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

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

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Table 1. 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
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

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Triton SI Joint Fixation System ^{TM†}	Choice Spine	3D printed screw with porous graft windows	Y	K211449	2021
Posterolateral Approach					
Rialto ^{TM†} SI Joint Fusion System	Medtronic	Cannulated screw	Y	K161210	2016
SacroFuse ^{®†} /SIJFuse TM	SpineFrontier	Solid or hollow-cored screw	Y	K150017	2015
Posterior Approach					
Catamaran ^{TM†}	Tenon Medical	Metal plug	Y	K180818	2018
NADIA ^{TM†} SI Fusion System (DIANA)	Ilion Medical	Metal plug	N	K190580	2020

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. These are listed in Table 2.

Table 2. Bone allograft Sacroiliac Fusion Devices

CornerLoc ^{TM†}	Fusion Foundation Solutions	Bone allograft	N	HCT/P	N/A
LinQ ^{TM†} SI Joint Stabilization	PainTEQ	Bone allograft	N	HCT/P	N/A
PsiF ^{TM†} Posterior Sacroiliac Fusion	Omnia Medical	Bone allograft	N	HCT/P	N/A

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SIFix System ^{®†}	NuTech	Bone allograft	N	HCT/P	N/A
TransFasten ^{™‡}	Captiva Spine	Bone allograft	N	HCT/P	N/A
SiLo	Aurora Spine	Bone allograft	N	HCT/P	N/A
SiJoin Direct Posterior Sacroiliac SI Joint Fusion	VGI Medical	Bone allograft	N	HCT/P	N/A
Prolix	Camber Spine	Bone allograft +Siconus Screw	N	HCT/P	N/A

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

Products using hybrid approach and combining the posterior graft placement with transfixing screw may have FDA 510(k) clearance and include (not limited to): Hybrid- SIros^{™‡} 3D Printed + Sirten[™] [‡] Allograft, Catamaran^{™‡} SI Joint Fusion System, SiLO TFX^{™‡} Transfixing SI Joint Fusion System, TransLoc 3D^{™‡} SI Joint Fusion System, VYRSA^{™‡} V1 implant. No clinical studies were found to support use of these devices.

Centers for Medicare and Medicaid Services (CMS)

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

For individuals who have SIJ pain who receive SIJ fixation/fusion with a transiliac triangular implant, the evidence includes 2 nonblinded RCTs of minimally invasive fusion, prospective cohorts

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with more than 85% follow-up, and case series. Relevant outcomes are symptoms, functional outcomes, QOL, 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 VAS pain scores and Oswestry Disability Index (ODI) scores in SIJ fusion individuals than in control groups. The reductions in pain and disability observed in the SIJ fusion group at 6 months were maintained out to 1 year compared with controls who had not crossed over. The RCTs were nonblinded without a placebo or an active control group. Prospective cohorts and case series with sample sizes ranging from 45 to 149 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 3 prospective cohort studies and retrospective case series. Relevant outcomes are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. Two 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.

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Policy History

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05/04/2017	Medical Policy Committee review
05/17/2017	Medical Policy Implementation Committee approval. New policy.
02/01/2018	Medical Policy Committee review
02/21/2018	Medical Policy Implementation Committee approval. Coverage statement changed to track AIM guidelines.
03/07/2019	Medical Policy Committee review
03/20/2019	Medical Policy Implementation Committee approval. Criteria revised per AIM guidelines to state:

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- Persistent pain greater than six (6) months' duration that interferes with functional activities as documented by all of the following: (See policy guidelines)
 - Pain score Visual Analogue Scale (VAS) of 5 or greater
 - Oswestry Disability Index (ODI) 30 or greater
- Failure of at least six (6) months of conservative management (See policy guidelines)

03/05/2020 Medical Policy Committee review

03/11/2020 Medical Policy Implementation Committee approval. Added “(with anesthetic only)” to last bullet under patient selection criteria.

03/04/2021 Medical Policy Committee review

03/10/2021 Medical Policy Implementation Committee approval. No change to coverage.

03/03/2022 Medical Policy Committee review

03/09/2022 Medical Policy Implementation Committee approval. Updated conservative care definitions. Added a more rigorous definition of the supervised home PT requirement. FDA and rationale updated.

05/05/2022 Medical Policy Committee review

05/11/2022 Medical Policy Implementation Committee approval. Expanded indication for percutaneous/minimally invasive SI joint fusion to include any FDA-approved structural device with fixation. Updated references.

06/02/2022 Medical Policy Committee review

06/08/2022 Medical Policy Implementation Committee approval. Added requirement for a trial of at least one therapeutic intra-articular SI joint injection. New criteria for revision minimally invasive SI joint fusion. Added exclusion for posterior (dorsal) minimally invasive SI joint fusion procedures using only bone grafts and no internal fixation device. Title changed to Sacroiliac Joint Fusion (Percutaneous/Minimally Invasive Techniques). FDA table split into 2 separate tables. Eligible and Not medically necessary. Bone allografts table was created.

12/06/2022 Coding update

06/01/2023 Medical Policy Committee review

06/08/2023 Coding update

06/14/2023 Medical Policy Implementation Committee approval. Added “intra-articular implant(s) (e.g., bone allograft[s], synthetic device[s])” to the Posterior (dorsal)

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minimally invasive surgical (MIS) SI joint fusion procedures using only intra-articular implant(s) (e.g., bone allograft[s], synthetic device[s]), and no internal fixation device statement. “Based on review of available data, the Company considers percutaneous or minimally invasive SI joint fusion procedures requiring placement of transfixing device(s) and intraarticular implants, including allograft or synthetic device(s) (e.g., Hybrid- SIros 3D Printed + SIrtten Allograft, Catamaran SI Joint Fusion System, SiLO TFX Transfixing Si Joint Fusion System, TransLoc 3D SI Joint Fusion System, and VYRSA V1 implant) to be investigational” was added as investigational.

12/12/2023 Coding update

Next Scheduled Review Date: 06/2024

Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	27279, 27299, 22899 Delete code effective 01/01/2024: 0775T, 0809T Add code effective 01/01/2024: 27278
HCPCS	No codes
ICD-10 Diagnosis	All related Diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;

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Sacroiliac Joint Fusion (Percutaneous/Minimally Invasive Techniques)

Policy # 00558

Original Effective Date: 08/01/2017

Current Effective Date: 07/01/2023

- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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