

Corporate Medical Policy

Sacroiliac Joint Fusion/Stabilization

File Name: sacroiliac_joint_fusion_stabilization
Origination: 11/2012
Last Review: 5/2024

Description of Procedure or Service

Sacroiliac joint fusion is a surgical procedure which fuses the iliac bone (pelvis) to the spine (sacrum) for stabilization. It may be performed for a variety of conditions including pain, trauma, infection, cancer, and spinal instability. The initial treatment for sacroiliac joint syndrome is usually non-surgical, however, surgical options may be explored when the individual is refractory to or unable to tolerate more conservative interventions.

Regulatory Status:

The following implants have received the U.S. Food and Drug Administration's (FDA) 510(k) approval:

Lateral Transiliac Approach:

iFuse Implant System®, iFuse-3D™, iFuse TORQ® Implant System (SI Bone)
SambaScrew®, FIREBIRD SI Fusion System™ (Orthofix)
SI-LOK® Sacroiliac Joint Fixation System (Globus Medical)
Silex Sacroiliac Joint Fusion® (X-Spine Systems)
Simmetry® Sacroiliac Joint Fusion System (RTI)
Slros™ (Genesys Spine)
Slimpact® Sacroiliac Joint Fixation System (Life Spine)
Triton SI Joint Fixation System™ (Choice Spine)
UNITY Sacroiliac Joint Fixation System (Dio Medical Corp.)
T-FIX® 3DSI Joint Fusion System (Cutting Edge Spine, LLC)
PathLoc SI Joint Fusion System (L&K Biomed Co., Ltd.)
SI-Cure Sacroiliac Joint Fusion Device System (Alevio, LLC)
Integrity-SI® Fusion System (OsteoCentric Technologies)
Sacrix® Sacroiliac Joint Fusion Device System (LESpine Innovations)

Posterolateral Approach:

Rialto™ SI Joint Fusion System (Medtronic)
SacroFuse®/SIJFuse™ (Spine Frontier)
SILO TFX MIS Sacroiliac Joint Fixation System (Aurora Spine, Inc.)

Posterior Approach:

SI-Fix System® (NuTech)
Catamaran™, CATAMARAN SI Joint Fusion System (Tenon Medical, Inc)
CornerLoc™ (Fusion Foundation Solutions)
LinQ™ SI Joint Stabilization (PainTEQ)
NADIA™ SI Fusion System (DIANA)
PsiF™ Posterior Sacroiliac Fusion (Omnia Medical)
TransFasten™ (Captiva Spine)

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Related Policies:

Diagnosis and Treatment of Sacroiliac Joint Pain

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

BCBSNC will provide coverage for sacroiliac joint fusion/stabilization when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Sacroiliac Joint Fusion/Stabilization is covered

Sacroiliac joint fusion or stabilization procedures may be considered medically necessary for any of the following indications:

1. For the treatment of back pain presumed to originate from the sacroiliac joint, using transiliac placement of a minimally invasive, titanium triangular implant (e.g. iFuse), when ALL of the following criteria have been met:
 - The pain is caudal to the lumbar spine (L5 vertebra), localized over the posterior sacroiliac joint, and consistent with sacroiliac joint pain, AND
 - The 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 (eg, somatoform disorder) or generalized pain disorders (eg, 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
 - On physical examination there is 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 (eg, thigh thrust test, compression test, Gaenslen sign, distraction test, Patrick test, posterior provocation test); AND
 - Diagnostic imaging studies include ALL of the following:
 - 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
 - anteroposterior plain radiograph of the pelvis rules out concomitant hip pathology; AND
 - computed tomography or magnetic resonance imaging of the lumbar spine is performed to rule out neural compression or other degenerative condition that can be causing low back or buttock pain; AND
 - sacroiliac joint imaging indicates evidence of injury and/or degeneration; AND

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- Diagnostic injections performed on 2 separate occasions, using an image-guided, contrast-enhanced, intra-articular sacroiliac joint injection, demonstrate at least a 75% reduction in pain for the expected duration of the anesthetic; AND
 - A trial of a therapeutic sacroiliac joint injection (ie, corticosteroid injection) has been performed at least once; AND
 - The procedure is performed by a physician trained in either neurosurgery or orthopedic spine surgery; AND
 - The provider performing the surgery has either completed procedure-specific training or has been granted hospital privileges to perform minimally invasive sacroiliac joint surgery.
2. as an adjunct to sacrectomy or partial sacrectomy related to tumors involving the sacrum; or
 3. as an adjunct to the medical treatment of sacroiliac joint infection/sepsis; or
 4. severe traumatic injuries associated with pelvic ring fracture; or
 5. when multisegment spinal constructs extend to the sacrum/ilium, as a component of medically necessary lumbar spine fusion procedures (See medical policy, 'Lumbar Spine Procedures').

When Sacroiliac Joint Fusion/Stabilization is not covered

When none of the above indications are present, the procedure is considered not medically necessary, including use of any other device not listed above (e.g., cylindrical threaded implant).

Policy Guidelines

For individuals who have SIJ pain who receive SIJ fusion/fixation with a triangular implant, the evidence includes two nonblinded randomized controlled trials (RCTs) of minimally invasive fusion, prospective cohorts with more than 85% follow-up, and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Both RCTs have reported outcomes past six months, after which crossover was allowed. Both studies reported significantly greater reductions in VAS pain scores and ODI scores in SIJ fusion patients than in control groups. The reductions in pain and disability observed in the SIJ fusion group at 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 patients and low dropout rates (<15%), also showed reductions in pain and disability out to five 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 patients and longer follow-up are needed to evaluate these devices. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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Ongoing and Unpublished Clinical Trials

NCT01861899 is a manufacturer-sponsored observational study of SI-LOK® sacroiliac joint fixation. Actual enrollment was 46 participants. This study was completed in April 2019. As of April 2024, no study results have been posted on ClinicalTrials.gov.

NCT02270203 is a manufacturer-sponsored extended follow-up study from two ongoing multicenter prospective US clinical trials (INSITE and SIFI). 103 participants are enrolled, all of whom have already undergone SI joint fusion with iFuse Implant System. The study is listed as completed July 2019. As of April 2024, no results have been posted.

NCT02074761 is a prospective, non-randomized post market study designed to evaluate fusion and pain reduction following the use of the SIMmetry System. This study will be conducted at up to 40 sites and 250 total subjects will be enrolled and followed through 24 months. Estimated study completion date is November 2020. As of May 2023, results had been submitted to ClinicalTrials.gov but are not yet publicly available.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 27278, 27279, 27280, 27299

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

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Medical Director – 10/2012

BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.23, 2/2013

Specialty Matched Consultant Advisory Panel – 5/2013

Senior Medical Director – 1/2014

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Ashman B, Norvell DC, Hermsmeyer JT. Chronic sacroiliac joint pain: fusion versus denervation as treatment options. Evid Based Spine Care J 2010; 1(3):35-44.

Cohen SP, Hurley RW, Buckenmaier CC, 3rd et al. Randomized placebo-controlled study evaluating lateral branch radiofrequency denervation for sacroiliac joint pain. Anesthesiology 2008;109(2):279-88.

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Spiker WR, Lawrence BD, Raich AL et al. Surgical versus injection treatment for injection-confirmed chronic sacroiliac joint pain. *Evid Based Spine Care J* 2012; 3(4):41-53.

Duhon BS, Cher DJ, Wine KD et al. Safety and 6-month effectiveness of minimally invasive sacroiliac joint fusion: a prospective study. *Med Devices (Auckl)* 2013; 6:219-29.

BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.23, 5/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.23, 4/2015

Specialty Matched Consultant Advisory Panel – 5/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.23, 11/12/2015

Specialty Matched Consultant Advisory Panel – 5/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.23, 8/11/16

BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.23, 10/13/16

Specialty Matched Consultant Advisory Panel – 5/2017

For policy renamed Sacroiliac Joint Fusion/Stabilization

BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.23, 12/14/2017

Specialty Matched Consultant Advisory Panel – 6/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.23, 11/8/2018

Specialty Matched Consultant Advisory Panel – 5/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.23, 11/14/2019

Specialty Matched Consultant Advisory Panel – 5/2020

BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.23, 11/12/2020

Specialty Matched Consultant Advisory Panel – 5/2021

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

Specialty Matched Consultant Advisory Panel – 5/2022

Specialty Matched Consultant Advisory Panel – 5/2023

Medical Director Review- 5/2024

Specialty Matched Consultant Advisory Panel – 5/2024

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Policy Implementation/Update Information

- 11/27/12 New policy. “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 severe traumatic injuries associated with pelvic ring fracture; or when multisegment spinal constructs extend to the sacrum/ilium, for covered lumbar spine fusion procedures (See medical policy, ‘Lumbar Spine Fusion Surgery’).” “When none of the above indications are present, the procedure is considered not medically necessary. Sacroiliac joint fusion surgery is considered investigational for the treatment of mechanical low back pain when the sacroiliac joint is the suspected cause.” Senior Medical Director review 10/28/2012. Notification given 11/27/12. Policy effective 2/26/13. (btw)
- 4/16/13 Added CPT code 27299 to Billing/Coding section. (btw)
- 7/1/13 Specialty Matched Consultant Advisory Panel meeting 5/2013. No change to policy intent. Added new July 2013 CPT code, 0334T, to Billing/Coding section. Reference added. (btw)
- 8/27/13 Removed CPT code 0334T from Billing/Coding section. Code implementation delayed. (btw)
- 11/26/13 Added CPT code 0334T to Billing/Coding section, code effective 7/1/2013. (btw)
- 2/11/14 Revised statement in the When Covered section for clarification. Statement changed from; “when multisegment spinal constructs extend to the sacrum/ilium, for covered lumbar spine fusion procedures (See medical policy, ‘Lumbar Spine Fusion Surgery’).” To “when multisegment spinal constructs extend to the sacrum/ilium, as a component of medically necessary lumbar spine fusion procedures (See medical policy, ‘Lumbar Spine Fusion Surgery’).” Senior Medical Director review 1/30/2014. (btw)
- 6/10/14 Specialty Matched Consultant Advisory Panel review 5/27/2014. No change to policy intent. (btw)
- 12/30/14 References added. Policy Guidelines updated. Added code 27279 to Billing/Coding section for effective date 1/1/2015. Deleted code 0334T. No change to Policy statement. (sk)
- 12/30/15 Specialty Matched Consultant Advisory Panel review 5/27/2015. Reference added. (sk)
- 2/29/16 Reference added. Policy Guidelines updated. (sk)
- 7/1/16 Specialty Matched Consultant Advisory Panel review 5/25/2016. (sk)
- 6/30/17 References added. Policy Guidelines updated. Clinical Trials information updated. Specialty Matched Consultant Advisory Panel review 5/31/2017. (sk)

For policy renamed Sacroiliac Joint Fusion/Stabilization

- 9/7/18 Reference added. Specialty Matched Consultant Advisory Panel review 6/2018. SIJ fusion/stabilization with a titanium triangular implant is considered medically necessary when criteria are met. Policy Guidelines updated. Clinical trials

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- information updated. Title changed from Sacroiliac Joint Fusion to Sacroiliac Joint Fusion/Stabilization. Medical Director review. (sk)
- 6/11/19 Reference added. Specialty Matched Consultant Advisory Panel review 5/15/2019. (sk)
- 6/9/20 Reference added. Clinical Trials information updated. Specialty Matched Consultant Advisory Panel review 5/20/2020. (sk)
- 6/15/21 Reference added. New implants added. Policy Guidelines updated. Clinical Trials information updated. Specialty Matched Consultant Advisory Panel review 5/19/2021. (sk)
- 6/14/22 Reference added. Description section updated. “Transiliac placement” and “e.g., iFuse” added to the medically necessary statement on sacroiliac joint fusion. Policy Guidelines updated. Clinical Trials information updated. Specialty Matched Consultant Advisory Panel review 5/18/2022. (sk)
- 12/30/22 Added code 0775T to Billing/Coding section. (sk)
- 6/30/23 Clinical Trials information updated. Specialty Matched Consultant Advisory Panel review 5/17/2023. Added new code 0809T to Billing/Coding section. (sk)
- 12/29/23 Added the following CPT code to the Billing/Coding section: 27278, effective 1/1/2024 and removed terminated CPT codes 0775T and 0809T. (ldh)
- 6/12/24 Regulatory Status section updated. Added Related Policies section. Clinical Trials information updated. Medical Director review 5/2024. Specialty Matched Consultant Advisory Panel review 5/2024. (ldh)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.