



An Independent Licensee of the Blue Cross Blue Shield Association

EVIDENCE-BASED GUIDELINES
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 01/02/24
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DIAGNOSIS AND TREATMENT OF SACROILIAC JOINT PAIN

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.

This Evidence-Based Criteria provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "**Description**" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "**Criteria**" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Evidence-Based Criteria are subject to change as new information becomes available.

For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

This policy does not address the treatment of sacroiliac joint (SIJ) pain due to infection, trauma, or neoplasm.

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.

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, corticosteroid injection, radiofrequency ablation, stabilization, and arthrodesis. Some procedures have been referred to as SIJ fusion but may be more appropriately called fixation due to little to no bridging bone on radiographs. Devices for SIJ fixation/fusion that promote bone ingrowth to fixate the implants include a triangular implant (iFuse Implant System) and cylindrical threaded devices (e.g., Rialto, SImmetry, Silex, SambaScrew, SI-LOK). Some devices also have a slot in the middle where autologous or allogeneic bone can be inserted. This added bone is intended to promote the fusion of the SIJ.

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

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®, 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.

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The following commercially available Sacroiliac Fusion Devices have been approved by the U.S. Food and Drug Administration (FDA) for the Lateral Transiliac Approach:

- iFuse®
- iFuse® 3D
- iFuse TORQ® Implant System
- FIREBIRD SI Fusion System™
- Integrity-SI® Fusion System
- PathLoc SI Joint Fusion System
- Sacrix® Sacroiliac Joint Fusion Device System
- SambaScrew®
- SI-Cure Sacroiliac Joint Fusion System
- Silex Sacroiliac Joint Fusion®
- SI-LOK® Sacroiliac Joint Fixation System
- Slimmetry® Sacroiliac Joint Fusion System
- Slimpact® Sacroiliac Joint Fixation System
- SIros™
- T-FIX® 3DSI Joint Fusion System
- Triton SI Joint Fixation System™
- UNITY Sacroiliac Joint Fixation System

The following commercially available Sacroiliac Fusion Devices have been approved by the U.S. Food and Drug Administration (FDA) for the Posterolateral Approach:

- Rialto™ SI Joint Fusion System
- SacroFuse®/SIJFuse™
- SILO TFX MIS Sacroiliac Joint Fixation System

The following commercially available Sacroiliac Fusion Devices have been approved by the U.S. Food and Drug Administration (FDA) for the Posterior Approach:

- Catamaran™
- CATAMARAN SI Joint Fusion System
- CornerLoc™
- Invictus® Spinal Fixation System
- LinQ™ SI Joint Stabilization
- NADIA™ SI Fusion System (DIANA)
- PsiF™ Posterior Sacroiliac Fusion
- SIFix System®
- TiLink-P SI Joint Fusion System
- TransFasten™

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Criteria:

- Injection of anesthetic for diagnosing SIJ pain is considered **medically necessary** with documentation of **ALL** of the following:
 1. Pain has failed to respond to 3 months of conservative management, which may consist of therapies such as nonsteroidal anti-inflammatory medications, acetaminophen, manipulation, physical therapy, and a home exercise program.
 2. Dual (controlled) diagnostic blocks with 2 anesthetic agents with differing duration of action are used.
 3. The injections are performed under imaging guidance.
- If the above criteria are not met, injection of anesthetic for diagnosing SIJ pain is considered **experimental or investigational** based upon **ONE** or more of the following:
 1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
 3. Insufficient evidence to support improvement of the net health outcome; or
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, or
 5. Insufficient evidence to support improvement outside the investigational setting
- Injection of corticosteroid for the treatment of SIJ pain is considered **medically necessary** with documentation of **ALL** of the following:
 1. Pain has failed to respond to 3 months of conservative management, which may consist of therapies such as nonsteroidal anti-inflammatory medications, acetaminophen, manipulation, physical therapy, and a home exercise program.
 2. The injection is performed under imaging guidance.
 3. No more than 3 injections are given in 1 year.
- If the above criteria are not met, injection of corticosteroid for the treatment of SIJ pain is considered **experimental or investigational** based upon **ONE** or more of the following:
 1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
 3. Insufficient evidence to support improvement of the net health outcome; or
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, or

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5. Insufficient evidence to support improvement outside the investigational setting
- Fusion/stabilization of the sacroiliac joint is considered **medically necessary** with documentation of **ANY** of the following:
 1. As an adjunct to sacrectomy or partial sacrectomy related to tumors involving the sacrum
 2. As an adjunct to the medical treatment of sacroiliac joint infection/sepsis
 3. Severe traumatic injuries associated with pelvic ring fracture
 4. During multisegment spinal constructs (e.g., correction of deformity in scoliosis or kyphosis surgery) extending to the ilium
- Minimally invasive fixation/fusion of the SIJ using transiliac placement of a titanium triangular implant (e.g., iFuse) is considered **medically necessary** with documentation of **ALL** of the following:
 1. Pain is at least 5 on a 0 to 10 rating scale that impacts quality of life or limits activities of daily living; and
 2. There is an absence of generalized pain behavior (e.g., somatoform disorder) or generalized pain disorders (e.g., fibromyalgia); and
 3. Individuals have undergone and failed a minimum 6 months of intensive nonoperative treatment that must include medication optimization, activity modification, bracing, and active therapeutic exercise targeted at the lumbar spine, pelvis, SIJ, and hip, including a home exercise program; and
 4. Pain is caudal to the lumbar spine (L5 vertebra), localized over the posterior SIJ, and consistent with SIJ pain; and
 5. 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
 6. There is a positive response to a cluster of 3 provocative tests (e.g., thigh thrust test, compression test, Gaenslen sign, distraction test, Patrick test, posterior provocation test); and
 7. Diagnostic imaging studies include **ALL** of the following:
 - Imaging (plain radiographs and computed tomography or magnetic resonance imaging) of the SIJ excludes the presence of destructive lesions (e.g., tumor, infection) or inflammatory arthropathy of the SIJ; and
 - Imaging of the pelvis (anteroposterior plain radiograph) rules out concomitant hip pathology; and

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- 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 SIJ indicates evidence of injury and/or degeneration; and
8. There is at least a 75% reduction in pain for the expected duration of the anesthetic used following an image-guided, contrast-enhanced intra-articular SIJ injection on 2 separate occasions; and
 9. A trial of a therapeutic SIJ injection (e.g., corticosteroid injection) has been performed at least once.
- Fixation/fusion of the SIJ for all other indications not previously listed or if above criteria not met is considered **experimental or investigational** when any **ONE** or more of the following criteria are met:
1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
 3. Insufficient evidence to support improvement of the net health outcome; or
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, or
 5. Insufficient evidence to support improvement outside the investigational setting

These indications include, *but are not limited to*:

- The treatment of back pain presumed to originate from the SIJ
- Arthrography of the sacroiliac joint (SIJ) is considered **experimental or investigational** when any **ONE** or more of the following criteria are met:
1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
 3. Insufficient evidence to support improvement of the net health outcome; or
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, or
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- Radiofrequency denervation of the SIJ is considered **experimental or investigational** when any **ONE** or more of the following criteria are met:
1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
 3. Insufficient evidence to support improvement of the net health outcome; or
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, or
 5. Insufficient evidence to support improvement outside the investigational setting

Resources:

Literature reviewed 07/02/24. We do not include marketing materials, poster boards and non-published literature in our review.

Resources prior to 07/02/24 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. Ab Aziz SNF, Zakaria Mohamad Z, Karupiah RK, Che Ahmad A, Omar AS. Efficacy of Sacroiliac Joint Injection With Anesthetic and Corticosteroid: A Prospective Observational Study. *Cureus*. Apr 2022;14(4):e24039. doi:10.7759/cureus.24039
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9. 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 1 2009;34(10):1066-77. doi:10.1097/BRS.0b013e3181a1390d
10. 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 4 2024;49(3):184-191. doi:10.1136/rapm-2023-104568
11. 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. doi:10.2147/mder.S160989
12. Dengler J, Kools D, Pflugmacher R, et al. Randomized Trial of Sacroiliac Joint Arthrodesis Compared with Conservative Management for Chronic Low Back Pain Attributed to the Sacroiliac Joint. *J Bone Joint Surg Am*. Mar 6 2019;101(5):400-411. doi:10.2106/jbjs.18.00022
13. Dengler J, Stureson 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. doi:10.1007/s00701-016-2953-7
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17. Duhon BS, Cher DJ, Wine KD, Kovalsky DA, Lockstadt H. Triangular Titanium Implants for Minimally Invasive Sacroiliac Joint Fusion: A Prospective Study. *Global Spine J*. May 2016;6(3):257-69. doi:10.1055/s-0035-1562912

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24. Kucharzyk D, Colle K, Boone C, Araghi A. Clinical Outcomes Following Minimally Invasive Sacroiliac Joint Fusion With Decortication: The EVoluSlon Clinical Study. *Int J Spine Surg.* Feb 2022;16(1):168-175. doi:10.14444/8185
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38. 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. doi:10.14444/3028
39. 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. doi:10.1097/ALN.0b013e3181c43103

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EVIDENCE-BASED GUIDELINES
SECTION: SURGERY

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LAST REVIEW DATE: 07/02/24
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Coding:

CPT: 0775T, 0809T, 20610, 27096, 27278, 27279, 27280, 64451, 64625
 HCPCS: G0259, G0260

<u>History:</u>	<u>Date:</u>	<u>Activity:</u>
Medical Policy Panel	07/02/24	Review with revisions
Medical Policy Panel	01/02/24	Review with revisions
Legal Division	12/21/23	Review with no revisions (Criteria)
Medical Director (Dr. Raja)	12/21/23	Review with revisions

Policy Revisions:

07/02/24 Added: CPT code: 27278
 07/02/24 Updated: Description section; Resource section



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If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ’s Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ’s Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

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Navajo: Dii kwe'é atah nilinigií Blue Cross Blue Shield of Arizona haada yit'éego bina'idilkidgo éi doodago Háida bį́já anilyeedigií t'áadoo le'é yina'idilkidgo beehaz'áanii hólo dii t'áa hazaadk'ehjí háká a'doowołgo bee haz'ą doo baqah ilinígóó. Ata' halne'ígíí kojį' bich'į' hodilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

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Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.

