SACROILIAC JOINT FUSION

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 Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline 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.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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SACROILIAC JOINT FUSION (cont.)

Description:

The sacroiliac (SI) joint is located in the pelvis and links the iliac bones (pelvis) to the spine. Similar to other joints, the SI joint can become damaged. Open, minimally invasive and percutaneous SI joint fusion are surgical procedures which fuses the iliac bone (pelvis) to the spine (sacrum) and are performed for a variety of orthopedic conditions including trauma, infection, cancer and as part of multisegmental long fusions for the correction of spinal deformity (e.g., idiopathic scoliosis, neuromuscular scoliosis). Plates and/or screws are placed to develop a bony fusion across the SI joint for stabilization. SI joint fusion has been investigated for treatment of back pain presumed to originate from the SI joint.

Percutaneous or minimally invasive fixation/fusion devices include iFUSE Implant System®, Simmetry® Sacroiliac Joint Fusion System, SI-LOK® Sacroiliac Joint Fixation System and Silex™ Sacroiliac Joint Fusion System.

Criteria:

- 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 (for example, correction of deformity in scoliosis or kyphosis surgery) extending to the ilium

- Fusion/stabilization of the sacroiliac joint for the treatment of back pain presumed to originate from the SI joint or if above criteria not met is considered experimental or investigational, including, but not limited to, percutaneous and minimally invasive techniques based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.
SACROILIAC JOINT FUSION (cont.)

Resources:

Literature reviewed 11/22/16. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.


SACROILIAC JOINT FUSION (cont.)

Resources: (cont.)


SACROILIAC JOINT FUSION (cont.)

Resources: (cont.)


SACROILIAC JOINT FUSION (cont.)

Resources: (cont.)


FDA Summary Statements for sacroiliac joint fixation. Device names include, *but are not limited to*:

- iFuse Implant System
- Silex Sacroiliac Joint Fusion System

  - FDA-approved indication: For sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroilitis.

FDA 510K Summary for Symmetry Sacroiliac Joint Fusion System:

  - FDA-approved indication: For fixation of large bones, including bones of the pelvis, for conditions including degenerative sacroilitis and sacroiliac joint disruptions.
SACROILIAC JOINT FUSION (cont.)

Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

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

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe’é atah niíñiigíí Blue Cross Blue Shield of Arizona haada yit’éego bina’idilkidgo éí doodago Háida bígí anílyeedígíí t’aadoo le’e yina’idilkidgo beehaz’áanií hólq díí t’aá hazaadk’éhjí háká a’dooowolgo bee haz’á doo bąq̈h ilínígóó. Ata’ halné’íígí kójí bíchí’ jí hodíilníih 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，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。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic: إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona الضرورية بلغتك من دون أية تكلفة، للتحدث مع مرجم التصلب ب 877-475-4799.
SACROILIAC JOINT FUSION (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutuuanan, ay may mga katarungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatang na makakuha ng tulong at impormasyon sa iyong wika ng walang gastos. Upang maaasap ang isang tagasalitin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799 로 전화하십시오.

French: Si vous, ou quelqu’un que vous êtes en train d’aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d’obtenir de l’aide et l’information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеется вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizonaについてご質問がございますから、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、877-475-4799 までお電話ください。

Farsi:

goo iraan, ya karmi ke shoma be omak meyekide, soval dar mordad az lafta to daragi daragand mardom tid-gi 475-477-4799, blue cross blue shield of arizona, az lafta to daragi daragand mardom tid-gi 475-477-4799. az lafta to daragi daragand mardom tid-gi 475-477-4799.

Assyrian:

Serbo-Croatian: Ukoliko Vi ili neko kome Vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijate pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodiocem, nazovite 877-475-4799.

Thai: หากคุณ หรือผู้ช่วยช่วยตรวจอาการของคุณ Blue Cross Blue Shield of Arizona คุณจะได้รับความช่วยเหลือและข้อมูลภาษา ของคุณได้โดยไม่เสียเงิน ที่หมายเลข โทรศัพท์ 877-475-4799.