BlueCross BlueShield of Arizona
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MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

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SACROILIAC JOINT FUSION

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.

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.

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 join 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.

SACROILIAC JOINT FUSION (cont.)

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.

Resources:

1. 6.01.23 BCBS Association Medical Policy Reference Manual. Diagnosis and Treatment of Sacroiliac Joint Pain. Re-issue date 05/22/2014, issue date 02/18/2000.

2. Cummings J, Jr., Capobianco RA. Minimally invasive sacroiliac joint fusion: one-year outcomes in 18 patients. *Ann Surg Innov Res.* 2013;7(1):12.

SACROILIAC JOINT FUSION (cont.)

Resources: (cont.)

3. Gaetani P, Miotti D, Risso A, et al. Percutaneous arthrodesis of sacro-iliac joint: a pilot study. *J Neurosurg Sci.* Dec 2013;57(4):297-301.

4. Kim JT, Rudolf LM, Glaser JA. Outcome of percutaneous sacroiliac joint fixation with porous plasma-coated triangular titanium implants: an independent review. *Open Orthop J.* 2013;7:51-56.

5. Miller LE, Reckling WC, Block JE. Analysis of postmarket complaints database for the iFuse SI Joint Fusion System(R): a minimally invasive treatment for degenerative sacroiliitis and sacroiliac joint disruption. *Med Devices (Auckl).* 2013;6:77-84.

6. Rudolf L. MIS Fusion of the SI Joint: Does Prior Lumbar Spinal Fusion Affect Patient Outcomes? *Open Orthop J.* 2013;7:163-168.

7. Sachs D, Capobianco R. One year successful outcomes for novel sacroiliac joint arthrodesis system. *Ann Surg Innov Res.* 2012;6(1):13.

8. Sachs D, Capobianco R. Minimally invasive sacroiliac joint fusion: one-year outcomes in 40 patients. *Adv Orthop.* 2013;2013:536128.

9. Schroeder JE, Cunningham ME, Ross T, Boachie-Adjei O. Early results of sacro-iliac joint fixation following long fusion to the sacrum in adult spine deformity. *HSS J.* Feb 2014;10(1):30-35.

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 Slmmetry Sacroiliac Joint Fusion System:

- FDA-approved indication: For fixation of large bones, including bones of the pelvis, for conditions including degenerative sacroiliitis and sacroiliac joint disruptions.