

## Clinical Policy: Sacroiliac Joint Fusion

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### Description

Sacroiliac joint (SIJ) fusion, or arthrodesis, is a surgical technique that fuses the iliac bone to the sacrum for stabilization. This procedure may be performed in a minimally invasive manner or as an open surgical procedure requiring a larger incision and subsequent increased recovery time.

### Policy/Criteria

- I. It is the policy of Pennsylvania Health and Wellness® (PHW) that open sacroiliac joint fusion is **medically necessary** for any of the following indications:
  - A. Stabilization of a traumatic, severe disruption, or fracture of the pelvic ring;
  - B. As an adjunct to sacrectomy or partial sacrectomy for the treatment of sacral tumors; or
  - C. As an adjunct to the medical treatment of sacroiliac joint infection or sepsis (e.g., osteomyelitis, pyogenic sacroiliitis);
  - D. During multi-segment spinal constructs (e.g., correction of deformity in scoliosis or kyphosis surgery, extending to the ilium).
- II. It is the policy of PWH that minimally invasive sacroiliac joint fusion is **medically necessary** for the treatment of low back/buttock pain when meeting all of the following:
  - A. Failure of at least six consecutive months of conservative treatment that includes all of the following:
    1. Medication optimization (unless contraindicated);
    2. Activity modification;
    3. At least four to six weeks of active therapeutic exercise targeted at the lumbar spine, pelvis, sacroiliac joint (SIJ) and hip, including a home exercise program or documentation of patient's inability to tolerate; and/or osteopathic or chiropractic manipulation;
  - B. Non-radiating, unilateral pain that is caudal to the lumbar spine (L5 vertebrae), localized over the posterior SIJ, and consistent with SIJ pain, that interferes with activities of daily living (ADLs);
  - C. Localized tenderness with palpation of the posterior SIJ in the absence of tenderness of similar severity elsewhere (e.g., greater trochanter, lumbar spine, coccyx) and other obvious sources of pain do not exist;
  - D. Positive response to the thigh thrust test or compression test and at least two of the following additional provocative tests (distraction, Gaenslen's, Patrick's test/FABER test);
  - E. Absence of generalized pain behavior (e.g., somatoform disorder) or generalized pain disorders (e.g., fibromyalgia);
  - F. Recent (within six months) diagnostic imaging studies that include all of the following:
    1. Plain radiographs and CT or MRI of the SI joint that excludes the presence of destructive lesions (e.g., tumor, infection), fracture, traumatic SIJ instability, or inflammatory arthropathy;
    2. Plain radiographs of the ipsilateral hip that excludes the presence of osteoarthritis;

3. CT or MRI of the lumbar spine that excludes neural compression or other degenerative conditions that can cause low back or buttock pain.
- G. At least 75% reduction in pain for the expected duration of the anesthetic used following an image guided, contrast-enhanced intra-articular (diagnostic) SIJ injection on two separate occasions, at least two weeks apart;
- H. A failure of at least one therapeutic intra-articular SIJ injection (i.e., corticosteroid injection), or a therapeutic injection is contraindicated;
- I. Procedure will be performed using the lateral transarticular approach.

**III.** It is the policy of PWH that the long-term safety and effectiveness of sacroiliac joint fusion procedures, either open or minimally invasive has not been proven for all other indications, including but not limited to, treatment of mechanical or axial low back pain, radicular pain syndromes, sacral insufficiency fractures, and pelvic girdle pain, due to limited clinical evidence.

**IV.** It is the policy of PHW that current evidence does not support sacroiliac joint fusion using implants other than those which are placed across the joint (transfixing) to promote fusion (e.g., allograft, nonmetallic implants).

### **Background**

Low back pain affects approximately 84% of adults during their lives with the sacroiliac joint being the source of chronic low back pain in approximately 15% to 30% of patients.<sup>3,11,17</sup> When the sacroiliac joint is the source of this pain, and all appropriate conservative measures fail to relieve symptoms of trauma associated with fracture, infection/sepsis, tumors involving the sacrum, cancer, or spinal instability, treatment options may include fusion of this joint or implantation of devices that stabilize this joint with minimally invasive surgery. To stabilize the sacroiliac joint, the iliac crest bone and the sacrum are held together by plates and/or screws or an interbody fusion cage, until the two bones fuse.<sup>3</sup>

There are a number of FDA-approved implants that have been proposed for sacroiliac joint disorders, but the majority of clinical trials and studies have been done on the iFuse implant system. This was initially called the SI Joint Fusion and received the original 510(k) clearance from the Food and Drug Administration in November 2008 for fracture fixation of long bones, large bone fragments of the pelvis and for conditions including sacroiliac joint disruptions and degenerative sacroiliitis. Additional FDA clearances were given on April 21, 2011, and on April 17, 2015. The iFuse system involves the fluoroscopically guided insertion of titanium implants across the sacroiliac joint. Under general anesthesia, a two to three centimeter incision is created, and after determining the appropriate size of the implant, a cannulated delivery system is used to insert the implants into the proper position. While the number varies, most patients receive three implants to stabilize the joint.<sup>7,8</sup>

Whang and Polly completed two randomized controlled trials with a six month and one year follow up, respectively, on sacroiliac joint fusion using iFuse versus non-surgical management. The iFuse led to better outcomes and similar safety compared with nonsurgical management, and to better operative outcomes and at least comparable efficacy compared with open surgery. However, uncertainty remains due to the lack of longer-term efficacy and safety follow-up with

radiologic confirmation, and to the lack of comparisons with other minimally invasive approaches.<sup>5,14</sup> There is additional evidence suggesting sacroiliac joint fusion with iFuse improves pain, enhances health-related quality of life, and decreases disability compared to non-surgical management.<sup>2,21,22</sup>

The percutaneous placement of an intraarticular stabilization device into the sacroiliac joint (SIJ) differs from the established percutaneous arthrodesis of the SIJ with placement of a transfixing device. Examples of SIJ stabilization devices that do not involve transfixation are CornerLoc<sup>™</sup>, TransFasten<sup>®</sup>, and LinQ<sup>™</sup>. These allograft devices are placed directly to the SIJ via posterior approaches, therefore, and do not involve drilling through the ilium to the sacrum or insertion of hardware. Minimally invasive SIJ arthrodesis involves the placement of screws, cages, or allograft dowels percutaneously using lateral transarticular (i.e., through the ilium to the sacrum) or posterior approaches. Implantation of SIJ fusion devices via a posterior approach is less invasive and potentially safer than the lateral approach since neurovascular structures are avoided. Although there is preliminary evidence that supports pain reduction with minimum complications using the posterior approach, current medical literature supports the lateral approach. There is a paucity of evidence to support the posterior and posterior lateral oblique approach.<sup>25,26</sup>

The sacroiliac joint remains a controversial source of primary low back pain, and surgery is rarely performed for sacroiliac joint dysfunction.<sup>11</sup> Minimally invasive sacroiliac joint fusion is becoming a more prevalent treatment for chronic refractory low back pain isolated to the sacroiliac joint with the development of various fusion devices over the past ten years. Additional randomized, controlled trials or comparison studies are needed to investigate different aspects of each device to identify unique features that may be of clinical benefit, as well as determine the impact on health outcomes and long-term efficacy and safety.<sup>11,24</sup>

#### *International Society for the Advancement of Spine Surgery (ISASS)*

The ISASS outlines eligibility criteria and contraindications relative to minimally invasive surgical sacroiliac joint fusion (MIS SIJF), but does not endorse any specific MIS SIJ system.<sup>17,25</sup> A meta-analysis was conducted, and the results for patients following MIS SIJF demonstrated steadily and considerably lower SIJ pain scores and ODI (Oswestry Disability Index) scores when compared to baseline scores. Evidence from two random controlled trials and five multicenter prospective studies specifically demonstrated pain relief, disability reduction and improvement in QOL (quality of life) were significantly higher in patients treated with MIS SIJF when compared to nonsurgically treated patients. The ISASS concludes that MIS SIJF is “a recognized safe, predictable, and preferred surgical method for the management of intractable, debilitating primary or secondary SIJ pain disorders”.<sup>17</sup> The ISASS noted a scarce amount of published literature on minimally invasive SIJ fusion using a posterior approach. The society concluded that the instrumentation utilized in a MIS SIJ procedure is the surgeon’s preference.<sup>25</sup>

#### *North American Spine Society (NASS)*

NASS recommends percutaneous sacroiliac joint (SIJ) fusion for the treatment of sacroiliac joint pain for patients with low back/buttock pain who meet specific criteria.<sup>4</sup>

#### *National Institute for Health and Care Excellence (NICE)*

NICE recommends minimally invasive sacroiliac (SI) joint fusion surgery for treatment of chronic SI pain in patients with a confirmed diagnosis of unilateral or bilateral SI joint dysfunction due to degenerative sacroiliitis or SI joint disruption.<sup>21</sup> The committee indicates that this procedure stabilizes the joint, but fusion of the joint does not happen in many cases.<sup>16</sup> The NICE guidelines only describe the lateral transarticular approach.<sup>25</sup> Additionally, NICE recommends iFuse implant system as an option for treating chronic sacroiliac joint pain for patients with a confirmed diagnosis of chronic sacroiliac joint pain that is inadequately controlled by non-surgical management. The confirmed diagnosis should be based on a clinical assessment and a positive response to a diagnostic injection of local anesthetic in the sacroiliac joint.<sup>21</sup>

Tobacco cessation is recommended to improve the outcome of spinal fusion surgery. The success of fusion surgery is determined by the ability of the joints to heal into a solid unit; however, the fusion rate of smokers is significantly lower than non-smokers.<sup>19,20</sup> Smoking increases the rate of perioperative complications, especially pseudoarthrosis; therefore, smoking cessation for four weeks following surgery is recommended to reduce risks.<sup>18,19</sup> One study of patients undergoing spinal fusions in the lower back demonstrated an 80-85% success rate for non-smokers or patients who quit smoking following surgery, and < 73% success rate for smokers.<sup>20</sup>

### **Coding Implications**

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### **Codes that support coverage criteria**

| <b>CPT® Codes</b> | <b>Description</b>   |
|-------------------|--|
| 27279             | Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device |
| 27280             | Arthrodesis, open, sacroiliac joint, including obtaining bone graft, including instrumentation, when performed   |

### **Codes that do not support coverage criteria**

| <b>CPT® Codes</b> | <b>Description</b>  |
|-------------------|---|
| 0775T             | Arthrodesis, sacroiliac joint, percutaneous, with image guidance, includes placement of intra-articular implant(s) (e.g., bone allograft[s], synthetic device[s]) |

| Reviews, Revisions, and Approvals   | Revision Date | Approval Date |
|---|---------------|---------------|
| New Policy  | 9/18          |               |
| References reviewed and updated. Codes reviewed and updated. ICD-10 codes added: C41.4, C79.51, D16.8, D48.0, D49.2, M46.28, M46.38, and S32.810A-S32.811S. Specialty review.   | 10/19         |               |
| Annual review completed. References reviewed and updated. Changed ICD-10 code M53.2X7 to M53.2X6. Corrected numbering in Reference Section and applicable footnotes. Added clarification to section II., “that sacroiliac joint fusion procedures, either open or minimally invasive (e.g., iFuse), are investigational for all other indications, including but not limited to, treating treatment of.....”  | 10/2020       |               |
| Annual review complete. Replaced all instances of member with member/enrollee. Background updated. Section I updated to indicate criteria specific to open SIJ fusion. New criteria added for section II, specific to minimally invasive SIJ fusion. Updated section III “experimental/investigational” verbiage: replaced with “long-term safety and effectiveness has not been proven” and removed reference to iFUSE and sacroiliac joint examples.. Changed “review date” in the header to “last revision date; changed “date” in the revision log header to “revision date.” Added “at least 4-6 weeks” to II.A.3. and added option for inability to tolerate exercise program. Section II.F.1 updated to include “fracture, traumatic SIJ instability”. Background updated with information regarding smoking cessation. References reviewed by specialist, updated, and reformatted. | 12/8/2022     |               |
| Annual review completed. Added Criteria II.I. describing procedure approach. Added criteria IV. to address sacroiliac fusion using implants other than those which are placed across the joint (transfixing) to promote fusion. Additional minor rewording with no clinical significance. Background updated. Created tables to convey codes that do/do not support coverage criteria. Added new CPT code 0775T to table that does not support coverage criteria. ICD-10 code table removed. References reviewed and updated. External specialist reviewed.   | 06/2023       |               |

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