02-61000-36 Original Effective Date: 03/15/10 Reviewed: 09/26/24 Revised: 10/15/24

Subject: Minimally Invasive Fusion Techniques

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions	Related Guidelines
Other	References	Updates			

DESCRIPTION:

Axial Lumbar Interbody Fusion (AxiaLIF)

Axial lumbosacral interbody fusion (also called presacral, transsacral, or paracoccygeal interbody fusion) is a minimally invasive technique designed to provide anterior access to the L4-S1 disc spaces for interbody fusion, while minimizing damage to muscular, ligamentous, neural, and vascular structures. It is performed under fluoroscopic guidance.

Sacroiliac joint fusion/stabilization

The sacroiliac (SI) joint connects the sacrum with the pelvis. The SI joint lies between the sacrum and the ilium, and functions more for stability than for movement. Similar to other structures in the spine, it is assumed that the sacroiliac joint may be a source of low back pain. Sacroiliac fusion involves bony fusion of the sacroiliac joint for stabilization. This has been proposed for treatment of chronic sacroiliac pain. Sacroiliac joint fusion may be performed as a minimally invasive procedure or as an open surgical procedure. For joint damage resulting from trauma, infection, cancer, or fracture, sacroiliac joint fusion is an established treatment.

Surgical devices for annular repair/modulation

The annulus fibrosus is composed of highly organized collagen-rich lamellae that wrap around the intervertebral disc. During some spine surgeries, a defect is made in the annulus fibrosus, which is left to heal. Surgical devices for annular repair or modulation after spinal surgery are intended for use in soft tissue approximation, or repair of annular defect. There are several FDA-approved, commercially marketed devices.

Summary and Analysis of Evidence: Schroeder et al (2016) reported on a systematic review of L5-S1 disc space fusion rates following axial lumbosacral interbody fusion compared with anterior lumbar

interbody fusion or transforaminal lumbar interbody fusion. Reviewers included 42 articles (total 507 patients). There were 11 articles with 466 patients who underwent anterior lumbar interbody fusion, 21 articles with 432 patients who underwent transforaminal lumbar interbody fusion, and 11 articles with 609 patients who underwent axial lumbosacral interbody fusion. Overall fusion rates were 99.2% for transforaminal lumbar interbody fusion, 97.2% for anterior lumbar interbody fusion, and 90.5% for axial lumbosacral interbody fusion. Fusion rates for transforaminal lumbar interbody fusion were significantly higher than those for axial lumbosacral interbody fusion. However, when either bone morphogenetic protein or bilateral pedicle screws were used with the procedures, the differences in fusion rates between transforaminal lumbar interbody fusion and axial lumbosacral interbody fusion were no longer statistically significant. The findings of this systematic review were limited by the lack of comparative studies and differences in how fusion rates were determined across studies. Whang et al (2014) reported on a multicenter, retrospective comparison of axial lumbosacral interbody fusion with anterior lumbar interbody fusion of the L5-S1 disc space in 96 patients who had a minimum of 2 years of followup. Most procedures were performed for degenerative disc disease or spondylolisthesis and used bilateral pedicle screws. Various graft materials were used, including recombinant human bone morphogenetic protein-2 (in 29 axial lumbosacral interbody fusion and 11 anterior lumbar interbody fusion procedures). Fusion rates, assessed at 24 months by 2 independent evaluators and based on radiographs and multiplanar computed tomography images, were similar for the 2 procedures (85% for axial lumbosacral interbody fusion vs 79% for anterior lumbar interbody fusion; p>0.05). The incidence of adverse events was also similar, with no cases of rectal perforation. Interpretation of this study is uncertain given its retrospective design, variability in procedures, the absence of validated clinical outcome measures, and lack of randomization. The largest case series included in the 2016 systematic review was a retrospective analysis by Tobler et al (2011), which evaluated 156 patients from 4 clinical sites in the United States. Patients were selected if they underwent an L5 through S1 interbody fusion via the axial approach and had both presurgical and 2-year radiographic or clinical follow-up. The number of patients who underwent axial lumbosacral interbody fusion but were excluded from the analysis was not reported. The primary diagnosis was degenerative disc disease (61.5%), spondylolisthesis (21.8%), revision surgery (8.3%), herniated nucleus pulposus (8.3%), spinal stenosis (7.7%), or other (8.3%). Pain scores on a numeric rating scale improved from a mean of 7.7 to 2.7 (n=155), while the Oswestry Disability Index scores improved from a mean of 36.6 preoperatively to 19.0 (n=78) at 2-year follow-up. Clinical success rates, based on an improvement of at least 30%, were 86% (n=127/147) for pain and 74% (n=57/77) for the Oswestry Disability Index scores. The overall radiographic fusion rate at 2 years was 94% (145/155). No neural, urologic, or bowel injuries were reported in this study group. Study limitations included its retrospective analysis, lack of controls, and potential for selection bias because it only reported on patients who had 2 years of follow-up. Lindley et al (2011) found high complication rates when retrospectively reviewing 68 patients who underwent axial lumbosacral interbody fusion between 2005 and 2009. Patient diagnoses included degenerative disc disease, spondylolisthesis, spinal stenosis, degenerative lumbar scoliosis, spondylolysis, pseudoarthrosis, and recurrent disc herniation. Ten patients underwent 2-level axial lumbosacral interbody fusion (L4-S1), and 58 patients underwent a single-level axial lumbosacral interbody fusion (L5-S1). A total of 18 complications in 16 (23.5%) patients were identified at a mean 34-month follow-up (range, 17-61 months). Complications included pseudoarthrosis (8.8%), superficial infection (5.9%), sacral fracture (2.9%), pelvic hematoma (2.9%), failure of wound closure (1.5%), and rectal perforation (2.9%). Because of the potential complications, the authors recommended full bowel preparation and preoperative

magnetic resonance imaging before an axial lumbosacral interbody fusion procedure to assess the size of the presacral space, to determine rectal adherence to the sacrum, to rule out vascular abnormalities, and to determine a proper trajectory.

Shaffrey, Smith (2013) stated, "arthrodesis of the SIJ is a surgical procedure with a long history dating to the beginnings of spinal surgery. Poor results, high complication rates and the need for additional surgical procedures have generally diminished the enthusiasm for this procedure until recently. Dydyk et al (2023) stated, "injuries to the sacroiliac joint can occur from various etiologies. 88% of cases of SI joint injury are due to either repetitive microtrauma or acute trauma. There is a high prevalence of SI joint injury in athletes. Separately, 20% of cases are pregnancy-related, while 4% are idiopathic. Trauma in the context of pelvic ring injuries is one example of SI joint injury. Pelvic ring traumatic injuries include three main categories, including anteroposterior compression, lateral compression, and vertical shear-type injuries. Furthermore, injuries to the sacroiliac joint include incomplete SI dislocations, complete SI dislocations, and SI fracture-dislocations. Treatment can vary significantly between cases. For example, pregnancy-related SI joint pain often resolved in the months following delivery, while traumatic SI joint injury may require prompt surgical repair. When all else fails, surgical fusion can be done. 80% of patients endorsed clinically significant pain improvement following surgical fusion."

Whang et al (2015) reported an industry-sponsored nonblinded RCT, Investigation of Sacroiliac Fusion Treatment (INSITE) of the iFuse Implant System in 148 patients. The 12-month follow-up to this RCT was reported by Polly et al (2015), and a 2-year follow-up was reported by Polly et al (2016). However, by 12 months, almost all patients in the control group had crossed over to SIJ fusion, precluding a comparison between groups. Trial inclusion was based on a determination of the SIJ as a pain generator from a combination of a history of SIJ-localized pain, positive provocative testing on at least 3 of 5 established physical tests, and at least a 50% decrease in SIJ pain after image-guided local anesthetic injection into the SIJ. The duration of pain before enrollment averaged 6.4 years. A large proportion of subjects (37%) had previously undergone lumbar fusion, SIJ steroid injections (86%), and RFA (16%). Patients were randomized 2:1 to minimally invasive SIJ fusion (n=102) or to nonsurgical management (n=46). Nonsurgical management included a stepwise progression of nonsurgical treatments, depending on individual patient choice. During follow-up, control patients received physical therapy (97.8%), intraarticular steroid injections (73.9%), and RFA of sacral nerve roots (45.7%). The primary outcome measure was the 6-month success rate, defined as the proportion of treated subjects with a 20-mm improvement in SIJ pain in the absence of severe device-related or neurologic AEs or surgical revision. Patients in the control arm could crossover to surgery after 6 months. Baseline scores indicated that the patients were severely disabled, with VAS pain scores averaging 82.3 out of 100, and ODI scores averaging 61.9 out of 100 (0=no disability, 100=maximum disability). At 6 months, success rates were 23.9% in the control group versus 81.4% in the surgical group. A clinically important (≥15-point) improvement in ODI score was found in 27.3% of controls compared with 75.0% of fusion patients. Measures of QOL (36-Item Short-Form Health Survey, EuroQol-5D) also improved to a greater extent in the surgery group. Of the 44 nonsurgical management patients still participating at 6 months, 35 (79.5%) crossed over to fusion. Compared with baseline, opioid use at 6 months decreased from 67.6% to 58% in the surgery group and increased from 63% to 70.5% in the control group. At 12 months, opioid use was similar between groups. Polly et al (2016) reported 2-year outcomes from the SIJ fusion arm of this RCT. Of 102 subjects originally assigned to SIJ fusion and treated, 89 (87%) were evaluated at 2 years. In this report, clinical outcomes were based on the amount of improvement in SIJ pain and in ODI scores. The

improvement was defined as a change of 20 points in the SIJ pain score and 15 points in the ODI score. Substantial improvement was defined as a change of 25 points in SIJ pain score-or an SIJ pain score of 35 or less-and an improvement of 18.8 points in the ODI score. At 24 months, 83.1% had improvements in SIJ pain score, and 68.2% had improvements in ODI scores. By 24 months, the proportion taking opioids was reduced from 68.6% at baseline to 48.3%. Three-year follow-up results of the INSITE and Sacroiliac Joint Fusion with iFuse Implant System (SiFi) trials were published by Darr et al (2018). Of 103 patients with SIJ dysfunction who were treated with minimally invasive SIJ fusion with triangular titanium implants, 60 (72.3%) patients reported an improvement in ODI scores of ≥15 points from baseline to 3 years. The mean ODI score decreased from 56 to 28 for the same time frame, an improvement of 28 points; similarly, the mean SIJ pain score decreased to 26.2, reflecting a decrease of 55 points. Follow-up at 6 months was available for 49 of 51 patients in the control group and for all 52 patients in the iFuse group. Six-month results as reported by Sturesson et al (2017) showed VAS pain scores improved by 43.3 points in the iFuse group and by 5.7 points in the control group. ODI scores improved by 25.5 points in the iFuse group and by 5.8 points in the control group. An improvement in lower back pain by at least 20 VAS points (a minimal clinically important difference) was achieved in 78.8% of the SIJ fusion group versus 22.4% of controls. Quality of life outcomes showed a greater improvement in the iFuse group than in the control group. Changes in pain medication use were not reported. Patients in the conservative management group were allowed to cross over to SIJ fusion at 6 months.

National Institute for Health and Clinical Excellence's guideline on "Minimally invasive sacroiliac joint fusion surgery for chronic sacroiliac pain" (NICE, 2017) provides the following recommendations:

1) Current evidence on the safety and efficacy of minimally invasive sacroiliac (SI) joint fusion surgery for chronic SI pain is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit.

2) Patients having this procedure should have a confirmed diagnosis of unilateral or bilateral SI joint dysfunction due to degenerative sacroiliitis or SI joint disruption.

3) Conservative treatments for SI joint pain include analgesics, non-steroidal anti-inflammatory drugs, physiotherapy, manipulative therapy, intra-articular SI joint corticosteroid injections, periarticular injections, botulinum toxin injections and radiofrequency denervation. Surgical treatment is considered for persistent chronic symptoms that are unresponsive to conservative treatment. Surgical techniques include open SI joint fusion surgery or minimally invasive SI joint fusion using percutaneous implants to stabilize the joint and treat joint pain.

Miller et al (2020) published a systematic review and meta-analysis of the Barricaid annular device in patients at high risk for lumbar disc reherniation. Four trials (2 RCTs) were included in the meta-analysis. The trial by Thomé et al (2018) (described below) was the only trial to find a significant decrease in symptomatic reherniation or reoperation at 2 years. The other 3 trials all indicated nonsignificant reduction for both outcomes. Overall, results of the meta-analysis favored the use of an annular device for post-discectomy patients with large annular defects, but limitations included lack of blinding. Thomé et al (2018) conducted an open-label RCT comparing lumbar discectomy alone or lumbar discectomy with annular closure. A total of 554 patients who had failed nonsurgical treatment and had a disc height of at least 5 mm were randomized. Longer follow-up data at 3 years found continued lower risk of reherniation (14.8% vs. 29.5%) and reoperation (11% vs. 19.3%) in patients receiving an annular closure device (Kienzler et al, 2019). At 5-year follow-up, the risk of symptomatic reherniation (18.8% vs. 31.6%)

and reoperation (16.0% vs. 22.6%) remained lower in patients receiving an annular closure device (Thomé et al, 2021). None of the investigators were blind to treatment assignment, and only patients at specific sites were blind. Cho et al (2019) published a smaller RCT conducted solely in Korea. Patients were followed for 24 months and the primary endpoint of the trial was disc height. Patients treated with an annular closure device maintained disc height at 24 months to a greater extent than those with discectomy alone (86.3% vs. 79.2%). Back pain and leg pain were similarly improved in both treatment groups. Recurrent herniation was more common with discectomy alone. The small sample size, large loss to follow-up (<70% at 2-year follow-up), and unclear blinding limit the validity of this trial. Klassen et al (2018) conducted a post hoc analysis of a prospective, multicenter, randomized controlled trial (RCT) designed to investigate the safety and efficacy of an annular closure device (ACD). All 550 patients (both ACD treated and control) from the RCT with follow-up data through 2 years were included in this analysis (69 reoperated and 481 non-reoperated). Reoperations were defined as any revision surgery of the index level, regardless of indication. The authors concluded that an ACD helped minimize patient morbidity, missed work, and direct treatment costs in a population at high risk for reherniation. The authors also noted several study limitations, stating "since the findings of this study are limited to highrisk patients with large annular defects undergoing limited discectomy, they may not translate to patients beyond these specific criteria. Another possible limitation of this study is that the reoperated patient cohort had significantly worse VAS back and leg pain scores as well as PCS scores at baseline compared to non-reoperated patients. Although statistically significant, these baseline differences in mean VAS leg pain (difference=4.3), VAS back pain (difference=12.8), and PCS score (difference=1.8) are unlikely to be clinically meaningful considering that they were less than the MCID values of 15 for VAS pain scores 41 and 4.9 for PCS scores. Additionally, the missed work and physiotherapy time were only measured for a subset of the patient population (~20%) ..."

POSITION STATEMENT:

Axial lumbosacral interbody fusion (Axial LIF) is considered **experimental or investigational** for **all** indications. There is insufficient scientific evidence to permit conclusions concerning the effect of this technology on net health outcomes.

Open sacroiliac joint fusion/stabilization (27280) meets the definition of medical necessity for any of the following indications:

- A tumor involving the sacrum and/or sacroiliac joint
- As adjunctive treatment of sacroiliac joint infection, following successful treatment of the infection
- Following traumatic injury of the sacroiliac joint (e.g., following pelvic ring fracture)
- When performed as a part of multi-segment long fusion to correct spinal deformity associated with scoliosis or kyphosis

Open sacroiliac joint fusion/stabilization for the treatment of all other indications, including chronic back pain, is considered **experimental or investigational**. The available scientific evidence remains insufficient to permit conclusions concerning the effect of this technology on net health outcomes.

Minimally invasive sacroiliac joint fusion/stabilization using a U.S. Food and Drug Administration (FDA) approved implant **meets the definition of medical necessity** when **ALL** of the following criteria have been met:

- Pain is at least 5 on a 0 to 10 rating scale; and pain 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**
- Has undergone and failed a minimum 6 months of intensive nonoperative treatment that must include all of the following:
 - Medication optimization (which should include use of prescription-strength analgesics for several weeks at a dose sufficient to induce a therapeutic response, including antiinflammatory medications with or without adjunctive medications such as nerve membrane stabilizers or muscle relaxants)
 - Activity modification
 - Bracing
 - Evaluation and appropriate management of associated cognitive, behavioral, or addiction issues, if any
 - Participation in at least 6 weeks of active physical therapy targeted at the lumbar spine, pelvis, sacroiliac joint, and hip, including a home exercise program, AND
- Pain is caudal to the lumbar spine (L5 vertebra), localized over the posterior sacroiliac joint, and consistent with sacroiliac joint pain, **AND**
- 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**
- There is a positive response to a cluster of 3 provocative tests (eg, thigh thrust test, compression test, Gaenslen sign, distraction test, Patrick test, or posterior provocation test), **AND**
- Diagnostic imaging studies include **ALL** of the following:
 - Imaging (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
 - Imaging of the pelvis (anteroposterior plain radiograph) rules out concomitant hip pathology, AND
 - Imaging of the lumbar spine (computed tomography or magnetic resonance imaging) is performed to rule out neural compression or other degenerative condition that can be causing low back or buttock pain, AND
 - Imaging of the sacroiliac joint indicates evidence of injury and/or degeneration, AND
- 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 sacroiliac joint injection on 2 separate occasions, **AND**

• A trial of a therapeutic sacroiliac joint injection (ie, corticosteroid injection) has been performed at least once

Minimally invasive sacroiliac joint fusion/stabilization using a posterior (dorsal) approach is considered experimental or investigational. There is insufficient published clinical evidence to support the safety and effectiveness of this approach. Devices and grafts intended for a posterior (dorsal) approach to SI joint fusion include Catamaran[™] (metal plug), CornerLoc[™] (bone allograft), LinQ[™] SI Joint Stabilization (bone allograft), NADIA[™] SI Fusion System (DIANA) (metal plug), PsiF[™] Posterior Sacroiliac Fusion (bone allograft), SIFix System[®] (bone allograft), TransFasten[™] (bone allograft).

Minimally invasive fusion/stabilization of the sacroiliac joint for the treatment of back pain presumed to originate from the sacroiliac joint is considered **experimental or investigational** under all other conditions, as there is a lack of clinical scientific evidence published in peer-reviewed literature to permit conclusions on safety and net health outcomes.

The use of surgical devices for annular repair/closure/modulation following spinal surgery (e.g. Inclose[™] Surgical Mesh System, Xclose[™] Tissue Repair System, Barricaid[®] Anular Closure Device, Disc Annular Repair Technology (DART) System, Discseel Procedure) is considered **experimental or investigational** due to the lack of scientific peer-reviewed literature demonstrating improvement in health outcomes.

BILLING/CODING INFORMATION:

22586	Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when
07070	performed, L5-S1 interspace (investigational)
27278	Arthrodesis, sacroiliac joint, percutaneous, with image guidance, including placement of
	intra-articular implant(s) (eg, bone allograft[s], synthetic device[s]), without placement of
	transfixation device (investigational)
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, sacroiliac joint, open, includes obtaining bone graft, including
	instrumentation, when performed

CPT Coding:

HCPCS Coding:

C9757	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial
	facetectomy, foraminotomy and excision of herniated intervertebral disc, and repair of
	annular defect with implantation of bone anchored annular closure device, including
	annular defect measurement, alignment and sizing assessment, and image guidance; 1
	interspace, lumbar (investigational)

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at <u>Coverage</u> <u>Protocol Exemption Request</u>.

DEFINITIONS:

Annulus fibrosus: The ring of fibrocartilage and fibrous tissue forming the circumference of the intervertebral disc; surrounds the nucleus pulpous, which can herniate when the anulus is diseased or injured.

Interbody: Between the bodies of two adjacent vertebra.

Interspace: Any space between two similar objects.

RELATED GUIDELINES:

Bone Morphogenetic Protein (BMP), 02-20000-32

Interspinous and Interlaminar Stabilization/Distraction (Spacers) and Fixation (Fusion) Devices, 02-20000-36

<u>Automated Percutaneous Discectomy, Laser Discectomy, Percutaneous Endoscopic Discectomy, and</u> <u>DISC Nucleoplasty™, 02-61000-32</u>

OTHER:

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

FIREBIRD SI Fusion System[™] iFuse® iFuse® 3D Rialto[™] SI Joint Fusion System SacroFuse®/SIJ-Fuse® SambaScrew® Silex[™]Sacroiliac Joint Fusion System Si-LOK® Sacroiliac Joint Fixation System Simmetry® Sacroiliac Joint Fusion System Simpact® Sacroiliac Joint Fixation System Siros[™] Triton SI Joint Fixation System[™]

REFERENCES:

- Ackerman SJ, Polly Jr DW, Knight T, Schneider K, Holt T, Cummings J. Comparison of the costs of nonoperative care to minimally invasive surgery for sacroiliac joint disruption and degenerative sacroiliitis in a United States Medicare population: potential economic implications of a new minimally-invasive technology. ClinicoEconomics and outcomes research: CEOR (2013), 5, 575.
- 2. AHRQ national Guideline Clearinghouse. Guideline Summary NGC-8134. Laminectomy and fusion for the treatment of cervical degenerative myelopathy. American Association of Neurological Surgeons; Congress of Neurological Surgeons. 2009 Aug.
- 3. AHRQ national Guideline Clearinghouse. Guideline Summary NGC-8766. Diagnosis and treatment of degenerative lumbar spinal stenosis. North American Spine Society (NASS); 2011.
- 4. AHRQ national Guideline Clearinghouse. Guideline Summary NGC-9903. Clinical guidelines for diagnosis and treatment of lumbar disc herniation with radiculopathy. North American Spine Society; 2012.
- 5. AHRQ national Guideline Clearinghouse. Guideline Summary NGC-9327. Low back disorders. American College of Occupational and Environmental Medicine (ACOEM); 2011.
- 6. AHRQ national Guideline Clearinghouse. Guideline Summary NGC-10118: Hip & pelvis (acute & chronic). Work Loss Data Institute; 2013.
- 7. AHRQ national Guideline Clearinghouse. Guideline Summary NGC-10121. Low back lumbar & thoracic (acute & chronic). Work Loss Data Institute; 2013.
- 8. American Academy of Orthopaedic Surgeons. Anterior Lumbar Interbody Fusion. Accessed at http://orthoinfo.aaos.org/topic.cfm?topic=A00595. Copyright 2010 American Academy of Orthopaedic Surgeons.
- 9. American Academy of Orthopaedic Surgeons. Posterior Lumbar Interbody Fusion and Transforaminal Lumbar Interbody Fusion. Accessed at http://orthoinfo.aaos.org/topic.cfm?topic=A00596. Copyright 2010 American Academy of Orthopaedic Surgeons.
- 10. Anand N, Baron EM. Minimally invasive approaches for the correction of adult spinal deformity. Eur Spine J. 2013 Mar;22 Suppl 2:S232-41. Doi: 10.1007/s00586-012-2344-6. Epub 2012 May 10.
- Aryan HE, Newman CB, Gold JJ, Acosta Jr. FL, Coover C, Ames CP. Percutaneous Axial Lumbar Interbody Fusion (AxiaLIF) of the L5-S1 Segment: Initial Clinical and Radiographic Experience. Minim Invas Neurosurg 2008; 51: 225 – 230.
- 12. Ashman B, Norvell DC, Hermsmeyer JT. Chronic sacroiliac joint pain: fusion versus denervation as treatment options. Evidence-Based Spine-Care JournalVolume 1/Issue 3 2010.
- 13. Bahtia NN, Timon S, Wieser ES, Wang JC. TLIF, XLIF or ALIF for adjacent segment degenerative disc disease. NASS SpineLine, May/June 2008.
- Bailey A, Messer J, Griffith SL. (2010). Prospective, Randomized Controlled Study of Repairing the Anulus Fibrosus after Lumbar Discectomy: A Single Surgeon's Experience. The Spine Journal, 10(9), S127.
- 15. Barricaid® Dossier. Intrinsic Therapeutics. Accessed at https://barricaid.com/key-evidence/.
- 16. Beck CE, Jacobson S, Thomasson E. A Retrospective Outcomes Study of 20 Sacroiliac Joint Fusion Patients. Cureus. 2015;7(4):e260. Published 2015 Apr 1. Doi:10.7759/cureus.260.
- 17. Blue Cross Blue Shield Association Evidence Positioning System®. 6.01.23 Diagnosis and Treatment of Sacroiliac Joint Pain, 12/23.
- 18. Blue Cross Blue Shield Association Evidence Positioning System®. 7.01.130 Axial Lumbosacral Interbody Fusion, 05/24.
- 19. Blue Cross Blue Shield Association Evidence Positioning System®. 7.01.146 Discectomy, 07/24.

- Blumenthal, SL, Guyer RD. (2010, October). Anular Repair After Lumbar Discectomy: Preliminary Observations From An Ongoing, Prospective, Randomized, Controlled Clinical Trial: 41. In Spine Journal Meeting Abstracts (p. 41).
- 21. Boachie-Adjei O, Cho W, King AB. Axial lumbar interbody fusion (AxiaLIF) approach for adult scoliosis. Eur Spine J. 2013 Mar;22 Suppl 2:S225-31.
- 22. Bohinski RJ, Jain VV, Tobler WD. Presacral retroperitoneal approach to axial lumbar interbody fusion: a new, minimally invasive technique at L5-S1: Clinical outcomes, complications, and fusion rates in 50 patients at 1-year follow-up. SAS J. 2010 Jun 1;4(2):54-62. Doi: 10.1016/j.esas.2010.03.003. eCollection 2010.
- 23. Bradley WD, et al. Minimally invasive trans-sacral approach to L5-S1 interbody fusion: Preliminary results from 1 center and review of the literature. Int J Spine Surg. 2012 Dec 1;6:110-4. Doi: 10.1016/j.ijsp.2011.12.005. eCollection 2012.
- 24. Capobianco R, et al. Safety and effectiveness of minimally invasive sacroiliac joint fusion in women with persistent post-partum posterior pelvic girdle pain: 12-month outcomes from a prospective, multi-center trial. Springerplus. 2015 Oct 5;4:570.
- 25. Caputo AM, Michael KW, Chapman Jr TM, Massey GM, Howes CR, Isaacs RE, Brown CR. Clinical outcomes of extreme lateral interbody fusion in the treatment of adult degenerative scoliosis. ScientificWorldJournal. 2012;2012:680643.
- 26. Castro V, Cunha E Sa M. Annular closure devices-here to stay or here to go? Acta Neurochir (Wien). 2021 Feb;163(2):561-562. doi: 10.1007/s00701-020-04613-1. Epub 2020 Oct 16.
- 27. Centers for Medicare & Medicaid Services (CMS). Local Coverage Article: Noncovered services revision to LCD (A55109) (06/16/16) (Retired 07/01/20).
- 28. Centers for Medicare & Medicaid Services (CMS). Local Coverage Article: Medical review article for percutaneous minimally invasive fusion/stabilization of the sacroiliac joint (A55120) (06/01/16).
- 29. Cher DJ, Polly DW. Improvement in Health State Utility after Sacroiliac Joint Fusion: Comparison to Normal Populations. Global Spine Journal. 2016 Mar;6(2):100.
- 30. Cher DJ, Reckling WC, Capobianco RA. Implant survivorship analysis after minimally invasive sacroiliac joint fusion using the iFuse Implant System (®). Medical devices (Auckland, NZ). 2015 Nov 23;8:485.
- Cho CB, et al, Anterior Lumbar Interbody Fusion with Stand-Alone Interbody Cage in Treatment of Lumbar Intervertebral Foraminal Stenosis: Comparative Study of Two Different Types of Cages, J Korean Neurosurg Soc, 47: 352-357, 2010.
- Cho PG, Shin DA, Park SH, Ji GY. Efficacy of a Novel Annular Closure Device after Lumbar Discectomy in Korean Patients : A 24-Month Follow-Up of a Randomized Controlled Trial. J Korean Neurosurg Soc. 2019 Nov;62(6):691-699. doi: 10.3340/jkns.2019.0071. Epub 2019 Oct 30.
- 33. Choy W-S, Kim KJ, Lee SK, Park HJ. Anterior Pelvic Plating and Sacroiliac Joint Fixation in Unstable Pelvic Ring Injuries. Yonsei Med J 53(2):422-426, 2012.
- Claus CF, Lytle E, Kaufmann A, et al. Minimally Invasive Sacroiliac Joint Fusion Using Triangular Titanium versus Cylindrical Threaded Implants: A Comparison of Patient-Reported Outcomes. World Neurosurg. 2020;133:e745-e750. doi:10.1016/j.wneu.2019.09.150. PMID: 31605853.
- 35. ClinicalTrials.gov, A Clinical Study of the GO-LIF® Approach for Lumbar Spinal Fixation. NCT00810433. Sponsored by Mazor Surgical Technologies, Ltd, last updated: February 6, 2011.
- 36. ClinicalTrials.gov. Osteocel® Plus in eXtreme Lateral Interbody Fusion (XLIF®), NCT00948532. Sponsored by NuVasive, last updated June 10, 2011.
- 37. ClinicalTrials.gov. XLIF® vs. MAS®TLIF for the Treatment of Symptomatic Lumbar Degenerative Spondylolisthesis With or Without Central Stenosis. NCT01024699. Sponsored by NuVasive, accessed 01/06/12. last updated on June 10, 2011.

- 38. ClinicalTrials.gov. Randomized Study of Anular Repair with the Xclose Tissue Repair System. NCT00760799. Sponsored by Anulex Technologies, Inc, last updated: May 1, 2012.
- 39. ClinicalTrials.gov. NCT00965380. Trinity Evolution in Posterior or Transforaminal Lumbar Interbody Fusion (PLIF/TLIF) (TLF), Sponsored by Orthofix Inc., last updated on May 22, 2012.
- 40. ClinicalTrials.gov. Osteocel® Plus in Anterior Lumbar Interbody Fusion (ALIF). NCT00948831. NuVasive, last updated June 10, 2011.
- 41. ClinicalTrials.gov. NCT01640353: Sacroiliac Joint Fusion With iFuse Implant System (SIFI). August 2014.
- 42. ClinicalTrials.gov. NCT01681004: Investigation of Sacroiliac Fusion Treatment (INSITE). September 2014.
- 43. ClinicalTrials.gov. NCT01741025: iFuse Implant System® Minimally Invasive Arthrodesis (iMIA). January 2014.
- 44. ClinicalTrials.gov. NCT01861899: Treatment of Sacroiliac Dysfunction With SI-LOK® Sacroiliac Joint Fixation SI-SI-LOK. May 2013.
- 45. ClinicalTrials.gov. NCT02074761: Evolusion Study Using the Zyga SImmetry Sacroiliac Joint Fusion System. July 2015.
- 46. ClinicalTrials.gov. NCT02064322: SAIF: Sacroiliac Fusion Study. April 2015.
- 47. ClinicalTrials.gov. NCT02270203: LOIS: Long-Term Follow-Up in INSITE/SIFI (LOIS) (SI-Bone, Inc.) (August 2016).
- 48. Cohen A, Miller LE, Block JE. Minimally invasive presacral approach for revision of an Axial Lumbar Interbody Fusion rod due to fall-related lumbosacral instability: a case report. J Med Case Rep. 2011 Sep 29;5:488. doi: 10.1186/1752-1947-5-488,
- 49. Cummings Jr J, Capobianco RA. Minimally invasive sacroiliac joint fusion: one-year outcomes in 18 patients. Ann Surg Innov Res. 2013 Sep 16;7(1):12.
- Darr E, Meyer SC, Whang PG, Kovalsky D, Frank C, Lockstadt H, Limoni R, Redmond A, Ploska P, Oh MY, Cher D, Chowdhary A. Long-term prospective outcomes after minimally invasive trans-iliac sacroiliac joint fusion using triangular titanium implants. Med Devices (Auckl). 2018 Apr 9;11:113-121. doi: 10.2147/MDER.S160989.
- Deer TR, Rupp A, Budwany R, et al. Pain Relief Salvage with a Novel Minimally Invasive Posterior Sacroiliac Joint Fusion Device in Patients with Previously Implanted Pain Devices and Therapies. J Pain Res. 2021 Sep 2;14:2709-2715. doi: 10.2147/JPR.S325059.
- 52. Dengler J, Duhon B, et al. Predictors of Outcome in Conservative and Minimally Invasive Surgical Management of Pain Originating From the Sacroiliac Joint: A Pooled Analysis. Spine (Phila Pa 1976). 2017 Nov 1;42(21):1664-1673.
- 53. Dengler JD, Kools D, et al. 1-Year Results of a Randomized Controlled Trial of Conservative Management vs. Minimally Invasive Surgical Treatment for Sacroiliac Joint Pain. Pain Physician. 2017 Sep;20(6):537-550.
- Derman PB, Albert TJ. Interbody Fusion Techniques in the Surgical Management of Degenerative Lumbar Spondylolisthesis. Curr Rev Musculoskelet Med. 2017 Dec;10(4):530-538. doi: 10.1007/s12178-017-9443-2.
- 55. DeVine JG, Gloystein D, Singh N. A novel alternative for removal of the AxiaLif (TranS1) in the setting of pseudarthrosis of L5–S1. The Spine Journal 9 (2009) 910–915.
- Dydyk AM, Forro SD, Hanna A. Sacroiliac Joint Injury. [Updated 2023 Jul 4]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK557881/.

- 57. Duhon BS, Cher DJ, Wine KD, Lockstadt H, Kovalsky D, Soo CL. Safety and 6-month effectiveness of minimally invasive sacroiliac joint fusion: a prospective study. Med Devices (Auckl). 2013 Dec 13;6:219-29.
- 58. Duhon BS, et al. Triangular Titanium Implants for Minimally Invasive Sacroiliac Joint Fusion: A Prospective Study. Global Spine Journal. June 30, 2015.
- 59. Duhon BS, et al. Triangular Titanium Implants for Minimally Invasive Sacroiliac Joint Fusion: 2-Year Follow-Up from a Prospective Multicenter Trial. Int J Spine Surg. 2016 Apr 20;10:13.
- 60. Duhon BS, et al. Triangular Titanium Implants for Minimally Invasive Sacroiliac Joint Fusion: A Prospective Study. Global spine journal. 2016 May;6(3):257-69.
- 61. Eck JC, Hodges S, Humphreys SC. Minimally invasive lumbar spinal fusion. J Am Acad Orthop Surg. 2007; 15(6):321-329.
- 62. ECRI Clinical Evidence Assessment. Barricaid Anular Closure Device (Intrinsic Therapeutics, Inc.) for Preventing Recurrent Vertebral Disc Herniation after Lumbar Discectomy (June 2020).
- 63. ECRI Institute Health Technology Information Service: Product Brief. iFuse Implant System (SI-Bone, Inc.) for Minimally Invasive Sacroiliac Joint Fusion (May 2016).
- 64. Endres S, Ludwig E. Outcome of distraction interference arthrodesis of the sacroiliac joint for sacroiliac arthritis. Indian journal of orthopaedics (2013), 47(5), 437.
- 65. Erkan S, et al, Biomechanical Evaluation of a New AxiaLIF Technique for Two-Level Lumbar Fusion, Eur Spine J (2009), 18:807-814.
- 66. Falowski S, Sayed D, et al. A Review and Algorithm in the Diagnosis and Treatment of Sacroiliac Joint Pain. J Pain Res. 2020 Dec 8;13:3337-3348. doi: 10.2147/JPR.S279390.
- 67. Florida Medicare Part B Local Coverage Determination. Non-covered Services (L29288) (02/02/09) (Retired 09/30/15).
- 68. First Coast Service Options, Inc. (FCSO). Local Coverage Determination (LCD) L33777: Noncovered Services. Retired 07/01/20.
- 69. Fokter SK. Update review and clinical presentation on chronic low back pain treated by AxiaLIF. Eur J Orthop Surg Traumatol (2011) 21:39–42.
- 70. Garber T, Ledonio CG, Polly Jr DW. How Much Work Effort is Involved in Minimally Invasive Sacroiliac Joint Fusion?. International journal of spine surgery. 2015 Nov 6;9:58.
- Griffith SL, Davis RJ, Hutton WC. Repair of the anulus fibrosus of the lumbar disc. In: Davis RJ, Girardi FP, Cammisa FP editor. Nucleus arthoplasty technology in spinal care, volume II: biomechanics and development. Bloomington, MN: Raymedica Inc; 2007;p. 41–48.
- 72. Guardado AA, Baker A, Weightman A, Hoyland JA, Cooper G. Lumbar Intervertebral Disc Herniation: Annular Closure Devices and Key Design Requirements. Bioengineering (Basel). 2022 Jan 19;9(2):47. doi: 10.3390/bioengineering9020047.
- Gundanna MI, Miller LE, Block JE. Complications with axial presacral lumbar interbody fusion: A 5year postmarketing surveillance experience. SAS Journal 5 (2011) 90–94.
- 74. Ha KY, Lee JS, Kim KW. Degeneration of sacroiliac joint after instrumented lumbar or lumbosacral fusion: a prospective cohort study over five-year follow-up. Spine (Phila Pa 1976). 2008 May 15;33(11):1192-8.
- 75. Habib A, Smith ZA, Lawton CD, Fessler RG. Minimally Invasive Transforaminal Lumbar Interbody Fusion: A Perspective on Current Evidence and Clinical Knowledge. Minimally Invasive Surgery Volume 2012, Article ID 657342.
- Hadjipavlou A, Alpantaki K, Katonis P, Vastardis G, Tzermiadianos M, Benardos N. Safety and effectiveness of retrorectal presacral approach for lumbosacral axial instrumentation. A clinical study. Acta Orthop Belg. 2013 Apr;79(2):222-9.

- 77. Heiney J, Capobianco R, Cher D. A systematic review of minimally invasive sacroiliac joint fusion utilizing a lateral transarticular technique. Int J Spine Surg. 2015 Jul 22;9:40.
- 78. Inamasu J, Guiot BH. Laparoscopic Anterior Lumbar Interbody Fusion: A Review of Outcome Studies. Minim Invas Neurosurg 2005; 48: 340±347.
- 79. International Society for the Advancement of Spine Surgery (ISASS). Proposed Recommendations for "Coverage Criteria": Minimally Invasive Sacroiliac Joint Fusion. March 2014. Accessed at http://www.isass.org/.
- 80. International Society for the Advancement of Spine Surgery. Statement on Coding Changes for Minimally Invasive SI Joint Fusion July 2013. Accessed at www.isass.org.
- 81. Issack PS, et al. Axial lumbosacral interbody fusion appears safe as a method to obtain lumbosacral arthrodesis distal to long fusion constructs. HSS J. 2012 Jul; 8(2): 116–121.
- Janjua MB, Ozturk A, Piazza M, Passias P, Arlet V, Welch WC. Technical nuances of percutaneous sacroiliac joint fixation: A cadaveric study. J Clin Neurosci. 2019 Mar;61:315-321. doi: 10.1016/j.jocn.2018.10.130. Epub 2018 Nov 10. PMID: 30424968.
- Kienzler JC, Fandino J, et al. Barricaid® Annular Closure RCT Study Group. Risk factors for early reherniation after lumbar discectomy with or without annular closure: results of a multicenter randomized controlled study. Acta Neurochir (Wien). 2021 Jan;163(1):259-268. doi: 10.1007/s00701-020-04505-4. Epub 2020 Oct 21. PMID: 33085021.
- Kienzler JC, Heidecke V, et al. Intraoperative findings, complications, and short-term results after lumbar microdiscectomy with or without implantation of annular closure device. Acta Neurochir (Wien). 2021 Feb;163(2):545-559. doi: 10.1007/s00701-020-04612-2. Epub 2020 Oct 18. PMID: 33070235.
- Kienzler JC, Klassen PD, Miller LE, Assaker R, Heidecke V, Fröhlich S, Thomé C; Annular Closure RCT Study Group. Three-year results from a randomized trial of lumbar discectomy with annulus fibrosus occlusion in patients at high risk for reherniation. Acta Neurochir (Wien). 2019 Jul;161(7):1389-1396. doi: 10.1007/s00701-019-03948-8. Epub 2019 May 15.
- 86. Klassen PD, Hsu WK, Martens F, Inzana JA, van den Brink WA, Groff MW, Thomé C. Post-lumbar discectomy reoperations that are associated with poor clinical and socioeconomic outcomes can be reduced through use of a novel annular closure device: results from a 2-year randomized controlled trial. Clinicoecon Outcomes Res. 2018 Jun 26;10:349-357. doi: 10.2147/CEOR.S164129.
- Kucharzyk D, Colle K, Boone C, Araghi A. Clinical Outcomes Following Minimally Invasive Sacroiliac Joint Fusion With Decortication: The EVoluSion Clinical Study. Int J Spine Surg. 2022 Feb;16(1):168-175. doi: 10.14444/8185.
- Lange N, Meyer B, Shiban E. Symptomatic annulus-repair-device loosening due to a low-grade infection. Acta Neurochir (Wien). 2018 Jan;160(1):199-203. doi: 10.1007/s00701-017-3371-1. Epub 2017 Oct 26. PMID: 29075906.
- Ledonio CGT, Polly DW, Swiontkowski MF, Cummings Jr JT. Comparative effectiveness of open versus minimally invasive sacroiliac joint fusion. Medical Devices: Evidence and Research 2014:7 187–193.
- 90. Ledonio CG, Polly DW Jr, Swiontkowski MF. Minimally invasive versus open sacroiliac joint fusion: are they similarly safe and effective? Clin Orthop Relat Res. 2014 Jun;472(6):1831-8.
- Lee DW, Patterson DG, Sayed D. Review of Current Evidence for Minimally Invasive Posterior Sacroiliac Joint Fusion. Int J Spine Surg. 2021 Jun;15(3):514-524. doi: 10.14444/8073. Epub 2021 May 7.
- 92. Lee KH, Yue WM, Yeo W, Soeharno H, Tan SB. Clinical and radiological outcomes of open versus minimally invasive transforaminal lumbar interbody fusion. Eur Spine J. 2012 Nov;21(11):2265-70.
- 93. Lindley EM, McCullough MA, Burger EL, Brown CW, Patel VV. Complications of axial lumbar interbody fusion. J Neurosurg Spine 15:273–279, 2011.

- Lindsey DP, et al. Evaluation of a minimally invasive procedure for sacroiliac joint fusion an in vitro biomechanical analysis of initial and cycled properties. Medical Devices: Evidence and Research 2014:7 131–137.
- 95. Lindsey DP, Kiapour A, Yerby SA, Goel VK. Sacroiliac Joint Fusion Minimally Affects Adjacent Lumbar Segment Motion: A Finite Element Study. International journal of spine surgery. 2015 Nov 13;9:64.
- 96. Lindsey DP, Kiapour A, Yerby SA, Goel VK. Sacroiliac joint stability: Finite element analysis of implant number, orientation, and superior implant length. World J Orthop. 2018 Mar 18;9(3):14-23. doi: 10.5312/wjo.v9.i3.14.
- 97. Lorio MP. ISASS Policy 2016 Update Minimally Invasive Sacroiliac Joint Fusion. Int J Spine Surg. 2016 Jul 13;10:26.
- Lorio M, Kim C, Araghi A, Inzana J, Yue JJ. International Society for the Advancement of Spine Surgery Policy 2019-Surgical Treatment of Lumbar Disc Herniation with Radiculopathy. Int J Spine Surg. 2020 Feb 29;14(1):1-17. doi: 10.14444/7001.
- 99. Lorio M, Kim C, Araghi A, Inzana J, Yue JJ. International Society for the Advancement of Spine Surgery Policy 2019—Surgical Treatment of Lumbar Disc Herniation with Radiculopathy. International Journal of Spine Surgery. 2020 Feb 1;14(1):1-7.
- 100. Lorio M, Kube R, Araghi A. International Society for the Advancement of Spine Surgery. Minimally Invasive Surgical Sacroiliac Joint Fusion (for Chronic Sacroiliac Joint Pain): Coverage Indications, Limitations, and Medical Necessity (2020 Update). International Journal of Spine Surgery December 2020, 14 (6) 860-895; DOI: https://doi.org/10.14444/7156.
- 101. Lorio MP, Polly Jr DW, Ninkovic I, Ledonio CGT, Hallas K, Andersson G. Utilization of Minimally Invasive Surgical Approach for Sacroiliac Joint Fusion in Surgeon Population of ISASS and SMISS Membership. The Open Orthopaedics Journal, 2014, 8, 1-6.
- 102. Lorio MP , Rashbaum R. ISASS Policy Statement Minimally Invasive Sacroiliac Joint Fusion. International Journal of Spine Surgery Volume 8 Article 25.
- 103. MacMillan M, et al. Description of a transosseous approach to the L5-S1 disc and 2 clinical case reports. Int J Spine Surg. 2012 Dec 1;6:178-83. doi: 10.1016/j.ijsp.2012.06.001. eCollection 2012.
- 104. Majd ME. Wednesday, September 26, 2018 1: 00 PM–2: 00 PM What's New in MIS: 38. Retrospective analysis of Sacroiliac Joint (SIJ) fusions comparing the percutaneous transgluteal approach to the posterior oblique approach. The Spine Journal. 2018 Aug 1;18(8):S18-9.
- 105. Malham GM, Ellis NJ, Parker RM, Seex KA. Clinical outcome and fusion rates after the first 30 extreme lateral interbody fusions. ScientificWorldJournal. 2012;2012:246989.
- 106. Manchikanti L, et al. An Update of Comprehensive Evidence-Based Guidelines for Interventional Techniques in Chronic Spinal Pain. Part II: Guidance and Recommendations. Pain Physician 2013; 16:S49-S283 • ISSN 1533-3159.
- 107. Marawar S, et al. Changes in neuroforaminal height with 2 level axial presacral lumbar interbody fusion at L4-S1. Int J Spine Surg. 2014 Dec 1;8. doi: 10.14444/1002. eCollection 2014.
- Marchi L, Abdala N, Oliveira L, Amaral R, Coutinho E, Pimenta L. Stand-Alone Lateral Interbody Fusion for the Treatment of Low-Grade Degenerative Spondylolisthesis. ScientificWorldJournal. 2012; 2012:456346.
- 109. Marotta N, Cosar M, Pimenta L, et al. A novel minimally invasive presacral approach and instrumentation technique for anterior L5 S1 intervertebral discectomy and fusion: technical description and case presentations. Neurosurg Focus. 2006 Jan 15; 20(1):E9.
- 110. Martin CT, Haase L, Lender PA, Polly DW. Minimally Invasive Sacroiliac Joint Fusion: The Current Evidence. Int J Spine Surg. 2020 Feb 10;14(Suppl 1):20-29. doi: 10.14444/6072.

- 111. McGrath KA, Schmidt ES, Loss JG, Gillespie CM, Colbrunn RW, Butler RS, Steinmetz MP. Assessment of L5-S1 anterior lumbar interbody fusion stability in the setting of lengthening posterior instrumentation constructs: a cadaveric biomechanical study. J Neurosurg Spine. 2021 Dec 17:1-9. doi: 10.3171/2021.9.SPINE21821. Epub ahead of print. PMID: 34920420.
- 112. Melgar MA, et al. Segmental and global lordosis changes with two-level axial lumbar interbody fusion and posterior instrumentation. Int J Spine Surg. 2014 Dec 1;8. doi: 10.14444/1010. eCollection 2014.
- 113. Miller LE, Allen RT, Duhon B, Radcliff KE. Expert review with meta-analysis of randomized and nonrandomized controlled studies of Barricaid annular closure in patients at high risk for lumbar disc reherniation. Expert Rev Med Devices. 2020 May;17(5):461-469. doi: 10.1080/17434440.2020.1745061. Epub 2020 Apr 1.
- 114. Miller LE, Block JE. Minimally invasive arthrodesis for chronic sacroiliac joint dysfunction using the SImmetry SI Joint Fusion system. Medical Devices: Evidence and Research 2014:7 125–130.
- 115. Miller LE, Reckling WC, Block JE. Analysis of postmarket complaints database for the iFuse SI Joint Fusion System®: a minimally invasive treatment for degenerative sacroiliitis and sacroiliac joint disruption. Med Devices (Auckl). 2013 May 29;6:77-84.
- 116. Murphy TP, Panarello NM, Baird MD, Helgeson MD, Wagner SC. Should Annular Closure Devices Be Utilized to Reduce the Risk of Recurrent Lumbar Disk Herniation? Clin Spine Surg. 2022 Jun 1;35(5):187-189. doi: 10.1097/BSD.00000000001104. Epub 2020 Oct 23.
- 117. Nanda D, Arts MP, et al. Annular closure device lowers reoperation risk 4 years after lumbar discectomy. Med Devices (Auckl). 2019 Sep 4;12:327-335. doi: 10.2147/MDER.S220151.
- 118. Nandyala SV, Fineberg SJ, Pelton M, Singh K. Minimally invasive transforaminal lumbar interbody fusion: one surgeon's learning curve. Spine J. 2013 Oct 3. pii: S1529-9430(13)01493-9.
- 119. National Institute for Health and Clinical Excellence (NICE). Lateral (Including Extreme, Extra and Direct Lateral) Interbody Fusion in the Lumbar Spine- Interventional Procedure Guidance 321, Issue Date: November 2009, accessed at guidance.nice.org.uk.
- 120. National Institute for Health and Clinical Excellence (NICE). Interventional Procedures Guidance 387, Transaxial interbody lumbosacral fusion. Issue date: March 2011.
- 121. National Institute for Health and Clinical Excellence (NICE). Transaxial Interbody Lumbosacral Fusion- consultation Document, London UK: NICE; December 2010.
- 122. National Institute for Health and Care Excellence (NICE). Interventional Procedures Guidance 578: Minimally invasive sacroiliac joint fusion surgery for chronic sacroiliac pain (April 2017).
- 123. National Institute for Health and Care Excellence (NICE). Medical technologies guidance [MTG39]: iFuse for treating chronic sacroiliac joint pain (October 2018).
- 124. NeurosurgeryToday.org. Minimally Invasive Spine Surgery (MIS). January 2009.
- 125. North American Spine Society. North American Spine Society. Evidence-Based Clinical Guidelines for Multidisciplinary Spine Care: Diagnosis & Treatment of Low Back Pain (2020) (Updated 01/21/21). Accessed at https://www.spine.org/Research-Clinical-Care/Quality-Improvement/Clinical-Guidelines.
- 126. North American Spine Society. Percutaneous Sacroiliac Joint Fusion: Defining Appropriate Coverage Positions. May 31, 2015.
- 127. North American Spine Society (NASS). Public Education Series. Spinal Fusion. 2006 2009 North American Spine Society.
- 128. North American Spine Society Coverage Policy Recommendations: Percutaneous Sacroiliac Joint Fusion (June 2015). Accessed at https://www.spine.org/.

- 129. Nunley P, Strenge KB, Huntsman K, Bae H, DiPaola C, Allen RT, Shaw A, Sasso RC, Araghi A, Staub B, Chen S, Shum LC, Musacchio M. Lumbar Discectomy With Bone-Anchored Annular Closure Device in Patients With Large Annular Defects: One-Year Results. Cureus. 2023 Jun 9;15(6):e40195. doi: 10.7759/cureus.40195.
- 130. Official Disability Guidelines (ODG). Medical Treatment and Return to Work Guidelines. Evidence-Based Decision Support: Percutaneous Sacroiliac Joint Fusion.
- 131. Osman, SG. Endoscopic transforaminal decompression, interbody fusion, and percutaneous pedicle screw implantation of the lumbar spine: A case series report. Int J Spine Surg. 2012; 6: 157–166.
- 132. Ozgur BM, Aryan HE, Pimenta L, Taylor WR. Extreme Lateral Interbody Fusion (XLIF): a novel surgical technique for anterior lumbar Interbody fusion. Spine J. 2006 July August; 6(4): 435-43.
- 133. Park P, Foley KT. Minimally invasive transforaminal lumbar interbody fusion with reduction of spondylolisthesis: technique and outcomes after a minimum of 2 years' follow-up. Neurosurg Focus 25 (2):E16, 2008.
- 134. Patil SS, Lindley EM, et al, Clinical and Radiological Outcomes of Axial Lumbar Interbody Fusion, Spine Center, Department of Orthopedics, University of Colorado Denver, Colorado, accessed at orthosupersite.com 01/05/11.
- 135. Petersen T, Laslett M, Juhl C. Clinical classification in low back pain: best-evidence diagnostic rules based on systematic reviews. BMC Musculoskelet Disord. 2017 May 12;18(1):188.
- 136. Polly DW, et al. Does Level of Response to SI Joint Block Predict Response to SI Joint Fusion? Int J Spine Surg. 2016 Jan 21;10:4.
- 137. Polly DW, et al. Neurosurgery. 2015 Nov;77(5):674-90; discussion 690-1. Randomized Controlled Trial of Minimally Invasive Sacroiliac Joint Fusion Using Triangular Titanium Implants vs Nonsurgical Management for Sacroiliac Joint Dysfunction: 12-Month Outcomes.
- 138. Polly DW, 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 Aug 23;10:28.
- 139. Rajpal S, Burneikiene S. Minimally Invasive Sacroiliac Joint Fusion with Cylindrical Threaded Implants Using Intraoperative Stereotactic Navigation. World Neurosurg. 2019;122:e1588-e1591. doi:10.1016/j.wneu.2018.11.116.
- 140. Rapp SM, Miller LE, Block JE. AxiaLIF system: minimally invasive device for presacral lumbar interbody spinal fusion. Med Devices (Auckl). 2011;4:125-31.
- 141. Rappoport LH, Helsper K, Shirk T. Minimally invasive sacroiliac joint fusion using a novel hydroxyapatite-coated screw: final 2-year clinical and radiographic results. J Spine Surg. 2021 Jun;7(2):155-161. doi: 10.21037/jss-20-627.
- 142. Rappoport LH, Luna IY, Joshua G. Minimally Invasive Sacroiliac Joint Fusion Using a Novel Hydroxyapatite-Coated Screw: Preliminary 1-Year Clinical and Radiographic Results of a 2-Year Prospective Study. World Neurosurg. 2017 May;101:493-497. doi: 10.1016/j.wneu.2017.02.046. Epub 2017 Feb 16. PMID: 28216399.
- 143. Resnick DK, Choudhri TF, Dailey AT, Groff MW, Khoo L, Matz PG, et al. Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 11: interbody techniques for lumbar fusion. J Neurosurg Spine. 2005 June;2(6):692-9.
- 144. Rudolf L. MIS Fusion of the SI Joint: Does Prior Lumbar Spinal Fusion Affect Patient Outcomes? The open orthopaedics journal (2013), 7, 163.
- 145. Rudolf L. Sacroiliac joint arthrodesis-MIS technique with titanium implants: report of the first 50 patients and outcomes. The open orthopaedics journal (2012), 6, 495.

- 146. Rudolph L, Capobianco R. Five-Year Clinical and Radiographic Outcomes After Minimally Invasive Sacroiliac Joint Fusion Using Triangular Implants. The Open Orthopaedics Journal, 2014, 8, 375-383.
- 147. Saavoss JD, Koenig L, Cher DJ. Productivity benefits of minimally invasive surgery in patients with chronic sacroiliac joint dysfunction. ClinicoEconomics and outcomes research: CEOR. 2016 Apr 11;8:77.
- 148. Sachs D, Capobianco R. One year successful outcomes for novel sacroiliac joint arthrodesis system. Ann Surg Innov Res. 2012 Dec 27;6(1):13.
- 149. Sachs D, Capobianco R. Minimally invasive sacroiliac joint fusion: one-year outcomes in 40 patients. Advances in orthopedics, 2013.
- 150. Sachs D, et al. One-year outcomes after minimally invasive sacroiliac joint fusion with a series of triangular implants: a multicenter, patient-level analysis. Medical Devices: Evidence and Research 2014:7 299–304.
- 151. Sachs D, et al. Durable intermediate-to long-term outcomes after minimally invasive transiliac sacroiliac joint fusion using triangular titanium implants. Med Devices (Auckl). 2016 Jul 13;9:213-22.
- 152. Schmidt GL, Bologna M, Schorr R. Patient Reported Clinical Outcomes of Minimally Invasive Sacroiliac Joint Arthrodesis. Orthop Surg. 2021 Feb;13(1):71-76. doi: 10.1111/os.12832. Epub 2020 Dec 7.
- 153. Schroeder GD, Kepler CK, Millhouse PW, Fleischman AN, Maltenfort MG, Bateman DK, Vaccaro AR. L5/S1 Fusion Rates in Degenerative Spine Surgery: A Systematic Review Comparing ALIF, TLIF, and Axial Interbody Arthrodesis. Clin Spine Surg. 2016 May;29(4):150-5. doi: 10.1097/BSD.00000000000356. PMID: 26841206.
- 154. 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 Journal® (2014) 10(1), 30-35.
- 155. Shaffrey CL, Smith JS. Stabilization of the sacroiliac joint. Neurosurg Focus. 2013 Jul;35(2 Suppl):Editorial. doi: 10.3171/2013.V2.FOCUS13273. PMID: 23829837.
- 156. Sharma AK, Kepler CK, Girardi FP, Cammisa FP, Huang RC, Sama AA. Lateral lumbar interbody fusion: clinical and radiographic outcomes at 1 year: a preliminary report. J Spinal Disord Tech. 2011 Jun;24(4):242-
- 157. Shen FH, Samartzis D, Khanna AJ, et al. Minimally invasive techniques for lumbar interbody fusions. Orthop Clin North Am. 2007 Jul; 38(3):373-86.
- 158. Smith AG, Capobianco R, Cher D, Rudolf L, Sachs D, Gundanna M, Shamie AN. Open versus minimally invasive sacroiliac joint fusion: a multi-center comparison of perioperative measures and clinical outcomes. Ann Surg Innov Res. 2013 Oct 30;7(1):14. doi: 10.1186/1750-1164-7-14.
- 159. Society for Minimally Invasive Spine Surgery. Position Statement on Presacral Lumbar Interbody Fusion (February 29, 2012). Accessed at www.smiss.org.
- 160. Spain K, Holt T. Surgical Revision after Sacroiliac Joint Fixation or Fusion. Int J Spine Surg. 2017 Jan 19;11:5.
- 161. Stark, John G., J. Abner Fuentes, Tania I. Fuentes, and Christopher Idemmili. The history of sacroiliac joint arthrodesis: a critical review and introduction of a new technique. Current Orthopaedic Practice 22, no. 6 (2011): 545-557.
- 162. Stippler M, Turka M, & Gerszten P. C. Outcomes after Percutaneous TranS1 AxiaLIF® L5 S1 Interbody Fusion for Intractable Lower Back Pain. The Internet Journal of Spine Surgery. 2009 Volume 5, Number 1.
- 163. Strenge KB, DiPaola CP, et al. Multicenter study of lumbar discectomy with Barricaid annular closure device for prevention of lumbar disc reherniation in US patients: A historically controlled post-market

study protocol. Medicine (Baltimore). 2019 Aug;98(35):e16953. doi: 10.1097/MD.000000000016953.

- 164. Stuber KJ. Specificity, sensitivity, and predictive values of clinical tests of the sacroiliac joint: a systematic review of the literature. J Can Chiropr Assoc. 2007 Mar;51(1):30-41.
- 165. Sturesson B, et al. Six-month outcomes from a randomized controlled trial of minimally invasive SI joint fusion with triangular titanium implants vs conservative management. Eur Spine J. 2016 May 14.
- 166. Szadek KM, van der Wurff P, van Tulder MW, Zuurmond WW, Perez RS. Diagnostic validity of criteria for sacroiliac joint pain: a systematic review. J Pain. 2009 Apr;10(4):354-68.
- 167. Tang S. Does TLIF Aggravate Adjacent Segmental Degeneration More Adversely than ALIF? A Finite Element Study. Turkish Neurosurgery 2012, Vol: 22, No: 3, 324-328.
- 168. Tender GC, et al. Percutaneous pedicle screw reduction and axial presacral lumbar interbody fusion for treatment of lumbosacral spondylolisthesis: A case series. J Med Case Rep. 2011 Sep 12;5:454. doi: 10.1186/1752-1947-5-454.
- 169. Thomé C, Klassen PD, Bouma GJ, Kuršumović A, Fandino J, Barth M, Arts M, van den Brink W, Bostelmann R, Hegewald A, Heidecke V, Vajkoczy P, Fröhlich S, Wolfs J, Assaker R, Van de Kelft E, Köhler HP, Jadik S, Eustacchio S, Hes R, Martens F; Annular Closure RCT Study Group. Annular closure in lumbar microdiscectomy for prevention of reherniation: a randomized clinical trial. Spine J. 2018 Dec;18(12):2278-2287. doi: 10.1016/j.spinee.2018.05.003. Epub 2018 May 3.
- 170. Thomé C, Kuršumovic A, Klassen PD, et al; Annular Closure RCT Study Group. Effectiveness of an Annular Closure Device to Prevent Recurrent Lumbar Disc Herniation: A Secondary Analysis With 5 Years of Follow-up. JAMA Netw Open. 2021 Dec 1;4(12):e2136809. doi: 10.1001/jamanetworkopen.2021.36809.
- 171. Tobler WD, Ferrara LA. The presacral retroperitoneal approach for axial lumbar interbody fusion: A prospective study of clinical outcomes, complications and fusion rates at a follow-up of two years in 26 patients. J Bone Joint Surg [Br] 2011; 93-B:955-60.
- 172. Tobler WD, Melgar MA, Raley TJ, Anand N, Miller LE, Nasca RJ. Clinical and radiographic outcomes with L4-S1 axial lumbar interbody fusion (AxiaLIF) and posterior instrumentation: a multicenter study. Medical Devices (Auckland, NZ) (2013), 6, 155.
- 173. Tobler WD, Gerszten PC, Bradley WD, Raley TJ, Nasca RJ, Block JE. Clinical Case Series: Minimally Invasive Axial Presacral L5–S1 Interbody Fusion. Two-Year Clinical and Radiographic Outcomes. SPINE Volume 36, Number 20, pp 1–6, September 2011.
- 174. Tohmeh AG, Watson B, Tohmeh M, Zielinski XJ.Allograft cellular bone matrix in extreme lateral interbody fusion: preliminary radiographic and clinical outcomes. ScientificWorldJournal. 2012;2012:263637.
- 175. Tran ZV, Ivashchenko A, Brooks L. Sacroiliac Joint Fusion Methodology Minimally Invasive Compared to Screw-Type Surgeries: A Systematic Review and Meta-Analysis. Pain Physician. 2019 Jan;22(1):29-40. PMID: 30700066.
- 176. Tsahtsarlis A, Wood M. Minimally invasive transforaminal lumber interbody fusion and degenerative lumbar spine disease. Eur Spine J. 2012 Nov;21(11):2300-5.
- 177. U.S. Food & Drug Administration (FDA). Approval Order K122074: iFuse Implant System® (10/12/12). Accessed at https://www.accessdata.fda.gov/.
- 178. U.S. Food & Drug Administration (FDA). Approval Order P160050: Barricaid® Anular Closure Device (ACD) (02/08/19). Accessed at https://www.accessdata.fda.gov/.
- 179. U.S. National Library of Medicine MedlinePlus. Fibromyalgia. Accessed at https://medlineplus.gov/fibromyalgia.html.

- 180. Vanaclocha VV, Verdú-López F, Sánchez-Pardo M, Gozalbes-Esterelles L, Herrera JM. (2014). Minimally Invasive Sacroiliac Joint Arthrodesis: Experience in a Prospective Series with 24 Patients. J Spine, 3(185), 2.
- 181. Vleeming A, Albert HB, Ostgaard HC, Sturesson B, Stuge B. European guidelines for the diagnosis and treatment of pelvic girdle pain. Eur Spine J. 2008 Jun;17(6):794-819.
- 182. Wang Y, He X, Chen S, Weng Y, Liu Z, Pan Q, Zhang R, Li Y, Wang H, Lin S, Yu H. Annulus Fibrosus Repair for Lumbar Disc Herniation: A Meta-Analysis of Clinical Outcomes From Controlled Studies. Global Spine J. 2024 Jan;14(1):306-321. doi: 10.1177/21925682231169963. Epub 2023 Apr 17.
- 183. Wang X, Xu J, Zhu Y, Li J, Zhou S, Tian S, Xiang Y, Liu X, Zheng Y, Pan T. Biomechanical analysis of a newly developed shape memory alloy hook in a transforaminal lumbar interbody fusion (TLIF) in vitro model. PLoS One. 2014 Dec 4;9(12):e114326.
- 184. WebMD. Somatic Symptom and Related Disorders. Accessed at https://www.webmd.com/mentalhealth/somatoform-disorders-symptoms-types-treatment#1.
- 185. Whang P, et al. Sacroiliac Joint Fusion Using Triangular Titanium Implants vs. Non-Surgical Management: Six-Month Outcomes from a Prospective Randomized Controlled Trial. Int J Spine Surg. 2015 Mar 5;9:6.
- 186. Whang PG, Sasso RC, Patel VV, Ali RM, Fischgrund JS. Comparison of axial and anterior interbody fusions of the L5-S1 segment: a retrospective cohort analysis. J Spinal Disord Tech. 2013 Dec;26(8):437-43.
- 187. Wong CK, Johnson EK. A narrative review of evidence-based recommendations for the physical examination of the lumbar spine, sacroiliac and hip joint complex. Musculoskelet. Care 10 (2012) 149–161.
- 188. Wu WJ, Liang Y, Zhang XK, Cao P, Zheng T. Complications and clinical outcomes of minimally invasive transforaminal lumbar interbody fusion for the treatment of one- or two-level degenerative disc diseases of the lumbar spine in patients older than 65 years. Chinese Medical Journal 2012;125(14):2505-2510.
- 189. Zeilstra DJ, Miller LE, Block JE. Axial lumbar interbody fusion: a 6-year single-center experience. Clinical interventions in aging (2013), 8, 1063.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 09/26/24.

GUIDELINE UPDATE INFORMATION:

03/15/10	New Medical Coverage Guideline.
02/15/11	Annual review; position statement maintained and references updated.
01/26/12	Scheduled review. Position statement maintained; updated description section and
	references.
01/01/13	Annual CPT coding update. Added 22586 and 0309T. Revised code descriptors for 0195T
	and 0196T.
02/15/13	Scheduled review. Position statement maintained. Revised description and updated
	references.
03/15/14	Scheduled review. Revised description, position statement, program exceptions and CPT
	coding. Updated references.

12/15/14	Unscheduled review. Revised position statement (coverage for open SI joint fusion).		
	Updated references.		
01/01/15	Annual CPT/HCPCS update. Added 27279. Revised 27280 descriptor. Deleted 0334T.		
03/15/15	Scheduled review. Position statement maintained. Updated references. Reformatted guideline.		
03/15/16	Scheduled review. Position statement maintained. Updated references.		
02/15/17	Scheduled review. Position statement maintained. Updated references.		
01/01/18	Annual CPT/HCPCS coding update: deleted code 0309T. Reformatted guideline.		
02/15/18	Scheduled review. Revised description section. Added coverage criteria for minimally invasive sacroiliac joint fusion/stabilization. Revised definitions and related guidelines sections. Updated references.		
06/15/18	Revision: deleted bracing as a requirement for minimally invasive sacroiliac joint fusion. Updated Medicare Advantage program exception and references.		
10/15/18	Unscheduled review. Position statement maintained. Revised program exceptions. Updated references.		
01/01/19	Annual CPT/HCPCS coding update. Deleted 0195T, 0196T.		
01/01/20	Annual CPT/HCPCS coding update. Added C9757.		
08/15/20	Scheduled review. Revised description and position statement. Updated references.		
05/15/21	Unscheduled review. Position statement maintained. Updated references.		
06/15/22	Scheduled review. Maintained position statement and updated references.		
01/01/23	Annual CPT/HCPCS coding update. Added 0775T. Revised 27280.		
05/15/23	Revision. Added coverage statement for SI joint fusion via posterior (dorsal) approach. Updated definitions, index terms and references.		
07/01/23	Quarterly CPT/HCPCS coding update. Added 0809T.		
08/21/23	Update to Program Exceptions section.		
01/01/24	Position statements maintained.		
	Annual CPT/HCPCS coding update. Added 27278; deleted 0775T, 0809T.		
02/15/24	Revision. Updated references and maintained position statements.		
10/15/24	Scheduled review. Revised description. Maintained position statement and updated references.		