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Subject: Minimally Invasive Fusion Techniques

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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 follow-up. 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. Balsano et al (2020) evaluated the radiographic and clinical results of patients treated with AxiaLif® Technique (AxiaLif®, AMSGroup, Italy) using a minimally invasive pre-sacral approach. From 2013 to 2018 a total of 52 patients have been treated (12 M, 40 F; mean age 46.3 years). Diagnosis included L5 isthmic spondylolisthesis low-grade dysplasia, primary and secondary degenerative disc disease. Forty-three patients were followed for at least 2 years. Fusion assessment was based on plain radiographs and Brantigan fusion criteria at 1, 6, 12 and 24 months after surgery. All patients completed the VAS and ODI at baseline through last follow-up. Clinical results showed good pain resolution. VAS back demonstrated an average reduction over baseline of 50%, 57%, 71%, 77% at 3, 6, 12 and 24 months, respectively. ODI demonstrated an average reduction over baseline of 38%, 51%, 67%, and 72% at the same time points. Complete fusion was demonstrated in 65% of cases, 30% partial fusion and 5% in the absence of bony bridges visible radiographically. There were two major complications, 1 retroperitoneal hematoma and 1 spondylodiscitis, and one minor complication, a superficial infection of the surgical wound. The authors concluded "(t)he surgical treatment of degenerative disc disease at L5-S1 with minimally invasive technique Axialif showed good radiographic and clinical outcomes with an acceptable rate of complications. Moreover, shorter hospitalization and faster functional recovery are adding factors to choice this technique." Korytkowski et al (2025) reviewed all identifiable cases of the AxiaLIF procedure performed at a single, academic medical center. Six patients underwent AxiaLIF between July 2010 and May 2022. Indications for AxiaLIF as a salvage approach included hardware failure with a significant risk of recurrence with traditional revision techniques; a lack of segmental fixation at the distal end of the spinal construct; avoiding extensive tissue disruption in the setting of staged realignment surgery or previously compromised tissue; and comorbidities such as muscular dystrophy, abdominal hernias, and severe obesity. Two patients were fused solely across the L5 to S1 level, and 4 patients were fused from L4 to S1. The mean operative time, estimated blood loss, time under fluoroscopy, complications, and follow-up were noted. The authors concluded that this case series introduces the utility of AxiaLIF as a salvage approach, stating "(w)e believe the AxiaLIF procedure may be a valuable alternative to traditional lumbar interbody fusion in salvage situations when traditional techniques are not feasible or pose significant risk to the patient. In such situations, surgeon awareness of this approach has the potential to improve patient outcomes and safety … when other surgical options pose significant risk or are not feasible."

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%), intra-articular 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 high-risk 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%) …"

An International Society for the Advancement of Spine Surgery (ISASS) 2025 policy update, "Use of Bone-Anchored Annular Closure to Prevent Reherniation in High-Risk Lumbar Discectomy Patients" (2025) states, "(t)here has been the observation that bone-anchored annular closure is associated with the radiological occurrence of endplate lesions. As noted in the 2019 policy guideline, the ISASS task force concluded that no negative clinical outcomes were associated with the endplate lesions, based on patient-reported outcomes, reoperations, or serious adverse events. The analyses to support these conclusions from the RCT have been published for multiple follow-up time points, and the results are consistent with recent publications from other studies that have reported no clinical impact of the presence or size of endplate lesions in patients treated with bone-anchored annular closure. A case series of 107 annular closure patients reported stabilization—or, in some cases, a decrease in size—of all bone resorption by the 8-year time point based on the presence of a clear sclerotic rim around the endplate lesions. There were no statistically significant associations of endplate lesions with clinical outcomes, and using computed tomography–based volume measurements, the maximum lesion size was estimated to be 12% of the vertebral body. Taken together, current evidence suggests that the endplate lesions do not impact device function or clinical outcomes through 8 years of follow-up. The policy further states "(b)ased on the accumulating clinical evidence, ISASS reiterates its position that in patients with symptomatic LDH with radiculopathy undergoing primary discectomy with large (≥6 mm wide) annular defects, bone-anchored annular closure may be used to sustain the treatment benefits of discectomy by reducing the risk of recurring LDH and the need for reoperation. Barricaid is the only US Food and Drug Administration (FDA)–approved bone-anchored annular closure device commercially available in the United States indicated for the prevention of recurrent LDH."

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 anti-inflammatory 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 and/or using an intra-articular implant(s) (eg, bone allograft or synthetic device) 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® Annular 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:

CPT Coding:

22586	Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, L5-S1 interspace **(investigational)**
27278	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive, with image guidance, includes obtaining bone graft when performed, unilateral; placement of intra-articular device(s), without cortical piercing **(investigational)**
27279	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive, with image guidance, includes obtaining bone graft when performed, unilateral; placement of transarticular device(s) and/or intra-articular device(s) piercing the lateral or medial cortices of the ilium and the lateral cortex of the sacrum
27280	Arthrodesis, sacroiliac joint, open, includes obtaining bone graft, including instrumentation, when performed
63032	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; with repair of annular defect by implantation of bone-anchored annular closure device, including all imaging guidance, 1 interspace, lumbar (List separately in addition to code for primary procedure) (**investigational**)

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 Coverage Protocol Exemption Request.

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

Automated Percutaneous Discectomy, Laser Discectomy, Percutaneous Endoscopic Discectomy, and DISC Nucleoplasty™, 02-61000-32

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
Siimpact® Sacroiliac Joint Fixation System
Siros™
Triton SI Joint Fixation System™

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 09/25/25.

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.
10/15/25	Scheduled review. Revised description. Maintained position statement and updated references.
01/01/26	Annual CPT/HCPCS coding update. Added 63032; revised 27278, 27279.