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## 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.

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### DESCRIPTION:

#### **Axial Lumbar Interbody Fusion (AxialLIF)**

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.

## **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 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:

### 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 ( <b>investigational</b> )
27279	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device
27280	Arthrodesis, sacroiliac joint, open, includes obtaining bone graft, including instrumentation, when performed
0775T	Arthrodesis, sacroiliac joint, percutaneous, with image guidance, includes placement of intra-articular implant(s) (eg, bone allograft[s], synthetic device[s])

## 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 ( <b>investigational</b> )
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## 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.

## 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.

**Fibromyalgia:** A disorder that causes muscle pain and fatigue in the form of "tender points" on the body in response to applied pressure; generally on the neck, shoulders, back, hips, arms, and legs.

**Interbody:** Between the bodies of two adjacent vertebra.

**Interspace:** Any space between two similar objects.

**Somatoform disorder:** A form of mental illness that causes one or more bodily symptoms, including pain; symptoms may or may not be traceable to a physical cause including general medical conditions, other mental illnesses, or substance abuse; also known as somatic symptom disorder or somatization disorder.

## RELATED GUIDELINES:

[Bone Morphogenetic Protein \(BMP\), 02-20000-32](#)

[Interspinous and Interlaminar Stabilization/Distracton \(Spacers\) 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.

iFuse® Implant System

Rialto™ SI Joint Fusion System

SIJ-Fuse®

SImmetry® Sacroiliac Joint Fusion System

Silex™ Sacroiliac Joint Fusion System

SambaScrew®

SI-LOK® Sacroiliac 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 05/26/22.

### 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.