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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.

Position Statement | Billing/Coding | Reimbursement | Program Exceptions | Definitions | Related Guidelines

Other | References | Updates

DESCRIPTION:

Axial Lumbar Interbody Fusion (AxiaLIF)

The procedure for 1-level axial lumbosacral interbody fusion (axial LIF) is as follows (1): Under fluoroscopic monitoring, a blunt guide pin introducer is passed through a 15- to 20-mm incision lateral to the coccyx and advanced along the midline of the anterior surface of the sacrum. A guide pin is introduced and tapped into the sacrum. A series of graduated dilators are advanced over the guide pin, and a dilator sheath attached to the last dilator is left in place to serve as a working channel for the passage of instruments. A cannulated drill is passed over the guide pin into the L5-S1 disc space to rest on the inferior endplate of L5. It is followed by cutters alternating with tissue extractors, and the nucleus pulposus is debulked under fluoroscopic guidance. Next, bone graft material is injected to fill the disc space. The threaded rod is placed over the guide pin and advanced through the sacrum into L5. The implant is designed to distract the vertebral bodies and restore disc and neural foramen height. Additional graft material is injected into the rod, where it enters into the disc space through holes in the axial rod. A rod plug is then inserted to fill the cannulation of the axial rod. Percutaneous placement of pedicle or facet screws may be used to provide supplemental fixation. An advantage of axial LIF is that it allows preservation of the annulus and all paraspinous soft tissue structures. However, there is an increased need for fluoroscopy and an inability to address intracanal pathology or visualize the discectomy procedure directly. Complications of the axial approach may include perforation of the bowel and injury to blood vessels and/or nerves.

Sacroiliac joint fusion/stabilization

Sacroiliac fusion involves bony fusion of the sacroiliac joint for stabilization. This has been proposed for treatment of chronic sacroiliac pain. Several percutaneous or minimally invasive fixation/fusion devices have received marketing clearance by the FDA. These include the SI-FIX Sacroiliac Joint Fusion System (cortical implant with cancellous autograft), the IFUSE® Implant System (titanium triangular implant), the

SImmetry® Sacroiliac Joint Fusion System (system of threaded screws), the Silex™ (cylindrical implant) and the SI-LOK® (hydroxyapatite coated screw system).

Surgical devices for annular repair or modulation after spinal surgery, according to FDA documentation, are intended for use in soft tissue approximation, or repair of annular defect, for procedures such as general and orthopedic surgery. 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 titanium triangular 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**
- Patients have undergone and failed a minimum 6 months of intensive nonoperative treatment that must include medication optimization, activity modification, and 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, and with any devices other than a titanium triangular implant.

The use of surgical devices for annular repair/modulation following spinal surgery (e.g. Inclose™ Surgical Mesh System, Xclose™ Tissue Repair System) 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)**
27279	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device
27280	Arthrodesis, open, sacroiliac joint, including obtaining graft, including instrumentation, when performed

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: The following coverage article was reviewed on the last guideline reviewed date: Local Coverage Article: Medical review article for percutaneous minimally invasive fusion/stabilization of the SACROILIAC JOINT (A55120) located at cms.gov.

The following Local Coverage Determination (LCD) was reviewed on the last guideline review date: Local Coverage Determination (LCD) L33777: Noncovered Services. located at fcso.com.

DEFINITIONS:

Anulus 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/Distraction (Spacers) and Fixation (Fusion) Devices, 02-20000-36
Automated Percutaneous Discectomy, Laser Discectomy, Endoscopic Discectomy, or DISC Nucleoplasty™ as Techniques of Intervertebral Disc Decompression, 02-61000-32

OTHER:

None applicable

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy & Coverage Committee on 09/27/18.

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.