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0.00.00 – Axial Lumbar Interbody Fusion (axiaLIF)

Description

Axial lumbar interbody fusion (also called trans-sacral 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.

The AxiaLIF® (Axial Lumbar Interbody Fusion) and AxiaLIF 2 Level Systems were developed by TranS1® and consist of techniques and surgical instruments for creating a pre-sacral access route to perform percutaneous fusion of the L5 - S1 or L4 – S1 vertebral bodies. FDA Premarket Notification [510(k)J] summaries indicate that the procedures are intended to provide anterior stabilization of the spinal segments as an adjunct to spinal fusion and for assisting in the treatment of degeneration of the lumbar disc, performing lumbar discectomy, or for assistance in the performance of interbody fusion. The AxiaLIF® systems are indicated for patients requiring fusion to treat pseudoarthrosis, unsuccessful previous fusion, spinal stenosis, spondylolisthesis (Grade 1), or degenerative disc disease as defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. They are not intended to treat severe scoliosis, severe spondylolisthesis (Grades 2, 3 and 4), tumor, or trauma. The device is not meant to be used in patients with vertebral compression fractures or any other condition where the mechanical integrity of the vertebral body is compromised. Their usage is limited to anterior supplemental fixation of the lumbar spine at L5-S1 or L4-S1 in conjunction with legally marketed facet or pedicle screw systems. (1,2)

The procedure for one level axiaLIF is as follows. Under fluoroscopic monitoring, a blunt guide pin introducer is passed through a 15-20 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 is passed along the guide pin and a dilator sheath attached to the last dilator is left in place to serve as a working channel for passage of instruments. A threaded reamer is then passed 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 pulposis is debulked under fluoroscopic guidance. Next, bone graft material is injected to fill the disc space. The threaded rod designed to distract the vertebral bodies, restore disc height, and neural foramen height is then introduced over the guide pin into the S1 and L5 interbodies.

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Bone void filler is injected into the rod and enters 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 completes the procedure.(3)

Policy

Axial lumbar interbody fusion is considered investigational.

Policy Guidelines

Rationale

The published literature reporting patient outcomes for axial lumbar interbody fusion is limited to a technical report with presentation of 2 cases(4) and one retrospective case series with patients who received AxiaLIF at L5-S1. The AxiaLIF 2 level system received premarket notification in April 2008. Aryan and colleagues(5) report on their series of 35 patients with average follow-up of 17.5 months. These patients had pain secondary to lumbar degenerative disc disease, degenerative scoliosis, or lytic spondylolisthesis. In 21 of the patients, the axiaLIF procedure was followed by percutaneous pedicle screw-rod fixation, 2 patients had extreme lateral interbody fusion combined with posterior instrumentation, and 10 had a stand alone procedure. Two patients had axial LIF as part of a larger construct after unfavorable anatomy prevented access to the L5-S1 disc space during open lumbar fusion. Thirty-two patients had radiographic evidence of stable cage placement and fusion at last follow-up.

In their 2007 review of minimally invasive techniques for lumbar interbody fusion, Shen, et al note that experience with the technique is limited and complication rates are unknown. Complications may include perforation of the bowel and injury to blood vessels and/or nerves as well as infection. They also voice concerns about the increased need for fluoroscopy and the inability of the surgeon to address intracanal pathology or visualize the discectomy procedure directly.(3)

There is insufficient evidence to determine if axial lumbar interbody fusion is as effective or as safe as other surgical techniques, therefore the technology is considered investigational.

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References

1. U.S. Food and Drug Administration Center for Devices and Radiological Health. Premarket Notification [510(K)] Summary. TranS1® AxiaLIF® Fixation System. Available at http://www.fda.gov/cdrh/pdf7/K073514.pdf

2. U.S. Food and Drug Administration Center for Devices and Radiological Health. Premarket Notification [510(K)] Summary. TranS1® AxiaLIF® II System. Available at http://www.fda.gov/cdrh/pdf7/K073643.pdf

3. Shen FH, Samartzis D, Dip EBHC, et al. Minimally invasive techniques for lumbar interbody fusion. Orhtop Clin N Am 2007;38(373-386).

4. Marotta N, Cosar M, Pimenta L, Khoo LT. 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;20(1)E9.

5. Aryan HE, Newman CB, Gold JJ, et al. Percutaneous axial lumbar interbody fusion (AxiaLIF) of the L5-S1 segment: initial clinical and radiographic experience. Minim Invasive Neurosurg 2008;51(4):225-30.

Codes	Number	Description
CPT	0195T	Arthrodesis, pre-sacral interbody technique, including instrumentation, imaging (when performed), and discectomy to prepare interspace, lumbar; single interspace
	0196T	Each additional interspace

Policy History

Date	Action	Reason

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