

Protocol

Axial Lumbosacral Interbody Fusion

(701130)

Medical Benefit	Effective Date: 04/01/12	Next Review Date: 01/15
Preauthorization	No	Review Dates: 01/12, 01/13, 01/14

*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is not required but is recommended if despite this Protocol position, you feel this service is medically necessary; supporting documentation must be submitted to Utilization Management.** Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Description

Axial lumbosacral interbody fusion (also called pre-sacral, 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.

Background

The procedure for one 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.

Regulatory Status

The AxiaLIF® and AxiaLIF II 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. (In 2013, TranS1 acquired Baxano and changed the company name to Baxano Surgical.) The U.S. Food and Drug Administration (FDA) 510(k) marketing clearance summaries indicate that the procedures are intended to provide anterior stabilization of the spinal segments as an adjunct to spinal fusion and to assist in the treatment of degeneration of the lumbar disc; to perform lumbar discectomy; or to assist in the performance of interbody fusion. (2, 3) The AxiaLIF® systems are indicated for patients requiring fusion to treat

pseudoarthrosis, unsuccessful previous fusion, spinal stenosis, spondylolisthesis (Grade 1), or degenerative disc disease, 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 devices are not meant to be used in patients with vertebral compression fractures or any other condition in which 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.

Related Protocols

Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)

Facet Arthroplasty

Interspinous Fixation (Fusion) Devices

Policy (Formerly Corporate Medical Guideline)

Axial lumbosacral interbody fusion (axial LIF) is considered **investigational**.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

1. Shen FH, Samartzis D, Khanna AJ et al. Minimally invasive techniques for lumbar interbody fusions. *Orthop Clin North Am* 2007; 38(3):373-86.
2. U.S. Food and Drug Administration Center for Devices and Radiological Health. Premarket Notification [510(K)] Summary. TranS1® AxiaLIF® Fixation System. Available online at: http://www.accessdata.fda.gov/cdrh_docs/pdf7/K073514.pdf. Last accessed October, 2013.
3. U.S. Food and Drug Administration Center for Devices and Radiological Health. Premarket Notification [510(K)] Summary. TranS1® AxiaLIF® II System. Available online at: http://www.accessdata.fda.gov/cdrh_docs/pdf7/K073643.pdf. Last accessed October, 2013.
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5. Zeilstra DJ, Miller LE, Block JE. Axial lumbar interbody fusion: a 6-year single-center experience. *Clin Interv Aging* 2013; 8:1063-9.

6. Gerszten PC, Tobler W, Raley TJ et al. Axial presacral lumbar interbody fusion and percutaneous posterior fixation for stabilization of lumbosacral isthmic spondylolisthesis. *J Spinal Disord Tech* 2012; 25(2):E36-40.
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9. Gundanna MI, Miller LE, Block JE. Complications with axial presacral lumbar interbody fusion: A 5-year postmarketing surveillance experience. *SAS Journal* 2011; 5:90-94.
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12. Resnick DK, Choudhri TF, Dailey AT 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; 2(6):692-9.