

(701130)

Medical Benefit		Effective Date: 04/01/12	Next Review Date: 01/18
Preauthorization	No	Review Dates: 01/12, 01/13, 01/14, 01/15, 01/16, 01/17	

This protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. 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.

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> • With degenerative spine disease at the L4-S1 disc spaces 	Interventions of interest are: <ul style="list-style-type: none"> • Axial lumbar interbody fusion 	Comparators of interest are: <ul style="list-style-type: none"> • Standard lumbar interbody fusion surgery 	Relevant outcomes include: <ul style="list-style-type: none"> • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity

Description

Axial lumbar interbody fusion (LIF; 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.

Summary of Evidence

The evidence for axial LIF in individuals who have degenerative spine disease at the L4-S1 disc spaces includes case series and one retrospective comparative study. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The evidence is insufficient to evaluate whether axial LIF is as effective or as safe as other surgical approaches to LIF, due to the variable natural history of the disorder and the subjective nature of the main outcomes. In addition, there are a relatively large number of adverse event reports in the MAUDE database for axial LIF, which raises the possibility of an increased risk of complications. Controlled trials are needed to better define the benefits and risks of this procedure compared with treatment alternatives. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy

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

Background

The procedure for one-level axial LIF is as follows¹: 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 preserves the annulus and all paraspinal 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 (TranS1) consist of techniques and surgical instruments for creating a presacral 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. Quandry Medical acquired the TranS1 technology in 2014 and re-established distribution of AxiaLIF in 2015.) The instruments were cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process 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, grade one or two spondylolisthesis, 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 three and four), tumor, or trauma. The devices are not meant to be used for 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 the L5-S1 or L4-S1 disc spaces in conjunction with legally marketed facet or pedicle screw systems. FDA product code: KWQ.

Related Protocols

Facet Arthroplasty

Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)

Interspinous Fixation (Fusion) Devices

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.* Jul 2007; 38(3):373-386. PMID 17629985
2. U.S. Food and Drug Administration Center for Devices and Radiological Health. Premarket Notification [510(K)] Summary. TranS1® AxiaLIF® Fixation System. http://www.accessdata.fda.gov/cdrh_docs/pdf7/K073514.pdf. Accessed September 5, 2014.
3. U.S. Food and Drug Administration Center for Devices and Radiological Health. Premarket Notification [510(K)] Summary. TranS1® AxiaLIF® II System. http://www.accessdata.fda.gov/cdrh_docs/pdf7/K073643.pdf. Accessed September 5, 2014.
4. Tobler WD, Gerszten PC, Bradley WD, et al. Minimally invasive axial presacral L5-s1 interbody fusion: two-year clinical and radiographic outcomes. *Spine (Phila Pa 1976).* Sep 15 2011; 36(20):E1296-1301. PMID 21494201
5. Zeilstra DJ, Miller LE, Block JE. Axial lumbar interbody fusion: a 6-year single-center experience. *Clin Interv Aging.* 2013; 8:1063-1069. PMID 23976846
6. Whang PG, Sasso RC, Patel VV, et al. Comparison of axial and anterior interbody fusions of the L5-S1 segment: a retrospective cohort analysis. *J Spinal Disord Tech.* Dec 2014; 26(8):437-443. PMID 24196923
7. 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.* Apr 2012; 25(2):E36-40. PMID 21964453
8. Marchi L, Oliveira L, Coutinho E, et al. Results and complications after 2-level axial lumbar interbody fusion with a minimum 2-year follow-up. *J Neurosurg Spine.* Sep 2012; 17(3):187-192. PMID 22803626
9. Patil SS, Lindley EM, Patel VV, et al. Clinical and radiological outcomes of axial lumbar interbody fusion. *Orthopedics.* Dec 2010; 33(12):883. PMID 21162514
10. Gundanna MI, Miller LE, Block JE. Complications with axial presacral lumbar interbody fusion: A 5-year post-marketing surveillance experience. *SAS J.* 2011; 5(3):90-94. PMID 25802673
11. Lindley EM, McCullough MA, Burger EL, et al. Complications of axial lumbar interbody fusion. *J Neurosurg Spine.* Sep 2011; 15(3):273-279. PMID 21599448
12. North American Spine Society. Diagnosis and treatment of degenerative lumbar spondylolisthesis. 2014; <https://www.spine.org/Documents/ResearchClinicalCare/Guidelines/Spondylolisthesis.pdf>. Accessed April 13, 2016.
13. 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.* Jun 2005; 2(6):692-699. PMID 16028739
14. National Institute for Health and Clinical Excellence (NICE). Transaxial interbody lumbosacral fusion, IPG 387. 2011; <http://www.nice.org.uk/nicemedia/live/13025/53631/53631.pdf>. Accessed September 5, 2014.
15. National Government Services, Inc. Local Coverage Determination (LCD): Category III CPT® Codes (L33392), Revision Effective Date for services performed on or after 10/01/2016.