Protocol

Axial Lumbosacral Interbody Fusion

(701130)

Medical Benefit		**Effective Date**: 04/01/12	**Next Review Date**: 01/20
Preauthorization	No	**Review Dates**: 01/12, 01/13, 01/14, 01/15, 01/16, 01/17, 01/18, 01/19	

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: • With degenerative spine disease at the L4-S1 disc spaces	Interventions of interest are: • Axial lumbosacral interbody fusion	Comparators of interest are: • Standard lumbosacral interbody fusion	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity

DESCRIPTION

Axial lumbosacral 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

For individuals who have degenerative spine disease at the L4-S1 disc spaces who receive axial LIF, the evidence includes a comparative systematic review of case series and a retrospective comparative study. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The systematic review found that fusion rates were higher following transforaminal LIF than following axial LIF, although this difference decreased with use of bone morphogenetic protein or pedicle screws. The findings of this systematic review were limited by the lack of prospective comparative studies and differences in how fusion rates were determined. Studies have suggested that complication rates may be increased with two-level axial LIF. Controlled trials with clinical outcome measures 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 lumbosacral interbody fusion is considered **investigational**.

BACKGROUND

INTERBODY FUSION

Interbody fusion is a surgical procedure that fuses two adjacent vertebral bodies of the spine. Lumbar interbody fusion may be performed in patients with spinal stenosis and instability, spondylolisthesis, scoliosis, following a discectomy, or for adjacent-level disc disease.

Axial Lumbosacral Interbody Fusion

Axial lumbosacral 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.

The procedure for one-level 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. The 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 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 U.S. Food and Drug Administration has cleared for marketing multiple anterior spinal intervertebral body fixation device systems through the 510(k) pathway (See Table 1). The systems are not intended to treat severe scoliosis, severe spondylolisthesis (grades 3 and 4), tumor, or trauma. The devices are also not meant 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 a legally marketed facet or pedicle screw systems. Food and Drug Administration product code: KWQ.

Table 1. Select Anterior Spinal Intervertebral Body Fixation Orthoses Cleared by FDA

Orthotic	Manufacturer	Date Cleared	510(k) No.
TranS1® AxiaLIF™ System • For patients requiring fusion to treat pseudoarthrosis, unsuccessful previous fusion, spinal stenosis, spondylolisthesis (grade 1 or 2), or degenerative disc disease limited to anterior supplemental fixation of L5-S1 in conjunction with legally marketed pedicle screws	TranS1	12/04	K040426
TranS1® AxiaLIF™ System • Indication modified to include facet screws	TranS1	06/05	K050965

Orthotic	Manufacturer	Date Cleared	510(k) No.
TranS1® AxiaLIF® II System • For patients requiring fusion to treat pseudoarthrosis, unsuccessful previous fusion, spinal stenosis, spondylolisthesis (grade 1 or 2), or degenerative disc disease limited to anterior supplemental fixation of L4-S1 in conjunction with legally marketed facet and pedicle screws	TranS1	04/08	K073643
TranS1® AxiaLIF® 2L System • Indication unchanged, marketed with branded bone morphogenetic protein	TranS1	01/10	K092124
TranS1® AxiaLIF® Plus System • Intended to provide anterior stabilization of the L5-SI or L4-Sl spinal segment(s) as an adjunct to spinal fusion • This device's instruments are used for independently distracting the L5-S1 or L4-S1 vertebral bodies and inserting bone graft material (Dt3M, autograft or autologous blood) into the disc space. • Use limited to anterior supplemental fixation of the lumbar spine at L5-SI or L4-S1 in conjunction with use of legally marketed facet screw or pedicle screw systems at the same levels that are treated with AxiaLIF	TranS1	03/11	K102334

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.

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14. National Institute for Health and Care Excellence (NICE). Transaxial interbody lumbosacral fusion [IPG387]. 2011; https://www.nice.org.uk/guidance/ipg387. Accessed March 8, 2018.