

(701130)

Medical Benefit		Effective Date: 04/01/12	Next Review Date: 01/21
Preauthorization	No	Review Dates: 01/12, 01/13, 01/14, 01/15, 01/16, 01/17, 01/18, 01/19, 01/20	

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 lumbosacral interbody fusion 	Comparators of interest are: <ul style="list-style-type: none"> • Standard lumbosacral interbody fusion 	Relevant outcomes include: <ul style="list-style-type: none"> • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity

DESCRIPTION

Axial lumbosacral interbody fusion (LIF; also called presacral, transsacral, or para coccygeal 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 para coccygeal 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.

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 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 three and four), 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
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 <ul style="list-style-type: none"> Intended to provide anterior stabilization of the L5-S1 or L4-S1 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. 	TranS1	03/11	K102334

Orthotic**Manufacturer****Date Cleared****510(k) No.**

- Use limited to anterior supplemental fixation of the lumbar spine at L5-S1 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

Adapted from the Food and Drug Administration (2007, 2008).^{1,2}
 FDA: Food and Drug Administration.

RELATED PROTOCOLS

Facet Arthroplasty

Interspinous and Interlaminar Stabilization/Distrraction Devices (Spacers)

Interspinous Fixation (Fusion) Devices

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services 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. U.S. Food and Drug Administration. Premarket Notification [510(K)] Summary. TranS1 AxiaLIF Fixation System. 2007; https://www.accessdata.fda.gov/cdrh_docs/pdf7/K073514.pdf. Accessed March 8, 2018.
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3. 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.
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5. 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.
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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. 2nd Ed. 2014; <https://www.spine.org/Documents/ResearchClinicalCare/Guidelines/Spondylolisthesis.pdf>. Accessed March 13, 2019.
13. National Institute for Health and Care Excellence (NICE). Transaxial interbody lumbosacral fusion [IPG387]. 2011; <https://www.nice.org.uk/guidance/ipg387>. Accessed March 13, 2019.
14. National Institute for Health and Care Excellence (NICE). Transaxial interbody lumbosacral fusion for severe chronic low back pain [IPG620]. 2018; <https://www.nice.org.uk/guidance/ipg620>. Accessed March 13, 2019.