

## Percutaneous Axial Lumbosacral Interbody Fusion (LIF)

**Effective:** September 1, 2023

**Next Review:** May 2024

**Last Review:** July 2023

### IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

### DESCRIPTION

Percutaneous 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 or L5-S1 disc spaces for interbody fusion, while minimizing damage to muscular, ligamentous, neural, and vascular structures. It is performed under fluoroscopic guidance.

### MEDICAL POLICY CRITERIA

Percutaneous axial lumbosacral interbody fusion is considered **investigational**.

*NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.*

### CROSS REFERENCES

1. [Interspinous Fixation \(Fusion\) Devices](#), Surgery, Policy No. 172
2. [Image-Guided Minimally Invasive Decompression \(IG-MSD\) for Spinal Stenosis](#), Surgery, Policy No. 176
3. [Lumbar Spinal Fusion](#), Surgery, Policy No. 187

### BACKGROUND

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 or L5-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<sup>[1]</sup>: 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 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 Device Systems Cleared by FDA**

Device	Manufacturer	Date Cleared	510(k) No.
TranS1® AxiaLIF™ System <ul style="list-style-type: none"> <li>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</li> </ul>	TranS1	12/2004	K040426
TranS1® AxiaLIF™ System Indication modified to include facet screws	TranS1	06/2005	K050965

Device	Manufacturer	Date Cleared	510(k) No.
TranS1® AxiaLIF® II System <ul style="list-style-type: none"> <li>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</li> </ul>	TranS1	04/2008	K073643
TranS1® AxiaLIF® 2L System <ul style="list-style-type: none"> <li>Indication unchanged, marketed with branded bone morphogenetic protein</li> </ul>	TranS1	01/2010	K092124
TranS1® AxiaLIF® Plus System <ul style="list-style-type: none"> <li>Intended to provide anterior stabilization of the L5-S1 or L4-S1 spinal segment (s) as an adjunct to spinal fusion</li> <li>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.</li> <li>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</li> </ul>	TranS1	03/2011	K102334

Adapted from the Food and Drug Administration (2007, 2008)

**Note:** This policy does not address other minimally invasive techniques for lumbar fusion such as extreme lateral interbody fusion (XLIF).

## EVIDENCE SUMMARY

Assessment of efficacy for therapeutic interventions involves a determination of whether the intervention improves health outcomes. The optimal study design for a therapeutic intervention is a randomized controlled trial (RCT) that includes clinically relevant measures of health outcomes. Intermediate outcome measures, also known as surrogate outcome measures, may also be adequate if there is an established link between the intermediate outcome and true health outcomes. Nonrandomized comparative studies and uncontrolled studies can sometimes provide useful information on health outcomes, but are prone to biases such as noncomparability of treatment groups, the placebo effect, and variable natural history of the condition.

Prospective RCTs that compare outcomes of axial LIF with other approaches to LIF are necessary to determine whether any beneficial treatment effects from LIF provide a significant advantage over conventional spinal fusion techniques. In addition, the rate of adverse events related to complications must be considered in evaluating the net health impact of the various approaches and fusion devices.

## SYSTEMATIC REVIEW AND TECHNOLOGY ASSESSMENTS

Schroeder (2016) reported a systematic review (SR) of L5-S1 disc space fusion rates following axial LIF compared to ALIF or transforaminal lumbar interbody fusion (TLIF).<sup>[2]</sup> Reviewers included 42 peer reviewed articles (total N=1507 patients). There were 11 articles with 466 patients who underwent ALIF, 21 articles with 432 patients who underwent TLIF, and 11 articles with 609 patients who underwent axial LIF. Overall fusion rates were 99.2% for TLIF,

97.2% for ALIF, and 90.5% for axial LIF. Fusion rates for TLIF were significantly higher than those for axial LIF ( $p=0.002$ ). However, when either bone morphogenetic protein (BMP) or bilateral pedicle screws were used with the procedures, the differences in fusion rates between TLIF and axial LIF were no longer statistically significant. The findings of this SR were limited by the lack of comparative studies and differences in how fusion rates were determined.

In 2010, the National Institute for Health and Care Excellence (NICE) performed a technology assessment for transaxial interbody lumbosacral fusion.<sup>[3]</sup> No RCTs were identified. The review only included case series. Due to the methodological limitation of the evidence, NICE recommended further research be conducted to determine the effectiveness and safety of transaxial interbody lumbosacral fusion.<sup>[4]</sup>

## **RANDOMIZED CONTROLLED TRIALS**

No RCTs were identified.

## **NONRANDOMIZED STUDIES**

Published evidence is limited to small case series, preliminary feasibility studies, and retrospective reviews that do not permit conclusions about the long-term effectiveness or durability of LIF.<sup>[5-19]</sup> These studies have significant methodological limitations including but not limited to the lack of randomized comparison with conventional anterior LIF techniques to control for potential bias, placebo effect, or the natural course of the disease being treated. Further, the small study populations limit the ability to rule out the role of chance as an explanation of study outcomes. In addition, current studies had significant heterogeneity in both patient characteristics, particularly in the level of disease progression, and in surgical techniques such as 1-level LIF versus non-FDA approved two-level LIF.

## **ADVERSE EVENTS**

An industry-sponsored five-year voluntary postmarketing surveillance study of 9152 patients was reported by Gundanna in 2011.<sup>[20]</sup> A single-level L5-S1 fusion was performed in 8034 (88%) patients and a two-level (L4-S1) fusion was performed in 1118 (12%) patients. A predefined database was designed to record device- or procedure-related complaints through spontaneous reporting. Several procedures, including the presence of a TransS1 representative during every case, were implemented to encourage complication reporting. Complications recorded included bowel injury, superficial wound and systemic infections, transient intraoperative hypotension, migration, subsidence, presacral hematoma, sacral fracture, vascular injury, nerve injury, and ureter injury (pseudoarthrosis was not included). Follow-up period ranged from three months to five years three months. Complications were reported in 120 (1.3%) patients at a median of 5 days (mean, 33 days; range, 0-511 days). Bowel injury was the most commonly reported complication (0.6%), followed by transient intraoperative hypotension (0.2%). All other complications had an incidence of 0.1% or lower. There were no significant differences in complication rates for single-level (1.3%) and two-level (1.6%) fusion procedures. Although this study included a large number of patients, it depended on spontaneous reporting, which could underestimate the true incidence of complications.

Lindley found high complication rates in a retrospective review of 68 patients who underwent axial LIF between 2005 and 2009.<sup>[21]</sup> Patient diagnoses included degenerative disc disease, spondylolisthesis, spinal stenosis, degenerative lumbar scoliosis, spondylolysis, pseudoarthrosis, and recurrent disc herniation. Ten patients underwent 2-level axial LIF (L4-

S1) and 58 patients underwent a single-level axial LIF (L5-S1). A total of 18 complications in 16 (23.5%) patients were identified at a mean 34-month follow-up (range, 17-61 months). Complications included pseudoarthrosis (8.8%), superficial infection (5.9%), sacral fracture (2.9%), pelvic hematoma (2.9%), failure of wound closure (1.5%), and rectal perforation (2.9%). Both patients with rectal perforation underwent emergency repair and had no long-term sequelae. Patients with nonunion underwent additional fusion surgery with an anterior or posterior approach. The two patients with sacral fractures had preexisting osteoporosis. Because of the potential complications, the authors recommended full bowel preparation and preoperative MRI before an axial LIF procedure to assess the size of the presacral space, to determine rectal adherence to the sacrum, to rule out vascular abnormalities, and to determine a proper trajectory.

Other studies have been published reporting on adverse events for LIF.<sup>[5-9, 13, 22, 23]</sup> In addition, a search of the U.S. Food and Drug Administration's MAUDE database in May 2018 (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm>) identified over 90 adverse event reports for axial LIF, including possible and confirmed bowel injuries.

## PRACTICE GUIDELINE SUMMARY

### NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

The National Institute for Health and Care Excellence (NICE) provided guidance on transaxial interbody fusion in the lumbosacral spine in 2011.<sup>[4]</sup> The guidance stated that current evidence on the efficacy of transaxial interbody lumbosacral fusion is "limited in quantity but shows symptom relief in the short term in some patients. Evidence on safety shows that there is a risk of rectal perforation. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research."

## SUMMARY

There is not enough research to show that percutaneous axial lumbosacral interbody fusion (LIF) improves health outcomes compared to other procedures. No clinical guidelines based on research recommend percutaneous axial LIF. Therefore, percutaneous axial LIF is considered investigational.

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## CODES

Codes	Number	Description
CPT	22586	Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, L5-S1 interspace
	22899	Unlisted procedure, spine
HCPCS	None	

**Date of Origin:** June 2007