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Medical Policy



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Title: Axial Lumbosacral Interbody Fusion

Professional

Original Effective Date: December 11, 2008
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December 29, 2017; June 18, 2018;
January 1, 2019

Current Effective Date: January 15, 2013

Archived Date: August 24, 2018

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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 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.

Objective

The objective of this evidence review is to determine whether interbody fusion of the L4-S1 disc spaces using the axial approach improves health outcomes compared to standard lumbosacral interbody fusion surgery in individuals with degenerative spine disease.

Background

Interbody Fusion

Interbody fusion is a surgical procedure that fuses 2 adjacent vertebral bodies of the spine. Lumbar interbody fusion may be performed in patients with spinal stenosis and instability, spondylolisthesis, scoliosis, following 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 1-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

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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 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 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 <ul style="list-style-type: none"> 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

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Orthotic	Manufacturer	Date Cleared	510(k) No.
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 • 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. • 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	TranS1	03/11	K102334

Adapted from the Food and Drug Administration (2007, 2008).^{2,3}

FDA: Food and Drug Administration.

POLICY

Axial lumbosacral interbody fusion is considered **experimental / investigational**.

RATIONALE

This evidence review has been updated with searches of the MEDLINE database. The most recent literature update was performed through February 5, 2018.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and

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whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

The literature on axial lumbosacral interbody fusion (axial LIF) includes a systematic review of case series and a retrospective comparison of axial LIF with anterior lumbar interbody fusion (ALIF). No prospective randomized controlled trials have been identified comparing outcomes of axial LIF with other approaches to LIF.

Axial Lumbosacral Interbody Fusion

Single-Level Axial LIF

Schroeder et al (2016) reported on a systematic review of L5-S1 disc space fusion rates following axial LIF compared with ALIF or transforaminal lumbar interbody fusion (TLIF).⁴ Reviewers included 42 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 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 systematic review were limited by the lack of comparative studies and differences in how fusion rates were determined across studies.

The largest case series included in the 2016 systematic review was a retrospective analysis by Tobler et al (2011), which evaluated 156 patients from 4 clinical sites in the United States.⁵ Patients were selected if they underwent an L5 through S1 interbody fusion via the axial approach and had both presurgical and 2-year radiographic or clinical follow-up. The number of patients who underwent axial LIF but were excluded from the analysis was not reported. The primary diagnosis was degenerative disc disease (61.5%), spondylolisthesis (21.8%), revision surgery (8.3%), herniated nucleus pulposus (8.3%), spinal stenosis (7.7%), or other (8.3%). Pain scores on a numeric rating scale improved from a mean of 7.7 to 2.7 ($n=155$), while the

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Oswestry Disability Index (ODI) scores improved from a mean of 36.6 preoperatively to 19.0 (n=78) at 2-year follow-up. Clinical success rates, based on an improvement of at least 30%, were 86% (n=127/147) for pain and 74% (n=57/77) for the ODI scores. The overall radiographic fusion rate at 2 years was 94% (145/155). No neural, urologic, or bowel injuries were reported in this study group. Study limitations included its retrospective analysis, lack of controls, and potential for selection bias because it only reported on patients who had 2 years of follow-up.

The second largest series included in the systematic review was that by Zeilstra et al (2013), who retrospectively assessed 131 axial LIF procedures (L5-S1) performed at their institution over a 6-year period.⁶ All patients had had a minimum of 6 months (mean, 5 years) of unsuccessful nonsurgical management and had magnetic resonance imaging, radiography, provocative discography, and anesthetization of the disc. Magnetic resonance imaging of the sacrum and coccyx was performed to identify vascular anomalies, tumor, or surgical scarring that would preclude safe access through the presacral space. Percutaneous facet screw fixation was used in all patients beginning mid-2008. No intraoperative complications were reported. At a mean follow-up of 21 months (minimum, 1 year), back pain had decreased by 51% (change in visual analog scale score, 70 to 39), leg pain decreased by 42% (from 45 to 26), and back function scores (ODI) improved by 50% compared with baseline. With clinical success defined as an improvement of 30% or more, 66% of patients met criteria for reduction in back and leg pain severity. Employment increased from 24% to 64% at follow-up. The fusion rate was 87.8%, with 9.2% indeterminate on radiograph and 3.1% showing pseudoarthrosis. There were 8 (6.1%) reoperations at the index level.

Whang et al (2014) reported on a multicenter, retrospective comparison of axial LIF with ALIF of the L5-S1 disc space in 96 patients who had a minimum of 2 years of follow-up.⁷ Most procedures were performed for degenerative disc disease or spondylolisthesis and used bilateral pedicle screws. Various graft materials were used, including recombinant human bone morphogenetic protein-2 (in 29 axial LIF and 11 ALIF procedures). Fusion rates, assessed at 24 months by 2 independent evaluators and based on radiographs and multiplanar computed tomography images, were similar for the 2 procedures (85% for axial LIF vs 79% for ALIF; $p>0.05$). The incidence of adverse events was also similar, with no cases of rectal perforation. Interpretation of this study is uncertain given its retrospective design, variability in procedures, the absence of validated clinical outcome measures, and lack of randomization.

Gerszten et al (2012) reported on a series of patients who had a minimum 2-year follow-up after axial LIF with percutaneous posterior fixation with pedicle screws for the stabilization of grade 1 or 2 lumbosacral isthmic spondylolisthesis.⁸ There were no perioperative procedure-related complications. The spondylolisthesis grade in the 26 consecutive patients was significantly improved at follow-up, with 50% of patients showing a reduction of at least 1 grade. Axial pain severity was reduced (change in visual analog scale score, 8.1 to 2.8), and 81% of patients had

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excellent or good results based on Odom criteria. At 2 years posttreatment, all patients showed solid fusion.

Two-Level Axial LIF

Marchi et al (2012) reported on prospective 2-year follow-up for 27 patients who underwent 2-level axial LIF at the L4-5 and L5-S1 disc spaces.⁹ Average back pain decreased from a visual analog scale score of 8.08 to 4.04 and ODI scores improved from 51.7 to 31.4. Although no intraoperative complications occurred, the authors reported malpositioned rods in 3 cases due to difficulty attaining an adequate route for the double-level access. In one of these cases, the rod migrated and perforated the bowel. Five (18.5%) patients underwent additional surgery for malpositioned rods, broken posterior screws, rod failure, or collapse of spine levels. Total complications observed at follow-up included screw breakage (14.8%), transsacral rod detachment (11.1%), radiolucency around the transsacral rod (52%), and disc collapse with cephalic rod migration (24%). A gain in disc height was observed 1 week after surgery, but, by the 24-month follow-up, the disc space was less than that of the preoperative state. Only 22% of levels had solid fusion at the 24-month radiologic evaluation, and only 2 patients had solid fusion at both levels.

Adverse Events

An industry-sponsored, 5-year, voluntary postmarketing surveillance study of 9152 patients was reported by Gundanna et al (2011).¹⁰ A single-level (L5-S1) fusion was performed in 8034 (88%) patients, and a 2-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 TranS1 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 ranged from 3 months to 5 years 3 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 2-level (1.6%) fusion procedures. Although this study included a large number of patients, it relied on spontaneous reporting, which could underestimate the true incidence of complications.

Lindley et al (2011) found high complication rates when retrospectively reviewing 68 patients who underwent axial LIF between 2005 and 2009.¹¹ 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).

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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 2 patients with sacral fractures had preexisting osteoporosis. Because of the potential complications, the authors recommended full bowel preparation and preoperative magnetic resonance imaging 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.

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 2-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.

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted. In response to requests, input was received from 2 specialty medical societies and 3 academic medical centers while this policy was under review in 2011. Input considered axial lumbosacral interbody fusion to be investigational.

Practice Guidelines and Position Statements

North American Spine Society

The North American Spine Society published guidelines on the treatment of degenerative spondylolisthesis in 2014.¹² The Society gave a grade B recommendation for surgical decompression with fusion in patients with spinal stenosis and spondylolisthesis. The guidelines discussed posterolateral fusion, 360° fusion, and minimally invasive fusion; it did not address axial lumbosacral interbody fusion.

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American Association of Neurological Surgeons

The American Association of Neurological Surgeons published guidelines for interbody techniques for lumbar fusion in 2005 (part 11).¹³ There was insufficient evidence to recommend a treatment standard. Minimally invasive procedures were not reviewed.

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence provided guidance on transaxial interbody fusion in the lumbosacral spine in 2011.¹⁴ 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." The Institute encouraged "further research into transaxial interbody lumbosacral fusion. Research outcomes should include fusion rates, pain and functional scores, quality of life measures, and the frequency of both early and late complications."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Unpublished			
NCT01716182 ^a	RAMP Study: A Prospective Randomized Study Comparing Two Lumbar Fusion Procedures	200	Jul 2014 (terminated)

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

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CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT/HCPCS

- 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

- There is a CPT category I code for this procedure: 22586.

DIAGNOSIS

Experimental / Investigational for all diagnoses related to this policy.

<u>REVISIONS</u>	
02-08-2010	Policy added to the bcbsks.com web site. No change in policy language.
01-15-2013	In Title section: <ul style="list-style-type: none"> ▪ Revised policy name from "Percutaneous Axial Anterior Lumbar Fusion" to "Axial Lumbosacral Interbody Fusion"
	Description section updated
	In Policy section: <ul style="list-style-type: none"> Revised policy language from: "Percutaneous Axial anterior lumbar fusion is considered experimental / investigational." to "Axial lumbosacral interbody fusion (axial LIF) is considered experimental / investigational."
	In Coding section: <ul style="list-style-type: none"> ▪ Added CPT codes: 22586, 0309T (effective 01-01-2013) ▪ Revised nomenclature for CPT codes: 0195T, 0196T (effective 01-01-2013) ▪ Added updated coding instructions.
	Rationale section updated
	References updated
02-10-2015	Description section updated
	Rationale section updated
	References updated
08-04-2016	Description section updated
	Rationale section updated
	In Coding section: <ul style="list-style-type: none"> ▪ Updated coding notations
	References updated

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REVISIONS	
12-29-2017	Description section updated
	Rationale section updated
	In Coding section: <ul style="list-style-type: none"> ▪ Removed 0309T (Effective 12-31-2017) ▪ Added 64999 (Effective 01-01-2018) ▪ Updated coding notations
	References updated
06-18-2018	Updated Description section
	Rationale section updated
	In Coding Section: <ul style="list-style-type: none"> ▪ Removed CPT Code: 64999 ▪ Added CPT Code: 22899 ▪ Updated Coding notations
	References updated
08-24-2018	Policy Archived
01-01-2019	In Coding section: <ul style="list-style-type: none"> ▪ Removed CPT Codes: 0195T, 0196T (Codes Termed 01-01-2019) ▪ Coding notations updated

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