



Louisiana

Axial Lumbosacral Interbody Fusion

Policy # 00236

Original Effective Date: 04/15/2009

Current Effective Date: 06/20/2018

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers axial lumbosacral interbody fusion (axial LIF) to be **investigational**.*

Background/Overview

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 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 1-level axial LIF is as follows: 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 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.

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FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

The U.S. FDA 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. FDA 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
TranS1 AxiaLIF System <ul style="list-style-type: none"> Indication modified to include facet screws 	TranS1	06/05	K050965
TranS1 AxiaLIF [®] II 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 L4-S1 in conjunction with legally marketed facet and pedicle screws 	TranS1	04/08	K073643
TranS1 AxiaLIF [®] 2L System <ul style="list-style-type: none"> 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. 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).

FDA: Food and Drug Administration.

Centers for Medicare and Medicaid Services (CMS)

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

Rationale/Source

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

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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 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 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). 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. 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 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%

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(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. 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. 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. 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 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. Average back pain decreased from a visual analog scale score of 8.08

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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). 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. 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 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.

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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.

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Policy History

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04/02/2009 Medical Director review

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04/15/2009	Medical Policy Committee approval. New policy.
04/08/2010	Medical Director review
04/21/2010	Medical Policy Committee approval. No change to coverage.
04/07/2011	Medical Policy Committee review
04/13/2011	Medical Policy Implementation Committee approval. No change to coverage.
04/12/2012	Medical Policy Committee review
04/25/2012	Medical Policy Implementation Committee approval. No change to coverage. References added.
04/04/2013	Medical Policy Committee review
04/24/2013	Medical Policy Implementation Committee approval. Title changed. Entire policy redone to track BCBSA new policy.
03/06/2014	Medical Policy Committee review
03/19/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/05/2015	Medical Policy Committee review
03/20/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/02/2016	Medical Policy Committee review
06/20/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
06/01/2017	Medical Policy Committee review
06/21/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/07/2018	Medical Policy Committee review
06/20/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date:	06/2019

Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0195T, 0196T, 22586 Code deleted eff 1/1/2018: 0309T
HCPCS	No codes
ICD-10 Diagnosis	M43.00-M43.19, M48.06-M48.07, M51.06, M51.114-M51.117, M51.34-M51.37, M54.14-M54.17, M96.0, M99.23, M99.33, M99.43, M99.53, M99.63, M99.73, Z98.1

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 - 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 - 3. Reference to federal regulations.

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