Axial Lumbosacral Interbody Fusion

Policy # 00236
Original Effective Date: 04/15/2009
Current Effective Date: 06/21/2017

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 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 (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 foram 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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
The AxiaLIF™ and AxiaLIF™ II Level systems (TranS1) consist of techniques and surgical instruments for creating a presacral access route to perform percutaneous fusion of the L5-S1 or L4-S1 vertebral bodies. (In 2013, TranS1 acquired Baxano and changed its name to Baxano Surgical. Quandary Medical acquired the TranS1 technology in 2014 and re-established distribution of AxiaLIF in 2015.) The instruments were
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cleared for marketing by the U.S. FDA through the 510(k) process to provide anterior stabilization of the spinal segments as an adjunct to spinal fusion and to assist in the treatment of degeneration of the lumbar disc; to perform lumbar discectomy; or to assist in the performance of interbody fusion. The AxiaLIF systems are indicated for patients requiring fusion to treat pseudoarthrosis, unsuccessful previous fusion, spinal stenosis, grade 1 or 2 spondylolisthesis, or degenerative disc disease, defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. 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 legally marketed facet or pedicle screw systems. FDA product code: KWQ.

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
Assessment of efficacy for therapeutic interventions involves a determination of whether an 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. 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.

The literature on axial lumbosacral interbody fusion (axial LIF) includes a systematic review of case series and 1 retrospective comparison of axial LIF versus anterior lumbar interbody fusion (ALIF). No prospective RCTs have been identified that compare outcomes of axial LIF with other approaches to LIF.

AXIAL LUMBOSACRAL INTERBODY FUSION
Single-Level Axial LIF
In 2016, Schroeder et al reported a systematic review of L5-S1 disc space fusion rates following axial LIF compared to ALIF or transfemoral 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 (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 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 is a 2011 retrospective analysis of 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-
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The number of patients who underwent axial LIF but were excluded from 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% (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 by only reporting 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 (MRI), radiography, provocative discography, and anesthetization of the disc. MRI 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 [VAS] 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 improvement of 30% or more, 66% of patients were improved 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 versus ALIF of the L5-S1 disc space in 96 patients with 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, assessed at 24 months by 2 independent evaluators based on radiographs and multiplanar computed tomography images, was 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, absence of validated clinical outcome measures, and lack of randomization.

In 2012, Gerszten et al 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 improved (change in VAS 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 prospective 2-year follow-up on 27 patients who underwent 2-level axial LIF at the L4-5 and L5-S1 disc spaces. Average back pain decreased from a VAS 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 1 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 in 2011. A single-level (L5 through S1) fusion was performed in 8034 (88%) patients and a 2-level (L4 through 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 in a retrospective review of 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 lumbosacral interbody fusion (LIF), the evidence includes a comparative systematic review of case series and 1 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 transfemoral 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 suggest that complication rates may also 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.

References

Policy History
Original Effective Date:  04/15/2009
Current Effective Date:  06/21/2017
04/02/2009  Medical Director review
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.

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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.

Next Scheduled Review Date:  06/2018

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

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*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:
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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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