BlueCross BlueShield of Louisiana

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Axial Lumbosacral Interbody Fusion

Policy # 00236
Original Effective Date: 04/15/2009
Current Effective Date: 03/19/2014

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

Axial lumbosacral interbody fusion (also called pre-sacral, trans-sacral 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 one 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. 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 allows preservation of 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 were developed by TranS1®‡ and consist of techniques and surgical instruments for creating a pre-sacral access route to perform percutaneous fusion of the L5-S1 or L4–S1 vertebral bodies. The U. S. FDA 510(k) marketing clearance summaries indicate that the procedures are intended 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, spondylolisthesis (Grade 1), or

degenerative disc disease, defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. They are not intended to treat severe scoliosis, severe spondylolisthesis (Grades 2, 3, and 4), tumor, or trauma. The devices are not meant to be used in patients with 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 L5-S1 or L4-S1 in conjunction with legally marketed facet or pedicle screw systems.

Centers for Medicare and Medicaid Services (CMS)
There is no national coverage decision.

Rationale/Source

The literature on axial LIF consists of case series. No controlled trials have been identified that compare outcomes of axial LIF with other approaches to lumbosacral interbody fusion.

Single-Level Axial Lumbosacral Interbody Fusion

The largest case series published to date is a 2011 retrospective analysis of 156 patients from 4 clinical sites in the U.S. Patients were selected for inclusion if they underwent a L5-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 not included in 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 (NRS) improved from a mean of 7.7 to 2.7 (n = 155), while the Oswestry Disability Index (ODI) 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% for pain (n = 127/147) and 74% for the ODI (n = 57/77). The overall radiographic fusion rate at 2 years was 94% (145 of 155). No vascular, neural, urologic, or bowel injuries were reported in this study group. Limitations of this study include the retrospective analysis, lack of controls, and potential for selection bias by only reporting on the patients who had 2 years of follow-up.

Zeilstra et al. conducted a retrospective review of 131 axial LIF procedures (L5-S1) performed at their institution over a period of 6 years. All patients had undergone a minimum of 6 months (mean, 5 years) of unsuccessful nonsurgical management and had magnetic resonance imaging (MRI), radiographs, 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, and patients followed a bowel preparation protocol the night before surgery. 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% (from a visual analog score [VAS] of 70 to 39), leg pain decreased by 42% (from 45 to 26), and back function scores (ODI) improved by 50% compared to 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 47% 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 reoperations (6.1%) at the index level.

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In 2012, Gerszten et al. reported 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 grade 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 from a VAS score of 8.1 to 2.8, and 81% of patients were considered to have excellent or good results by Odom criteria. At 2 years posttreatment, all patients showed solid fusion.

Additional series with fewer than 100 patients are reviewed by Zeilstra et al. Improvement in back pain in these studies ranges from 49% to 67% and improvement in the ODI ranges from 50% to 56%.

Two-level Axial Lumbosacral Interbody Fusion
Marchi et al. reported prospective 2-year follow-up on 27 patients who underwent 2-level (L4-5 and L5-S1) axial LIF. Average back pain improved from a VAS score of 8.08 to 4.04 and the ODI improved from 51.7 to 31.4. Although no intraoperative complications occurred, the authors reported that the rod was malpositioned in 3 cases due to difficulty in attaining an adequate route for the double-level access, and in one of these cases, the rod eventually migrated and perforated the bowel. Five patients (18.5%) underwent additional surgery for malpositioned rods, broken posterior screws, failure of the rods, and 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 reduced compared to 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.

Axial Lumbosacral Interbody Fusion Combined with Another Procedure
In 2010, Patil et al. reported a retrospective review of 50 patients treated with axial LIF. Four patients (8%) underwent 2-level axial LIF, and 16 patients (32%) underwent a combination of axial LIF with another procedure for an additional level of fusion. There were 3 reoperations due to pseudoarthrosis (n = 2) and rectal injury (n = 1). Other complications included superficial infection (n = 5), hematoma (n = 2), and irritation of a nerve root by a screw (n = 1). At 12- to 24-month follow-up, VAS scores had decreased from 8.1 to 3.6 (n = 48). At an average 12-month follow-up, 47 of 49 patients (96%) with postoperative radiographs achieved solid fusion. There were no significant differences between pre- and postoperative disc space height and lumbar lordosis angle.

Adverse Events
An industry-sponsored 5-year voluntary postmarketing surveillance study of 9,152 patients was reported by Gundanna et al. in 2011. A single-level L5-S1 fusion was performed in 8,034 patients (88%), and a 2-level (L4-S1) fusion was performed in 1118 patients (12%). 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. The complications that were 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). The follow-up

period ranged from 3 months to 5 years 3 months. Complications were reported in 120 patients (1.3%) 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 includes a large number of patients, it is limited by the dependence on spontaneous reporting, which may underestimate the true incidence of complications.

Lindley et al. 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 patients (23.5%) were identified with a mean 34 months' 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 of the patients with rectal perforation underwent emergency repair and were reported to have no long-term sequelae. The patients with nonunion underwent additional fusion surgery with an anterior or posterior approach. The 2 patients with sacral fractures had preexisting osteoporosis; one was treated with long iliac screws. Because of the potential for these complications, the authors recommend full bowel preparation and preoperative MRI prior to an axial LIF procedure to assess the size of the presacral space, determine rectal adherence to the sacrum, rule out vascular abnormalities, and determine a proper trajectory.

A search of the FDA's MAUDE database (available online at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm identified 131 adverse event reports for axial LIF, including possible and confirmed bowel injuries.

Clinical Input Received Through Specialty Medical 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. The input considered axial LIF to be investigational.

Summary
The available published evidence on axial LIF consists of case series. This evidence is insufficient to evaluate whether axial LIF is as effective or as safe as other surgical approaches to lumbosacral interbody fusion, due to the variable natural history of the disorder and the subjective nature of the main outcomes. In addition, there are a relatively large number of adverse event reports in the MAUDE database for axial LIF, which raises the possibility of an increased risk of complications. Controlled trials are needed to better define the benefits and risks of this procedure compared to alternative treatment options. Due to limited

evidence and concerns about the safety and efficacy of the axial approach, axial LIF is considered investigational.

References

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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, 0309T, 22586
HCPCS	No codes
ICD-9 Diagnosis	722.51 thru 722.52, 722.73, 724.02, 724.03, 724.4, 738.4, V45.4
ICD-9 Procedure	81.08

Policy History

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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.
Next Scheduled Review Date: 03/2015

*****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. Food and Drug Administration (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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