Axial Lumbar Interbody Fusion

Policy # 00236
Original Effective Date: 04/15/2009
Current Effective Date: 11/05/2023

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.

Note: Interspinous and Interlaminar Stabilization Distraction Devices (Spacers) is addressed separately in medical policy 00221.

Note: Interspinous Fixation (Fusion) Devices is addressed separately in medical policy 00679.

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 or presacral lumbar interbody fusion to be **investigational.***

Background/Overview

Axial LIF is a percutaneous technique utilizing a paracoccygeal approach and trans-sacral instrumentation to stabilize the L4 to S1 or L5 to S1 spinal segment(s) that has been proposed as a method of achieving fusion with reduced complications when compared to open spinal fusion surgery. The AxiaLIF®‡ and subsequent variations such as the AxiaLIF®‡ II or 2-Level Systems (TranS1®, Wilmington, NC)‡ were cleared for marketing through the U.S. Food and Drug Administration (FDA) 510(k) process. In the original 510(k) clearance document, AxiaLIF was determined to be substantially equivalent to a previously cleared spinal fixation system and no clinical data on the AxiaLIF were reported (FDA, 2004).

The AxiaLIF and AxiaLIF II Level Systems 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 procedure utilizes fluoroscopic guidance for a blunt guide introducer that is passed through a 15-20 millimeter (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 passed along the guide pin to open a working channel for the passage of instruments. After debulking the nucleus pulposis, bone graft material is injected to fill the disc space. A threaded rod designed to restore disc and neural foramen height is then secured in place. This procedure can be performed at two levels.

FDA documents state that the procedures are intended to provide anterior stabilization of the spinal segments as an adjunct to spinal fusion and for assisting in the treatment of degeneration of the lumbar disc, performing lumbar discectomy, or for assistance in the performance of interbody fusion. The AxiaLIF Systems are indicated for use in individuals requiring fusion to treat pseudoarthrosis, unsuccessful previous fusion, spinal stenosis, spondylolisthesis (Grade 1), or degenerative disc disease as defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The technique is not intended to treat severe scoliosis, severe spondylolisthesis (Grades 2, 3 and 4), tumor, or trauma. In addition, the AxiaLIF is not intended for use in individuals with vertebral compression fractures or other conditions where the mechanical integrity of the vertebral body is compromised. Use of axial lumbar interbody fusion is limited to anterior supplemental fixation of the lumbar spine at L4-S1 or L5-S1 in conjunction with legally marketed facet or pedicle screw systems.

Complications after an axial LIF procedure may include perforation of the bowel and injury to blood vessels and/or nerves as well as infection (Shen, 2007). Since the procedure uses fluoroscopic guidance, the length of a procedure can expose the individual to high doses of radiation.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The published studies evaluating axial lumbar interbody fusion (axial LIF) are limited to technical reports (Gerszten, 2012; Lindley, 2011; Marchi, 2012), case series (Balsano, 2020; Melgar, 2011; Michael, 2019; Patil, 2010; Tobler, 2013; Tobler; 2011; Whang; 2013; Zeilstra, 2013), or systematic reviews of the available studies (Schroeder, 2015; Schroeder, 2016). Case series lack control or

comparison groups and many of them were retrospective and/or had relatively short-term follow-up. No published randomized controlled trials (RCTs) or other prospective controlled studies evaluating the efficacy and safety of axial LIF were identified.

One of the larger case series was published by Tobler and colleagues in 2011. The authors reported 24-month follow-up results from a retrospective series of 156 individuals who underwent axial LIF procedures at L5-S1 using the AxiaLIF®‡ system. Participants with a primary diagnosis of 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%) had preoperative and postoperative radiographic imaging. Back pain was evaluated on an 11-point scale, and functional impairment with the Oswestry Disability Index (ODI) preoperatively and at 24 months. Mean pain scores improved from 7.7 ± 1.6 (n=155) preoperatively to 2.7 ± 2.4 (n=148) at 24 months, reflecting an approximate 63% overall improvement ($p<0.001$). Mean ODI scores improved from 36.6 ± 14.6% (n=86) preoperatively to 19.0 ± 19.2% (n=78) at 24 months, or approximately 54% ($p<0.001$). The 2-year clinical success rates on the basis of change relative to baseline of at least 30% were 86% (n=127 of 147) and 74% (n=57 of 77) for pain and function, respectively. The overall radiographic fusion rate at 2 years was 94% (n=145 of 155).

Whang and colleagues (2013) retrospectively compared the radiographic fusion rates and adverse events for 96 individuals who underwent L5-S1 interbody fusions through either a standard anterior retroperitoneal approach or use of the AxiaLIF system in conjunction with supplemental posterior fixation. Multiplanar computed tomography images were evaluated by two independent observers to assess fusion success at 24 months using a 4-point grading scale. According to the radiographic analysis, the arthrodesis rates recorded for the anterior lumbar interbody fusion (ALIF) and AxiaLIF cohorts were 79% and 85%, respectively ($p>0.05$). The numbers and types of adverse events recorded for these procedures appeared to be similar with one serious intraoperative complication (iliac artery laceration) noted in the ALIF group. In addition, a wide variety of adjunctive graft materials were used which may have affected the results of the radiographic assessment (that is, more individuals in the AxiaLIF group were treated with recombinant growth factors than those in the ALIF group (29 vs. 11, respectively), accounting for the higher fusion rate in the AxiaLIF group). Michael and colleagues (2019) retrospectively reviewed medical records of 149 individuals who had undergone two-level axial LIF and had at least 2 years of follow-up. The mean duration of follow-up was 6 years. A total of 20 individuals (13.4%) developed adjacent-segment disease (ASD) during follow-up. Kaplan-Meier estimates of disease-free ASD survival rate were 95.3% (95% confidence

interval [CI], 90.4% to 97.7%) at 2 years and 89.1% (95% CI, 82.8% to 93.2%) at 5 years after two-level fusion.

In 2020, Balsano and colleagues published retrospective data on 52 individuals who were treated with AxilaLIF. Diagnoses included L5 isthmic spondylolisthesis low-grade dysplasia, primary degenerative disc disease and disc disease secondary to previous discectomy. Data on pain assessed by a visual analogue scale (VAS) were reported for 43 individuals who had 2 years of follow-up. The mean VAS score at baseline was 7.8 and this decreased significantly to 2.3 at 12 months and 1.7 at 24 months. Similarly, scores on the Oswestry Disability Index (ODI), which was 0.502 at baseline, improved significantly to a mean of 0.168 at 12 months and 0.138 at 24 months. As is true for other case series, this study lacks a comparison group.

Results of an industry-sponsored post-marketing study reporting on complications with AxiaLIF were reported by Gundanna and colleagues (2011). The study reported on a database of 9152 individuals who underwent interbody fusion with the AxiaLIF device. A total of 120 complications (1.3%) were reported, 54% of which occurred within 5 days of surgery. The most commonly reported complication was bowel injury (n=59, 0.6%), followed by transient intraoperative hypotension (n=20, 0.2%). All other complications had an incidence of 0.1% or lower.

Schroeder and colleagues published two systematic reviews. Their 2015 systematic review identified 15 publications on axial interbody arthrodesis of the L5-S1 spine using the AxiaLIF device, 13 case series and 2 retrospective cohort studies. Based primarily on the case series, the authors reported a high overall fusion rate (93.15%) and a complication rate of 12.9% associated with axial interbody arthrodesis. However, due to the limited prospective data, the actual fusion rates may be lower and complications rate may be higher than reported in the studies.

In 2016, Schroeder and colleagues published a systematic review comparing fusion rates after ALIF, transforaminal lumbar interbody fusion (TLIF), and axial LIF at the lumbosacral junction in adults undergoing surgery for one- and two-level degenerative spine conditions. A total of 42 articles and 1507 subjects were included in the review. A difference in overall fusion rates was identified, with a rate of 99.2% (range, 96.4%-99.8%) for TLIF, 97.2% (range, 91.0%-99.2%) for ALIF, and 90.5% (range, 79.0%-97.0%) for axial interbody fusion (p=0.005). In a paired analysis directly comparing fusion techniques, only the difference between a TLIF and an axial interbody fusion was statistically significant. No statistically significant difference between the three techniques was identified when

bilateral pedicle screws supported the interbody fusion (p>0.05). A limitation of this review includes a paucity of RCTs directly comparing the techniques. Additionally, of the reviewed studies, only 12 were found to have a low risk of bias. There was significant heterogeneity in how a solid fusion was determined (that is, use of computed tomography versus radiographs). Confounding variables not accounted for in this review included adequacy of the endplate preparation and medical comorbidities of evaluated subjects.

In 2014, the American Association of Neurological Surgeons (AANS) (Mummaneni, 2014) published guidelines on fusion procedures for degenerative disease of the lumbar spine, stating, "There is no conclusive evidence demonstrating improved clinical or radiographic outcome based on the different interbody fusion techniques."

In summary, to date, there are no RCTs evaluating axial LIF as a minimally invasive or percutaneous surgical procedure for the treatment of L5-S1 conditions. There is insufficient credible scientific evidence demonstrating that axial LIF procedures materially improve health outcomes such as pain and function. Moreover, due to the variable natural history of the disorder and subjective nature of outcomes such as pain, the available uncontrolled studies do not allow conclusions about whether axial LIF is as beneficial as other surgical approaches to lumbosacral interbody fusion.

Supplemental Information/Definitions

Anterior: The front surface of the body.

Axial skeleton (as related to the human body): Is comprised of the vertebral column, the spine and much of the skull.

Fluoroscopy: Imaging technique to obtain real-time moving images of the internal structures of the body; this imaging uses an x-ray source and fluorescent screen; modern fluoroscopes couple the screen to an x-ray image intensifier and video camera allowing the images to be recorded and shown on a monitor.

Presacral: Anterior to the sacrum.

Spondylolisthesis: A forward dislocation of one vertebra over the one beneath it producing pressure on spinal nerves.

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Peer Reviewed Publications:

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16. Zeilstra DJ, Miller LE, Block JE. Axial lumbar interbody fusion: a 6-year single-center experience. Clin Interv Aging. 2013; 8:1063-1069.

Government Agency, Medical Society, and Other Authoritative Publications:

1. Mummaneni PV, Dhall SS, Eck JC, et al. Guideline update for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 11: Interbody techniques for lumbar fusion. J Neurosurg Spine. 2014; 21(1):67-74.
2. U.S. Food and Drug Administration (FDA). 510(k) Premarket Notification Database. TranS1® AxiaLIF® Fixation System. Summary of Safety and Effectiveness. No. K040426. December 17, 2004. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf4/K040426.pdf.

Policy History

Original Effective Date: 04/15/2009
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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.
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

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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.
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.
06/06/2019	Medical Policy Committee review
06/19/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/06/2020	Medical Policy Committee review
08/12/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/05/2021	Medical Policy Committee review
08/11/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/04/2022	Medical Policy Committee review
08/10/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2023	Medical Policy Committee review

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08/09/2023 Medical Policy Implementation Committee approval. Policy extensively rewritten. Title changed to Axial Lumbar Interbody Fusion.
Next Scheduled Review Date: 08/2024

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	22586, 22899
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

*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 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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NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.