Anthem

Medical Policy

Subject: Axial Lumbar Interbody Fusion
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Description/Scope

This document addresses axial or presacral lumbar interbody fusion, a minimally invasive technique in which anterior access to the L4-S1 disc spaces is used for interbody fusion to minimize damage to muscular, ligamentous, neural, and vascular structures. It is performed under fluoroscopic guidance using specialized instrumentation.

Position Statement

Investigational and Not Medically Necessary:

Axial or presacral lumbar interbody fusion is considered **investigational and not medically necessary.**

Rationale

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.

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.

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.

Coding

The following codes for treatments and procedures applicable to this document 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 policy. 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.

When services are Investigational and Not Medically Necessary:

CPT

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 [when specified as pre-sacral interbody arthrodesis lumbar. L4-L5 interspace with instrumentation, or pre-sacral interbody arthrodesis L4-L5 or L5-S1 interspace without instrumentation]

ICD-10 Procedure

0SG03A0	Fusion of lumbar vertebral joint with interbody fusion device, anterior approach, anterior column, percutaneous approach
0SG13A0	Fusion of 2 or more lumbar vertebral joints with interbody fusion device, anterior approach, anterior column, percutaneous approach
0SG33A0	Fusion of lumbosacral joint with interbody fusion device, anterior approach, anterior column, percutaneous approach

ICD-10 Diagnosis

All diagnoses

References

Peer Reviewed Publications:

1. Balsano M, Spina M, Segalla S, Michele DB, Doria C. Efficacy and safety of minimally invasive axial presacral L5-S1 interbody fusion in the treatment of lumbosacral spine pathology: a retrospective clinical and radiographic analysis. Acta Biomed. 2020; 91(14-S):e2020035.
2. Gerszten PC, Tobler W, Raley TJ, et al. Axial presacral lumbar interbody fusion and percutaneous posterior fixation for stabilization of lumbosacral isthmic spondylolisthesis. J Spinal Disord Tech. 2012; 25(2):E36-E40.
3. Gundanna MI, Miller LE, Block JE. Complications with axial presacral lumbar interbody fusion: a 5-year postmarket surveillance experience. SAS J. 2011; 5(3):90-94.
4. Lindley EM, McCullough MA, Burger EL, et al. Complications of axial lumbar interbody fusion. J Neurosurg Spine. 2011; 15(3):273-279.
5. Marchi L, Oliveira L, Coutinho E, Pimenta L. Results and complications after 2-level axial lumbar interbody fusion with a minimum 2-year follow-up. J Neurosurg Spine. 2012; 17(3):187-192.
6. Marotta N, Cosar M, Pimenta L, Khoo LT. A novel minimally invasive presacral approach and instrumentation technique for anterior L5-S1 intervertebral discectomy and fusion: technical description and case presentations. Neurosurg Focus. 2006; 20(1):E9.
7. Melgar MA, Tobler WD, Ernst RJ, et al. Segmental and global lordosis changes with two-level axial lumbar interbody fusion and posterior instrumentation. Int J Spine Surg. 2014; 8:10.
8. Michael AP, Weber MW, Delfino KR, et al. Adjacent-segment disease following two-level axial lumbar interbody fusion. J Neurosurg Spine. 2019 Apr 19:1-8. [Epub ahead of print]
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10. Schroeder GD, Kepler CK, Millhouse PW, et al. L5/S1 fusion rates in degenerative spine surgery: a systematic review comparing ALIF, TLIF, and axial interbody arthrodesis. Clin Spine Surg. 2016; 29(4):150-155.
11. Schroeder GD, Kepler CK, Vaccaro AR. Axial interbody arthrodesis of the L5-S1 segment: a systematic review of the literature. J Neurosurg Spine. 2015; 23(3):314-319.
12. Shen FH, Samartzis D, Khanna AJ, et al. Minimally invasive techniques for lumbar interbody fusion. Orthop Clin N Am. 2007; 38(373-386).
13. Tobler WD, Gerszten PC, Bradley WD, et al. Minimally invasive axial presacral L5-S1 interbody fusion: two-year clinical and radiographic outcomes. Spine (Phila Pa 1976). 2011; 36(20):E1296-E1301.
14. Tobler WD, Melgar MA, Raley TJ, et al. Clinical and radiographic outcomes with L4-S1 axial lumbar interbody fusion (AxiaLIF) and posterior instrumentation: a multicenter study. Med Devices (Auckl). 2013; 6:155-61.
15. Whang PG, Sasso RC, Patel VV, et al. Comparison of axial and anterior interbody fusions of the L5-S1 segment: a retrospective cohort analysis. J Spinal Disord Tech. 2013; 26(8):437-443.
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. Accessed on February 17, 2023.

Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	05/11/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. References section updated.
Reviewed	05/12/2022	MPTAC review. References section updated.
Reviewed	05/13/2021	MPTAC review. Rationale, Background/Overview and References sections updated.
Reviewed	05/14/2020	MPTAC review. Rationale, Background/Overview and References sections updated.
Reviewed	11/07/2019	MPTAC review. Rationale and References sections updated.
Reviewed	01/24/2019	MPTAC review. Rationale, References and Index sections updated.
	12/27/2018	Updated Coding section with 01/01/2019 CPT changes; removed 0195T and 0196T deleted 12/31/2018.
Reviewed	03/22/2018	MPTAC review. Updated Description, Rationale, Background, References and Index sections.
	12/27/2017	The document header wording updated from “Current Effective Date” to “Publish Date.” Updated Coding section with 01/01/2018 CPT changes; removed 0309T deleted 12/31/2017, added 22899.
Reviewed	05/04/2017	MPTAC review. Updated Rationale and References sections.
Reviewed	05/05/2016	MPTAC review. Updated Rationale and References sections. Removed ICD-9 codes from Coding section.

Reviewed	05/07/2015	MPTAC review. Updated Rationale and References sections. Format changes throughout document.
Reviewed	05/15/2014	MPTAC review. Updated Rationale, Background, and References sections.
Reviewed	05/09/2013	MPTAC review. Updated Rationale, References, and Index.
	01/01/2013	Updated Coding section with 01/01/2013 CPT changes.
Reviewed	05/10/2012	MPTAC review. Rationale and References updated.
Reviewed	05/19/2011	MPTAC review. Rationale and References updated.
Reviewed	05/13/2010	MPTAC review. References updated.
New	05/21/2009	MPTAC review. Initial document development.

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