Percutaneous Axial Lumbosacral Interbody Fusion (LIF)

Effective: June 1, 2017

Next Review: May 2018
Last Review: May 2017

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Percutaneous 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 or L5-S1 disc spaces for interbody fusion, while minimizing damage to muscular, ligamentous, neural, and vascular structures. It is performed under fluoroscopic guidance.

MEDICAL POLICY CRITERIA

Percutaneous axial lumbosacral interbody fusion is considered investigational.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. Interspinous Fixation (Fusion) Devices, Surgery, Policy No. 172
2. Image-Guided Minimally Invasive Decompression (IG-MSD) for Spinal Stenosis, Surgery, Policy No. 176
3. Lumbar Spinal Fusion, Surgery, Policy No. 187
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 or L5-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 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.

REGULATORY STATUS

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 the company name to Baxano Surgical. Quandry Medical acquired the TranS1 technology in 2014 and re-established distribution of AxiaLIF in 2015) The instruments were cleared for marketing by the U.S. Food and Drug Administration (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. They are not intended to treat severe scoliosis, severe spondylolisthesis (grades 3 and 4), tumor, or trauma. The devices are not meant to be used 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.

Note: This policy does not address other minimally invasive techniques for lumbar fusion such as extreme lateral interbody fusion (XLIF).
Assessment of efficacy for therapeutic interventions involves a determination of whether the 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. Intermediate outcome measures, also known as surrogate outcome measures, may also be adequate if there is an established link between the intermediate outcome and true 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.

Prospective RCTs that compare outcomes of axial LIF with other approaches to LIF are necessary to determine whether any beneficial treatment effects from LIF provide a significant advantage over conventional spinal fusion techniques. In addition, the rate of adverse events related to complications must be considered in evaluating the net health impact of the various approaches and fusion devices.

SYSTEMATIC REVIEW AND TECHNOLOGY ASSESSMENTS

Schroeder (2016) reported a systematic review (SR) of L5-S1 disc space fusion rates following axial LIF compared to ALIF or transforaminal lumbar interbody fusion (TLIF). Reviewers included 42 peer reviewed 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 SR were limited by the lack of comparative studies and differences in how fusion rates were determined.

In 2010, the National Institute for Health and Care Excellence (NICE) performed a technology assessment for transaxial interbody lumbosacral fusion. No RCTs were identified. The review only included case series. Due to the methodological limitation of the evidence, NICE recommended further research be conducted to determine the effectiveness and safety of transaxial interbody lumbosacral fusion.

RANDOMIZED CONTROLLED TRIALS

No RCTs were identified.

NONRANDOMIZED STUDIES

Published evidence is limited to small case series, preliminary feasibility studies, and retrospective reviews that do not permit conclusions about the long-term effectiveness or durability of LIF. These studies have significant methodological limitations including but not limited to the lack of randomized comparison with conventional anterior LIF techniques to control for potential bias, placebo effect, or the natural course of the disease being treated. Further, the small study populations limit the ability to rule out the role of chance as an explanation of study outcomes. In addition, current studies had significant heterogeneity in
both patient characteristics, particularly in the level of disease progression, and in surgical
techniques such as 1-level LIF versus non-FDA approved two-level LIF.

ADVERSE EVENTS

An industry-sponsored five-year voluntary postmarketing surveillance study of 9152 patients
was reported by Gundanna et al in 2011.[20] A single-level L5-S1 fusion was performed in 8034
(88%) patients and a two-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 TransS1
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 period ranged from three months to five years three 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 two-level
(1.6%) fusion procedures. Although this study included a large number of patients, it depended
on spontaneous reporting, which could 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.[21] Patient diagnoses included degenerative disc
disease, spondylolisthesis, spinal stenosis, degenerative lumbar scoliosis, spondyloysis,
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 two patients with sacral fractures had preexisting osteoporosis.
Because of the potential complications, the authors recommended full bowel preparation and
preoperative MRI 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.

Other studies have been published reporting on adverse events for LIF.[5-9,13,22,23] In addition, a
search of the U.S. Food and Drug Administration’s MAUDE database in April 2016
(http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm) identified 134
adverse event reports for axial LIF, including possible and confirmed bowel injuries.

PRACTICE GUIDELINE SUMMARY

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

The National Institute for Health and Care Excellence (NICE) provided guidance on transaxial
interbody fusion in the lumbosacral spine in 2011.[4] The guidance stated that current evidence
on the efficacy of transaxial interbody lumbosacral fusion is “limited in quantity but shows
symptom relief in the short term in some patients. Evidence on safety shows that there is a risk
Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.”

**SUMMARY**

There is not enough research to show that percutaneous axial lumbosacral interbody fusion (LIF) improves health outcomes compared to other procedures. No clinical guidelines based on research recommend percutaneous axial LIF. Therefore, percutaneous axial LIF is considered investigational.

**REFERENCES**

12. Gerszten, PC, Tobler, W, Raley, TJ, Miller, LE, Block, JE, Nasca, RJ. Axial presacral lumbar interbody fusion and percutaneous posterior fixation for stabilization of


**CODES**

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**HCPCS** None

**Date of Origin:** June 2007