Clinical Review Criteria
Axial Lumbar Interbody Fusion System

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Criteria
For Medicare Members

<table>
<thead>
<tr>
<th>Source</th>
<th>Policy</th>
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<tbody>
<tr>
<td>CMS Coverage Manuals</td>
<td>None</td>
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<td>National Coverage Determinations (NCD)</td>
<td>None</td>
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<tr>
<td>Local Coverage Determinations (LCD)</td>
<td>Local Coverage Determination (LCD); Non-Covered Services (L35008)</td>
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<td>Local Coverage Article</td>
<td>None</td>
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For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this procedure is as safe as standard procedures and/or provides better long-term outcomes than current standard procedure.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, KPWA will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Interbody fusion in the lumbar spine is performed to treat painful symptoms caused by instability of the vertebrae, such as spondylolisthesis, spinal stenosis, or degenerative disc disease. Traditional methods of spinal fusion include bone grafts or metal implants; however, insertion of these implants is not without risk. The technique requires excision of the problematic disc often coupled with decompression procedures, followed by instrumentation and bone grafting to provide stabilization and to promote a solid fusion. These procedures have the potential to destabilize the spine, cause significant morbidity and reduce the clinical effectiveness. Numerous open and minimally invasive techniques have been developed all with their advantages and disadvantages. The transaxial anterior lumbar interbody fusion was developed to capitalize on the presacral access route to the L5-S1 intervertebral space preventing the need for the surgeon to cut through paraspinal muscles and remove laminae and facet joints, potentially lessening postoperative patient pain and the likelihood of complications.

The Axial Lumbar Interbody Fusion System (AxiaLIF®) (TranS1®, Inc., Wilmington, NC) is a minimally invasive approach to the L5-S1 disc space. It consists of techniques and surgical instruments for creating a presacral 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 mm incision lateral to the coccyx and advanced along the midline of the anterior surface of the sacrum. It was designed to mitigate soft tissue trauma during lumbar fusion surgery. This approach minimizes the need to cut through soft tissue lessening patient pain and the likelihood of complications. In addition, the procedure allows patients to be discharged from the hospital the day after surgery allowing quicker return to work.

The AxiaLIF system was cleared by the U.S. Food and Drug Administration (FDA) 510(k) process. According to the FDA 510(k) letter to the manufacturer, the system is indicated for patients requiring fusion to treat pseudoarthrosis, unsuccessful previous fusion, spinal stenosis, spondylolisthesis (grade 1 or 2), or degenerative
The AxiaLIF has not previously been reviewed by the Medical Technology and Assessment Committee (MTAC) and is currently being reviewed for decision-making guidance.

Medical Technology Assessment Committee (MTAC)
AxiaLIF
12/16/2013: MTAC REVIEW
Evidence Conclusion: Efficacy The literature search revealed five case series that report on outcomes associated with AxiaLIF. The largest, published in 2011, was a retrospective analysis of 156 patients from 4 clinical sites in the US. Ultimately, the mean pain and ODI scores improved by approximately 63% and 54% respectively (P<0.001) and the overall radiographic fusion rate at 2 years was 94%. The study did not report any adverse events. The patient population was reported to be homogenous, however, the variable nature and progression of the disease compromises the reliability of this claim. Limitations of this study include the retrospective analysis, industry funding as well as selection bias. Outcome measures were not all objective and relied on patient reporting. Only half of the patients were accounted for in the preoperative and postoperative ODI outcome (Tobler, Gerszten et al. 2011). Several smaller case series were also identified and are summarized in a table 1. Ultimately, all of the studies report similar results and conclusions but are subject to the bias of any retrospective series. Further limitations include a lack of control subjects, potential for selection bias as only one of the studies enrolled consecutive patients and unclear study objectives. All studies, with the exception of the publication by Patil and colleagues, received industry funding from TranS1 (Patil, Lindley et al. 2010; Gerszten, Tobler et al. 2012; Marchi, Oliveira et al. 2012). Safety Two publications addressed the safety of AxiaLIF with conflicting results. The first study was a 5-year surveillance study of 9,152 patients (Gundanna, Miller et al. 2011) and the second, a retrospective review of 68 patient records (Lindley, McCullough et al. 2011). Gundanna and colleagues reported minimal complications (1.3%) in their study while Lindley et al. reported high complication rates (23.5%). The observed adverse events across both the studies included pseudoarthrosis, superficial infection, sacral fracture, pelvic hematoma, failure of wound closure, and rectal perforation. Although both studies were designed to be systematic in their investigation, neither study had a control group for comparison and the results are dependent on either spontaneous reporting or the accuracy of medical records. In addition, both of the studies are subject to a variety of bias due to patient selection and industry funding. Conclusion: There is insufficient evidence to determine the efficacy of AxiaLIF compared to standard fusion procedures. There is insufficient evidence to establish whether the AxiaLIF is as safe as standard fusion procedures.


The use of AxiaLIF does not meet the Kaiser Permanente Medical Technology Assessment Criteria.
**Codes**

CPT: 22586, 0195T, 0196T, 0309T