Axial Lumbosacral Interbody Fusion

SUMMARY

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

For individuals who have degenerative spine disease at the L4-S1 disc spaces who receive axial LIF, the evidence includes a comparative systematic review of case series and a retrospective comparative study. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The systematic review found that fusion rates were higher following transforaminal LIF than following axial LIF, although this difference decreased with use of bone morphogenetic protein or pedicle screws. The findings of this systematic review were limited by the lack of prospective comparative studies and differences in how fusion rates were determined. Studies have suggested that complication rates may be increased with 2-level axial LIF. Controlled trials with clinical outcome measures are needed to better define the benefits and risks of this procedure compared with treatment alternatives. The evidence is insufficient to determine the effects of the technology on health outcomes.

OBJECTIVE

The objective of this evidence review is to determine whether interbody fusion of the L4-S1 disc spaces using the axial approach improves the net health outcome compared with standard lumbosacral interbody fusion surgery in individuals who have...
degenerative spine disease.

**POLICY STATEMENT**

Axial lumbosacral interbody fusion is considered **investigational**.

**BENEFIT APPLICATION**

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

**FDA REGULATORY STATUS**

The U.S. Food and Drug Administration has cleared for marketing multiple anterior spinal intervertebral body fixation device systems through the 510(k) pathway (See Table 1). The systems are not intended to treat severe scoliosis, severe spondylolisthesis (grades 3 and 4), tumor, or trauma. The devices are also not meant 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 a legally marketed facet or pedicle screw systems. Food and Drug Administration product code: KWQ.

**Table 1. Select Anterior Spinal Intervertebral Body Fixation Orthoses Cleared by FDA**

<table>
<thead>
<tr>
<th>Orthotic</th>
<th>Manufacturer</th>
<th>Date Cleared</th>
<th>510(k) No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>TranS1 AxiaLIF™ System</td>
<td>TranS1</td>
<td>12/04</td>
<td>K040426</td>
</tr>
<tr>
<td>For patients requiring fusion to treat pseudoarthrosis, unsuccessful previous fusion, spinal stenosis, spondylolisthesis (grade 1 or 2), or degenerative disc disease limited to anterior supplemental fixation of L5-S1 in conjunction with legally marketed pedicle screws</td>
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<td></td>
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</tr>
<tr>
<td>TranS1 AxiaLIF™ System</td>
<td>TranS1</td>
<td>06/05</td>
<td>K050965</td>
</tr>
<tr>
<td>Indication modified to include facet screws</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>TranS1 AxiaLIF II System</td>
<td>TranS1</td>
<td>04/08</td>
<td>K073643</td>
</tr>
<tr>
<td>For patients requiring fusion to treat pseudoarthrosis, unsuccessful previous fusion, spinal stenosis, spondylolisthesis (grade 1 or 2), or degenerative disc disease limited to anterior supplemental fixation of L4-S1 in conjunction with legally marketed facet and pedicle screws</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TranS1 AxiaLIF 2L System</td>
<td>TranS1</td>
<td>01/10</td>
<td>K092124</td>
</tr>
<tr>
<td>Indication unchanged, marketed with branded bone morphogenetic protein</td>
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</table>

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.
TranS1 AxiaLIF Plus System

- Intended to provide anterior stabilization of the L5-S1 or L4-S1 spinal segment(s) as an adjunct to spinal fusion
- This device’s instruments are used for independently distracting the L5-S1 or L4-S1 vertebral bodies and inserting bone graft material (DBM, autograft or autologous blood) into the disc space.
- Use limited to anterior supplemental fixation of the lumbar spine at L5-S1 or L4-S1 in conjunction with use of legally marketed facet screw or pedicle screw systems at the same levels that are treated with AxiaLIF

Adapted from the Food and Drug Administration (2007, 2008).1, 2

FDA: Food and Drug Administration.

### RATIONALE

#### Summary of Evidence

For individuals who have degenerative spine disease at the L4-S1 disc spaces who receive axial LIF, the evidence includes a comparative systematic review of case series and a retrospective comparative study. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The systematic review found that fusion rates were higher following transforaminal LIF than following axial LIF, although this difference decreased with use of bone morphogenetic protein or pedicle screws. The findings of this systematic review were limited by the lack of prospective comparative studies and differences in how fusion rates were determined. Studies have suggested that complication rates may be increased with 2-level axial LIF. Controlled trials with clinical outcome measures are needed to better define the benefits and risks of this procedure compared with treatment alternatives. The evidence is insufficient to determine the effects of the technology on health outcomes.

### SUPPLEMENTAL INFORMATION

#### Practice Guidelines and Position Statements

**North American Spine Society**


**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. 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 of rectal perforation.” The Institute encouraged “further research into transaxial interbody lumbosacral fusion. Research outcomes should include fusion rates, pain and functional scores, quality of life measures, and the frequency of both early and late complications.”

In July 2018, the NICE guidance was updated and replaced by evidence-based recommendations on transaxial interbody lumbosacral fusion for low back pain in adults. The recommendation, based on a literature review conducted in December 2017, states, “Evidence on the safety of transaxial interbody lumbosacral fusion for severe chronic low back pain shows that there are serious but well-recognized complications. Evidence on efficacy is adequate in quality and quantity.

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Therefore, this procedure may be used provided that standard arrangements are in place for clinical governance, consent and audit. This procedure should only be done by a surgeon with specific training in the procedure, who should carry out their initial procedures with an experienced mentor."

**U.S. Preventive Services Task Force Recommendations**

Not applicable.

**Medicare National Coverage**

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

**REFERENCES**


## POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tbody>
<tr>
<td>March 2013</td>
<td>New policy</td>
<td></td>
</tr>
<tr>
<td>March 2014</td>
<td>Replace policy</td>
<td>Policy updated with literature review, reference 5 added, one reference removed; policy statement unchanged.</td>
</tr>
<tr>
<td>June 2018</td>
<td>Replace policy</td>
<td>Policy updated with literature review through February 5, 2018; references 4 and 12 added. Policy statement unchanged except “not medically necessary” corrected to “investigational” for FDA 510k approval.</td>
</tr>
<tr>
<td>June 2019</td>
<td>Replace policy</td>
<td>Policy updated with literature review through February 5, 2019; reference 15 added, reference 13 removed Policy statement unchanged.</td>
</tr>
</tbody>
</table>

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