FEP 7.01.130 Axial Lumbosacral Interbody Fusion

Effective Date: July 15, 2018

Related Policies:
7.01.107 Interspinous Distraction Devices (Spacers)
7.01.120 Facet Arthroplasty
7.01.138 Interspinous Fixation (Fusion) Devices

Axial Lumbosacral Interbody Fusion

Description

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.

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. The Food and Drug Administration product code: KWQ.

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

Orthotic	Manufacturer	Date Cleared	510(k) No.
TranS1® AxiaLIF™ System • 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	TranS1	12/04	K040426
TranS1® AxiaLIF™ System • Indication modified to include facet screws	TranS1	06/05	K050965
TranS1® AxiaLIF® II System • 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	TranS1	04/08	K073643
TranS1® AxiaLIF® 2L System • Indication unchanged, marketed with branded bone morphogenetic protein	TranS1	01/10	K092124
TranS1® AxiaLIF® Plus System • Intended to provide anterior stabilization of the L5-SI or L4-Sl 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 (Dt3M, autograft or autologous blood) into the disc space.	TranS1	03/11	K102334

- Use limited to anterior supplemental fixation of the lumbar spine at L5-SI 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).[2,3]
FDA: Food and Drug Administration.

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).

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

The North American Spine Society published guidelines on the treatment of degenerative spondylolisthesis in 2014.[12] The Society gave a grade B recommendation for surgical decompression with fusion in patients with spinal stenosis and spondylolisthesis. The guidelines discussed posterolateral fusion, 360º fusion, and minimally invasive fusion; it did not address axial lumbosacral interbody fusion.

American Association of Neurological Surgeons

The American Association of Neurological Surgeons published guidelines for interbody techniques for lumbar fusion in 2005 (part 11).[13] There was insufficient evidence to recommend a treatment standard. Minimally invasive procedures were not reviewed.

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence provided guidance on transaxial interbody fusion in the lumbosacral spine in 2011.[14] 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.”

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

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

REFERENCES

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POLICY HISTORY

Date	Action	Description
March 2013	New Policy	
March 2014	Update Policy	Policy updated with literature review, reference 5 added, one reference removed; policy statement unchanged.
June 2018	Update Policy	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.