BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 7.01.130 Axial Lumbosacral Interbody Fusion

Effective Policy Date: July 1, 2023

Original Policy Date: March 2013

Related Policies:

7.01.107 - Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)
7.01.120 - Facet Arthroplasty

Axial Lumbosacral Interbody Fusion

Description

Description

Axial lumbosacral interbody fusion (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.

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**.

POLICY GUIDELINES

None

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 (FDA) 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. FDA product code: KWQ.

Table 1. Select Anterior Spinal Intervertebral Body Fixation Orthoses Cleared by U.S. Food and Drug Administration

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-SI spinal segment (s) as an adjunct to spinal fusion	TranS1	03/11	K102334

• 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. • 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 U.S. 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 lumbosacral interbody fusion, 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 lumbosacral interbody fusion than following axial lumbosacral interbody fusion, 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 lumbosacral interbody fusion. 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 that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information" if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

North American Spine Society

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

National Institute for Health and Care Excellence

In July 2018, the National Institute for Health and Care Excellence (NICE) provided evidence-based recommendations on transaxial interbody lumbosacral fusion for low back pain in adults.[13,] 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. 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

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2. U.S. Food and Drug Administration. Premarket Notification [510(K)] Summary. TranS1 AxiaLIF II System. 2008; https://www.accessdata.fda.gov/cdrh_docs/pdf7/K073643.pdf. Accessed March 10, 2023.
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11. Lindley EM, McCullough MA, Burger EL, et al. Complications of axial lumbar interbody fusion. J Neurosurg Spine. Sep 2011; 15(3): 273-9. PMID 21599448
12. North American Spine Society. Diagnosis and treatment of degenerative lumbar spondylolisthesis. 2nd Ed. 2014; https://www.spine.org/Documents/ResearchClinicalCare/Guidelines/Spondylolisthesis.pdf. Accessed March 9, 2023.
13. National Institute for Health and Care Excellence (NICE). Transaxial interbody lumbosacral fusion for severe chronic low back pain IPG620 2018; https://www.nice.org.uk/guidance/ipg620 Accessed March 9, 2023.

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

Date	Action	Description
March 2013	New policy	
March 2014	Replace policy	Policy updated with literature review, reference 5 added, one reference removed; policy statement unchanged.
June 2018	Replace 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 510(k) approval.
June 2019	Replace policy	Policy updated with literature review through February 5, 2019; reference 15 added, reference 13 removed Policy statement unchanged.
June 2020	Replace policy	Policy updated with literature review through January 31, 2020; no references added. Policy statement unchanged.
June 2021	Replace policy	Policy updated with literature review through January 11, 2021; no references added. Policy statement unchanged.
June 2022	Replace policy	Policy updated with literature review through January 17, 2022; no references added. Policy statement unchanged.
June 2023	Replace policy	Policy updated with literature review through January 16, 2023; no references added. Policy statement unchanged.