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MEDICAL POLICY – 7.01.130

Axial Lumbosacral Interbody Fusion

BCBSA Ref. Policy:	7.01.130
Effective Date:	Jul. 1, 2025
Last Revised:	Jun. 23, 2025
Replaces:	N/A

RELATED MEDICAL POLICIES:

7.01.107	Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)
7.01.138	Interspinous Fixation (Fusion) Devices
7.01.542	Lumbar Fusion
7.01.551	Lumbar Spine Decompression Surgery: Discectomy, Foraminotomy, Laminotomy, Laminectomy

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

Clicking this icon returns you to the hyperlinks menu above.

Introduction

Fusing the bones at the lowest part of the back may be one choice to treat lower back (lumbar) pain. When this kind of fusion is needed, it's usually done by making an opening (an incision) through the back muscles and other tissue. In axial lumbar interbody fusion, the incision is made in the buttock. A tube, long enough to reach the spine, is inserted upwards along a specific path. Special tools are then threaded through the tube to reach the disc that sits between the bones. The surgeon cuts way the damaged disk and removes it through the tube. The tube also guides the path for the bone graft material and a small implant. The bone graft material promotes bone growth, and over time the two bones grow together and are permanently joined. Because more studies are needed to determine the risks and benefits of this procedure compared to other methods of lumbar fusion, this service is considered unproven (investigational).

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

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

Coding

Code	Description
CPT	
22586	Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, L5-S1 interspace.
22899	Unlisted procedure, spine

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

N/A

Evidence Review

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.

Background

Interbody Fusion

Interbody fusion is a surgical procedure that fuses two adjacent vertebral bodies of the spine. Lumbar interbody fusion may be performed in individuals with spinal stenosis and instability, spondylolisthesis, scoliosis, following discectomy, or for adjacent-level disc disease.

Axial Lumbosacral Interbody Fusion

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.

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.

Summary of Evidence

For individuals with degenerative spine disease at the L4-S1 disc spaces who receive axial LIF, the evidence includes 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 also 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 that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

A search of **Clinicaltrials.gov** in March 2025 did not identify any ongoing trials that would influence this review.

Clinical Input from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from two specialty medical societies and three academic medical centers while this policy was under review in 2011. The input considered axial LIF to be investigational.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion in 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 LIF.

National Institute for Health and Clinical 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."

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

The US Food and Drug Administration (FDA) has cleared for marketing multiple anterior spinal intervertebral body fixation device systems through the 510(k) pathway (see **Table 2**). 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 L5-S1 or L4-S1 disc spaces in conjunction with legally marketed facet or pedicle screw systems.

FDA product code: KWQ

Table 2. Select Anterior Spinal Intervertebral Body Fixation Orthoses Cleared by FDA

Orthotic	Description	Manufacturer	Date Cleared	501(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-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 (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	TranS1	03/11	K102334

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

FDA: Food and Drug Administration

References

1. U.S. Food and Drug Administration. Premarket Notification [510(K)] Summary. TranS1 AxiaLIF Fixation System. 2007; **https://www.accessdata.fda.gov/cdrh_docs/pdf7/K073514.pdf**. Accessed May 15, 2025.
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 May 15, 2025.
3. Shen FH, Samartzis D, Khanna AJ, et al. Minimally invasive techniques for lumbar interbody fusions. Orthop Clin North Am. Jul 2007; 38(3): 373-86; abstract vi. PMID 17629985
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6. Tobler WD, Gerszten PC, Bradley WD, et al. Minimally invasive axial presacral L5-S1 interbody fusion: two-year clinical and radiographic outcomes. Spine (Phila Pa 1976). Sep 15 2011; 36(20): E1296-301. PMID 21494201
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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 May 15, 2025.
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 May 15, 2025.

History

Date	Comments
02/27/12	Replace Policy – Policy Section on axial LIF moved from policy 7.01.542 (Minimally Invasive Lumbar Interbody Fusion) and updated with literature search through September 2011.
09/27/12	Update Coding Section – ICD-10 codes are now effective 10/01/2014.
01/29/13	Replace policy. Policy updated with literature review through August 2012; references 7 and 8 added; one reference removed. Policy statement unchanged. CPT coding updated: CPT codes 22586 and 0309T, effective 1/1/13, added; descriptors changed for codes 0195T and 1096T.
07/25/13	Update Related Policies. Change title to 7.01.107.
09/30/13	Update Related Policies. Change title to 7.01.120.
01/21/14	Replace policy. Policy updated with literature review through September 30, 2013. Reference 5 added; others renumbered/removed. Policy statement unchanged. ICD-9 code 81.08 descriptor updated.
01/28/15	Annual Review. Policy updated with literature review through September 24, 2014; references 6, 13 added; policy statement unchanged.
06/01/15	Coding update. ICD-10 PCS codes added; these were inadvertently removed at last publication.
07/01/16	Annual Review, approved June 14, 2016. Reference 12 added. Policy statement unchanged.
07/01/17	Annual Review, approved June 6 2017. Policy moved into new format. Policy updated with literature review through February 23, 2017; reference 4 added. Policy statement unchanged.
07/01/18	Annual Review, approved June 22. Policy updated with literature review through February 2018; no references added. Policy statement unchanged.
01/01/19	Removed CPT code 0309T from policy as it was terminated 1/1/18.
07/01/19	Annual Review, approved June 20, 2019. Policy updated with literature review through February 2019; reference 15 added, reference 13 removed. Policy statement unchanged.
01/01/20	Coding update, removed CPT codes 0195T and 0196T as they were terminated 1/1/19.
07/01/20	Annual Review, approved June 4, 2020. Policy updated with literature review through January 2020; no references added. Policy statement unchanged.
07/01/21	Annual Review, approved June 1, 2021. Policy updated with literature review through January 11, 2021; no references added. Policy statement unchanged.
07/01/22	Annual Review, approved June 13, 2022. Policy updated with literature review through January 17, 2022; no references added. Policy statement unchanged.

Date	Comments
10/01/22	Update to Related Policies. Removed related policy 7.01.120 Facet Arthroplasty due to archival.
07/01/23	Annual Review, approved June 12, 2023. Policy updated with literature review through January 16, 2023; no references added. Policy statement unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
07/01/24	Annual Review, approved June 10, 2024. Policy updated with literature review through March 2, 2024; no references added. Policy statement unchanged.
07/01/25	Annual Review, approved June 23, 2025. Policy updated with literature review through March 28, 2025; no references added. Policy statement unchanged.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.