

Corporate Medical Policy

Axial Lumbosacral Interbody Fusion

File Name:	axial_lumbosacral_interbody_fusion
Origination:	6/2009
Last CAP Review:	11/2011
Next CAP Review:	11/2012
Last Review:	1/2012

Description of Procedure or Service

Axial lumbosacral interbody fusion (also called pre-sacral, trans-sacral 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

The procedure for one level axial lumbosacral interbody fusion (axial LIF) is as follows: Under fluoroscopic monitoring, a blunt guide pin introducer is passed through a 15- to 20-mm incision lateral to the coccyx and advanced along the midline of the anterior surface of the sacrum. A guide pin is introduced and tapped into the sacrum. A series of graduated dilators are advanced over the guide pin, and a dilator sheath attached to the last dilator is left in place to serve as a working channel for the passage of instruments. A cannulated drill is passed over the guide pin into the L5-S1 disc space to rest on the inferior endplate of L5. It is followed by cutters alternating with tissue extractors, and the nucleus pulposus is debulked under fluoroscopic guidance. Next, bone graft material is injected to fill the disc space. The threaded rod is placed over the guide pin and advanced through the sacrum into L5. The implant is designed to distract the vertebral bodies and restore disc and neural foramen height. Additional graft material is injected into the rod, where it enters into the disc space through holes in the axial rod. A rod plug is then inserted to fill the cannulation of the axial rod. Percutaneous placement of pedicle or facet screws may be used to provide supplemental fixation. An advantage of axial LIF is that it allows preservation of the annulus and all paraspinal 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.

Regulatory Status

The AxiaLIF® and AxiaLIF II Level systems were developed by TranS1® and consist of techniques and surgical instruments for creating a pre-sacral access route to perform percutaneous fusion of the L5-S1 or L4-S1 vertebral bodies. The U. S. Food and Drug Administration (FDA) premarket clearance 510k summaries indicate that the procedures are intended to provide anterior stabilization of the spinal segments as an adjunct to spinal fusion and to assist in the treatment of degeneration of the lumbar disc; to perform lumbar discectomy; or to assist in the performance of interbody fusion. The AxiaLIF® systems are indicated for patients requiring fusion to treat pseudoarthrosis, unsuccessful previous fusion, spinal stenosis, spondylolisthesis (Grade 1), or degenerative disc disease, defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. They are not intended to treat severe scoliosis, severe spondylolisthesis (Grades 2, 3, and 4), tumor, or trauma. The devices are not meant to be

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used in patients with 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 in conjunction with legally marketed facet or pedicle screw systems.

Related Policies

Spinal Surgery Using Interspinous Distraction Technology
Total Facet Arthroplasty
Lumbar Spine Fusion Surgery

****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.*

Policy

Axial Lumbosacral Interbody Fusion is considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Axial Lumbosacral Interbody Fusion is covered

Not applicable

When Axial Lumbosacral Interbody Fusion is not covered

Axial lumbosacral interbody fusion (axial LIF) is considered investigational.

Policy Guidelines

The available published evidence on axial LIF consists of case series. This evidence is insufficient to evaluate whether axial LIF is as effective or as safe as other surgical approaches to lumbosacral interbody fusion, due to the variable natural history of the disorder and the subjective nature of the main outcomes. In addition, there are a relatively large number of adverse event reports in the MAUDE database for axial LIF, which raises the possibility of an increased risk of complications. Due to limited evidence and concerns about the safety and efficacy of the axial approach, axial LIF is considered investigational.

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Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 0195T, 0196T

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Percutaneous Axial Anterior Lumbar Fusion

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.115, 3/12/2009

Senior Medical Director - 5/2009

Specialty Matched Consultant Advisory Panel – 11/2010

Policy Renamed: Axial Lumbosacral Interbody Fusion

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.130, 11/10/2011

Specialty Matched Consultant Advisory Panel – 11/2011

Medical Director – 1/2012

Policy Implementation/Update Information

Percutaneous Axial Anterior Lumbar Fusion

6/8/09 New policy adopted from the BCBS Association. Reviewed by Senior Medical Director 5/7/09. "Percutaneous Axial Anterior Lumbar Fusion is considered investigational." Notification given 6/8/09. Policy effective 9/14/09. (btw)

6/22/10 Policy Number(s) removed (amw)

12/21/10 Specialty Matched Consultant Advisory Panel review 11/29/2010. No changes to policy intent. References added. (btw)

Policy Renamed: Axial Lumbosacral Interbody Fusion

2/7/12 Policy name changed from Percutaneous Axial Anterior Lumbar Fusion to Axial Lumbosacral Interbody Fusion. Description section revised. No change to policy intent.

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Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review
11/30/2011. References added. (btw)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.