Medical Coverage Policies

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Percutaneous Axial Anterior Lumbar Fusion

EFFECTIVE DATE	07/07/2009	LAST UPDATED	10/19/2010

Description:

Percutaneous anterior lumbar 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. Performed under fluoroscopic guidance, percutaneous anterior lumbar fusion may also be referred to as axial, trans-sacral, or paracoccygeal interbody fusion.

The AxiaLIF® (Axial Lumbar Interbody Fusion) and AxiaLIF 2 Level systems were developed by TranS 1® 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 United States Food and Drug Administration (FDA) premarket notification (510[k]) 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 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.[3]

Published literature reporting patient outcomes for percutaneous axial anterior lumbar interbody fusion is limited to a technical report with presentation of 2 cases[1] and 1 retrospective case series with patients who received AxiaLIF at L5-S1. In a 2007 review of minimally invasive techniques for lumbar interbody fusion, Shen et al note that experience with the technique is limited and complication rates are unknown. Complications may include perforation of the bowel and injury to blood vessels and/or nerves as well as infection. They also express concern about the increased need for fluoroscopy and the inability of the surgeon to address intracanal pathology or visualize the discectomy procedure directly.[2] In conclusion, there is insufficient evidence to determine if percutaneous axial anterior lumbar interbody fusion is as effective or as safe as other surgical techniques; therefore, the technology is considered not medically necessary.

Note: This policy does not address other minimally invasive techniques for lumbar fusion such as extreme lateral interbody fusion (XLIF).

Medical Criteria:

Not applicable.

Policy:

Percutaneous anterior lumbar fusion is considered **not medically necessary** as there is insufficient peer reviewed medical literature to support the efficacy of this treatment.

Coverage

Benefits may vary between group/contract. Please refer to the Evidence of Coverage, Subscriber Agreement, Benefit Booklet, or RIte Care Contract for applicable **not medically necessary** coverage/benefits.

Coding:

0195T
0196T

Also known as:

Axial, trans-sacral, or paracoccygeal interbody fusion

Related topics:

Not applicable

Published:

Provider Update, Sep 2009
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References:

Aryan HE, Newman CB, Gold JJ et al. *Percutaneous axial lumbar interbody fusion (AxiaLIF) of the L5-S1 segment: initial clinical and radiographic experience.* Minimimally Invasive Neurosurgery;2008;51(4):225-30.

[2]Shen FH, Samartzis D, Dip EB et al. *Minimally invasive techniques for lumbar interbody fusion.*Orthopedic Clinics of North America;2007;38:373-86.

[3]U.S. Food and Drug Administration Center for Devices and Radiological Health. *Premarket Notification [510(K)] Summary. TranS1® AxiaLIF® II System.*Accessed 5/22/09 at: http://www.fda.gov/cdrh/pdf7/K073643.pdf.

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