Axial Lumbosacral Interbody Fusion

**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. (In 2013, TranS1 acquired Baxano and changed the company name to Baxano Surgical. Quandry Medical acquired the TranS1 technology in 2014 and re-established distribution of AxiaLIF in 2015.) The U. S. Food and Drug Administration (FDA) 510 (k) marketing clearance 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 2), or degenerative disc disease, defined as back pain of discogenic
Axial Lumbosacral Interbody Fusion

origin with degeneration of the disc confirmed by history and radiographic studies. They are not intended to treat severe scoliosis, severe spondylolisthesis (Grades 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.

**Related Policies**
- Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)
- Total Facet Arthroplasty
- Lumbar Spine Fusion Surgery
- Interspinous Fixation (Fusion) Devices

***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**

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 1 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 suggest 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 the effects of the technology on health outcomes.

**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
Axial Lumbosacral Interbody Fusion

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, 0309T, 22586

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


Senior Medical Director - 5/2009


Policy Renamed: Axial Lumbosacral Interbody Fusion


Medical Director – 1/2012


Policy Implementation/Update Information

Percutaneous Axial Anterior Lumbar Fusion

Axial Lumbosacral Interbody Fusion

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


**Policy Renamed: Axial Lumbosacral Interbody Fusion**


11/13/12 Specialty Matched Consultant Advisory Panel review 10/17/2012. No change to policy intent. (btw)

12/28/12  Added new CPT codes effective 1/1/2013, 0309T and 22586 to Billing/Coding section. Reference added. (btw)


2/11/14  “In 2013, TranS1 acquired Baxano and changed the company name to Baxano Surgical.” added to the Description section. Reference added. (btw)


2/10/15  Reference added. (sk)


5/31/16  Reference added. (sk)

11/22/16  Specialty Matched Consultant Advisory Panel review 10/26/2016. (sk)

5/26/17  Reference added. Policy Guidelines updated. (sk)

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.