Medical Coverage Policy | Axial Lumbosacral Interbody Fusion

EFFECTIVE DATE: 01|01|2013
POLICY LAST UPDATED: 04|16|2014

OVERVIEW
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. This policy was formerly known as "Lumbar Fusion."

PRIOR AUTHORIZATION
Not applicable.

POLICY STATEMENT
BlueCHiP for Medicare and Commercial
Axial lumbosacral interbody fusion (axial LIF) is considered **not medically necessary** as there is insufficient peer-reviewed literature that demonstrates that the procedure is effective.

MEDICAL CRITERIA
Not applicable.

BACKGROUND
The procedure for 1-level axial lumbosacral interbody fusion (axial LIF) is as follows (1): 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 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.

The AxiaLIF® and AxiaLIF II Level systems were developed by TranS1 and consist of techniques and surgical instruments for creating a presacral 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.) 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.(2,3) The AxiaLIF® systems are indicated for patients requiring fusion to treat pseudoarthrosis, unsuccessful previous fusion, spinal stenosis, Grade 1 or 2 spondylolisthesis,

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 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.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for limitations of benefits/coverage when services are not medically necessary.

CODING

BlueCHiP for Medicare and Commercial

The following codes are considered not medically necessary:

22586, 0195T, 0196T, 0309T

RELATED POLICIES

Not applicable.

PUBLISHED

Provider Update	2014	
Provider Update	Aug	2013
Provider Update	Dec	2012

REFERENCES

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3. U.S. Food and Drug Administration Center for Devices and Radiological Health. Premarket Notification [510(K)] Summary. TranS1® AxiaLIF® II System. Available online at: http://www.accessdata.fda.gov/cdrh_docs/pdf7/K073643.pdf. Last accessed October, 2013.

4. 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) 2011; 36(20):E1296-301.

5. Zeilstra DJ, Miller LE, Block JE. Axial lumbar interbody fusion: a 6-year single-center experience. Clin Interv Aging 2013; 8:1063-9.

6. Gerszten PC, Tobler W, Raley TJ et al. Axial presacral lumbar interbody fusion and percutaneous posterior fixation for stabilization of lumbosacral isthmic spondylolisthesis. J Spinal Disord Tech 2012; 25(2):E36-40.

7. Marchi L, Oliveira L, Coutinho E et al. Results and complications after 2-level axial lumbar interbody fusion with a minimum 2- year follow-up. J Neurosurg Spine 2012; 17(3):187-92.

8. Patil SS, Lindley EM, Patel VV et al. Clinical and radiological outcomes of axial lumbar interbody fusion. Orthopedics 2010; 33 (12):883.

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