Medical Coverage Policy | Axial Lumbosacral Interbody Fusion

EFFECTIVE DATE: 03|03|2015
POLICY LAST UPDATED: 10|02|2018

OVERVIEW
Axial lumbosacral interbody fusion (axial 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.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
BlueCHiP for Medicare
Axial lumbosacral interbody fusion is not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products
Axial lumbosacral interbody fusion is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE
Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for not medically necessary/not covered benefits/coverage.

BACKGROUND
INTERBODY FUSION
Interbody fusion is a surgical procedure that fuses 2 adjacent vertebral bodies of the spine. Lumbar interbody fusion may be performed in patients with spinal stenosis and instability, spondylolisthesis, scoliosis, following a discectomy, or for adjacent-level disc disease.

Axial Lumbosacral Interbody Fusion
The procedure for 1-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 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.

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

For individuals who have degenerative spine disease at the L4-S1 disc spaces who receive axial LIF, the evidence is insufficient to determine the effects of the technology on health outcomes.

CODING

The following codes are not covered for BlueCHiP for Medicare and not medically necessary for Commercial Products.

22586 Arthrodesis, presacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, L5-S1 interspace

0195T Arthrodesis, presacral interbody technique, disc space preparation, discectomy, without instrumentation, with image guidance, includes bone graft when performed; L5-S1 interspace (Code Deleted Effective 12/31/2018)

0196T Arthrodesis, presacral interbody technique, disc space preparation, discectomy, without instrumentation, with image guidance, includes bone graft when performed; L4-L5 interspace (List separately in addition to code for primary procedure) (Code Deleted Effective 12/31/2018)

RELATED POLICIES

BlueCHiP for Medicare National and Local Coverage Determinations
New Technology

PUBLISHED

Provider Update, November/December 2018
Provider Update, January 2018
Provider Update, January 2017
Provider Update, May 2015
Provider Update, December 2014

REFERENCES

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3. 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 March 8, 2018.
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