Medical Coverage Policy | Axial Lumbosacral Interbody Fusion

EFFECTIVE DATE: 03|03|2015
POLICY LAST UPDATED: 11|21|2017

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

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

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

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

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. Quandry Medical acquired the TranS1 technology in 2014 and re-established distribution of AxiaLIF in 2015) The instruments were cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process 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, 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.

The available published evidence on axial LIF is insufficient to evaluate whether the procedure 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. Due to limited evidence and concerns about the safety and efficacy of the axial approach, axial LIF is considered not medically necessary.

CODING

BlueCHiP for Medicare and Commercial Products

The following codes are considered not medically necessary:

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

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)

0309T Arthrodesis, presacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft, when performed, lumbar, L4-L5 interspace (List separately in addition to code for primary procedure) (Code Deleted Effective 12/31/2017)

RELATED POLICIES

Not applicable

PUBLISHED

Provider Update, January 2018
Provider Update, January 2017
Provider Update, May 2015
Provider Update, December 2014
Provider Update, August 2013
Provider Update, December 2012

REFERENCES

1. Shen FH, Samartzis D, Khanna AJ, et al. Minimally invasive techniques for lumbar interbody fusions. Orthop Clin North Am. Jul 2007;38(3):373-386. PMID 17629985
2. U.S. Food and Drug Administration Center for Devices and Radiological Health. Premarket Notification [510(K)] Summary. TranS1® AxiaLIF® Fixation System. http://www.accessdata.fda.gov/cdrh_docs/pdf7/K073514.pdf. Accessed September 5, 2014.
3. U.S. Food and Drug Administration Center for Devices and Radiological Health. Premarket Notification [510(K)] Summary. TranS1® AxiaLIF® II System. http://www.accessdata.fda.gov/cdrh_docs/pdf7/K073643.pdf. Accessed September 5, 2014.

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). Sep 15 2011;36(20):E1296-1301. PMID 21494201
5. Zeilstra DJ, Miller LE, Block JE. Axial lumbar interbody fusion: a 6-year single-center experience. Clin Interv Aging. 2013;8:1063-1069. PMID 23976846
6. Whang PG, Sasso RC, Patel VV, et al. Comparison of axial and anterior interbody fusions of the L5-S1 segment: a retrospective cohort analysis. J Spinal Disord Tech. Dec 2014;26(8):437-443. PMID 24196923
7. 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. Apr 2012;25(2):E36-40. PMID 21964453
8. 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. Sep 2012;17(3):187-192. PMID 22803626
9. Patil SS, Lindley EM, Patel VV, et al. Clinical and radiological outcomes of axial lumbar interbody fusion. Orthopedics. 2010;33(12):883. PMID 21162514
10. Gundanna MI, Miller LE, Block JE. Complications with axial presacral lumbar interbody fusion: A 5-year postmarketing surveillance experience. SAS Journal. 2011;5:90-94. PMID
11. Lindley EM, McCullough MA, Burger EL, et al. Complications of axial lumbar interbody fusion. J Neurosurg Spine. Sep 2011;15(3):273-279. PMID 21599448
12. North American Spine Society. Diagnosis and treatment of degenerative lumbar spondylolisthesis. 2014; https://www.spine.org/Documents/ResearchClinicalCare/Guidelines/Spondylolisthesis.pdf. Accessed April 13, 2016.
13. Resnick DK, Choudhri TF, Dailey AT, et al. Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 11: interbody techniques for lumbar fusion. J Neurosurg Spine. Jun 2005;2(6):692-699. PMID 16028739
14. National Institute for Health and Clinical Excellence (NICE). Transaxial interbody lumbosacral fusion, IPG 387. 2011; http://www.nice.org.uk/nicemedia/live/13025/53631/53631.pdf. Accessed September 5, 2014.