Axial lumbosacral interbody fusion (AxiaLIF), also referred to as anterior para-axial, presacral, trans-sacral or paracoccygeal interbody fusion is a minimally invasive technique that has been investigated for providing 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.
AXIAL LUMBOSACRAL INTERBODY FUSION (cont.)

Criteria:

- Axial lumbosacral interbody fusion (AxiaLIF) is considered experimental or investigational based upon:
  
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

Resources:

Resources prior to 02/06/13 may be requested from the BCBSAZ Medical Policy and Technology Research Department.


FDA 510K Summary for AxiaLIF® System:

- FDA-approved indication: For patients requiring fusion to treat pseudoarthrosis, unsuccessful previous fusion, spinal stenosis, spondylolisthesis (Grade 1 or 2), or degenerative disc disease as defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The TranS1® AxiaLIF™ is not intended to treat severe scoliosis, severe spondylolisthesis (Grades 3 and 4), tumor or trauma. Its usage is limited to anterior supplemental fixation of the lumbar spine at L5-S1 in conjunction with legally marketed facet and pedicle screw systems.
AXIAL LUMBOSACRAL INTERBODY FUSION (cont.)

Resources: (cont.)

FDA 510K Summary for AxiaLIF® II Level System:

- FDA-approved indication: For patients requiring fusion to treat pseudoarthrosis, unsuccessful previous fusion, spinal stenosis, spondylolisthesis (Grade 1), or degenerative disc disease as defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The AxiaLIF® 2-LEVEL System is not intended to treat severe scoliosis, severe spondylolisthesis (Grades 2, 3 and 4), tumor, or trauma. The device is not meant to be used in patients with vertebral compression fractures or any other condition where the mechanical integrity of the vertebral body is compromised. Its usage is limited to anterior supplemental fixation of the lumbar spine at L4-S1 in conjunction with legally marketed facet or pedicle screw systems.

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