



AxiaLIF™ AXIAL LUMBAR INTERBODY FUSION

Effective Date: July 1, 2009

Review Dates: 2/08, 2/09, 4/09, 4/10

Date Of Origin: February 13, 2008

Status: Current

I. DESCRIPTION

The AxiaLIF™ axial lumbar interbody fusion system is manufactured by TranS1® Inc. of Wilmington, NC. The system consists of instruments designed to allow minimally invasive presacral access to the lumbar spine. The AxiaLIF™ System enables surgeons to access the surgical area via small incisions, decreasing the degree of soft-tissue injury and trauma to the patient. The system includes stainless steel and titanium surgical instruments, titanium alloy implantable devices, and a proprietary anterior fixation rod (3D Axial Rod™). AxiaLIF™ is used for decompression, distraction and spinal fusion at the L5-S1 junction in conjunction with facet and pedicle screw systems. It is used to treat a variety of disorders including pseudoarthrosis, spinal stenosis, Grade 1 or 2 spondylolisthesis, unsuccessful previous fusion, or degenerative disc disease.

A very small body of published literature was found related to this technology. No randomized controlled trials were retrieved but a total of 5 abstracts were found including 2 technical notes describing the technology and the associated surgical procedure, 1 biomechanical animal (bovine) study (n=24), 1 clinical study including a combination of human, animal and cadaver subjects with n not specified, and 1 study (n=54) for revision spinal surgery.

The FDA issued 510(k) approval (K050965) for the TranS1® AxiaLIF™ System on June 14, 2005. It is listed as substantially equivalent to another product developed by TranS1, the TranS1 Axial Fixation System (K040426), which was approved on December 17, 2004. According to the FDA approval summary, the AxiaLIF™ system is an anterior spinal fixation device intended for patients requiring spinal fusion to treat pseudoarthrosis, unsuccessful previous fusion, spinal stenosis, spondylolisthesis (Grade 1 or 2), or degenerative disc disease defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device 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.

No randomized controlled trials were found in the peer-reviewed literature supporting safety and efficacy. Improvement in net health outcomes has not been demonstrated when compared to standard surgical methods, and it remains

unclear whether this surgical technique results in clinical benefits that are as good as or superior to standard surgical techniques. The evidence is insufficient to allow any conclusions regarding short- or long-term clinical outcomes.

II. POLICY/CRITERIA

The AxiaLIF™ axial lumbar interbody fusion system is considered experimental and investigational and is not a covered benefit due to lack of evidence of its effectiveness.

III. MEDICAL NECESSITY REVIEW

Required Not Required Not Applicable

IV. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- ❖ **HMO/EPO:** *This policy applies to insured HMO/EPO plans.*
- ❖ **POS:** *This policy applies to insured POS plans.*
- ❖ **PPO:** *This policy applies to insured PPO plans.*
- ❖ **ASO:** *For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.*
- ❖ **INDIVIDUAL:** *For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.*
- ❖ **MEDICARE:** *Coverage is determined by the Centers for Medicare and Medicaid Services (CMS).*
- ❖ **MEDICAID:** *For Medicaid members, this policy will apply.*
- ❖ **MICHILD:** *For MICHILD members, this policy will apply unless MICHILD certificate of coverage limits or extends coverage.*

V. CODING INFORMATION

ICD-9 Codes that may support medical necessity

Not applicable

CPT/HCPCS Codes:

Not Covered

0195T Arthrodesis, pre-sacral interbody technique, including instrumentation, imaging (when performed), and discectomy to prepare interspace, lumbar; single interspace

0196T Arthrodesis, pre-sacral interbody technique, including instrumentation, imaging (when performed), and discectomy to prepare interspace, lumbar; each additional interspace (List separately in addition to code for primary procedure)

VI. REFERENCES:

- AxiaLIF™ (Axial Lumbar Interbody Fusion) System (TranS1® Inc.) for Percutaneous Minimally Invasive Anterior Lumbosacral Surgery, Hayes, Inc. April 2006
- Trans-sacral Lumbar Interbody Fusion, The Regence Group, June 2007. Available on the World Wide Web @ www.regence.com Retrieved February 24, 2010)
- Hayes, Inc. AxiaLIF® (Axial Lumbar Interbody Fusion) System (TranS1® Inc.) for Percutaneous Minimally Invasive Anterior Lumbosacral Surgery Search & Summary, February 2008.
- Lumbar Fusion for Spinal Instability and Degenerative Disc Conditions, Cigna Medical Coverage Policy, 12/15/2008. Available on the World Wide Web @ http://www.cigna.com/customer_care/healthcare_professional/coverage_positions/medical/mm_0303_coveragepositioncriteria_lumbar_fusion_degenerative_conditions.pdf (Retrieved March 25, 2009 & February 24, 2010)
- Axial lumbar interbody fusion (AxiaLIF™), Aetna Clinical Policy Bulletin, 11/2008. Available on the World Wide Web @ http://www.aetna.com/cpb/medical/data/cpb_alpha.html. (Retrieved March 25, 2009 & February 24, 2010).
- Percutaneous axial lumbar interbody fusion (AxiaLIF) of the L5-S1 segment: initial clinical and radiographic experience. Aryan HE, Newman CB, Gold JJ, Acosta FL Jr, Coover C, Ames CP. *Minim Invasive Neurosurg*. 2008 Aug;51(4):225-30.

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