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.

### Related Policies
- Facet Arthroplasty
- Interspinous Distraction Devices
- Lumbar Spinal Fusion

### Policy
Axial lumbosacral interbody fusion (axial LIF) is considered investigational.

### Policy Guidelines
There are specific CPT codes for this procedure:
- **22586**: Arthrodesis, presacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, L5-S1 interspace and a new category III add-on code for the additional interspace:
- **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)

There are category III codes that represent the procedure without instrumentation:
- **0195T**: Arthrodesis, presacral interbody technique, disc space preparation, discectomy, without instrumentation, with image guidance, includes bone graft when performed; L5-S1 interspace
- **0196T**: L4-L5 interspace (List separately in addition to code for primary procedure)
Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Rationale

Background

Axial lumbosacral interbody fusion (LIF; also called presacral, transacral, 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.

The procedure for 1-level 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 foramal 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.

Regulatory Status

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.

FDA product code: KWQ

Literature Review

Assessment of efficacy for therapeutic interventions involves a determination of whether the intervention improves health outcomes. The optimal study design for a therapeutic intervention is a randomized controlled trial (RCT) that includes clinically relevant measures of health outcomes. Intermediate outcome measures, also known as surrogate outcome measures, may also be adequate if there is an established link between the intermediate outcome and true health outcomes. Nonrandomized comparative studies and uncontrolled studies can sometimes provide useful information on health outcomes, but are prone to biases such as noncomparability of treatment groups, the placebo effect, and variable natural history of the condition.

The literature on axial lumbosacral interbody fusion (axial LIF) consists of case series and one retrospective comparison of axial LIF versus anterior lumbar interbody fusion (ALIF). No prospective RCTs have been identified that compare outcomes of axial LIF with other approaches to lumbosacral interbody fusion.

Single-Level Axial LIF

The largest case series published to date is a 2011 retrospective analysis of 156 patients from 4 clinical sites in the U.S.(4) Patients were selected for inclusion if they underwent a L5-S1 interbody fusion via the axial approach and had both presurgical and 2-year radiographic or clinical follow-up. The number of patients who underwent axial LIF but were not included in the analysis was not reported. The primary diagnosis was degenerative disc disease (61.5%), spondylolisthesis (21.8%), revision surgery (8.3%), herniated nucleus pulposus (8.3%), spinal stenosis (7.7%) or other (8.3%). Pain scores on a numeric rating scale (NRS) improved from a mean of 7.7 to 2.7 (n=155), while the Oswestry Disability Index (ODI) improved from a mean of 36.6 preoperatively to 19.0 (n=78) at 2-year follow-up. Clinical success rates, based on an improvement of at least 30% were 86% for pain (n=127/147) and 74% for the ODI (n=57/77). The overall radiographic fusion rate at 2 years was 94% (145 of 155). No vascular, neural, urologic, or bowel injuries were reported in this study group. Limitations of this study include the retrospective analysis, lack of controls, and potential for selection bias by only reporting on the patients who had 2 years of follow-up.

Zeilstra et al. conducted a retrospective review of 131 axial LIF procedures (L5-S1) performed at their institution over a period of 6 years.(5) All patients had undergone a minimum of 6 months (mean, 5 years) of unsuccessful nonsurgical management and had magnetic resonance imaging (MRI), radiographs, provocative discography and anesthetization of the disc. MRI of the sacrum and coccyx was performed to identify vascular anomalies, tumor, or surgical scarring that would preclude safe access through
the presacral space, and patients followed a bowel preparation protocol the night before surgery. Percutaneous facet screw fixation was used in all patients beginning mid-2008. No intraoperative complications were reported. At a mean follow-up of 21 months (minimum 1 year), back pain had decreased by 51% (from a visual analog score [VAS] of 70 to 39), leg pain decreased by 42% (from 45 to 26), and back function scores (ODI) improved by 50% compared to baseline. With clinical success defined as improvement of 30% or more, 66% of patients were improved in back and leg pain severity. Employment increased from 47% to 64% at follow-up. The fusion rate was 87.8%, with 9.2% indeterminate on radiograph and 3.1% showing pseudoarthrosis. There were 8 reoperations (6.1%) at the index level.

Whang et al reported a multicenter retrospective comparison of axial LIF versus ALIF of L5-S1 in 96 patients with a minimum of 2 years of follow-up. Most of the procedures were performed for degenerative disc disease or spondylolisthesis and included the use of bilateral pedicle screws. A variety of graft materials was used, including the use of recombinant human bone morphogenetic protein-2 (in 29 axial LIF and 11 ALIF procedures). Fusion, assessed at 24 months by 2 independent evaluators based on radiographs and multiplanar CT images, was similar for the 2 procedures (85% for axial LIF, 79% for ALIF, p >0.05). The incidence of adverse events was also similar, with no cases of rectal perforation. Interpretation of this study is limited by the retrospective nature of the study, variability in procedures, absence of validated clinical outcome measures, and lack of randomization. Although the authors comment that a prospective trial is expected to begin enrollment soon, a search of online site www.clinicaltrials.gov in October 2014 shows a large clinical trial terminated due to slow enrollment (see Ongoing and Unpublished Clinical Trials section).

In 2012, Gerszten et al. reported a series of patients who had a minimum 2-year follow-up after axial LIF with percutaneous posterior fixation with pedicle screws for the stabilization of grade 1 or grade 2 lumbosacral isthmic spondylolisthesis. There were no perioperative procedure-related complications. The spondylolisthesis grade in the 26 consecutive patients was significantly improved at follow-up, with 50% of patients showing a reduction of at least 1 grade. Axial pain severity improved from a VAS score of 8.1 to 2.8, and 81% of patients were considered to have excellent or good results by Odom criteria. At 2 years posttreatment, all patients showed solid fusion.

Additional series with fewer than 100 patients are reviewed by Zeilstra et al. Improvement in back pain in these studies ranges from 49% to 67% and improvement in the ODI ranges from 50% to 56%.

**Two-level Axial LIF**

Marchi et al. reported prospective 2-year follow-up on 27 patients who underwent 2-level (L4-5 and L5-S1) axial LIF. Average back pain improved from a VAS score of 8.08 to 4.04 and the ODI improved from 51.7 to 31.4. Although no intraoperative complications occurred, the authors reported that the rod was malpositioned in 3 cases due to difficulty in attaining an adequate route for the double-level access, and in one of these cases, the rod eventually migrated and perforated the bowel. Five patients (18.5%) underwent additional surgery for malpositioned rods, broken posterior screws, failure of the rods, and collapse of spine levels. Total complications observed at follow-up included screw breakage (14.8%), transsacral rod detachment (11.1%), radiolucency around the transsacral rod (52%), and disc collapse with cephalic rod migration (24%). A gain in disc height was observed 1 week after surgery, but by the 24-month follow-up, the disc space was reduced compared to the preoperative state. Only 22% of levels had solid fusion at the 24-month radiologic evaluation, and only 2 patients had solid fusion at both levels.
Axial LIF Combined with Another Procedure

In 2010, Patil et al. reported a retrospective review of 50 patients treated with axial LIF. (9) Four patients (8%) underwent 2-level axial LIF, and 16 patients (32%) underwent a combination of axial LIF with another procedure for an additional level of fusion. There were 3 reoperations due to pseudoarthrosis (n=2) and rectal injury (n=1). Other complications included superficial infection (n=5), hematoma (n=2), and irritation of a nerve root by a screw (n=1). At 12- to 24-month follow-up, visual analog scale (VAS) scores had decreased from 8.1 to 3.6 (n=48). At an average 12-month follow-up, 47 of 49 patients (96%) with postoperative radiographs achieved solid fusion. There were no significant differences between pre- and postoperative disc space height and lumbar lordosis angle.

Adverse Events

An industry-sponsored 5-year voluntary postmarketing surveillance study of 9,152 patients was reported by Gundanna et al. in 2011. (10) A single-level L5-S1 fusion was performed in 8,034 patients (88%), and a 2-level (L4-S1) fusion was performed in 1118 patients (12%). A predefined database was designed to record device- or procedure-related complaints through spontaneous reporting. Several procedures, including the presence of a TransS1 representative during every case, were implemented to encourage complication reporting. The complications that were recorded included bowel injury, superficial wound and systemic infections, transient intraoperative hypotension, migration, subsidence, presacral hematoma, sacral fracture, vascular injury, nerve injury, and ureter injury, (pseudoarthrosis was not included). The follow-up period ranged from 3 months to 5 years 3 months. Complications were reported in 120 patients (1.3%) at a median of 5 days (mean, 33 days; range, 0-511 days). Bowel injury was the most commonly reported complication (0.6%), followed by transient intraoperative hypotension (0.2%). All other complications had an incidence of 0.1% or lower. There were no significant differences in complication rates for single-level (1.3%) and 2-level (1.6%) fusion procedures. Although this study includes a large number of patients, it is limited by the dependence on spontaneous reporting, which may underestimate the true incidence of complications.

Lindley et al. found high complication rates in a retrospective review of 68 patients who underwent axial LIF between 2005 and 2009. (11) Patient diagnoses included degenerative disc disease, spondylolisthesis, spinal stenosis, degenerative lumbar scoliosis, spondylolysis, pseudoarthrosis, and recurrent disc herniation. Ten patients underwent 2-level axial LIF (L4-S1), and 58 patients underwent a single-level axial LIF (L5-S1). A total of 18 complications in 16 patients (23.5%) were identified with a mean 34 months' follow-up (range, 17-61 months). Complications included pseudoarthrosis (8.8%), superficial infection (5.9%), sacral fracture (2.9%), pelvic hematoma (2.9%), failure of wound closure (1.5%), and rectal perforation (2.9%). Both of the patients with rectal perforation underwent emergency repair and were reported to have no long-term sequelae. The patients with nonunion underwent additional fusion surgery with an anterior or posterior approach. The 2 patients with sacral fractures had preexisting osteoporosis; one was treated with long iliac screws. Because of the potential for these complications, the authors recommend full bowel preparation and preoperative magnetic resonance (MR) imaging prior to an axial LIF procedure to assess the size of the presacral space, determine rectal adherence to the sacrum, rule out vascular abnormalities, and determine a proper trajectory.
A search of the FDA’s MAUDE database through October 2014 (available online at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm) identified 135 adverse event reports for axial LIF, including possible and confirmed bowel injuries.

**Ongoing and Unpublished Clinical Trials**

A search of online site ClinicalTrials.gov in October 2014 found an industry-sponsored randomized trial comparing transacral LIF and transfemoral LIF (NCT01716182). The study was projected to enroll 200 patients, but was terminated due to slow enrollment.

**Summary**

The available published evidence on axial lumbosacral interbody fusion (LIF) consists of case series. This evidence is insufficient to evaluate whether axial LIF 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. In addition, there are a relatively large number of adverse event reports in the MAUDE database for axial LIF, which raises the possibility of an increased risk of complications. Controlled trials are needed to better define the benefits and risks of this procedure compared to alternative treatment options. Due to limited evidence and concerns about the safety and efficacy of the axial approach, axial LIF is considered investigational.

**Practice Guidelines and Position Statements**

The United Kingdom’s National Institute for Health and Clinical Excellence (NICE) provided guidance on transaxial interbody fusion in the lumbar spine in 2011.(12) The guidance states that current evidence on the efficacy of transaxial interbody lumbosacral fusion is limited in quantity but shows symptom relief in the short term in some patients. Evidence on safety shows that there is a risk of rectal perforation. Therefore this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. NICE encourages further research into transaxial interbody lumbosacral fusion. Research outcomes should include fusion rates, pain and functional scores, quality-of-life measures, and the frequency of both early and late complications. NICE may review this procedure on publication of further evidence.

The American Association of Neurological Surgeons published guidelines for interbody techniques for lumbar fusion in 2014 (part 11).(13) The 2014 guideline states that there is no evidence that conflicts with the previous recommendations of the first generation of lumbar fusion guidelines. There was insufficient evidence to recommend a treatment standard. Minimally invasive procedures were not reviewed.

**U.S. Preventive Services Task Force Recommendations**

The U.S. Preventive Services Task Force (USPSTF) has not addressed axial lumbosacral interbody fusion.

**Medicare National Coverage**

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

**References**

2. U.S. Food and Drug Administration Center for Devices and Radiological Health. Premarket Notification [510(K)] Summary. TranS1® Axia LIF® Fixation System.


**Documentation Required for Clinical Review**

- No records required

**Coding**

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before
applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

**IE**

The following services are considered investigational and therefore not covered for any indication.

<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
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<td>CPT®</td>
<td>0195T</td>
<td>Arthrodesis, pre-sacral interbody technique, disc space preparation, discectomy, without instrumentation, with image guidance, includes bone graft when performed; L5-S1 interspace</td>
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<tr>
<td>CPT®</td>
<td>0309T</td>
<td>Arthrodesis, pre-sacral 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)</td>
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<tr>
<td>CPT®</td>
<td>22586</td>
<td>Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, L5-S1 interspace</td>
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| HCPCS | None |
| ICD-9 Procedure | 81.08 |

**ICD-10 Procedure**

For dates of service on or after 10/01/2015

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<td>Fusion of Lumbar Vertebral Joint, Anterior Approach, Anterior Column, Percutaneous Endoscopic Approach</td>
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<tr>
<td>0SG14Z0</td>
<td>Fusion of 2 or more Lumbar Vertebral Joints, Anterior Approach, Anterior Column, Percutaneous Endoscopic Approach</td>
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<td>0SG34Z0</td>
<td>Fusion of Lumbosacral Joint, Anterior Approach, Anterior Column, Percutaneous Endoscopic Approach</td>
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**ICD-9 Diagnosis**

All Diagnoses

**ICD-10 Diagnosis**

For dates of service on or after 10/01/2015

All Diagnoses
Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

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<tr>
<td>12/15/2014</td>
<td>BCBSA Medical Policy adoption</td>
<td>Medical Policy Committee</td>
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Definitions of Decision Determinations

**Medically Necessary:** A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements

This service (or procedure) is considered medically necessary in certain instances and investigational in others (refer to policy for details).

For instances when the indication is medically necessary, clinical evidence is required to determine medical necessity.

For instances when the indication is investigational, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.