Prior Authorization Review Panel  
MCO Policy Submission

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**Type of Submission – Check all that apply:**

- [ ] New Policy
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**CPB 0772 Axial Lumbar Interbody Fusion (AxiaLIF)**

Clinical content was never revised. Additional non-clinical updates were made by Corporate since the last PARP submission, as documented below.

**Update History since the last PARP Submission:**

03/01/2019-This CPB has been updated with additional background information and references.

**Name of Authorized Individual (Please type or print):**  
Dr. Bernard Lewin, M.D.

**Signature of Authorized Individual:**  
[Signature]

Revised July 22, 2019
Axial Lumbar Interbody Fusion (AxiaLIF)

Policy

Aetna considers axial lumbar interbody fusion (AxiaLIF), a percutaneous pre-sacral access route to the L5 - S1 vertebral bodies for spinal fusion, experimental and investigational because of insufficient evidence of its effectiveness.

See also CPB 0016 - Back Pain - Invasive Procedures (../1_99/0016.html) and CPB 0743 - Spinal Surgery: Laminectomy and Fusion (../700_799/0743.html).

Background

Interbody fusion (arthrodesis) in the lumbar spine is performed to treat painful symptoms caused by instability of the vertebrae, such as spondylolisthesis, spinal stenosis, or degenerative disc disease. Methods of spinal fusion include bone grafts or metal implants placed either anteriorly, posteriorly, or laterally; however, insertion of these implants is not without surgical risk. Numerous open and minimally invasive techniques have been developed but all of these approaches experience the same shortcomings related to biomechanics or inherent iatrogenic destabilization.
In an attempt to alleviate many of the limitations of previous techniques, a pre-sacral approach to the lumbosacral junction has been investigated. Transaxial anterior lumbar interbody fusion is an emerging minimally invasive spinal fusion procedure used to treat patients with chronic lower back pain (Ollendorf et al., 2011). This procedure is an alternative to traditional fusion techniques that utilize anterior or posterior approaches to directly expose the lumbosacral spine. In the case of transaxial anterior lumbar interbody fusion the spine is accessed percutaneously via the anterior surface of the sacrum.

The axial lumbar interbody fusion (AxiaLIF) system (TranS1, Inc., Wilmington, NC) combines a minimally invasive technique with a novel corridor approach. Through a small para-coccygeal incision, a pre-sacral corridor is percutaneously created for access to the anterior lumbosacral body and, subsequently, to the L5 - S1 intervertebral space. Proponents of this approach report minimal risk to adjacent vital structures and no annular disruption. The AxiaLIF system was cleared for marketing through the Food and Drug Administration (FDA) 510(k) process. The device includes instruments for creating a small pre-sacral axial track to the L5 - S1 vertebral bodies for the insertion of bone graft material into the disc space. The device also includes an anterior fixation rod that is implanted through the same track. According to the FDA 510(k) letter to the manufacturer, the system is indicated for patients requiring 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 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 marked facet and pedicle screw systems.

According to TranS1’s website, the risks of the AxiaLIF system are similar to any spine stabilization surgery (e.g., bleeding, neurological damage, damage to soft tissue, spinal cord impingement or damage, infection, loss of bowel or bladder function, loss of erectile or ejaculatory function, meningitis, or pain). The website states that the risks associated with the implant include: breakage of the implants, loosening or expulsion of the implants possibly causing delayed nerve root impingement or damage, fracture of osseous structures, and bursitis.

The most common comparison of interbody techniques in the literature has been between anterior and posterior interbody techniques. There are no randomized controlled trials comparing the outcomes of lumbar fusion using the pre-sacral technique with standard approach techniques. Current published literature consists of feasibility reports and small non-randomized case series with limited follow-up.
The American Association of Neurological Surgeons/Congress of Neurological Surgeons guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine (Resnick et al, 2005) reported that posterior lumbar interbody fusion, transformal interbody fusion, or anterior lumbar interbody fusion techniques are the treatment options for patients with low-back pain due to degenerative disc disease at one or two levels. The guideline did not mention a pre-sacral approach for spinal fusion or the AxiaLIF system. The guideline stated, "Future studies focusing on patient outcomes are required to establish whether the increased fusion rates seen with interbody techniques are truly associated with improved functional outcomes. Application of reliable, valid, and responsive outcome measures in a multi-center randomized trial would serve to answer this question. In terms of the techniques used to achieve an interbody arthrodesis, it is likely that certain techniques will be more applicable to different patient populations. Future studies should be focused on evaluating the individual techniques within specific patient populations. Well-designed cohort studies would provide needed Class II medical evidence. Randomized studies would need to include adequate numbers of patients to ensure sufficient power to be able to assess whether the incremental improvement achieved with interbody techniques is clinically significant."

The AxiaLIF percutaneous lumbar interbody fusion procedure may provide an alternative access route to the L5 - S1 inter-space in those patients who may have unfavorable anatomy or contraindications to the traditional open anterior approach (Aryan et al, 2008). However, there is insufficient evidence of the effectiveness of a pre-sacral approach with the AxiaLIF system.

Duan and colleagues (2009) reviewed the feature, biomechanics, and clinical application of percutaneous 360 degree AxiaLIF technique, which is different from other lumbar interbody fusion techniques due to its capability in maintaining the integrity of the bilateral facet joints, the anterior/posterior longitudinal ligament, and the annulus fibrosus. The 3-dimensional AxiaLIF Rod provided axial support and fixation, thus relieving stenosis of the lumbar intervertebral foramen and restoring the intervertebral disc height and the whole height and physiological curvature of the lumbar spine. The recovery of the intervertebral disc height could restore the folded or crumpled flavum, the posterior longitudinal ligament, and the herniated annulus, resulting in the improvement of stenosis symptoms of nerve root canal or central vertebral canal. The authors concluded that percutaneous 360 degree AxiaLIF technique achieves satisfying therapeutic effects, although it has fairly narrow indication and needs long-term follow-up observation.

Luther et al (2009) reported on a case series of transaxial lumbar interbody fusion in patients with chronic back pain and radiographic evidence of lumbar degenerative disc disease at L5-S1. Five patients received a single-level fusion and 1 patient received a 2-level fusion. Bony fusion
was seen on post-operative imaging in one patient after 12 months. Limitations of this study included its small size, limited followup, lack of comparison group and retrospective nature.

Patel et al (2010) conducted a review of the charts of 50 patients who underwent axial lumbar interbody fusion surgery at a single institution between 2006 and 2008. The 50 patients (32 women, 18 men; mean age of 49.29 years) treated with axial lumbar interbody fusion, 48 had pre-operative visual analog scale (VAS) scores and 16 had pre-operative Oswestry Disability Index (ODI) scores available. Complete radiographic data were available at the pre-operative, initial post-operative, and final post-operative time-points for 46 patients (92 %). At last follow-up (average of 12 months), ODI scores were reduced from 46 to 22, and VAS scores were lowered from 8.1 to 3.6. Of the 49 patients with post-operative radiographs, 47 (96 %) went on to a solid fusion. There were no significant differences between pre- and post-operative disk space height and lumbar lordosis angle. The most common complications were superficial infection and pseudoarthrosis. Other complications were rectal injury, hematoma, and irritation of a nerve root by a screw. Limitations of this study included its retrospective nature, small size, limited duration of follow-up and lack of comparison group.

Tobler et al (2011) reported the 2-year clinical and radiographic outcomes associated with a L5-S1 interbody fusion procedure that employs an axial presacral surgical approach. A total of 156 patients from 4 clinical sites were selected for inclusion if they underwent a L5-S1 interbody fusion via the presacral approach with the AxiaLIF system and had both pre-surgical and 2-year radiographic or clinical follow-up. Back pain and functional impairment were evaluated with an 11-point numeric scale and the Oswestry Disability Index (ODI), respectively, pre-operatively and at 2 years. Standard radiographic imaging techniques were used to determine fusion status. Marked clinical improvements were realized in back pain severity and functional impairment through 2 years of follow-up. Mean pain scores improved from 7.7 +/- 1.6 (n = 155) pre-operatively to 2.7 +/- 2.4 (n = 148) at 24 months, reflecting an approximate 63 % overall improvement (p < 0.001). Mean ODI scores improved from 36.6 +/- 14.6 % (n = 86) pre-operatively to 19.0 +/- 19.2 % (n = 78) at 24 months, or approximately 54 % (p < 0.001). Two-year clinical success rates on the basis of change relative to baseline of at least 30 % were 86 % (127 of 147) and 74 % (57 of 77) for pain and function, respectively. The overall radiographic fusion rate at 2 years was 94 % (145 of 155). The authors concluded that findings from this clinical series of patients treated with a pre-sacral interbody fusion procedure, stabilized with the AxiaLIF rod, reflect favorable and durable outcomes through 2 years of follow-up. Moreover, they noted that while the results from the current study are encouraging, especially in contrast to previously published systematic reviews and randomized controlled trials (RCTs), they must be interpreted with caution. In fact, Andersson et al (2006) noted that there was an identifiable trend for RCTs to report a smaller magnitude of improvement in most clinical outcomes compared with other types of trials. For example, there was a 36 % median reduction in pain
severity realized after spinal fusion in RCTs compared with a median reduction of 53 % for retrospective case series. It is probable that the selection criteria utilized in the current series effectively excluded the worst cases by requiring 2 years of post-operative radiographical or clinical follow-up. Consequently, the authors acknowledged that this retrospective study offers only level IV evidence of clinical effectiveness. However, it does provide a foundation for future studies to confirm or modify the current findings. Tobler et al (2011) also stated that "[t]he minimally invasive presacral interbody fusion is a procedure that allows preservation of the annulus and all paraspinous soft tissue structures. The distinctness of the procedure requires that surgeons be well familiarized with the presacral anatomy. Additionally, the methodology to prepare the interspace for fusion requires that the surgeon relies on fluoroscopic imaging as opposed to direct visualization of the disc space. These procedural characteristics have resulted in a level of uncertainty among surgeons about widely adopting this technique. The distinct limitations of the current study notwithstanding, the clinical and radiographic findings remain promising but require corroboration in additional patient groups".

Gundanna et al (2011) evaluated complications associated with axial interbody lumbar fusion procedures using the AxiaLIF system in the post-marketing period. Between March 2005 and March 2010, 9,152 patients underwent interbody fusion with the AxiaLIF system through an axial presacral approach. A single-level L5 to S1 fusion was performed in 8,034 patients (88 %), and a 2-level (L4 to S1) fusion was used in 1,118 (12 %). A pre-defined database was designed to record device- or procedure-related complaints via spontaneous reporting. The complications that were recorded included bowel injury, superficial wound and systemic infections, transient intra-operative hypotension, migration, subsidence, pre-sacral hematoma, sacral fracture, vascular injury, nerve injury, and ureter injury. Complications were reported in 120 of 9,152 patients (1.3 %). The most commonly reported complications were bowel injury (n = 59, 0.6 %) and transient intra-operative hypotension (n = 20, 0.2 %). The overall complication rate was similar between single-level (n = 102, 1.3 %) and 2-level (n = 18, 1.6 %) fusion procedures, with no significant differences noted for any single complication. The authors concluded that the 5-year post-marketing surveillance experience with the AxiaLIF system suggested that axial interbody lumbar fusion through the pre-sacral approach is associated with a low incidence of complications. The overall complication rates observed in this evaluation compares favorably with those reported in trials of open and minimally invasive lumbar fusion surgery. The major drawback of this study was that fusion rates were not reported in this series. Another drawback was the spontaneous complication-reporting mechanism, which may under-estimate the true incidence of complications.

An assessment of the Axialif procedure by the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S) (Leopardi, 2010) noted the lack of high quality studies of the Axialif procedure and the need for long-term studies. The assessment
concluded: "Overall, the AxiaLIF procedure appears to offer some symptom improvement in patients suffering from back pain, without major compromise to their safety. High-quality comparative studies are needed to completely assess the safety and efficacy of the AxiaLIF procedure."

Guidance from the National Institute for Health and Clinical Excellence (NICE, 2011) concluded 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. The guidance stated that 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. The guidance noted the need for further research into transaxial interbody lumbosacral fusion, and stated that research outcomes should include fusion rates, pain and functional scores, quality of life measures and the frequency of both early and late complications. Specialist advisors to NICE listed key efficacy outcomes as improvement in low back pain and radiological evidence of fusion. Adverse events reported in the literature include rectal perforation and presacral abscess, rectal injury, pseudarthrosis, and intractable pain. One specialist advisor to NICE reported anecdotal events of infection and peritoneal injury and another reported pelvic abscess in one patient. The specialist advisors to NICE considered theoretical adverse events to include infection, bowel or bladder perforation, vascular injury, nerve damage, damage to parasympathetic plexus, cerebrospinal fluid leak due to dural tear, implant migration, loosening or breakage, and difficulty in revision. The guidance noted that transaxial interbody lumbosacral fusion was used as the sole procedure in a minority of the patients reported in the literature. Most patients had other adjunctive procedures and this made the evidence difficult to interpret.

Li and colleagues (2012) stated that AxiaLIF is a novel, minimally invasive surgery. Although there were a few clinical reports on its safety, AxiaLIF is less used in current practice because of the unfamiliarity of surgeons with the regional anatomy of pre-sacral space. These researchers performed a precise anatomical study of the pre-sacral space and examined the approach safety of AxiaLIF in an anatomical aspect. A total of 16 adult cadaveric pelvic specimens were divided along the median sagittal plane. The pre-sacral fascial structures, the recto-sacral fascia, and the pelvic splanchnic nerves were dissected and measured. In the simulated operation, a blunt guide pin was inserted bilaterally to determine the relation of the guide pin's path with important anatomic structures. Mean distances with 95% confidence intervals (CIs) were calculated. The results showed that the fascial structures of the pre-sacral space were divided into 5 layers, and the pelvic splanchnic nerves limited the dissection of the lower rectum, the mean length of which was 2.2 cm (1.9 to 2.5 cm). In the simulated operation, the mean minimum distance from the guide pin to the pelvic splanchnic nerves was 0.8 cm (0.4 to 1.2 cm), and the mean vertical distance to the S3 to S4 junction was 1.5 cm (1.2 to 1.7 cm). The authors concluded that these findings suggested that the approach for AxiaLIF is risky and requires further modification.
Hadjipavlou and colleagues (2013) quantified the risks and complications associated with AxiaLIF in a series of 29 patients. AxiaLIF is a fusion technique using a percutaneous retro-rectal, pre-sacral corridor approach to access the L5 to S1 and L4 to L5 intervertebral spaces transaxially, through the body of S1 and L5 vertebrae. The fusion rate in the present series was 92 % and the reported results ranged from 68 % to 100 %. The only serious complication in the authors’ series was 1 pre-sacral hematoma (1/29, or 3.5 %). Symptomatic subsidence occurred in the stand alone group, resulting in foraminal stenosis and radiculopathy in 2 patients (7 %) and back pain in 1 (3.5 %). Painful radiolucent halo around the rod was noted in a spondylolytic case (1/29, or 3.5 %); it resolved after transpedicular instrumentation. The authors concluded that AxiaLIF is a novel truly minimally invasive technique not requiring blood transfusion and can be safely performed as a day surgery. Retroperitoneal hematoma, ureteral and vascular injuries can be avoided by respecting the regional anatomical landmarks as guided by accurate fluoroscopy. Only expanding hematomas may have to be drained. Bowel perforation can be prevented by gently sweeping away the rectum from the sacrum before inserting the guide probe. Moreover, they stated that “The main objective of this clinical study was to scrutinize the complications of this procedure in our series in order to establish technical guidelines for avoiding potential pitfalls and render AxiaLIF a safer procedure. It remains to determine its level of effectiveness in relation to other techniques in controlled randomized studies …. Since in our series we encountered no serious complications, and the fusion rate is relatively high, this suggests encouraging perspectives”.

Zeilstra et al (2013) reported their 6-year single-center experience with L5-S1 axial lumbar interbody fusion (AxiaLIF). A total of 131 patients with symptomatic degenerative disc disease refractory to non-surgical treatment were treated with AxiaLIF at L5-S1, and were followed for a minimum of 1 year (mean of 21 months). Main outcomes included back and leg pain severity, Oswestry Disability Index score, working status, analgesic medication use, patient satisfaction, and complications. Computed tomography was used to determine post-operative fusion status. No intra-operative complications, including vascular, neural, urologic, or bowel injuries, were reported. Back and leg pain severity decreased by 51 % and 42 %, respectively, during the follow-up period (both p < 0.001). Back function scores improved 50 % compared to baseline. Clinical success, defined as improvement greater than or equal to 30 %, was 67 % for back pain severity, 65 % for leg pain severity, and 71 % for back function. The employment rate increased from 47 % before surgery to 64 % at final follow-up (p < 0.001). Less than 1 in 4 patients regularly used analgesic medications post-surgery. Patient satisfaction with the AxiaLIF procedure was 83 %. The fusion rate was 87.8 % at final follow-up. During follow-up, 17 (13.0 %) patients underwent 18 re-operations on the lumbar spine, including pedicle screw fixation (n = 10), total disc replacement of an uninvolved level (n = 3), facet screw fixation (n = 3), facet screw removal (n = 1), and interbody fusion at L4-L5 (n = 1); 8 (6.1 %) re-operations were at the index level. The authors concluded that single-level AxiaLIF is a safe and effective means to achieve
lumbosacral fusion in patients with symptomatic degenerative disc disease. Moreover, they noted that “Our study is limited by the retrospective nature of the analysis. Additionally, all patients underwent fusion at L5 to S1 and, therefore, no conclusions can be drawn regarding the effectiveness or safety of 2-level AxiaLIF from this report. Lastly, mean patient follow-up was 21 months. Although this represents one of the longest follow-up reports following AxiaLIF surgery, long-term clinical and radiographic outcomes are unknown”.

In a retrospective study, Whang et al (2013) reviewed the findings of 96 patients who underwent L5 to S1 interbody fusions through either a standard anterior retroperitoneal approach or using a novel device inserted through the pre-sacral space (AxiaLIF) in conjunction with supplemental posterior fixation between 2002 and 2010. Patient information and procedural data were obtained from hospital charts. Multi-planar computed tomography images were evaluated by 2 independent observers to assess fusion success at 24 months using a 4-point grading scale. In addition to reviewing the medical records to identify any complications, all of the sites were queried regarding any device-related adverse events that may have occurred. According to the radiographic analysis, the arthrodesis rates recorded for the anterior lumbar interbody fusion (ALIF) and AxiaLIF cohorts were 79 % and 85 %, respectively (p > 0.05). The numbers and types of adverse events recorded for these procedures appeared to be similar although there was 1 serious intra-operative complication (iliac artery laceration) noted in the ALIF group. The authors concluded that the radiographic success and adverse events associated with AxiaLIF appear to be similar to that observed for ALIF, suggesting that this technique represents a safe and effective method for achieving an interbody fusion across the L5 to S1 disk space when utilized in conjunction with posterior fixation. The author noted that this study had several drawbacks – “The retrospective nature of this analysis obviously did not allow for randomization of subjects or the utilization of other controls to minimize patient or procedural variability. It is conceivable that the wide range of adjunctive graft materials employed in this series may have affected the results of the radiographic assessment. For example, more individuals in the AxiaLIF group were treated with recombinant growth factors than those in the ALIF group (29 versus 11, respectively); this finding can account for the higher fusion rate in the AxiaLIF group. Many interbody fusion studies have noted a high fusion rate with the use of recombinant proteins. However, specific to the AxiaLIF procedure, Gerszten et al and Tobler et al failed to identify any significant differences between the radiographic findings of AxiaLIF devices filled with either rhBMP-2 or other bone graft materials. Similarly, the multiple different fixation strategies that were used to enhance the segmental stability of these interbody constructs may represent a confounding variable as well. Finally, this study did not consider outcomes measures like Tobler et al who employed validated instruments to assess the clinical and functional improvements of their patients following their surgeries. It is expected that this particular deficiency will be addressed by an upcoming prospective post-market trial that is scheduled to begin enrollment in the near future. Nevertheless, we are confident that none of
these methodological flaws detract from the overall significance of these results, which indicate that the safety and efficacy of AxiaLIF appear to be similar to that of ALIF for interbody fusions involving the L5-S1 intervertebral disk space”.

Issack and Boachie-Adjei (2012) performed a retrospective evaluation of 9 patients who underwent pre-sacral axial lumbosacral interbody fixation and fusion at the end of long fusion constructs using the AxiaLIF implant. Pre-operative diagnoses included adjacent segment degeneration below a long fusion construct for adult scoliosis and progressive sagittal plane deformity. There were 2 pseudoarthroses, 1 at L4 to L5 and 1 at L5 to S1. No major complications occurred. There were no significant differences in coronal or sagittal plane alignment at the time periods measured. There was no significant difference in implant position between immediate post-operative and final follow-up periods. There were significant post-operative improvements in Scoliosis Research Society-22 scores, specifically in the pain, self-image, and satisfaction with management domains. The authors concluded that the axial lumbosacral interbody fusion is a minimally invasive and safe method to obtain lumbosacral fixation and arthrodesis distal to a long fusion construct. Moreover, they stated that longer follow-up of larger numbers of patients are needed prior to recommending this procedure as a routine method to fuse L4 to L5 or L5 to S1.

Hofstetter et al (2013) analyzed clinical and radiographic outcomes of 1- or 2-level AxiaLIF procedures with focus on durability of the construct. This was a retrospective study of 38 consecutive patients who underwent either 1-level (32 patients) or 2-level (6 patients) AxiaLIF procedures at the authors' institution. The ODI (minimum clinically important difference [MCID] greater than or equal to 12 and VAS; MCID greater than or equal to 3) scores were collected. Disc height and Cobb angles were measured on pre- and post-operative radiographs. Bony fusion was determined on computed tomography (CT) scans or flexion/extension radiographs. Implantation of a trans-sacral rod allowed for intra-operative distraction of the L5/S1 intervertebral space and resulted in increased segmental lordosis post-operatively. At a mean follow-up time of 26.2 ± 2.4 months, however, graft subsidence (1.9 mm) abolished partial correction of segmental lordosis. Moreover, subsidence of the construct reduced L5/S1 lordosis in patients with 1-level AxiaLIF by 3.2° and L4 to S1 lordosis in patients with 2-level procedures by 10.1° compared with pre-operative values (p < 0.01). Loss of segmental lordosis predicted failure to improve VAS scores for back pain in the patient cohort (p < 0.05). Overall, surgical intervention led to modest symptomatic improvement; only 26.3 % of patients achieved an MCID of the ODI and 50 % of patients an MCID of the VAS score for back pain. At last follow-up, 71.9 % of L5/S1 levels demonstrated bony fusion (1-level AxiaLIF 80.8 %, 2-level AxiaLIF 33.3 %; p < 0.05), whereas none of the L4/5 levels in 2-level AxiaLIF fused. Five constructs developed pseudoarthrosis and required surgical revision. The authors concluded that the AxiaLIF procedure constitutes a minimally invasive technique for L5/S1 instrumentation, with low peri-
operative morbidity. However, the axial rod provides inadequate long-term anterior column support, which leads to subsidence and loss of segmental lordosis. Furthermore, they stated that modification of the trans-sacral technique to allow for placement of a solid interposition graft may counteract subsidence of the construct.

In a prospective monocentric study, Stúlík et al (2014) evaluated clinical and radiographic results in the patients who underwent L5 to S1 fixation using the technique of percutaneous lumbar interbody fusion (AxiaLIF). The study comprised 23 patients, 11 women and 12 men, aged 21 to 63 years (average of 48.2 years). In all patients, surgical posterior stabilization involving the L5 to S1 segment had previously been done. The initial indications for surgery were L5 to S1 spondylolisthesis in 20 and L5 to S1 spondylosis and stenosis in 3 patients. The AxiaLIF technique for L5 to S1 fixation was indicated in over-weight patients and in those after repeated abdominal or retroperitoneal surgery. A suitable position and shape of the sacrum or lumbosacral junction was another criterion. The patients were evaluated between 26 and 56 months (average of 40.4 months) after primary surgery and, on the basis of CT and radiographic findings, bone union and lumbosacral junction stability were assessed. The clinical outcome was investigated using the ODI and VAS systems and the results were statistically analyzed by the Wilcoxon test for paired samples with statistical significance set at a level of 0.05. The average VAS value was 6.6 before surgery and, after surgery, 5.2 at 3 months, 4.2 at 6 months, 3.1 at 1 year, 2.9 at 2 years and 2.1 at 3 years (n = 18). At 2 post-operative years, improvement in the VAS value by 56.1 % was recorded. The average pre-operative ODI value was 25.1; the post-operative values were 17.0 at 6 months, 12.3 at 1 year, 10.6 at 2 years and 8.2 at 3 years (n = 18). At 2 years after surgery the ODI value improved by 57.8 %. To the question concerning their willingness to undergo, with acquired experience, surgery for the same diagnosis, 21 patients (91.3 %) gave an affirmative answer. Neither screw breakage nor neurovascular damage or rectal injury was found. Computed tomographic scans showed complete interbody bone fusion in 22 of the 23 patients (95.6 %). In 1 patient the finding was not clear. Also, posterolateral fusion was achieved in 95.6 % patients. A stable L5 to S1 segment was found in all patients at all follow-up intervals. The improvement in both VAS and ODI values was statistically significant. The authors concluded that the percutaneous axial pre-sacral approach to the L5 to S1 interbody space with application of a double-treaded screw is another option for the management of this much strained segment. The technique is useful particularly when contraindications for conventional surgical procedures are present in patients with anatomical anomalies, in over-weight patients or in those who have had repeated surgery in the region. Clinical outcomes and the success rate for L5 to S1 bone fusion are comparable with conventional techniques. Complications are rare but their treatment is difficult. The findings of this small study need to be validated by well-designed studies with larger sample size and longer follow-up.

www.aetna.com/cpb/medical/data/700_799/0772.html
Fleischer et al (2014) used a cadaveric lumbosacral spondyloytic spondylolisthesis model to evaluate the biomechanical function of 2 different interbody spacers. They analyzed and compared the reduction in pedicle screw strain and spine range of motion (ROM) between transforaminal lumbar interbody fusion (TLIF) and an axial interbody threaded rod (AxialITR) in a destabilized L5 to S1 spondylolisthesis model. Pure-moment flexibility testing was performed on L3 to S1 cadaveric specimens in 4 conditions: (i) Intact, (ii) L5 to S1 pedicle screws (PS) + L5 to S1 disc destabilization (DDS), (iii) TLIF at L5 to S1 + PS + DDS, and (iv) AxialITR at L5 to S1 + PS + DDS. Specimens were destabilized by performing a complete denucleation at L5 to S1 and sectioning 2/3 of the annulus' width from anterior to posterior. The S1 PSs were instrumented with strain gauges to measure screw-bending moments and ROM was quantified with a non-contact camera system. S1 screw strains were highest with PS but were significantly reduced by 73% in flexion and 31% in extension with TLIF (p ≤ 0.004). AxialITR significantly reduced strain by 78% in flexion and 81% in extension (p ≤ 0.001). Range of motion was smallest with AxialITR in each test direction at 1.7 ± 1.8° in flexion-extension, 1.6 ± 0.9° in lateral bending and 1.3 ± 0.8° in torsion. The authors concluded that the findings of this study demonstrated that ROM and S1 screw-bending moments were reduced with the use of AxialITR and TLIF. Although the TLIF and AxialITR both reduced strains and motion, the AxialITR provided a significant reduction in extension strain when compared with TLIF. Level of Evidence: N/A. (This was a cadaveric study).

Marawar and associates (2014) examined the changes in neuroforaminal height at L4 to L5 and L5 to S1 after insertion and graduated foraminal distraction using the 2-level trans-sacral implant in a cadaveric model. Discectomy and trans-sacral instrumentation was performed in 6 fresh human cadavers at L4 to S1. The neuroforaminal height was measured at L4 to L5 and L5 to S1 before and after insertion of the implant and then at each stage of manual distraction. Mean L4 to L5 neuroforaminal height increased from 18.2 ± 3.1 mm to 20.3 ± 2.9 mm (11%) on the left and from 18.8 ± 2.8 mm to 20.6 ± 2.3 mm (12%) on the right (p < 0.05). Mean L5 to S1 neuroforaminal height increased from 15.7 ± 3.0 mm to 18.4 ± 2.8 mm (17%) on the left and from 15.6 ± 2.1 mm to 18.3 ± 1.8 mm (17%) on the right (p < 0.05). When the neuroforaminal height was plotted against amount of rotation of the screw driver it was found that the neuroforaminal height at L5 to S1 increased by 1 mm on average for every complete revolution of the screw driver. At least 2 full rotations of the screw driver were achieved in all cadavers. The authors concluded that the trans-sacral screw construct distracted the disc space and neuroforaminal height in a cadaveric spine model without soft tissue envelope. During the initial process, manual control of disc space distraction predictably correlated with the increase in the neuroforaminal height to a maximum. However, they stated that further research is needed to examine variables affecting disc space pliability, implant subsidence, in-vivo application, and clinical benefit of this procedure.
Schroeder and colleagues (2015) determined the fusion rate and safety profile of an axial interbody arthrodesis of the L5 to S1 motion segment. These investigators performed a systematic search of MEDLINE for literature published between January 1, 2000, and August 17, 2014. All peer-reviewed articles related to the fusion rate of L5 to S1 and the safety profile of an axial interbody arthrodesis were evaluated. A total of 74 articles were identified, but only 15 (13 case series and 2 retrospective cohort studies) met the study inclusion criteria. The overall pseudarthrosis rate at L5 to S1 was 6.9 %, and the rate of all other complications was 12.9 %. A total of 14.4 % of patients required additional surgery, and the infection rate was 5.4 %.

Deformity studies reported a significantly increased rate of complications (46.3 %), and prospectively collected data demonstrated significantly higher complication (36.8 %) and revision (22.6 %) rates. Lastly, studies with a conflict of interest reported lower complication rates (12.4 %). The authors concluded that a systematic review of the literature indicated that an axial interbody fusion performed at the lumbo-sacral junction is associated with a high fusion rate (93.15 %) and an acceptable complication rate (12.90 %). However, they stated that these results were based mainly on retrospective case series by authors with a conflict of interest. The limited prospective data available indicated that the actual fusion rate may be lower and the complication rate may be higher than currently reported.

Furthermore, an UpToDate review on “Subacute and chronic low back pain: Surgical treatment” (Chou, 2015) does not mention axial lumbar interbody fusion/AxiaLIF as a surgical option.

Tobler et al (2013) stated that previous studies have confirmed the benefits and limitations of the pre-sacral retroperitoneal approach for L5 to S1 interbody fusion. These researchers examined the safety and effectiveness of the minimally invasive AxiaLIF for L4 to S1 fusion. In this retrospective series, 52 patients from 4 clinical sites underwent L4 to S1 interbody fusion with the AxiaLIF 2-level system with minimum 2-year clinical and radiographic follow-up (range of 24 to 51 months). Outcomes included back pain severity (on a 10-point scale), the ODI, and Odom’s criteria. Flexion and extension radiographs, as well as computed tomography scans, were evaluated to determine fusion status. Longitudinal outcomes were assessed with repeated measures analysis of variance. Mean subject age was 52 ± 11 years and the male to female ratio was 1:1. Patients sustained no intra-operative bowel or vascular injury, deep infection, or neurologic complication. Median procedural blood loss was 220 cc and median length of hospital stay was 3 days. At 2-year follow-up, mean back pain had improved 56 %, from 7.7 ± 1.6 at baseline to 3.4 ± 2.7 (p < 0.001). Back pain clinical success (i.e., greater than or equal to 30 % improvement from baseline) was achieved in 39 (75 %) patients at 2 years. Mean ODI scores improved 42 %, from 60 % ± 16 % at baseline to 35 % ± 27 % at 2 years (p < 0.001); ODI clinical success (i.e., greater than or equal to 30 % improvement from baseline) was achieved in 26 (50 %) patients. At final follow-up, 45 (87 %) patients were rated as good or excellent, 5 as fair, and 2 as poor by Odom’s criteria. Interbody fusion observed on imaging was achieved in 97
(93 %) of 104 treated interspaces. During follow-up, 5 patients underwent re-operation on the lumbar spine, including facet screw removal (n = 2), laminectomy (n = 2), and TLIF (n = 1). The authors concluded that the AxiaLIF 2-level device is a safe, effective treatment adjunct for patients with L4 to S1 disc pathology resistant to conservative treatments. Moreover, the authors noted that although the results from were encouraging and corroborated data from previously published systematic reviews and clinical trials, these findings must be interpreted cautiously. Given that this was a retrospective case series, the data were subject to potential bias associated with this study design. The fact that ODI was only collected at 2 of 4 study sites also limited the robustness of these back function data.

In a retrospective study, Anand et al (2013) evaluated minimally invasive surgery (MIS) technique’s clinical and functional outcomes during a 2- to 5-year period. These investigators reviewed 71 patients who underwent MIS correction of spinal deformity with fusion of 2 or more levels including: degenerative scoliosis (n = 54), idiopathic scoliosis (n = 11), and iatrogenic scoliosis (n = 6). All underwent a combination of 3 MIS techniques: direct lateral interbody fusion (n = 66), AxiaLIF (n = 34), and posterior instrumentation (n = 67); 36 patients were staged with direct lateral interbody fusion done first followed by the posterior instrumentation and fusion including AxiaLIF done 3 days later. Mean age was 64 years (20 to 84). Mean follow-up was 39 months (24 to 60). Patients with 1-stage same-day surgery had a mean blood loss of 412 ml and a mean surgical time of 291 minutes. Patients with 2-stage surgery had a mean blood loss of 314 ml and surgical time of 183 minutes for direct lateral interbody fusion and 357 ml and 243 minutes, respectively for posterior instrumentation and AxiaLIF. Mean hospital stay was 7.6 days (2 to 26). The mean pre-operative Cobb angle was 24.7° (8.3° to 65°), which corrected to 9.5° (0.6° to 28.8°). Mean pre-operative coronal balance was 25.5 mm, which corrected to 11 mm. Mean pre-operative sagittal balance was 31.7 mm and corrected to 10.7 mm. The mean pre-operative lumbar apical vertebral translation was 24 mm and corrected to 12 mm. Fourteen patients had adverse events requiring intervention: 4 pseudarthrosis, 4 persistent stenosis, 1 osteomyelitis, 1 adjacent segment discitis, 1 late wound infection, 1 proximal junctional kyphosis, 1 screw prominence, 1 idiopathic cerebellar hemorrhage, and 2 wound dehiscence. The authors concluded that a combination of 3 novel MIS techniques allowed comparable correction of adult spinal deformity, with low pseudarthrosis rates, significantly improved functional outcomes, and excellent clinical and radiological improvement, but considerably lowered morbidity and complication rates at early and long-term follow-up. The main drawbacks of this study were its retrospective design and small sample size (n = 34) for AxiaLIF; and the findings were confounded by the use of a combination of 3 MIS techniques.

Melgar et al (2014) stated that loss of lumbar lordosis has been reported after lumbar interbody fusion surgery and may portend poor clinical and radiographic outcome. These researchers measured changes in segmental and global lumbar lordosis in patients treated with pre-sacral
axial L4 to S1 interbody fusion and posterior instrumentation and examined if these changes influenced patient outcomes. These investigators performed a retrospective, multi-center review of prospectively collected data in 58 consecutive patients with disabling lumbar pain and radiculopathy unresponsive to non-surgical treatment who underwent L4 to S1 interbody fusion with the AxiaLIF 2-level system. Main outcomes included back pain severity, ODI, Odom's outcome criteria, and fusion status using flexion and extension radiographs and CT scans. Segmental (L4 to S1) and global (L1 to S1) lumbar lordosis measurements were made using standing lateral radiographs. All patients were followed for at least 24 months (mean of 29 months, range of 24 to 56 months). There was no bowel injury, vascular injury, deep infection, neurologic complication or implant failure. Mean back pain severity improved from 7.8 ± 1.7 at baseline to 3.3 ± 2.6 at 2 years (p < 0.001). Mean ODI scores improved from 60 ± 15 % at baseline to 34 ± 27 % at 2 years (p < 0.001). At final follow-up, 83 % of patients were rated as good or excellent using Odom's criteria. Interbody fusion was observed in 111 (96 %) of 116 treated interspaces. Maintenance of lordosis, defined as a change in Cobb angle less than or equal to 5°, was identified in 84 % of patients at L4 to S1 and 81 % of patients at L1 to S1. Patients with loss or gain in segmental or global lordosis experienced similar 2-year outcomes versus those with less than a 5° change. The authors concluded that 2-level axial interbody fusion supplemented with posterior fixation did not alter segmental or global lordosis in most patients. Patients with post-operative change in lordosis greater than 5° have similarly favorable long-term clinical outcomes and fusion rates compared to patients with less than 5° lordosis change.

Schroeder et al (2016) stated that an L5/S1 interbody fusion is a commonly performed procedure for pathology such as spondylolisthesis with stenosis; however, it is unclear if 1 technique leads to superior fusion rates. In a systematic review, these investigators determined the fusion rate of an ALIF, TLIF, and axial arthrodesis at the lumbo-sacral junction in adult patients undergoing surgery for 1- and 2-level degenerative spine conditions. They performed a systematic search of Medline for literature published between January 1, 1992 and August 17, 2014. All peer-reviewed articles related to the fusion rate of L5/S1 for an ALIF, TLIF, or axial interbody fusion were included. In total, 42 articles and 1,507 patients were included in this systematic review. A difference in overall fusion rates was identified, with a rate of 99.2 % (range of 96.4 % to 99.8 %) for a TLIF, 97.2 % (range of 91.0 % to 99.2 %) for an ALIF, and 90.5 % (range of 79.0 % to 97.0 %) for an axial interbody fusion (p = 0.005). In a paired analysis directly comparing fusion techniques, only the difference between a TLIF and an axial interbody fusion was significant. However, when only cases in which bilateral pedicle screws supported the interbody fusion, no statistical difference (p > 0.05) between the 3 techniques was identified. The authors concluded that the current literature available to guide the treatment of L5/S1 pathology is poor, but the available data suggest that a high fusion rate can be expected with the use of an ALIF, TLIF, or axial interbody fusion. Moreover, they stated that any technique-dependent benefit in fusion rate
can be eliminated with common surgical modifications such as the use of bilateral pedicle screws.

Interventional Procedure Guidance from the National Institute for Health and Care Excellence (NICE, 2018) stated that the evidence of efficacy is adequate in quality and quantity. The guidance stated that the evidence on the safety of transaxial interbody lumbosacral fusion for severe chronic low back pain shows that there are serious but well-recognized complications.

CPT Codes / HCPCS Codes / ICD-10 Codes

*Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+".*

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
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<tbody>
<tr>
<td></td>
<td>CPT codes not covered for indications listed in the CPE</td>
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<tr>
<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>
</tr>
</tbody>
</table>

The above policy is based on the following references:

5. TranS1. For surgeons AxiaLIF: Indications, contraindications, and warnings [website]. Wilmington, NC: TranS1; 2008.


32. Issack PS, Boachie-Adjei O. Axial lumbosacral interbody fusion appears safe as a method to obtain lumbosacral arthrodesis distal to long fusion constructs. HSS J. 2012;8(2):116-121.


35. Fleischer GD, Hart D, Ferrara LA, et al. Biomechanical effect of transforaminal lumbar interbody fusion and axial interbody threaded rod on range of motion and S1 screw loading


AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: 0772 Axial Lumbar Interbody Fusion (AxiaLIF)

There are no amendments for Medicaid.