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Axial Lumbosacral Interbody Fusion

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Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

Axial lumbosacral interbody fusion (AxiaLIF) **is considered experimental, investigational and/or unproven.**

Policy Guidelines

None.

Description

Interbody Fusion
Interbody fusion is a surgical procedure that fuses 2 adjacent vertebral bodies of the spine. Lumbar interbody fusion may be performed in patients with spinal stenosis and instability, spondylolisthesis, scoliosis, following a discectomy, or for adjacent-level disc disease.

Axial Lumbosacral Interbody Fusion

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.

An advantage of axial lumbosacral interbody fusion is that it preserves 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 U.S. Food and Drug Administration (FDA) has cleared for marketing multiple anterior spinal intervertebral body fixation device systems through the 510(k) pathway (See Table 1). The systems are not intended to treat severe scoliosis, severe spondylolisthesis (grades 3 and 4), tumor, or trauma. The devices are also not meant for 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 the L5-S1 or L4-S1 disc spaces in conjunction with a legally marketed facet or pedicle screw systems. FDA product code: KWQ.

Table 1. Select Anterior Spinal Intervertebral Body Fixation Orthoses Cleared by the FDA

Orthotic	Manufacturer	Date Cleared	510(k) No.
TranS1® AxiaLIF™ System • For patients requiring fusion to treat pseudoarthrosis, unsuccessful previous fusion, spinal stenosis, spondylolisthesis (grade 1 or 2), or degenerative disc disease limited to anterior supplemental fixation of L5-S1 in conjunction with legally marketed pedicle screws	TranS1	12/04	K040426
TranS1® AxiaLIF™ System • Indication modified to include facet screws	TranS1	06/05	K050965
TranS1® AxiaLIF® II System • For patients requiring fusion to treat pseudoarthrosis, unsuccessful previous fusion, spinal stenosis, spondylolisthesis (grade 1 or 2), or degenerative disc disease limited to anterior supplemental fixation of L4-S1 in conjunction with legally marketed facet and pedicle screws	TranS1	04/08	K073643
TranS1® AxiaLIF® 2L System	TranS1	01/10	K092124

• Indication unchanged, marketed with branded bone morphogenetic protein			
TranS1® AxiaLIF® Plus System • Intended to provide anterior stabilization of the L5-SI or L4-Sl spinal segment (s) as an adjunct to spinal fusion • This device's instruments are used for independently distracting the L5-S1 or L4-S1 vertebral bodies and inserting bone graft material (Dt3M, autograft or autologous blood) into the disc space • Use limited to anterior supplemental fixation of the lumbar spine at L5-SI or L4-S1 in conjunction with use of legally marketed facet screw or pedicle screw systems at the same levels that are treated with AxiaLIF	TranS1	03/11	K102334

Adapted from the U. S. Food and Drug Administration (2007, 2008). (1, 2)
FDA: U.S. Food and Drug Administration.

Rationale

This medical policy has been updated regularly with searches of the PubMed database. The most recent literature update was performed through January 16, 2023.

Medical policies assesses the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials (RCTs) are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used

for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Axial Lumbosacral Interbody Fusion

Clinical Context and Therapy Purpose

The purpose of axial lumbosacral interbody fusion in individuals who have L4-S1 disc space diseases is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this medical policy is: Does axial lumbosacral interbody fusion improve net health outcomes in individuals who have L4-S1 disc space diseases?

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest are individuals who have degenerative spine disease at the L4-S1 disc spaces.

Interventions

The therapy being considered is axial lumbosacral interbody fusion (also called presacral, transsacral, or paracoccygeal interbody fusion). Axial lumbosacral 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.

The procedure for 1-level axial lumbosacral interbody fusion is as follows (3): 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. The 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.

Comparators

The following practice is currently being used to treat degenerative spine disease: standard lumbosacral interbody fusion and conservative therapy.

Outcomes
The outcomes of interest are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Follow-up was up to 24 months.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Single-Level Axial Lumbosacral Interbody Fusion
The literature on axial lumbosacral interbody fusion includes a systematic review of case series and a retrospective comparison of axial lumbosacral interbody fusion with anterior lumbar interbody fusion. No prospective RCTs have been identified comparing outcomes of axial lumbosacral interbody fusion with other approaches to lumbosacral interbody fusion.

Systematic Reviews
Schroeder et al. (2016) reported on a systematic review of L5-S1 disc space fusion rates following axial lumbosacral interbody fusion compared with anterior lumbar interbody fusion or transforaminal lumbar interbody fusion. (4) Reviewers included 42 articles (total N=1,507 patients). There were 11 articles with 466 patients who underwent anterior lumbar interbody fusion, 21 articles with 432 patients who underwent transforaminal lumbar interbody fusion, and 11 articles with 609 patients who underwent axial lumbosacral interbody fusion. Overall fusion rates were 99.2% for transforaminal lumbar interbody fusion, 97.2% for anterior lumbar interbody fusion, and 90.5% for axial lumbosacral interbody fusion. Fusion rates for transforaminal lumbar interbody fusion were significantly higher than those for axial lumbosacral interbody fusion (p=0.002). However, when either bone morphogenetic protein or bilateral pedicle screws were used with the procedures, the differences in fusion rates between transforaminal lumbar interbody fusion and axial lumbosacral interbody fusion were no longer statistically significant. The findings of this systematic review were limited by the lack of comparative studies and differences in how fusion rates were determined across studies.

Nonrandomized Comparative Studies
Whang et al. (2014) reported on a multicenter, retrospective comparison of axial lumbosacral interbody fusion with anterior lumbar interbody fusion of the L5-S1 disc space in 96 patients who had a minimum of 2 years of follow-up. (5) Most procedures were performed for degenerative disc disease or spondylolisthesis and used bilateral pedicle screws. Various graft materials were used, including recombinant human bone morphogenetic protein-2 (in 29 axial lumbosacral interbody fusion and 11 anterior lumbar interbody fusion procedures). Fusion rates, assessed at 24 months by 2 independent evaluators and based on radiographs and

multiplanar computed tomography images, were similar for the 2 procedures (85% for axial lumbosacral interbody fusion vs 79% for anterior lumbar interbody fusion; p>0.05). The incidence of adverse events was also similar, with no cases of rectal perforation. Interpretation of this study is uncertain given its retrospective design, variability in procedures, the absence of validated clinical outcome measures, and lack of randomization.

Case Series

The largest case series included in the 2016 systematic review was a retrospective analysis by Tobler et al. (2011) which evaluated 156 patients from 4 clinical sites in the United States. (6) Patients were selected if they underwent an L5 through 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 lumbosacral interbody fusion but were excluded from 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 improved from a mean of 7.7 to 2.7 (n=155), while the Oswestry Disability Index (ODI) scores 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% (n=127/147) for pain and 74% (n=57/77) for the ODI scores. The overall radiographic fusion rate at 2 years was 94% (145/155). No neural, urologic, or bowel injuries were reported in this study group. Study limitations included its retrospective analysis, lack of controls, and potential for selection bias because it only reported on patients who had 2 years of follow-up.

The second largest series included in the systematic review was that by Zeilstra et al. (2013), who retrospectively assessed 131 axial lumbosacral interbody fusion procedures (L5-S1) performed at their institution over a 6-year period. (7) All patients had had a minimum of 6 months (mean, 5 years) of unsuccessful nonsurgical management and had magnetic resonance imaging, radiography, provocative discography, and anesthetization of the disc. Magnetic resonance imaging of the sacrum and coccyx was performed to identify vascular anomalies, tumor, or surgical scarring that would preclude safe access through the presacral space. 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% (change in visual analog scale score, 70 to 39), leg pain decreased by 42% (from 45 to 26), and back function scores (ODI) improved by 50% compared with baseline. With clinical success defined as an improvement of 30% or more, 66% of patients met criteria for reduction in back and leg pain severity. Employment increased from 24% 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 (6.1%) reoperations at the index level.

Gerszten et al. (2012) reported on a series of patients who had a minimum 2-year follow-up after axial lumbosacral interbody fusion with percutaneous posterior fixation with pedicle screws for the stabilization of grade 1 or 2 lumbosacral isthmic spondylolisthesis. (8) 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 was reduced (change in visual analog scale score, 8.1 to 2.8), and 81% of patients had excellent or good results based on Odom criteria. At 2 years post-treatment, all patients showed solid fusion.

Two-Level Axial Lumbosacral Interbody Fusion

Marchi et al. (2012) reported on prospective 2-year follow-up for 27 patients who underwent 2 level axial lumbosacral interbody fusion at the L4-5 and L5-S1 disc spaces. (9) Average back pain decreased from a visual analog scale score of 8.08 to 4.04 and ODI scores improved from 51.7 to 31.4. Although no intraoperative complications occurred, the authors reported malpositioned rods in 3 cases due to difficulty attaining an adequate route for the double-level access. In one of these cases, the rod migrated and perforated the bowel. Five (18.5%) patients underwent additional surgery for malpositioned rods, broken posterior screws, rod failure, or 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 less than that of 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.

Adverse Events

An industry-sponsored, 5-year, voluntary postmarketing surveillance study of 9,152 patients was reported by Gundanna et al. (2011). (10) A single-level (L5-S1) fusion was performed in 8,034 (88%) patients, and a 2-level (L4-S1) fusion was performed in 1,118 (12%) patients. A predefined database was designed to record device- or procedure-related complaints through spontaneous reporting. Several procedures, including the presence of a TranS1 representative during every case, were implemented to encourage complication reporting. Complications 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). Follow-up ranged from 3 months to 5 years 3 months. Complications were reported in 120 (1.3%) patients 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 included a large number of patients, it relied on spontaneous reporting, which could underestimate the true incidence of complications.

Lindley et al. (2011) found high complication rates when retrospectively reviewing 68 patients who underwent axial lumbosacral interbody fusion 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 lumbosacral interbody fusion (L4-S1), and 58 patients underwent a single-level axial lumbosacral interbody fusion (L5-S1). A total of 18 complications in 16 (23.5%) patients were identified at a mean 34-month 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 patients with rectal perforation underwent emergency repair and had no long-term sequelae. Patients with nonunion underwent additional fusion surgery with an anterior or posterior approach. The 2 patients with sacral fractures had preexisting osteoporosis. Because of the potential complications, the authors recommended full bowel preparation and preoperative magnetic resonance imaging before an axial lumbosacral interbody fusion procedure to assess the size of the presacral space, to determine rectal adherence to the sacrum, to rule out vascular abnormalities, and to determine a proper trajectory.

Summary of Evidence

For individuals who have degenerative spine disease at the L4-S1 disc spaces who receive axial lumbosacral interbody fusion, the evidence includes a comparative systematic review of case series and a retrospective comparative study. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The systematic review found that fusion rates were higher following transforaminal lumbosacral interbody fusion than following axial lumbosacral interbody fusion, although this difference decreased with use of bone morphogenetic protein or pedicle screws. The findings of this systematic review were limited by the lack of prospective comparative studies and differences in how fusion rates were determined. Studies have suggested that complication rates may be increased with 2-level axial lumbosacral interbody fusion. Controlled trials with clinical outcome measures are needed to better define the benefits and risks of this procedure compared with treatment alternatives. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

North American Spine Society

In 2014, the North American Spine Society published guidelines on the treatment of degenerative spondylolisthesis. (12) The North American Spine Society gave a grade B recommendation for surgical decompression with fusion in patients with spinal stenosis and spondylolisthesis. The guidelines discussed posterolateral fusion, 360º fusion, and minimally invasive fusion; it did not address axial lumbosacral interbody fusion.

National Institute for Health and Care Excellence

In July 2018, the National Institute for Health and Care Excellence (NICE) provided evidence-based recommendations on transaxial interbody lumbosacral fusion for low back pain in adults. (13) The recommendation, based on a literature review conducted in December 2017, states, "Evidence on the safety of transaxial interbody lumbosacral fusion for severe chronic low back pain shows that there are serious but well-recognized complications. Evidence on efficacy is adequate in quality and quantity. Therefore, this procedure may be used provided that standard arrangements are in place for clinical governance, consent and audit. This procedure should only be done by a surgeon with specific training in the procedure, who should carry out their initial procedures with an experienced mentor."

Ongoing and Unpublished Clinical Trials

A search of Clinicaltrials.gov in March 2023 did not identify any ongoing trials that would influence this policy.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	22586, 22899
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
11/15/2024	Reviewed. No changes.
12/15/2023	Document updated with literature review. Coverage unchanged. No new references added.
10/15/2022	Document updated with literature review. Coverage unchanged. Reference 1 added.
08/01/2021	Reviewed. No changes.
08/15/2020	Document updated with literature review. Coverage unchanged. Reference 13 added, some references removed.
08/01/2019	Reviewed. No changes.
11/15/2018	Document updated with literature review. Coverage unchanged. Reference 4 added, one reference removed.
07/15/2017	Reviewed. No changes.
09/15/2016	Document updated with literature review. Coverage unchanged.
05/15/2015	Reviewed. No changes.

08/01/2014	New medical document. Axial lumbosacral interbody fusion (axial LIF) is considered experimental, investigational and/or unproven. Coverage is unchanged. (This topic was previously addressed on SUR712.004 Intervertebral Techniques to Treat Chronic Discogenic Back Pain).