Axial Lumbosacral Interbody Fusion

Policy

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

Related Policies

7.01.107 Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)
7.01.120 Facet Arthroplasty
7.01.138 Interspinous Fixation (Fusion) Devices
7.01.542 Lumbar Fusion
7.01.551 Lumbar Spine Decompression Surgery: Discectomy, Foraminotomy, Laminotomy, Laminectomy

Policy Guidelines

Coding

<table>
<thead>
<tr>
<th>CPT</th>
<th>Description</th>
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<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>0196T</td>
<td>L4-L5 interspace (List separately in addition to code for primary procedure)</td>
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<tr>
<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>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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Axial lumbosacral interbody fusion (LIF; also called pre-sacral, trans-sacral 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.

Axial 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 foramen 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 (TranS1) consist of techniques and surgical instruments for creating a pre-sacral 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.) Quandry Medical acquired the TranS1 technology in 2014 and re-established distribution of AxiaLIF in 2015). The instruments were cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process 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

Scope

Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
Benefit Application

N/A

Rationale

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individuals:</td>
<td>Interventions of interest are:</td>
<td>Comparators of interest are:</td>
<td>Relevant outcomes include:</td>
</tr>
<tr>
<td>With degenerative spine disease at the L4-S1 disc spaces</td>
<td>• Axial lumbosacral interbody fusion</td>
<td>• Standard lumbar interbody fusion surgery</td>
<td>• Symptoms</td>
</tr>
</tbody>
</table>

This evidence review was created in 2011 and has been updated periodically using the MEDLINE database. The most recent literature review was performed through February 12, 2016.

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 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 randomized controlled trials 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 United States. (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 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% (145/155). 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 with 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. (6) 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 next).

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. (7) 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 post-treatment, all patients showed solid fusion.

Additional series with fewer than 100 patients are reviewed by Zeilstra et al. (5) 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. (8) 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%), trans-sacral rod detachment (11.1%), radiolucency around the trans-sacral 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 with 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, 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 post marketing 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 1,118 patients (12%). A pre-defined 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 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 of the patients with rectal perforation underwent emergency repair and were reported to have no long-term sequelae. The patients with non-union underwent additional fusion surgery with an anterior or posterior approach. The 2 patients with sacral fractures had pre-existing 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 before 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 FDA’s MAUDE database in April 2016 (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
Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
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<tr>
<td>Unpublished</td>
<td>RAMP Study: A Prospective Randomized Study Comparing Two Lumbar Fusion Procedures</td>
<td>200</td>
<td>Terminated (enrollment)</td>
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NCT: national clinical trial.
* Denotes industry-sponsored or cosponsored trial.

Summary of Evidence
The evidence for axial lumbosacral interbody fusion (LIF) in individuals who have degenerative spine disease at the L4-S1 disc spaces includes case series and 1 retrospective comparative study. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The evidence is insufficient to evaluate whether axial LIF is as effective or as safe as other surgical approaches to LIF, 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 increased risk for complications. Controlled trials are needed to better define the benefits and risks of this procedure compared with treatment alternatives. The evidence is insufficient to determine the effects of the technology on health outcomes.

Clinical Input Received from Physician Specialty Societies and Academic Medical Centers
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 2 specialty medical societies and 3 academic medical centers while this policy was under review in 2011. The input considered axial LIF to be investigational.
Practice Guidelines and Position Statements

North American Spine Society
The North American Spine Society (NASS) published a guideline on the treatment of degenerative spondylolisthesis in 2014. (12) NASS gave a Grade B recommendation for surgical decompression with fusion in patients with spinal stenosis and spondylolisthesis. The guideline discussed posterolateral fusion, 360° fusion, and minimally invasive fusion, but did not address axial LIF.

National Institute for Health and Clinical Excellence
The United Kingdom’s National Institute for Health and Clinical Excellence (NICE) provided guidance on transaxial interbody fusion in the lumbar spine in 2011. (13) 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.

American Association of Neurological Surgeons
The American Association of Neurological Surgeons published guidelines for interbody techniques for lumbar fusion in 2014 (part 11). (14) 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

**Appendix**

<table>
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<tr>
<th>Date</th>
<th>Reason</th>
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<td>02/27/12</td>
<td>Replace Policy – Policy Section on axial LIF moved from policy 7.01.542 (Minimally Invasive Lumbar Interbody Fusion) and updated with literature search through September 2011.</td>
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<tr>
<td>09/27/12</td>
<td>Update Coding Section – ICD-10 codes are now effective 10/01/2014.</td>
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<td>01/29/13</td>
<td>Replace policy. Policy updated with literature review through August 2012; references 7 and 8 added; one reference removed. Policy statement unchanged. CPT coding updated: CPT codes 22586 and 0309T, effective 1/1/13, added; descriptors changed for codes 0195T and 1096T.</td>
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<td>09/30/13</td>
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<td>01/21/14</td>
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<td>Annual Review. Policy updated with literature review through September 24, 2014; references 6, 13 added; policy statement unchanged.</td>
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<td>06/01/15</td>
<td>Coding update. ICD-10 PCS codes added; these were inadvertently removed at last publication.</td>
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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
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