MEDICAL POLICY – 7.01.130

Axial Lumbosacral Interbody Fusion

RELATED MEDICAL 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

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
Policy Coverage Criteria

<table>
<thead>
<tr>
<th>Service</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Axial lumbosacral interbody fusion</td>
<td>Axial lumbosacral interbody fusion is considered investigational.</td>
</tr>
</tbody>
</table>

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td></td>
</tr>
<tr>
<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 (code terminated 1/1/19)</td>
</tr>
<tr>
<td>0196T</td>
<td>Arthrodesis, pre-sacral interbody technique, disc space preparation, discectomy, without instrumentation, with image guidance, includes bone graft when performed; L4-L5 interspace (List separately in addition to code for primary procedure) (code terminated 1/1/19)</td>
</tr>
<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>
<tr>
<td>22899</td>
<td>Unlisted procedure, spine</td>
</tr>
</tbody>
</table>

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Related Information

N/A

Evidence Review
Description

Axial lumbosacral interbody fusion (LIF; 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.

Background

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 discectomy, or for adjacent-level disc disease.

Axial Lumbosacral Interbody Fusion

Axial lumbosacral interbody fusion (LIF; 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 LIF 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.

Summary of Evidence

For individuals with degenerative spine disease at the L4- S1 disc spaces who receive axial LIF the evidence includes 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 transfemoral LIF than following axial LIF, 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 suggest that complication rates may also be increased with 2-level axial LIF. 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 the effects of the technology on health outcomes.

**Ongoing and Unpublished Clinical Trials**

An unpublished trial that might influence this policy is listed in Table 1. A search of ClinicalTrials.gov in March 2019 did not identify any ongoing trials that would likely influence this policy.

### Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Unpublished</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01716182a</td>
<td>RAMP Study: A Prospective Randomized Study Comparing Two Lumbar Fusion Procedures</td>
<td>200</td>
<td>July 2014 (terminated) slow enrollment</td>
</tr>
</tbody>
</table>

NCT: national clinical trial

*a Denotes industry-sponsored or cosponsored trial

**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 lumbosacral interbody fusion to be investigational.
Practice Guidelines and Position Statements

North American Spine Society


National Institute for Health and Clinical Excellence

The National Institute for Health and Clinical Excellence (NICE) provided guidance on transaxial interbody fusion in the lumbar spine in 2011. The guidance stated 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.” The Institute encouraged “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.”

In July 2018, the NICE guidance was updated and replaced by evidence-based recommendations on transaxial interbody lumbosacral fusion for low back pain in adults. 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.”

Medicare National Coverage

There is no national coverage determination.
Regulatory Status

The U.S. Food and Drug Administration has cleared for marketing multiple anterior spinal intervertebral body fixation device systems through the 510(k) pathway (see Table 2). The systems 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 disc spaces in conjunction with legally marketed facet or pedicle screw systems. Food and Drug Administration product code: KWQ

Table 2. Select Anterior Spinal Intervertebral Body Fixation Orthoses Cleared by FDA

<table>
<thead>
<tr>
<th>Orthotic</th>
<th>Description</th>
<th>Manufacturer</th>
<th>Date Cleared</th>
<th>501(k) No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>TranS1® AxiaLIF™ System</td>
<td>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</td>
<td>TranS1</td>
<td>12/04</td>
<td>K040426</td>
</tr>
<tr>
<td>TranS1® AxiaLIF™ System</td>
<td>Indication modified to include facet screws</td>
<td>TranS1</td>
<td>06/05</td>
<td>K050965</td>
</tr>
<tr>
<td>TranS1® AxiaLIF® II System</td>
<td>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</td>
<td>TranS1</td>
<td>04/08</td>
<td>K073643</td>
</tr>
<tr>
<td>TranS1® AxiaLIF® 2L System</td>
<td>Indication unchanged, marketed with branded bone morphogenetic protein</td>
<td>TranS1</td>
<td>01/10</td>
<td>K092124</td>
</tr>
<tr>
<td>TranS1® AxiaLIF® Plus System</td>
<td>Intended to provide anterior stabilization of the L5-S1 or L4-S1</td>
<td>TranS1</td>
<td>03/11</td>
<td>K102334</td>
</tr>
</tbody>
</table>
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 (D3M, autograft or autologous blood) into the disc space.
Use limited to anterior supplemental fixation of the lumbar spine at L5-S1 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

Adapted from the Food and Drug Administration (2007, 2008)...
FDA: Food and Drug Administration

References


### History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<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>
</tr>
<tr>
<td>09/27/12</td>
<td>Update Coding Section – ICD-10 codes are now effective 10/01/2014.</td>
</tr>
<tr>
<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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<tr>
<td>09/30/13</td>
<td>Update Related Policies. Change title to 7.01.120.</td>
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<tr>
<td>01/21/14</td>
<td>Replace policy. Policy updated with literature review through September 30, 2013. Reference 5 added; others renumbered/removed. Policy statement unchanged. ICD-9 code 81.08 descriptor updated.</td>
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<tr>
<td>01/28/15</td>
<td>Annual Review. Policy updated with literature review through September 24, 2014; references 6, 13 added; policy statement unchanged.</td>
</tr>
<tr>
<td>06/01/15</td>
<td>Coding update. ICD-10 PCS codes added; these were inadvertently removed at last publication.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
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</tr>
<tr>
<td>07/01/18</td>
<td>Annual Review, approved June 22. Policy updated with literature review through February 2018; no references added. Policy statement unchanged.</td>
</tr>
<tr>
<td>01/01/19</td>
<td>Removed CPT code 0309T from policy as it was terminated 1/1/18.</td>
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</table>

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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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