Clinical Policy Title: Axial lumbar interbody fusion

Clinical Policy Number: 14.03.09

Effective Date: July 1, 2017
Initial Review Date: May 19, 2017
Most Recent Review Date: May, 2018
Next Review Date: May 2019

Policy contains:
- Spondylolisthesis.
- Lumbar fusion.
- Minimally-invasive surgery.

Related policies:
- CP# 03.03.03 Spinal surgeries
- CP# 03.03.01 Spinal cord stimulators for chronic pain
- CP# 03.02.02 Radiofrequency ablation treatment for spine pain
- CP# 03.03.04 Spine pain — epidural injections
- CP# 03.03.08 Intravenous lidocaine infusion for neuropathic pain
- CP# 03.03.06 Biofeedback for chronic pain
- CP# 03.02.07 Spine pain — facet joint injections
- CP# 03.03.05 Spine pain — trigger point injections

ABOUT THIS POLICY: Prestige Health Choice has developed clinical policies to assist with making coverage determinations. Prestige Health Choice’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Prestige Health Choice when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Prestige Health Choice’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Prestige Health Choice’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Prestige Health Choice will update its clinical policies as necessary. Prestige Health Choice’s clinical policies are not guarantees of payment.

Coverage policy

Prestige Health Choice considers the use of axial lumbar interbody fusion (AxiaLIF) for treatment of infection, tumor, trauma, deformity, and degenerative diseases of the spine to be investigational and, therefore, not medically necessary (Derman, 2017; North American Spine Society, 2014).

Limitations:
Coverage determinations are subject to benefit limitations and exclusions as delineated by the state Medicaid authority. The Florida Medicaid website may be accessed at http://ahca.myflorida.com/Medicaid/.

All other uses of AxiaLIF are not medically necessary.

**Alternative covered services:**

- Facet joint injection.
- Chiropractic manipulation in the first four weeks if there is no radiculopathy.
- Heat or cold modalities for home use.
- Low-impact exercise (e.g., stationary bike, swimming, or walking).
- Pharmacotherapy (e.g., non-narcotic analgesics, non-steroidal anti-inflammatory drugs, or muscle relaxants).
- Trigger point injections.
- Epidural spinal injections.
- Cognitive-behavioral therapy.
- Interdisciplinary rehabilitation.

**Background**

AxiaLIF is a minimally-invasive surgical technique applied via a small incision at the lower back to arrange into place and prevent displacement of the vertebral bodies that make up the lower lumbar and sacral spine.

The AxiaLIF system (TranS1 Inc, Wilmington, NC) includes instruments for creating the pre-sacral tunnel that permits operative access to the L5-S1 intervertebral space. It offers an advantage over traditional open spinal fusion techniques in that it enables direct operative access to the lower back while still providing adequate exposure to insure suitable placement of a bone graft which in time will provide the desired permanent fixation.

AxiaLIF may reduce the risk of operative injury to the vasculature supply and innervation of the spine, and reduce the length of hospital-stays for patients undergoing surgical treatment for back pain. It is particularly pertinent in patients who are obese or who have other relative or absolute contraindications to a transabdominal surgical approach to the lower spine. Conversely, those patients who have compressed spinal nerve or scar tissue in the vicinity of the coccyx and/or sacrum may be unsuitable for AxiaLIF. Pseudarthrosis, rectal injury, transient nerve irritation, and intrapelvic hematoma are well-known complications from the procedure.

**Searches**

Prestige Health Choice searched PubMed and the databases of:
We conducted searches on April 26, 2017. Search terms were: "spinal fusion," "lumbar fusion," and "spondylolisthesis."

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

Comparison of the outcome of different lumbar fusion procedures for the various indications indicated above has not been done systematically. The performance of lumbar fusion in the case of spondylolisthesis is now considered routine, with minimal disagreement among the guidelines. However, reviews by the Agency for Health Research and Quality (AHRQ), American College of Physicians (ACP), and American Academy of Orthopaedic Surgeons (AAOS) have all suggested that there may be some potential greater benefit of fusion over conservative therapies, but that the studies were not designed to make specific conclusions in this regard.

The North American Spine Society (NASS 2014) has stated that there is insufficient evidence to make a recommendation for or against the cost-effectiveness of minimal access-based surgical treatments compared to traditional open surgical treatments for degenerative lumbar spondylolisthesis. Grade of Recommendation: I (Insufficient Evidence). Furthermore, an UpToDate review on “Subacute and chronic low back pain: Surgical treatment” (Chou, 2015) does not mention AxiaLIF as a surgical option.

**Policy updates:**

One review of interbody fusion techniques for the surgical management of degenerative lumbar spondylolisthesis did not identify any studies comparing axial lumbar interbody fusion to other techniques (Derman, 2017), while a systematic review did not include this approach as one of the examined procedures (Teng, 2017).
### Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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Key points:  
- A systematic review sought to determine the fusion rate of anterior lumbar interbody fusion (ALIF), TLIF, and axial arthrodesis at the lumbosacral junction in adult patients undergoing surgery for 1- and 2-level degenerative spine conditions.  
- In total, 42 articles and 1507 patients were included in this systematic review.  
- A difference in overall fusion rates was identified, with a rate of 99.2% (range, 96.4%-99.8%) for a TLIF, 97.2% (range, 91.0%-99.2%) for an ALIF, and 90.5% (range, 79.0%-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 available evidence suggests that a high fusion rate can be expected with the use of an ALIF, TLIF, or axial interbody fusion.  
- Any technique-dependent benefit in fusion rate can be eliminated with common surgical modifications such as the use of bilateral pedicle screws. |
Key points:  
- An UpToDate review on “Subacute and chronic low back pain: Surgical treatment” does not mention axial lumbar interbody fusion/AxiaLIF as a surgical option. |
Key points:  
- A systematic review inclusive of 45 randomized controlled studies (RCTs) assessed radiographic imaging used to diagnose and treat lumbar pseudarthrosis as a complication of fusion.  
- Plain radiographs and thin-cut CT scans were the most common methods employed to make the diagnosis.  
- The authors found there is an average time of 3.5 years (range 12–131 months) before the detection of pseudarthrosis using plain radiographs; and that CT imaging has the strongest correlation with the intraoperative assessment of fusion status.  
- Positron emission tomography (PET) was shown to be a valid imaging modality for monitoring in vivo active bone formation.  
- Eight studies compared the surgical techniques for managing and preventing failed lumbar fusion, and found that the success rates are enhanced with the use of rigid instrumentation. |
| Fujimori (2015) | Does transforaminal lumbar interbody fusion have advantages over posterolateral lumbar fusion for degenerative spondylolisthesis?  
Key points:  
- A retrospective study (n=66) compared the clinical and radiographic outcomes of TLIF and posterolateral lumbar fusion (PLF) in the treatment of degenerative spondylolisthesis.  
- Outcomes were assessed by VAS for low back pain and leg pain, physical component summary (PCS) of the 12-item Short-Form Health Survey (SF36), and the Oswestry Disability Index (ODI).  
- Radiographic parameters included slippage of the vertebra, local disk lordosis, the |
<table>
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<tbody>
<tr>
<td></td>
<td>• Improvement in measure by VAS of leg pain was significantly greater in TLIF than in PLF unilaterally (3.4 versus 1.0; ( p = 0.02 )).</td>
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<td>• The improvement of VAS of low back pain was significantly greater in TLIF than in PLF (3.8 versus 2.2; ( p = 0.02 )); however, there was no significant difference in improvement of ODI or PCS between TLIF and PLF.</td>
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<td>• Reduction of slippage and the postoperative disk height was significantly greater in TLIF than in PLF.</td>
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<td>• There was no significant difference in local disk lordosis, lumbar lordosis, or pelvic parameters.</td>
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<td>• The fusion rate was 96% in TLIF and 84% in PLF (( p = 0.3 )).</td>
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<td>• There was no significant difference in fusion rate, estimated blood loss, adjacent segmental degeneration, or complication rate.</td>
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**Key points:**

- A systematic review of seventy-four articles sought to determine the fusion rate and safety profile of an axial interbody arthrodesis of the fifth lumbar-first sacral (L5-S1) motion segment.
- The overall pseudarthrosis rate at L5-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 ALIF is associated with a high fusion rate (93.15%) and an acceptable complication rate (12.90%); however, these results are based mainly on retrospective case series by authors with a conflict of interest.
- The limited prospective evidence indicates that the actual fusion rate may be lower and the complication rate may be higher than currently reported.

| Key points:           |                                                                 |
|                       | • A narrative review opined that computed tomography (CT) with fine-cut axial images and multiplanar views is the most sensitive for assessing fusion following instrumented posterolateral and anterior lumbar interbody fusions. |
|                       | • For suspected symptomatic pseudarthrosis, a combination of techniques including static and dynamic radiographs as well as CT images is recommended as an option. |
|                       | • Lack of facet fusion is considered to be more suggestive of a pseudarthrosis compared with absence of bridging posterolateral bone. |
|                       | • Studies exploring additional noninvasive modalities of fusion assessment have demonstrated either poor potential, such as with 99m Tc bone scans, or provide insufficient information to formulate a definitive recommendation. |

<p>| Deyo (2014)           | Key points:                                                                                       |
|                       | • A retrospective study of Medicare claims for surgery for lumbar spinal stenosis from 2002-2007 (( n = 32,152 )) grouped cohorts into 3 gradations of invasiveness: decompression alone, simple fusion (1 or 2 disk levels, single surgical approach), or complex fusion. |</p>
<table>
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<tr>
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| surgery for lumbar spinal stenosis in older adults.                     | (more than 2 disk levels or combined anterior and posterior approach).                                                                                                                                                          | • Although surgical rates declined slightly from 2002-2007, the rate of complex fusion procedures increased 15-fold, from 1.3 to 19.9 per 100,000 beneficiaries.  
  • Life-threatening complications increased with increasing surgical invasiveness, from 2.3% among patients having decompression alone to 5.6% among those having complex fusions.  
  • After adjustment for age, comorbidity, previous spine surgery, and other features, the odds ratio (OR) of life-threatening complications for complex fusion compared with decompression alone was 2.95 (95% confidence interval [CI], 2.50-3.49).  
  • A similar pattern was observed for rehospitalization within 30 days, which occurred for 7.8% of patients undergoing decompression and 13.0% having a complex fusion (adjusted OR, 1.94; 95% CI, 1.74-2.17).  
  • Adjusted mean hospital charges for complex fusion procedures were US $80,888 compared with US $23,724 for decompression alone.                                                                 |
| Høy (2014)                                                             | Transforaminal lumbar interbody fusion (TLIF) versus posterolateral instrumented fusion (PLF) in degenerative lumbar disorders: a randomized clinical trial with 2-year follow-up.                                                   | • A RCT (n=100) randomized patients for either posterolateral lumbar fusion [titanium TSRH (Medtronic)] or TILF [titanium TSRH (Medtronic)] with anterior intervertebral support by tantalum cage (Impex/Zimmer).  
  • The primary outcome scores were obtained using the Dallas Pain Questionnaire (DPQ), ODI, SF-36, and low back pain Rating Scale.  
  • At 2-years of follow-up after surgery no statistical difference in outcome between groups could be detected concerning daily activity, work leisure, anxiety/depression or social interest.  
  • There was no statistical difference concerning back pain or leg pain.  
  • In both the TLIF and the PLF groups the patients had significant improvement in functional outcome, back pain, and leg pain compared to preoperatively.  
  • Operation time and blood loss in the TLIF group were significantly higher than in the PLF group (p < 0.001).  
  • No statistical difference in fusion rates was detected.                                                                                                          |
| North American Spine Society (2014)                                    | Diagnosis and treatment of degenerative lumbar spondylolisthesis.                                                                                                                                                             | • North American Spine Society (NASS 2014) has stated that there is insufficient evidence to make a recommendation for or against the cost-effectiveness of minimal access-based surgical treatments compared to traditional open surgical treatments for degenerative lumbar spondylolisthesis.  
  o Grade of Recommendation: I (Insufficient Evidence)                                                                                                             |
| Stulík (2014)                                                          | Axial lumbar interbody fusion: Prospective monocentric study.                                                                                                                                                                 | • A prospective study enrolled 23 patients (11 women and 12 men, age 21 to 63 years, with an average of 48.2 years) to evaluate surgical posterior stabilization involving the L5-S1 segment by percutaneous lumbar interbody fusion (AxiaLIF).  
  • The initial indications for surgery were L5-S1 spondylolisthesis in 20 patients and L5-S1 spondylosis and stenosis in three patients.  
  • The average visual analog score (VAS) value was 6.6 before surgery and, after surgery, 5.2 at three months, 4.2 at six months, 3.1 at one year, 2.9 at two years and 2.1 at three years (n=18).                                                                 |
### Anand (2013)
**Minimally invasive approaches for the correction of adult spinal deformity.**

- At two post-operative years, improvement in the VAS value by 56.1% was recorded.
- 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.
- CT scans showed complete interbody bone fusion in 22 of the 23 patients (95.6%),
  - In one patient the finding was not clear.
  - Also, posterolateral fusion was achieved in all but one patients (95.6%).
- A stable L5-S1 segment was found in all patients at all follow-up intervals.
- The authors concluded that the percutaneous axial pre-sacral approach to the L5-S1 interbody space with application of a double-treaded screw is a valid option for patients with anatomical anomalies, in overweight patients or in those who have had repeated surgery in the region; and that clinical outcomes and the success rate for L5-S1 bone fusion are comparable with conventional techniques.

### Anand (2013)
**Key points:**

- A narrative review discussed the transpsoas and presacral approaches for discectomy and fusion, and reviewed multilevel posterior percutaneous pedicle instrumentation and rod placement for deformity correction.
- The authors noted that early clinical results are similar to open techniques, with reduced blood loss and less complications than traditional approaches.
- Meticulous technique and careful patient selection are required for good results and to avoid complications.

### Anand (2013)
**Long term 2 to 5 year clinical and functional outcomes of minimally invasive surgery (MIS) for adult scoliosis.**

- A retrospective study assessed MIS technique in adult patients (n=71) with scoliosis to assess clinical and functional outcomes during a 2- to 5-year period.
- Indications were degenerative scoliosis (54), idiopathic scoliosis (11), and iatrogenic scoliosis (6).
- All of the subjects underwent a combination of 3 MIS techniques: direct lateral interbody fusion (66), ALIF (34), and posterior instrumentation (67).
- The authors sought to demonstrate that MIS technique allows comparable correction of adult spinal deformity, with low pseudarthrosis rates and improved functional outcomes, with lower morbidity and complication rates at early and long-term follow-up.
- Thirty-six patients were staged with direct lateral interbody fusion done first followed by the posterior instrumentation and fusion including axial lumbar interbody fusion done 3 days later.
- 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 axial lumbar interbody fusion.
- Mean hospital stay was 7.6 days (2-26 d).
- The mean preoperative Cobb angle was 24.7° (8.3°-65°), which corrected to 9.5° (0.6°-28.8°).
- Mean preoperative Coronal balance was 25.5 mm, which corrected to 11 mm. Mean preoperative sagittal balance was 31.7 mm and corrected to 10.7 mm.
- The mean preoperative lumbar apical vertebral translation was 24 mm and corrected to...
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| Boachie-Adjei (2013) Axial lumbar interbody fusion (AxiaLIF) approach for adult scoliosis. | 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.  

| Key points: |  
- A narrative review of AxiaLIF suggested indications for the technique have been expanded to include adult scoliosis surgeries, and that the procedure is relatively safe even though traversing blood vessels and the pelvic splanchnic nerve can be at risk.  
- AxiaLIF in the long construct for adult scoliosis surgeries can protect the first sacral (S1) screw as effectively as pelvic fixation.  
- Successful clinical outcomes after AxiaLIF were reported in the degenerative lumbar spine, adult scoliosis, and spondylolisthesis; and cited high fusion rate up to 96%.  
- Complications included pseudarthrosis, rectal injury, transient nerve irritation, and intrapelvic hematoma; and that for a safer procedure, surgeons should seek out prior colorectal surgical history and review preoperative imaging studies carefully.  

Nasca (2013) Newer lumbar interbody fusion techniques. | Key points:  
- A narrative review opined that, in contrast to the more traditional open methods of performing anterior and posterior interbody fusions, less invasive techniques of TLIF, extreme lateral and direct lateral interbody fusion, and the presacral axial approach are associated with less morbidity, shorter hospital stays, high rates of fusion, and improved patient outcomes.  

| References |  
Professional society guidelines/other:  

Peer-reviewed references:  
Chou R. Subacute and chronic low back pain: Surgical treatment. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed July 2015.


**CMS National Coverage Determinations (NCDs):**

Local Coverage Determinations (LCDs):


InterQual


**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comments</th>
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<tbody>
<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</td>
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<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)</td>
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<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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<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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<tr>
<th>ICD-10 Code</th>
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<tr>
<td>M43.17</td>
<td>Spondylolisthesis, lumbosacral region</td>
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<tr>
<td>M43.16</td>
<td>Spondylolisthesis, lumbar region</td>
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<tr>
<td>M51.36</td>
<td>Other intervertebral disc degeneration, lumbar region</td>
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<tr>
<td>M51.37</td>
<td>Other intervertebral disc degeneration, lumbosacral region</td>
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<tr>
<th>HCPCS Level II Code</th>
<th>Description</th>
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<td>N/A</td>
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